

# **TRANSNATIONAL REGULATORY AUTHORITY AND GLOBAL ECONOMIC GOVERNANCE**

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## ABSTRACT

The aim of this thesis is to contribute to our understanding of the emergence, nature, and significance of non-state transnational governance. This research objective is pursued by examining an aspect of transnational non-state governance often neglected, the role of the state in the emergence and operation of non-state governance schemes. The role of the state in this context is illuminated by identifying and explaining the emergence of a particular type of authority, called *transnational regulatory authority*. Transnational regulatory authority emerges when the authority of creating regulation bearing a degree of legal obligation about an issue-area or industry at a global level, is delegated to non-state actors. This delegation of regulatory authority is puzzling, as it implies a loss of regulators' control over the regulatory governance of their jurisdictions, but also raises significant normative concerns, since authority has been entrusted to the state under specific procedures which form the very foundation of a democratic political association.

An explanation to this puzzle is proposed by a theoretical framework created through the synthesis of insights provided by the economic theory of international regulation and the political theory of authority. The propositions that emerge from this synthesis are tested through the examination of two case-studies, the International Accounting Standards Board (IASB) and the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceutical Products (ICH). The principal finding of the thesis is that the delegation of rule-making authority to transnational organizations is the result of explicit redistributive regulatory strategies, domestic or international, designed to satisfy specific domestic constituencies. However, regulators need to allay the normative concerns raised by this delegation of authority. To do this, they have to justify their decision by persuading the political establishment and the public that this delegation is necessary for the provision of adequate regulatory governance.

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## **Abbreviations**

ABPI	Association of British Pharmaceutical Industries
ADR	Adverse Drug Reaction
AERS	Adverse Event Reporting System
ARC	Accounting Regulatory Committee
ASCA	Arab Society of Certified Accountants
BIS	Bank for International Settlements
CDER	Centre for Drug Evaluation and Research
CDT	Common Technical Document
CESR	Committee of European Securities Regulators
CHMP	Committee for Medicinal Products for Human Use
CICA	Canadian Institute of Chartered Accountants
CMEs	Coordinated Market Economies
CMI	Comité Maritime International
CPMP	Committee for Proprietary Medicinal Products
DNS	Domain Name System
EASDAQ	European Association of Securities Dealers Automatic Quotation System
EC	European Commission
ECOFIN	Economic and Financial Affairs Council
ECSAFA	Eastern, Central and Southern African Federation of Accountants
EEA	European Economic Area
EEC	European Economic Community
EFPIA	European Federation of Pharmaceutical Industries' Associations
EFRAG	European Financial Reporting Advisory Group
EFTA	European Free Trade Area
EMEA	European Medicines Agency*
EMEA	European Medicines Evaluation Agency**
ETSI	European Telecommunications Standards Institute
EU	European Union
EWG	Expert Working Group
FASB	Financial Accounting Standards Board
FATF	Financial Action Task Force
FDA	Food and Drug Administration
FDAMA	Food and Drug Administration Modernization Act
FSF	Financial Stability Forum
GAAP	Generally Accepted Accounting Principles
GPP	Global Public Policy
IACS	International Association of Classification Societies
IAIS	International Association of Insurance Supervisors
IAS	International Accounting Standard
IASB	International Accounting Standards Board
IASC	International Accounting Standards Committee
ICANN	Internet Corporation for Assigned Names and Numbers
ICC	International Chamber of Commerce



ICDRA	International Conference of Drug Regulatory Authorities
ICH	International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceutical Products
IDN	Internationalized Domain Names
IDS	Integrated Disclosure System
IESG	Internet Engineering Steering Group
IFAC	International Federation of Accountants
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
IFRIC	International Financial Reporting Interpretations Committee
IFRS	International Financial Reporting Standard
IND	Investigational New Drug
IOSCO	International Organization of Securities Commissions
ISAR	Intergovernmental Working Group of Experts on International Standards of Accounting
ISO	International Organization for Standardization
JPMA	Japan Pharmaceutical Manufacturers Association
LDCs	Less Developed Countries
LMEs	Liberal Market Economies
MCA	Medicines Control Agency
MeDRA	Medical Dictionary for Regulatory Activities Terminology
MHLW	Ministry of Health, Labour and Welfare
MNCs	Multinational Companies
MOSS	Market-Oriented-Sector-Selected
MoU	Memorandum of Understanding
NASDAQ	National Association of Securities Dealers Automated Quotations System
NCE	New Chemical Entity
NDA	New Drug Application
NGOs	Non-Governmental Organizations
NIEO	New International Economic Order
NSAs	Non-state Actors
NYSE	New York Securities Exchange
OECD	Organization for Economic Cooperation and Development
OTA	Office of Technology Assessment
PDMA	Pharmaceutical and Medical Devices Agency
PDUFA	Prescription Drug User Fee Act
PhRMA	Pharmaceutical Research and Manufacturers of America
R&D	Research and Development
SAC	Standards Advisory Council
SEC	Securities and Exchange Commission
SIC	Standing Interpretations Committee
SMEs	Small and Medium-Sized Enterprises
TNCs	Transnational Corporations
TRIPS	Trade-Related Intellectual Property Rights
TSE	Tokyo Securities Exchange

UN	United Nations
UNCITRAL	United Nations Commission on International Trade Law
UNCTAD	United Nations Conference on Trade and Development
UNIDO	United Nations Industrial Development Organization
WHO	World Health Organization
WSIS	World Summit of the Information Society
WTO	World Trade Organization

\*EMEA has changed its name (see\*\*) but has kept the same acronym.

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# **Chapter 1**

## **Introduction**

### **1.1 Global governance and non-state actors: a new challenge**

In international relations' literature, the state has traditionally been considered the principal entity with the ability and legitimacy to decide both the form and content of international institutional and legal arrangements. As a result, non-state actors (NSAs) have traditionally been treated as marginal actors with no great bearing on developments in the international arena. In recent years however, this academic paradigm has been seriously undermined. The varied and multi-layered processes of globalization have transformed the role of NSAs in an increasingly inter-connecting world. First, a variety of non-state actors are increasingly engaged in a widening array of transnational activities which transform all aspects of international economic relations (production, trade, finance), but also affect cultural exchanges, migration movements, environmental preoccupations and even the way war is conceived and conducted (Held et al. 2000).

In this context, the autonomy of states to select and implement unilaterally a range of policy options has been seriously constrained (Strange 1996; Reinicke 1998; Held 2004). The flurry of transnational activity has meant that increasingly, several aspects of everyday life, particularly in the economic realm, are operating in the context of a functional geography, which often is at odds with the territorial geography of political authority (O'Brien 1991; Neuer 1998; Kobrin 2002). This disjuncture between the functional, economic geography of non-state actors and the territorial geography of states is threatening the internal operational sovereignty of states, that is, their capacity to create and enforce public policy (Reinicke 1998; Held 2004)<sup>1</sup>. Meanwhile, international law and the inter-state governance system that sustains it, have also eroded, to a degree, the ideal of the "sovereign state" as the

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<sup>1</sup> Internal sovereignty "involves the belief that a political body established as sovereign rightly exercises the 'supreme command' over a particular society. Government- however defined- must enjoy the 'final and absolute authority' within that terrain". External sovereignty on the other hand "involves the claim that there is no final and absolute authority above and beyond the sovereign state" (Held 2004, p.100).

supreme authority in the international system, and have therefore contained the external sovereignty of states (Held 2004).

Notwithstanding these constraints on states' authority, this new complex transnational reality necessitates regulatory arrangements to guide the widening array of participants in their interactions with each other and with the existing national and international regulatory frameworks. The international and transnational structures and mechanisms that have emerged in recent years in response to this demand for governance feature some novel characteristics that have significant consequences for both national and world politics. Two significant characteristics of this emerging global governance infrastructure, particularly in the realm of political economy, are the processes of "pluralization" and "privatization" (Cutler 2003). Pluralization refers to the emergence of a variety of rule-making arrangements, which transform the traditional conceptualizations of both the subjects and sources of international law, associated with states and inter-state legal agreements respectively (Cutler 2003, pp. 21-23). The proliferation and diversity of subjects and sources lie at the heart of the pluralization process. Such alternative legal subjects can be trans-governmental organizations or organizations comprising public national regulators with varying degrees of statutory independence from their governments, like the International Organization of Securities Commissions (IOSCO), the Basle Committee on Banking Supervision of the Bank for International Settlements (BIS) and the International Association of Insurance Supervisors (IAIS). The guidelines, standards and agreements produced by these organizations have increasingly been used as sources of transnational regulation, especially in the area of finance, and have become the driving force for the harmonization of national regulatory frameworks<sup>2</sup>.

Privatization refers to the fact that a significant drive behind pluralization is the emergence of a variety of private governance schemes. Civil society movements and non-governmental organizations (NGOs), transnational corporations (TNCs), international industry associations and chambers of commerce, transnational groups of experts, think tanks and lobbies, engage individually or in cooperation with each other, as well as with state agencies and other public entities, in the construction of an

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<sup>2</sup> For an analysis of trans-governmental governance networks see Slaughter (2000; 2004).

array of organizations, networks and regimes for the governance of an issue-area or an industry. These schemes vary in terms of organizational structure and formality, and their work ranges from technical standards,<sup>3</sup> to commercial standards,<sup>4</sup> to the harmonization of diverse national legal frameworks<sup>5</sup>.

As a result, we now observe an increasing array of governance functions taking place away from the territorial cradle of political authority, the nation-state (Cutler et al. 1999; Hall and Biersteker 2002; Held 2004; Koenig-Archibugi and Zürn 2006). Indeed, the term “global governance” which “includes formal institutions and regimes empowered to enforce compliance, as well as informal arrangements that people and institutions have agreed to or perceive to be in their interests”<sup>6</sup>, implies a departure of politics and political analysis from the exclusive preoccupation with “government” and the “intergovernmental” institutions that traditionally have been the focus of international relations’ analysts. Governance is not the same as government (Rosenau 1992). The fact that an amalgam of transnational and international regulatory arrangements has an increasingly significant impact on the lives and operation of national societies and economies raises significant issues of legitimacy and accountability (Underhill and Zhang 2003; Keohane 2003; Held and Koenig-Archibugi 2005; Zürn and Koenig-Archibugi 2006; Graz and Nölke 2008). This is because this situation undermines one of the central tenets of modern democratic theory. According to Held:

Throughout the nineteenth and twentieth centuries theorists of democracy have tended to assume a ‘symmetrical’ and ‘congruent’ relationship between political decision-makers and the recipients of political decisions. In fact, symmetry and congruence have often been taken for granted at two crucial points: first, between citizen-voters and the decision-makers whom they are, in principle, able to hold to account; and secondly, between the output (decisions, policies and so on) of decision-makers and their constituencies-ultimately, ‘the people’ in a delimited territory.

(2004, p. 16)

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<sup>3</sup> International Organization for Standardization (ISO); European Telecommunications Standards Institute (ETSI); Internet Engineering Steering Group (IESG).

<sup>4</sup> Internet Corporation for Assigned Names and Numbers (ICANN); International Chamber of Commerce (ICC); International Association of Classification Societies (IACS).

<sup>5</sup> International Accounting Standards Board (IASB); International Conference on Harmonization (ICH); Comité Maritime International (CMI).

<sup>6</sup> Commission on Global Governance (1995, p.2).

This symmetrical and congruent relationship however, is increasingly undermined on both counts. First, citizen-voters are not able to hold to account many of these transnational regulatory arrangements. There are three types of justification for an accountability requirement from the point of view of democratic theory: authorization, support and impact (Keohane 2003)<sup>7</sup>. Obviously, the majority of transnational, particularly non-state, arrangements have been neither authorized nor supported by voters, who often are not even aware of them. Nonetheless, such governance schemes may exert a considerable impact on the lives of the citizens of many countries. This raises a serious deficit of “external accountability: accountability to people outside the acting entity, whose lives are affected by it” (Keohane 2003, p. 141). Secondly, the congruence between the output of these decision-makers and their constituents is not guaranteed anymore, as the latter are organized along the principles of a territorially demarked space while the former extend beyond territorial borders along the lines of the functional geography described above. A potentially unaccountable and therefore illegitimate global governance structure represents a significant risk for democracy. Its operation may compromise the principle of autonomy in democratic societies, that is, the ability of persons to “enjoy equal rights, and accordingly, equal obligations in the specification of the political framework which generates and limits the opportunities available to them” (Held 2004, p. 147).

## **1.2 Coping with the challenge of global governance: what role for the state?**

The discussion above, demonstrates the urgent need to improve our understanding of the emerging multi-faceted and multi-level global governance structure. The examination and analysis of the role of non-state actors is particularly interesting in this context. Their participation is increasingly important, so much so, that in recent years an entirely new strand of research has emerged in order to examine the role of NSAs in the design and creation of the institutional and regulatory framework of global governance (Cutler et al. 1999; Higgott et al. 2000; Josselin and Wallace 2001;

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<sup>7</sup> “An accountability relationship is one in which an individual, group or other entity makes demands on an agent to report on his or her activities, and has the ability to impose costs on the agent. We can speak of an authorized or institutionalized accountability relationship when the requirement to report, and the right to sanction, are mutually understood and accepted” (Keohane 2003, p.139).

Hall and Biersteker 2002; Graz and Nölke 2008). The bulk of the first wave of this research was primarily concerned with examining a variety of non-state governance arrangements in order to reveal their existence and illustrate their significance as new transnational regulatory mechanisms. As a result, most of this literature focused on the role of NSAs in global governance and tended to neglect the role of the state in this process. Analysts tended to treat states as unwilling or unable to provide adequate governance structures; in view of this governance deficit, NSAs stepped in and increasingly assumed this role. Globalization, and particularly new technological and scientific developments and their impact on the operation of global markets, have usually been cited as the principal explanatory variables for states' attitude (Cerny 1995; Spar 1999; Florini 2000; Kobrin 2002).

The "inability/unwillingness of the state" thesis attributes to state actors a passive role. Contrary to this tendency, and without denying the constraints that globalization often poses to state action, some analysts have pointed out that states and their policies have also been responsible for the emergence of this complex transnational governance structure (Josselin and Wallace 2001; Pauly 2002). As the global governance literature matures from more general analyses and descriptive case-studies to engagement with specific institutional aspects of non-state governance arrangements, the relationship between the state and this plethora of transnational regulatory mechanisms is being explored in a more systematic way (Knill and Lehmkuhl 2002; Sassen 2006; Koenig-Archibugi and Zürn 2006; Graz and Nölke 2008).

This thesis aims to contribute to this emerging literature by exploring the role of state actors in the emergence of non-state governance structures. By emphasizing the role of state actors, this thesis aims to illuminate an aspect of non-state global governance often neglected. This approach reverses the usual course of enquiry, which investigates the reasons behind private actors' coordination to create governance mechanisms at the transnational level, and asks instead why and under what conditions do states tolerate, endorse or even participate in transnational regulatory arrangements?



### **1.3 Delineating the puzzle: identifying and explaining transnational regulatory authority**

In order to provide an answer to these questions, the role of the state in non-state governance structures shall be examined in the context of hybrid (public-private) global governance schemes. In such cases, the state is not simply tolerating or generally endorsing the work of a non-state forum, but it is intentionally and explicitly participating in its work. Both the institutional configuration of the hybrid forum and its history, and the elimination of alternative courses of action by states can provide us with material for analysis. What is more, this thesis will not investigate just any type of hybrid governance arrangements, since often the role and weight of the participating parties are very different and the resulting governance outcomes are characterized by varying levels of regulatory impact and/or legalization. In the theoretical and empirical analysis that follows, we shall focus on a specific type of hybrid global economic governance, increasingly visible in recent years. This specific type of hybrid governance refers to transnational institutions which involve both state and non-state actors and which produce regulatory outcomes that are being adopted by states as *legally binding*.

By focusing on those schemes that produce legally binding results, we hope to bring the state's role in non-state governance much more sharply and clearly into focus. This is an extreme paradigm of states' participation in non-state global governance structures; states not only get involved, but intentionally decide to invest the regulatory output of such hybrid collaborations with formal legality. In this case, it is not necessary to engage in a legal discussion about the actual impact or the proper status of soft-law instruments (Abbott and Snidal 2000; Cutler 2003) or to articulate a new theory of global law (Teubner 1997), when we want to investigate the consequences of states' participation in multi-level global governance. We can instead focus on a very specific question which is why traditional, hard-law, binding obligation has been attributed by states to regulation coming out of transnational non-state institutions.

In addition, the creation by a non-state institution of rules that acquire a legally binding force, is by itself, a truly novel and consequential aspect of global

governance worth investigating. By investing the rules of hybrid, non-state institutions with legal force, states are effectively surrendering part of their control over one of the most distinctive powers of the modern nation-state. Legal obligation is intertwined with the essence of the nation-state itself, as within the boundaries of states it is based on an explicit or implicit threat of physical coercion. The threat of physical coercion in turn, stems from what is perhaps considered the core distinctive feature of the state as a social institution: “the monopoly of the legitimate use of physical force within a given territory” (Weber in Hall and Biersteker 2002, p.3). However, the state is entrusted with this unique monopoly over the legitimate use of force on the basis of the democratic guarantees described earlier; when these guarantees are weakened at the transnational level, the normative questions raised from investing non-state rules with formal legality become even more pronounced.

In order to fully articulate the issues emerging from this kind of hybrid process we need a concept able to capture both its political and normative aspects. For this reason, the analysis in this thesis will be founded on one of the central concepts of political theory, that of *authority*. The most common and perhaps succinct definition of authority is that authority is legitimate power (Friedman 1990). Conceived in this way, authority can be an extremely useful concept as it embodies both a political dimension, the power of the state to rule within a given territory, and a normative dimension, the requirement of consent by the subjects of state power in order for this power to be regarded as legitimate and therefore authoritative. By using the concept of authority, we are effectively following the strand of research initiated by Cutler, Haufler and Porter (1999), who edited a volume that focused specifically on the under-researched role of corporate sector non-state actors in global governance. In that volume, the authors introduced an interesting and novel approach to examine NSAs’ involvement in global governance, the concept of *private authority*. This approach was further elaborated in Hall and Biersteker (2002) who extended the concept of private authority beyond the economic arena to the private moral authority of non-state religious movements and non-governmental organizations (NGOs) and to the illicit authority of mercenaries and mafias.

Despite its positive contribution, it should be said that the literature on private authority is still in its initial stages and significant work remains to be done, especially when one takes into account the inherent theoretical and normative problems associated with the concept of authority. One of the problems with the concept of private authority is that it does not address adequately the particular characteristics of *in* authority. *In* authority “is a property of rules and offices created by rules. Individuals possess it by virtue of holding an office in an organization, such as a state, a corporation, a university or a trade union that is (partially) governed by more or less formalized or codified rules” (Flathman 1980, p. 16-17). This is different from either expertise (*an* authority) or simply power to change the behaviour of others. It is only those *in* authority that issue and apply rules and commands which entail obligations to act. Political authority therefore always refers to *in* authority (Flathman 1980). Many transnational non-state arrangements enjoy *an* authority based on the expertise of the participating parties, or have the power to enforce de facto their decisions in a given issue-area or industry. These arrangements should not be considered authoritative since they are not, for the most part, viewed as obligatory or legitimate by the parties potentially affected by them. This distinction is not adequately stressed by the private authority literature and as a result, a variety of non-state governance arrangements are treated as authoritative even when they lack the particular attributes of *in* authority. This tendency confuses rather than clarifies both the institutional and political characteristics of various non-state governance arrangements and obscures the clarity of the concept of private authority itself.

The purpose here is to use the concept of authority in a way that captures the political and normative consequences of attributing legal force to non-state rules, while differentiating the resulting governance arrangements from other non-state governance structures. For this reason, following an analysis of the concept of authority at both the domestic and international level, we introduce in the following chapter the concept of *transnational regulatory authority* which refers to transnational, non-state, authoritative rule-making. This concept, used to illustrate the delegation of regulatory authority (*in* authority) to non-state actors, will become the focus of the thesis. This delegation of authority is puzzling as it implies costs not only

in terms of an erosion of the internal sovereignty of states, described earlier, but also in terms of legitimacy, since authority has been entrusted to the state under specific procedures which form the very foundation of a democratic political association. Delegating part of this authority to transnational non-state actors potentially violates these procedures and undermines the legitimacy of the state.

Consequently, I believe that in order to provide a comprehensive explanation for the puzzle of transnational regulatory authority three fundamental questions need to be answered:

- Why do regulators and/or politicians participate in hybrid governance schemes or acknowledge the rules produced by non-state governance schemes giving rise to transnational regulatory authority?
- Under what conditions do they have an incentive to use or endorse transnational regulatory authority, compared to other international and/or transnational institutional mechanisms?
- How are they able to reconcile this delegation of authority to private actors with the principles of public *in* authority?

The answers to these questions are provided through a theoretical framework that combines the insights of the economic theory of international regulation (Oatley and Nabors 1998; Richards 1999) and the political theory of authority (Friedrich 1958; Pennock and Chapman 1987; Flathman 1980; Raz 1983, 1990). The answers to the first two questions proposed above, address the functional preoccupations of the holders of regulatory authority by focusing on their efforts to ensure their political survival through the use of transnational regulatory authority. The basic argument of the thesis is that national regulators and/or politicians will use transnational regulatory authority to satisfy specific domestic constituencies, in their effort to maximize their own political gains. To achieve this, they are likely to use transnational regulatory authority in two cases. First, when it allows them to effect redistribution among domestic constituencies with lower political costs than through other alternatives. This is more likely to happen when, in issue-areas with highly complex scientific, technical and/or technological content, the issues being regulated

have a high potential to mobilize wide public opposition. Secondly, regulators and/or politicians may use transnational regulatory authority in order to redistribute wealth from foreign to domestic constituencies. This strategy may be employed when, in issue-areas or industries characterized by an oligopolistic global market structure, there are significant distributional conflicts among the dominant market players, which cannot be resolved through international institutions; in this case transnational regulatory authority may be used as a forum-shifting strategy.

However, the political equilibrium that regulators and politicians strive to achieve is affected not only by interest-driven considerations stemming from their substantive goal of being re-elected or re-appointed, but also, as pointed out previously, by normative and institutional constraints that stem from their position as holders of authority. These constraints are addressed by the third research question. Here, apart from procedural criteria that have to be satisfied, we would expect regulators and/or politicians to justify the delegation of regulatory authority by arguing that it is necessary, because changes in scientific knowledge and/or technology have altered the nature of an issue-area or industry, thereby hindering the ability of traditional state and/or inter-state mechanisms to provide an adequate standard of governance, on their own.

These two sets of constraints are not irreconcilable. Their basic difference is that they address different aspects of public *in* authority. While interest considerations refer to the reality of *authority as practice*, normative considerations relate to the *concept of authority* itself. I believe that the key for understanding when states delegate their regulatory authority is to be found at the crossroads of the normative foundation of public *in* authority and the functional foundation of its institutional manifestation; in other words at the intersection of the interest-based political behaviour illustrated by the positive theory of regulation and the normative and institutional limits outlined by the political theory of authority.

#### **1.4 Locating the empirical puzzle: introducing the case studies**

The propositions developed in the theoretical framework presented above, will be tested for their empirical validity through the use of two case studies. The first case study will examine the transnational regulatory authority of the International

Accounting Standards Board (IASB) while the second case study will focus on the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceutical Products (ICH).

The IASB and its predecessor, the International Accounting Standards Committee (IASC), have been engaged in the international harmonization of accounting standards for the past three decades. The IASB is one of the most successful examples of transnational non-state governance, but more importantly, it is embedded in formal institutional structures alongside state and other public actors, sharing part of their regulatory authority. Since 2005 the International Financial Reporting Standards (IFRSs) produced by the IASB have replaced national accounting standards for the consolidated accounts of listed companies in the European Economic Area (EEA), while a similar process has already been adopted or is under way in an increasing number of countries.

The history of the IASB has been marked by significant differences among the interested parties. Particularly important for its development has been a conflict between the Securities and Exchange Commission (SEC), the United States' financial markets' regulator, and the European Commission (EC), about the direction of accounting harmonization and consequently about the burden of adjustment for this harmonization. As we shall argue, the emergence of the IASB as an authoritative global accounting standard-setter is the result of a forum-shifting strategy employed by the European Commission when unable to persuade the SEC of a mutually acceptable harmonization of accounting standards. While the overall strategy of the EC has been successful, since the SEC has come to accept a roadmap for allowing IFRSs as a legitimate set of accounting standards that can be used in the US capital markets, the content and direction of harmonization have not exactly been what the EC had hoped for. This is because the SEC engaged the IASC first, in the context of a forum-shifting strategy of its own, albeit in an effort not to establish transnational regulatory authority but rather to control and if possible prevent its emergence.

The ICH on the other hand, is a transnational body which brings together regulators and industry associations from Europe, Japan and the US. The ICH issues Harmonized Tripartite Guidelines which aim to provide common guidance in the

three states/region on how to conduct the evaluation of applications for new medicines for human use. The ICH is one of the most successful examples of transnational non-state governance, and is embedded in a formal institutional structure where non-state actors and regulators share in equal part the authority to regulate the drug approval procedure. So far the ICH has issued more than 50 guidelines which have been adopted by the three regulators and have been incorporated in the national/regional regulatory framework alongside other guidelines and regulations, often replacing the latter.

Following sustained pressure from their respective industries, the regulators of these three states/region had started looking for alternative harmonization forums since the early 1980s, as soon as it became clear that the regulatory direction pursued by the World Health Organization (WHO) was linked to demands for a New International Economic Order (NIEO)<sup>8</sup>. While distributional conflicts among the major players in the pharmaceutical industry account to some degree for the push for international harmonization, they were not a dominant factor, as all three significant market players agreed on the need and basic purpose of harmonization. This agreement was mainly a result of the coordinated pressure from their domestic research-based pharmaceutical industries. The industry was in favour of harmonization as regulatory diversity produces significant problems in terms of both monetary costs in the research and development process (R&D), and time delays in the introduction of new drugs in the market. This agreement was given an additional boost in the late 1980s by domestic public and political pressure to make more efficient the drug approval process. The coincidence of industry pressure and domestic political circumstances favourable to harmonization gave added urgency to the regulators' move towards the harmonization of drug approval and registration procedures. Harmonization however did not have to occur in a transnational regulatory forum like the ICH. The fact that it did is a testimony to the ability of the

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<sup>8</sup> The increasing influence of developing countries in the United Nations apparatus, which wanted to use the UN as a forum for rebalancing their political and economic relations with the developed countries and with multinational corporations, led to the adoption of the Declaration and Programme of Action on the Establishment of a New International Economic Order (NIEO) in 1974 (General Assembly Resolution 3201, UN). The goal of the NIEO was "to eliminate the widening gap between the developed and the developing countries" (UN 1974).

industry to influence the pharmaceutical regulatory process. The ICH has offered the industry a privileged position while excluding other stakeholders, and has followed closely the objectives and agenda of the industry. In other words, the ICH represents a case of domestic redistribution in all three regions of the ICH, where the interests of the pharmaceutical industry have been given priority over the interests of the public.

### **1.5 Methodology**

In this final section an overview of the methodology used in this thesis is presented and potential methodological questions and concerns are addressed. First, we need to justify the choice of the case study method. The case study method was chosen here because it is uniquely suited to the study of a complex social phenomenon such as transnational regulatory governance and authority. The case study method is particularly relevant when the number of cases is relatively limited and large-n studies are not possible, but also when it is difficult to disaggregate the phenomenon under study into constituent dimensions that can be examined through the use of alternative methods. This is particularly the case when the issues involved are not amenable to statistical analysis (King et al. 1994) or when the boundaries between the phenomenon under examination and its context are not clearly evident (Yin 2003). All of these factors apply to the phenomenon of transnational regulatory authority which is an extremely complex phenomenon comprising public and private, national and transnational actors, engaging in complex regulatory governance at a transnational, and often a global level. Cases of this phenomenon are not yet numerous but they exist and their number is likely to increase in the coming years. Moreover, the issues that characterize transnational regulatory authority and indeed set it apart from other non-state governance schemes are issues such as legitimacy, authority and accountability which cannot be quantified, and which are intricately linked to a specific political context within the confines of a given political community.

The organizations at the centre of the two case studies have been examined through the use of both secondary and primary research material. Review and analysis of textbooks, research monographs and articles in academic and professional journals formed the basis and starting point for their study, which was complemented



and completed with the analysis of original press articles and news reports, primary documentary sources (official documents and reports, press releases, pieces of national and international legislation and regulatory codes, standards and guidelines, internal guidelines and notifications of national, international and transnational organizations) and finally, semi-structured, in-depth interviews with a number of active and former representatives of both these two organizations and other organizations which are actively involved in their work, some of whom have played a defining role in their evolution and current success.

The choice of these two particular case studies was based on three factors. First, they are cases that exhibit clearly the characteristics of transnational regulatory authority. As discussed earlier, this phenomenon has not been discussed as a distinct phenomenon in the private authority literature and finding cases that clearly demonstrate its difference from other non-state governance schemes is essential in order to illustrate the new and unique nature of this phenomenon. Secondly, these two organizations are extremely successful and have produced impressive regulatory results especially when compared with the results of other non-state governance schemes. As such they should provide us with an in-depth understanding of the conditions under which this strategy can be successfully pursued by regulators. Thirdly, while both of these organizations bear the mark of transnational regulatory authority, they are different enough to make their comparison a compelling exercise and one that would significantly enhance the validity of the arguments and our ability to claim a wider generalization of the conclusions of this thesis. Both the institutional characteristics and the historical development of these two organizations differ significantly. Thus, while the IASB was established as a pure private sector professional organization whose work gradually begun to be adopted by states, the ICH was created from the beginning as a public-private hybrid regulatory project with well-defined roles for both parties. Moreover, the issue-areas for which these organizations provide regulatory governance are considerably different; the policy and normative issues that arise are therefore varied enough to provide an additional test for the generalization of our framework's propositions. Indeed, as we shall see, these two cases represent the two different types of redistribution (domestic and

international) proposed by our theoretical framework, providing thus a stronger test for the validity of the thesis' main redistributive argument.

A final issue which deserves to be addressed in this methodological section is whether these two case studies are enough to support the theoretical validity and generalization of the argument presented here. I believe that these two case studies provide sufficient evidence to establish the theoretical validity of the propositions made in this thesis. This belief is grounded on three factors. First, as already mentioned, this is a new and emerging phenomenon and there are few cases that could be examined. The ability of including a large number of case studies is therefore as of yet quite limited. Secondly, the question of the appropriate number of case studies is founded on a "sampling logic" which treats multiple cases in the same way as multiple respondents in a survey; this procedure is used when we want to determine the prevalence or frequency of a particular phenomenon and is ill-suited for the case study method (Yin 2003, pp. 47-48). Moreover, a sampling logic necessitates random selection of cases (to ensure that selection is not biased) which in small-n cases can have the opposite results and lead to significant bias distortions (King et al. 1994, p. 126). Contrary to sampling rationality, "each individual case study consists of a 'whole' study, in which convergent evidence is sought regarding the facts and conclusions for the case; each case's conclusions are then considered to be the information needing replication by other individual cases" (Yin 2003, p. 50). This is why multiple case studies are similar to multiple experiments which are replicated to verify the results; in this case what we are after is not *statistical generalization* but *analytic generalization*, where "a previously developed theory is used as a template with which to compare the empirical results of the case study" (Yin 2003, pp. 32-33). Thirdly, the two case studies examined here offer a sufficient number of *observations* for the examination of each proposition. It should be remembered that the dependent variable of the thesis is the behaviour of regulators and/or politicians. Here we focus on a total of five regulators: two for the IASB case and three for the ICH case. Given that the thesis examines three different research questions each with one or two explanatory variables, which often operate complementary to each other and at

different levels of analysis, I believe that the observations available are sufficient to support the theoretical propositions of the thesis.

Following this introduction, the next chapter develops the conceptual basis upon which the rest of the thesis shall be developed. After engaging with an analysis of the phenomenon of non-state authority, we introduce the concept of *transnational in authority* and demonstrate its analytical distinction from other forms of transnational non-state governance.

## Chapter 2

### Conceptualizing Transnational Non-state Authority

#### 2.1 Introduction

The introduction of the concept of authority in the analysis of non-state governance arrangements (Cutler et al. 1999; Hall and Biesteker 2002) has been a positive contribution to the global governance literature, since earlier works did not discriminate adequately between private power and private authority and often used the terms interchangeably<sup>9</sup>. Despite this positive development, as we have already argued, the literature on private authority is still in its initial stages and significant work remains to be done. This chapter aims to contribute to our understanding of the phenomenon of *non-state authority* at the domestic and the transnational level. This objective is pursued first, by outlining the main characteristics of authority and identifying the sometimes loose and inconsistent use of the term in the private authority literature. This can hopefully help us distinguish between cases of authority limited to a private setting, of authoritative knowledge and expertise, and of authoritative non-state governance of areas of public life and activity. This latter phenomenon, which is of interest here, will be defined more narrowly as a type of authority which partakes of what is traditionally called political authority. In order to understand this new type of authority we shall demonstrate the analytical foundations of its constitution and examine the conditions of its emergence.

#### 2.2 Authority

The identification and analysis of instances of non-state authority has to begin with a clarification of the concept of private authority, as this has been proposed in the

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<sup>9</sup> Strange (1996) for example often refers to power and authority interchangeably without making any analytical distinction between them. She defines politics as “those processes and structures through which the mix of values in the system as a whole, and their distribution among social groups and individuals was determined” (Strange 1996, p.34). According to Strange, her definition is derived from Easton’s famous definition of politics as: “the authoritative allocation of values in the system” (Easton 1953, p. 143). Her definition however, departs from Easton’s in one significant point: Easton speaks of the authoritative allocation of values, while Strange is concerned only with the actual distribution of values. By omitting the crucial qualification “authoritative”, Strange effectively equates authority with power; she defines politics as the effective allocation of values, without examining whether this allocation is regarded by its recipients as legitimate and obligatory or not.

literature. To do this however, it is first necessary to define authority. Authority is a very complex concept and different meanings have been ascribed to it from the early days of the Roman Republic when the term was first used<sup>10</sup>. Since then different approaches have been competing to establish their own definition of authority<sup>11</sup>. Despite the differences however, there are some characteristics which are commonly accepted as essential constitutive features of authority by most scholars.

Perhaps the most significant of these is the acknowledgement that authority is not a homogeneous concept. In different contexts, authority can have different meanings. Based on this observation, a basic distinction is commonly made between “an” and “in” authority (Flathman 1980; Friedman 1990). *An* authority “is based on, is possessed by virtue of, demonstrated knowledge, skill, or expertise concerning a subject matter or activity”, while *in* authority “is a property of rules and offices created by rules. Individuals possess it by virtue of holding an office in an organization, such as a state, a corporation, a university or a trade union that is (partially) governed by more or less formalized or codified rules” (Flathman 1980, p. 16-17). This distinction is crucial for the purposes of this thesis, because as will be shown later in this chapter, it can help us delineate the various aspects of private authority and identify those instances that constitute a truly consequential change in the structure of global economic governance.

Another significant distinction is that between authority and power. Authority is usually called legitimate power to distinguish it from pure power, the main difference being that authority has to be viewed as legitimate by the people that are subject to it. As Flathman (1980, p.164) argues, the main analytical difference between authority and power is that authority entails the obligation of its subject to conform to its rules and commands, while the acceptance of power does not result in a comparable obligation to yield to it; indeed it could actually be a reason to resist it. Legitimacy, or a sense of obligation, therefore, is a distinct characteristic of authority. This sense of obligation also distinguishes authority from persuasion. This is because

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<sup>10</sup> For a discussion of what the concept of authority meant for the Romans see Arendt (1958); also Lincoln (1994).

<sup>11</sup> For a number of different approaches to the concept of authority see Friedrich (1958); Pennock and Chapman (1987); Flathman (1980) and Raz (1979, 1990).

authority is not founded on the exercise of rational calculation and the exchange of argument, but rests on the fact that the person or organization that issue a pronouncement or a command warrant acceptance solely on the basis of their authoritative status. Authority is not obeyed because people consider its individual commands and pronouncements to be in their individual interest but due to a sense of obligation and an acknowledgement of the legitimate right of authority to issue commands and pronouncements. The exercise of either coercion or persuasion therefore, is not compatible with authority. As Arendt (1958, p. 82) puts it: “where force is used, authority itself has failed” and “where arguments are used, authority is left in abeyance”.

By differentiating authority from both persuasion and coercion and therefore the rational calculation of both interests and threats, we are left with what has been characterised as a central element of authority, the “surrender of private judgement”. While the surrender of private judgement is considered central to the concept of authority, there is no general agreement on exactly how much judgement people are supposed to surrender. First of all, it should be made clear that the surrender of private judgement is not equally important for both *in* and *an* authority. Indeed, in the case of *an* authority often there needs to be no surrender of individual judgement at all. This is ironic given that *an* authority is founded on the fact that some individuals know more about certain issues than others. This inequality is the very source of *an* authority; it is antecedent to the authority relation, since *an* authority is based on the fact that “it is *because* of the superior insight of some person that he should be acknowledged as “an authority” by others: the deference relation is thus supposed to reflect the antecedent concrete “personal” differences between the parties” (Friedman 1990, p.82). Therefore, someone who is *an* authority can make a statement that carries his or her authority as an expert and for that reason people can give such a statement added weight compared to other statements or factors in order to make a judgement. By doing so however, people do not necessarily surrender their judgement for that of the expert (although often they do so) but can actually exercise their individual judgement to both weigh the expert view against other views, and after considering all views, to reach a judgement of their own. To use Raz’s language, *an*

authority gives another reason to be added in the balance of reasons that one has to judge before making a decision (Raz 1979).

Things are quite different with *in* authority however. This is because *in* authority, contrary to *an* authority, is based on a premise of equality, not inequality; it is a subtle type of equality: “the assumption is not that nobody actually knows more than anyone else, that no one is wiser, better or superior; but rather that no one can “persuade” the others that his judgement is superior, such as to justify deference” (Friedman 1990, p.82). It is because of the difficulty to reach collectively agreed decisions therefore that *in* authority is established as the remedy to collective action problems. As Friedman puts it: “the authority relationship will then appear as an elaborate contrivance designed to achieve agreement at the procedural level in the face of disagreement at the substantive level – by defining whose judgement is to count as “public” and whose judgement is to be deemed “private” (1990, p.78). Private in this sense does not refer to judgement pertaining to issues of the private sphere or “apolitical” matters, but rather on judgement that is non-authoritative, that is, not entitled to prescribe behaviour. Nonetheless, this does not mean that individuals do not exercise their judgement. The surrender of private judgement even in this extreme sense, does not entail surrendering judgement altogether. Friedman acknowledges that people may judge and disagree with the content of a specific pronouncement or command but they will obey it nonetheless; in this sense “what is suspended is not judgement but choice: the subject desists from acting on his own judgement, even though he may “privately” dissent from the authoritative utterance” (Friedman 1990, p.72).

In addition to this type of judgement, Flathman (1980) adds another layer of private judgement: at the very least subjects of authority must exercise judgement in order to decide whether a command is indeed authoritative and therefore warrants their obedience as such. To do this, people use certain criteria, usually referred to as the “mark of authority”. These criteria can be specific procedures, uniforms, insignia or even social attributes such as wealth. They offer a public verification of the authoritativeness of the source that makes a pronouncement. Their identification and acceptance are dependent on a number of shared beliefs and values that form the basis

and constitute a precondition for the acknowledgement of authority. Moreover, shared beliefs and values are necessary not just for the practical operation and identification of authority, but for its very existence. The common acknowledgement of these beliefs and values "...posits acceptance of some set of propositions according to which it is right or proper that there be authority at all and that such authority be established, lodged, distributed, exercised and so on in this or that manner" (Flathman 1980, p.20). However, once people have established that a rule, command or pronouncement is authoritative, they surrender their right to make obedience to them contingent to their judgement about their substantive merits. As we saw, individuals can still judge these statements on grounds of merit (although often they will not) but they will not act on them; they surrender their right to act on their substantive judgements. Therefore, authority can be thought of as "the ability to change reasons for action" (Raz 1979, p.16). In the case of *in* authority, commands and orders are not only a reason to act by themselves, but they also exclude other reasons for consideration before acting. A person can judge the "balance of reasons" for an action but accepting *in* authority means "giving up one's right to act on one's judgement on the balance of reasons" (Raz 1979, p.26).

### **2.3 Private authority in global governance**

Having identified the central elements of authority, we can now move on to the concept of private authority as used in the literature on global economic governance. A straightforward definition of private authority would need to include the above features of authority in addition to an acknowledgment that its source can be found in the private sector. Indeed, Cutler et al. (1999, p. 5) argue that authority exists when an individual or organization has decision-making power over a particular issue-area and is regarded as exercising that power legitimately. They also distinguish authority from cooperation, and argue that cooperative relations become authoritative when they are considered to be binding, when the element of obligation is introduced into them. Finally, they make the significant point that such authority need not be associated exclusively with government institutions.

While capturing much of the essence of non-state authority, these characteristics reveal a significant omission in the conceptualization of private



authority. They do not distinguish adequately between *in* and *an* authority. By failing to distinguish analytically between the two aspects of authority, the authors attribute to private *an* authority characteristics that do not belong to it; therefore, such a conceptualization confuses rather than clarifies what is exactly meant by private authority. Thus while the authors note that obligation is an essential element of authority and link this obligation, rightly so, with the “right to rule” (Cutler et al. 1999, p.363-364), they then go on to ascribe this right to rule to both *in* and *an* authority. Regulating the behaviour of others in an obligatory way however, is a feature associated with *in* authority not *an* authority.

To illustrate why this is so and to demonstrate why the consequences of such a misconception of private *an* authority are significant, let us return to the concepts of *in* and *an* authority. As we saw, *in* authority requires the surrender of private judgement because it is created to design and enforce rules necessary for the community that perhaps would not otherwise exist given the problematic nature of collective action. If people acted on their own judgements about substantive issues, even if that meant disobeying the rules of the established authority, then there would be no point in having such an authority. Individuals have to obey the utterances of *in* authority; it has to be obligatory to be meaningful. This is why *in* authority is usually accompanied by the ability to use sanctions to enforce its rules. This ability to wield force is considered legitimate as long as it operates to enforce the rules of the authority in a manner consistent with the rules that created authority in the first place. On the contrary, as was described above, *an* authority does not require the surrender of private judgement; while people take seriously an expert opinion, its pronouncements need not be obligatory. It follows therefore that obligation is a feature associated exclusively with *in* authority: “whereas those *in* authority issue and apply rules and commands which themselves entail obligations to act, *an* authorities make statements, pronouncements, and performances” (Flathman 1980, p. 18).

The omission to adequately distinguish between private *an* and *in* authority leads to an exaggeration of both its novelty and significance for the global governance structure and obscures analytical work. Treating thus the expertise of non-state actors as private authority, without any qualification, makes analysis

difficult; the qualification of such authority as *an* authority is essential because it places it in its proper context and restores it to its proper dimensions. Hall and Biersteker for example, argue that the capacity of NGOs to provide expertise grants them “regulatory authority” (2002 p.218). The expertise of non-state actors however, is not something new. Indeed, when we talk about an expert we usually mean a person or perhaps an organization and hardly ever a state. Expertise constitutes an essential part of the role often played by non-state actors. Moreover, this has been acknowledged by states for a long time. Indeed, the advice of non-state actors has been formally sought since the establishment of the United Nations, as article 71 of the UN Charter makes clear: “The Economic and Social Council may make suitable arrangements for consultation with non-governmental organizations which are concerned with matters within its competence” (UN 1945). While the involvement of both civil society NGOs and private sector actors in the United Nations’ structure and agencies and indeed in most international organizations has increased dramatically in recent years, this development by itself does not constitute a substantially new phenomenon in the area of international governance. These actors still perform, for the most part, the traditional consultative and lobbying roles of non-state actors. The increased significance of technology and functional differentiation is a determining factor of the globalizing world economy and it is increasingly making expert knowledge a significant asset in the hands of non-state actors. Nonetheless, the possession of this knowledge *by itself* does not provide NSAs with authoritative decision-making capacity over an issue-area.

What we are really interested in, and what the definition proposed by the authors above implies, are instances of private *in* authority. The authority to regulate in a legitimate and binding way the behaviour and activities of actors in a sphere of activity or an issue-area. This regulatory authority has to be *in* authority since it has to flow and operate according to rules that spell out its purpose, its scope and its mode of operation. These specific institutional characteristics of *in* authority are also ignored by Biersteker and Hall (2002) who introduce another type of market authority, “normative market authority”, which “refers to the general acceptance of the more abstract idea that markets should determine decision-making over important

issues” (2002, p.214). However, such abstract ideas about the role of the market in the governance of economic activity are not necessarily related to the ability of particular actors to govern authoritatively an issue-area or industry. Moreover, state leaders’ proclamations that “the forces of the global market give them little room for manoeuvre” do not create “the authority of the market” as the authors argue (2002, p.6), but constitute admissions of the reduced ability of the state to control transnational market forces. These forces, by eroding the ability of the state to exercise its authority, do not in any sense become themselves the authoritative regulators of the world economy. On the contrary, their actions raise significant concerns of legitimacy over their role, concerns entirely inconsistent with notions of authority.

Ambiguity is also encountered in other aspects of the analytical work underpinning the concept of private authority as well as in the analysis of empirical data. In the first case, this leads to a problematic conceptualization of private authority and to an analytical treatment of its features that is often inconsistent, while in the latter it often results in the erroneous characterization of non-state governance mechanisms as authoritative. Obviously the two are related, since it is the analytical and theoretical inconsistencies that lead to incorrect interpretations of empirical cases.

To illustrate the point let us look at the way Cutler et al. (1999, p.365-369) address the conceptual and theoretical obstacles inherent in the notion of private authority<sup>12</sup>. The authors identify at least two obstacles to theorizing about private authority: a) conceptualizing international authority in conditions of anarchy, and b) conceptualizing private action as authoritative. In this part of the chapter we will concentrate on the second obstacle since it is that which deals directly with the concept of private authority, while the first obstacle will be addressed later in the chapter. The authors admit that the common understanding of public governance is associated with the concept of *in* authority. This concept is in turn associated with hierarchical depictions of authority relations, which depend on rules and procedures according to constitutions that guarantee the representativeness and accountability of

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<sup>12</sup> The reason for selecting Cutler, Haufler and Porter (1999) as the main target for criticism is that their work represents the most comprehensive attempt to conceptualize private authority in global governance to date.

government. Political authority is thus public by definition, because only public judgement is regarded as legitimate and authoritative in the sense of being able to “prescribe behaviour”. Under this view, private judgement in contrast is non-authoritative: it is not accountable to democratic institutions. The legitimacy of political authority is inescapably linked with its public nature and inconsistent with decentralized, horizontal, self-governance arrangements, as well as with notions of private governance and the concept of *an* authority.

However, they argue that this obstacle of the established conceptualization of authority is only convincing if one accepts that the normative argument, that private power “ought” not be regarded as legitimate and binding, is enough to validate the empirical statement that in fact private power is non-authoritative and legitimate. The public dimension of authority is only an obstacle if one accepts that private power does not *in fact* operate in an obligatory and legitimate way. The authors thus argue that it is only a normative statement that prevents us from conceptualizing private authority. Moreover, the authors also argue that this conceptual obstacle is only convincing if one limits rules to commands and directives. They acknowledge that private actors lack the authority to enforce and prescribe domestic laws of general application unless such authority is delegated to them by governments and that the rules most relevant to private authority are those called “soft law”, which is based on its mutually consensual nature (Kratochwil 1989). They assert however, that the instruments of “soft law”, while not law proper, do in effect govern relations among a variety of actors and therefore the obstacle of conceptualizing private authority can be overcome.

I would argue that this thesis is untenable. First of all, it is not only a hypothetical normative argument that stands in the way of acknowledging private authority. The fact is that in reality, instances of such private regulation are not generally regarded as legitimate and binding. The concerns about the legitimacy and accountability of such private rules (Hall and Biersteker 2002; Cutler 2003; Keohane 2003; Held 2004; Held and Archibugi 2005; Zürn and Archibugi 2006) is a point in case; increasing anxiety about the unaccountability of non-state organizations, given their influence, points to the fact that such *de facto* rules represent instances of private

power and not private authority. Secondly, as we saw above, the authority to regulate an issue-area has to be *in* authority. The fact is that in most, if not all of the cases that the authors have in mind, the private organizations that attempt to regulate an issue-area do not have an explicit or implicit mandate from *all the parties* that are affected by their rules, that is, there exists no procedural agreement that establishes the authority of these organizations. These organizations represent only the parties that are involved in their work and not the totality of the people and institutions that would be affected by their rules. Therefore, the argument that private rules “ought” not to be considered authoritative is not only a normative argument, but derives from an empirical fact, their unaccountability, that is, their failure to satisfy the conditions of *in* authority. Interestingly, many of the analysts of private authority “raise explicit concerns about the limited degree (or virtual absence) of accountability of private authority” (Biersteker and Hall 2002, p.211). An unaccountable authority however, is a contradiction in terms. Thirdly, and following from above, the normative argument that private power ought not to be regarded as authoritative would not be possible if private power was in fact authoritative. If there were instances of such private authority, this argument would not be advocated since private power would already be considered legitimate. As we saw previously, the identification and acknowledgement of authority is itself a normative process; it depends on the inter-subjective values and norms shared among the subjects of authority. The question of whether a rule is authoritative or not, cannot be considered apart from the question of whether it is legitimate or “ought” to be considered as legitimate. If people see private power as unaccountable and undemocratic then by definition they do not consider it legitimate and thus authoritative. The very nature of authority, the necessity of a sense of obligation and legitimacy, makes the issue of identifying and acknowledging authority an inescapably normative one.

The argument concerning the obligatory nature of private rules also deserves detailed examination. In the first instance, since the authors have defined as a constituent feature of authority the binding nature of rules, the acknowledgment that non-state actors lack the capacity to enforce their rules makes their characterization of “soft law” as adequate in order to bestow authority on its creators a self-contradictory

statement. Indeed, their agreement with Kratochwil on the characterization of “soft law” as mutually consensual and their acknowledgement of the uncertainty of the exact nature of these instruments which are not “strictly binding norms of law” (Akenhurst 1987, p.54), underlines that the essence of these instruments is their mutual, voluntary adoption by the participating actors. The voluntary nature of soft law instruments is not by itself a reason for disqualifying them as authoritative. Indeed, all authority is ultimately voluntary for if it was not, then we would be talking about coercion not authority. As we saw however, *in* authority explicitly involves obligation. This obligation can take two forms<sup>13</sup>: a) legal obligation, defined strictly as an obligation to conform to certain rules. Failure to do so can result in the use of (legitimate) force to bring about obedience with the rules; b) “moral” obligation, defined as the voluntary acceptance of authority as legitimate which produces a voluntary decision to consider the commands of authority as binding on one’s self.

Soft law instruments clearly do not have the ability to invoke legal obligation as defined above, since no legal sanctions usually emanate from disobeying or ignoring them. What is more, I would argue that soft law arrangements in the private sector do not exhibit signs of moral obligation either. The reason is that the organizations that produce such rules are explicitly instrumental. This means that they address specific regulatory needs of the participating parties. In that sense they represent one of the strongest manifestations of what Oakeshott (1991) calls “enterprise associations”<sup>14</sup>. The crucial element that distinguishes such an association is its purpose. The members of these associations, which form for the pursuit of a common substantive purpose, may have some rules that can be considered authoritative and which establish the association and determine its procedural mode of operation. However, “these rules are not to be confused with the managerial decisions, agreements, etc., which constitute the pursuit of the purpose” (Oakeshott 1991, p.116). These managerial decisions are the most important distinctive element

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<sup>13</sup> Friedman (1990) makes a similar distinction for legitimacy in relation to authority: a) legitimate reasons to obey an authority and b) legitimate use of force to exact obedience to authority.

<sup>14</sup> Oakeshott defines an enterprise association as a “relationship in terms of the pursuit of some common purpose, some substantive condition of things to be jointly procured, or some common interest to be continuously satisfied” (1991, p. 114); moreover the enterprise association is also a relationship “in terms of ...the “management” of its pursuit” (1991, p. 115), where “management” signifies the actions or utterances that actors make in the pursuit of their common purpose.

of the association not the procedural rules that establish it, because it is the former that are decisive for the pursuit of the common objective. For the same reason, the desirability of the procedural rules is contingent on their contribution to the achievement of the common goal. Therefore, these rules are only considered authoritative as long as they contribute towards the achievement of the common purpose. It follows then that “even a denial of the authority of these rules would not itself be an act of dissociation, as it would be if the terms of association were the rules themselves” (Oakeshott 1991, p.117).

While therefore, the creation of a private “regulatory” organization represents to some degree a collective agreement on a procedural level in order to resolve differences at a substantial level, very much like the establishment of *in* authority, this procedural agreement does not define the organization but acts only as a facilitating factor. The reason behind the creation of such an organization is not to have an authority which can then decide which rules are appropriate. In other words such an organization does not enjoy self-sufficiency,<sup>15</sup> a characteristic that Oakeshott (1991, p.110) describes as “being always self-complete in the sense of having no extrinsic substantive purpose”. These organizations have an explicit substantive purpose: to produce specific rules that address their particular needs. All else is subordinate to this objective. The procedural rules that establish and define the structure and operation of the organization do not create an authority that can claim surrender of the judgement of the participating actors irrespective of the content of its proposals. Therefore, if the organization (authority) proposes a rule that is not desirable to some of the members, they may feel entitled not to endorse that particular rule since they have not agreed to defer their judgement to the organization; they will only agree with its proposals as long as they judge (individually) the substantive merit of these proposals to be satisfactory.

This becomes more evident when we consider that in such organizations the parties subject to the “authority” of the organization are not adequately separate from it. They are the ones that really create the rules through a continuous process of

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<sup>15</sup> This characteristic refers to Aristotle’s view that self-sufficiency (*autarkeia*) is the ultimate goal and a basic constitutive element of a political society (*polis*). See Αριστοτέλης (1993).

bargaining and negotiation that represents their conflicting interests. The operation of such organizations does not reflect a mutual deference of authoritative decision making over the activities of interested parties to an independent organization. Instead such organizations resemble more a meeting place, an agreed procedural and institutional context within which the interested parties meet to deliberate and decide upon mutually agreed norms, rules and standards, through processes of negotiation, bargaining and power politics. In this context therefore, the differences on the substantive merit of the proposed rules, which is the priority of the members, become an obstacle for the establishment of a true authority over the members of the organization. Obviously this is not what happens with *in* authority where the procedural rules which establish it are the very source of authority. It is exactly because of the legitimacy of the procedural rules that parties believe the substantive rules to be authoritative. It is therefore the legitimacy of the procedure that creates the moral obligation on the subjects of authority to abide by its rules even when they disagree with it. In this type of voluntary organizations, the participating parties do not feel a moral obligation towards the rules that establish the organization and its decision-making body<sup>16</sup>. Thus, they feel free to disobey substantive rules when they disagree with their content. In other words they do not surrender their private judgement. The enforcement of the rules is dependent upon the continuous rational calculation of interests by the participating parties, which may very well decide to depart from the informal agreement to uphold these norms and rules if they deem that these no longer serve their interests.

It follows therefore, that *in* authority needs to be able to claim both legal and moral obligation (legitimacy) from its subjects. The former cannot exist without the latter and even if it did, it would amount to coercion, not authority, since the use of force would not be deemed legitimate anymore. Moral obligation is necessary to maintain obedience to authority even when the content of its commands is not popular. Without it, authority would not be effective. While, initially this would not be a problem since efficiency is not a necessary pre-condition for the existence of *in*

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<sup>16</sup> This does not mean that moral authority cannot exist in non-state organizations. Religious authority for example is founded on moral authority.



authority, eventually the continuous use of force to impose the rules of authority would lead to its discredit and collapse, since people would judge that it has departed from the rules that established it and that the use of force has become abusive and eventually coercive.

These conceptual and analytical problems can lead to a deceptive diagnosis of reality. It is not surprising therefore, that some of the empirical analysis identifies as instances of private authority cases that at best refer only to *an* authority and at worst exhibit no features of authority at all. Thus, when talking about enforcement of private authority, the authors rightly argue that this can occur through the presence of the state. While enforcement through the state is rightly regarded as a mechanism that can be consistent with the idea of private authority, whether this is actually the case or not depends on the mode of this coexistence. It is thus inaccurate to characterize (as the authors do) the endorsement and adoption of the TRIPS agreement as an instance of private authority because of the influential role of the Intellectual Property Committee (IPC), a private organization representing the interests of the American industry<sup>17</sup>. The TRIPS agreement was an intergovernmental agreement in the context of the WTO, an intergovernmental organization. The significant, even decisive influence of private sector lobbying, is not a case of private authority, it is a case of private power and influence that was able to persuade the US government to adopt its cause in this international negotiation.

In a similar vein, other examples of non-state governance, like the emerging private regime for the operation of the internet (Spar 1999) and global knowledge-based network oligopolies (Mytelka and Delapierre 1999; Kobrin 2002) should not be treated as examples of private authority without qualifying this characterization. The private initiatives on the internet examined by Spar do not form an established regime but as she points out, they are the response of individual organizations operating on the internet. Such organizations are often forced, in the absence of a central authority that can create property rights, exchange rules and enforcement and security mechanisms, to proceed and provide these essential institutional arrangements individually. They create secure sites over which they have legal ownership and

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<sup>17</sup> See Sell (1999; 2003).

develop software to ensure the security of their clients. This however does not constitute private authority. These organizations act on their own behalf, without representing other companies or organizations and without exercising authority over others; therefore they do not regulate authoritatively the internet. They are trying to individually address the problems that anarchy poses for their business, and while they may be driving, in an ad hoc fashion, the future governance structure of the internet towards a particular direction, they do not constitute *in* authorities.

Similarly, knowledge-based network oligopolies do not govern authoritatively their industries. Such networks may be able to extend beyond territorial boundaries, redefine the structure of particular industries, generate new knowledge or even control the generation of new knowledge as Kobrin (2002) argues. They may even be able to use their control over knowledge to erect barriers to entry (Mytelka and Delapierre 1999). These activities however are not a testament to authority but rather to private power: the ability to use financial and other corporate assets to gain control over valued resources, such as knowledge, in order to manipulate the market structure and rip abnormal profits. While limiting the ability of the state to control and regulate them effectively, their networked, transnational structure is by no means a mark of authority. Changing the way business is done in an industry, may affect the regulatory framework that governs that industry, but does not in itself constitute an assumption of authoritative regulatory powers. At best it confers competitive advantage to the pioneering firms and potentially, a temporary loosening of regulatory control due to the emergence of new, previously unanticipated consequences of economic activity.

## **2.4 Non-state in authority**

The review of the use of the concept of private authority in the global governance literature made apparent a number of analytical and theoretical problems which as we saw, lead unavoidably to misleading interpretations of empirical findings. It follows from the above discussion that we need a conceptualization of private authority that addresses these difficulties. Moreover, we need a conceptualization of private authority that identifies with clarity what is really new in this concept. If private authority is to be proven a useful analytical tool in our examination of the role of non-

state actors in global economic governance, we need to identify and clearly qualify the characteristics and consequences of its different aspects.

From the previous analysis, it appears that most of the case studies identified as instances of private authority refer either to private *an* authority or do not refer to private authority at all but rather to private power, influence or cooperation. The question then emerges, is private *an* authority the only type of private authority that exists in the context of global economic governance? I believe that the answer is no: private *in* authority is also possible. To see how this can occur, let us first consider the possibility of private *in* authority at a more abstract level.

Private *in* authority is really the type of authority that analysts imply when they argue that many of the non-state transnational organizations hold private authority in the context of global economic governance. For the reasons that we described earlier most of the times this assertion is inaccurate. While private *in* authority may not reside in such organizations, it is nonetheless not impossible to find. Thus, individuals working in a private organization experience private *in* authority since they acknowledge as legitimate and obligatory the power of their supervisor or manager in the context of that organization. Indeed, the manager has the right to issue commands that he or she expects to be obeyed by the employees; the employees in turn acknowledge the right of the manager to issue these commands<sup>18</sup>.

Two objections could be levelled against characterizing this type of private power as authority. First, the managers or supervisors in a private organization do not have an unlimited power and often the employees may disagree with them, refuse to obey them and even act against them, through for example legal action or strike. This indeed happens, but it does not negate the authority of the management. The employees may resort to such actions, but they do so when they believe that the

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<sup>18</sup> The observation that private *in* authority is possible does not contradict our previous analysis concerning “enterprise associations”. The critique about the lack of moral obligation of such organizations, referred to a specific type of non-state organizations which aim to provide governance for an issue-area or a type of economic activity, that is, to provide public governance, and derives from the empirical observation of the mode of operation of such organizations. Moreover, it was offered as a critique to the proclaimed authority of this type of organizations found in the literature on private authority. On the other hand, the propositions developed in this section refer to the theoretical possibility of *in* authority existing in the private realm. This discussion is based on a more abstract/theoretical argument which examines whether the conditions of *in* authority can be found and satisfied in the private realm.

content of the commands by their superiors is not in line with the rules and principles that give them their authority, that is, the authority of their offices and their positions within the organization, not simply when they just do not like or agree with the content of these commands. These foundational rules and principles can be found in a corporate charter or a constitutional document that sets out the fundamental goals and policies of the organization, in specific organizational policies adopted by management (for example policies relating to age, sex or race relations within the organization), and in the private contracts according to the terms of which the employees have agreed to work for the organization. Moreover, these reactions to the substantive commands of management usually take a form that is consistent with authority. Strike for example, is a workers' right that is acknowledged by the "authority" of the enterprise as a legitimate way to voice the antithesis of workers to its substantive commands. As long as this reaction remains within the limits of the legitimate means available to the employees, it is not authority which is questioned, only the behaviour of the people that hold it at a specific point in time<sup>19</sup>.

The second objection has to do with the fact that this type of authority is limited to private organizations or more generally to private areas of activity. While this is true, it does not constitute a significant obstacle for characterizing this private power as *in* authority. As long as employees in an organization regard the power of their superiors, as determined from their position in the organization, as legitimate and obligatory and defer to them the right to make significant decisions about the future of the organization, this power exhibits the basic elements of *in* authority and therefore could be characterized as private *in* authority. The limits of a private area of activity do not preclude the possibility of authority, but they do constrain the area of its application, its scope. This authority is limited to the boundaries of the organization which are defined by the property rights of the owners of the organization, and by the employment contracts between the organization and its employees. Therefore, this authority cannot be characterized as public authority.

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<sup>19</sup> See Flathman (1980) for a detailed discussion of how opposition to the commands of authority can be reconciled with the concept of authority.

This qualification presents another difficulty with regard to our proposed type of authority. While private *in* authority can exist, it usually is so *private* in scope that it would not fit in the context of the global governance structure that we are interested in. This is because the type of private *in* authority that we seek should not be restricted to the boundaries of a social or economic space determined by private contracts among the parties that occupy this space. The type of authority we are looking for needs to be able to provide governance at a transnational level for a whole industry, issue-area or sphere of economic activity; in other words it needs to be public. But as it was just argued, private *in* authority cannot be public.

Public *in* authority needs to be based on rules and constitutions that are founded on a mandate by society. There is however, no separate public mandate for the regulation of the various aspects of public life. The public mandate of *in* authority creates an overarching mechanism of authority that will itself decide on the substantive aspects of the regulation of the various issue-areas and activities. Given the dominance of the state as the political structure for the organization of human life, this overarching authority resides (at least today) with the state. That means that private actors cannot just assume the governance of an issue-area on their own initiative, at least not in an authoritative way, without the participation or at least consent of the state. Moreover, as we have seen, private actors cannot enforce rules without the participation of the state. As Anscombe notes for the difference between state authority and the authority found in voluntary cooperative associations, the authority of the latter doesn't entail "...an unconditional demand for obedience" (1990, 144). This unconditional demand for obedience can only come from the state which enjoys both a monopoly of "the legitimate use of physical force" and a sense of moral obligation from its citizens.

The ability to legitimately enforce the implementation of decisions is crucial not only for the distinction between private and state authority, but also for the distinction between government and governance. As Rosenau argues, both government and governance refer to:

purposive behaviour, to goal-oriented activities, to systems of rule; but government suggests activities that are backed by formal authority, by police powers to insure the implementation of duly constituted policies whereas governance refers to activities

backed by shared goals that may or may not derive from legal and formally prescribed responsibilities and that do not necessarily rely on police powers to overcome defiance and attain compliance.

(1992, p.4)

Even more relevant for our understanding of non-state governance, is his consequent elaboration that governance without government can be conceived as “regulatory mechanisms in a sphere of activity which function effectively even though they are not endowed with formal authority” (1992, p.5).

The characterization of governance as a regulatory mechanism is important because it allows us to link governance to *in* authority in a more concrete and visible way. We can therefore place the abstract identification of public *in* authority with state authority that we described above, in the context of regulation. Indeed, regulation scholars have long acknowledged this dominance of the state; one of the most common definitions of regulation is “all state initiatives to intervene in the economy” (Baldwin et al. 1998, p. 2-4). However, the centrality of the state for the conceptualization of regulation does not mean that the state has to regulate itself all aspects of public life. It does not preclude the possibility of non-state regulation. It does mean however that non-state regulation needs the explicit or implicit acknowledgement of state authority in order to be considered itself legitimate and therefore authoritative.

A good illustration of how this can actually happen is provided by the concept of self-regulation. Contrary to the widely-held notion that self-regulation is an instance of regulation without the state, the fact is that self-regulatory schemes are never entirely independent and free of public scrutiny and state involvement. Indeed, regulation analysts see the relation between self-regulation and state regulation as an important, mutually constitutive element of both these mechanisms. Thus, Page (1986) makes the point that public regulation and self-regulation are interconnected and interpenetrated. This view is reinforced by Black (1996) who distinguishes four different types of relation between self-regulation and the state: a) mandated self-regulation; b) sanctioned self-regulation; c) coerced self-regulation and d) voluntary self-regulation. It becomes obvious from Black’s typology that the consent of the state is needed for the *legitimate* existence of self-regulatory schemes. The state either

promotes actively self-regulation (enforced, sanctioned, mandated self-regulation) or at least allows it to exist (voluntary), usually under some form of indirect supervision or monitoring.

It is in this same sense that private *in* authority can acquire a public dimension. This type of authority, while consistent with the separation between government and governance that Rosenau suggests, goes beyond it by acknowledging the possibility of a third type of governance which is neither entirely private nor entirely state, but it is backed by formal state authority and therefore is able to govern public social and economic space. This is why it would be more appropriate to call it *non-state in authority* rather than private *in* authority. Therefore, we could define non-state *in* authority as, *the type of in authority that resides with a hybrid<sup>20</sup> governance mechanism in a sphere of activity, which functions not only effectively, but also authoritatively due to the partial participation of the state which lends it formal authority, but which due to the partial participation of non-state actors cannot be considered as part of government.*

## 2.5 Transnational in authority

Having shown that non-state *in* authority is possible at least on a theoretical level, we can now address the original question of whether non-state *in* authority can be reproduced at the transnational level<sup>21</sup>. The task of conceptualizing non-state *in* authority at the transnational level presents even more complications. As we saw earlier, Cutler et al. (1999, p.366) identified the lack of international government as one of two main obstacles that stand in the way of conceptualizing private authority.

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<sup>20</sup> The term hybrid is used here to indicate the participation of two different types of actors (public and private) in the same governance mechanism. This mechanism is termed hybrid because the participation of both types of actors is an essential constitutive feature of this mechanism; the emergence of this type of governance necessitates both the element of legal obligation and therefore the presence of public actors, and the element of non-state participation in a significant and acknowledged role.

<sup>21</sup> The use of the term “transnational” in this thesis is based on the definition of transnational relations put forward by Risse-Kappen which refers to: “regular interactions across national boundaries when at least one actor is a non-state agent or does not operate on behalf of a national government or intergovernmental organization” (1995, p.3). In the context of our analysis of transnational governance (authoritative or not) the above definition should be extended/modified to refer to governance schemes that aim to regulate transnational interactions, and which comprise themselves, at least one actor which is a non-state agent or does not operate on behalf of a national government or intergovernmental organization. A more comprehensive description of the different formats that this make-up can take is provided in the next section.

The difficulty here is not limited to the issue of trying to combine private power and public authority, but it extends to the difficulty of identifying instances of any type of *in* authority, in an international system comprised of nominally equal and sovereign states.

Obviously this difficulty does not extend to *an* authority. Both international and transnational (non-state) *an* authority is not difficult to find. As we saw previously, *an* authority does not rest on rules, institutions and procedures, it is not defined by the nature of the association that it affects and therefore it is not subject to the strict limitations of the public-private divide. *An* authority is a feature of individuals and organizations. Therefore, we could say that *an* authority is essentially a non-state type of authority. Hence, there is no a priori reason why international or transnational organizations or individuals acting in a transnational or transgovernmental capacity should not be able to hold considerable authority as experts. Indeed, many international and transnational organizations who aim among other things to promote the exchange of information among experts in a specific area of activity and collect and store this information, are considered as the foremost authorities for that specific field and act as consultants to governments and other organizations.

Things are more complicated for *in* authority however. In the previous section we saw that the construction of the concept of non-state *in* authority presupposes the existence of a state authority (or more precisely a political authority) that would merge with non-state actors to produce a hybrid governance mechanism. This presents an obstacle for conceptualizing non-state *in* authority at the transnational level because there is no overarching international government that exercises political authority at that level.

Part of the problem lies with the now entrenched notion that political authority is synonymous with the state. Although we previously acknowledged the primacy of the state as the dominant political structure today, and accepted that in most countries, if not all, political authority resides with the state, this does not mean that political authority and the state are one and the same thing, nor does it mean that there can be no political authority without a state. Indeed, as analysts have observed



(e.g. Ruggie 1993) while the nation-state is currently the dominant form of political organization, it is not the only possibility. Monarchy, feudalism, theocracy and classical democracy have been some of the dominant forms of political organization in different places at different times. A variety of ruling bodies have held political authority, often combined with other types of authority, and governed their respective societies. While they all had a “stately” mechanism of performing the necessary functions of governing such as issuing directives and commands, ensuring their implementation and arbitrating disputes relating to them, their authority did not rest with this mechanism but with the king, the feudal lord, the church or the *dimos*. Likewise, state bureaucracy, while governing and regulating most areas of public life, enjoys a delegated authority from the elected government, which in turn derives its political authority from the constitution. Furthermore, while this state mechanism is organized along the principles of territoriality and hierarchical centralization this is not the only way to exercise political authority as is evident from the examples of feudalism and classical democracy where personal or lineage allegiance and polyarchy replaced territoriality and hierarchy respectively. It follows therefore, that the existence of an overarching hierarchical or territorial state is necessary neither for the existence nor for the exercise of political authority.

This approach to political authority does not contradict the analysis made previously which stressed the requirement of democratic accountability for authority and the legitimacy problems that non-state governance encounters because of its lack of such accountability. The previous analysis referred to the democratic form of political authority dominant today throughout the world and the inherent legitimacy problems that non-state governance schemes without a democratic mandate face today. This however does not mean that democratic authority is the only possible form of authority. The different governance modes presented above were considered legitimate and obligatory by their subjects at the time of their prevalence and this is what makes them legitimate forms of political authority. What is different among these forms of authority and between them and democratic forms of authority, is that they had different mechanisms for asserting the legitimacy of authority. In other words, authority still needed to be considered as legitimate to be truly authoritative in

the cases of monarchy or theocracy as well, but the marks of authority which determined its legitimacy were different. So, in a monarchy for example, the evidence of blood lineage might be considered the prime criterion for establishing the authority of a monarch, while in a theocracy the relevant criterion might be the knowledge and stringent observance of divine truths contained in sacred texts. In a democratic polity in contrast, the basis of authority is the public mandate, and therefore the legitimacy of that authority is judged using a criterion of public accountability and inclusiveness, among other things. That is not to say that accountability is entirely absent from monarchy or theocracy. In these regimes accountability may also exist, but this is owed to a limited body of nobles or the principals of the clergy and not to the people at large. So even in these cases we may have some mechanisms of accountability but these will be secret and limited and not public and inclusive. Democratic accountability in this sense, is not an end to itself but rather a control device designed to establish the legitimacy and therefore the authority of democratic government. For this reason non-state or private authority may be quite compatible with different forms of authority as has been the case in medieval times with *lex mercatoria*, a private body of laws developed among merchants, which governed maritime trade and was considered legitimate, authoritative, and compatible with the feudal model of political authority prevalent at the times, which was not based on democratic principles. In contrast, today, in the context of democratic liberal states, private governance schemes operating without adequate mechanisms of public accountability and inclusiveness, cannot be considered legitimate and therefore authoritative.

There should be no a priori reason therefore, why decentralized loci of political authority cannot arise to provide governance for specific issue-areas and spheres of activity. After all, as we saw previously, the scope of *in* authority does not affect the prospect of its existence although it can determine its characterization as private or public. Therefore, as long as there are institutions that govern an issue-area or sphere of activity at the international or transnational level which exhibit the features of *in* authority, there is no reason why such institutions should not be characterized as authoritative.

The question arises then, are any institutions that exhibit the features of *in* authority in the international system? Hurd (1999) demonstrates how the institution of sovereignty enjoys almost universal acceptance as an authoritative institution among states. Sovereignty is an overarching principle that manifests itself in more concrete rules and norms such as non-intervention and mutual recognition among states. Sovereignty, and the rules of conduct that follow from it are authoritative because they are seen by states as legitimate; states feel obliged to abide by these rules even when their interests seem to run against them or rather because “...their *interests*,...have been conditioned by a community standard that delimits the acceptable (territorial) reach of state sovereignty” (Hurd 1999, p.397). These rules thus, govern the relations of states in a manner that is deemed by them both obligatory and legitimate, and which leads states to abandon their own *private* judgement<sup>22</sup> on their substantive benefits, and obey them. Such authority is not to be found only in fundamental rules and principles like sovereignty that could perhaps be dismissed as exceptional since they lay the basic framework for any type of communication among states. In December 2003, the United States revoked the tariff it had imposed the previous year on all steel imports entering its markets. This policy change occurred after the World Trade Organization (WTO) judged that the tariff was illegal under its rules and therefore should be scrapped immediately. The fact that even the United States, the unquestionably dominant force in the world economy, felt obliged to abide by the ruling of the WTO, despite its obvious disagreement with this decision, is a clear example of the authority of the WTO. Its rules and judgements are regarded as legitimate and obligatory by states which surrender their *private* judgement, even when this is at odds with their interests. Indeed, many similar examples can be found in other issue-areas, where the rules of international organizations are considered authoritative and are obeyed as such by states.

Despite these examples of international authority, skeptics could still dispute them as a definite proof of authority. A traditional realist argument could be leveled

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<sup>22</sup> Private judgement here is meant in the sense that Friedman (1990) uses it to describe the judgement that is not entitled to prescribe behaviour, irrespective of what individual or institution holds it. In a society of sovereign states, the judgement of any one is private in relation to the others, that is, it is not entitled to prescribe the behaviour of other states.

against them: such governance mechanisms are not really authoritative because states can ultimately exit agreements and leave international organizations. Consequently, they are not obliged to follow the international rules they have adhered to. In principle, the argument that states can ultimately exit these organizations and agreements is correct, but is this enough to dismiss the authoritative status of these institutions? I think that it is inaccurate to characterize such arrangements as non-authoritative because of this possibility. As was argued previously, authority is voluntary by definition: people choose to consider it obligatory. It follows therefore, that just as people are free to choose to acknowledge and obey authority they are equally free to abandon it. Indeed, even in a domestic society individuals may place themselves outside the rule of authority and refuse to recognize its power over them. Such an action however would not be considered as proof that authority does not exist in that society. Authority presupposes the existence of inter-subjective values and norms that establish, among other things, the necessity of authority itself. Obviously, no human society can exhibit a complete consensus of values, norms and principles. As long as the authority that stems out of this inter-subjective framework is accepted by the majority of the people in a society, then the concept of authority should not be rejected when a few individuals choose to place themselves outside of its sphere of influence. Indeed these individuals are usually treated as abnormal and potentially dangerous by the rest of society. The same applies for the international society of states. Hurd makes a similar observation about states that decide to reject the institution of sovereignty:

Those states that do question such fundamentals [the institution of sovereignty] are regarded with horror by the other actors in the system. The fact that these states are so few, and thus so notable, is what allows the rest to define them as 'rogues' in contrast to the bulk of the population of states, who take the institution for granted.

(1999, p. 397)

As long as a significant number of states consider the power of these institutions legitimate and obligatory, and abide by their decisions and rules even when they do not agree with them, then these institutions should be considered as authoritative.

The examples that were given above refer only to inter-state and inter-governmental institutions. Are these the only institutions that can enjoy authority in

the international system? What about non-state *in* authority? The question is again more complicated than is the case at the domestic level. The problem lies with the decentralized nature of international authority described above. Because there is no overarching international government to assume or delegate the governance of the various aspects of international and transnational activities, governance often occurs in a haphazard and erratic way. One of the consequences of this pattern is that many issue-areas, spheres of activity, or industries are not regulated at all or are only subject to minimal and usually inadequate governance. The problem is becoming more acute as both the number of transnational actors and the intensity of their interactions have increased significantly in recent years. Their need for governance structures to bring order and predictability to their business is therefore often addressed by non-state transnational organizations that aim to provide guidance, to educate, even to create transnational standards and rules that will fill the gap of international rules. Can such organizations be considered authoritative?

First of all we should acknowledge that there exists a significant variety of non-state governance schemes. Many of them do not aspire to provide governance and regulation but rather guidance and assistance. A number of non-state organizations act as meeting fora for the exchange of information and ideas; they aim to build a sense of community among their members and to provide education for members lacking the necessary technical infrastructure or for all members when new issues arise in their sphere of activity. Others seek to regulate not behaviour but rather technical specifications of particular products that will facilitate their cross-border operability, connectivity and compatibility. Even when the aim is to regulate behaviour there are often governance schemes that do not address an industry or sphere of activity but rather target specific organizations. Such is the case of the corporate codes of conduct that are increasingly being adopted by transnational companies. Obviously the types of rules and organizations just described cannot be considered authoritative in the sense of *in* authority.

However, there are organizations at the transnational level that explicitly aim to provide governance for a whole or issue-area or industry. These organizations obviously aspire to achieving authoritative status as regulators. Despite their ambition

however their governance cannot be considered authoritative. First of all, these organizations are subject to the same criticism that was developed previously with regard to the potential for private *in* authority. Like voluntary associations at the domestic level, non-state transnational organizations cannot just assume governance of an area of public life even if it is dominated by activities of a transnational nature. The reason is that every individual and organization in the private sector that engages in transnational activities is legally anchored in one (or many) national, legal jurisdictions. Moreover, their overseas activities also have to take place within the boundaries of a national legal jurisdiction. Within these jurisdictions, the regulation of the issue-areas that these actors engage in, is undertaken by local regulatory authorities. As a result, issues pertaining to individuals or private organizations in a transnational capacity are addressed by private international law, which treats them as issues between different national legal jurisdictions, a conflict of laws approach (Cutler 2003). At the international level on the other hand, only states hold the legitimate use of force; under international law only states are considered as subjects of rights and obligations<sup>23</sup>. Therefore, in the absence of transnational legal space, in order to characterize any rules as legally binding, they need to be applied in some national jurisdiction and be incorporated in its legal or regulatory structure. Non-state transnational organizations cannot do that; states are needed for the incorporation of transnational non-state rules in the body of domestic regulation.

As was argued previously, members of private voluntary associations also lack the sense of moral obligation that would make them regard the rules of the association as obligatory and therefore surrender their private judgement to its authority. The argument was that the explicit instrumentality of these organizations is an obstacle for the establishment of *in* authority. Again, this argument applies to transnational organizations since their members share little else than the common

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<sup>23</sup> The state has traditionally been thought as the principal, if not the unique, subject of international law. This absolute domination of the state in the domain of international law has been undermined to some degree in the course of the twentieth century, especially in the area of human rights, where a number of international court decisions and international agreements have bestowed to individuals certain “rights and obligations over and above those set down in their own judicial and authority systems” (Held 2004, p.101). Still, many legal experts seem to consider this an exception and to maintain that the state continues to be the predominant, and perhaps, the only true subject of international law (see for example Malanczuk 1997, and Brownlie 1998).

objective to provide a set of rules for addressing a set of specific issues. Their objective in other words is not to set up an authority to make decisions about these rules, but to set up an organization that will provide a forum for the negotiation of these rules. They participate in these organizations to achieve concrete, material benefits like reducing costs and increasing information and predictability by establishing a common set of rules. Therefore, it is highly unlikely that they will be willing to view as obligatory rules that may run contrary to their interests.

One could argue that international organizations could similarly be conceived as instrumental organizations, where likewise, negotiation and bargaining are taking place and therefore they should not be considered authoritative. I believe that this is not the case. I would argue that international organizations are primarily self-sufficient associations. That is, like political authority at the domestic arena, they do not have an explicit substantive purpose. Obviously they are created to provide governance and therefore a set of rules for a sphere of activity. However, they are created to provide governance according to some procedural rules that establish the authoritative nature of their substantive decisions. When the organization is established fierce negotiations and bargaining will ensue, but once an agreement has been reached and a decision has been made the authority of the organization will make this agreement obligatory on its members and they will see it as such. Indeed, the most common criticism of international organizations is that they are not productive enough; they do not produce an adequate number of sufficiently detailed and up-to-date rules to provide much needed governance at the international and transnational levels. This happens because states negotiate fiercely at the preparatory stage, exactly because they know that once they have signed an international agreement its authority makes it extremely difficult to renege on their obligations.

In addition to the inability to enforce their rules, transnational organizations also face a considerable problem of external legitimacy. They often represent only a small part of the actors, national or transnational, that would be affected by their rules if these were obligatory. To a greater extent than voluntary domestic associations, these organizations cannot be said to be truly representative of and accountable to the actors active in their industries or sphere of activity. This impression is made worse

by the fact that the power differential among their participants is much greater than in the case of domestic organizations. Indeed, the participation in these organizations often entails costs that are not affordable by many small actors who could nonetheless be affected by their rules.

The rules of transnational non-state organizations cannot therefore be considered authoritative in the strict sense of *in* authority. The lack of legitimacy, and of legal and moral obligation, and the inescapably state-based character of the activities they aim to regulate, make the governance of such organizations non-authoritative. Non-state *in* authority at the transnational level needs political authority to infuse it with obligation and legitimacy. However, political authority at the international level is fragmented and decentralized. Therefore, this political authority can come from two different sources: a) from international organizations that already enjoy such authority in an issue-area and b) from the consent of a sufficient number of states, or at least of a number of sufficiently significant states in an issue-area, to make the rules of these organizations authoritative at the international level.

## **2.6 The anatomy of transnational *in* authority**

The next question that we need to answer is how non-state *in* authority can be identified. There can be a variety of ways that non-state actors can come together in an authoritative structure with public authorities. To identify these different modes of blending private power with state authority we need to take a step back and examine the variety of functions that *in* authority can undertake in the context of public governance. Rosenau's distinction between government and governance can help us here. According to his definition both governance and government refer to "purposive behaviour, to goal-oriented activities, to systems of rule". In other words, both share the same underlying purpose of *governing behaviour* and therefore need to perform a similar set of functions to attain it. Consider Raz's definition of political authority as "a right to make laws and regulations, to judge and to punish for failing to conform to certain standards, or to order some redress for the victims of such violations, as well as a right to command" (1990, p.2). We can also encounter these functions in the context of the private organizations we examined previously. Management makes rules and regulations that determine the operation of the organization; it issues



directives and commands; it can reward or punish its employees for attaining or failing to meet performance or behavioural standards and it can offer compensation to the parties that suffered by the violation of the rules by other employees or even the organization itself.

The essence of these activities can be captured by three functions that *in* authority performs in any structure of governance and therefore government as well: creating rules, implementing them and adjudicating the disputes that arise from them. We are now therefore in a position to answer our question, at least on a general and abstract level. Non-state *in* authority emerges when one or more of these functions are undertaken by non-state actors while the remaining functions are performed by state authorities. Table 2.1 exhibits all the possible modes of combining state and non-state actors in the performance of these governance functions<sup>24</sup>.

**Table 2.1 Variations of Non-state in Authority**

Authority Functions	Type of Actors	
Rule-Making Implementation Adjudication	1. State State State	2. Non-State State State
Rule-Making Implementation Adjudication	3. State Non-State State	4. State State Non-State
Rule-Making Implementation Adjudication	5. Non-State Non-State State	6. State Non-State Non-State
Rule-Making Implementation Adjudication	7. Non-State State Non-State	8. Non-State Non-State Non-State

We see that there are eight possible combinations of non-state and state actors that produce different governance structures. Evidently, group one represents pure state governance, in other words government at the domestic level, or inter-state

<sup>24</sup> A similar type of categorization of global governance institutions has been proposed by Abbott et al. (2000) with regard to the three aspects of legalization which is defined as "...a particular form of institutionalization characterized by three components: obligation, precision, and delegation" (Abbott et al. 2000, p. 401), and by Koenig-Archibugi (2006) with regard to the three characteristics of publicness, delegation and inclusiveness. For a detailed definition and analysis of these institutional characteristics see Abbott et al. (2000) and Koenig-Archibugi (2006) respectively.

governance at the international level. At the opposite end we have group eight, which represents what Rosenau calls governance without government. Here we find the majority of transnational non-state governance schemes, where various types of regulatory mechanisms operate on a voluntary basis among participating parties. Between these two extremes we can find a number of possible combinations of state and non-state actors' cooperation which render the resulting governance structure into an authoritative mechanism. In these intermediate combinations, one or two of the functions can be performed by a state institution and the remaining function(s) by a non-state organization. It is in these cases therefore (2-7) that we see the emergence of non-state in authority.

To review the simplest cases where non-state actors assume only one of these functions, we could have a state agency deciding the rules for an issue-area and referring any disputes about them to public courts, while the actual implementation of the rules is taking place through the actions and procedures of a non-state organization such as a self-regulatory agency. At the transnational level, a comparable situation has been encountered increasingly in recent years, when inter-state organizations delegate the implementation of policies decided at the international level to non-state actors and organizations. This is a very interesting development in the context of global governance and undoubtedly this delegation confers, to some degree, public *in* authority to the specified non-state organizations. These organizations have the authority to implement on the ground the decisions agreed at the international level; they are the embodiment of inter-state authority at the local level where the implementation of policies takes place.

Alternatively, we can have a situation where non-state actors have undertaken not the implementation but the adjudication of disputes relating to a specific set of rules which have been drawn by state authorities or the legislature. This is an increasingly recurrent phenomenon in commercial disputes, especially in transnational disputes, and it is known as private commercial arbitration. Cutler (2003), who studied this phenomenon in her study of the transnational merchant law regime, describes how companies may agree to mutually abide by the decisions of private arbitration tribunals. The rules to be used however are usually drawn from a

specific national, legal jurisdiction, commonly agreed by the parties as most relevant for the dispute at hand. Likewise, the implementation of the decisions of such tribunals takes place through the public courts and authorities of the jurisdiction in question<sup>25</sup>.

Finally, there can be a situation where the rules regulating an issue-area, sphere of activity or industry are designed by non-state actors but implemented by state authorities and adjudicated by public courts. I would argue that this is the most consequential manifestation of non-state in authority. This is because, the function of rule-making, of designing the rules and determining their content, is arguably the most fundamental and most political of the three. Implementation and adjudication are to a considerable extent dependent upon the content of the rules they are intended to implement and interpret respectively. The content of the rules determines to a large degree the distributional outcomes for a variety of actors and structures. These outcomes affect not only the present balance of interests and power but also determine future governance through the institutionalization and therefore embedding of current values, ideas and policy priorities, and through the realignment or entrenchment of current power configurations. In this sense, rules are particularly important for the distribution and shaping of structural power, that is, “the power to shape and determine the structures of the global political economy” (Strange 1994, p.24).

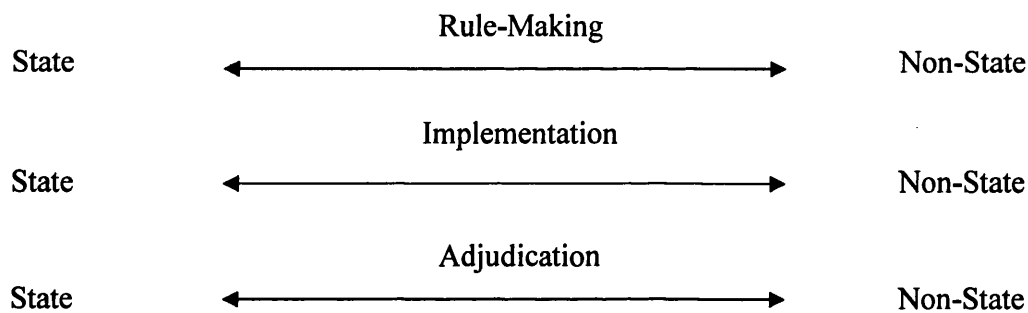
However, these are not the only modes of governance that can result from the cooperation of state and non-state actors. Things can be even more complicated. Thus it may be the case that state and non-state actors share not only different functions in the governance structure of an issue-area but that they also share different parts or stages of the same function. Figure 2.1 demonstrates how each function can be jointly performed by both state and non-state actors. In such a case, all different modes of governance collapse to the same basic format which can exhibit a high degree of

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<sup>25</sup> The United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards (New York Convention) obliges the signatory states to acknowledge and enforce such arbitration awards. According to Cutler (2003, p.230) 119 countries have now adhered to this convention. Moreover UNCITRAL developed in 1976 its Arbitration Rules and in 1985 the Model Law on International Commercial Arbitration, which lay down rules to be used in private arbitration procedures.

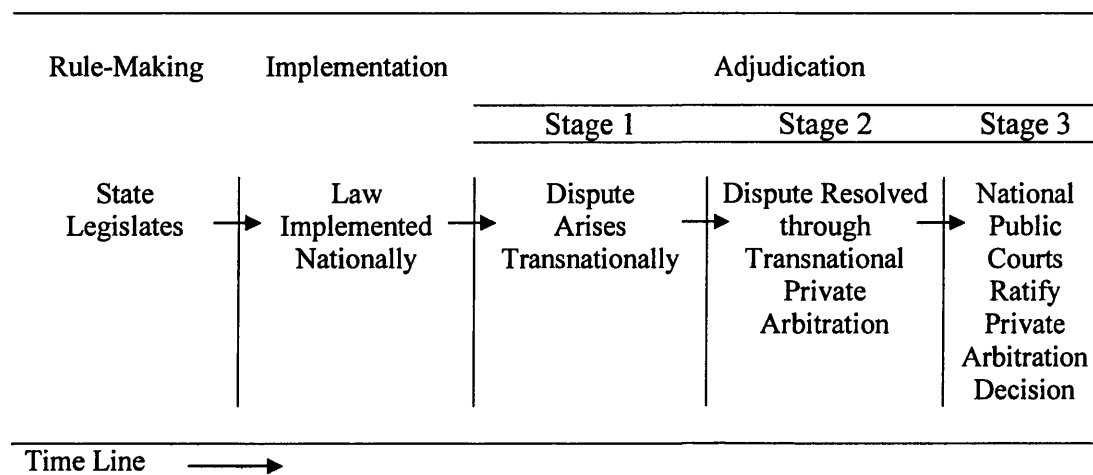
variation depending on the balance between state and non-state actors within any single function. As figure 2.1 demonstrates, the exact configuration of non-state in authority becomes a matter of degree, as the balance between state and non-state actors often shifts along a continuum rather than taking discrete positions. This depends to a large extent on the nature of the issue-area which may allow or even require that different parts or stages of the same function are performed by different actors.

### Figure 2.1 Same Function Variations of Non-State In Authority



Therefore, considering again the examples we reviewed above, we may have NGOs implementing only part of a particular project authorized by an inter-state organization, while the remainder is carried out by the executive organs of that inter-state organization or perhaps by local governmental agencies. Similarly, in the case of adjudication private commercial arbitration forms only the initial part of the adjudication process, since the decision reached through the arbitration process has to be implemented in a specific national, legal jurisdiction and therefore requires ratification by the local, public courts (Figure 2.2). Finally, state and non-state actors could assume different parts of the legislative process. It is thus common, state supervisory agencies or ministries to set the general guidelines or principles that form the foundation of governance in an issue-area, while the day-to-day, detailed regulation and governance of that issue-area is assigned to a non-state organization whose rules and decisions, while independent, have to abide by the general principles set out by the state.

**Figure 2.2 An Example of Same Function Variation: Fragmented Adjudication  
in Private Transnational Commercial Arbitration**



## 2.7 Summary and conclusions

The purpose of this chapter was to delineate the concept of non-state authority in the context of global governance. In the course of this process the somewhat loose and inconsistent use of the term in the literature on private authority in global governance was criticised, and a more thoroughly defined and analytically consistent concept of *non-state in authority* was presented. This concept, which represents a hybrid type of governing authority where public and private actors participate in the governance functions of an issue-area, activity or industry, satisfies the conditions of *in authority*, which is the type of authority that a political authority such as the state exercises. This concept was then transposed at the transnational level as *transnational in authority* in order to describe the emergence of transnational governance schemes where non-state and state actors participate as institutionally defined and acknowledged members with distinct and explicit roles. The concept of transnational *in authority* can hopefully help us distinguish between cases of authority limited to the private sector, authoritative knowledge and expertise, and authoritative non-state governance of areas of public life and activity. It is the latter case of non-state authority that is the most novel and consequential development in the context of global governance because it makes non-state actors part of the institutional structure of political

authority, legitimizing thus their claim to the governance of public life. It is the analysis and explanation of the emergence of this type of non-state authority, and in particular, of transnational authoritative rule-making, that will be the focus of the next chapter.

## **Chapter 3**

### **Transnational Regulatory Authority and Global Economic Governance: A Theoretical Framework**

#### **3.1 Introduction**

In the previous chapter we identified a hybrid form of regulatory authority labelled transnational *in* authority, illustrated its conceptual and analytical distinction from other forms of transnational non-state governance, and argued that this type of authority can be found in any one of the three governance functions of rule-making, implementation and adjudication. In this thesis, the focus will be on the rule-making function. This is because, as was previously argued, this is the most consequential of the governance functions and the one most closely linked to notions of democratic accountability and representation. Therefore, the assumption of such rule-making authority by non-state actors represents the greatest and most interesting challenge to our understanding of political authority and sovereignty. In this chapter, we will develop a theoretical framework and propose conditions for the emergence of transnational, authoritative rule-making in global economic governance.

#### **3.2 Transnational Regulatory Authority**

In order to proceed with the development of a theoretical framework, it is first necessary to define more precisely what is meant by transnational authoritative rule-making. Although regulation analysts themselves do not agree about the precise definition of regulation and many would include a much wider array of functions and actions beyond rule-making, including implementation and adjudication (Baldwin et al. 1998; Baldwin and Caves 1999), in this thesis the term will be used in a narrower sense to refer mainly to the creation of rules for the governance of an issue-area or industry. The ability of certain non-state governance schemes to produce rules that are deemed authoritative will hereafter be referred to, as transnational regulatory authority.

Transnational regulatory authority emerges when the authority of *taking decisions* about the regulation of a given issue-area is shared between state and non-

state actors. This does not refer to preparatory work to be discussed or even adopted by state actors before producing rules, nor pressure and/or influence on the positions adopted by state actors before or during the negotiations of these rules. It means specific, institutionally defined and acknowledged voting or veto powers for the non-state actors participating in a regulatory regime. Moreover, these voting or veto powers have to refer to the substance of the rules being created; in other words they refer to the ability of non-state actors to *decide*, alone or in collaboration with state actors, the *substantive* content of the rules and not only procedural or implementation issues. These two conditions taken together constitute the first criterion for identifying transnational regulatory authority: the existence of an institutionally defined right of non-state actors, acknowledged by states, to decide wholly or partly the substantive content of the rules being created by a non-state forum for the governance of an issue-area or industry. However, non-state actors can participate in any number of non-state fora without the need to get permission for such activities by state authorities. Obviously, what makes the first criterion significant and meaningful is the fact that this decision-making power does not refer to just any non-state organization. It was previously argued, that transnational *in* authority differs from other non-state governance schemes in that its pronouncements are authoritative, that is, they have a binding effect on the behaviour of the regulated parties. Therefore, to establish the existence of transnational regulatory authority we also need to establish whether the rules of the non-state forum under consideration are backed by the force of law. In practical terms this means that transnational regulatory governance exists when the rules being produced by a non-state forum confer some degree of *legal* obligation on the parties that adopt them. Finally, we need to establish the scope of the impact of transnational regulatory authority, that is, the degree to which its rules govern an industry or issue-area at a global level. This characteristic, while not a necessary precondition for the existence of transnational regulatory authority, is nonetheless significant because the latter becomes a significant new characteristic of global economic governance when it provides governance at a level beyond that of the individual state.



### 3.3 Transnational regulatory authority in the world economy

Before proposing a theoretical framework for the explanation of transnational regulatory authority, we first need to specify what exactly such a framework aims to achieve. Based on the analysis presented in the previous chapter, a comprehensive explanation of transnational regulatory authority requires answers to three fundamental questions: a) Why do regulators and/or politicians participate in hybrid governance schemes or acknowledge the rules produced by non-state governance schemes giving rise to transnational regulatory authority? b) Under what conditions do they have an incentive to use or endorse transnational regulatory authority, compared to other international and/or transnational institutional mechanisms? c) How are they able to reconcile this delegation of authority to private actors with the principles of public *in* authority?

All three questions emanate from the nature of public *in* authority. As argued in the previous chapter, today, the authority to regulate public life rests with the state. This is why transnational *in* authority, presupposes a choice made by state authorities to delegate their authority to a transnational non-state organization. Without the explicit adoption of the state, non-state governance initiatives remain, for the most part, voluntary, consultative, non-binding instruments. This thesis does not dispute for one moment the importance that such instruments can have for global economic governance. I nonetheless aim to distinguish between such mainly market-operated standards and guidelines, and instruments that have official and formally acknowledged legality and which are a product of an explicit and institutionalized collaboration between non-state actors and the state. Given the sovereignty costs associated with such a delegation of authority, we need to provide an explanation for this decision, which is the aim of the first question. The second question seeks to “operationalize” the explanation provided to the first question, by identifying the specific framework conditions that will lead to the emergence of transnational regulatory authority.

Finally, the third research question addresses the normative aspects of the delegation of regulatory authority from state to non-state actors. The focus of our attention is a type of transnational governance whose principal innovative and

consequential element is not the content but the mode of regulation. What is examined here, and what has been the inspiration for this thesis, is the decision to delegate the authority to regulate issue-areas and economic activities, previously regulated by national public bodies, to transnational non-state actors. The delegation of the authority to decide such issues to a non-state organization raises an issue of legitimacy, a concern about the conformity of such a decision with the principles behind public *in* authority. This concern becomes even greater when we consider that in the case of transnational regulatory authority the delegation of authority is not limited to domestic non-state actors but also to foreign non-state actors. As argued in the previous chapter, public *in* authority rests on a set of inter-subjective values and principles that inform its mission and its mode of operation. These values and principles translate into specific institutional and normative constraints placed on the freedom of the holders of authoritative offices and titles to exercise the authority entrusted to them. In modern democratic polities these constraints include high standards of accountability and inclusiveness, usually absent in transnational, non-state governance schemes. Therefore, in order to have a complete explanation for the emergence of transnational regulatory authority, we not only need to inquire into the politics of the decision to employ transnational regulatory authority. We also need to describe and follow the process of justifying this decision that seems to run contrary to the democratic underpinnings of modern political authorities, and to see how the decision to delegate regulatory authority to transnational non-state actors can be reconciled with the principles of public *in* authority. This is necessary, because if the regulatory pronouncements of the non-state organization are to be considered authoritative and therefore binding, there needs to be a process that reconciles its right to regulate with the principles of public *in* authority. Therefore, the third question is complementary to the first two, and all three operate as a whole in order to provide a rounded and complete account of a phenomenon with potentially significant institutional but also normative implications.

Where can we look for a theoretical framework that provides answers to these questions? Can existing theories of international relations and international political economy help us understand the phenomenon of transnational regulatory authority?

The next section of this chapter explores the available theoretical schemata that could potentially provide us with answers to our research questions, highlighting their positive insights, but also pointing to their limitations in providing a comprehensive account of transnational regulatory authority.

### 3.3.1 Private authority literature

The literature on transnational non-state governance, and particularly on private authority, would be an obvious place to look for a theoretical explanation of transnational regulatory authority. While this literature has significant insights to offer to our analysis of transnational regulatory authority, its contribution is limited by its analytical inconsistency in its treatment of the concept of authority. As was argued in the previous chapter, studies of private authority in the context of global economic governance do not adequately distinguish between transnational regulatory authority and other forms of non-state governance. The resulting analytical ambiguity poses an obstacle to the construction of theoretical propositions that could help us explain the emergence and the particular features of transnational regulatory authority. Moreover, because hybrid authority is not examined separately from other private governance schemes, work on private regimes and transnational governance arrangements tends to focus exclusively on private actors, examining the incentives of private actors for creating these schemes and the processes through which they achieve them. The problem with this approach is that it does not adequately address the incentives of states to accept transnational self-regulation. This is a significant problem for the purposes of this study, because as we saw above, transnational regulatory authority presupposes a choice made by state authorities to collaborate with non-state actors to provide governance for the global economy. For these reasons, these approaches are ill-suited to answer our first two questions. Moreover, by ignoring the analytical difference between *in* and *an* authority, private authority approaches do not raise adequately the legitimacy issues related with non-state *in* authority. Therefore, these approaches are not in a position to offer an explanation or even a description of the process of justification for the delegation of public *in* authority.

### 3.3.2 Efficiency approaches

For answers to these questions it seems that we need to turn to theories that focus on state behaviour. Theories that specifically address the state's decision to delegate regulatory authority to non-state actors can be found in the literature on domestic regulation and self-regulation. The traditional explanation for economic regulation is the public interest theory. The theory argues that regulation is established for the pursuit of the interest of the public at large and the protection of the interests of the consumers. This is necessary because often the market fails to operate properly, resulting either in inadequate provision of services and products or in the provision of such services and products in terms economically or socially unacceptable<sup>26</sup>. If we accept the public interest explanation, we would expect states to delegate their regulatory authority to non-state actors when this delegation serves the public interest better than state regulation; that is, when it results in more efficient or effective regulation. Indeed, regulation analysts argue that often self-regulation presents several advantages compared to state regulation<sup>27</sup>: i) self-regulatory arrangements are usually informed by greater expertise than public law clauses or public agencies, as their members are the expert practitioners of the activity being regulated; ii) following from the expertise advantage, the information costs will be much lower as information will be readily available to the regulators; iii) monitoring and enforcement costs will be lower as the regulated parties are themselves part of the monitoring and enforcement mechanisms; iv) rules are more informal and thus cheaper and easier to change when circumstances change; v) self-regulation will usually produce much more acceptable rules for the industry than public regulation, which also raises the probability of increased compliance with the rules. When these positive aspects of self-regulation are combined with the fiscal restraints of the public budget which often make monitoring and enforcement inconsistent and sporadic and the inflexibility, high cost and poor coverage of public laws, the self-regulation alternative becomes all the more attractive. The state therefore could be willing to

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<sup>26</sup> For a presentation and analysis of the most commonly cited market imperfections, see Noll (1995) and Breyer (1982, 1998).

<sup>27</sup> See Baldwin and Cave (1999), Black (1996), Graham (1994) and Ogus (1995).

delegate its regulatory authority to a non-state organization provided that this move would result in improved regulatory efficiency and effectiveness.

The argument of functional efficiency for involving non-state actors in the regulatory process is also supported by work on international regulation. Perhaps the best example of this type of argument is the work of Reinicke (1998). Reinicke builds his approach around the challenges that globalization poses for the formulation and implementation of public policy and treats global regulation as the cooperative regulatory response of states to these challenges. He believes that globalization is not threatening the external sovereignty of states but their internal operational sovereignty, that is, their capacity to create and enforce public policy. States therefore cooperate in order to get some hold over their internal ability to govern and regulate. According to Reinicke, this cooperation should go quite deep in order to counter the constraints of globalization resulting in the formulation and implementation of global public policy (GPP).

Reinicke argues that if global public policy is going to work as a strategy, the principle of subsidiarity must be embraced. Horizontal subsidiarity, which is more relevant for our purposes, refers to the involvement of non-state actors in the process of global public policy. Through this concept Reinicke emphasizes an explicit and institutionalized role for non-state actors. He values the contribution and importance of non-state actors in global governance and doubts its effectiveness without their participation:

horizontal subsidiarity seeks the same improvements [improve legitimacy, acceptability, efficiency, and effectiveness of public policies] as the vertical variant by delegating, or “outsourcing,” part, but not all of public policymaking to non-state actors...these actors’ better information, knowledge and understanding of increasingly complex, technology-driven, and fast-changing public policy issues will generate greater acceptability and legitimacy for global public policy. Such public-private partnerships...will also produce a more efficient and effective policy process for the design and implementation of public policies for a particular global industry.

(1998, p.89-90)

Is efficiency an adequate explanation for transnational regulatory authority? While there is no doubt that often non-state regulation enjoys a comparative advantage in terms of efficiency and effectiveness relative to state regulation, this is not enough to

provide a comprehensive explanation for transnational regulatory authority. There are a number of significant problems with the efficiency hypothesis for our purposes. First, we have to assume that the state operates with the sole purpose of satisfying the “public interest” in the case of domestic regulation or “national interest” in the case of international regulation. This implies first, that it is possible to define such a public or national interest and second, that the regulators are impartial and trustworthy and operate only with the interest of the public or the nation in mind. Both of these propositions are problematic at both a theoretical and an empirical level<sup>28</sup>. The public interest theory has been heavily criticised by the “economic theory of regulation”, which has argued that rational regulators seek a structure of costs and benefits that maximise their own political returns<sup>29</sup>. Moreover, the concept of a national interest effectively turns the incentives of the various actors at both the sub-national and supra-national level to exogenous variables. This makes the explanation of transnational regulatory authority very difficult, because a theory based on national interest would work well only as an ad hoc theory; it would not allow us to predict when and in which issue-areas we are more likely to see hybrid forms of governance.

A second problem with the efficiency hypothesis is that it does not adequately address the weaknesses associated with self-regulation. Despite the advantages of self-regulatory schemes described earlier, before taking the decision to delegate regulatory authority to non-state actors, a regulator needs to also take into account a series of potential problems related to self-regulation. While we argued earlier that self-regulatory schemes can potentially produce better compliance with the rules being created, this is not always the case; indeed one of the most cited weaknesses of self-regulation is poor enforcement and non-compliance with the produced regulation (Graham 1994; Baldwin and Caves 1999). Other identified weaknesses of self-regulation include insufficient coverage of the industry; exploitation of regulatory powers to introduce anti-competitive regulation (e.g. erecting barriers to entry); lack of transparency and exclusion of third parties (Graham 1994). Finally, the most often

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<sup>28</sup> For a critique of the public interest theory see Stigler and Freidland (1962) and Averch and Johnson (1962); for a critique of the normative assumptions assigned to the behaviour of regulators see Fiorina and Noll (1978), Weingast (1981) and Levine and Forrence (1990).

<sup>29</sup> See Stigler (1972), Peltzman (1976), and Becker (1983).

cited criticism of self-regulation concerns the lack of accountability and legitimacy of the private sector to produce regulation (Page 1986; Baldwin and Caves 1999).

These problems gain additional weight when delegation of regulatory authority takes place at the transnational level. This is because delegating regulatory authority to a domestic non-state organization is quite different from doing so in the context of a transnational regulatory forum. In part this is due to two significant characteristics of the international system: the lack of authoritative governmental institutions and pervasive uncertainty about other actors' actions and intentions (Keohane 1984). These characteristics create in turn significant concerns over the effective enforcement and implementation of international agreements. It is for this reason that states often look to set their commitments in binding, hard law, international agreements. Indeed, recent work on legalization has shown that legalization<sup>30</sup> "is one of the principal methods by which states can increase the credibility of their commitments...precision of individual commitments, coherence between individual commitments and broader legal principles, and accepted modes of legal discourse and argument all help limit...opportunistic behavior"; as a result "there are few alternatives to legalization when states wish to identify undertakings as reliable commitments" (Abbott and Snidal 2000, p.427)<sup>31</sup>. In addition to making commitments more credible, legalization also "facilitates interpretation, application, and elaboration by setting relatively clear bounds on dispute resolution and negotiation...procedurally, hard law constraints the techniques of dispute settlement and negotiation" (Abbott and Snidal 2000, p.429). This makes legalization a more cost efficient approach for the enforcement of commitments compared to other alternatives such as coercion, persuasion or frequent renegotiation (Abbott and Snidal 2000, p.430). On the contrary, the main benefits of informal, soft law agreements seem to be their flexibility and vagueness which can facilitate compromise

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<sup>30</sup> Legalization is used here as synonymous to the hard law variety of legal institutions in contrast to soft law arrangements. Hard law in the context of the legalization concept is defined as legal arrangements exhibiting a high level in all three constitutive elements of legalization (see footnote 24). For a presentation and analysis of the concept of legalization in international relations see the International Organization special issue on legalization (2000).

<sup>31</sup> Simmons in her study on the legalization of international monetary relations supports this finding. She shows that harder legal commitments have encouraged greater compliance by increasing the reputational costs associated with reneging on a legal obligation (Simmons 2000).

particularly when agreement is not forthcoming (Lipson 1991; Abbott and Snidal 2000). This however means that when soft law is used “states face a tradeoff between the advantages of flexibility in achieving agreement and its disadvantages in ensuring performance” (Abbott and Snidal 2000, p.446). This tradeoff however, creates a problem for the efficiency hypothesis in relation to transnational regulatory authority, because participation in non-state governance schemes is usually unilateral and even when it is the result of an agreement among states, it does not, by definition, emanate from a binding agreement among the participating state authorities, but from some more informal agreement or mechanism. This in turn makes the commitment of state authorities to the implementation of the produced regulation (and the regulatory process more generally) weaker when compared to the obligations assumed under a legally binding international agreement or treaty. Therefore, when the interests of the participating parties coincide to a considerable degree and there is agreement on the way to increase the functional efficiency and/or effectiveness of the existing regulatory framework<sup>32</sup>, we would not expect states to use transnational regulatory authority from an efficiency/effectiveness point of view, since an international, legally binding agreement would be more effective in delivering credible commitments, and more efficient in enforcing them than alternative non-state governance schemes.

The effect of these factors is augmented by another feature of international affairs, which the efficiency hypothesis fails to address adequately: the role of power and contrasting interests. The efficiency hypothesis implies not only that there is a national interest but that the national interests of different states coincide to a considerable degree in order to agree on a common set of rules. Moreover, it implicitly assumes that any potential disagreements can be solved in a fashion satisfactory to all parties involved, without more powerful players taking advantage of their capabilities to rip abnormal gains. Reinicke’s work is characteristic of this criticism. He seems to assume that in the face of the common challenge posed by globalization, states will unite in a common policy front and cooperate efficiently.

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<sup>32</sup> This assumption of harmonious cooperation to resolve functional problems is an integral part of the efficiency hypothesis as explained in the next paragraph.



Subsidiarity will ensure the efficiency and effectiveness of the system as each part of the process will be done by the “best man for the job”<sup>33</sup>. He underestimates however the role of power and the conflict of interests among both states and private economic actors and this problem becomes evident in the analysis of his case studies. In the case of the Basle Accord on capital adequacy, while acknowledging the importance of the pressure from the U.S. for achieving the final compromise, he nonetheless argues that this case validates his framework because in the end states got together to overcome the challenges that financial globalization posed to them. This is a self-contradicting assessment, since without the pressure from the U.S. and its bilateral agreement with the UK, the Accord may have never been achieved despite the common problems facing regulators (Oatley and Nabors 1998; Simmons 2001). Similarly, in the case of the anti-money laundering regulation and the Financial Action Task Force (FATF), he admits that progress has not been very satisfactory in recent years, the main obstacle being the unwillingness of states to cooperate, despite evident efficiency gains from such cooperation.

Also, many of the efficiency gains associated with domestic self-regulation will be absent or at least limited in the case of transnational regulatory authority, because private sector actors from different countries will have far more varied and often contradictory interests than is the case at the domestic level. Therefore, in many cases it is likely that achieving agreement will be just as difficult for a non-state organization as it would be for an inter-state organization. In fact, given the hybrid nature of transnational regulatory governance where both state and non-state foreign actors may participate directly at the negotiating table, we would expect the efficiency of a transnational regulatory organization, as a forum for deliberation and agreement, to be less efficient than a comparable international organization. Moreover, power differences among non-state actors will be far greater at the transnational level. Given the absence of an international authority, there are

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<sup>33</sup> Reinicke’s argument is reminiscent of the functionalist theory put forward by Mitrani (1948, 1966, 1975). Like Mitrani, he too, believes that re-organization of economic regulation along functional lines, in effect by adjusting political geography to economic geography, will provide a much more efficient and durable solution for international cooperation. For a critique of Mitrani’s work see Haas (1968).

considerable doubts about the ability of powerful non-state actors to put overall efficiency first and avoid exploiting their power advantage.

These problems in turn highlight what is the most significant problem of transnational regulatory authority: lack of legitimacy. The legitimacy problem is far greater at the transnational level because regulators delegate authority not only to domestic but also to foreign non-state actors. The inability to resolve this issue based only on efficiency grounds is again evident in Reinicke, who admits that there are potential democratic accountability issues with subsidiarity. In order to resolve this problem he wants to impose on non-state actors the professionalism and ethics of a proper regulator. There are three problems with his solution however. First, Reinicke uses again the notion of an impartial and trustworthy regulator that we criticized above as problematic. Secondly, by attributing such characteristics to non-state actors, he is effectively turning them into something they are not. This is neither very realistic nor very helpful; a proper examination of private actors should keep in mind their private interests. It is these private interests that have led to the concerns described earlier over the misuse and abuse of self-regulatory powers. Finally, the need to change the morality of non-state actors into that of an impartial and trustworthy regulator signifies, by itself, an acknowledgement of the failure of efficiency to resolve, on its own, the problem of accountability. In other words, efficiency is not enough.

### 3.3.3 Epistemic communities

Another approach to international regulation, and cooperation more generally, which explicitly involves non-state actors, is the “epistemic communities” approach (Haas 1992; 1994). This approach is of particular interest for our purposes, since it has been recently employed to analyze the history of one of the non-state organizations also examined in this thesis, the International Accounting Standards Board (IASB) (Martinez-Diaz 2005). The epistemic communities approach emphasizes the role of learning and communication. It is particularly relevant for our analysis, because it is based on the significance that expertise, that is, *an* authority, can have for policy coordination: “an epistemic community is a network of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-

relevant knowledge within that domain or issue-area” (Haas 1992, p.3). The members of the community share the same set of normative, principled and causal beliefs, the same notions of how knowledge is validated, and participate in a common policy enterprise (Haas 1992). These characteristics set them apart from other types of interest groups such as general professional or industrial associations.

According to this approach, the growing bureaucratization of the state and its increasing involvement in regulation, coupled with the increasingly technical and complex nature of the issues addressed by regulation and public policy, have led to an increasing reliance on experts for a widening array of regulatory and policy decisions. This process has been reinforced at the international level by the continuously widening agenda of international regulation. This situation has increased the uncertainty of state authorities and regulators as to the regulatory decisions they have to take. Uncertainty is a significant prerequisite for the growing influence of these knowledge-based networks which, using their claim to authoritative knowledge can influence, shape and even redefine states’ interests (Haas 1992, 1994).

Despite the centrality of non-state actors and authoritative knowledge in its explanatory structure, there are a number of limitations to the usefulness of this approach here. First, epistemic communities refer to a specific type of non-state actor, which as we saw above is quite different from other more typical and common types of non-state groups such as national and international industry or professional associations. The concept may therefore cover only part of the phenomenon of transnational regulatory authority, leaving instances of such authority outside its explanatory framework. Given that most of the non-state actors encountered today as significant players in global economic governance schemes are usually associations that do not fall under the rather strict conception of epistemic communities, this creates problems for our analysis. Indeed, none of the non-state groups or organizations that play an important role in the case studies presented in this thesis satisfies the criteria of an epistemic community.

In addition, this approach does not provide us with an adequate justification for delegating authority to non-state actors, since experts can still influence and inform politicians and regulators without this delegation. Given the fact that this

approach refers mainly to networks of independent experts and not to non-state organizations it would be far more probable to assume that these experts could be individually integrated within their corresponding state authorities' apparatus. Indeed, according to empirical findings (Haas 1992; 1994) the influence of epistemic communities grows as their incorporation into national or international bureaucracies increases.

These problems can be seen in Martinez-Diaz's (2005) effort to use the concept of epistemic communities to explain the rise of the IASB to prominence in recent years. Martinez-Diaz believes that domestic pressure for harmonization increased in the 1990s due to changes in the international system, and that the status of the International Accounting Standards Committee (IASC)<sup>34</sup> as an epistemic community allowed it to legitimately claim technical authority and become a compelling solution to the harmonization dilemma. This assertion however is not easy to support. Research in international and comparative accounting has demonstrated how different economic, social, cultural and legal conditions have created different reporting needs and priorities and therefore different conceptions of accounting's predominant role<sup>35</sup>. As a result, the objectives of accounting systems vary greatly and so do the accounting principles and practices that they have developed. This diversity is somewhat at odds with the concept of epistemic community, which refers to "a specific community of experts sharing a belief in a common set of cause-and-effect relationships as well as common values" (Haas 1994, p.138). This diversity has been evident within the IASC, which for the first fifteen years of its life dealt with disagreements by allowing so many alternatives in its standards that these were not taken seriously by most analysts<sup>36</sup>. It is also worth noting that this difficulty to agree on "proper" accounting standards was happening at a time when the IASC was comprised solely by accountants and therefore the grounds for an epistemic consensus were ideal. In any case, since the early 1980s the IASC has explicitly

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<sup>34</sup> IASC was the IASB's predecessor; the IASB emerged from a reconstruction of the IASC in 2001.

<sup>35</sup> For a review of the relevant literature see Nobes and Parker (2000); Roberts et al. (2002) and Weetman et al. (2003).

<sup>36</sup> In the view of some prominent experts of the time: "IASC standards tend to be somewhat bland compromises" (Gray et al. 1981, p. 127).

incorporated other interest constituencies in its structure so that even the appearance of an epistemic community seems implausible.

In his effort to “squeeze” the IASC into the profile of an epistemic community, Martinez-Diaz has had to change the definition of an epistemic community to accommodate the possibility that “communities of experts *strategically modify* their output of policy relevant knowledge in order to promote its adoption by powerful patrons” (2005, p.7). Relaxing the narrow definition of epistemic communities however does not solve the problem. In fact, this would undermine any insights that the theory has to offer. This is because this approach is inspired by a constructivist view of international relations (Checkel 1998, Ruggie 1998; Hasenclever et al. 2000). The core of the theory revolves around the possibility of learning. Epistemic communities through their privileged knowledge can persuade state authorities and regulators of the correctness of their views and perhaps shape and even redefine their interests. This is in line with one of the core tenets of constructivist thought, the possibility that actors, including states, can change interests and even identities; they can learn to see themselves and others in a different light (Wendt 1992). This understanding of learning refers to a complex learning process “whereby actors alter not only how they deal with particular policy problems but also their prevailing concept of problem solving” (Ruggie 1998, p.868). It is obvious thus that manipulating knowledge to fit with regulators’ wishes in order to obtain their support, as Martinez-Diaz suggests, defeats the very purpose of the concept. If regulators do not change interests and experts only use knowledge to accommodate these predetermined interests and thus advance their own influence in the policy-making process, then we are not talking about epistemic communities anymore but about traditional interest-group politics.

#### 3.3.4 Power approaches

One of the main explanatory variables of international cooperation has traditionally been power. Could power explanations of international regulation fare better than efficiency or knowledge approaches? Setting international rules for any issue-area unavoidably involves making distributional choices. Even when all parties are better off with a set of rules than without one distributional issues arise, and often they are

significant enough to create conflicts and stall cooperation. In these cases, power approaches would argue that it is the distribution of power capabilities that decides the final point of equilibrium: “there are, however, many points along the Pareto frontier: the nature of institutional arrangements is better explained by the distribution of national power capabilities than by efforts to solve problems of market failure” (Krasner 1991, p.337).

Nonetheless, there are limits to the extent to which power can provide, on its own, a convincing argument for transnational regulatory authority. First, power explanations of international regulation, like approaches based on efficiency, use the concept of national interest which as was argued above is difficult to define satisfactorily and creates problems for the predictive power of the theory. Secondly, power explanations of international regulation seem to be incompatible with transnational *in* authority. Realist and neo-realist explanations based on power considerations tend to ignore non-state actors. This is understandable to a degree, in the sense that non-state actors lack the power capabilities of states both at the domestic and the international level; the state is the basic actor of the international system because it is the most powerful actor and the only one that has the right to use force legitimately. Therefore, it would make little sense for states to delegate their authority to non-state actors and lose direct control over one of their most important resources: legal obligation. Indeed, the dominant power-based explanation of international regulation, the hegemonic theory<sup>37</sup>, seems to deny any role for hybrid governance schemes. After all, if one state enjoys a hegemonic status in an issue-area, it would have no incentives to pursue hybrid governance schemes, since it can use its power advantage to impose a legally binding inter-state agreement that best serves its interests.

Simmons’ (2001) work exemplifies these problems. She focuses on the international harmonization process that has been taking place in the area of capital markets in recent years. In this context, she includes not only cases of inter-governmental cooperation but also non-state organizations such as the IASC which as we have already mentioned is one of the case studies examined in this thesis. Despite

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<sup>37</sup> See Krasner (1976) and Giplin (1975; 1981).

the broad array of actors covered by her analysis, Simmons focuses exclusively on state power; she believes that state power and particularly the power of a hegemon, or a “dominant financial center” in the case of capital markets, is the catalyst that explains the variations in international harmonization efforts. This dominant centre is a “regulatory innovator” that produces regulation for domestic purposes, which are treated as exogenous. The international harmonization process is explained as an effort from the dominant centre, to minimize the costs (externalities) that its regulation may result in, if other states have incentives to react negatively to it. If these costs are significant for the dominant centre, then it will apply international political pressure to bring about a change in the policies of the other states and bring them in line with its own regulation.

Simmons’ focus on state power leads her to problems which are evident in the way she treats the case of the IASC. First, she underestimates the role that non-state institutions can play in the global regulatory process. Yet, this attitude towards non-state actors is often at odds with empirical findings. In her treatment of the IASC she dismisses it as providing a mere “cover of multilateral legitimacy to mostly U.S. standards” which “does not explain harmonization in this area” (2001, p.611). As we shall see in the chapter on international accounting standards, this position is empirically weak and represents a gross underestimation of the role of the IASC and its successor the IASB. This organization has been the architect of the international accounting standards (IASs)<sup>38</sup> around which effectively *all* harmonization occurs in this issue-area. Indeed, developments in the international harmonization process shortly after Simmons’ article was published, have demonstrated that she greatly underestimated the importance of IASC and overplayed the importance of rival inter-state forums for harmonization. Secondly, she does not consider the possibility that regulatory harmonization may not be initiated by a state but by non-state or hybrid organizations, as is the case with international accounting standards as well as in other issue-areas, such as the internet<sup>39</sup> or the transnational maritime trade regime<sup>40</sup>. Indeed, the application of the “regulatory innovator” concept in the case of

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<sup>38</sup> IASs are now called International Financial Reporting Standards (IFRSs).

<sup>39</sup> See Spar (1999).

<sup>40</sup> See Cutler (1999, 2003).

international accounting standards makes no sense: at the time of Simmons' article the U.S. had made no new significant domestic regulatory change since the early 1970s in this area. Moreover, because of Simmons' exclusive focus on state actors in the international arena, non-state actors are only treated as part of the domestic political scene usually acting through lobbying to influence their respective governments. Simmons effectively treats transnational governance schemes as traditional inter-state or trans-governmental regimes, choosing to ignore their hybrid nature. This makes her approach ill-suited for the examination of governance structures where non-state actors have significant, explicit and institutionalized roles to perform.

Finally, since power explanations seem to deny the possibility of a delegation of authority to the private sector, they have nothing to say about the legitimacy issues raised by transnational regulatory authority. Private power, while acknowledged and playing a significant role as the basis for the power capabilities of the state and therefore its negotiating power vis a vis other states, is only manifested through lobbying activities at the domestic or international level. Non-state authority never emerges.

### **3.4 Transnational regulatory authority and the politics of delegation**

From the previous analysis, it becomes clear that current international regulation theories that explicitly aim to incorporate non-state actors in their theoretical framework cannot provide us with a single, comprehensive account of transnational regulatory authority. Nonetheless, the various approaches examined above hold significant insights for understanding the possible motives of, and conditions under which, state authorities may decide to delegate their regulatory authority to a transnational non-state organization. The theoretical analysis that follows in the next sections aims to incorporate some of these insights into a framework designed to achieve an eclectic yet, meaningful explanation of transnational regulatory authority.

#### **3.4.1 Explaining the emergence of transnational regulatory authority**

To achieve this synthesis, a fundamental ingredient is recognition of the importance of domestic politics for international regulation. Emphasis on domestic politics is



necessary because it is the only way to link the world of international institutions with the realm of domestic political community. As was illustrated in the previous chapter, political and thus regulatory authority is intricately and essentially linked to domestic politics; indeed, domestic politics could be considered as the institutional and operational manifestation of the various aspects of political authority<sup>41</sup>. In addition, a domestic politics approach allows us to identify the interests of domestic groups that are affected by international economic regulation and are therefore likely to press their governments in specific directions. This enables us to analyze states' positions in international negotiations with reference to these interests, thereby opening up the black box of the state as a unitary actor that "defends" the national interest (Putnam 1988; Milner 1998).

A domestic politics approach that is particularly interesting for our purposes, is one which uses the theory of economic regulation as its theoretical foundation (Oatley and Nabors 1998; Richards 1999). The economic theory of regulation was introduced by Stigler (1971), who advocated not a theory of regulatory capture but a "cartel theory", where agencies were not captured gradually by the regulated industry, but regulation was created from the beginning in order to serve its interests. Stigler argued that parties and politicians seek money and votes, and that this is exactly what the winning interest groups will offer them. Due to the nature of the political decision, small groups will probably face fewer organizational problems (less free-rider problems and less information costs), and at the same time they will enjoy a higher per capita interest in specific regulatory issues than large groups (for example consumer associations). Such groups are therefore expected to have more incentives to "invest" in political procedures, capturing politicians and through them promoting the regulation that best serves their interests. Peltzman (1976) formalized and generalized the theory of Stigler. A central result of Peltzman's model is that the costs of using the political process limit not only the size of the winning group but also the potential gains it may enjoy. For Peltzman the rational regulator seeks a structure of costs and benefits that maximises his political returns. This means that the regulator

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<sup>41</sup> Oakeshott (1991) argues that the legislative, adjudicatory and executive processes (along with a very specific understanding of the term "politics") exist to make authority operational in practice, that is, in reference to specific problems with distinct circumstances at a given point in time.

gives attention not only to economic factors but also to political ones and thus political criteria will substitute for economic ones to some degree when he makes his decisions. This means that even though smaller, and better organized groups will probably be on the winning side of the regulators' auction, as argued by Stigler, their victory will not be absolute and some compensation to the losers will be arranged by the regulator. Becker (1983) developed this idea further by emphasizing the presence of deadweight costs. Deadweight costs are "the distortions in the use of resources induced by different taxes and subsidies" (Becker 1983, p.373). Because deadweight costs to the groups that are "taxed" rise at an increasing rate as the "subsidies" to the winning group increase, the subsidies will tend to be lower than what the winning group would like, since higher subsidies will induce stronger opposition from the losing groups.

The international strand of the theory expands the model to an open economy. The principal insight of the theory is that *international cooperation can be used in an open economy context to satisfy domestic constituencies*. Given that politicians want to win the support of a variety of constituencies, they will use international institutions, if they can, to increase the resources available for distribution to these constituencies. This in turn will increase the political returns they expect from these constituencies: "international institutions will be created only when such institutions are utility enhancing for national politicians. In other words, international institutions will be created when they are politically efficient (that is, increase electoral support) for national politicians" (Richards 1999, p.3).

The economic theory of international regulation is a domestic politics approach to international regulation and thus fits exceptionally well with the type of theoretical framework we are trying to develop in this thesis. As such, it fulfils the two functions we posited as necessary at the beginning of this section: it focuses on domestic politics and examines the role of interest constituencies in the regulatory process. In addition, the way the theory addresses these issues counters another weakness of the explanations examined earlier. Instead of relying on normative assumptions about the behaviour and motives of the regulator, it assigns the regulator rational and self-regarding behaviour, similar to that of other actors, while

acknowledging the distinct characteristics of the political process. The combination of these two elements provides us with a richer explanation of regulation because, while on the one hand it stresses the role of resource capabilities and thus power in domestic politics, on the other hand it acknowledges the peculiarities of the “political market”, allowing thus for efficiency explanations. Indeed, the characteristic of the deadweight costs, implies a “tyranny of the status quo” when a political equilibrium exists among pressure groups, which makes it difficult for winning groups to gain higher subsidies. The level of subsidies may rise however if new regulation increases efficiency, because higher subsidies can be extracted from the same level of taxes; if efficiency rises marginally with new regulation, then the winning groups will have an incentive to increase their pressure. Because of this effect, “policies that raise efficiency are more likely to be adopted than policies that lower efficiency” (Becker 1983, p.384).

The argument put forward in this thesis is founded on the main insight of the economic theory of international regulation: regulators will often use international regulation to satisfy domestic constituencies. The aim here however, is to extend this basic insight beyond traditional inter-state institutions to the realm of transnational regulation by acknowledging that regulators can use not only international institutions but also non-state, transnational organizations to satisfy domestic constituencies. Given the nature of transnational regulatory authority, which, as was shown earlier, hinges on the explicit endorsement of state authorities, the argument put forward here can be presented as:

*Proposition (1): we expect state authorities to endorse, encourage, or bring about themselves the emergence of transnational economic governance schemes that enjoy regulatory authority, when they want to distribute wealth to specific domestic interest constituencies.*

Also, in line with the economic theory of regulation:

*Condition (1a): we expect the winning constituencies to be small, well-organized and with a high per capita interest in the regulation being promoted.*

This extension to the transnational level however, raises two significant problems in relation to the economic theory of regulation. First, the delegation of authority to the private sector runs contrary to the main tenet of the theory, that is, the self-interest of the regulator. By delegating their regulatory powers away, politicians and regulators give up their leverage over the private sector and thus remove the incentive of the private sector to support them financially. Indeed, Peltzman (1989) regards the economic theory's inability to predict the de-regulatory wave of the 1970s and 1980s as one of its most significant failures, since it was obviously not in the regulators' interest. However, this is only true if we adopt a very narrow definition of deregulation and self-regulation. By adopting a policy of hybrid regulation, the regulator can retain a significant role in the regulatory process. Deregulation and self-regulation need not be a complete surrender of power if the state reserves a role in the regulatory process, threatening at any time a revocation of the private sector's regulatory powers and the introduction of state regulation. The experience from the deregulatory wave in domestic economies in recent decades seems to verify our argument: what has taken place is not deregulation but rather re-regulation. The "deregulatory" wave of recent years has really been a surge in both mandated and sanctioned self-regulatory schemes<sup>42</sup>. What is more, in the case of transnational regulatory authority, since the transnational regulatory forum receiving the grant of authority also includes foreign non-state actors, with possibly different interests from the domestic constituencies that the regulators try to satisfy, retaining a role in the regulatory process becomes necessary, in order to influence the produced regulation towards the desired direction. The economic theory of regulation therefore sets a limit to the degree of delegation of transnational regulatory authority:

*Condition (1b): we expect national regulators/policicians to embed their delegation of authority to a transnational regulatory forum with an institutional mechanism or procedure which ensures that they retain a significant role in the regulatory process, and thus the ability to control the regulatory outcome if they so choose.*

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<sup>42</sup> For interesting accounts of this process see Harden and Lewis (1986), Cerny (1991), Majone (1994), Baldwin et al. (1998). A similar argument has also been made by the literature on private interest governments (Streeck and Schmitter 1985).

There remains however, another even more difficult problem to overcome. The economic theory of international regulation, which underpins our argument, is not in a position to address our third research question, concerning the justification of the delegation of authority. The economic theory of international regulation refers to international institutions. International cooperation however, is quite different from transnational regulatory governance because in the latter it is not only the content but also the nature of regulation itself that is under consideration. In this context, the economic theory of regulation offers at best a justificatory argument based on the efficiency gains offered to the voting public as a counter-balance to the privileged role offered to specific interest groups in the regulatory process. As we saw above however, efficiency may be adequate for justifying the content of regulation, but it is not enough to justify its delegation to transnational non-state actors. The adoption of hybrid or even entirely private forms of regulation is inexorably linked with questions of legitimacy and authority, which the positive theory of regulation with its focus on interests and rational, egoistic actors is ill-suited to address. Indeed, one of the major criticisms of the economic theory of regulation has been the fact that it ignores almost entirely the political and institutional constraints on the ability of the regulator to use regulation to satisfy particular domestic constituencies<sup>43</sup>.

The solution proposed in this thesis is to relax and widen the rationalist assumptions of the economic theory of regulation by acknowledging the constraints outlined by the political theory of authority. Such a synthesis can help us contextualize the insights of the economic theory of regulation, by placing regulators and private actors within the boundaries of a political community. As we have seen, the normative and institutional limitations grounded on the rules that establish authority set the boundaries of legitimacy; they determine whether the actions of governments and regulators are legitimate and authoritative and therefore establish the boundaries of the “feasible” in political action, including the delegation of regulatory powers to non-state actors. In a liberal, democratic society, where authority has been established based on democratic principles, public *in* authority can only be

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<sup>43</sup> For reviews of the problems identified more generally with the economic theory of regulation, see Peltzman (1989), and Baldwin et al. (1998).

held by the democratically elected government. Therefore, governments need not only compensate the general public for granting self-regulatory powers to the private sector, but they also need to *justify* the transfer of their democratically entrusted right to regulate public life to parties without a comparable mandate. While therefore the positive theory of regulation can help us understand *why* regulators may be willing to delegate their regulatory powers away, the political theory of authority can help us understand *when* they are able to do so.

The next sections operationalize these arguments. First, we attempt to provide an answer to our second research question by identifying the conditions that may provide regulators with the incentives to choose transnational regulatory governance, over other international and/or transnational institutions, in order to satisfy the preferred constituencies. Secondly, we address the problematique raised by our third research question by describing the justificatory process regulators have to follow when they have an incentive to use transnational regulatory authority.

#### 3.4.2 Using transnational regulatory authority

The economic theory of international regulation proposes two major strategies for using international institutions for political gains: a) create institutions that increase efficiency and therefore the resources available for distribution to domestic constituencies and b) create institutions that transfer wealth from foreign actors to particular domestic constituencies (Oatley and Nabors 1998; Richards 1999). By expanding the strategic arsenal of regulators' economic diplomacy tools to the transnational arena however, we give them a choice between international and transnational regulatory solutions. Given this option, two questions emerge in relation to transnational regulatory governance. First, can the strategies outlined above also work with transnational non-state regulatory institutions? Secondly, given the option to use international or transnational non-state institutions, when would regulators choose to use the latter? We address these questions for each of the strategies outlined above.

#### *3.4.2.1 Transnational regulatory authority and efficiency gains*

The first strategy follows from the discussion on deadweight costs, and its extension to the international realm presents no difficulties to the degree that it raises efficiency gains for all parties involved and the parties have no dominant strategies<sup>44</sup>. As we argued earlier, regulation that raises efficiency will generally be preferable to the regulators than regulation that does not. The same strategy could be used in the case of transnational regulatory authority by extending the same line of argument not only to the content, but also the method of regulation. We have seen that the typical argument in favour of self-regulation is that it is a cost-reducing regulatory method for the government (cost of regulatory process passed on, at least partly, to the private sector), and that it often leads to more efficient and/or effective regulation. Both characteristics translate in increased resources available to the regulator for distribution to domestic constituencies. In principle therefore, it seems that the same argument could be made for transnational regulatory governance.

However, as we saw earlier, the efficiency and effectiveness gains generated by delegating regulatory authority to transnational actors are significantly reduced compared to domestic self-regulatory schemes. At the same time, it was previously argued that transnational regulatory governance presents many of the problems associated with self-regulation, many of which are even more pronounced at the transnational level. These problems translate into significant political costs, especially when compared to regulation pursued through international institutions, costs, which cannot go unnoticed by the politically minded regulator. This is particularly the case, if the objective is to increase efficiency gains through international regulation for all states involved, when as we saw, we expect binding, hard law, international agreements, to be more effective and efficient institutional solutions.

For these reasons, we would not expect regulators to treat transnational regulatory authority as their first strategic choice when their objective is to increase efficiency gains. Therefore, the use of transnational regulatory authority means that enhancing efficiency through international institutions has failed as a regulatory

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<sup>44</sup> A dominant strategy is a strategy that results always in better outcomes for a player than an alternative strategy, irrespective of their opponents' strategies.

strategy. In this case however, it is obvious that international agreement on the content of regulation is not forthcoming and therefore efficiency might no longer be the criterion for the use of transnational regulatory governance.

#### *3.4.2.2 Redistribution and transnational regulatory authority*

It is often the case that a proposed institution or agreement does not increase welfare for all parties involved and unsurprisingly, distributional conflicts cause cooperation to stall. International cooperation may not be forthcoming even when overall efficiency is enhanced because different actors may have different strategies on how to achieve the desired efficiency gains, which means that even when all actors gain, some actors may gain more than others<sup>45</sup>. In cases of distributional conflict, the use of international or transnational institutions as a redistributive strategy may be quite difficult to implement. This is because unlike domestic state regulation, international cooperation is by definition voluntary, which makes the possibility of redistributive agreements unlikely (Oatley and Nabors 1998; Richards 1999)<sup>46</sup>.

Nevertheless, as Richards (1999) notes, there are two reasons why politicians/regulators might actually accept voluntarily a wealth-reducing agreement. First, “wealth-transferring international regulations can benefit national politicians if

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<sup>45</sup> See Krasner (1991), Stein (1983), and Snidal (1985).

<sup>46</sup> The concept of redistribution is used here in a similar vein as in the literature of economic regulation which forms the theoretical basis for our argument. Therefore, redistribution refers to the transfer of wealth among different interest-constituencies, through the medium of regulation. This however, does not refer to wide-ranging, systematic schemes that aim to direct the economy and society as a whole towards a specific model of wealth distribution, often driven by transnational elites, along the lines of critical theorists (e.g. Gill 1995; Cutler 2003). Rather, it takes place in the context of policy/regulatory politics within specific issue-areas or industries, always depending on the institutional characteristics and the nature of the issue-area or industry in question. As it has been made clear earlier, the decision to pursue a distributional policy favourable to particular interest constituencies, depends on the rational calculation by the regulator and/or politician of the structure of costs and benefits that maximises his political returns in a specific policy area. In this sense redistribution as used in this thesis is closer to traditional political science's interest-group accounts of public policy and regulation. Still, caution is needed not to confuse it with Lowi's (1964) classic conception of redistribution as a type of public policy. Lowi's redistribution actually refers to wide-ranging, largely class-based, redistributive policies that may have significant impact on the relative distribution of wealth across society and whose importance is determined more by their potential and the expectations they generate rather by the actual outcome of the policy process (Lowi 1964). In this sense Lowi's conception of redistribution is closer to critical theorists' views and indeed Lowi admits that in such cases the political process can be most closely approximated by an elitist approach, similar to the ones advocated by critical theory. The concept of redistribution used here is more likely to be encountered in Lowi's *regulatory* category of public policy which is most often encountered at the level of specific sectors.



the domestic actors who actually transfer wealth abroad are not part of the politicians' coalition or if coalition members stand to gain from an international agreement" (1999, p.12). In other words, international regulation can be used as a means to achieve redistribution between domestic constituencies, even at the expense of society's overall well-being. This should come as no surprise since:

international cooperation in this model is attractive due to the private goods it creates, not the public goods. Although public goods are not irrelevant, they effect political choice through their effects on private wealth. Thus international cooperation might be politically attractive even if it creates public "bads".

(Oatley and Nabors 1998, p. 40)

Why would regulators and/or politicians choose transnational regulatory authority over an international agreement as a means to achieve domestic redistribution? The use of international institutions to achieve domestic redistribution offers the advantage, compared to voluntary, non-state institutions, that international agreements bind national politicians/regulators, but also their successors (who may favour different interest constituencies) to specific obligations and policies, especially when these agreements are characterized by a high degree of legalization (Abbott and Snidal 2000; Kahler 2000). Transnational regulatory authority however also offers this advantage. By leading to binding legal results that transform the domestic legal framework, transnational regulatory authority makes the reversal of the obligations assumed under its auspices unlikely and thus binds to a considerable degree the successor regulators/politicians to its agreements. Even so, the use of transnational regulatory authority entails significant sovereignty costs and might raise legitimacy concerns regarding the regulators' choice. An advantage of transnational regulatory authority, that could potentially compensate regulators/politicians for the sovereignty costs they would incur and the legitimacy concerns they would raise by using it, could be its less formal set-up, which might result in less public attention and scrutiny for the regulator (Lipson 1991). This presents a considerable advantage, when the objective is domestic redistribution. Less public awareness could reduce significantly the legitimacy concerns and the corresponding political costs making this option particularly attractive for the regulator.

Whether this is enough of an incentive for the use of transnational regulatory authority will depend on the nature of the regulatory dilemma that regulators/politicians face. For example, when regulators want to bypass strong domestic opposition of well-organized constituencies, which have sufficient interest and resources to identify and denounce publicly this strategy, the less formal set-up of transnational regulatory governance could become a disadvantage. Regulators/politicians would be pressed to withdraw from the transnational governance scheme and they would not be able to invoke any binding international agreement allowing them to resist such calls. On the other hand, if opposition comes from large, poorly organized constituencies with low awareness of the issues at hand, which usually means the general public or some large subgroup thereof (e.g. consumers) we would expect regulators/politicians to bind this weak opposition to a formal international agreement, since it is very likely that the redistributive agreement would not be detected or understood from the opposition. However, when the nature of the issue-area in question is such, that increased public awareness associated with negotiations in an international forum has the potential to mobilize significant opposition from the public, including civil society movements/organizations, then regulators and/or politicians might have enough of an incentive to resort to transnational regulatory authority. Heightened risk of public reaction in turn, is more likely, the more politically sensitive is the issue-area where domestic redistribution is sought. Using transnational regulatory governance in this case, allows regulators/politicians to lower the visibility of the issues addressed, by locating the negotiations in a technical, expert-dominated forum. The potential benefits from such a move in turn, are more likely to be available in issue-areas with highly complex scientific, technical and/or technological content. It is in such issue-areas or industries that the public will probably be less organized, and more likely to be either unaware or less capable of understanding the issues being regulated. Also, in such issue-areas it would be easier for the regulators and/or politicians to shift the regulatory forum to a transnational non-state organization without drawing significant public attention. Summarizing the previous discussion, we have:

*Proposition (2): when their objective is domestic redistribution, we would expect regulators and/or politicians to choose transnational regulatory authority: (a) in issue-areas with highly complex scientific, technical and/or technological content, and (b) when the issues regulated have a high potential to mobilize wide public opposition.*

A second reason why regulators/politicians may accept a wealth-reducing agreement or institution is that they are forced into it. This can happen in two cases: when unanimity is not the choice rule and when there is an actor that has the ability to manipulate the choice set, that is, the set of alternatives from which the outcome will be selected. If unanimity is not the choice rule, the majority can extract wealth from the minority. However, when unanimity is the rule of choice, as is often the case in international politics<sup>47</sup>, convincing voting parties to a redistributive agreement is very difficult. Oatley and Nabors suggest that this difficulty can be overcome when a player has the ability to propose alternatives that are costly to other parties, forcing them to choose the less costly, but still wealth-reducing choice. In this case even if unanimity is required the dominant actor can still get their desired outcome. This is usually the case when a state enjoys a significant advantage of structural power in the issue-area, which allows it to shape the possible outcomes:

the...reason national politicians might voluntarily accept wealth-reducing international regulations stems from the potential for states with market power to unilaterally define the reversion point of international negotiations. The reversion point is the set of marketplace rules that will result if there is no new international agreement.

(Richards 1999, pp.12-13)

In other words, redistributive cooperation can occur, even when unanimity is required, provided there is a hegemon. However, there are two problems with the hegemonic argument in terms of international redistribution. First, few global industries display so asymmetrical a distribution of power that one state can determine on its own the reversion point. Most industries that exhibit high levels of concentration at a global level could be better characterized as oligopolies rather than monopolies, and the companies that make up these oligopolies usually come from

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<sup>47</sup> Oatley and Nabors themselves admit that, "majority rule is not the dominant decision rule in international politics" (1998, p.41).

more than one country. There is therefore a significant problem for the hegemonic argument when the other important players are not in agreement with the “dominant” centre. In the case of the banking industry for example, the US and the UK acted in coordination, in effect creating a powerful front that threatened the other players because of the combined structural power of these two countries in the area of banking (Simmons 2001). In other instances however, this has not been the case. Underhill (1995) describes how the UK did not agree with the US approach on a similar capital adequacy standard, this time for securities firms. UK views were in line with the EU Directive on the issue which was also in line with an IOSCO/Basle Committee Accord. As a result there is still no comparable capital adequacy agreement for securities firms today.

Secondly, even in cases where a hegemon exists, the nature of the international political process may attach costs to an international agreement that the hegemon may consider unacceptably high. First, the one-state, one-vote system reduces significantly the impact of the underlying power asymmetries among states, since all states in international negotiations are statutorily equal. Secondly, the “noise” in the process of voting in international negotiations cancels out, to some degree, the power advantage of the hegemon. Stigler describes the voting process in domestic political systems as gross or noisy: “the expressions of preferences in voting will be less precise than the expressions of preferences in the marketplace because many uninformed people will be voting and affecting the decision” (1971, p.11-12). The uninformed people are voters that have no incentive to get informed because the costs they have to incur in order to acquire information are disproportionate to their gains, especially when the issue under consideration does not directly affect them. Moreover, they cannot trade their voting power for favours, unless they first coordinate into blocks of votes, because the large number of domestic voters precludes any one of them having an impact on the voting outcome. Voting in international organizations is like domestic voting in the sense that there may be many voters (states) that are not directly interested in a particular issue; in other words there is *noise* in international voting as well. Unlike domestic voting however, due to the small numbers involved in international negotiations, states that do not

have a direct (or significant) stake in an issue, know that they can nonetheless affect the final outcome. Therefore, they often have an incentive to exploit their influence over the voting outcome in order to bargain for concessions in other issues. Because these states do not have a direct interest in the issues that the hegemon is trying to pursue, they are not considerably affected by the manipulation of the choice set by the hegemon; preserving the status quo entails no costs for them and therefore the reversion point threat is not an effective tool against them. If the deal these countries offer to the hegemon affects negatively some of its domestic constituencies, the hegemon's regulator may face a backlash at home from the reaction of the adversely affected constituencies. Therefore, depending on the relative wealth and electoral importance of these constituencies, the costs associated with the deal, which we shall hereafter call *compensatory costs*, may be considered too high and international negotiations may stall<sup>48</sup>.

Because of the difficulty of international negotiations in certain issues, states (even those considered as hegemonic) may prefer to either forgo an international agreement altogether or to pursue alternative strategies such as bilateral agreements, or agreements in alternative international fora, where membership will be limited to states with more compatible interests. When states are selecting such alternative solutions, they are in effect pursuing a strategy of *forum-shifting*. Forum-shifting is not a new strategy. As Braithwaite and Drahos (2000) argue, forum-shifting has been used in international regulation since the Second World War in a number of issue-areas<sup>49</sup>, its use made easier by the growth in the number of international institutions. There is no reason however why forum-shifting could not be extended to non-state or hybrid organizations. Indeed, what is argued here is that when regulators seek but are unable to achieve redistribution through international institutions, they may resort to the solution of transnational regulatory authority as a forum-shifting strategy.

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<sup>48</sup> The negotiations currently under way at the WTO in the context of the Doha Round are a case in point: developed states push for concessions in issues of investment, technology and services, while developing countries press for concessions mainly in agriculture. Because farmers are a well-organized and politically significant group in both the European Union and the United States, the latter find it difficult to agree to the concessions demanded by the developing countries.

<sup>49</sup> For example in financial regulation, intellectual property rights, telecommunications, labour standards, competition policy, air and sea transport, nuclear safeguards, privacy standards, food standards and drugs' regulation (Braithwaite and Drahos 2000, p. 564-571).

### 3.4.2.2.1 Transnational forum-shifting

To understand in which issue-areas or industries regulators will have an incentive to use transnational regulatory authority as a forum-shifting strategy, we need to look at the different strategic configurations that they may face following the failure of international agreement, in line with the discussion in the previous section. Table 3.1 outlines the different possible combinations of simple or distributional coordination<sup>50</sup> and different levels of compensatory costs in the context of a hegemonic power structure. We see that when there are low compensatory costs the presence of a hegemon facilitates international cooperation and there is no need for employing forum-shifting strategies on the part of the hegemon. Other market players have no incentive to engage in forum-shifting either, since they can either free-ride on the hegemon (benign hegemony), or if the content of rules is important for them and they disagree with the hegemon on this issue, they are likely to be coerced into a set of rules favourable to the hegemon (coercive hegemony).

**Table 3.1 Forum-Shifting in a Hegemonic Power Structure**

		<i>Type of cooperation problem</i>	
		<i>Simple Coordination</i>	<i>Distributional Coordination</i>
<b>Compensatory Costs</b>	<b>Low</b>	International Agreement (Benign Hegemony)	International Agreement (Coercive Hegemony)
	<b>High</b>	International Forum-Shifting	International Forum-Shifting

<sup>50</sup> This category refers to the type of problem for the resolution of which international cooperation is sought after. Simple coordination refers here to problems where there are no significant conflicts of interest among the interested parties. They usually concern “common aversion dilemmas”. In such cases actors have a common interest in avoiding a particular outcome whose resolution requires mainly coordination among the affected parties, and thus it does not affect significantly their patterns of behaviour. Nonetheless, significant distributional differences can emerge even in common aversion dilemmas. These cases along with problems usually characterized as “dilemmas of common interests” are included in the distributional coordination category. In common interests’ dilemmas agreement is much more difficult and actors must collaborate, establishing strict patterns of behaviour and ensuring that no one cheats. For a detailed discussion of different cooperation problems see Stein (1983), Snidal (1985) and Martin (1992).

When compensatory costs are high, the hegemon may decide that it prefers to use an alternative forum. In cases of simple coordination, states with regulatory concerns similar to those of the hegemon have an incentive to join the new forum and free-ride on the hegemon. In cases of distributional conflict, the hegemon can again try to overcome both the high compensatory costs and the distributional conflicts through bilateral agreements where it enjoys a negotiating advantage. Alternatively, it can form an alternative forum and again press other market players into compliance through its market power. From this overview, it is obvious that there is ultimately, no compelling reason for the hegemon's regulators to use hybrid forms of governance, thereby delegating part of their regulatory control to the private sector, incurring thus significant sovereignty costs, and potentially raising sensitive legitimacy questions over their choice. The hegemon's asymmetrical power advantage ensures binding international agreements either through principal or alternative international fora, or through bilateral agreements.

Table 3.2 outlines the possible combinations of simple or distributional coordination among market players and different levels of compensatory costs in an environment characterized by an oligopolistic distribution of market power. When compensatory costs are low and the objective of the group of strong market players is a common set of rules, an international agreement is feasible and forum-shifting will not be used as a strategy. In the case of high compensatory costs and agreement among the significant market players, the latter can form an alternative forum and cooperate to provide a common set of rules while other small players can free-ride on them<sup>51</sup>. It should be noted here, that it is only states that enjoy considerable structural or market power in the issue-area in question that are able to employ successfully a

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<sup>51</sup> According to collective action theory, no individual has an economic rational incentive to contribute to the provision of collective goods, since everyone would be better off by free-riding on the contributions of others (Olson 1965). A group can enjoy a collective good however when there is one or more members of the group for which the net benefit of providing the good is larger than its cost even if everybody else free-rides on them. Hardin (1982) has showed that, what is important for collective action is the factor  $k$ , rather than the number of group members  $n$ ;  $k$  being the "the size of the smallest subgroup that could benefit more than the total cost of the whole group's good" (Hardin 1982, p. 46). In an "oligopolistic" industry where a small number of states enjoy significant market power, they may have the incentive and the capabilities to provide a collective good because their benefits from collectively doing so are likely to be greater than the cost of providing it.

forum-shifting strategy, inter-state or hybrid. There are two reasons for this. First, it is only the departure of a state that is a significant player in an issue-area that can weaken the abandoned forum and thus have any impact on its international standing. It is only in such a case therefore, that the other states participating in the forum may be willing to change their position. Secondly, only a state with significant market power in an issue-area will be able to endow a non-state organization with enough influence to be considered a significant forum for global economic regulation.

When distributional conflicts emerge among the dominant market players and international agreement is not likely, then one or more of these states might have an incentive to form an alternative forum to pursue international regulation. But would the states that form these alternative fora have an incentive to use transnational regulatory governance? Having one or more inter-state fora would only repeat the impasse of international negotiations at different fora, unless a “critical mass” of the dominant players, either in numbers or in market weight, can create a common front, which would make opposition from the other significant players unsustainable (e.g. the case of the bilateral capital adequacy standard between the US and the UK).

**Table 3.2 Forum-Shifting in an Oligopolistic Power Structure**

		<i>Type of cooperation problem</i>	
		<i>Simple Coordination</i>	<i>Distributional Coordination</i>
<i>Compensatory Costs</i>	<i>Low</i>	International Agreement	Forum-Shifting
	<i>High</i>	Forum-Shifting	Forum-Shifting

If this is not possible, then transnational regulatory governance may be chosen in the context of a forum-shifting strategy. The states that opt for transnational regulatory governance are bound to exert significant influence over the work of the transnational regulatory forum. As we have seen, regulators will embed their



cooperation with a transnational organization, with an institutional mechanism that provides them with a measure of control over the regulatory outcome. After all, that is the reason for deciding to engage with the organization in the first place: to overcome the resistance of opposing states and promote their own version of international regulation. At the same time, the participation of the private sector in the new forum, which is considered “an authority” and can contribute to more efficient and effective regulation, allows the initiating states to advertise the new transnational forum as an “experts” forum promoting efficient, market-based regulation. This claim may attract a number of smaller market players, which could raise the status of the new organization and therefore the probabilities that it will become the new dominant forum for the particular issue-area.

Moreover, the claim of *an* authority that the private sector can bring to such a hybrid forum makes a compromise between the opposing states more feasible. First, while undoubtedly favourable to the initiating states’ position, the rules produced by such a forum may be moderate enough to provide a reasonable basis for a future compromise with the opposing states. Secondly, a transnational regulatory forum may provide a face-saving solution for regulators/politicians locked in a regulatory stalemate. Thus, when regulators/politicians are under pressure from domestic interest constituencies to reach an international agreement, they may be willing to compromise their initial negotiating position to overcome the negotiating deadlock. However, doing so in the context of an international forum, would be a clear admission of defeat and put regulators/politicians in difficult position vis a vis their domestic constituents and the political establishment. On the other hand, compromising their earlier position in the context of a new transnational forum, either by participating in a forum first engaged by the opposing states, or by initiating first such a move, allows them to present the agreed regulation as efficient, market-based regulation developed by the experts, avoiding the impression of a forced and perhaps damaging compromise.

However, the most significant advantage of transnational regulatory authority, is the fact that the initiating states effectively change the *reversion point*, a considerable advantage, especially when compared to other non-state governance

schemes. This is because unlike other non-state governance schemes, transnational regulatory authority has concrete legal effects. Once a state has adopted the hybrid organization's rules, the costs of not complying with them will be high for foreign competitors, since they won't be able to conduct business in its jurisdiction. The more economically significant that state's market is for them, the higher will these costs be. Further, if foreign competitors adopt the new rules for this jurisdiction (and perhaps a number of other important jurisdictions participating in the scheme), they will then have an incentive to either adopt this set of rules globally, or compromise their earlier position in order to achieve one set of rules for their global operations and avoid the costs and uncertainty of having to comply with multiple sets of rules. In this way, dominant market players can achieve many of the benefits of hard international legalization, that is, to bind their competitors into concrete legal obligations.

The same arguments can be made in the case of a distributional conflict with high compensatory costs. The crucial factor that impedes agreement is not so much the opposition of weaker states, not directly involved in the particular issue-area, but the conflict among the dominant markets players. Still, the existence of high compensatory costs adds another reason for pursuing a forum-shifting strategy. Opting for transnational regulatory authority has the added advantage of preventing states without a significant presence in the industry, and therefore expertise, from participating in the regime. In other words, transnational regulatory governance acts as a *barrier to regulatory entry* for these states and deprives them of the opportunity to demand compensatory costs in return for granting their consent to an agreement. Summarizing the previous discussion, we have:

*Proposition (3): when their objective is international redistribution, we would expect regulators and/or politicians to use transnational regulatory authority: (a) in issue-areas or industries characterized by an oligopolistic global market structure, and (b) when there are significant distributional conflicts among the dominant market players, which cannot be resolved through international institutions; in this case transnational regulatory governance may be used as a forum-shifting strategy.*

With proposition (3), we conclude the discussion of section 3.4.2, which examined the conditions under which transnational regulatory authority may be used in order to

satisfy domestic interest constituencies. The discussion showed that we would expect regulators and/or politicians to use transnational regulatory authority only in the context of a redistributive strategy and not in order to achieve an international agreement aiming primarily to enhance efficiency for all parties involved. Therefore, we are now in a position to restate proposition (1) in more precise terms:

*Proposition (1): we expect state authorities to endorse, encourage, or bring about themselves the emergence of transnational economic governance schemes that enjoy regulatory authority, when they want to redistribute wealth to specific domestic interest constituencies. Transnational regulatory authority may be used to redistribute wealth either from other domestic constituencies (domestic redistribution), or from foreign constituencies (international redistribution).*

#### 3.4.3 Justifying transnational regulatory authority

As we have seen, the political theory of authority can help us contextualize the insights of the economic theory of international regulation, by placing politicians and private actors within the boundaries of a political community. In this political community, governments need to satisfy the political establishment and the public that the delegation of regulatory authority does not violate the rules and principles of their own authority, and that it is legitimate and therefore authoritative. The authoritativeness of the decision to delegate authority, like that of any governmental action, is determined by a two-stage assessment process. First, an *institutional-procedural* assessment, where both the office making an authoritative pronouncement and the pronouncement itself are assessed in order to verify their authoritative status according to the appropriate and acknowledged rules and procedures that establish authority. Thus for example, a law will not be considered authoritative if it has not passed through parliament according to the appropriate procedures; likewise a ministerial executive decision will not be considered authoritative if it violates existing law. The second type of assessment we shall call a *substantive-normative* assessment because it does not assess the actions and pronouncements of authority according to the procedures of their appearance but according to their substance. This assessment does not negate the characteristics of authority described in the previous

chapter. What is judged here is not the personal appeal of the actions and pronouncements of authority. Rather, what is judged is the conformity of the content of these actions and pronouncements to the principles and beliefs according to which authority itself is established. This type of assessment therefore, operates as a second order mark of authority in the process of evaluation, whereby the subjects of authority determine whether a command or pronouncement is indeed authoritative and therefore warrants their acceptance as such<sup>52</sup>. For example, we often see, courts cancelling governmental actions or rules not because the government did not follow the appropriate procedures but because such actions and rules are judged “unconstitutional” in the sense that they violate the principles embodied in the constitution, which is the source of governmental authority and from which all decisions taken by this authority should flow.

For the institutional-procedural assessment of the delegation of regulatory authority, the traditional model of administrative authority suggests that the delegation of authority operates in principle in a hierarchical fashion (Bayles 1987). This means that “delegated authority is justified if the authority of the delegator is justified” (Bayles 1987, p. 290). For the case of regulatory *in* authority therefore, this delegation of authority must come from the state. Moreover, the procedural conditionality of the delegation process means that it must conform to certain procedures, and that the organizations receiving the grant of authority must operate according to the standards and principles of the organization that delegates it. This usually translates into a set of formal attributes such as adequate standards of transparency, openness, interest representation and due process; in other words the attributes that an institution entrusted with public authority would be expected to possess. Finally, the state cannot delegate all its regulatory authority away because that would mean that the people entrusted with the authority to regulate public life have neither the power to exercise this authority nor the responsibility for the consequences of its exercise. The state therefore must retain a role, often a supervisory one, in order to establish an institutional, formal procedure that ensures

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<sup>52</sup> See pp.33-34 for Flathman’s point that people have to judge whether a pronouncement is authoritative before accepting it as such.

that the government retains the ultimate authority for the regulation of public life and that the regulatory process does truly satisfy the formal procedural attributes described above. The institutional-procedural constraints of authority therefore, provide us with another, more rigorous reason, for the adoption of hybrid forms of regulatory authority than the success of regulators' redistributive strategies. Even if the configuration of voting and financial power was such that it gave politicians and/or regulators an incentive to allow an entirely self-regulatory regime in a particular industry, they would still not be able to do so because such an action would violate the institutional-procedural conditions of authority and would be judged not only illegitimate but also illegal.

However, the procedures and limitations associated with the delegation of authority do not help us *justify*, and therefore *legitimize*, the delegation of authority. They only refer to the process of delegation not to its justification. As argued above, the ability to delegate authority also rests on a substantive-normative assessment regarding the validity of the regulator's claim. The justification for delegating *in* authority needs to emanate from the purpose and principles underlying *in* authority as these are outlined in the constitutional rules of authority. This helps us qualify the justifiability of delegating authority "to the extent that it helps the holder of authority to achieve the ends towards which his authority is geared" (De George 1985, p.106).

What can non-state actors contribute to the achievement of public policy objectives? As we have seen, non-state actors are considered "authorities". Most people would agree that a person, that is considered *an* authority in some issue-area or activity, would be best placed to provide guidance to others for issues relating to their area of expertise. Indeed, that is the essence and pre-condition of being *an* authority; it is not only the superior knowledge that one has, but also the acknowledgment by others that such a person has superior knowledge. From this follows that in issue-areas where non-state actors can be considered *authorities*, they would also be considered as well placed actors to provide guidance to others relating to this issue-area. Lacking a democratic mandate therefore being "an authority" is a prerequisite for the assumption of *in* authority by the private sector.

Still, as we have argued before, expertise, while able to contribute towards achieving better regulation, is not an adequate justification for the delegation of authority to transnational non-state actors. The justification based on the contribution to policy objectives should therefore be further qualified; the regulator needs to be able to argue not only that the expertise of the private sector is necessary for regulation, but that the delegation of authority to the private sector is necessary for regulation<sup>53</sup>. This can only be claimed when the delegation of authority contributes towards the regulation of an issue-area, which the state cannot satisfactorily provide on its own, that is, when there are evident and generally acknowledged limitations on the *functional ability* of the state to provide an adequate standard of governance. This argument in turn, could be convincingly made, when changes in the nature of an issue-area or an industry occur, which hinder the ability of the state to regulate domestically or internationally certain issue-areas or industries. Changes like this can usually emanate from changes in scientific knowledge and/or technology.

The increasing rate of technological innovation in recent years has created entirely new industries and fundamentally transformed existing ones. These changes have had significant consequences for their regulation. First, the increasing rate of technological innovation changes the operational reality of many industries with an increasing frequency, rendering rules obsolete within a short period of time of being introduced. State authorities are usually hampered by bureaucratic procedures and red tape which makes their response to new technological and scientific developments too slow and inadequate. Private sector actors are often the only parties with adequate knowledge and understanding of the rapid changes taking place in such industries or issue-areas. Secondly, the importance of the technological and scientific knowledge for the everyday operation of many industries is now such that any attempt to regulate such industries must be founded on a deep understanding of the role of technology and science in their operation. In many industries the level of expertise that is

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<sup>53</sup> The fact that the regulator needs to persuade the political establishment and the public that the delegation to non-state actors is necessary does not negate the authority of the regulator. It should be reminded that this justification takes place in the context of the substantial-normative assessment described above, which does not evaluate the personal appeal of regulatory pronouncements; what is judged is not authority itself but whether the holder of public authority exercises it according to its underlying principles and purpose.

required is only or mainly available in the private sector, because it is the private sector that is responsible for many of the technological and scientific breakthroughs and innovations. This is especially true for the so-called high-tech industries as well as for areas that combine a high technological component with advanced scientific knowledge, such as biotechnology, biochemistry, aeronautics, etc.

However, it is not only technological and scientific sectors that governments have a difficult time regulating. Technically complex professions such as accounting, law and banking are also undergoing changes as the underlying transactions have become increasingly complex. Moreover, technology has allowed the proliferation and distribution of vast amounts of information and has contributed to an increasingly complex division of labour (Clarke 2000). The regulatory work becomes increasingly complex and resource-consumptive as vast and specialized amounts of information are increasingly available and needed for the efficient regulation of many industries. In such cases, the task of regulators unavoidably becomes extremely difficult, costly and time-consuming, to such a degree that often their ability to provide an adequate level of governance is questioned. This difficulty becomes even greater when these changes affect issue-areas with a significant transnational aspect or industries operating at a global level, since the amount of information that needs to be collected and assessed and the complexity of the issues involved increase significantly.

All these changes have deeply affected the way companies to do business across borders. Kobrin (2002) for example argues that the scale of technology in many strategic industries (its cost, risk and complexity) renders the minimum efficient market size larger than that of the largest national markets, while the migration of markets to cyberspace renders geographic space problematic as a basis for effective economic governance. As a result, the structure of industries themselves changes and networks are replacing hierarchies and markets as a basic form of economic organization (Mytelka and Delapierre 1999; Kobrin 2002). These new organizational forms are not consistent with authority exercised through bounded and discrete geographic territory and therefore affect the ability of states to regulate them effectively (Reinicke 1998; Kobrin 2002). In such cases, regulators can claim the necessity of hybrid regulation. Highly complex technical and technological problems

and developments, continuous change in business practices and new organizational forms which transcend the traditional boundaries of time and space, may be used to illustrate the inability of state regulation to achieve an adequate provision of regulatory governance and the potential risks and dangers if cooperation with the private sector is not pursued. In this situation, opposing constituencies and/or part of the public may accept the necessity of transnational regulatory authority. In sum:

*Proposition (4): we would expect regulators and/or politicians to justify the delegation of regulatory authority to a transnational regulatory forum by arguing that it is necessary, because traditional state and/or inter-state mechanisms are unable to provide an adequate standard of governance on their own.*

*Proposition (5): the inability of traditional state and/or inter-state mechanisms to provide an adequate standard of governance, is likely to be justified on grounds of fundamental transformations in the nature of an issue-area or industry, due to significant changes in scientific knowledge and/or technology.*

### **3.5 Summary and conclusions**

The aim of this chapter has been to construct a theoretical framework that will allow us to explain the phenomenon of transnational regulatory authority. To achieve this objective we put forward three research questions. We have tried to answer these questions by combining the insights of the economic theory of international regulation and the political theory of authority. A summary of the resulting propositions and their accompanying scope conditions is provided in table 3.3. The three research questions and their suggested answers address two basic theoretical dimensions of transnational regulatory authority. First, a political/functional dimension that seeks to understand the political reasons behind the emergence of transnational regulatory authority, and to identify the winners and losers of the decision to delegate authority to a transnational non-state organization. Secondly, a normative dimension that seeks to understand the process through which this delegation of authority to transnational non-state actors is reconciled with the principles of public *in* authority.



**Table 3.3 Summary of the Theoretical Framework**

<p><i>Research Question 1:</i> Why do regulators and/or politicians participate in hybrid governance schemes or acknowledge the rules produced by non-state governance schemes giving rise to transnational regulatory authority?</p>	
<p><i>Proposition (1):</i> we expect state authorities to endorse, encourage, or bring about themselves the emergence of transnational economic governance schemes that enjoy regulatory authority, when they want to redistribute wealth to specific domestic interest constituencies. Transnational regulatory authority may be used to redistribute wealth either from other domestic constituencies (domestic redistribution), or from foreign constituencies (international redistribution).</p>	<p><i>Condition (1a):</i> we expect the winning constituencies to be small, well-organized and with a high per capita interest in the regulation being promoted.</p>
	<p><i>Condition (1b):</i> we expect national regulators/policians to embed their delegation of authority to a transnational regulatory forum with an institutional mechanism or procedure which ensures that they retain a significant role in the regulatory process, and thus the ability to control the regulatory outcome if they so choose.</p>
<p><i>Research Question 2:</i> Under what conditions do regulators and/or politicians have an incentive to use or endorse transnational regulatory authority, compared to other international and/or transnational institutional mechanisms?</p>	
<p><i>Proposition (2):</i> when their objective is domestic redistribution, we would expect regulators and/or politicians to choose transnational regulatory authority: (a) in issue-areas with highly complex scientific, technical and/or technological content, and (b) when the issues regulated have a high potential to mobilize wide public opposition.</p>	<p><i>Proposition (3):</i> when their objective is international redistribution, we would expect regulators and/or politicians to use transnational regulatory authority: (a) in issue-areas or industries characterized by an oligopolistic global market structure, and (b) when there are significant distributional conflicts among the dominant market players, which cannot be resolved through international institutions; in this case transnational regulatory governance may be used as a forum-shifting strategy.</p>
<p><i>Research Question 3:</i> How are regulators and /or politicians able to reconcile this delegation of authority to private actors with the principles of public in authority?</p>	
<p><i>Proposition (4):</i> we would expect regulators and/or politicians to justify the delegation of regulatory authority to a transnational regulatory forum by arguing that it is necessary, because traditional state and/or inter-state mechanisms are unable to provide an adequate standard of governance on their own.</p>	<p><i>Proposition (5):</i> the inability of traditional state and/or inter-state mechanisms to provide an adequate standard of governance, is likely to be justified on grounds of fundamental transformations in the nature of an issue-area or industry, due to significant changes in scientific knowledge and/or technology.</p>

These two dimensions are not irreconcilable. While interest considerations refer to the reality of *authority as practice*, normative considerations relate to the *concept of authority* itself. I believe that the interplay of these two different sets of constraints lies at the heart of the decision to use transnational regulatory authority. In order to test empirically these propositions, the next chapter offers an introduction to the first case study of this thesis, the IASB.

## **Chapter 4**

### **Transnational Regulatory Authority in Practice (1): International Accounting Harmonization and the International Accounting Standards Board**

#### **4.1 Introduction**

The first of the two case studies examined in this thesis, concerns the International Accounting Standards Board (IASB) and its predecessor, the International Accounting Standards Committee (IASC), which during the past three decades have been engaged in the international harmonization of accounting standards. This chapter will serve as an introduction to the issue of international accounting diversity, and provide a brief history of both the wider harmonization initiatives in this issue-area and the efforts undertaken in the context of the IASB and its predecessor the IASC. Following this introduction, the aim of this chapter is to establish, based on the three criteria set out in the theoretical framework, our claim that the IASB is indeed a case of transnational regulatory authority.

#### **4.2 International accounting diversity: causes and consequences**

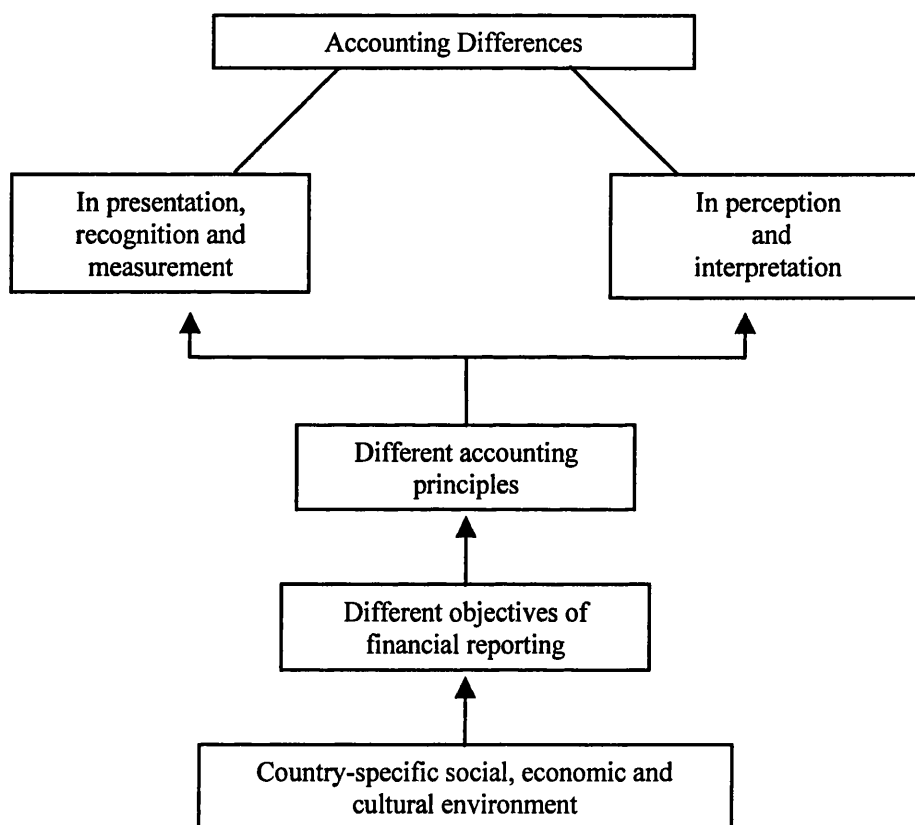
Until recently, accounting was considered a craft valued for its ability to perform a number of functions deemed necessary for the operation of the economy (Hopwood 1987; Beaver 1998; Scott 2003). Accounting methods were not considered part of the process of deciding what is economically or socially desirable and accounting debates were limited to purely technical issues. This view of accounting however has been seriously questioned in recent decades; accounting is increasingly seen not only as reflective of its surroundings, but also as a force that shapes its environment (Hopwood 1987; Burchell et al. 1980; Burchell et al. 1985). New research has demonstrated how accounting information exerts significant influence on almost all aspects of economic and social activity<sup>54</sup>. In view of these findings a debate has

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<sup>54</sup> Accounting information can affect agency relations in the context of the firm (Jensen and Meckling 1976; Watts and Zimmerman 1986), the internal organizational structure and operation of a firm (Burchell et al. 1980; Hopwood 1985), the efficient operation of financial markets (Ball and Brown

begun in both academic and policy circles about the economic consequences of accounting information and therefore the unavoidably political nature of accounting standard setting (Rappaport 1977; Zeff 1978; Solomons 1978; Brown 1990; Biener 1994; Leuz, Pfaff and Hopwood 2004). As a result, it is now widely acknowledged that “the selection among financial reporting systems can be viewed essentially as an issue of social choice involving trade-offs among constituencies. Under this view, standard-setting is the outcome of a political process” (Beaver 1998, p. 16).

**Figure 4.1 Explaining International Accounting Diversity**



Source: Haller and Walton 2003, p.2.

The political nature of accounting standard-setting becomes even more apparent at the international level. Research in international and comparative accounting has

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1968; Lang and Lundholm 1996; Botosan 1997; Beaver 1998), economic development (McKee and Ganer 1992), the design and implementation of state policies (Briston 1981; Burchell et al. 1985) and even wider social issues and policies (Glautier and Underdown 2001).

demonstrated how different economic, social, cultural and legal conditions will unavoidably lead to different accounting systems as they create different reporting needs and priorities, and therefore different conceptions of accounting's predominant role<sup>55</sup>. As a result, the objectives of accounting systems will vary, and so will the accounting principles and practices that will be developed. This process is displayed in figure 4.1. Given the significant influence of local factors on accounting standards' development, it is not surprising that there exists a high degree of international accounting diversity. Despite three decades of international efforts to harmonize accounting standards, a recent survey concluded that approximately half of the more than sixty countries surveyed displayed significant differences and showed no inclination for convergence<sup>56</sup>.

This diversity can have significant economic consequences, especially for actors that operate or have interests in more than one accounting jurisdiction. The most obvious consequence of having different national accounting standards is the cost that multinational companies (MNCs) have to incur in order to comply with different accounting requirements. MNCs are forced to reproduce their reporting procedures as their foreign subsidiaries have to prepare their accounts according to their own national accounting standards, and then produce a second set of accounts for the consolidated accounts of the parent company. The complexity and costs of this process are even greater for companies that want to have a presence in foreign capital markets. Companies have to comply with the accounting requirements of the foreign stock exchange and its national regulator. Regulators may require that foreign companies prepare a second set of accounts using the host country's standards; alternatively, companies may be allowed to use their home-country standards but be required to provide a reconciliation to host country standards, which means that they must explain the main differences between the two sets of accounting principles and rules, and also quantify their effects so that key figures like net income, equity and

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<sup>55</sup> For a review of the relevant literature see Nobes and Parker (2000), Roberts et al. (2002) and Walton et al. (2003).

<sup>56</sup> "GAAP 2001: A Survey of National Accounting Rules Benchmarked against International Accounting Standards", Andersen, BDO, Deloitte Touche Tohmatsu, Ernst & Young, Grant Thornton, KPMG, PricewaterhouseCoopers, 2001.

earnings per share can be presented as if the statements were prepared according to the host country standards.

Apart from the significant translation and extra legal and auditing costs that this process entails, significant costs may also arise from internal changes in the company structure as more and perhaps new types of information may need to be collected for the preparation of the new set of accounts (Roberts et al. 2002). Moreover, new types of information sought by a foreign regulator can also create problems when this information was not previously disclosed. Disclosing such *proprietary* information is often seen by companies as putting them at a competitive disadvantage (Roberts et al. 2002). Finally, using a second set of accounting principles and standards, or even a reconciliation, may affect the image and the financial standing of the company in ways not previously anticipated. Different accounting treatments can lead to significant differences in the reported information between the two sets of figures. Empirical studies consistently show that accounting diversity can lead to significantly different figures depending on the rules applied (e.g. Gray 1980; Wygal et al. 1987; Simmonds and Azières 1989; Weetman and Gray 1991; Walton 1992; Weetman et al. 1998). Moreover, differences in interpretations and practices can lead to significant differences in accountants' judgements even when the facts and rules are the same (Schultz and Lopez 2001).

These differences create uncertainty and confusion for investors who have to deal with two sets of figures for the same company and are not entirely sure which the correct one is and why these differences exist in the first place (Gernon et al. 1990). This confusion can lead investors to invest in a company that they would not invest in had they properly understood its performance, to avoid investing in foreign companies altogether, or to demand a higher price (higher cost of capital) for accepting the increased uncertainty and perceived risk. Obviously, this has adverse effects for the efficiency of capital markets, and could undermine confidence in them. Empirical studies have confirmed that different accounting requirements create significant problems for participants in capital markets (Choi and Levich 1991; Joos and Lang 1994; Miles and Nobes 1998).

The costs of diverse accounting rules and requirements would suggest that companies decide, at least partly, where to list their shares according to the accounting and disclosure requirements of foreign jurisdictions and the perceived effects these would have on their accounts, and consequently their image. Studies by Biddle and Saudagaran (1989) and Saudagaran and Biddle (1992; 1995) confirm that differences in disclosure requirements are a significant factor in companies' decision on where to list their shares. This suggests that excessive accounting and disclosure requirements may adversely affect the international competitiveness of a stock exchange if companies decide that the cost for listing there is higher than the expected benefits. This pressure in turn, could create incentives for a regulatory "race to the bottom" with significant consequences for the security and efficiency of capital markets worldwide (Haller and Walton 2003; Roberts et al. 2002).

Finally, accounting diversity may hinder the ability of states (particularly developing states with limited capacity to collect and assess accounting information), labour unions and other social actors to observe and compare the performance and activities of multinational companies.

#### **4.3 Early international harmonization efforts**

Given the costs associated with accounting diversity, it is not surprising that the debate on accounting differences and their consequences, as well as initiatives towards reducing these differences date back to the early International Congresses of Accountants at the beginning of the twentieth century (Samuels and Piper 1985). Following the Second World War, interest in the subject of international accounting harmonization grew and a number of regional professional associations and conferences appeared in the early post-war period aiming to promote mutual understanding and cooperation. In the late 1960s and early 1970s, the first concrete initiatives for the harmonization of accounting regulation appeared.

The first non-regional international organization to initiate efforts for the harmonization of accounting standards was the United Nations. In the context of its mandate to understand and regulate the operation and effects of transnational corporations (TNCs), the Commission on Transnational Corporations of the Economic and Social Council established an Expert Group on International Standards

of Accounting and Reporting in 1975. The creation of this group was proposed by the Group of Eminent Persons, formed in 1973 to examine the effects of the activities of transnational corporations on development and international relations in the aftermath of a number of scandals involving TNCs (Kline 1985). The work of the Group of Experts was directed towards the identification of differences across accounting systems and the formulation of lists of common minimum requirements for disclosure. These lists could then be used "...for the purpose of working out, within the framework of the United Nations, an internationally accepted set of reporting standards" (United Nations 1977, p.28). For this purpose an Ad Hoc Intergovernmental Working Group of Experts on International Standards of Accounting and Reporting was created in 1979 with a mandate "to work towards the long-term objective of formulating an international, comparable system of standardized accounting and reporting"; in doing so it would take into account "the needs of home and host countries particularly those of developing countries" (Zünd 1983, p. 111).

The work of the Group had limited success. The participants could not reach agreement on fundamental questions such as the overriding aim of multinational companies' financial statements, or the nature of the information that should be disclosed by individual enterprises (Choi and Mueller 1984, p.485). The difficulties that the Group faced in reaching any substantial agreement were due to its mandate and the type of harmonization it promoted. The emphasis of the work of the Group was directed towards disclosure rules, and particularly extended disclosure requirements for MNCs. The information needs sought to be satisfied at the UN Group were the "needs of individual national governments, particularly in developing countries, for information about the economic, social and political impact of MNCs" (Gray et al. p.121). As expected, developed countries, from which the majority of MNCs originate, were not very sympathetic towards this type of harmonization. Consequently, work in the Group was stalled by continuous conflicts during the negotiating process: "the performance of the Working Group so far is notable largely for its political rhetoric and the serious basic conflict of views between representatives of the developed nations and the Group of 77. The latter group seems



determined to use the UN effort for purposes of demanding detailed disclosures by transnational enterprises” (Fitzgerald 1981, p.29). This description is verified by Zünd, an insider<sup>57</sup> in these negotiations, who testifies to an almost belligerent atmosphere: “in addition to conceptual [accounting] differences, there are considerations relating to national prestige and the North-South conflict. There are two established blocks: the OECD countries and Group 77. Both groups meet separately at first, and only then in plenary” (1983, p. 117).

By the time the UN Group released its interim report in 1981, it was evident that agreement was lacking on many of issues. In 1982 the Commission on TNCs recommended that an experts’ group would be established to review developments in the field but not to set standards (Choi and Mueller 1984, p.486). Following this recommendation, the Intergovernmental Working Group of Experts on International Standards of Accounting (ISAR) was established the same year. It abandoned the previous objective of becoming an international standard-setter for a much broader mandate which envisaged that the Group would serve as a general forum for discussion on harmonization (UN 1988). In 1993, the Group was transferred under the auspices of the United Nations Conference on Trade and Development (UNCTAD). In parallel and as a reflection of this change, a shift in the focus of the Group also came about. Since the early 1990s it has focused more on helping developing and transition countries with accounting standards and in promoting accounting education and a global accounting qualification.

Shortly after the UN, the OECD also became involved in the harmonization of accounting standards through its Guidelines for Multinational Enterprises (1976), and in particular through a chapter on the disclosure of information by MNCs. The OECD’s Working Group on Accounting Standards, set up in 1979, was never meant to be a standard-setting body. Its mission was to engage with other actors interested in the harmonization of accounting standards, with a general task “...to encourage exchange of views on matters relating to accounting and reporting standards with the objective of supporting efforts...toward increased international comparability of these

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<sup>57</sup> Zünd represented the Swiss government in both the UN and the OECD international accounting groups.

standards” (Denman 1980). This however does not mean that the OECD did not have a significant impact on the harmonization process.

The “battle” between developed and developing nations was not played out only in the context of the United Nations. Arguably, the OECD initiative was a strategic move to set up a competing forum to the UN where the interests of the developed countries (contrary to the UN context) would be dominant. Indeed, it has been suggested that the OECD Guidelines for Multinational Enterprises were themselves a pre-emptive initiative to set limits to the requirements proposed in the U.N. Code of Conduct for TNCs developed during the same period at the instigation of developing countries (Flower 2002; Nobes and Parker 2000). The same rationale seems to be behind OECD’s initiative in the area of accounting standards; as Haller and Walton put it when reviewing the success of the UN recommendations “their main effect was to trigger the OECD into producing its own recommendations on the subject” (2003, p. 18). This proposition has been given further support by Zünd, who admits that the motivation for creating the OECD Group was “the desire for the formation of a group of specialists from the industrial nations in view of the formation of a UN Working Group” (1983, p.116).

Following the “decommissioning” of the UN group in the early 1980s, the OECD Working Group continued its work by providing information and research towards the harmonization of accounting standards. The Group has published a series of reports investigating international accounting differences, and has organized conferences, like the 1985 forum on International Harmonization of Accounting Standards, bringing together representatives of governments, standard-setters, business organizations, trade unions and other interested parties.

#### **4.4 Transnational harmonization: from the IASC to the IASB**

At the same time that international organizations engaged the issue of accounting harmonization, the accounting profession established its own organization to address the problem of accounting diversity. The International Accounting Standards Committee (IASC) was set up in 1973 as a private transnational organization of professional accounting bodies from Australia, Canada, France, Germany, Japan,

Mexico, the Netherlands, the United Kingdom and the United States. The IASC's objectives were:

- (a) To formulate and publish in the public interest accounting standards to be observed in the presentation of financial statements and to promote their worldwide acceptance and observance.
- (b) To work for the improvement and harmonization of regulations, accounting standards and procedures relating to the presentation of financial statements.

(IASC Constitution, 2, 1982)

In 1982 after long negotiations with the recently established International Federation of Accountants (IFAC), the IASC became the designated, global standard-setting professional body:

IFAC recognizes IASC as the sole body having responsibility and authority to issue, in its own name, pronouncements on international accounting standards with full authority in so doing to negotiate and associate with outside bodies and to promote the world-wide acceptance and observance of those standards.

(IASC/IFAC Mutual Commitments, 6, 1982)

The IASC proved productive from early on; during the first ten years of its life it was able to issue twenty-five International Accounting Standards (IASs), covering a range of issues. This productivity (at a time when the UN was facing serious problems) and the fact that these standards were produced by the "experts", enhanced the profile of the IASC, which by the early 1980s was widely considered the "premier international body and the most productive issuer of international accounting standards" (Evans and Taylor 1982, p.117). As a result, the IASC was invited in an observer capacity to the plenary sessions of the United Nations Intergovernmental Group of Experts, while the OECD invited the IASC to be a permanent participant in the work of its Working Group on Accounting Standards (Denman 1980).

The status of the IASC was given a further boost in 1987, when the newly established International Organization of Securities Commissions (IOSCO) accepted IASC's invitation to join its consultative group and indicated that it would be interested in using the IASs as a benchmark standard for listings in international stock exchanges, provided that the options allowed under the IASs were reduced (Cairns

2003)<sup>58</sup>. The IASC agreed to begin its Comparability Project with the aim of eliminating the alternatives allowed in IASs and proposing instead a benchmark treatment. The Statement of Intent on the Comparability of Financial Statements (1990) identified the issues for change and resulted in the revision of a number of IASs through the Improvements Project. The cooperation of IASC and IOSCO on these projects, eventually led to the landmark 1995 “core standards” agreement. The agreement was that the IASC would develop a comprehensive set of core accounting standards used in cross-border offerings and other foreign listings. Provided that these were acceptable to IOSCO, the latter would then “recommend endorsement of IAS for cross-border capital raising and listing purposes in all global markets” (IASC Insight, July 1995). This agreement was crucial for IASC since it “projected IASC into a new situation, where it moves from being a self-appointed body with no political power base or formal constituency, to being the world’s leading standard-setter with a mandate to set standards for listings on the world’s stock exchanges (Raffournier and Walton 2003, p. 40).

The increasing involvement of IOSCO and the 1995 core standards agreement raised the status of the IASs. The prospect of using the IASs in most of the major stock exchanges proved to be a significant incentive for their adoption by standard-setters, companies and stock exchanges. The rise of the IASs’ status was confirmed in 1999 when they were included in the Compendium of Standards, a list of standards considered key for the stability and efficiency of financial systems, drawn up by the Financial Stability Forum (FSF), in the aftermath of the Asian Financial Crisis. During the same period the IASC completed the core standards project and in May 2000 the IOSCO’s Technical Committee issued a report which recommended to IOSCO’s members the “use of 30 selected IASC standards for cross-border listings and offerings by multinational enterprises, as supplemented in the manner described in this report (i.e., reconciliation, supplemental disclosure and interpretation)” (IOSCO 2000, p.1). Shortly after the IOSCO’s decision to endorse IASC’s core standards, the European Commission announced a new financial reporting strategy

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<sup>58</sup> See also the comments of the Chairman of IOSCO during the proceedings of the International Financial Reporting Forum on IASC’s Comparability Project (Gernon et al. 1990).

for the European Union, which would transform the role and status of the IASC: the European Commission proposed that all EU listed companies should be *legally required* to prepare consolidated accounts in accordance with IASs from 2005 onwards, in effect replacing national accounting standards. This proposal, which was endorsed and has become a reality for all European listed companies since 2005, transformed the IASC from a private transnational body into the designated accounting standards-setter for twenty-eight countries, including several of the world's most developed economies<sup>59</sup>.

In view of the increasing influence of its work, the IASC appointed a strategy working party in 1996 to review the IASC's overall strategy following the completion of the IOSCO's core standards project. Following long negotiations, in 2001 the IASC was finally restructured into the IASC Foundation which is a private, non-profit entity. The objectives of the IASC Foundation are:

- (a) to develop, in the public interest, a single set of high quality, understandable and enforceable global accounting standards that require high quality, transparent and comparable information in financial statements and other financial reporting to help participants in the world's capital markets and other users make economic decisions;
- (b) to promote the use and rigorous application of those standards; and
- (c) in fulfilling the objectives associated with (a) and (b), to take account of, as appropriate, the special needs of small and medium-sized entities and emerging economies;
- (d) to bring about convergence of national accounting standards and International Accounting Standards and International Financial Reporting Standards to high quality solutions.

(IASC Foundation Constitution, Part A, 2, July 2005)

The restructuring that took place in 2001 transformed the IASC and created the IASB, which effectively replaced the IASC's Board, as well as three new bodies: the Trustees, the Standards Advisory Council (SAC) and the International Financial Reporting Interpretations Committee (IFRIC):

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<sup>59</sup> The new reporting framework also applies to the countries of the European Economic Area (EEA).

### International Accounting Standards Board (IASB)

Within the institutional context of the IASC Foundation the International Accounting Standards Board (IASB) is the body responsible for issuing the accounting standards, which are now called International Financial Reporting Standards (IFRSs). The IASB is also responsible for amending and withdrawing older IASs. It comprises fourteen members selected on the basis of their expertise and professional experience in the area of financial reporting and accounting standard setting.

### Trustees

There are twenty-two Trustees, all outstanding individuals with a good understanding of the importance of the task and of the challenges related to the creation of a single set of global accounting standards. Their selection is based on both geographical and professional criteria. The Trustees are responsible for the strategic, financial, operational and legal governance of the IASC Foundation. They also have the power to appoint the members of the IASB, the SAC and the IFRIC.

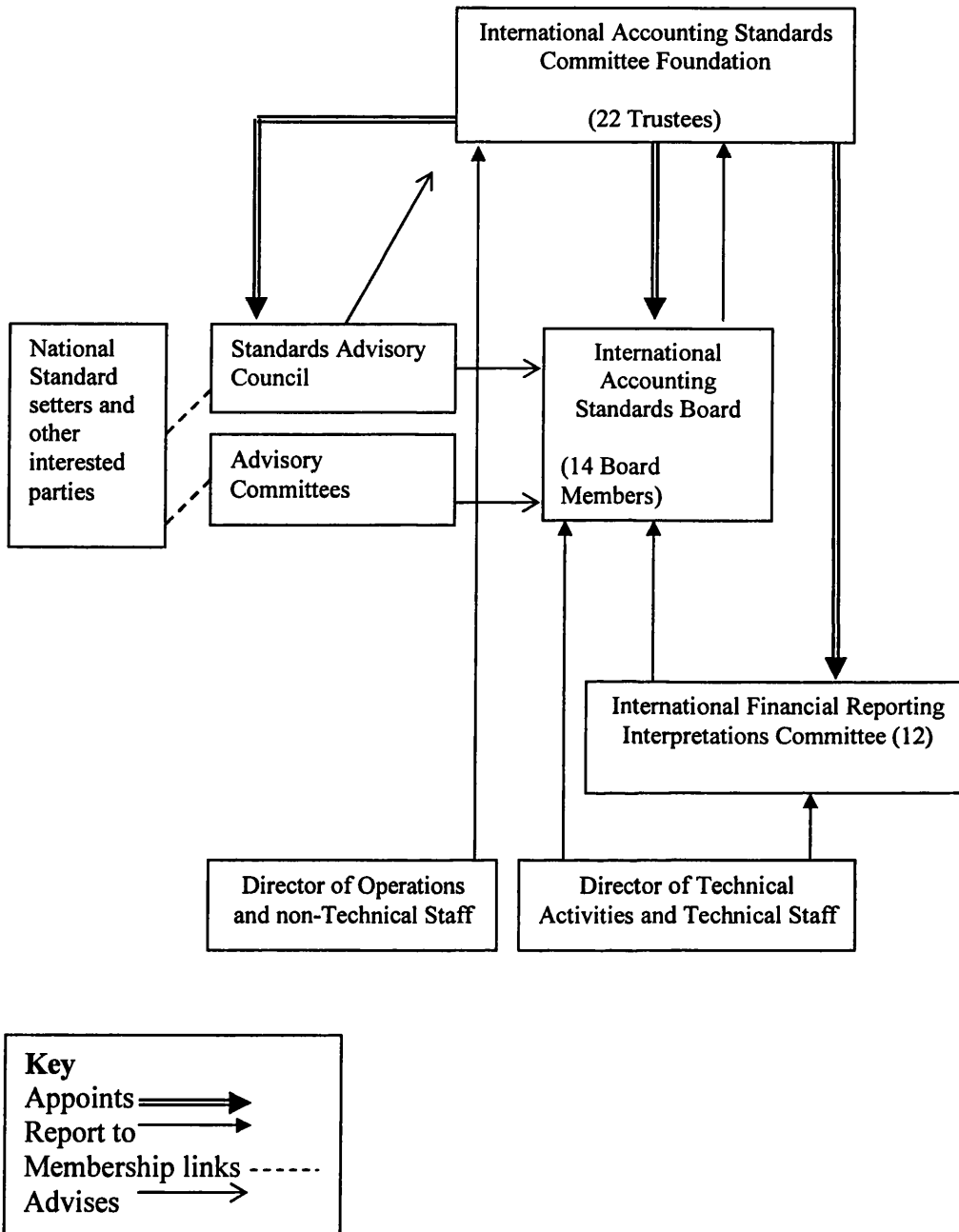
### Standards Advisory Council (SAC)

The SAC aims to bring in the working process of the IASB the opinions and views of a number of interested organizations, with diverse geographical and functional backgrounds.

### International Financial Reporting Interpretations Committee (IFRIC)

The IFRIC comprises twelve members whose main mission is to interpret the application of IASs and IFRSs and provide timely guidance on financial reporting issues not specifically addressed in the standards. The members of the Committee are selected on the basis of their technical expertise and their ability to maintain awareness of current issues in accounting. Its composition also reflects geographical and functional diversity. Figure 4.2 presents a graphic representation of IASC Foundation's new structure.

**Figure 4.2 The Structure of the IASC Foundation**



Source: IASB website, <http://www.iasb.org/about/structure.asp>, accessed 10/04/2006.

Following the restructuring, a significant step, which greatly enhanced the IASB's global status, was taken in 2002 with the signature of the Norwalk Agreement between the IASB and the United States' accounting standard-setter, the Financial

Accounting Standards Board (FASB). In October 2002 the two boards issued a Memorandum of Understanding stating their commitment to develop “high-quality, compatible accounting standards”<sup>60</sup>. To achieve this compatibility the two boards agreed to:

- a) undertake a short-term project aimed at removing a variety of individual differences between U.S. GAAP and International Financial Reporting Standards (IFRSs, which include International Accounting Standards, IASs);
- b) remove other differences between IFRSs and U.S. GAAP that will remain at January 1, 2005, through coordination of their future work programs; that is, through the mutual undertaking of discrete, substantial projects which both Boards would address concurrently;
- c) continue progress on the joint projects that they are currently undertaking; and,
- d) encourage their respective interpretive bodies to coordinate their activities

(Memorandum of Understanding, FASB and IASB, October 2002)

The United States’ securities markets regulator, the Securities and Exchange Commission (SEC), responded positively to the Norwalk agreement, and in April 2005 a “roadmap” towards equivalence between the IFRSs and the U.S. Generally Accepted Accounting Principles (GAAP) was agreed between the SEC Chairman and the EU Internal Market Commissioner. The roadmap foresees the elimination of the requirement to provide a quantified reconciliation to the US standards for foreign companies that want to list in the United States’ capital markets and use IFRSs, by 2009 at the latest<sup>61</sup>. In view of the roadmap provisions and following consultations with the SEC and the European Commission, the FASB and the IASB renewed their commitment to harmonize their standards in a new Memorandum of Understanding in February 2006, and provided a more concrete schedule for the process they anticipate in the years to the 2009 deadline.

#### **4.5 IASB’s transnational regulatory authority**

From the previous discussion, it is evident that accounting diversity is not a simple problem and that the effort to harmonize diverse accounting systems can lead to

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<sup>60</sup> IASC Insight, October 2002, p.1.

<sup>61</sup> IASB Insight, April/May 2005.



significant distributional conflicts. Given this situation, the puzzle of IASB's emergence as the premium forum for accounting harmonization becomes even greater, particularly as IASB's standards have taken on a legally binding nature. In order to explain this puzzle, the first step is to show that the IASB and the standards that it produces are indeed instances of transnational regulatory authority. In the second chapter of this thesis three criteria were spelled out for identifying transnational regulatory authority. The first criterion refers to the ability of non-state actors to *decide wholly or partly* the *substantive* content of regulation for an issue-area or industry. The second criterion requires that these rules confer some degree of *legal obligation* on the parties that adopt them. Finally, the third criterion addresses the scope of the impact of transnational regulatory authority, that is, the degree to which its rules govern an industry or issue-area at a global level.

#### 4.5.1 The decision-making power of non-state actors

As we saw earlier, the IASC was initially set up by private sector, professional accounting bodies. For the first years of its life the IASC worked much like an international professional association and, as we saw, its standard-setting function was officially endorsed in the early 1980s by the newly founded IFAC. This composition however did not last long. By the late 1970s, the IASC had already realized that in order to achieve the widest possible support for its standards, it had to involve in its work non-accountant constituencies that were affected by accounting standards, as well as national accounting standard-setters and regulators. To this end the IASC tried to upgrade its engagement with non-accountant constituencies interested in international financial reporting. The first initiative towards this goal was the creation of a consultative group in 1981 which included representatives of financial executives and analysts, stock exchanges, trade and business unions, and international organizations such as the World Bank, the OECD, and the Centre for Transnational Corporations of the United Nations. Also in 1981 the IASC set up the first joint working party with national accounting standard-setters to seek a common solution for the accounting treatment of deferred taxes. The involvement of standard-setters in IASC's work became gradually deeper as more joint projects were initiated and standard-setters played a significant role in the Comparability and Improvements

Projects and the development of IASC's Conceptual Framework in 1989<sup>62</sup>. Since 1991 the IASC has been holding conferences of standard-setters to encourage the convergence of national accounting standards with IASs, while between 1993 -2001 the IASC also participated in the meetings of the G4+1 group<sup>63</sup>, a group of standard setters working on harmonization in a variety of accounting issues.

In 1995, following an effort to re-organize the IASC, the Advisory Board was created comprising outstanding individuals from a variety of backgrounds, aiming to advise IASC's Board on its strategy, raise awareness and acceptance of the IASs and ensure the funds necessary for IASC's operation. Moreover, in 1996 the Standing Interpretations Committee (SIC) was established to offer advice on the different interpretations in the implementation of IASs in different national accounting frameworks. These institutional channels provided various actors and constituencies interested in the work of the IASC with an opportunity to contribute to, and influence, the international accounting harmonization process. Indeed, many of these and other actors not represented in one of these bodies participated actively in the consultations and preparatory work that took place in the context of the steering committees. The steering committees were appointed by the Board to examine each new project and to submit draft statements of principles and exposure drafts to the Board (Cairns 2003).

Despite the openness of the IASC's process to many different constituencies throughout this period, the body responsible for carrying out the work of the IASC was its Board, later re-constituted as IASB. The Board had the power to issue the IASs, as well as exposure drafts and all documents relating to IASC's work. The Board also appointed the twelve members of the SIC. Initially representatives from accounting associations occupied all the seats on the Board, but this changed when in 1982, in line with the strategy of engaging with non-accounting constituencies outlined above, the IASC added four places to its Board which were to be filled by organizations interested in the harmonization of accounting standards. The additional

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<sup>62</sup> See Cairns (2001b and 2003) and Gernon et al. (1990).

<sup>63</sup> In the second conference for standard-setters in 1992, hosted by the FASB, the Canadian, UK and US standard setting bodies invited other national standard-setters to join them in a work group interested in international harmonization; their call was answered by Australia and later New Zealand. The IASC accepted an invitation to participate in the group. In 2001 the G4+1 was disbanded because it was decided that its activities could divert valuable resources from the work of the newly formed IASB. See IASB Insight, March 2001, p.18.

places were gradually filled by the representatives of financial analysts (1986), the Federation of Swiss Industrial Holding Companies (1995), and the representatives of financial executives (1996). The fourth place remained empty after IOSCO and the International Chamber of Commerce (ICC) declined the offer of a seat in the Board. This composition of the Board remained in place until the 2001 restructuring.

While the new seats affected the Board's functional composition, they did not alter the fact that the membership of the Board remained entirely in the hands of the private sector. This was not the result of a conscious effort to exclude public actors; IASC's Constitution generally invited "up to four organizations having an interest in financial reporting to be represented on the Board" (IASC Constitution, 12 (a), 1982). Indeed, as was mentioned above, the IASC invited IOSCO, an organization of public regulators to take up the fourth seat. The result was that while much of the research and preparatory work that went into the IASs was undertaken jointly with a number of actors representing a variety of constituencies, including public agencies and regulators, the decision-making power over the final form and content of the standards remained exclusively with the Board, that is, with private sector actors.

The 2001 restructuring strengthened and extended the institutional channels of communication and cooperation among the various constituencies interested in international accounting harmonization and the bodies of the IASC Foundation. The relation with national standard-setters in particular was significantly strengthened with the establishment of official liaisons between seven of the IASB members and significant national standard-setters. The Norwalk Memorandum of 2002 reinforced this close cooperation, with the FASB and the IASB now working together both on short-term convergence and in longer-term projects. Finally, the SEC, the Financial Services Agency of Japan and the European Commission (EC) participate as observers in the proceedings of the SAC while the EC and IOSCO also participate as observers in the proceedings of the IFRIC. In addition, the working procedures of the IASB have been broadened to facilitate participation and consultation with as many interested parties as possible. Ensuring a broad synthesis of working groups established to examine new projects, providing for extensive public comment periods and seeking continuous consultation with the Trustees, the SAC, and the IFRIC are

part and parcel of a new extensive due process which now pervades the IASB's work<sup>64</sup>.

However, these new institutional links with national-standard setters, regulators and other actors have not altered fundamentally the character of the decision-making process. As was the case with the IASC Board, the IASB has:

complete responsibility for all IASB technical matters including the preparation and issuing of International Accounting Standards, International Financial Reporting Standards and Exposure Drafts, each of which shall include any dissenting opinions, and final approval of Interpretations by the International Financial Reporting Interpretations Committee.

(IASC Foundation Constitution, Part B, 31(a), July 2005)

The Board comprises fourteen members, twelve full-time and two part-time. The members serve in their individual capacity as experts in international accounting. The Constitution of the IASC Foundation states clearly that “the main qualifications for membership of the IASB shall be professional competence and practical experience” (IASC Foundation Constitution, Part B, 19, July 2005). No geographical criterion applies to the selection of the Board members although the Board has to exhibit, professional, that is, functional background diversity, including auditors, users and preparers of financial statements and academics<sup>65</sup>. Each member has one vote, and for the publication of an Exposure Draft, International Accounting Standard, International Financial Reporting Standard, or final Interpretation of the IFRIC, approval by nine of the fourteen members of the IASB is required. Other decisions of the IASB, including the publication of a discussion paper, require a simple majority of the members of the IASB present at a meeting that is attended by at least 60% of the members of the Board.

From the above, it becomes apparent that throughout its history, the Board has wielded the authority to release, amend, reject and withdraw IASs, IFRSs and Interpretations. Despite changes in its composition, the Board has always been comprised solely by private sector actors, either representing their private constituencies or in their capacity as individual experts. A variety of public actors

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<sup>64</sup> “Due Process Handbook for the IASB”, IASC Foundation, March 2006.

<sup>65</sup> See Appendix 6 for a list of the criteria for Board membership as described in the Annex of the IASC Foundation's Constitution.

have been invited to participate from the early stages of the IASC's work, but while they have contributed to the preparatory work and consultations of the IASC/IASB, they have never had the institutional authority to either vote in the Board or veto its decisions. On the contrary, the recent practice (and constitutional provision)<sup>66</sup> which encourages the outsourcing of much of the IASB's research work to national standard-setters, illustrates particularly vividly a reversal of the traditional roles of the expert/consultant and regulator/decision-maker. It is worth noting that these "research projects are normally carried out by other standard-setters under the supervision of, and in collaboration with, the IASB"<sup>67</sup>. When national standard-setters and regulators engage in the preparatory work for the standards being produced, while the supervision for this work and the ultimate decision-making power rests with the private sector experts, then it is obvious that the first criterion of transnational regulatory authority has been satisfied.

#### 4.5.2 The legal status of the IFRSs

The previous section established that the IASC/IASB satisfies the first criterion of transnational regulatory authority, but as we have argued previously, this is not enough. While having the authority to devise international accounting standards, the IASB has no authority to enforce these standards in national jurisdictions. In order to determine whether the IASB wields transnational regulatory authority we need to show that the IFRSs have been adopted by states in a way which confers at least some degree of legal obligation to the parties that use them.

The adoption of international accounting standards has been neither swift nor trouble-free. From the very beginning "the IASC recognized that no country could or would yield its sovereignty in setting standards" (Cummings 1975, p.358). Indeed, despite the rise of the IASC's profile that we described earlier, early empirical research on the actual impact of the IASC on national accounting standards and practices suggested that this was quite limited at least until the mid-1980s (Lafferty et al. 1979; Nair and Frank 1981; Evans and Taylor 1982; McKinnon and Jannell 1984;

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<sup>66</sup> See the IASC Foundation Constitution, Part B, 31c, July 2005.

<sup>67</sup> "Due Process Handbook for the IASB", 26, 2006.

Nobes 1990). The IASC understood that compliance was crucial if its standards were to become true international benchmarks (Benson 1976). It is at this time that the IASC began the process of opening up to other actors and interest constituencies that was described above.

In 1986, the IASC's Board decided to undertake a survey of the use and application of the IASs. The survey was based on responses from seventy countries and its results were published in 1988. A first reading of the findings suggests that contrary to the empirical evidence mentioned above, the majority of companies (both private and public), conformed in all material aspects with IASs and that in the majority of countries national requirements or practice conformed with 23 of the 25 IASs existing at the time<sup>68</sup>. However, as the IASC secretary-general himself admitted in the preface of the survey, the IASC was aware that conformity in some cases was the result of the alternative treatments allowed under IASs<sup>69</sup>. Indeed, as Gernon et al. (1990) note, the degree of conformity was higher for the early standards which were more generic. As we saw above, in the early years the IASC was comprised solely by accounting associations. This meant that it depended on the lobbying and support of its member organizations to convince national standard setters and regulators to comply with IASs and if possible to adopt them. Because of this dependency the IASC standards for the most part did not break any new ground, and basically represented a compromise; in essence a classification of current accounting practices. As a consequence, early IASs repeatedly received criticism for allowing a considerable range of alternative treatments, reflecting the various approaches in use by different jurisdictions at the time (De Bruyne 1980; Fitzgerald 1981; Gernon et al. 1990). Some put it bluntly: "IASC standards tend to be somewhat bland compromises which are generally either ignored because they are easily accommodated or cannot be enforced" (Gray et al. 1981, p. 127). This in turn meant that most countries could exhibit conformity with the IASs without actually having done anything towards greater harmonization. Nevertheless IASs did score some success, as they were used

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<sup>68</sup> "Survey of the use and application of International Accounting Standards", IASC, 1988.

<sup>69</sup> Ibid, p.1.

as national standards or as a basis for developing national standards in a number of developing countries.

During the 1990s, the situation gradually changed. The Comparability and Improvements projects reduced the alternative treatments and improved the quality of many standards. Moreover, the increasing involvement of IOSCO and the 1995 core standards agreement seemed to change the status of IASs. While fears that fewer alternative treatments could lead to reduced adoption rates were to some extent realized (Gernon et al. 1990; Cairns 2001a)<sup>70</sup>, the improved quality of the standards following the revision process, and more importantly the prospect of the use of IASs in most of the major stock exchanges, proved to be significant incentives for the adoption of the IASs<sup>71</sup>. As a result, in the mid-1990s the first signs of endorsement appeared, particularly from a number of big German multinationals such as Bayer, Heidelberger Zement, Schering, Hoescht and Deutsche Bank, which started publishing their consolidated financial statements in conformity with IASs, either partially, or as a complete second set of accounts. As voluntary adoption by companies started gathering pace, the European Commission published in 1995 its new strategy for international accounting harmonization, which proposed working with and through the IASC since it was the only body with “results which have a clear prospect of recognition in the international capital markets” (EC 1995). This move boosted further the status of the IASs and an increasing number of countries and stock exchanges began allowing their use or even requiring it. In 1998 a number of European countries (Italy, Germany, France and Belgium) passed legislation that allowed the use of IASs by companies under certain conditions (usually for the consolidated accounts of listed companies). New exchanges like the European Association of Securities Dealers Automatic Quotation System (EASDAQ), a pan-European exchange for growth companies, and the Neue Markt, created in 1997 in Germany for young and innovative firms, required that listed companies publish

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<sup>70</sup> The Canadian case is the most striking; in the 1980s over one hundred Canadian companies referred to IASs in their statements; by 1998 only five companies referred to IASs in their statements as a result of the elimination of alternatives under the Comparability project (Cairns 2001a).

<sup>71</sup> IASC Insight, March 1996, p. 14.

consolidated accounts in accordance with the IASs<sup>72</sup>. A survey conducted in 1998, revealed that most stock exchanges in the world allowed the use of IASs with or without conditions<sup>73</sup>.

The great change in IASB's status however came in 2000 when the European Commission proposed that all EU listed companies should be legally required to prepare consolidated accounts in accordance with IASs from 2005 onwards. With EC Regulation 1606/2002, this proposal became a *binding legal requirement* for all European listed companies. This decision has had far-reaching consequences as it replaced, literally overnight, national standards with the IASs in twenty-eight countries. The new strategy has affected more than 7000 companies, compared to the 275 companies that used IASs voluntarily before their mandatory adoption. This is even more extraordinary when we consider that most continental countries, contrary to many Anglo-Saxon countries, are characterized by Code legal systems<sup>74</sup> where accounting regulations have traditionally been part of Commercial Codes or Accounting Plans produced by government and approved by parliament. This bold move was followed by Russia, Australia and New Zealand which also replaced national accounting standards with IFRSs in 2004, 2005 and 2007 respectively, while more countries are endorsing IFRSs every year. A recent survey from PriceWaterhouseCoopers<sup>75</sup> reveals that of the 110 countries listed in the survey, seventy countries require use of IFRSs for listed companies, i.e. the use of IFRSs is legally mandatory, and another eleven countries allow its use, that is, IFRSs are one of the legally accepted alternatives. Finally, in a number of countries that prohibit IFRSs for domestic companies, this is allowed for foreign companies listing in their jurisdictions (usually under certain conditions; examples include the U.S.A, Canada and Japan). From the evidence presented above therefore, it is evident that the IFRSs have clear and binding legal force in an increasing number of countries. As a result, it is obvious that the IASB satisfies the second criterion of transnational regulatory authority.

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<sup>72</sup> The Neue Markt also allowed the use of US GAAP.

<sup>73</sup> IASC Insight, October 1998.

<sup>74</sup> For a classification of legal systems see David and Brierley (1985).

<sup>75</sup> World Watch, Issue 2, 2005.



#### 4.5.3 The scope of IASB's authority

The fact that IFRSs have been adopted as legally mandatory standards in an increasing number of national jurisdictions around the world provides concrete evidence for IASB's regulatory authority. Obviously, the fact that seventy countries currently require the use of IASB's standards verifies, by itself, that IFRSs are now a global set of accounting standards. Their use is not anymore limited to a small number of developing or underdeveloped states free-riding on the expertise of the IASB. This is not only because of the decision of the European Commission to replace national accounting standards with IFRSs. Beyond Europe, and even before the European Commission's strategy was put forward, an increasing number of countries had been adopting IASs and IFRSs. Between 1997 and 2000 many countries (including Kazakhstan, Peru, Kenya, Armenia, Jordan, the United Arab Emirates and Panama) adopted IASs as a requirement for some (e.g. listed) or all of their companies. At the same time the Eastern, Central and Southern African Federation of Accountants (ECSAFA) initiated a project to reduce differences between national standards and the IASs<sup>76</sup>, while the Arab Society of Certified Accountants (ASCA) called on its members to adopt IASs as their national standards<sup>77</sup>. Meanwhile, China had been using IASs for certain types of shares<sup>78</sup> since the early 1990s.

Following its re-structuring the IASB has gone from strength to strength towards becoming the global accounting standard-setter. We have already seen that since 2002 the FASB and the IASB have been working closely on the convergence project that will render IFRSs one of the legally permitted options for foreign companies wishing to list in the United States. Also as we saw, following the decision of the EU to adopt the IASs, Russia, Australia and New Zealand have followed suit. Moreover, in January 2005 the IASB and the Accounting Standards Board of Japan agreed to launch a joint project to reduce the differences between IFRSs and the

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<sup>76</sup> IASC Insight, March 1997.

<sup>77</sup> IASC Insight, June 1997.

<sup>78</sup> These are *B-shares* traded on the stock exchanges of Shanghai and Shenzhen; B-shares are shares sold to foreign individuals or enterprises. IASs are also used for H-shares; these are shares listed on the Hong Kong stock exchange.

Japanese accounting standards<sup>79</sup>, while in November 2005 the IASB and the China Accounting Standards Committee issued a joint statement where they agree to coordinate closer their future work<sup>80</sup>. Finally, Canada's Accounting Standards Board has also proposed a convergence project with the aim to replace Canadian standards with IFRSs by the end of a five-year period<sup>81</sup>.

Beyond endorsement by national standard-setters and regulators the scope of IASB's influence can also be demonstrated by its status and direct role in global economic governance mechanisms. Developments between 1998 and 2000 in particular, embedded the IASC in the global economic governance infrastructure and gave it the authority of the global accounting standard-setter. The first step in this new role for the IASC was taken, as we have seen, with IOSCO's endorsement of IASC's set of core standards. It is worth noting that IOSCO makes it clear in its report that the work on the harmonization of accounting standards, especially in regard to cross-border capital raising, is an on-going process and that it will continue to work closely with, and be part of IASC's work program and operations. The IASB therefore, has become part of the global governance mechanism dealing with the issue of capital market access in a globalizing economy. The endorsement of IASs by the Basle Committee of Banking Supervisors following their review in April 2000, only reaffirms this observation<sup>82</sup>.

A second step was taken in the context of the international debate on what has come to be called the international financial architecture. In the aftermath of the East-Asian crisis of 1997, the quality of accounting information was portrayed as one of the most important aspects of the crisis and also a crucial component of any solution. In October 1998, the G-22 Working Party on Transparency and Accountability reported that "weaknesses in the provision and use of information played a major part in the development and spread of recent international financial crises"; the report moreover argued that "firms should publish a comprehensive set of financial statements on a periodic and timely basis...using a set of high quality, internationally

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<sup>79</sup> IASB Insight, January 2005.

<sup>80</sup> IASB Insight, October/November 2005.

<sup>81</sup> IASB Insight, April/May 2005.

<sup>82</sup> "Report to G7 Finance Ministers and Central Bank Governors on International Accounting Standards", Basel Committee on Banking Supervision, April 2000.

acceptable accounting standards”<sup>83</sup>. This point was echoed at the highest political level. President Clinton applauded the Working Party’s recommendations for strong international standards including accounting and loan standards for private institutions, while Britain’s Prime Minister Tony Blair informed the NYSE in a speech that in the 1998 summit, G8 leaders had agreed “that we must press ahead with the development of international accounting standards”<sup>84</sup>. These calls for international accounting standards were given concrete substance with the Declaration of G7 Finance Ministers and Central Bank Governors in October 1998 which called specifically upon “the IASC to finalise by early 1999 a proposal for a full range of internationally agreed accounting standards”. Part of this multilateral effort to reshape the international financial architecture was the establishment of the Financial Stability Forum (FSF) in 1999, which issued the Compendium of Standards: a list of the various economic and financial standards that are internationally accepted as important or sound in stable and well functioning financial systems<sup>85</sup>. The Compendium highlights 12 key standards which the FSF has designated as deserving priority implementation, after taking account of country circumstances. The Compendium of Standards established the IASC standards as the internationally acknowledged set of accounting standards, becoming an integral part of the global financial governance structure. It is worth noting that IASC and IFAC are the only private organizations in the Compendium.

#### **4.6 Summary and conclusions**

International accounting diversity has been a pervasive characteristic of the global economy until very recently. Despite its significant negative consequences international harmonization has not been an easy task, notwithstanding more than thirty years of harmonization efforts. This is because the causes of accounting diversity are rooted deeply in the idiosyncratic nature of national economic and financial systems. As a result, accounting standards’ harmonization has stumbled on fierce conflicts of interests and ideology concerning its direction and consequently the

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<sup>83</sup> IASC Insight, October 1998.

<sup>84</sup> Ibid.

<sup>85</sup> See Appendix 7.

share of the adjustment burden among the interested parties. Given these difficulties, it is surprising to see that the IASB, a private sector organization, has become the dominant forum for the global harmonization of accounting standards. More than that, in recent years the IASB has been elevated to the position of *the* transnational regulatory authority in the area of global financial reporting standards. Our overview of IASC/IASB's history and of the legal status and influence of their standards both in the context of national jurisdictions and international regulatory and governance fora, has demonstrated beyond any doubt that the IASB satisfies the three criteria we set out at the beginning of the theoretical framework. Private sector actors have always held the reigns of the Board in both the IASC and IASB eras, and with it the exclusive authority to approve, modify and cancel international accounting standards. These standards have progressively been adopted by almost one hundred countries either as legally required standards or as one of the explicitly legally allowed options for participants in capital markets. Moreover, the standards have also acquired an independent, institutionally acknowledged standing in global public economic governance fora such as the IOSCO and the FSF. There is no doubt that the IASB exhibits all the characteristics of transnational regulatory authority and that it is truly on its way to becoming the world's *designated* accounting standard-setter.

## **Chapter 5**

### **Explaining IASB's Transnational Regulatory Authority**

#### **5.1 Introduction**

Having demonstrated that the IASB represents a case of transnational regulatory authority, we can now examine why and how the IASB has become the global accounting standard-setter. In accordance with propositions (3a) and (3b), we shall argue that, in the context of an oligopolistic global market for capital, the emergence of the IASB as an authoritative global accounting standard-setter is the result of a forum-shifting strategy employed by the European Commission when faced with the resistance of the SEC to agree on a mutually acceptable harmonization of accounting standards. While the overall strategy of the EC has been successful in that it has forced the SEC to accept the IFRSs as a set of accounting standards that can be used in US capital markets without reconciliation, the content and direction of harmonization have been mainly influenced by the American view of accounting. This is because the SEC engaged the IASC first, in the context of a forum-shifting strategy of its own, albeit in an effort not to establish transnational regulatory authority but rather to control and if possible prevent its emergence.

#### **5.2 Regulators' dilemmas**

The theoretical framework developed in this thesis locates the reasons for the emergence of transnational regulatory authority in domestic politics. Therefore, our effort to account for the emergence of the IASB as the global accounting standard-setter, needs to begin with an overview of the dilemmas facing the regulators of the United States and the European Union, as these will provide the basis for understanding their consequent moves and initiatives at the international and transnational level.

##### **5.2.1 SEC and international accounting harmonization**

The politics of accounting harmonization in the United States have been heavily influenced by the SEC's view of accounting's role in the economy. This view reflects

the structural characteristics of the US financial system. Traditionally, the main source of finance for US companies has been the capital market. Capital markets are characterized by large numbers of external investors with no access to privileged information. The information that these investors use to make their investment decisions, is the information that companies make public through their financial statements. In the US therefore, accounting standards for financial statements have always been linked to the operation of capital markets. This link has been reinforced by the fact that the SEC was set up following the Great Crash of 1929. Not surprisingly, the Securities Act of 1933 and the Securities Exchange Act of 1934, which established the SEC, focus on the protection of investors and their ability to make sound investment decisions. The SEC's accounting philosophy has consequently been informed by this mission:

The SEC requires public companies to disclose to the public meaningful financial and other information so that investors may judge for themselves if a company's securities are a sound investment. Only through the steady flow of accurate, comprehensive, and timely information can the public make informed investment decisions.

(SEC 2004, p.6)

Accounting standards in the US have been developed since 1973 by the Financial Accounting Standards Board (FASB), an independent private sector organization. However, the FASB operates under the supervision of the SEC, which is ultimately responsible for accounting regulation and has the authority to reject FASB proposals as well as make proposals of its own. Unsurprisingly, the SEC's view of accounting is echoed by the FASB:

The objectives [of general purpose external financial reporting by business enterprises] stem primarily from the informational needs of external users who lack the authority to prescribe the financial information they want from an enterprise and therefore must use the information that management communicates to them.

(FASB 2002, No. 1, par. 28)

Investor protection being the overriding priority, US authorities traditionally did not afford any significant exceptions for foreign issuers wanting to list in the US markets:

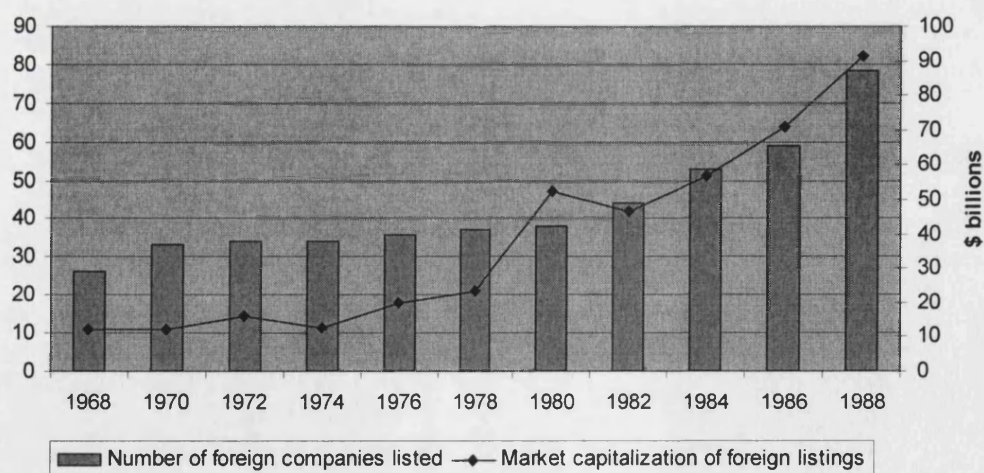
The legislative history of the Securities Act indicates an intent to treat foreign private issuers...the same as domestic issuers. The Commission's rulemaking authority in this

area is conditioned upon findings that the relevant rule or form is necessary for the protection of investors and in the public interest.

(Nikolaisen 2005)

If high quality foreign issuers wanted to list in the US, they were expected to welcome the high regulatory standards of the US markets which protected them and ensured a fair price for their securities (Schuetze 1994). Relying on the supremacy of the US capital markets and the fact that capital markets around the world remained largely national and isolated, the SEC could afford to follow this policy untroubled until the late 1970s, since multinational companies wanting to raise money invariably listed their shares there. In their empirical study, Lafferty et al. (1979) indicate that one of the most important factors of the moderate harmonization taking place in the 1970s were the SEC rules, particularly for companies listed or aiming to list in the US. Things however were about to change. The internationalization of national economies and financial markets started being increasingly felt by the SEC as the number of foreign companies wanting to list in the US started to rise (graph 5.1), and as the amount of foreign and US equities traded by foreign investors on US markets increased rapidly (graph 5.2).

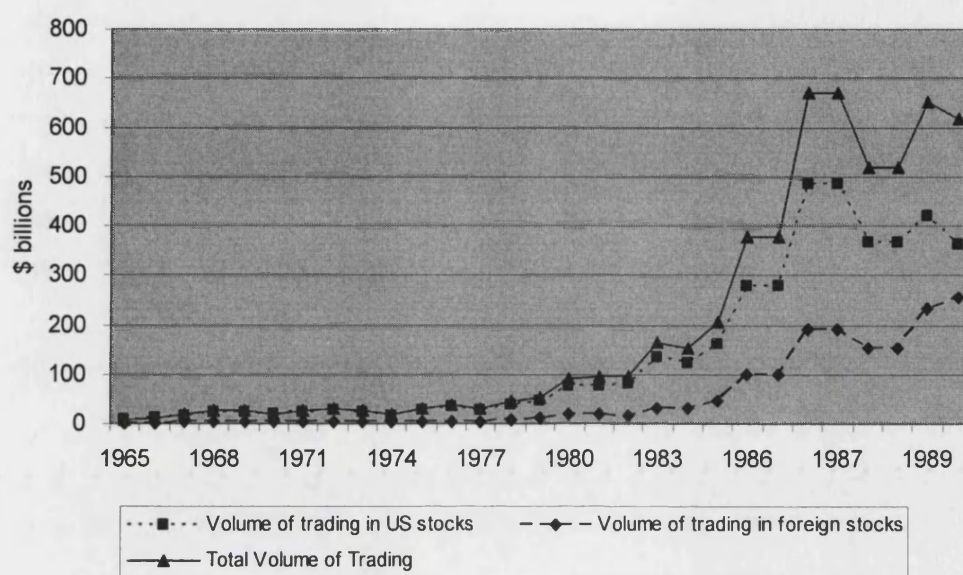
**Graph 5.1 Number and Capitalization of Foreign Stocks Listed on the NYSE**



Source: New York Stock Exchange Fact Book, issues 1969-1989



**Graph 5.2 Stock Transactions in U.S. Equity Markets by Foreign Investors**



Source: New York Stock Exchange Fact Book, issues 1965-1990

This trend was also facilitated by the growing influence of institutional investors who played an increasingly important role in the US capital markets (table 5.1).

**Table 5.1 Holdings of NYSE Listed Stocks by Institutional Investors**  
(USD Billions)

	U.S. Institutions	Foreign Institutions	Total	Percentage of NYSE market value held by institutional investors
1960	52.9	-	52.9	17.2
1965	114.4	-	114.4	21.3
1970	166.4	-	166.4	26.1
1975	216.7	25.1	241.8	35.3
1980	382.7	57.5	440.2	35.4

Source: New York Stock Exchange Fact Book 1985



For all these companies and investors, the array of accounting and disclosure regulations burdening foreign companies started becoming a significant issue. The SEC acknowledged that changes were necessary. These changes came in 1982, in the form of the Integrated Disclosure System (IDS). The IDS reduced and simplified, to some degree, the previous burdensome and complicated registration and documentation procedures for foreign issuers in the US, and allowed them to prepare their statements according to foreign GAAP provided that it was “a comprehensive body of accounting principles”<sup>86</sup>. However, companies that made use of this exemption had to provide a quantified reconciliation between those principles and the figures that would result had they used the US GAAP<sup>87</sup>.

While the SEC felt that the IDS changes constituted major concessions to foreign issuers (Saudagaran and Biddle 1995), critics were not very impressed, as foreign companies still had to produce a significant amount of new information and to provide a reconciliation using different accounting standards. The principal concern of the critics was that this regulatory burden was undermining the competitiveness of the US stock exchanges (Baumol and Malkiel 1993; Edwards 1993). Their case was given the evidence they needed when in 1983 the SEC extended the new requirements of the IDS to the securities traded on the NASDAQ (National Association of Securities Dealers Automated Quotations system). Until that time, companies that were traded over-the-counter on the NASDAQ did not need to be registered and therefore needed to provide much less information than the official registration procedure required. Between 1977 and 1983 the number of foreign securities on the NASDAQ increased from 85 to 294. When the new regulations came into force things changed dramatically. As SEC Commissioner Lochner later admitted, “new foreign participation in NASDAQ was halted when the Commission imposed new reporting requirements” (Baumol and Malkiel 1993, p. 21). Between 1983 and 1991 foreign firm listings on the NASDAQ fell from 294 to a low of 213 Edwards (1993).

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<sup>86</sup> See 47 Fed. Reg. 54, 787 (1982).

<sup>87</sup> It should be noted here that in most other developed markets US companies could list their shares using their home-country accounting standards (US GAAP) without being required to provide a reconciliation to host-country standards.

At the same time that the attraction of US stock markets was diminishing, foreign capital markets were undertaking regulatory initiatives to increase their international competitiveness. In 1983, the Tokyo Stock Exchange (TSE) amended its own regulations, by reducing the documentation required to be filed by foreign companies, and by simplifying and reducing the frequency of several reports submitted by foreign issuers. Moreover, after pressure from the TSE, the Ministry of Finance (MOF) also amended existing regulations to relax certain disclosure requirements for foreign listings (Saudagaran and Biddle 1995). Meanwhile, in 1983 the Paris Stock Exchange and in 1986 the London Stock Exchange, also underwent significant organizational changes to boost their international competitiveness. Although these changes were not related to accounting and disclosure issues (Saudagaran and Biddle 1995), they nonetheless added to the anxiety over the competitiveness of American capital markets.

Concern over the future of American capital markets reached its peak in the late 1980s and early 1990s. At the time, the TSE contested closely the NYSE for the position of the world's largest stock exchange by market capitalization, and American exchanges lagged far behind foreign capital markets in terms of international listings (table 5.2). It was in this context that an open, public confrontation erupted between the newly appointed Chairman of the NYSE William Donaldson, and the SEC Chairman Richard Breeden (Jarrell 1992). Donaldson warned that the NYSE was in danger of becoming a "regional exchange" (Jarrell 1992), and demanded the relaxing of SEC requirements for large foreign companies, putting forward a proposal concerning 200 "world class issuers" which would satisfy specific requirements in terms of size, market capitalization, and trading volume, and provide a written explanation of material accounting differences (Freund 1993; Cochrane 1994). Moreover, the NYSE proposed a number of investor safeguards for the listing of foreign companies if these were allowed to list without the full disclosure requirements of the SEC (Jarrell 1992). These proposals were rejected by the SEC.

**Table 5.2 Foreign Firm Listings on Major Exchanges by Domicile in 1992**

<b>Domicile</b>	<b>Stock Exchange</b>							
	<b>NYSE/AMEX</b>	<b>TOR</b>	<b>LDN</b>	<b>AMS</b>	<b>PAR</b>	<b>TKY</b>	<b>FRA</b>	<b>ZUR</b>
USA	-	66	159	111	49	67	134	109
Canada	77	-	30	9	9	7	10	9
UK	35	11	-	18	19	19	33	14
Netherlands	7	0	37	-	11	2	27	21
France	5	0	55	9	--	2	31	9
Japan	9	1	108	26	38	-	61	16
Germany	0	0	32	16	14	8	-	41
Switzerland	0	0	15	2	2	4	17	-
Other	65	13	520	64	51	11	155	33
<b>Total</b>	<b>198</b>	<b>91</b>	<b>956</b>	<b>255</b>	<b>193</b>	<b>120</b>	<b>468</b>	<b>252</b>
<b>Percentage Foreign</b>	<b>4%</b>	<b>8%</b>	<b>39%</b>	<b>51%</b>	<b>19%</b>	<b>7%</b>	<b>37%</b>	<b>54%</b>

Source: Saudagaran and Biddle 1995, p.323.

There were two major arguments that the SEC employed to justify its reluctance to accommodate foreign issuers (Edwards 1993). The first was that foreign accounting rules were not good enough to ensure the protection of the US investors. This view was rejected by the SEC's critics, who argued that foreign rules were not inferior, only different, and that by discouraging foreign firms from listing in the US, the SEC was actually undermining the protection of US investors (Baumol and Malkiel 1993; Edwards 1993; Freund 1993; Longstreth 1994). This happened because investors were already buying foreign shares and bonds either through the over-the-counter market where foreign companies did not have to register with the SEC and where the information available for the companies and their trading was minimal (Edwards 1993; Cochrane 1994), or directly in foreign markets where the SEC rules did not apply anyway and the transaction costs for US investors were much higher (Baumol and Malkiel 1993; Edwards 1993; Freund 1993). The second argument of the SEC was that allowing foreign issuers to list with less disclosure requirements would discriminate against the US firms and create a competitive disadvantage for them. Again, this argument was rejected by the critics who argued that allowing firms to list

without reconciliation did not put American firms at a disadvantage because, if investors thought that foreign firms did not provide adequate information their cost of capital would reflect this and if not, then that would be a clear signal that the SEC rules were redundant and imposed unnecessary costs on American firms (Edwards 1993). Despite the critique by prominent academics and policy experts<sup>88</sup> however, the SEC did not change its position.

The SEC's reluctance to accommodate foreign issuers was due to the fact that it was caught in the midst of a difficult regulatory dilemma that pitted domestic interest constituencies against each other (Jarrell 1992). On the one hand, there was SEC's main regulatory "clients", the stock exchanges, which were opposed to the imposition of burdensome and costly accounting and disclosure requirements that were driving away foreign issuers and putting them at a competitive disadvantage compared to foreign capital markets. On the other hand, the SEC had to consider the interests of investors the protection of whom is its primary mission. Irrespective of whether one accepted the arguments of the critics about investors' protection, the SEC was not willing to risk a scandal involving a foreign company's less strict home-country disclosure requirements, which would be blamed entirely on the SEC (Jarrell 1992). Moreover, in such a case, the entire stock market, including US issuers, would be adversely affected as investors withdrew from the market (Jarell 1992). In addition, US business was not willing to surrender its significant comparative advantage of being able to draw significant funds at low cost from both the US and international capital markets using their home-country accounting standards, something their competitors could not do. Obviously, US issuers resisted even more the idea that foreign issuers could be allowed to follow less costly accounting and disclosure requirements. The pressure from American firms would be significant in such a case and could take the form of lawsuits against the SEC (Zeff 1998). Moreover, allowing foreign issuers to follow less demanding accounting and disclosure requirements, could encourage US issuers to press for a loosening of the accounting and disclosure requirements applicable to them, leading thus to a potential

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<sup>88</sup> Among the critics were William Baumol an Economics' Nobel Prize winner, William Freund a former NYSE Chief Economist, and Bevis Longstreth a former SEC Commissioner.

regulatory “race to the bottom” (Dye and Sunder 2001). Indeed, the answers of respondents representing US issuers, such as the Financial Executives Institute, or the US Business Round Table, to the 2000 SEC Concept Release<sup>89</sup>, indicated that endorsement of IASs by the SEC could be acceptable only as long as the choice to use IASs in financial statements was not limited to foreign issuers but was also extended to US issuers. In such a situation, the SEC would find itself in an extremely difficult position since refusal to accommodate the demands for a looser regulatory framework could lead to a relocation of a number of US companies to less demanding jurisdictions (Jarrell 1992; Zeff 1998).

The risk associated with these scenarios was too high for the SEC to accept since they threatened another powerful constituency: the SEC establishment itself. The SEC administration did not see favourably the idea of reducing its complex regulatory requirements, because that could undermine its own status as a regulatory agency. As Jarrell, a former SEC chief economist commented at the time: “the U.S. has an army of accountants, lawyers and government bureaucrats who are well-employed as a direct result of the SEC’s strict financial disclosure rules. Any threat to them is a serious threat to an enormously influential set of SEC constituents. The prospect of the SEC allowing foreign firms to be traded on the Big Board without adhering to U.S. GAAP should bother them greatly” (1992, p. A10).

#### 5.2.2 EC and international accounting harmonization

European accounting has always been characterized by considerable diversity. As the President of the Fédération des Experts Comptables Européens (FEE)<sup>90</sup> once noted: “It must be recognised that the major divergences between financial reporting standards are within Europe, not between Europe and the rest of the world” (Nordemann in Cairns 1997, p. 311). Europe sought to remedy this divergence and the problems it created for intra-European business in the context of the European Economic Community (EEC). The Treaty of Rome (1957) which established the EEC called for the freedom of movement of labour, capital, goods and services. In line

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<sup>89</sup> In 2000 the SEC issued a Concept Release asking for the first time the views of interested parties on whether the reconciliation requirement should be abolished.

<sup>90</sup> The FEE is the European association of accounting professionals.

with this requirement, the Common Industrial Policy (1970) called for the creation of a unified business environment, including the harmonization of company law and taxation. Accounting and financial reporting harmonization initiatives are part of the company law harmonization programme.

The two most important instruments produced by the European harmonization programme were the Fourth (1978) and the Seventh (1983) Directives which deal with the financial statements of all limited liability companies and with consolidated statements respectively. The initial drafts of both instruments were heavily influenced by the German Aktiengesetz (the German company law) which was enacted in 1965 and was considered at the time the most advanced company law, at least compared to the legal frameworks in force in the other members of the EEC. The German approach however was at odds with the British accounting tradition, which presented a problem in view of UK's entrance in the EEC in 1973. According to some experts, the vision of a potential harmonization of accounting standards along the lines of Continental accounting was terrifying to the British accounting profession: "The imminence of this [entrance in the EC] had brought fear to the British accountancy bodies who were worried by the potential consequences of what they saw as the imposition of continental European statutory and state control on the much more discretionary relationship between corporate management and the auditor in the UK" (Hopwood 1994, p.243) <sup>91</sup>. In order to safeguard its discretion in the establishment and interpretation of accounting standards, the British accounting profession sought to introduce "what they saw as the strategic ambiguities of the British notion of "true and fair" into the draft of the Fourth Directive" (Hopwood 1994, p.243). Indeed, the secretary of the Elmendorff Committee (the committee responsible for drafting the Fourth Directive), and officials of the European Commission, have confirmed that the

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<sup>91</sup> Traditionally, accounting systems have been classified into two main categories: the Anglo-Saxon and the Continental tradition. One of their basic differences is the reliance on the concept of *fairness* in the Anglo-Saxon tradition which refers to the view that financial accounts should present as accurate a picture of a company's operations as possible, even at the cost of formal legality, correctness or cohesiveness of accounts. The Continental tradition on the other hand relies mostly on conservatism which refers to the notion that figures should be reported in a conservative manner in order to avoid unfounded optimism that could lead in misleading economic decisions, even if this leads to a not entirely accurate picture of the company's operations and potential. This classification however is not absolute and its validity has been questioned in accounting circles (e.g. Cairns (1997) and Alexander and Archer (2000)).

changes in the second draft of the Fourth Directive were introduced as a result of UK's accession to the EEC (Nobes 1993). Subsequently, the British were also able to introduce changes in 14 out of 19 main features of the final draft of the Seventh Directive, either by substituting UK rules for German ones, or by adding a UK option to a German rule (Diggle and Nobes 1994).

The Directives had significant effects for many European countries in a number of accounting areas: they introduced specific formats for the presentation of accounting information, increased the level of disclosure required by companies, increased and extended the publication and audit requirements for many companies, made consolidated accounts a legal requirement,<sup>92</sup> and introduced world-wide consolidations and segmental disclosure by type and geographical area of activity. As we saw however, they were the result of a long and arduous negotiating process and effectively represented a compromise between the Anglo-Saxon and Continental traditions of accounting (Gray et al. 1981; Nobes 1993; Nobes and Parker 2000). This has meant that often, when agreement was not possible, alternative options were introduced, thereby limiting the restrictiveness of the clauses of the Directives and thus their contribution to the harmonization of European accounting. This made compliance with the Directives a relatively effortless affair with limited effect on the actual practices of European companies. Empirical studies (Simmonds and Azieres 1989; Walton 1992; Archer et al. 1995; Emenyonu and Gray 1996) have shown that the harmonization of European accounting systems remained rather limited, even many years after the adoption of the Directives.

Following the approval of the first two accounting Directives, the EEC continued to address accounting-related issues. However, while new Directives addressed specific areas of concern (e.g. reporting for banks and insurance companies or audit regulations), the feeling in the Community during this period was that the progress of accounting harmonization in Europe had stalled. No significant new regulatory initiative was undertaken despite the agreement of member states that further harmonization was needed (EC 1990; Hulle 1993). This was largely because

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<sup>92</sup> In a number of countries such as Austria, Italy, Spain and France there was no legal requirement for consolidated accounts prior to the Seventh Directive.

of the problems inherent to the Directives' process. Apart from the deep-seated disagreements described earlier, there were also significant implementation problems associated with the Directives. First, while adopted at a European level, Directives were not actually implemented in national jurisdictions for many years. In some countries it took more than ten years to fully implement them. This situation was further exaggerated by the entrance of new members in the EU. The lengthy process of negotiating and implementing the Directives meant first, that for long periods of time while the Directives were at different stages of implementation in different countries, there remained significant differences in accounting requirements among member states, and second, that by the time they were implemented, they were largely outdated, and thus often stood in the way of the modernization of European accounting systems (Haller and Walton 2003).

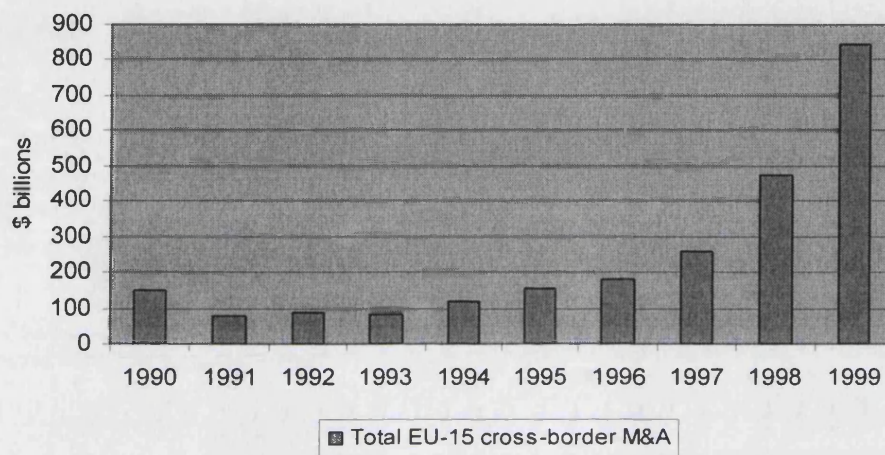
These problems became increasingly important. One reason for this was the urgency that the 1992 project gave to the EC's efforts to reduce the obstacles that accounting diversity created for a common European market. The answer to this problem was an increasing reliance on the mutual recognition policy, which signalled a break from the previous policy of harmonization of accounting rules and principles through the Directives' process. However, this did not eliminate differences, only made them mutually acceptable. This created problems not only for the internal market project, but also for Europe's role in international harmonization. The slow, ambivalent pace of European accounting harmonization meant that there was no European accounting model to be proposed for use in foreign jurisdictions (e.g. the US) or to be used as a negotiating tool in a wider harmonization process. One possible solution was the creation of a European Accounting Standard Setting Body which given the familiar disagreements and a number of legal obstacles did not seem plausible; discussions during the 1980s on the issue had led to an impasse (Hulle 1992).

These problems became increasingly significant for the European Union, as structural changes in the wider international and European economic environment created new accounting needs for a number of accounting constituencies. Economic liberalization and de-regulation combined with technological changes that reduced



costs to transportation and communication, increased capital mobility and allowed both direct and portfolio investment to grow at a gathering pace. In Europe, the completion of the internal market and the forthcoming adoption of the Euro made some of these changes even more pronounced. European companies expanded their operations globally, and in Europe, engaging heavily in mergers and acquisitions (Graph 5.3).

**Graph 5.3 European Cross-Border M&A Transactions**



Source: Adapted from Haller 2002, p.161

Traditionally, European multinationals had not considered accounting diversity a major issue. Until the late 1970s capital markets were for the most part isolated and, outside the US and the UK, underdeveloped. Continental companies relied mostly on credit-based sources of finance in their home countries. However, the expansion of European companies meant that they could no longer rely solely on their traditional sources of finance, and raising money in capital markets became increasingly necessary<sup>93</sup>. Given the urgency for fresh capital, it was inevitable that European companies would want to list their securities in the US markets, the largest and most liquid markets in the world. Listing in the US capital markets would also provide them with added public relations' and marketing benefits (Saudagaran and Biddle 1995), particularly important for those companies wanting to expand in the large US

<sup>93</sup> See tables in Appendix 2.

market. This trend was reinforced by other structural changes, most notably the rise of institutional investors. Increasingly, European shares were held not only by “sister” banks and corporations, but by institutional investors, both domestic and international (Table 5.3).

**Table 5.3 Bank and Institutional Intermediation Ratios (Proportion of Intermediated Claims Held by Banks and Institutional Investors)**

		1970	1980	1990	1995	1998	Change 1970-1998
United Kingdom	Bank	0.58	0.64	0.55	0.47	0.46	-0.12
	Institutional	0.28	0.26	0.32	0.38	0.40	0.12
Germany	Bank	0.84	0.86	0.83	0.78	0.74	-0.10
	Institutional	0.10	0.12	0.17	0.21	0.23	0.13
France	Bank	0.94	0.68	0.82	0.74	0.66	-0.28
	Institutional	0.05	0.04	0.19	0.24	0.29	0.24
Italy	Bank	0.98	0.98	0.95	0.91	0.92	-0.06
	Institutional	0.06	0.05	0.11	0.09	0.10	0.04

Source: Adapted from Davis and Steil 2001, p.7.

At the same time, governments themselves were increasingly under pressure from the competition rules for the internal market and the provisions regarding the adoption of the Euro, which demanded deregulation and privatization of the previously protected state monopolies. These changes led to an unprecedented wave of privatizations during the 1990s<sup>94</sup>. However, this meant that governments were also in need of liquid and developed capital markets to sell the shares of these companies. Some of these privatizations were so large in terms of market value that the US capital markets were needed to complete successfully their floating, as domestic markets did not have the required liquidity (Raghavan and Sesit 1993). Yet, listing European shares in the United States was not so easy. The problem was that European companies had to provide, among other things, a quantitative reconciliation of their financial statements according to the US GAAP. As we have seen, this is a costly exercise with

<sup>94</sup> See Appendix 3.

unpredictable results, which can create confusion and undermine the image of the listed companies, with adverse consequences for their cost of capital<sup>95</sup>.

Therefore, much like the SEC, the European Commission was facing a regulatory dilemma. The problem here however was not one of opposing domestic interest constituencies. The issue of diverse national accounting requirements at a European level had been temporarily resolved, albeit unsatisfactorily, with the mutual recognition policy. On the contrary, all interested European constituencies (European issuers and investors) seemed to share the same objective: they wanted European companies to be able to list their stocks abroad (and particularly in US markets) without the obligation of reconciliation and the costs that went with it. The changing economic and regulatory European environment made the need to provide big, global European issuers, both public and private, with the ability to list their shares in the US capital markets without having to incur the multiple costs of the reconciliation requirement, an increasingly important regulatory issue, which effectively dominated the discussions and efforts of European regulators and the EC in relation to international accounting harmonization (Hulle 1993; Biener 1994). These constituencies put pressure on national regulators and the EC to come up with a solution. The German side in particular had been raising the issue repeatedly and was pressing in both bilateral negotiations with the SEC and through the EC, for some kind of solution to the problem that did not require European companies to either adopt US standards or adjust their statements to accommodate the reconciliation requirement<sup>96</sup>. Several German MNCs had tried to get a listing based only on their German statements. They claimed that since US firms could have their shares listed in Frankfurt with US GAAP, they should have the same right in New York. The SEC would not accept this argument and as a result, no German company was listed on the NYSE before 1993.

For the EC this problem was fast becoming a significant cause for concern. The inability to resolve this issue could have dire repercussions for European harmonization and consequently for the EC's position as European accounting

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<sup>95</sup> See Appendix 4.

<sup>96</sup> Interview with former EC official, 08/06/2007.

regulator. This is because it could potentially lead global European issuers to seek a solution outside the European harmonization framework. Indeed, in the early 1990s senior executives of major European companies started suggesting publicly that they should be allowed to use only US GAAP, which was the dominant set of standards used internationally, or that the biggest stock exchanges (specifically the NYSE and the LSE) should develop jointly a set of standards and others should follow (Hulle 1993). The pressure from the industry was growing towards the national regulators, who were often dissatisfied with the Directives and did not pay the required attention to their proper implementation, which only slowed European harmonization further, and made the absence of a European set of standards comparable to the US GAAP even more apparent (Hulle 1993). The situation was made worse by the fact that many European companies were already using US GAAP since they had their shares listed on American capital markets. Under these circumstances, it seemed that some regulators were considering whether large companies should be allowed to use US GAAP for listing purposes (Hulle 1993).

The decision of Daimler-Benz to list its shares on the NYSE made matters worse. In 1993, Daimler-Benz decided to accept SEC's rules and provide reconciliation to US standards in order to get a listing. In Germany, Daimler-Benz's decision was seen by many as a betrayal that undermined the standing of German accounting (Haller 1995; Glaum 2000). The SEC would have no incentive to give in to European pressure since a company as prestigious as Daimler-Benz had already accepted its terms (Flower 1997). The problem was bound to get worse and put more pressure on regulators and politicians, given the need to privatize an increasing number of public companies. This was forcefully illustrated with the privatization of Deutsche Telekom which, given the company's size, also required flotation in the US markets. Deutsche Telekom lobbied the government to amend the law so that it could use US GAAP as its only set of standards (replacing German standards), and it seems that the government was prepared to accede to this demand (Flower 1997).

Such a decision however, was not an acceptable option for the European Commission. A unilateral compromise like this would mean that the EC would have failed to protect the interests of European companies, as European issuers would have

to bear the cost for using US GAAP for listing purposes, probably in combination with domestic accounting rules, necessary for taxation purposes, putting them at a significant competitive disadvantage vis à vis their American competitors. In addition, such initiatives from national regulators would breach the Seventh Directive and undermine the whole European harmonization edifice, threatening to undermine the accomplishments of thirty years of European accounting harmonization and of course the EC's role in European accounting regulation. Obviously this was not something the EC could accept (Hulle 1993). The EC's mission was to find a way around the SEC's resistance.

### **5.3 Resolving the dilemmas: regulatory strategies and the politics of transnational regulatory authority**

As we saw above, the EC and the SEC faced significant but quite different regulatory pressures from their regulatory constituencies. The SEC's dilemma was to find a way to resolve a conflict of interests among domestic constituencies in the most politically efficient way, while the EC's problem referred to its inability to satisfy its European constituencies because of foreign (US) resistance to harmonization. The two regulators devised two quite different regulatory and negotiating strategies, which they hoped could help them overcome these problems and satisfy their constituencies.

#### **5.3.1 Resisting harmonization: SEC, forum-shifting, and international redistribution**

As we saw previously, the SEC was determined not to back down from its position regarding the necessity of the reconciliation requirements for foreign issuers. Still, the SEC's position was difficult, as the opposing constituencies comprised powerful, well organized, and extremely knowledgeable constituents. As per our discussion in chapter 3, in this case, we would expect the SEC to resolve its dilemma by pursuing an international agreement that would harmonize foreign accounting standards to US GAAP. This way, the SEC could keep its regulatory framework intact and facilitate access to US markets, while the costs of the harmonization adjustment would burden foreign regulators, issuers and investors. Indeed, beyond the initial domestic reaction of the SEC with the IDS, which did not solve the problem, the SEC soon realized that

it also needed to plan an international response to meet the challenge of economic globalization, which was not going to go away:

a more unified effort by all countries will be necessary to respond fully to the business realities of the modern multinational corporation...the SEC and other securities regulators around the world will have to work together to develop a common framework of international accounting principles, disclosure standards, and trading market mechanisms.

(Thomas 1983, p. 134)<sup>97</sup>

Achieving an international agreement that would fit the SEC's strategy however did not seem plausible. On the one hand, the SEC considered most foreign accounting standards as inadequate and was particularly critical of some of the practices of the principal European accounting traditions such as the German discretionary reporting of earnings (Breen in Jarrell 1992). Moreover, the multiple alternative treatments allowed under the European Directives, was not acceptable to the SEC. Given the overriding objective of investors' protection, FASB's accounting standard-setting was characterized by a detailed rules-based approach, where ambiguity had to be avoided at all costs by explicitly spelling out what was permitted and under what circumstances. In view of these problems, as well as the difficulties associated with the Directives, and the past negotiating experience in international organizations<sup>98</sup>, it did not seem likely that the SEC could achieve a satisfactory international agreement that would include the Europeans. The adoption of the mutual recognition policy by the EC made the possibility of reaching an international agreement with the Europeans even less likely.

On the other hand, while the US markets held undoubtedly the dominant position in terms of market weight, liquidity and sophistication, the SEC was not in a position to force an international agreement on others. First, both Japan and Europe (which numbered several significant stock exchanges) were important players and grew rapidly, particularly during the 1980s (Table 5.4).

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<sup>97</sup> Thomas was at the time the SEC Delegate to the United States Inter-Departmental Committee on Foreign Investment.

<sup>98</sup> Zünd (1983) describes how disagreements were common in the context of the OECD Working Group among developed countries, and in particular between EEC countries and the US.

**Table 5.4 Global Shares of Domestic Market Capitalization†**

	<i>1980***</i>	<i>1990</i>	<i>1995</i>	<i>2000</i>
US	41%	38%	42%	52%
Europe*	12%	21%	18%	23%
Japan**	14%	33%	21%	10%
<b>Combined Total</b>	<b>67%</b>	<b>92%</b>	<b>81%</b>	<b>85%</b>

† Excludes foreign listings.

\* Includes the combined domestic market capitalizations of the six biggest European stock exchanges (LSE, Deutsche Börse, Amsterdam, Borsa Italiana, Paris and Spanish Exchanges). The share of Europe is underestimated because it does not include all European markets, and because the shares exclude foreign listings, an area where, as we have seen, Europe led the other regions.

\*\* Japan's share is also slightly underestimated because it includes only TSE's capitalization.

\*\*\* The US share includes only data from NYSE while the Europe share excludes the Spanish Stock Exchanges and includes Lisbon.

Source: Calculated from NYSE's international statistics, available on [www.nyse.com](http://www.nyse.com), and World Federation of Exchanges' time series statistics, available on [www.world-exchanges.org](http://www.world-exchanges.org).

Moreover, particularly in Europe, the harmonization programme touched all aspects of financial reporting and all limited liability companies<sup>99</sup>, which made the prospect of forcing the Europeans into an agreement with legal consequences for all European companies less likely. In other words, the global market for capital could be best described as oligopolistic, and the SEC did not have enough structural power to force a redistributive international agreement on the other significant players, particularly in the 1980s.

As we have argued in chapter 3, when international agreement is not forthcoming, a state may seek to employ an international forum-shifting strategy. We also argued, that such a strategy would be successful when the dominant players are able to mobilize other significant players to their side, effectively creating a powerful front that could potentially press the remaining players into agreement. Failing this, the impasse of international negotiations would only be repeated in different fora. Indeed, the SEC's first move was an international forum-shifting strategy. In 1985, the SEC published a discussion paper, which sought a tripartite solution by promoting the harmonization of cross-border listings' requirements between the US, the UK and Canada. This move bears remarkable resemblance to the Federal Reserve Board's

<sup>99</sup> In the US, the stringent SEC regulations apply only to listed companies.

bilateral agreement with the Bank of England on the issue of banking capital adequacy standards, which took place around the same time. The SEC sought to harmonize the listing disclosure requirements with the two most significant jurisdictions of the Anglo-Saxon camp, which shared to a considerable degree the US view of accounting. Should these three jurisdictions reach an agreement, the new disclosure requirements would apply to all North-American capital markets and the London Stock Exchange (LSE). Given the importance of the LSE, where a large number of European and Japanese companies listed their shares<sup>100</sup>, and the market weight of the American stock exchanges, it is very likely that other states would be willing to accept an agreement that converged significantly to US accounting standards, at least for the consolidated accounts of listed companies. The tripartite initiative however, did not have the successful conclusion of the banking capital adequacy bilateral initiative. Such a plan could not succeed, as the UK was already bound by the European Accounting Directives and the mutual recognition policy. The US did go ahead to complete a bilateral agreement with Canada, the Multijurisdictional Disclosure System (MJDS), in 1991, but the absence of the UK from this agreement meant that it did not have the critical mass it needed to start a move towards an international agreement.

As per proposition (3), it is in cases like this, when, in an oligopolistic market structure we have a distributional coordination problem, which cannot be resolved through international institutions, that we would expect to see states opting for a transnational forum-shifting solution. Therefore, following the failure of the tripartite agreement, we would expect the SEC to use transnational regulatory authority as a forum-shifting strategy. Indeed, representatives from the SEC and the IASC had already met in 1984 and discussed the possibility of a common disclosure document for cross-border listings. The SEC however did not take the IASs very seriously at the time, as it considered their quality poor and wholly inadequate for the US markets given the variety of options they allowed (Gernon et al. 1990). When it became obvious that a tripartite solution was not possible, the SEC went back to the IASC in

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<sup>100</sup> During the 1980s the LSE averaged 474 foreign companies listed on its table. Calculated from LSE's historic statistics, available from [www.lse.co.uk](http://www.lse.co.uk).



1987 to discuss the use of the IASs as possible benchmark standards in cross-border offerings. The SEC however was not satisfied with the number of options contained in the IASs and wanted the IASC to identify for each issue only one treatment as the benchmark or the “reconciling standard”. If this approach was endorsed, SEC representatives indicated that there was a possibility that the SEC might accept reconciliation to these benchmark standards instead of the US standards (Cairns 2003). In other words, provided that sufficient progress along the lines advocated by the SEC was made, a promise of regulatory authority was given to the IASC, that is, a promise to legally adopt the IASC standards for listing purposes.

According to condition (1b), regulators will always try to embed their relation with a transnational forum with some mechanism or procedure, which will allow them to exercise at least some degree of control over the regulatory process. The need for such a control mechanism was even greater for the SEC, since the IASC was already active for many years, and the SEC had to make sure that the existing standards would be revised in a way consistent with the philosophy of the US GAAP. For this reason, the SEC advanced its proposal through the newly founded International Organization of Securities Commissions (IOSCO)<sup>101</sup>. In 1987, the IOSCO, having accepted IASC’s invitation to join its consultative group, echoed SEC’s proposal, indicating that it would be interested in using IASs as a benchmark standard for listings in international stock exchanges, provided that the options allowed were reduced (Cairns 2003)<sup>102</sup>. Not surprisingly, the IASC decided in 1987 to begin its Comparability Project with the aim of eliminating the various alternatives allowed in IASs and proposing instead a benchmark treatment. As we have seen, the Statement of Intent on the Comparability of Financial Statements (1990) identified the issues for change and resulted in the revision of a number of IASs through the Improvements Project, while the cooperation of IASC and IOSCO on these projects eventually led to the landmark 1995 core standards agreement.

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<sup>101</sup> The IOSCO was founded in 1983, emerging as an international forum from its regional predecessor, the Inter-American Association of Securities Commissions. The IOSCO brought together national securities regulators in an attempt to deal with the growing internationalisation of securities markets (Underhill 1995).

<sup>102</sup> See also the comments of the Chairman of IOSCO during the proceedings of the International Financial Reporting Forum on IASC’s Comparability Project (Gernon et al. 1990).

IOSCO had a significant impact on IASC's work: "many of the changes made to IASs during the improvements project reflected the wishes of the IOSCO representatives" (Cairns 2003, p.44)<sup>103</sup>. However, the input of IOSCO was largely determined by the SEC. The SEC was the most important member of the IOSCO in relation to accounting standards, due to the attraction of the US capital markets, the SEC's tough line with foreign issuers, and its rigorous enforcement policy (Cairns 2003, p.57). SEC staff was present in almost all occasions of cooperation between the IASC and the IOSCO. It held posts with significant influence over the future of this cooperation, such as the chairmanship of working group 1, responsible for evaluating the revised IASs and recommending their endorsement or rejection by IOSCO (Cairns 1997), and "played a critical role in the comparability and improvements project, the IASC-CICA<sup>104</sup> financial instruments project, the determination of IOSCO's list of core standards and the subsequent evaluation of IASs" (Cairns 2003, p.58).

Beyond providing the SEC with a mechanism that allowed it to influence heavily the direction and content of the Improvements Project, the control that this setting offered the SEC, gave it the ability to pursue what seems to have been another objective of its forum-shifting strategy. The tactics of the SEC in the context of the IOSCO-IASC cooperation seemed to be part of a strategy designed to delay IASC's progress towards becoming the forum for international accounting harmonization. In this way, the SEC could retain the status quo, that is, the use of US GAAP by a considerable number of foreign multinationals, effectively hoping to bring about a de facto harmonization based on American accounting standards<sup>105</sup>.

Indeed, former IASC and SEC officials have acknowledged in interviews with the author that at least until the mid-1990s the SEC and the FASB still believed that the US accounting standards could become de facto global accounting standards. A

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<sup>103</sup> David Cairns was IASC Secretary General for the period 1985-1995.

<sup>104</sup> CICA is the Canadian Institute of Chartered Accountants.

<sup>105</sup> At the beginning of this chapter, we saw that until the 1980s the only harmonization that was taking place was that which was dictated by the need of MNCs to list their shares on American capital markets and were therefore obliged to adopt US GAAP as a secondary or reconciliation set of standards. The growth of financial markets since the 1980s had raised further the status of the US GAAP. By the early 1990s, the US GAAP was already considered an international set of accounting standards (Hulle 1993; Cairns 1994).

strategy to turn this belief into reality is the only way to explain SEC's behaviour in the context of the IOSCO-IASC cooperation, which could, at best, be characterized as ambivalent. This is obvious for example with the timetable for the adoption of the core standards; many regulators including Paul Guy, secretary-general of IOSCO, Jean Saint Geours, president of the French regulator and chairman of the technical committee of IOSCO, and Edward Waitzer, chairman of the Ontario Securities Commission, were in favour of an immediate, step-by-step endorsement process whereby the revised standards could be endorsed as they were completed. The SEC however thought otherwise and objected to this approach (Cairns 1997). The 1994 recommendation of working party 1 (whose chair was held by the SEC) reflected SEC's view and suggested that the core standards (including some which had been revised during the improvements project and had already been found to be acceptable to the IOSCO) should not be endorsed until the whole set of standards was completed. This decision produced acrimony and some tough words between the IASC and IOSCO (Cairns 1997), but eventually the SEC prevailed as this view was endorsed in the final core standards agreement in 1995. Following this, the SEC announced in April 1996 that, irrespective of IOSCO's verdict, it would conduct its own evaluation of the core standards, which would be based on whether they satisfied three key elements: a comprehensive set of accounting pronouncements, high quality standards and most importantly, their rigorous interpretation and application (SEC 1996). It is obvious, that the third criterion could never be satisfied by the IASC which did not have the authority to enforce the IASs in national jurisdictions. In other words, the SEC signalled that it was not going to accept use of the IASs without reconciliation. When asked by the author about these obstacles that the SEC seemed to keep putting in the way of IASC's progress, Sir Brian Carsberg, IASC Secretary-General for the period 1995-2001, suggested that indeed,

there were some in America who thought that their standards were the highest quality standards in the world and because they had such a strong position in the capital markets they had only to, sort of delay things, as far as international accounting standards were concerned, and more and more companies would adopt US standards

and so US standards would become the international standards almost by a process of default<sup>106</sup>.

The engagement with the IASC therefore constituted a two-pronged forum-shifting strategy. Either the US could stop from within the progress of the IASC, in effect employing a forum-blocking strategy<sup>107</sup>, hoping to bring about a de facto globalization of US standards, or failing this, it would influence the development of the next possible candidate, the IASs, so that they would resemble the US GAAP as close as possible. This meant that most of the adjustment costs of harmonization would be born by foreign companies, investors and regulators. The IOSCO provided the SEC with the necessary control device to pursue both ends. The IOSCO however was not the only way the SEC could influence the future of the IASC.

SEC's influence in IOSCO was complemented by an effort to influence the work of the IASC at the preliminary stages, that is, before and during the drafting stage of the standards. This was achieved to a large degree through the influence of the G4 group, which effectively represented another forum-shifting move similar to the tripartite harmonization proposal, but this time at a transnational level and within the wider strategy of engagement with the IASC. As we have seen, the G4 group comprised the standard-setters of the US, the UK, Canada, Australia and New Zealand. The IASC also accepted an invitation to participate in the group, and between 1993 and 2001 the G4+1 group issued a number of position papers on a variety of accounting issues. The formation of the G4 raised significant concerns among the other members of the IASC and was viewed as a threat to the IASC itself (Street and Shaughnessy 1998). Critics did not see this joint effort sympathetically and saw the G4 as an attempt to maintain Anglo-American dominance in the organization (Flower 1997; Nobes 2003). Indeed, the G4 played a very influential role: the G4 set and dominated to a large degree the agenda of the IASC (Nobes 2003), while the IASC steering committees relied heavily on the joint publication

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<sup>106</sup> Interview with author, 15/03/2007.

<sup>107</sup> According to Drahos and Braithwaite, forum-blocking is a variation of the forum-shifting strategy and occurs when a state prevents an organization from becoming the international forum for an issue-area (Braithwaite and Drahos 2000, p.564).

papers produced by the G4+1 during the time that it was active (Street and Shaughnessy 1998).

However, the greatest opportunity to control IASC's destiny came with the restructuring project. The Strategy Working Party that was established in 1996 to lead and coordinate the restructuring process initially proposed that an enlarged IASC board with twenty-five members representing professional accounting associations from more countries, and other organizations interested in harmonization of accounting standards, should have the final say in the approval of the standards. The standards themselves would be developed by a Standards Development Committee (SDC) comprising eleven members, most of whom would have to be voting members in their national standard-setting bodies<sup>108</sup>.

These proposals met with fierce resistance from the US. In reply to these proposals, the FASB published in 1999 its vision of international accounting standard-setting<sup>109</sup>. According to the FASB, "the ultimate objective of the international accounting system is simultaneously optimizing capital market efficiency and ensuring investor protection" (1999, p.10). This would be achieved by developing a single set of high-quality accounting standards with minimum alternative treatments which would be capable of rigorous interpretation and application. In turn, this set of standards would be developed by a mechanism that incorporates a standard-setting body, an interpretations committee and a consultative professional body. In other words, the FASB envisioned an international standard-setter after its own image. To secure this image, the FASB argued strongly for the independence of the decision-making body, which should be comprised of "standard setters with sound technical expertise"<sup>110</sup>. To ensure that its vision was duly noticed, the FASB did not hesitate to resort to threats. The FASB noted the importance of US markets and the American standard-setters, and warned that "worldwide acceptance of internationally recognized standards and a global standard-setting process is impossible without U.S. acceptance and participation...U.S. support is necessary to

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<sup>108</sup> These recommendations are included in "Shaping IASC for the Future", IASC Strategy Working Party, IASC Insight Supplement, December 1998.

<sup>109</sup> "International Accounting Standard Setting: A Vision for the Future", FASB, 1999.

<sup>110</sup> E.L. Jenkins, FASB chairman, IASC Insight, June 1999, p. 12.

the legitimacy of any set of international standards” (1999, p.1). The FASB suggested that if the current process failed there were other possible solutions: “the objectives and vision presented are also consistent with other possible alternatives, including the possibility that the FASB might reorganize itself to become an international standard setter or that an alternative international structure and process could be established that meets the FASB’s fundamental objectives” (1999, p. viii); this could be “a successor international organization..., perhaps based on the G4+1” (1999, p. 7). Echoing the views of the FASB, the SEC also argued for independence and technical skills.

Despite the fact that most other interested parties, including the European Union, the Japanese Institute of Certified Public Accountants, and even IOSCO itself (with the explicitly noted the disagreement of the SEC) were in favour of an enlarged Board and geographical representation<sup>111</sup>, the SEC had a major influence on the final report of the Strategy Working Party and in the end the American view prevailed (Cairns 2003). The decision was taken to have an independent board whose members would be chosen solely on the basis of their technical expertise and experience. The members of the new Board would be experts in all aspects of accounting and financial reporting, with significant professional experience. It should be noted that such experts could only be found in developed economies with developed capital markets, particularly since the reporting philosophy of the new organization was explicitly geared primarily towards the satisfaction of the reporting needs of capital market participants<sup>112</sup>. As a result of this decision, the resulting synthesis of the Board has played out to the advantage of the SEC and the FASB as most of the Board members fall within the Anglo-Saxon accounting tradition, sharing thus similar views on financial reporting, as well as a significant experience of close cooperation through the G4+1. Of the fourteen members of the first IASB, ten came from the US (5), UK (2), Canada, Australia and South Africa, effectively all the major countries in the

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<sup>111</sup> See IASC Insight, June 1999, pp.15-16.

<sup>112</sup> See the IASC Foundation Constitution, Part A, 2, July 2005, for the objectives of the IASC Foundation.

Anglo-Saxon tradition, while the remaining four came from Germany, France, Switzerland and Japan<sup>113</sup>.

### 5.3.2 Europe's response: transnational regulatory authority as a forum-shifting strategy

We saw previously that the EC's regulatory dilemma was quite different from the SEC's problems. The EC was put under pressure from its constituents who wanted to be able to list their shares in the US capital markets without having to reconcile their accounts to US GAAP. As we have seen, the SEC was not willing to grant this request. As we would expect, the first attempt of the EC to solve the problem was to seek an international agreement that would eliminate the costs for European issuers and balance the costs of analyzing foreign financial statements to European and American investors. Following its decision to adopt a mutual recognition policy in the context of European harmonization, which also meant that there was no single European accounting model to be used in negotiations with the Americans, the EC proposed to the SEC a mutual recognition agreement (Cairns 1994). Unfortunately, as the Commission later admitted: "the Commission has attempted to initiate such discussions, but has found little interest on the American side" (COM 1995, p.5). The SEC's refusal was hardly surprising. First, as it was just mentioned there was no European set of accounting principles for the SEC to recognize. As described above, the Directives were incomplete, often outdated and in many cases not yet adopted by all member states. Moreover, being a compromise between different accounting traditions, they allowed many options, a flexibility, which as we already have seen, was entirely inconsistent with the prescriptive standard-setting philosophy of the FASB and the SEC. Finally, the Commission had very little to negotiate with, since accounts prepared by US companies under US GAAP were already accepted in most

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<sup>113</sup> Although we cannot accept this view without reservations given the absence of direct evidence, it is worth mentioning that accounting scholars have often suggested that the synthesis of the Board has given a significant advantage to Anglo-Saxon countries when acting as a voting block. This has been achieved either by being able to block the approval of new standards in the old IASC, where they held five out of the sixteen seats, that is, more than the 25% of the votes needed to block a new standard (Flower 1997), or by being able to pass new standards in the new IASB, given that the required majority for the approval of a new IFRS is nine out of fourteen members (Nobes 2003). It is obvious that the new synthesis has greatly increased the representation of the Anglo-Saxon camp in the Board, and thus their ability to control the voting if they so chose.

Member States, and therefore the EC had nothing to offer the American side in exchange for the recognition of European accounting standards.

As was the case with the SEC, following the failure of international agreement in an oligopolistic global market for capital, we would expect the EC to try to resolve the international conflict of interest in favour of European issuers, using an international forum-shifting strategy. However, given, the weight of the US capital markets, the MJDS agreed between the US and Canada, and the difficulties of Europeans in agreeing amongst themselves, achieving a sufficiently powerful international front with other market players (e.g. Japan) to force the SEC to come to the negotiating table seemed unlikely. Therefore, in accordance with proposition (3b), we would expect the EC to pursue a transnational forum-shifting strategy. Given that there was already a prestigious transnational organization active in accounting standards setting, the IASC, it would seem reasonable for the EC to try to use the IASC in the context of a forum-shifting strategy. The prestige and highly regarded expert profile of the IASC provided an ideal forum for reaching a compromise with SEC along the lines of our argument.

Indeed, in view of the regulatory stalemate, the EC embarked on a strategy of gradual engagement with the IASC. In 1990, the European Commission organized a conference on the future of European accounting harmonization. The conference was meant as a way forward but produced very little concrete results and made apparent the disagreements about the direction of European accounting harmonization (EC 1990). However, despite these disagreements, and given the increasing pressure to facilitate European business' access to American capital markets, there was agreement on the increasing importance of international harmonization, especially in the IASC, and on the fact that it was absolutely necessary for Europe to be more involved in international accounting harmonization developments. It was thus decided that the EC should be proactive and participate in the IASC<sup>114</sup>. The Commission would take up the IASC's invitation to join the consultative group and take an observer position on the Board.

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<sup>114</sup> This does not mean that everyone approved of IASC's work. German and French officials in particular were explicitly opposed, at the time, to any potential delegation of accounting standard-setting authority to a non-state organization (EC 1990).



This initial decision to engage with the IASC, proved to be the prologue to a significant new strategy that was announced by the European Commission in 1995<sup>115</sup>. The EC acknowledged the fact that the difficulty of European issuers to list in foreign markets, and particularly the US capital markets, was a major problem for European business, which was only going to get worse:

Accounts prepared in accordance with the Directives and the national laws which implement them do not meet the more demanding standards required elsewhere in the world, notably by the Securities Exchange Commission in the United States. The result of this last problem is that large European companies seeking capital on the international capital markets, most often on the New York Stock Exchange, are obliged to prepare a second set of accounts for that purpose. This is burdensome and costly and constitutes a clear competitive disadvantage. Producing more than one set of accounts also causes confusion. Moreover, it involves companies in conforming with standards (US Generally Accepted Accounting Practices or GAAP) which are developed without any European input. As more and more Member States are implementing important privatisation programmes and as the capital needs of the companies concerned are increasing, the number of companies facing this problem is growing.

COM 1995, 1.2, 1.3

Moreover, the EC stressed the dangers that this situation posed for the European harmonization programme, should the problem remain unresolved:

The most urgent problem is that concerning European companies with an international vocation. The accounts prepared by those companies in accordance with their national legislation, based on the Accounting Directives, are no longer acceptable for international capital market purposes. These companies are therefore obliged to prepare two sets of accounts, one set which is in conformity with the Accounting Directives and another set which is required by the international capital markets. This situation is not satisfactory...there is a risk that large companies will be increasingly drawn towards US GAAP. They and the Member States are looking to the Union for a solution that can be implemented rapidly.

COM 1995, 3.3

Given this situation, the pressure was on the EC to come up with a solution promptly:

The Union needs to move promptly to offer the users and preparers of accounts a clear prospect that companies seeking listings on the US and other world markets will be able to remain within the EU accounting framework and that US GAAP, over which they and their governments can exercise no influence, is not the only option.

COM 1995, 6

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<sup>115</sup> "Accounting Harmonization: A new Strategy vis-à-vis International Harmonization", Commission of the European Communities, (COM 95) 508, 14.11.95.

The EC proposed the aligning of European Union's work with the harmonization efforts being undertaken by the IASC. In the context of this new cooperation with the IASC, Member States could allow companies to report under the IASs as long as these were not incompatible with the European Directives. The Commission proposed as a first step, to make a survey of the differences between the IASs and the Directives. For the first time, the Commission accepted that in case of incongruity it would be ready to review the Directives. A Contact Committee was established in 1996, comprising government experts, and was charged with undertaking an examination of the conformity between the European Directives and the IASs. Also, for the first time, the Commission made a distinction between consolidated accounts and annual accounts and proposed that the Contact Committee should focus on consolidated accounts since these would be less controversial (no tax implications) and more relevant for companies affected by the lack of harmonization. The conclusion of the Contact Committee's survey was that there were only two minor issues of incompatibility, if the options allowed in the European Directives were chosen by individual states, in such a way, as to comply with the IASs (EC 1996).

The change of approach by the EC while being quite dramatic, given the divergence of European views, was not surprising in view of the increasing pressure that European "global issuers" started putting on European regulators<sup>116</sup>. As we saw previously, faced with increasing pressure from big European TNCs, regulators started contemplating solutions outside the context of the European harmonization programme. Even in Germany, where both regulators and companies had opposed the SEC's insistence on reconciliation to such a degree that no German companies were listed on the NYSE until 1993, pressure eventually drove regulators to contemplate allowing big public companies to adopt the US GAAP. Moreover, as we saw above, and in the previous chapter, voluntary adoption by big European TNCs of both US GAAP and IASs started gaining ground at a gathering pace in the early 1990s, leading to a gradual de facto harmonization based on US GAAP and the IASs (Canibano and Mora 2000; Haller 2002). Given the inability of Europeans to find

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<sup>116</sup> Interview with Karel Van Hulle, 08/06/2007.

common ground amongst themselves, which was reaffirmed at the 1990 conference, and the growing significance and urgency of the problem, many regulators, in line with condition (1a), seemed less interested in the continuation of the extensive, all-pervasive European harmonization programme, and became more concerned with finding a solution for a specific regulatory clientele, the big global European issuers, a solution limited to consolidate accounts for listing purposes (Hoarau 1995; Canibano and Mora 2000). Indeed, it seems that a number of European regulators had endorsed this new direction for harmonization even before the announcement of the new European strategy, and their views informed its development. Already from the early 1990s, certain jurisdictions had begun the alignment of their national standards to IASs and incorporated IASs to domestic accounting or stock exchange listing regulations where possible (Haller 2002). This change of direction has been confirmed by Karel Van Hulle<sup>117</sup>, who prior to the adoption of the new strategy, embarked on a European tour trying to find a solution to the problem. After describing the unwillingness of European regulators to engage in the development of a European Standards Board or in a new process of revising the Accounting Directives, he explained that:

The majority of people [regulators] were saying why don't we try IASs? Let's open up the European area and allow the possibility for companies to use IASs in consolidated accounts, only consolidated accounts, because then we don't have the tax problem.

Given the difficulties of European harmonization, this approach presented a favourable alternative for both European regulators and the EC. First, it offered European "global issuers" the possibility to gain access to international capital markets based only on one international set of accounts. Secondly, it allowed European regulators to keep intact their domestic accounting regulatory frameworks for the individual accounts of limited liability companies, which ensured that there would be no tax implications (Hoarau 1995), and on the other hand, given the favourable report of the Contact Committee, it ensured the preservation of the European accounting framework. Therefore, this new approach seemed to offer a potential way out of the reconciliation problem without undermining the authority of

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<sup>117</sup> Ibid.

either the national regulators or the EC. As a result, it was not surprising to see that shortly after the announcement of the new European reporting strategy, a number of European countries (Austria, Italy, Germany, France and Belgium) passed legislation that allowed the use of IASs for consolidated accounts by listed companies, while new exchanges (EASDAQ, Neue Markt), required that listed companies publish consolidated accounts in accordance with the IASs.

The IASC was chosen, because it had already achieved global recognition as the prominent, independent, expert-driven forum for international accounting harmonization, a reputation institutionally established and recognized with the IOSCO core-standards agreement. The EC was obviously hoping that this move would force the SEC, in line with the IOSCO agreement, to acknowledge the IASs as an internationally accepted set of standards, which could be used for listing in the US without reconciliation:

The International Organization of Securities Commissions (IOSCO) has recently reached an agreement with IASC on a joint work programme, which aims to produce in the medium-term a core set of international accounting standards to be applied by companies seeking a multinational listing of their securities. The realisation of this objective would make it easier for European companies which apply International Accounting Standards (IAS) to have access to international capital markets and especially to the US capital market.

COM 1995, 2.8

Moreover, because of the IOSCO agreement, the EC did not have to move completely to transnational regulatory authority, but could only allow the voluntary incorporation of IASs in the European accounting framework and wait for the IOSCO endorsement of the core standards agreement to put in place the final legal component, which would allow European issuers to list their shares in the US using the IASs. Finally, as we have argued, transnational regulatory authority offers regulators the ability to exert influence on the operation of a transnational regulatory forum, while taking advantage of the prestige and proclaimed neutrality of experts, which can be used to facilitate compromise. Indeed, engaging with the IASC, the EC hoped to achieve agreement on an international set of standards that would not constitute a wholesale adoption of US GAAP and would be closer to a compromise between the Anglo-Saxon and Continental approaches to accounting. This would be

achieved by the active engagement of the EC in the IASC standard setting process which would allow it to exert influence on IASC's work so that the EC would not just accept the standards of the IASC which "should not be an American or Anglo-Saxon dominated body" (EC 1990, p.113). The Contact Committee would establish a common European position in future Exposure Drafts (EDs) and convey this unified position to the IASC, a process which would "allow the Union progressively to gain a position of greater influence on the IASC's work, including the determination of its agenda, so that its output will increasingly reflect the EU viewpoint" (COM 1995, 5.4).

However, while the 1995 strategy seemed a promising way out of the impasse, things in the next few years did not go exactly the way the EC had hoped for. First, as we saw, the IOSCO endorsement, while positive, was not automatic or mandatory and allowed national regulators various adjustments, including a reconciliation requirement. Moreover, irrespective of IOSCO's decision, the SEC signalled in 1996 that it would decide on its own and with rather stringent criteria whether to allow the IASs in US capital markets without reconciliation. Finally, FASB's influence through the work of the G4 had actually grown and dominated to a large degree the IASC agenda.

In view of this situation, the EC had to take its strategy to the next level. Following our theoretical discussion, we would expect the EC to move fully towards transnational regulatory authority, that is, to decide to adopt legally the IASs for use in European capital markets. This is not only because the EC had no other option, given that the only other available international set of standards was the US GAAP. It is true that following the failure of the IOSCO's core standards endorsement to deliver the desired outcome, the EC found itself in a difficult position. Obviously, the EC could never accept US GAAP in the development of which it had no input. Moving to the IASs therefore provided a way out of the impasse and allowed the EC to save face by claiming that it chose an international set of standards renown for their comprehensiveness and quality (COM 1995). While a certain degree of path dependency is evident in this decision, this is in line with our argument about international redistribution. As was argued in chapter 3, the use of transnational

regulatory authority in the context of a forum-shifting strategy, is not a pure forward-looking strategy, since it is employed as a second-best strategy, following the failure of international agreement. Moreover, it provides a number of advantages that facilitate compromise, including the opportunity given to regulators to save face when reaching difficult compromises. However, this is not the only advantage. Moving fully to transnational regulatory authority, would change the reversion point in a way that the inconclusive IOSCO endorsement could not. Such a decision would create a set of international standards with more market weight than the US GAAP; the SEC could not ignore a set of standards used by most of the developed economies in the world. SEC's objections about the multiple choices allowed by the Directives and the lack of a common European set of standards would not be valid anymore. Moreover, this move would satisfy the third and most troubling of the criteria that the SEC itself had set out for the adoption of the IASs: their rigorous interpretation and application. This criterion could be satisfied if IASs were a legal requirement in European jurisdictions. In addition, the decision to adopt the IASs would give the Europeans an even greater opportunity to influence the work of the IASC. By becoming the largest constituency actually implementing the IASs, the EU was bound to have more say and influence in IASC's work. Finally, we should remember that such a move would only be the continuation of a strategy which begun in the early 1990s. In its communication of the new financial reporting strategy in 1995, the Commission examined a number of possible alternatives to the strategy finally adopted, but decided that this suited European interests best at the time (COM 1995, 4). Moving fully to transnational regulatory authority would only be the reasonable continuation of the strategy of gradual engagement with the IASC.

Indeed, in 2000 the Commission issued a new financial reporting strategy<sup>118</sup> where it took an unprecedented step and proposed that all EU listed companies should be *required* to prepare consolidated accounts in accordance with IASs from 2005 onwards. This proposal was accepted by the European Council and the European Parliament without significant objections and consequently with EC Regulation

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<sup>118</sup> "EU Financial Reporting Strategy: the way forward", Commission of the European Communities, (COM 2000) 359, 13.06.00.

1606/2002, this proposal became a binding legal requirement for all European listed companies, and an option for single company accounts or the consolidated accounts of non-listed companies (the option is open to Member States). This deadline was extended to 2007 for companies that were using U.S. GAAP prior to 2005 and companies that have only debt securities listed in European markets.

The new strategy was a significant turning point as it effectively endowed the IASC with the regulatory authority to develop accounting standards that would be legally adopted by the European Union. The move to transnational regulatory authority represented a complete break from the previous policy of retaining national options. To attempt such a dramatic move, the European Commission took advantage of the new European Strategy for a single internal market in financial services. The Lisbon European Council of 2000 underlined the importance of a single financial market in the EU, and set as one of its priority objectives the comparability of companies' financial statements. The EC presented its new strategy as the best way to achieve this objective, arguing that to achieve comparability it was necessary to have common financial reporting standards (COM 2000, 2). However, the adoption of IASs as national accounting standards was really the EC's ultimate effort to gain a degree of control over international accounting harmonization. While the proposal to adopt the IASs for the consolidated accounts of listed companies served the purposes of the internal financial market project, this proposal did not emerge suddenly, following the new impetus for a single European financial market propagated at the Lisbon European Council. As noted above, and as the description of the new strategy by the EC itself makes clear:

A central objective – and one against which success can be measured – is that the policy should ensure that securities can be traded on EU and international financial markets on the basis of a single set of financial reporting standards.

COM 2000, 7

The issue therefore, was not simply to have comparability between European capital markets, which had operated on the basis of mutual recognition for many years without significant problems, but to have European issuers being able to use one set of standards in all international capital markets, which as we have seen really

meant the US capital markets<sup>119</sup>. The 2000 strategy was the culmination of the 1995 strategy, as Karel Van Hulle himself has admitted<sup>120</sup>.

Finally, in line with our previous discussion and condition (1b), an endorsement mechanism has also been created. It comprises an Accounting Regulatory Committee (ARC), a political body representing Member States, which gives its opinion on whether or not to adopt an IAS after having consulted the European Financial Reporting Advisory Group (EFRAG), a private sector organization, which includes all interested parties (including standard-setters) and provides the technical assessment of the proposed IASs. The EFRAG also participates in the consultative stages for the preparation of new IASs at the IASC. According to the Commission's communication, the endorsement mechanism's central task "should be to confirm that IAS are in full conformity with the Union's overall approach – more specifically, if there is conformity with the EU's Accounting Directives and that a suitable basis for financial reporting by listed EU companies is provided" (COM 2000, 21). In other words, the decision to adopt IASs was not a *cheque en Blanc*; the EU's endorsement apparatus was supposed to act as an approval mechanism hopefully giving leverage to the EU in the IASC process. The endorsement mechanism would help coordinate the views in the European Union "at all stages of the IAS standard setting process not least to influence the debate" (COM 2000, 25).

### 5.3.3 Struggling for influence: IASB and the politics of transnational regulatory authority

The success of the EC's forum-shifting strategy soon became evident. As we have seen, in October 2002 the FASB and the IASB came to an agreement to jointly develop high-quality, compatible accounting standards. The SEC responded positively to the Norwalk agreement and indicated for the first time, that it would be willing to abandon the reconciliation requirement: "the announcement was a major step towards a global system of accounting standards and would in particular help the

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<sup>119</sup> Financial statements of European companies prepared according to the European Directives have usually been accepted in all other jurisdictions except the United States (Biener 1994).

<sup>120</sup> Interview with the author, 08/06/2007.



SEC to accept financial statements prepared by EU companies in accordance with IASs, without reconciliation to US GAAP, for the purposes of listing on US markets”<sup>121</sup>. The turnaround in the SEC’s and the FASB’s attitude was dramatic. It should be remembered that as recently as 1999, the FASB in its proposals for the restructuring process had explicitly expressed misgivings about the quality of the IASC’s work and doubted the possibility of its use in the US without reconciliation:

The FASB is not convinced that their use [core standards] in their present form would improve financial reporting in the United States....At least within the FASB’s current planning horizon, it seems unlikely that the IASC’s core standards ...will be accepted in the United States without requiring reconciliation of some of those standards.

(FASB 1999, p.4)

These views were repeated in 2000 in FASB’s reply to a Concept Release by the SEC, seeking comments on whether the SEC should accept IASs statements of foreign issuers without reconciliation. Had the quality of the standards change so dramatically within two years, that the IFRSs were now of high enough quality to become the basis of a joint standard-setting process? Obviously not, particularly in a period when the IASC was absorbed by its restructuring process and actual standard-setting work had stalled. The EC’s strategy had been successful in forcing the SEC and the FASB to acknowledge the IASC as *the* forum for international accounting harmonization: in 2005 the SEC and the EC agreed on a *roadmap* towards eliminating the reconciliation requirement by 2009. At last, the EC had found a way out of the impasse.

Despite the undoubted success of the EC strategy, not everything worked out according to plan. Perhaps, the most important setback was its failure to push its own vision about the new structure of the IASC Foundation. This failure was made all the more costly by the SEC’s success in imposing a model entirely consistent with its own views. This gave the opportunity to the SEC and the FASB to influence to a considerable degree the agenda of the new organization. This was crucial in view of the 2005 deadline because, while the EC managed to get the SEC to retreat from its previous position, this success also meant that the SEC and the FASB would try to

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<sup>121</sup> IASC Insight, October 2002, p. 2.

influence the work of the IASC so that the standards that would be adopted in the EU would be as close as possible to the US GAAP. This is evident from the work plan agreed in the Norwalk agreement, which sets out both a short-term convergence project and a longer-term coordination schedule. The short-term project was meant to address major differences before 2005, while the long-term coordination project refers to other differences between IFRSs and U.S. GAAP that remain after January 1, 2005<sup>122</sup>. The whole agenda of the IASB was determined by the 2005 deadline. In 2002, a new Improvements Project was initiated. The IASB decided in view of the EU's and other countries' decision to adopt IASs by 2005, that it had to "examine as a matter of urgency the standards that it had inherited from its predecessor"; moreover in order "to avoid the prospect of companies having to change their accounting twice, first on applying international standards in 2005 and then as the standards were amended shortly afterwards, the Board decided to speed up this project" (Tweedie 2004, p.5). By the end of March 2004, a stable platform of standards had been created which would not change before the 2005 deadline to give time to adopting authorities to familiarize themselves with them. All in all, the new Improvements Project resulted in the revision of fifteen IASs, while five new IFRSs were also issued by the first quarter of 2004. During the same time, work begun on a common Conceptual Framework. The urgency and scope of these changes suggest an effort to create a core set of standards that would be quite similar to the US GAAP, and therefore acceptable to the SEC, and to get under way a number of other projects before the EU begun enforcing the IASs and the new IFRSs. This is obvious for example in the case of the revised standards on financial instruments, IAS 32 and IAS 39, which as we shall see proved extremely controversial. Despite the fact that the standards were heavily influenced by the US GAAP to begin with, through the improvements project "further convergence with US GAAP was achieved by eliminating ten differences between the two sets of standards"<sup>123</sup>. Indeed, it seems that officials of the European Commission were disappointed by the urgency and

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<sup>122</sup> See the "Memorandum of Understanding", FASB and IASB, October 2002.

<sup>123</sup> IASC Insight, January 2004, p. 2.

direction of the improvements project, seriously questioned its necessity, and expressed reservations about the true intentions behind the project<sup>124</sup>.

The urgency of these changes was given added impetus due to developments in the EU: in the context of the wider process of creating a single European capital market, and in the course of setting up its endorsement mechanism for the IASs and IFRSs, the EC started to exert pressure to the IASB and the SEC. The leverage of the EU endorsement mechanism was tested with the revised IAS 39 on financial instruments. According to David Cairns<sup>125</sup>, despite many years of preliminary work, IAS 39 was basically the result of a “quick fix” by the SEC which, due to the lack of an US standard explicitly dealing with derivative instruments, produced a summary standard incorporating most of US relevant regulation on the issue ahead of IOSCO’s endorsement of the core standards. Indeed, the IASB itself admits that the requirements in IAS 32 and IAS 39 are very similar to those in equivalent US standards; as we saw the improvements project brought the IASs even closer to the US GAAP<sup>126</sup>. The revised IAS 39 met with significant resistance as European banking supervisors and the European Central Bank were concerned that the recognition of derivatives at “fair” or market value, which the standard required with some limitations, could be used as a precedent for a move to a complete adoption of “fair” value accounting in financial instruments, which is not allowed under European Company Law. Moreover, regulators were concerned that fair value accounting could be used to inflate earnings and could result in a misleading image of the financial situation of the reporting companies<sup>127</sup>. Also there was significant resistance from European Banks especially on the issue of hedge accounting for banks<sup>128</sup>. Opposition came mainly from banks in France, Spain, Italy and Belgium<sup>129</sup>, which argued that IAS 39 would inject excessive volatility into balance sheets and income statements. As a result the European Commission endorsed IAS 39 in November 2004 with the

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<sup>124</sup> Interview with author, 08/06/2007.

<sup>125</sup> Interview with the author, 11/05/2006.

<sup>126</sup> IAS 32 deals with disclosure and presentation of financial instruments while IAS 39 deals with their measurement and recognition.

<sup>127</sup> Tweedie, in IASC Insight, October-November 2004, p. 6.

<sup>128</sup> Hedging refers to the use of financial instruments to mitigate against risk and volatility in international markets, for example from fluctuations in interest or exchanges rates.

<sup>129</sup> Financial Times, July 7, 2004, p. 19.

exception of two “carve outs” one relating to the fair value option and the other to the hedge accounting for banks. While this provoked reactions from both the IASC Foundation and the SEC, whose chief accountant warned that the SEC's offer to consider dropping the reconciliation requirement would not apply if European companies could not abide by all aspects of IFRSs<sup>130</sup>, a number of amendments were made to the standard. Eventually, *The Fair Value Option* amendment was issued in June 2005, which addressed the concerns of European regulators, and on the 8th of July 2005 the ARC approved an EC draft Regulation for the endorsement of the amendment. However, the second carve out for hedge accounting for banks remains an issue of dispute. What is more, this has not been the only disagreement to emerge. In June 2005, IFRS 3, a proposed standard on mergers and acquisitions, the result of the cooperation between the IASB and the FASB was issued, attracting criticism literally from all European constituencies and the European Commission<sup>131</sup>, which led to the revision of the standard finally adopted in January 2008. Meanwhile, the proposed IFRS 8 on segmental reporting received heavy criticism from the European Parliament, which instructed the European Commission to conduct an impact assessment before deciding on the adoption of the IFRS<sup>132</sup>. Although, following the study conducted by the EC, the European Parliament approved the adoption of IFRS 8, its decision was accompanied by a number of reservations and regrets about what it effectively considered the incorporation of the US standard SFAS 131, upon which IFRS 8 is based, into European law without due notice of the interests of European constituents<sup>133</sup>. Indeed, the European Parliament has recently issued a report where it points to a number of standards, which it believes merit further attention<sup>134</sup>.

Beyond disagreements on individual standards, confrontation has emerged in the wider issue of convergence. The creation of a pan-European securities regulator, the Committee of European Securities Regulators (CESR), seen by many as a type of “European SEC”, created anxiety in the SEC side: “creation of a coordinated European securities regulatory structure raises the possibility of real conflicts between

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<sup>130</sup> Ibid.

<sup>131</sup> Financial Times, December 8, 2005, p. 15.

<sup>132</sup> PE 387.132v01-00, 18.04.2007.

<sup>133</sup> PE 396.091v01-00, 07.11.2007.

<sup>134</sup> PE 392.258v03-00, 05.02.2008.

regulatory requirements” (Campos 2004). This anxiety was further fuelled by the fact that with Regulation 809/2004, the EC decided to allow non-European issuers to list their shares in Europe using either IFRSs or the national accounting standards of a third country, which are considered equivalent to IFRSs. Following a mandate by the European Commission, the CESR recommended that differences between IFRSs and other equivalent standards should be disclosed and in some cases the quantitative impact of a transaction reported<sup>135</sup>. Reactions from Japan and the US were immediate and concerns were expressed that this would effectively lead to a European requirement for reconciliation and would work against the convergence objective<sup>136</sup>. It is obvious that the adoption of IFRSs changed significantly the reversion point, giving the EC the power to yield the equivalence requirement in a stick and carrot fashion, similarly to the SEC’s use of the reconciliation requirement. Indeed, following consultations with the CESR, a mechanism for assessing the equivalence to IFRSs was established by the Commission with Regulation 1569/2007, which was issued on the 21st of December 2007, the same day that the SEC announced its decision to allow foreign issuers to list in the US capital markets using IFRS without reconciliation<sup>137</sup>. Still, this decision referred to the IASB version of the IFRS and not the EU version, which includes the hedge accounting carve out. Companies using the European version of the IFRSs have been allowed its use for another two years as long as they provide a reconciliation to the IASB version of IFRSs. After this time, they will have to adopt either the IASB’s version or the US GAAP. Following the SEC’s decision to abolish the reconciliation requirement, the CESR proposed in March 2008, that US and Japanese accounting standards should be considered equivalent for listing purposes in the EU<sup>138</sup>. Still, in view of the SEC’s requirement for the ultimate adoption of IASB’s version of IFRSs, it will be interesting to see how and when the EC decides to endorse the CESR’s proposal.

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<sup>135</sup> *The Review of Securities and Commodities Regulation*, Standard and Poor’s, Vol. 38, No 20, p. 251.

<sup>136</sup> Ibid.

<sup>137</sup> SEC Release No. 33-8879, December 21, 2007.

<sup>138</sup> “CESR’s advice on the equivalence of Chinese, Japanese and US GAAPs”, CSER/08-179, March 2008. It should be noted here that with the Tokyo Agreement of August 2007, Japan and the IASB agreed to converge their standards by eliminating major differences by 2008 and the remaining by 2011.

From the above, it is obvious that the redistributive strategies of the two regulators continue in the context of the IASB. Americans and European regulators use strategically their national and regional regulatory mechanisms, in a stick and carrot fashion to ensure influence over the IASB's work. What is more, the closer cooperation of the IASB with national and regional regulators has led to the involvement of other institutional components of the national and regional regulatory frameworks in the engagement with the IASB. Thus, the incorporation of the IFRSs in the European regulatory framework has led to frequent interventions by the European Parliament, which was also able to press the EC into an agreement to have "effect studies" conducted for new accounting standards and interpretations intended for endorsement in the European Union. Also, since 2006, following a request by the European Union's Economic and Financial Affairs Council (ECOFIN), the EC has been monitoring the governance of the IASCF and the IASB and conducting an annual report of governance developments. This request has been driven by the ECOFIN's concern over the legitimacy, transparency and accountability of the IASCF/IASB governance structure, aspects, which the Council believes should be improved by increasing for example, the public oversight of the IASCF, and the geographical representation of the Board's membership<sup>139</sup>. On the other hand, it is worth noting that the FASB's recommendation to the SEC in relation to the abolition of the reconciliation requirement, in November 2007, was not to proceed with it, until key international parties had committed to strengthen and sustain the IASB role as an independent standard setting body, and to abolish their separate review and endorsement procedures<sup>140</sup>, a condition obviously meant for EC's endorsement mechanism and the other EU institutions' interventions described above.

#### **5.4 Justifying IASB's transnational regulatory authority**

The decision to replace national accounting standards with the IASs in the EU was a remarkable decision. It was an unprecedented move, which has had far-reaching consequences as it essentially replaced, literally overnight, national standards with the

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<sup>139</sup> "Council Conclusions on IASB Governance", ECOFIN meeting, Brussels, 8 July, 2008.

<sup>140</sup> See FASB's reply to the SEC's Concept Release on June 2007 concerning the ability of foreign issuers to use accounts based only on IFRSs. FASB, November 7, 2007.

IASs in twenty-eight countries. The new strategy has affected more than 7000 companies compared to the 275 companies that adopted IASs voluntarily at the time that the new strategy was announced. Apart from the sheer scope and finality of this decision (making IASs mandatory), what makes this move even more extraordinary, but also more contestable in terms of legitimacy, are two additional factors.

First, most continental countries, unlike most Anglo-Saxon countries, are characterized by Code Law legal systems. In these countries, accounting has usually been regulated by the government and is part of the wider system of economic and business regulation where emphasis is usually given to the protection of various stakeholders. Also, the tax implications of accounting rules weigh heavily in the consideration of regulatory authorities. Usually there exists an accounting code, which is prescriptive detailed and procedural, and often industry-specific plans or codes exist as well (Salter and Doupnik 1992). Given this context, the decision to delegate the accounting standard-setting function to a private transnational organization marks a dramatic change in the regulatory tradition of these states. Indeed, only one year before announcing its new strategy, and in the context of the IASC's restructuring debate, the EC's Head of Accounting and Auditing Unit Karel Van Hulle had argued that the IASC needed:

greater credibility and acceptance of its work. That credibility has to be based on political legitimacy in how it sets its standards. The IASC needs to make a step change from being a body that is dominated by the accounting profession in a small number of countries to being a truly representative and publicly accountable international body<sup>141</sup>.

How were the EC and national regulators able to justify the decision to delegate the regulatory authority to set accounting standards for EU listed companies to the IASB? It is evident from the above that the Commission realized and probably shared the legitimacy concerns raised by its decision. In the presentation of its new strategy the Commission explicitly acknowledged them but sought to allay them by declaring that "the European Union cannot delegate responsibility for setting financial reporting requirements for listed EU companies to a non-governmental third party" (COM 2000, 19). To reconcile this strong statement with the actual reality of endorsing the standards that the IASB had produced and would produce in the future,

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<sup>141</sup> IASC Insight, June 1999, p.16

the EC made sure, in line with our argument in chapter 3, that an institutional structure, the endorsement mechanism, was in place, which gave it the power to control to some degree the regulatory outcome. This gave it the ability to claim that the EC and the national regulators retained the ultimate authority over accounting standard-setting. It is not surprising therefore that in its proposal the EC links this mechanism explicitly with issues of legitimacy and accountability and presents it as the means “to exercise the necessary regulatory oversight” (COM 2000, 19, 20). In this context, it is explicitly stated that the endorsement mechanism must have a political component and that “the technical level will need to be under the control set at a political level” (COM 2000, 22). The regulators and government agencies that comprise the political level, the ARC, have to approve the recommendation of the technical private-sector body, the EFRAG, and only following ARC’s endorsement does the EC proceed with the adoption of new IASs/IFRSs. The mechanism, as we saw, has been used to demonstrate the ultimate authority of the EC and national regulators in the case of IAS 39 when the EC decided that two carve outs should accompany the adoption of the standard.

A second factor that makes EC’s proposal truly remarkable is that it applies to twenty-eight countries, some among the world’s most developed economies that have both the means and the expertise to provide their own, highly efficient, accounting framework. In our theoretical framework, it was argued that justification of the decision to delegate regulatory authority has to be based on an acknowledged functional inability of the state to regulate on its own an issue-area or industry. How can this argument be sustained when some of the most developed states in the world decide to replace their accounting standard-setting frameworks with that of the IASB? As we have seen, the IASs started being used by a number of countries as national accounting standards wholly or partly already from the mid-1980s. However, the countries that used them in this way were as recently as 1996, only developing and least developed countries (LCDs)<sup>142</sup>. These countries lack the necessary expertise and

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<sup>142</sup> See “Survey on the status of IASs”, IASC Insight, October 1997.



resources to set up sophisticated national accounting systems (Wallace 1993). Clearly, in these countries, the state can convincingly make this argument when opting for the adoption of IASs. Indeed, in many cases these countries did not have the resources to participate in the IASC process, even when invited to do so (Cairns 1997). Obviously, the same kind of argument cannot be made in Europe's case.

As suggested by our framework, the justification put forward by the Commission was based on an argument of necessity created by changes in both the global and European economic environment and in accounting itself. It is worth bearing in mind that in all previous attempts to harmonize European accounting standards, the preference for national options was defended very strongly by national regulators and acknowledged by the EC, whose first strategic choice had been mutual recognition with the US. This was not the case anymore. In line with proposition (5), it was argued that the structure of the international and European economic system had changed: "Member States' securities markets are in a period of dramatic change and increasing consolidation, driven by new technologies, globalization and the effect of the Euro" (COM 2000, 3). In this context, national options could not be tolerated anymore:

Adaptation of financial statements to take account of local legal and tax conventions was justifiable when investors and other stakeholders were generally of the same nationality as the company. But today the securities of any one company tend to increasingly be held by an internationally diverse group of investors. The interests of investors from another Member State are not served by having to interpret, or decipher, financial statements prepared in accordance with the local conventions of the country where the company is incorporated.

(COM 2000, 10)

In addition, technological change was transforming accounting itself:

"The rapid development of information and communication technologies and, in particular, electronic trading platforms, are changing how transactions take place and the way financial information is disseminated. Financial reporting itself is also changing".

(COM 2000, 3)

In line with proposition (4), EC's rhetoric suggested that the situation could no longer be dealt within the context of existing regulatory frameworks, which fostered

diversity; the existing accounting framework was simply not good enough for a global marketplace:

Our existing directives do not meet the needs of companies that wish to raise capital on pan-European or international securities markets. This is because transparency, comparable financial reporting and more demanding disclosure requirements for listed companies are being sought by both investors and supervisors.

(COM 2000, 9)

In view of this situation, the Commission argued that the current regulatory framework needed to be changed in order to catch up with global developments. First, traditional, national regulatory mechanisms needed to be replaced by an internationally recognized financial reporting framework:

Standard setting itself is evolving rapidly. There is a strong pressure towards the convergence of accounting standards, raising the importance of international standard setting and thereby encouraging national standard setters to cooperate more closely.

(COM 2000, 5)

This framework should also be more efficient in providing the relevant information to the international business community:

With the accelerating pace of business the need for a more dynamic and responsive legislative framework for financial reporting increases. The Union's lengthy legislative processes need close examination to ensure they meet the challenges of the market. Ways to move from the rigid, sometimes overly-prescriptive nature of EU directives to a more efficient and responsive system for financial reporting best suited to the needs of the securities markets have to be considered.

(COM 2000, 12)

There were only two available options: the IASs and the US GAAP. The IASC met both challenges and it did so better than the US GAAP. First, it was an internationally recognized set of high quality accounting standards, particularly suited to the needs of international companies and investors:

Already IAS provides a comprehensive and conceptually robust set of standards for financial reporting that should serve the needs of the international business community. IAS also has the distinct advantage of being drawn up with an international perspective, rather than being tailored to the US environment. US GAAP on the other hand, is voluminous and is based on very detailed rules and interpretations. Considerable education and training is necessary in order to use its standards.

(COM 2000, 15)

Moreover, the IASC provided a more efficient regulatory forum, one ideal for the purposes sought by the European Commission:

Recently, major developments have also taken place within the IASC itself. Its new organisational structure should become effective next year driven by a clear determination to make IAS the highest quality, comprehensive accounting standards for use in capital markets throughout the world.

(COM 2000, 6).

A similar line of reasoning was followed by the SEC, although the 2005 roadmap agreement is in no way as consequential for the domestic capital market participants as the 2000 reporting strategy is for Europe. In 2004, in a speech at IOSCO, SEC Chairman William Donaldson talked at length about the dramatic changes taking place in today's global economy which have resulted in an increasing integration of financial markets and the gradual development of a global "shareholder society" (Donaldson 2004). Similar remarks about the tremendous changes taking place around the world and the emergence of a new global marketplace with new regulatory needs were made at various occasions by SEC Commissioners and other SEC officials following the Norwalk agreement (e.g. Herdman 2002; Campos 2004; Nicolaisen 2004, 2005). According to the SEC Chairman, high standards are vital for this new global world market, and the essential method of building support for high standards, is cross-border cooperation:

cooperation, for instance, is vital to the important project on converging our Generally Accepted Accounting Principles with the IASB's International Financial Reporting Standards. The ongoing convergence project holds out tremendous potential for investors and companies seeking to allocate or raise capital on a global basis.

(Donaldson 2004)

For the first time SEC officials acknowledged the quality of the IASs. In setting out his proposed "roadmap" for the elimination of the reconciliation requirement in April 2005, the SEC's Chief Accountant expressed his belief that "the IASB has demonstrated an ability to set high quality standards that provide needed and useful information to investors" (Nicolaisen 2005). IASB standards' quality was now considered high enough to allow both the SEC Commissioner and the SEC's Chief Accountant to talk about how the convergence-process is a "two-way street" and

improvements can be made by both sides through their cooperation (Donaldson 2004; Nicolaisen 2004, 2005). The FASB could actually learn on occasion from the IASB. The US investors were not endangered anymore by the possibility of using IFRSs in US capital markets but could actually benefit from it: “the inclusion in SEC filings of financial statements prepared under IFRSs should significantly benefit U.S. investors and others who rely on such financial information” (Nicolaisen 2005).

## **5.5 Summary and conclusions**

Proposition (1), suggested that transnational regulatory authority could be used in the context of a redistributive regulatory strategy devised by national regulators, in order to transfer wealth from foreign constituencies to specific domestic interest constituencies. As we saw in this chapter, the IASB’s transnational regulatory authority is the result of the interplay of two such international redistributive regulatory strategies by two of the dominant global financial players.

Both the SEC and the EC faced internal regulatory pressures vis a vis the issue of accounting harmonization. In the United States, there was a conflict of interests between those domestic constituencies that were in favour of abolishing the reconciliation requirement for foreign issuers (mainly stock exchanges), and those which opposed such a move (mostly US issuers but also the bureaucratic establishment built around the SEC itself). The situation was quite difficult for the SEC because the opposing interests were both well-organized and powerful. In line with both proposition (1) and condition (1a), the SEC sought to satisfy the demands of both these constituencies through a process of international harmonization based on US GAAP which would facilitate access to US capital markets while burdening with the costs of adjustment foreign issuers, investors and regulators. Following its failure to attain a satisfactory international agreement, the SEC, along the lines of propositions (3a) and (3b), sought to use the IASC in the context of a forum-shifting strategy by promising the endorsement of IASs without reconciliation, should the IASs be reviewed in a manner satisfactory to the SEC. Moreover, the ambivalent and contradictory attitude of the SEC towards the IASC in the context of their cooperation, has shown that the SEC tried to bring about a de facto globalization of US GAAP, by delaying the progress of the IASs. In this way, all domestic interest

constituencies could be satisfied and the SEC and its regulatory establishment retain and even increase their standing. As suggested by condition (1b), the SEC sought to effect its strategy through the means of an institutional mechanism that could provide it with a measure of control over the regulatory outcome. IOSCO proved to be an ideal setting because on the one hand it allowed the SEC, through its leadership in IOSCO, to control IASC's work effectively, while on the other hand the attraction of IOSCO's endorsement forced the IASC to follow its lead.

On the other hand, the European Commission managed to overcome the conflicts among different accounting traditions at the European level through the mutual recognition policy, but this policy did not help, and actually inhibited progress at the international level. Faced with the completion of the internal market and the creation of the Eurozone, significant changes in technology which changed the mode of operation of financial markets, and an increasingly globalizing economy, European "global issuers"(both public and private), needed access to international, and particularly American, capital markets. However, the SEC's resistance to a mutually agreed harmonization of accounting standards could not be overcome; the absence of a European accounting model, and the acceptance of US GAAP in most European jurisdictions left the Commission in an inferior negotiating position. As per proposition (3b) therefore, the EC decided to use the IASC/IASB in the context of a forum-shifting strategy. This strategy was developed and employed gradually, first through an increasing engagement with the work of the IASC, and then with the 1995 strategy which allowed the voluntary use of IASs for consolidated accounts of listed companies. As per proposition (1a), this solution was designed in order to address the concerns of the major European issuers. At the same time, it did not disturb the accounting framework applicable to the vast majority of European companies not listed in capital markets, and avoided creating problems for taxation. The choice of the IASC was made because of its prestigious global profile in accounting standard setting, recognized by IOSCO's decision to proceed to an agreement with the IASC for the preparation of an international set of standards for use in international capital markets. Still, this strategy was based on the assumption of the acceptance by the SEC of the set of core standards. When it became obvious that

the SEC was not willing to endorse without a reconciliation requirement the core standards, the EC took its strategy to the next level by proposing the replacement of national accounting standards with the IASs for the consolidated accounts of listed companies. By legally adopting the IASs the EC changed the reversion point, while it saved face vis a vis its domestic regulatory clientele and the European political establishment. The IASs were internationally acknowledged, high quality standards developed by experts. They did not allow many options, and were up-to-date, in some areas even ahead of the US accounting standards. Moreover, by being legally endorsed, the IFRSs were now a set of standards enforced and implemented rigorously across the EU, a criterion that the SEC had set unilaterally in anticipation of the completion of the IASC-IOSCO core standards. Finally, in line with condition (1b), the EC sought to embed its engagement with the IASB in an institutional mechanism, which would provide some degree of control over the produced standards. As we saw, the endorsement mechanism has already been used in this way. The EC's strategy proved successful as it resulted in the immediate engagement of the SEC and the FASB with the IASB to produce a set of standards that could be acceptable in US capital markets without reconciliation by 2009. However, while forced to acknowledge the new status quo, the FASB and the SEC moved fast and through their already established influence in the IASB process have been able to control the agenda of the organization in a way favourable to their own view of accounting.

Finally, in accordance with propositions (4) and (5), the EC justified its new financial reporting strategy by putting forward an argument based on swiping technological changes, globalization and the European integration process, which created a new pressing need for increased comparability and flexibility of financial information. This need could no longer be provided by the traditional European regulatory mechanisms. A more efficient and internationally acknowledged set of standards suitable for the needs of a globalizing economy was required and the best available was the IASs/IFRSs. Following the Norwalk agreement and the SEC's decision to accept the IFRSs in US capital markets without reconciliation by 2009, a similar rhetoric was adopted by the SEC.

## **Chapter 6**

### **Transnational Regulatory Authority in Practice (2): The International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceutical Products**

#### **6.1 Introduction**

The second case study of this thesis examines the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceutical Products (ICH). ICH is a transnational body comprising government and private sector actors. Its objective is to harmonize the technical requirements for the approval and market authorization of new medicines. In this first chapter, we shall introduce the concepts and issues related to the procedures for introducing a new drug for human use in the pharmaceutical market. Next, as was the case with the IASB, we shall examine the problems arising from the differences of the various national registration procedures and the principal efforts that have been made in international fora to address these problems, including a brief history and overview of the ICH and its work. We will then proceed to establish, using the three criteria outlined in the theoretical framework, the transnational regulatory authority of the ICH.

#### **6.2 The causes and consequences of international drug registration regulations**

The pharmaceutical industry is one of the most heavily regulated industries (McIntyre 1999). A new medicine for human use enters the market after a long cycle of research and development (R&D) which, including the marketing authorization procedures, lasts approximately thirteen years (EFPIA 2006)<sup>143</sup>. A large part of this long R&D process is devoted to an array of regulatory requirements regarding the safety, quality and efficacy of the new drug. This regulatory burden is one of the most important factors in the operation of a research-based pharmaceutical company<sup>144</sup>. The cause for

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<sup>143</sup> EFPIA is the European Federation of Pharmaceutical Industries' Associations.

<sup>144</sup> Not all pharmaceutical companies conduct original research and discover new drugs; many firms for example belong to the generics industry. Generics are usually produced by a manufacturer who is not the inventor of the original product and are marketed when intellectual property protection rights of the original product are exhausted (EFPIA 2006).

this heavy regulatory intervention is primarily the need to protect public health, which due to considerable negative externalities (e.g. time lag which can lead to loss of human life before a bad drug is identified by the market or lack of drugs for rare diseases) cannot be safeguarded by market mechanisms alone.

The pervasive regulatory intervention in the research and development process of a new drug has emerged mainly as a result of public health crises due to unsafe drugs, which spurred governments to prevent their reoccurrence through pre-marketing regulation. The first regulatory measures responding to such crises occurred in the late 19<sup>th</sup> and early 20<sup>th</sup> centuries (Jordan 1992; Schweitzer 1997). Nonetheless, undoubtedly the most significant crisis for today's pre-marketing regulatory landscape has been the 1961-1962 Thalidomide incident. Thalidomide was a drug used to treat nausea during pregnancy. Its use resulted in at least 8,000 deformed children being born in 46 countries, with an equal number estimated to have died at birth (McIntyre 1999). The most consequential regulatory response to the crisis came from the United States in the form of the 1962 Harris-Kefauver Amendments to the Food, Drug and Cosmetics Act in force since 1938. The drug was never approved in the US but a company had distributed 2.5 million tablets to doctors for a test run. The 1938 Act did not require approval before clinical trials. The Amendments introduced the need for an Investigational New Drug (IND) application which requires approval from the Food and Drug Administration (FDA) before proceeding to clinical trials. In order to apply for an IND the manufacturer has to check for toxicity and pharmacological activity first in the laboratory and then in animals. Moreover, the Amendments extended previous controls by the FDA to clinical trials and to the development process and required manufacturers to show that their drugs are not only safe but also effective. Following approval of the IND the clinical trials, which are conducted in three phases, can begin. The first phase is concerned mostly with toxicity and tolerable dosage in humans; the second phase aims to establish the first evidence of efficacy while continuing to look at the safety of the drug; in the third phase the efficacy claims of the manufacturer have to be established while also looking for adverse and long-term effects (Getzen 1997). The Amendments also required pharmaceutical firms to comply with "good



manufacturing and laboratory practices” as defined by the FDA, and gave the FDA the authority to inspect plants in order to confirm this compliance. Finally, the new legislation extended these requirements to “generic” and “me-too” drugs<sup>145</sup>. These requirements remain the fundamental regulatory framework of the United States until today.

Regulation in Europe and Japan was encouraged and heavily influenced by the basic framework of the US regulation (McIntyre 1999; Braithwaite and Drahos 2000; Ess et al. 2003). In the UK, the 1968 Medicines Act made statutory the voluntary arrangements that were adopted in the early 1960s following the thalidomide crisis. The Act created the Medicines Committee on Safety of Medicines and the Committee on the Review of Medicines. The Act also introduced an efficacy requirement which was implemented in 1971. Currently, all medicinal products are subject to a registration procedure under the authority of the Medicines Control Agency (MCA) and require similar data as those described for the US. In Germany, the 1976 Medicines Reform Act brought similar controls in the drug registration process while in Japan, the Ministry of Health, Labour and Welfare (MHLW) supervises approval and registration procedures very similar to that of the US and the UK, with the Pharmaceutical and Medical Devices Agency (PDMA) being in charge of the drug approval process. At the European level, the first pharmaceuticals directive adopted in January 1965<sup>146</sup>, identified the criteria of *safety*, *efficacy* and *quality* as pre-conditions for marketing authorizations, and introduced some of the requirements needed to ensure the appropriate evaluation of these criteria. More specific requirements for scientific and technical data and procedures were introduced in subsequent legislation<sup>147</sup>. The new European Medicines Agency (EMA), responsible for evaluating and recommending market authorizations to the European Commission, also makes use of a long list of technical and scientific requirements for the examination of a new medicine application, enshrined in EU legislation<sup>148</sup>.

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<sup>145</sup> The term ‘me-too’ “historically has most often referred to a new drug entity with a similar chemical structure or the same mechanism of action as that of a drug already on the market” (Di Masi and Paquette 2004, p. 2).

<sup>146</sup> Directive 65/65/EEC.

<sup>147</sup> Directives 75/318/EEC, 75/319/EEC and subsequent amendments.

<sup>148</sup> Directive 2001/83/EC, 6 November 2001.

The introduction of new regulatory measures in the US and other countries following the Thalidomide crisis created for the first time a nexus of different national regulations for producing and marketing a new medicine. This array of regulatory measures has increased significantly in recent decades (Schweitzer 1997; McIntyre 1999) and has resulted in a multitude of different national regulations dictating the specific safety, quality and efficacy characteristics of new drugs that each national regulator deems necessary. This diversity creates significant problems for the industry. National variations in these strict and lengthy testing requirements force companies to duplicate tests they have already conducted in one jurisdiction to gain access to another. Often tests conducted in one country are not accepted in another, although they do not present any problems from a scientific point of view. Several countries for example have had regulations stipulating that certain tests should be conducted in their own soil using patients or volunteers from their own population (Wall 1984; Jack 2005). The need to comply with many different national standards prolongs the R&D process, thus increasing its costs and reducing the effective patent period, making investment in R&D economically less attractive<sup>149</sup>. According to the European Commission (1991), eliminating double testing would reduce tests by 30%, while limiting the repeated dose toxicity studies to six rather than 12 months would result in substantial savings per new substance and spare the lives of thousands of laboratory animals. Moreover, diversity of regulatory requirements increases significantly the funds needed to achieve compliance with them, leaving less funds available for investment in research (Wall 1984). The resources needed to satisfy regulatory requirements can reach as much as 60% of the R&D budget (Abrahams 1991).

Another significant consequence of diverse regulatory requirements is the phenomenon of “drug lag”. Drug lag is the additional time it takes for a country to

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<sup>149</sup> Patent protection is a crucial factor for the research-based pharmaceutical industry. The discoveries made during the R&D process have to be legally protected in order to ensure that the industry continues to invest in R&D. Under the WTO TRIPS agreement patent protection is granted for a period of 20 years. Firms however usually seek patent protection when a new chemical compound has been identified; between that time and the introduction of a new drug to the market, intervenes a period of several years devoted to further research and development needed to transform the compound into a drug and to satisfy all the pre-clinical and clinical testing required to ensure the safety and efficacy of the new drug. As a result, the effective life of a patent is usually much shorter than 20 years.

approve a drug relative to another country, or its failure to ever approve a drug approved in another country (Schweitzer 1997). The issue was first raised in the United States by Wardell (1973; 1978) who compared approvals of new drugs in the US and the UK between 1960 and 1976, and concluded that US approvals lagged behind those in the UK and that the situation had become worse in the latter period. Other studies (Grabowski and Vernon 1977; Grabowski 1980) verified this drug lag in the United States. Moreover, more recent studies (Andersson 1992; Schweitzer 1997) have shown that drug lags exist in all countries, although variations exist depending on the exact nature of the regulatory framework of each country. The phenomenon of drug lag has important implications for public health because it means that new and potentially life-saving drugs are being introduced late in the market and some times perhaps not introduced at all (Katz 1993). Indeed, it is not unusual for patients to travel abroad to obtain these drugs or even smuggle them illegally (Jordan 1992). Of course, in these cases, patients acquire the drugs without adequate physician guidance, and often from countries with inadequate safety standards, risking side-effects or other complications. The problem of drug lag is particularly acute for people suffering from terminal and life-threatening diseases who do not have the luxury to wait for the entire drug approval process to be completed before they can have access to new, potentially life-saving drugs for their condition. The problem became particularly acute in the United States with AIDS patients, who in the 1980s conducted a concerted campaign to secure accelerated access to experimental drugs. In order to accommodate the particular medicinal needs of such patients, the FDA has made it possible to approve the use of drugs even before all phases of the clinical trials are completed. Recently the EU adopted similar legislation.

Apart from the potentially negative effects on innovation and the availability and quality of drugs, complicated and diverse national authorization regulations also affect public health by indirectly affecting the structure of the industry. At the domestic level Grabowski (1976) and Grabowski and Vernon (1977) have shown that innovation in the US following the 1962 regulation not only declined but also became concentrated in fewer firms. At the international level, increased R&D costs and

competitive pressures have led to a wave of M&A activity since the late 1980s which has led to higher concentration of the global pharmaceutical market, with the top ten firms now accounting for almost half of the world market (ABPI 2004)<sup>150</sup>. By increasing the cost of R&D and reducing the effective patent period, the diversity of national approval regulations reinforces the trend towards bigger and more international companies, as these alone are able to bear the costs of developing new drugs and launching them in multiple markets. A more concentrated market may lead to higher prices and less innovation as the top firms focus on more lucrative therapeutic markets with higher profit margins (Sarett 1974; Wall 1984). This leads to whole categories of diseases being neglected, leaving parts of the population in developed countries and entire populations in developing countries without adequate medicinal coverage, creating the phenomenon of “orphan drugs”.

Finally, regulatory diversity entails significant costs not only for companies and patients but for state agencies as well. Having a national regulatory agency requires significant resources. As Vogel (1998) reports, in 1993, before the creation of EMEA, EC’s twelve members employed between 2,000 and 2,500 full-time drug evaluation staff, in addition to approximately 1,000 expert consultants, at an annual cost of approximately \$300 million. This cost is borne by consumers through taxation and to some degree by the industry which pays licensing and registration fees. Apart from the obvious inefficiency in the use of public resources, the result has been to raise further the cost for companies, which have often avoided some smaller markets altogether (Orzack et al. 1992). Moreover, the higher prices that may result from increased R&D costs and reduced effective patent lives lead to increased costs for national welfare and health care budgets, as in most countries, at least a part of pharmaceutical expenses is covered by the national health care system.

### **6.3 Early international harmonization efforts**

Given the costs of national regulatory diversity and the consequent implications for public health it is not surprising that there have been various efforts at harmonizing pharmaceutical regulations and particularly drug approval regulations. The first

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<sup>150</sup> ABPI is the Association of British Pharmaceutical Industries.

international efforts at harmonization of pharmaceutical regulations took place in the context of the World Health Organization (WHO), a United Nations specialized agency set up in 1948 to address health issues. Within its broad mandate, the WHO has the institutional competence to deal with pharmaceutical issues and to “develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products”<sup>151</sup>. The rapid expansion of the industry in the post-war period and the resulting availability of a significant number of new medicines, coupled with the growing medicinal needs of an increasing number of developing countries following the decolonization process, led to an increasing interest in the international regulation of the pharmaceutical industry, particularly through the WHO apparatus (Cone 1983). Early proposals tended to emphasize the need for developing national laboratories to control pharmaceutical products. However, the lack of financial and technical resources in developing countries soon made the practical impossibility of implementing such measures apparent, and showed that international cooperation or regulation was a more promising avenue for action (Cone 1983). In 1975 the first concrete results occurred in the form of the “Certification Scheme on the Quality of Pharmaceutical products Moving in International Commerce” and the “Good Practices in the Manufacture and Quality Control of Drugs Act”. The Certification Scheme aimed at preventing the dumping of banned or flawed products in developing countries. This was achieved through a Certificate from the exporting country, at the request of the importing country, assuring that the medicines under consideration had been granted authorization for domestic sale in the exporting country and that they were manufactured in plants subject to regular inspections and in conformity with the WHO Good Manufacturing Practices Act.

The same year the World Health Assembly (WHO’s ruling body) requested the WHO to develop means of assisting Member States in formulating and implementing national drug policies for the selection of essential drugs, the appropriate procurement of quality drugs based on health needs, and the provision of education and training. In 1977 the WHO issued the first list of essential drugs

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<sup>151</sup> WHO Constitution article 2 (u).

(EDL), and in 1981, following intense lobbying from consumer groups (Chetley 1990; Abel-Smith 1994), formally established the Action Programme on Essential Drugs (APED). This more comprehensive approach to drugs' issues has become the dominant WHO strategy since the early 1980s, resulting in projects like the *Guidelines* for developing national drug policies. More specific proposals for an explicit system of international registration of drugs by an international inter-governmental evaluation agency were made in WHO meetings but never progressed (Cone 1983). Since the late 1980s the WHO's role in this issue area has diminished significantly, and international harmonization of technical requirements for the registration of pharmaceuticals has taken place in the context of the ICH. The WHO's work in the area of medicines today focuses on expanding access to essential medicines, particularly for low-income and disadvantaged populations and for the priority diseases of HIV/AIDS, TB, and malaria. In this context, the WHO provides expertise and technical assistance through various activities such as a system for regular exchange of information between Member States on the safety and efficacy of pharmaceutical products, or the Prequalification Programme set up in 2001, aiming to facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis<sup>152</sup>.

#### **6.4 International Conference on Harmonization**

In the late 1980s the dominant forum for the harmonization of drug approval procedures became the ICH. The ICH comprises the pharmaceutical regulatory authorities of the EU, US and Japan: the EC, the FDA and the Japanese ministry of Health, Labour and Welfare (MLHW), and the respective industry associations: the European Federation of Pharmaceutical Industries' Association (EFPIA), the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Japan Pharmaceutical Manufacturers Association (JPMA). The WHO, EFTA and Canada have observer status. The idea for the ICH originated in a 1988 meeting between Japan and the EU aiming to discuss ways to resolve differences in safety and efficacy requirements (Kidd 1997, p.185). This was one in a series of bilateral meetings on

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<sup>152</sup> See the WHO website, <http://www.who.int/medicines/en/>, accessed 16, 01, 2007.

harmonization between Europe, US and Japan that took place in the 1980s (Braithwaite and Drahos 2000; Abraham and Reed 2001). At the WHO International Conference of Drug Regulatory Authorities (ICDRA) in Paris in 1989, specific plans for action were decided, and soon afterwards the regulatory authorities proposed to the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) a joint harmonization initiative<sup>153</sup>. At a 1990 meeting hosted by EFPIA, the ICH started taking shape as plans for the first Conference were made, and the ICH Steering Committee (SC) was established. At the first SC meeting the terms of reference were agreed, and it was decided that the topics selected for harmonization would be divided into Safety, Quality and Efficacy to reflect the three criteria needed for approval and market authorization for new drugs<sup>154</sup>. It was also agreed that six-party Expert Working Groups (EWGs) should be established to discuss the scientific and technical aspects of harmonization topics<sup>155</sup>. The first ICH conference was held in Brussels in 1991 and over 1,000 participants attended. At this conference the first concrete harmonization results occurred, such as a “minimum data blueprint” guideline which defined control conditions for testing, a reduction of long-term toxicity tests to six months, and the abolition of the “Lethal Dose 50” toxicity test<sup>156</sup> (D’Arcy and Harron 1992). Perhaps the most important accomplishment of the meeting however, was the public demonstration from the three regulatory authorities that they were committed to the principle of harmonization and that this was just the beginning of an ongoing process (Jordan 1992). ICH2 took place in October 1993 in Orlando, Florida, with over 1,600 attendants. Progress was again made in the area of safety, and agreement was reached for issuing draft guidelines covering various aspects of Good Clinical Practices (D’Arcy and Harron 1994). In November 1995 a third conference attended by 2,400 delegates took place in Japan, where once again significant progress was made (Vogel 1998). The success of the conferences turned the ICH into a continuing harmonization process despite the fact that it was originally designed to be a six-year project (D’Arcy and Harron 1992, 1994; Vogel 1998). The

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<sup>153</sup> See the ICH website, <http://www.ich.org/cache/html/355-272-1.html>, accessed 17/01/2007.

<sup>154</sup> Ibid.

<sup>155</sup> Ibid.

<sup>156</sup> This was a very costly and ethically questionable toxicity test as it entailed increasing doses to laboratory animals until 50% of the animals died.

process has therefore continued to work and further conferences were held in Brussels in 1997, in San Diego in 2000 and in Osaka in 2003. The ICH has been very productive and by the end of 2006 it had completed over 50 guidelines,<sup>157</sup> while a number of new guidelines are at a development stage. A particularly important achievement of the ICH process has been the Common Technical Document (CDT) which provides a harmonized structure and format for new product applications. In 2000, during the San Diego conference, the Steering Committee issued a statement about the future of the ICH:

the ICH Steering Committee and other interested parties have agreed to continue in their commitment to pursue future harmonization activities. ICH has been successful in achieving harmonization, initially of technical guidelines and more recently on the format and content of registration applications. All parties agree that there is a need to maintain this harmonization.

(ICH Steering Committee 2000)<sup>158</sup>

## **6.5 ICH as a forum of transnational regulatory authority**

As was the case with the IASB, the first step in the analysis of ICH is to show that the ICH and the guidelines that it produces are indeed instances of transnational regulatory authority. For this purpose we shall use the three criteria outlined in chapter 3.

### **6.5.1 The decision-making power of non-state actors**

“ICH is a joint initiative involving both regulators and industry as equal partners in the scientific and technical discussions of the testing procedures which are required to ensure and assess the safety, quality and efficacy of medicines”<sup>159</sup>. This statement, taken from ICH’s own website, clearly demonstrates the relationship between state and non-state actors in the context of the ICH process: regulators (state authorities), view the industry (non-state participants), as partners with equal rights in the decision making process governing the procedures for the registration of medicines for human

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<sup>157</sup> Available from the ICH website, <http://www.ich.org/cache/compo/276-254-1.html>, accessed 18/01/2007.

<sup>158</sup> “Statement by the ICH Steering Committee on the Occasion of the Fifth International Conference on Harmonisation”, 9-11 November 2000, San Diego, available from the ICH website, <http://www.ich.org/cache/html/355-272-1.html>, accessed 18/01/2007.

<sup>159</sup> Available from the ICH website, <http://www.ich.org/cache/html/510-272-1.html>, accessed 17/01/2007.



use. The validity of this statement is confirmed by an examination of ICH's structure and mode of operation. The ICH comprises six parties, which were also its founding members: the three regulatory authorities and the three industry associations (national or regional) from the EU, Japan and the US respectively. This composition is reflected in the ICH Steering Committee, which is the organ that determines the policies and procedures of the ICH, selects topics for harmonization and monitors the progress of harmonization initiatives<sup>160</sup>. Each of the six parties holds two seats on the SC and their votes carry equal weight. The IFPMA which provides the Secretariat, also participates as a non-voting member as do the ICH Observers (WHO, Canada and EFTA).

The procedure towards adopting a new guideline involves five steps. The first step begins with the adoption of a Concept Paper for a new topic by the SC. The Concept Paper may be submitted by any one of the six SC members. A new or extended Expert Working Group comprising experts from the six parties is established and a Rapporteur prepares an initial draft of the guideline, based on the objectives of the Concept Paper and in consultation with the EWG. When, usually after a number of revisions of the draft guideline, the EWG reaches a consensus among all six parties, it signs the Experts Document which is submitted to the SC to request adoption under step 2 of the ICH process. Step 2 is reached when the SC agrees, based on the report of the EWG, that there is sufficient scientific consensus for the draft guideline to proceed to the next stage of regulatory consultation. All six parties need to give their consent for this decision (Step 2 adoption). In the third step the draft guideline becomes the subject of the normal regulatory consultation procedure of each of the three regulatory jurisdictions. After obtaining all consultation results, the original EWG is resumed, comprising representatives from the six parties and often from the Observers. If the previous Rapporteur came from the industry a new regulatory Rapporteur takes over, and the consultation process with the EWG resumes, resulting once consensus is reached, in what is called the step 4 Experts Document. Step 4 is reached when the SC members agree, based on the report of the Rapporteur, that there is sufficient scientific consensus in the EWG; its

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<sup>160</sup> Ibid.

endorsement is based on the signature of the three regulators, who affirm that the Guideline is recommended for adoption by the regulatory bodies of the three states/region. In the event that one or more parties from the industry have strong objections to the adoption of the guideline, the regulatory parties may agree that further consultation is needed and the EWG discussion may be resumed. The Step 4 Final Document is signed off by the SC regulatory parties as an ICH Harmonized Tripartite Guideline. The final step is regulatory implementation. This is carried out according to the national/regional procedures that apply to other regulatory guidelines and requirements in the three states/region<sup>161</sup>. Information on this regulatory action and the implementation dates are reported back to the SC and published on the ICH website.

As is evident from the above description, the first criterion of transnational regulatory authority is fully satisfied. First, the institutionally defined and acknowledged decision-making power of the non-state participants materializes in the distribution and weighting of votes in the SC, the decision-making organ of the ICH; in the SC both state and non-state participants share an equal number of votes with equal weight. This is particularly important because, while industry representatives also participate in equal terms in the EWGs, it is voting in the SC which is required for the adoption of any new guideline (Step 2 adoption). It is thus evident that non-states actors participate equally in the decision-making process over the substantive content of new rules, that is, the ICH guidelines. This institutional role is reinforced by the mode of operation of the organization, which requires consensus throughout the process of developing a new guideline, both in the EWGs and in the SC. Indeed, during both step 1 and step 3, if consensus among the EWG has not been reached, the SC does not proceed to the next step but may allow for an extension of the discussions in the EWG (provided there are assurances that consensus may be reached within a short time); alternatively it suspends or abandons the harmonization project, either entirely or in its current form and restarts the procedure from step 1 (this last option only in case of failure to agree during step 3)<sup>162</sup>. It is also worth

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<sup>161</sup> See the ICH website, <http://www.ich.org/cache/html/2830-272-1.html>, accessed 17/01/2007.

<sup>162</sup> Ibid.

noting that the same procedure is required for any revision of an existing guideline<sup>163</sup>, and that when update of an existing guideline is required, the approval of the SC, by consensus, is again required<sup>164</sup>.

#### 6.5.2 The legal Status of the ICH Guidelines

The product of the ICH harmonization process are guidelines “aimed at eliminating duplication in the development and registration process so that a single set of studies can be generated to demonstrate the quality, safety and efficacy of a new medicinal product”<sup>165</sup>. In accordance with this goal, the guidelines fall into four topics; the first three follow the legal requirements for the registration of new medicinal products in the ICH region, that is, safety, quality and efficacy, while a fourth topic has been added for multidisciplinary issues that do not fit exclusively into one of the other categories. These guidelines “represent agreed-upon scientific guidance for meeting technical requirements for registration”<sup>166</sup>. Each of the regulatory authorities implements the guidelines according to the national or regional procedures that apply for other similar regulatory guidelines. The exact legal nature of the guidelines, therefore, depends on the legal and regulatory framework of each region and/or state.

##### *6.5.2.1 The Legal status of the ICH guidelines in the European Union*

In Europe, the guidelines are submitted for endorsement to the Committee for Medicinal Products for Human Use (CHMP) once they have reached Step 2 of the ICH process<sup>167</sup>. The CHMP decides on the duration of the consultation period and the EMEA distributes the guidelines for comments. Following their endorsement at step 4 by the CHMP, the guidelines are published by the European Commission in Volume III of the Rules Governing Medicinal Products in the European Union. “Once adopted by the CHMP, ICH guidelines have the same status as other European scientific

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<sup>163</sup> See the ICH website, <http://www.ich.org/cache/html/2832-272-1.html>, accessed 20/01/2007.

<sup>164</sup> See the ICH website, <http://www.ich.org/cache/html/2833-272-1.html>, accessed 20/01/2007.

<sup>165</sup> Available from the ICH website, <http://www.ich.org/cache/html/2834-272-1.html>, accessed 17/01/2007.

<sup>166</sup> Ibid.

<sup>167</sup> The CHMP replaced the Committee for Proprietary Medicinal Products (CPMP) in 2004. Much like the CPMP it comprises members from the regulatory authorities of the member states. The CHMP is the technical body responsible for evaluating new drug applications under EMEA’s marketing authorization procedure.

guidelines and replace existing guidelines on the subjects covered” (EMEA 2005, p.8)<sup>168</sup>. The Scientific Guidelines contained in Volume III, are part of a series of guidelines that support the basic legislation for pharmaceuticals and are published in different volumes of the Rules Governing Medicinal Products in the European Union (EMEA 2005). Under European law:

a guideline is a Community document, which is either referred to in the legislative framework as intended to fulfil a legal obligation laid down in the Community pharmaceutical legislation or considered to provide advice ... on the best or most appropriate way to fulfil an obligation laid down in the community pharmaceutical legislation.

(EMEA 2005, p.3)

The legal status of different guidelines may vary, but generally “guidelines do not have legal force and the definitive legal requirements are those outlined in the relevant Community legislative framework (Directives, Regulations, Decisions, etc.) as well as appropriate national rules. However, guidelines are to be considered as a harmonised Community position” (EMEA 2005, p.3).

From the above, it becomes evident that the legal status of the guidelines is somewhat unclear: on the one hand it is explicitly stated that guidelines have no legal force in terms of constituting legal requirements; on the other hand however, they clearly constitute part of European regulation and are therefore included in the European medicines rulebook. Moreover, as stated above, they are often referred to in legislation with the intent that these guidelines fulfil the legal obligations laid down in such legislation. Indeed, for the Scientific Guidelines, it is expressly stated in Annex I of Directive 2001/83/EC, which outlines all the technical requirements for registration of new medicinal products for human use, that “in assembling the dossier for application for marketing authorization, applicants shall take into account the Community guidelines relating to the quality, safety and efficacy of medicinal products published by the Commission”<sup>169</sup>. Directive 2005/28/EC on Clinical Trials, states in even stronger terms that “it is necessary that sponsors, investigators and other participants take into account the scientific guidelines relating to the quality,

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<sup>168</sup> “Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework”, EMEA 2005.

<sup>169</sup> Directive 2001/83/EC, Official Journal of the European Union, Annex I, Introduction, L.311/101.

safety and efficacy of medicinal products for human use, as agreed upon by the CHMP and published by the Agency”<sup>170</sup>. Moreover, according to EMEA, when applicants cannot comply with the requirements of a new guideline within the given timeframe, they have to justify their departure from the guideline: “the applicant's justification will then be considered on a case-by-case basis by the relevant competent regulatory authorities” (EMA 2005, p.12). This means that while applicants are not legally obliged to follow the guidelines, they are legally obliged to take them into account to such a degree that deviations from the guidelines have to be justified to the regulatory authorities which will evaluate them. So in practical terms the guidelines do confer obligations on the applicants.

In addition, several ICH guidelines, have assumed a formal legal binding status, for instance the MedDRA, the Medical Dictionary for Regulatory Activities Terminology, an international medical dictionary for the various phases of drug development, developed by the ICH. The use of MedDRA is mandatory in the EU since January 2002 for single case reports of adverse drug reactions (ADRs) after market authorization, and since January 2003 for regulatory reporting of all ADRs<sup>171</sup>. Moreover, the CDT, a uniform format of application for registration of new drugs which achieved ICH step 4 approval in 2000, has also become mandatory for all applications of new medicinal products for human use with Directive 2003/63/EC. Finally, the ICH Good Clinical Practice guideline (E6), was agreed in 1996 and in 1997 became mandatory in the EU for registration studies on unlicensed medicinal products. The more recent Directives on Clinical Trials 2001/20/EC and 2005/28/EC explicitly refer to this guideline and state that it should be taken into account when conducting clinical trials.

#### *6.5.2.2 The legal status of the ICH guidelines in the United States*

In the United States, the ICH guidelines are adopted as *Guidance* documents. Once step 2 has been reached, the FDA publishes a notice with the full text of the guidance

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<sup>170</sup> Directive 2005/28/EC, Official Journal of the European Union, L. 91/14, (9).

<sup>171</sup> Volume 9 – “Pharmacovigilance, Medicinal Products For Human Use And Veterinary Medicinal Products”, The Rules Governing Medicinal Products in the European Union, available from the EC website, [http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-9/pdf/vol9\\_10-2004.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-9/pdf/vol9_10-2004.pdf), accessed, 22/01/2007.

in the Federal Register with a date for receipt of written comment. Following step 4 approval, the guidances are available for use on the date they are published on the Federal Register<sup>172</sup>. According to the FDA,

Guidance documents represent the Agency's current thinking on a particular subject. These documents are prepared for FDA review staff and applicants/sponsors to provide guidelines to the processing, content, and evaluation/approval of applications and also to the design, production, manufacturing, and testing of regulated products. They also establish policies intended to achieve consistency in the Agency's regulatory approach and establish inspection and enforcement procedures. Because guidances are not regulations or laws, they are not enforceable, either through administrative actions or through the courts<sup>173</sup>.

From the last statement in FDA's comment, it seems that in the United States the ICH guidelines do not have formal legal status. However, things as was the case in the EU, are more complex than that. First, the characterization of the legal status of its own guidances by the FDA is not by itself adequate: "courts have held consistently that the label applied by an agency to a given rule is not dispositive of whether that rule is legislative ... or merely interpretive ..., accordingly, FDA's characterization of ICH Guidelines is not dispositive of their legal status" (Booth 1997, pp. 241-215). Moreover, as was briefly mentioned previously, a guidance although entailing no formal legal obligations, may create obligations as a practical matter:

a court might conclude, therefore, that the Guidelines were legislative after all. This is particularly true with regards to applications for approval, especially when the affected parties reasonably believe that failure to comply will produce denial of an application. Because it would be reasonable to believe that failure to meet an ICH Guideline's voluntary standard would result in failure to win approval for a new drug, it could be concluded that the ICH Guidelines are legislative rules subject to notice-and-comment rulemaking.

(Booth 1997, p.52)

Such a view is reinforced when we take into account instances of particularly strong FDA endorsement of ICH guidelines, as is the case with the use of the CTD format which the FDA strongly recommends to potential applicants (Cone 2003)<sup>174</sup>, or the

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<sup>172</sup> See the ICH website, <http://www.ich.org/cache/htmal/250-272-1.html>, accessed 22/01/2007.

<sup>173</sup> Available from the FDA website, [http://www.fda.gov/cder/regulatory/applications/ind\\_page\\_1.htm](http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm), accessed 22/01/2007.

<sup>174</sup> "Summary Report, Sixth International Conference on Harmonisation, New Horizons and Future Challenges", 13-15 November 2003, Osaka, Japan.

design of the Adverse Event Reporting System (AERS), aiming to support FDA's post-marketing safety surveillance program, according to the safety reporting guidance (ICH E2B) and its codification based on the MedDRA<sup>175</sup>. This also seems to apply to FDA employees who although not legally bound by the guidances, "may depart from guidance documents only with appropriate justification and supervisory concurrence"<sup>176</sup>. This binding nature of the guidelines, as an issue of actual practice, is reinforced by the fact that the consultation process does not afford an adequate opportunity for comment given the technical nature of the issues, the brief comment period, and the advanced state of the draft guidelines (Goldman 1994), all of which serve to practically bind interested parties such as consumers and manufacturers not participating in the ICH process to the guidelines. These considerations have led some legal experts to argue that "the ICH Guidelines should be treated as legislative rules" (Booth 1997 p.217).

#### *6.5.2.3 The legal status of the ICH guidelines in Japan*

In Japan, when step 2 consensus has been reached, the ICH text is translated into Japanese. Subsequently the Pharmaceutical and Medical Safety Bureau (PMSB) issues a *Notification* for consultation with a deadline for comments. When step 4 is reached, the notification is issued with an implementation date<sup>177</sup>. Notifications can be issued by the Director General of the Pharmaceutical and Food Safety Bureau (PFSB) or by the directors of the Divisions in the Ministry of Health, Labor, and Welfare, and together with ministerial ordinances and notices are prepared in order to enforce and manage the basic laws that govern the pharmaceutical industry<sup>178</sup>. Generally, ordinances are statutory orders which relate to civic duties and rights, while notifications and circulars are part of administrative regulation not concerning civil rights and duties (Slingsby et al. 2004, p.246). All these instruments together form the body of administrative legislation, which has relatively less legal binding

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<sup>175</sup> Available from the FDA website, <http://www.fda.gov/cder/aers/default.htm>, accessed 22/01/2007.

<sup>176</sup> Code of Federal Regulations, 21, Section 10.115, Good Guidance Practices, FDA, Federal Register: September 19, 2000 (Volume 65, Number 182).

<sup>177</sup> See the ICH website, <http://www.ich.org/cache/htmal/250-272-1.html>, accessed 22/01/2007.

<sup>178</sup> "Pharmaceutical Administration and Regulations in Japan", JPMA 2006, available from the JPMA website, <http://www.jpma.or.jp/english/parj/0607.html>, accessed 23/01/2007.

power than laws but “significantly more binding power than guidelines published by academic societies or professional organizations such as the Japan Medical Association” (Slingsby et al. 2004, p.249).

In addition to these administrative guidelines, as was the case in Europe, many guidelines have acquired formal legal binding force. Following the adoption of the ICH guideline on GCP in 1996, the MHLW issued an Ordinance on Standards for Implementation of Clinical Studies on Drugs (GCP) based on the ICH guideline<sup>179</sup>. Moreover, a MHLW notification issued in August 1998, also based on ICH guidelines, expanded the acceptance of foreign clinical test data for the approval of new pharmaceuticals<sup>180</sup>. Further, on the basis of agreements at the ICH concerning periodic safety update report (PSUR) systems, a new “periodic safety report system” was enacted into law at the time of the revision of the Pharmaceutical Affairs Law in April 1997<sup>181</sup>. Moreover, since March 2000, it has been possible to use MedDRA for clinical trial data, re-examination and re-evaluation data and package inserts, while from October 27, 2003, it became obligatory to use MedDRA in individual case safety reports<sup>182</sup>. Two notifications in 2001 (No. 899 and No. 663) introduced the CTD format for applications, which became obligatory for new products in applications filed on or after July 1, 2003.

#### *6.5.2.4 The legal authority of the ICH guidelines*

Given the evidence presented above, it is clear that the ICH guidelines do have an authoritative status in the sense described in chapter 3, and therefore satisfy the second criterion we set at the beginning of this chapter for transnational regulatory authority. First, as was described above, several of the ICH guidelines have become legally binding in EU and in Japan. As far as these guidelines are concerned, the regulatory authority of the ICH is clearly established. This however does not mean that the remainder of the guidelines are not authoritative. As we saw above, the guidelines are adopted by the regulatory authorities of EU, US and Japan. This means

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<sup>179</sup> MHW Ordinance No. 28 dated March 27, 1997.

<sup>180</sup> “Second Joint Status Report on the U.S.-Japan enhanced Initiative on Deregulation and Competition Policy”, Ministry of Foreign Affairs, Tokyo, 1999.

<sup>181</sup> “Pharmaceutical Administration and Regulations in Japan”, JPMA 2006.

<sup>182</sup> Ibid.

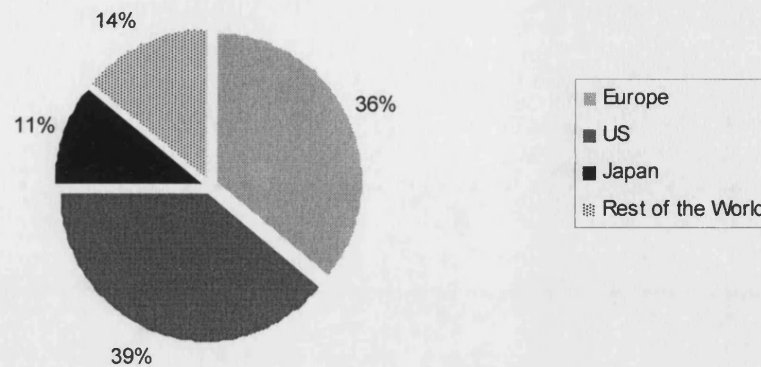


that these guidelines have become part of the regulatory infrastructure of these states/region and are therefore part of the body of their administrative and/or regulatory law. Indeed, in all three jurisdictions these guidelines have been added to the government rulebook for medicinal product registration and approval. They enjoy the same status as other guidelines adopted through the respective national regulatory procedures and have often replaced such national regulations. Moreover, often these guidelines enjoy a more binding status than is the case with usual guidelines (for example CDT in the US where the FDA “strongly recommends” its use, or the ordinances used for the adoption of CGP in Japan). In addition, their legal status is not uniform in all three areas; guidelines in Japan for example, can take a variety of formats, some more authoritative than others, and all “significantly more authoritative” than professional or academic guidelines. Finally, as was argued above, the explicit references to these guidelines in various pieces of basic legislation and the necessity to justify and receive judgment for deviating from these guidelines, point to a clear legal obligation on the private sector. Even if not obliged to adopt the ICH guidelines, companies are nonetheless *legally obliged* to take them into account and justify their decision when deviating from them. All these characteristics clearly demonstrate the authoritativeness of the ICH guidelines; indeed, it is these characteristics which, as we saw, have led legal experts to argue that they should be treated as legislative rules. This is not intended to be a legal treatise on the binding nature of governmental soft law instruments such as regulatory guidelines and standards. The fact is however, that the ICH guidelines have become national/regional regulations, and that they enjoy public regulatory authority of the nature that no other voluntary, non-state governance instrument can enjoy.

#### 6.5.3 The global authority of the ICH Guidelines

As we saw above, the three jurisdictions participating in the ICH have adopted over 50 ICH guidelines harmonizing a substantial part of their pharmaceutical regulatory framework. Relying solely on this fact it is beyond doubt that the ICH has a truly global scope given the dominant position of these three states/region in the global pharmaceutical industry. Between them these three players account for more than 85% of world pharmaceuticals’ production (graph 6.1).

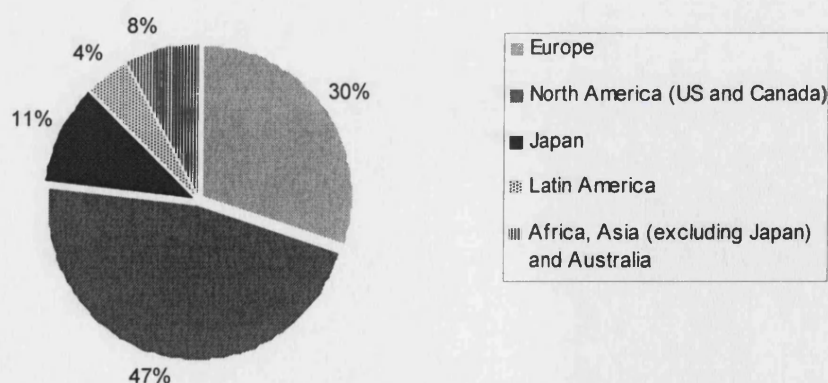
**Graph 6.1 Breakdown of World Pharmaceutical Production**



Source: EFPIA 2006

Moreover, the average per capita spending on pharmaceuticals in high-income countries is 100 times higher than in low-income countries: about US\$ 400 compared with US\$ 4 (WHO 2004, p. 3). As a result, according to WHO (2004), 15% of the world's population consumes over 90% of the world's production of pharmaceuticals by value. It is no surprise therefore that the "triad" accounts for 88% of global sales (graph 6.2).

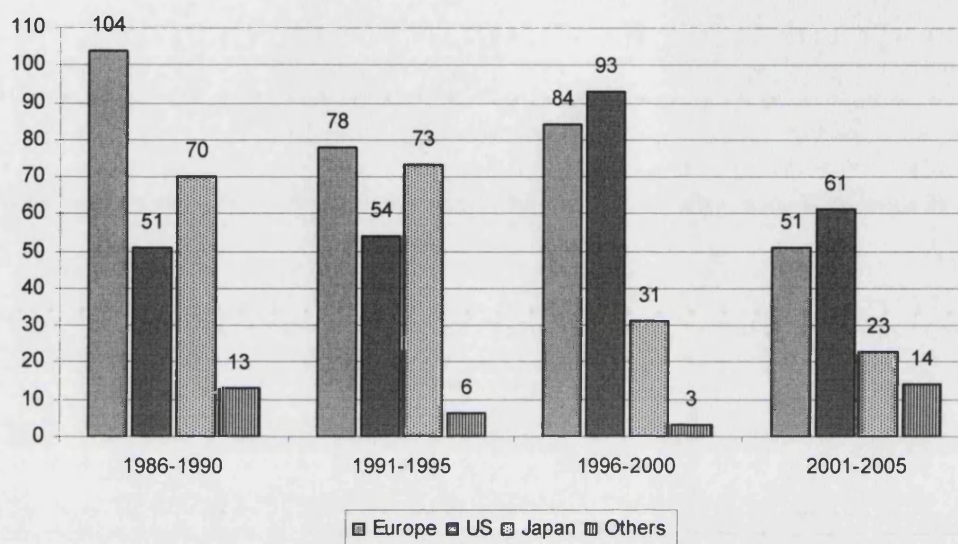
**Graph 6.2 Breakdown of World Pharmaceutical Sales**



Source: EFPIA 2006

Concentration of R&D activity in these regions is equally high. Over 90% of new chemical and biological substances are currently introduced in these markets.

**Graph 6.3 New Chemical or Biological Entities 1986-2005**



Source: EFPIA 2006

Given the progress of harmonization among these dominant players it is not surprising that several of the ICH guidelines have also been adopted by Canada and the EFTA countries which are observers in the ICH process (Abraham and Reed 2001). The adoption of ICH guidelines is also creating a de facto harmonization in many developing and less developed countries, whose markets are dominated by the major transnational pharmaceutical companies. As Vogel has noted “in light of the fact that virtually all nations have pharmaceutical industries dominated by American, European or Japanese firms, ICH guidelines are likely to become de facto international standards” (Vogel 1998, p.13). This de facto harmonization in developing countries is emerging not only due to the practices of transnational pharmaceutical companies, but increasingly also due to the practices of new pharmaceutical companies from large emerging markets (e.g. India) trying to establish themselves in the international pharmaceutical market. The appeal of gaining access to the large pharmaceutical markets of Europe, US and Japan often

prompts these companies to adopt the ICH guidelines as a matter of strategy (WHO 2002).

## **6.6 Summary and conclusions**

Differences in the national registration requirements for new drugs for human use create significant costs and delays to the introduction of new medicines in the market. Apart from the negative economic consequences for companies and governments, this situation also raises a public health issue, when new and potentially life-saving medicines cannot reach the market promptly and at a reasonable price. This dimension of public health risk makes it all the more surprising to discover that a transnational non-state organization is responsible for the harmonization of these divergent national registration requirements. From the discussion above, it is clear that the ICH satisfies the three criteria of transnational regulatory authority. Private sector actors share the same number of votes, with equal weight, at the decision-making organ of the ICH, and their consensus is required before any new guideline is adopted or any old guideline is amended or abandoned. The guidelines produced by the ICH are formally incorporated in the regulatory infrastructure of the three jurisdictions participating in the ICH, and enjoy a legal status equal with other similar national regulatory instruments. Some of the guidelines have become legally mandatory, while even when this is not the case, the guidelines have beyond any doubt a binding effect on the behaviour of pharmaceutical companies which are legally obliged to take them into account and justify any deviations from them. Finally, the fact that they have been adopted by the three states/region participating in the ICH is enough to establish their global scope, although this claim has been further strengthened by the adoption of some of the guidelines by most of the remaining developed markets (Canada, EFTA), and by a growing voluntary adoption in developing countries. The ICH clearly enjoys transnational regulatory authority and has already become the global forum for setting guidelines regarding the technical requirements for marketing approval of new medicines for human use.

## **Chapter 7**

### **Explaining ICH's transnational regulatory authority**

#### **7.1 Introduction**

Having established ICH's claim to transnational regulatory authority, we are now able to use the propositions of our theoretical framework to provide an explanation for ICH's emergence as the forum for harmonizing technical guidelines for the approval and registration of new medicines. Based on the available material, our analysis will demonstrate that in accordance with proposition (1) the creation of the ICH is the result of a regulatory strategy agreed by the three national/regional regulators, which aimed to satisfy the interests of their domestic research-based pharmaceutical industry. In line with propositions (2a) and (2b), the regulators of all three jurisdictions decided to address the regulatory diversity issue in a transnational organization that satisfied both institutionally and in the way of its agenda the industry's needs, while reducing with its exclusive and technically-based structure, the social visibility of the harmonization process thereby, minimizing the risk of incurring potentially significant political costs.

#### **7.2 Regulators' dilemmas**

As was the case with the IASB, the analysis of this case study has to begin with an examination of domestic regulatory politics. We first need to comprehend the regulators' dilemmas before we are able to understand why they opted to resolve them through the means of transnational regulatory authority.

##### **7.2.1 European pharmaceutical harmonization: integration vs. national control**

European states have traditionally had distinct regulatory frameworks concerning the pharmaceutical sector (Spivey et al. 1992). In terms of drug approval procedures, this is due to cultural factors and different medicinal, healing and even religious traditions (Burstall 1991). These factors have affected the assessment of regulators about the acceptable balance between the potential risks and benefits of approving a new medicine, and have therefore often dictated divergent regulatory requirements.

Consequently, in their mission to protect public health, European regulators have been unwilling to surrender control over their national regulatory policies. Beyond public health considerations, tight national control over pharmaceutical regulation is also due to a large extent, to the fact that drug approval regulation is part of a wider pharmaceutical regulatory mechanism, which also governs medicines' prices, pharmaceutical industries' profits and R&D subsidies and thus affects significantly governments' health care budgets (Vogel 1998). This intensive regulatory intervention in turn, is because regulation of the pharmaceutical sector is closely related to wider national health care and welfare policies. This has been particularly important for European states, which boast the most extensive social welfare systems (Mossialos and Le Grand 1999).

European efforts to reduce regulatory diversity began as early as 1963 when the European Commission (EC) called a meeting of all interested parties to discuss the standardization of pharmaceutical laws (Orzack et al. 1992). Despite evident disagreements among different interest groups in this first meeting, the EC went on in 1964 to propose the standardization of methods for carrying out tests on drugs and in January 1965 Directive 65/65/EEC was adopted. This first pharmaceutical directive spelled out the criteria of safety, quality and efficacy as preconditions for authorizing new drugs. Moreover, it required that submissions of medicinal products to national authorities were prepared and signed by experts and required member states to approve standards for marketing applications. In 1975, the EEC adopted two directives<sup>183</sup> that identified the types of data that governments should receive from manufacturers before issuing a license for a drug's sale and distribution, such as chemical, pharmaceutical, toxicological and clinical data (Orzack et al. 1992).

A major change in the European regulatory framework also came about in 1975 when the EC established the Committee for Proprietary Medicinal Products (CPMP) with members from the regulatory authorities of the member states and set up a multi-state procedure for the approval of new drugs. The role of the CPMP was advisory, giving its opinion on approval of marketing applications to national agencies, which however, the latter could disregard (Orzack et al. 1992). Following

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<sup>183</sup> Directive 75/318/EEC and Directive 75/319/EEC.

authorization by a national authority, the multi-state procedure allowed, the sending of concurrent applications to at least five other members, which would have to take into account the initial authorization by the first member state. They could only reject the application by submitting a “reasoned objection” to the CPMP, which would then issue its opinion, which was again not binding. The next significant step in the European harmonization programme came in 1987 with the “concertation procedure”, which concerned applications for biotechnology and high-technology products for which the EC thought it would be easier to achieve harmonization, given that member states did not yet have standards for such products (Vogel 1998). Under this centralized procedure, the initial evaluation of the application would be undertaken by the CPMP, which would then issue a non-binding opinion.

The concertation procedure was an ultimate effort to increase the efficiency of the European regulatory mechanism, a need that became increasingly pressing in view of the 1992 deadline. One of the objectives of the 1992 project was “to improve the welfare of European consumers by eliminating duplicative and unnecessarily restrictive national rules and regulations”, while at the same time “lowering the costs of national regulatory administration occasioned by the need to maintain fifteen regulatory bureaucracies” (Vogel 1998, p.18). These considerations had become particularly important in the late 1980s, as there was widespread frustration and disappointment with the Community regulatory interventions aimed at harmonizing the different national registration procedures (Orzack et al. 1992). The mutual recognition procedure set up by the European Commission had not achieved the desired results (Burstall 1991). Allowing national authorities to retain final control over the approval process, proved to be the weak spot of the mechanism. The process did not work as envisioned, as each state effectively conducted its own assessment and raised its own objections; according to the CPMP Chair: “in practice...there have been objections with regard to every case dealt with under the Multi-State procedure...on the whole Member States do not yet accept each other’s assessments” (Teijgeler in Orzack et al. 1992, p. 856).

This situation had negative consequences for European companies, regulators and patients. First, it meant that it took a long time to introduce new drugs in



European markets. The multi-state procedure set time limits: a state authority had four months to evaluate a dossier already approved by another state. However, given the insistence of national regulators on examining each application without consideration of the other states' approval, these limits were regularly violated. In many countries, the process lasted two or three years, sometimes even more (Vogel 1998). This delay resulted in significant costs for the companies, which in turn contributed to higher prices for medicines, an issue increasingly important for European governments. Public expenditure accounted for approximately 58% of all pharmaceutical expenditure in 1990<sup>184</sup>, while total per capita expenditure on pharmaceuticals more than doubled between 1980 and 1990 and continued to increase significantly throughout the 1990s (table 7.1).

**Table 7.1 Total per Capita Expenditure on Pharmaceuticals (\$ PPPs\*)**

	1980	1985	1990	1995	2000**
Belgium	100	139	193	309	328c
Denmark	50	77	109	171	223
Finland	54	82	122	199	259
France	-	-	254	346	473
Germany	110	172	228	269	312b
Greece	65	83	104	195	258
Ireland	50	58	88	126	187
Italy	-	-	280	311	459d
Luxembourg	88	132	223	255	307a
Netherlands	53	83	128	196	264
Portugal	53	97	152	266	316b
Spain	69	93	145	210	246c
Sweden	55	82	120	202	227c
United Kingdom	57	94	131	201	236c

Source: Mossialos et al. 2004, p.4

\*Purchasing Power Parities

\*\* Or latest available data: a1999, b1998, c1997, d2001.

Most European governments had to support extensive welfare and health care programmes, and in the late 1980s and early 1990s many European countries underwent significant health care reforms, focusing mainly on the overall efficiency

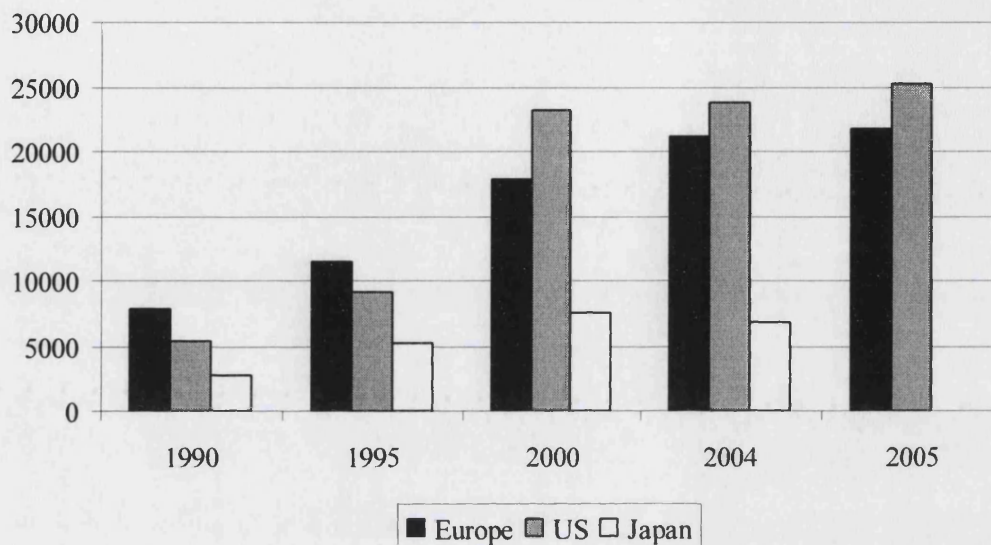
<sup>184</sup> Calculated from data in Mossialos et al. (2004, p.4).



of the system and the containment of costs “because of concerns about whether sufficient funds can be allocated to meet the demand for health care” (Wendt and Abel-Smith 1995, p.1). In many countries this meant new controls on pharmaceutical prices; Germany introduced price controls for pharmaceuticals in 1989 for the first time, while in France a new mechanism whereby prices were determined by the Ministry of Health was also put in place in the late 1980s (Le pen 1995). In this context, many governments started complaining about the effectiveness of the CPMP mechanism, while both the industry and consumers’ associations also lamented the existing situation (Orzack et al. 1992).

In addition, the regulatory diversity within Europe created problems for the competitiveness of the European pharmaceutical industry. The pharmaceutical industry has traditionally been one of the most successful European industries. In 1990 it contributed, at a European level, a trade surplus of over € 7 billion (EFPIA 2006). Traditionally, European companies invested heavily in R&D and held the leading position in the discovery of new chemical substances (NCEs). Since the 1970s however a relative decline has been increasingly observed compared to both the US and Japan (Poggiolini in D’Arcy and Harron 1992). During the 1980s, this decline became more obvious as Japan emerged as a significant global competitor, while in the 1990s US companies started to take the lead in R&D expenditure (graph 7.1). The European industry began complaining about the difficulty of competing with the US and Japanese pharmaceutical companies which had large domestic markets and did not have to make new drug applications to twelve regulatory authorities (Marsh 1990). The Cecchini Report on the single market, published by the European Commission in 1988, acknowledged the difficulties that the different national regulatory requirements presented for the industry. It was estimated that lost revenues for companies that had to wait beyond the 4-month period ranged between 100-175 million Ecus, while multiple registration requirements meant additional staff for companies at a cost of between 40 and 55 million Ecus (Cecchini Report 1988, p. 67).

**Graph 7.1 Pharmaceutical R&D Expenditure in Europe, US and Japan**  
(€ millions, 2006 exchange rates) 1990-2005\*



Source: EFPIA 2006

\* Estimates (Japan: N.A.)

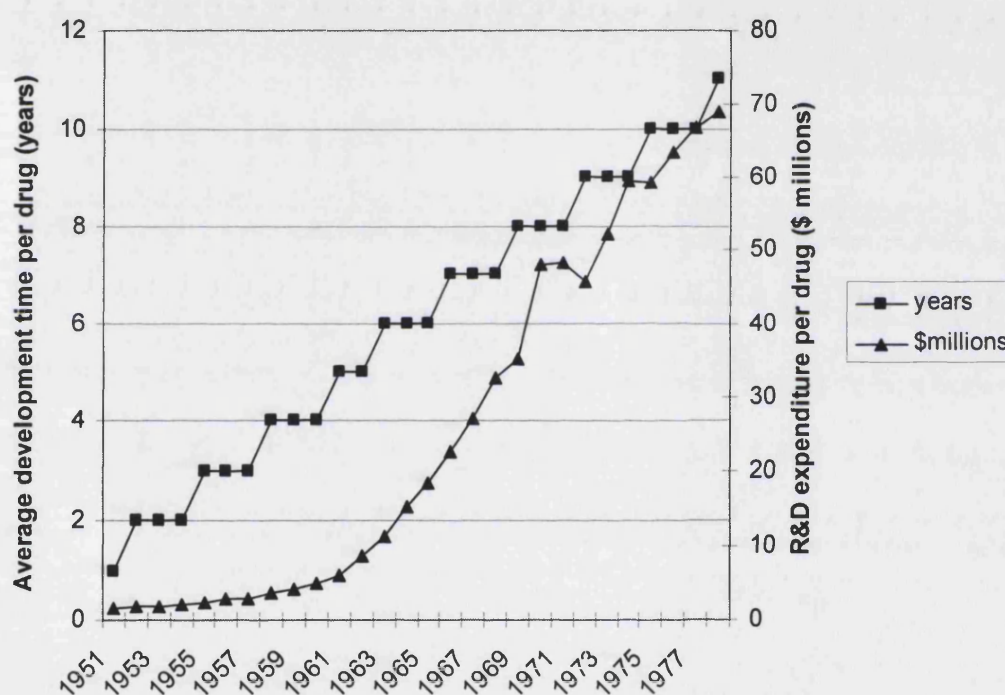
The European regulators faced a significant dilemma. On the one hand, they had to handle the politically sensitive issue of drug approval regulations and therefore jealously guarded their ability to control nationally the approval and registration procedures for new drugs, as a potential approval of a harmful substance could have dire political consequences. On the other hand, in the long term, their insistence on national control potentially undermined the quality of health care as it deprived European consumers and patients of potentially health improving and life-saving drugs for many years. Moreover, this attitude undermined governments' budgets by contributing to higher prices for pharmaceuticals. This was particularly important for European regulators who were operating in the context of extensive public welfare and health care systems. Finally, the situation create significant problems for the industry in terms of competitiveness and profitability.

#### 7.2.2 The FDA's dilemma: safety vs. innovation

The introduction of the 1962 Amendments in the United States had a significant impact on the US pharmaceutical sector. The 1962 Amendments increased

significantly the amount of testing that manufacturers had to conduct in order to accumulate “substantive evidence” to satisfy the safety and efficacy requirements of the FDA. These requirements increased substantially both the amount of time and the costs required for the development of new drugs (graph 7.2). Grabowski et al. (1976) estimated that the 1962 amendments roughly doubled the cost per NCE in the US. This increase in R&D time and costs proved to have significant consequences for the industry and consequently for the public and the FDA itself.

**Graph 7.2 Average Development Period for NCE Drugs Introduced Annually in the US Market and R&D Expenditures per Drug Unit (1951-1978)**



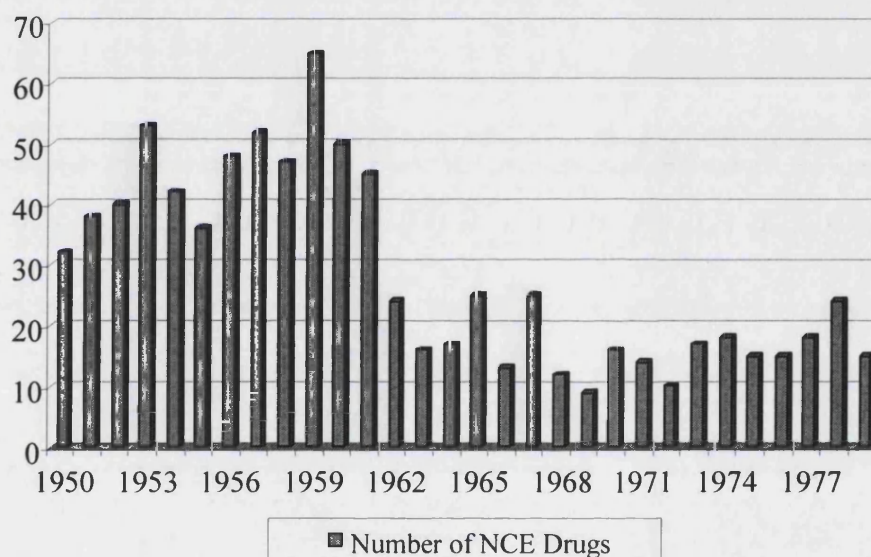
Source: Adapted from Statman 1983, p.28-29

- R&D expenditures for human-use drugs /moving average number of NCE drugs introduced by members of the Pharmaceutical Manufacturers Association (PMA).

The new regulatory environment, while undoubtedly contributing towards the protection of public health by establishing tougher drug safety standards, seemed to undermine public health in other ways. A significant consequence of the new regulations was the slowdown of pharmaceutical innovation, as R&D costs increased significantly and investment in new drugs became less economically attractive. As is

evident from graph 7.3 the number of NCE drugs introduced in the US market fell markedly after 1962. The average annual number of new drug introductions in the 12 years before 1962 was 45.6, while for the years from 1962 to 1979 this number fell to 16.8. According to Peltzman (1974), this slowdown of innovation was the direct and exclusive result of the 1962 Amendments. This assertion was contested by the FDA, whose Commissioner argued in the early 1970s, that this slowdown was mainly due to two other factors: the decrease in new drugs with little or no therapeutic gain and the fact that scientific knowledge had reached a “plateau” which made new breakthroughs increasingly difficult (Schmidt 1974).

**Graph 7.3 Number of NCE Drugs Introduced Annually in the US (1950-1979)**



Source: Adapted from Statman 1983, p.28

As far as the first point is concerned, significant disagreements existed among experts over the validity of this claim (Peltzman 1974), as well as over the ranking used by the FDA to characterize effective and ineffective drugs (Grabowski 1976). The FDA argued the second point based on the fact that innovation seemed to have declined at the time in other developed countries as well. However, this was not an entirely convincing argument because prior to the 1960s other countries had little or no regulation at all (Grabowski 1976). The introduction of new regulatory measures in these countries, although less stringent than the US regulations, had consequences for



their rate of innovation as well. Studies have found that the regulations introduced in the UK in the early 1970s added an extra two years or more to development time and significant costs, leading to a reduction in innovation (Hartley and Maynard 1982).

The reduced number of new drugs introduced in the United States was not only due to a slowdown of domestic innovation. The regulatory stance of the FDA raised costs not only for American companies, but also for foreign multinationals, which had to incur higher costs and longer approval periods for the drugs they wanted to either export to, or manufacture in the US market. The FDA traditionally did not accept foreign clinical data and required drugs developed abroad, even by American companies, to undergo substantial duplicative testing in the United States before granting them a marketing approval. This was justified on the grounds of FDA's inability to monitor data collected by foreign regulators in the same way that it monitored tests conducted in the United States (Jordan 1992). This resulted in significant delays in the introduction of foreign-discovered drugs into the United States, even when these represented significant therapeutic advances (Jordan 1992). This "drug-lag" problem came to be one of the most significant problems and a source of continued criticism for the FDA (Grabowski 1976).

Critique over the issue of drug-lag increased during the 1980s and the FDA came increasingly under pressure from patients, the Congress, and the government to increase the efficiency and effectiveness of its regulations. FDA approval times were becoming increasingly longer, from an average of two years in the 1970s to an average of three years in the 1980s, far above the statutory limit of 180 days (Gladwell 1991). Comparative studies revealed that the FDA approved drugs that were considered "therapeutically important", as much as five years after these drugs had been approved in the UK, while the NDA process was found to be approximately one year longer than comparable processes in Europe and Japan (Jordan 1992). As a result of this lag, most US companies were introducing their new drugs first into foreign markets. Of the 135 new drugs approved by the FDA during the period 1984 to 1989, 106 were first approved abroad (OTA 1991).

Under pressure, the FDA, much like the SEC in the case of accounting diversity, first sought to address the problem through unilateral action. In 1982, the

FDA Commissioner announced that in certain circumstances the FDA would approve new drugs solely on the basis of foreign data (Wall 1984). A new regulation promulgated in 1985 embedded this promise into the FDA's drug approval procedures and following this change, the FDA approved drugs based on a mix of both foreign and domestic data, and occasionally solely on foreign data (Kanusky 1994). Things did not change significantly however as the acceptance of foreign data occurred on a case-by-case basis which diminished the value of the new policy (Jordan 1992). Consequently, instead of abating, the drug-lag issue reached high levels of publicity when AIDS patients organized a concerted campaign, publicly criticizing the FDA's procedures and requesting shorter approval times for AIDS treatments. The public confrontation reached a climax when, in October 1988, AIDS protesters shut down the FDA headquarters (Jordan 1992). Under pressure, the FDA was forced to change part of its regulatory framework to accommodate the needs of these patients (Dillman 1991; Lindemann 1994). By that time however, concern over the drug-lag issue had reached the higher echelons of the administration. In November 1991, only a week after the first ICH conference, the Secretary of Health and Human Services Dr. Sullivan, announced a comprehensive reform of the FDA procedures in order to achieve shorter approval times for new drugs (Leary 1991).

This reform aimed at changing the way the FDA operated, since there was a belief that the drug-lag issue was at least partly the result of systemic institutional factors embodied in FDA's mission and structure. According to the critics, legislation was designed with a negative image of the industry in mind, and the FDA personnel perceived themselves as the protectors of the public against the malevolent firms that wanted to defraud it (Brozen in Grabowski 1976). This negative legislative mission of the FDA, was reinforced by the fact that FDA personnel faced adverse motives to release new drugs, as successful drugs' approval does not draw headlines whereas failure of a drug becomes a major theme; external signals such as congressional hearings for issues regarding approved drugs' safety reinforced this view (Grabowski 1976; Jordan 1992). As a result, FDA personnel were characterized by a bias towards withholding new, potentially valuable drugs from the market (Jordan 1992). This

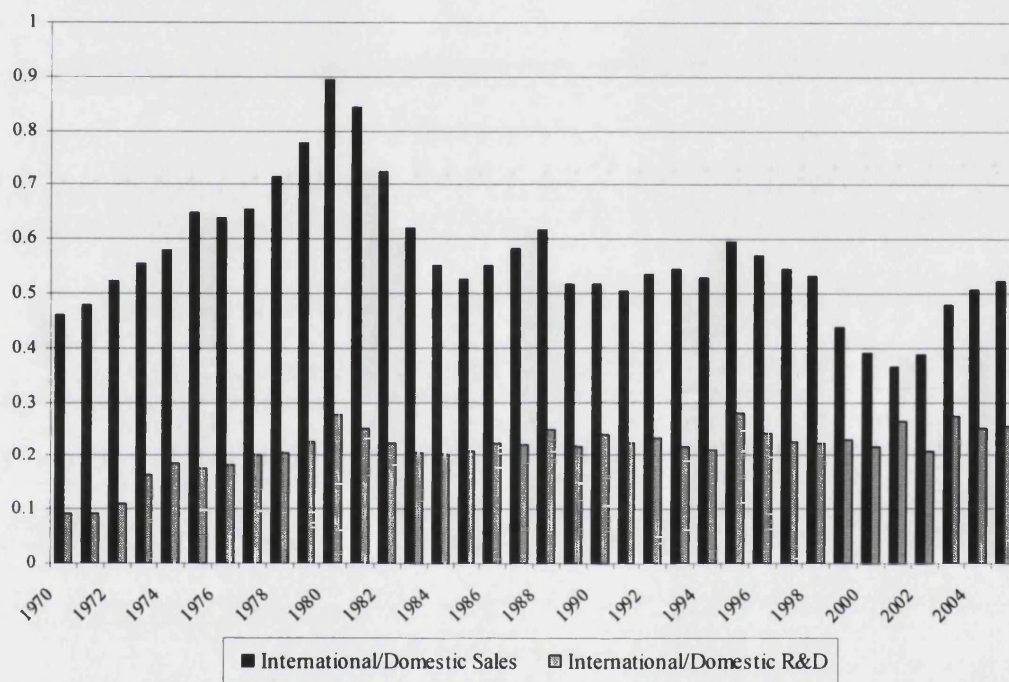
however can be as detrimental to public health as the release of an unsafe drug (Jordan 1992; Katz 1993).

In addition to public health considerations, pharmaceutical regulation seemed to create problems for the American pharmaceutical industry as well. The significant increase in R&D time and costs put the US industry at a competitive disadvantage, particularly as the same requirements applied for approving new drugs for exports. Confronted with higher costs and longer delays in both introducing new drugs in the American market and exporting to other markets, US multinationals changed their corporate strategies and expanded in foreign markets both in terms of R&D and in terms of manufacturing. A survey by Lasagna and Wardell (1975) reviewing fifteen large US companies (accounting for 80% of R&D in the US) showed that, while traditionally testing of NCEs was almost entirely conducted in the US, in the 1960s the situation began to change. Between 1966 and 1974, the percentage of NCEs first studied abroad grew from almost zero to roughly 50%. Other studies (Reis-Arndt and Elvers 1972; Reis-Arndt 1975) also found that after 1962 the majority of new NCE discoveries by US firms were first introduced abroad. Not surprisingly, international sales of US firms also grew rapidly (graph 7.4).

As is evident from above, the FDA had to tackle a similar dilemma to the one confronting European regulators. On the one hand, the mission of the FDA dictated a firm and thorough pre-marketing regulatory process, in order to safeguard public health. This view of FDA's mission was reinforced by the fact that all significant regulatory and legislative interventions in the US since the beginning of the twentieth century had occurred in the aftermath of a public health crisis. This as we saw promoted a conservative view of FDA's role, which preferred to forego the possibility of approving faster a potentially valuable new drug than risking a potential public health crisis. On the other hand, as was the case in Europe, this attitude undermined public health in other ways in the long term, and also undercut the competitiveness of the US pharmaceutical industry which had to turn to other jurisdictions to conduct much of its pre-marketing R&D. This situation had negative long-term effects for the FDA itself. If most multinational companies applied for new drugs first in European or Japanese markets, the FDA would lose its position as the

world's leading pharmaceutical regulatory agency (Katz 1993). This would undermine both the FDA's body of scientific expertise and its regulatory know-how, and thus undermine its ability to pursue its mission and protect effectively public health.

**Graph 7.4 Ratios of International to Domestic Sales and R&D of US companies (1970-2005\*)**



Source: PhRMA 2006

\* Estimate

### 7.2.3 Japanese industrial policy in the pharmaceutical sector

Unlike their American and European counterparts, the Japanese regulators did not face a regulatory dilemma pitting valid regulatory objectives against each other. Nonetheless, the Japanese also had to face significant challenges in the pharmaceutical sector. The first was to build up a domestic research-based industry. This goal was grounded first on an industrial policy rationale since Japan was the second largest national pharmaceutical market but relied almost entirely on foreign imports for new drugs. The Japanese industry was traditionally internally oriented and



comprised many small and medium-sized companies focusing mainly on generic copies of Western drugs (McIntyre 1999). This was largely due to the lack of investment incentives in R&D as under Japanese law, patent protection only applied to development processes and not products. A change in patent law in 1976 extended patent protection to products and Japanese R&D investment began to grow substantially. It has been estimated that from 1975 to 1985, R&D expenditure grew at an annual rate of 13% (McIntyre 1999). This was only the first of a number of measures taken in the context of a new industrial policy aiming to turn the Japanese industry into a global pharmaceutical power. Another particularly important legislative intervention in this direction was the 1987 Patent Bill that allowed for the possibility of extended patent protection for up to five years in order to compensate companies for the loss of effective patent protection due to regulatory requirements during the R&D process. As a result, Japanese companies began investing heavily in R&D, and were able to establish an international presence by the late 1980s. At that time, their expansion strategies, domestic pressures from increased foreign competition, and new price controls imposed by the government, drove them to expand their operations in foreign markets, entering into joint ventures with foreign companies, investing in US biotechnology companies and sponsoring research in American universities (OTA 1991, p.86).

At the same time, the Japanese government was under increasing pressure to contain health care costs. Health care costs were a major problem for the public budget, as public expenditure on health per capita, more than doubled between 1980 and 1990 (EFPIA 2006). A major component of this problem is the unusually high drug consumption of the Japanese population: in 1990, expenditure on drugs in Japan as a percentage of total health spending was 21.4% compared to 14% in Europe and only 9.2% in the US (EFPIA 2006), while in 1993, per capita drug spending in Japan was \$254 per year compared with \$179 for the US (Maurer 1994). Among other factors, this is due to a dramatic trend in Japanese demographics, whose population is aging at a pace unprecedented among developed countries. It is estimated that by 2020, 28.1% of Japan's population will be over the age of 65 (EFPIA 2006). Confronted with this situation, throughout the 1980s and 1990s the Japanese

government introduced a variety of regulatory and legislative changes to curb the cost of pharmaceuticals (JPMA 2006). According to experts, a basic paradigm shift started taking place in Japan in the early 1990s affecting regulators, payers, providers and the public; the focus on equality and guaranteed access to health care, which were traditionally the basic health care policy objectives, began to be circumscribed by financial strain, and new measures such as flat sum reimbursement tariffs for several categories of patients were introduced (Maurer 1994).

### **7.3 Resolving the dilemmas: ICH as a redistributive regulatory strategy**

In chapter 3, it was argued that transnational regulatory authority may be used when the objective of the regulators is redistribution, either domestic or international. In this part of the chapter, it will be shown first, that the ICH was *not* a case of international redistribution and therefore it was not forced by one or more of the regulators on their counterparts; rather it was a mutually acceptable and jointly agreed solution. Secondly, it will be demonstrated that this jointly agreed institutional solution, was part of a strategy to effect domestic redistribution.

#### **7.4.1 Pharmaceutical harmonization and international redistribution**

The previous discussion showed that, with the exception of Japan, national regulators found themselves in a dilemma which pitted valid public policy objectives against each other. On the one hand, the protection of public health dictated strict regulations and tight control of the regulatory process to avoid public health crises that could have dire political consequences. On the other hand, extreme focus on safety and national control could undermine public health in the long-term, by preventing the timely introduction of new drugs, raise the cost of health care by contributing to higher drug prices, and of course, it created significant problems for the industry. While it is obvious that the problems faced by the three regulators were quite distinct in their particular details, it is also obvious that reducing the diversity of regulatory requirements could contribute, by reducing the time and costs of the drug approval process, to the solution of their regulatory dilemmas. Indeed, the regulators in all three states/region begun considering international harmonization as a way out of

their problems. As was the case with accounting harmonization however, they initially pursued harmonization in different ways.

In Europe, the emphasis was on completing the internal market. Taking advantage of the looming 1992 deadline the European Commission put forward its ambitious plans for a central approval mechanism which could hopefully end the predominance of national control that had haunted its previous harmonization efforts. In 1990, it released four drafts of directives for the free movement of medicinal products in the European Community, which included a proposition for a single European Medicines Agency. After long negotiations this vision became reality, and in 1995 the overriding prevalence of national regulatory authorities came to an end with the creation of the European Medicines Evaluation Agency (EMEA)<sup>185</sup>. The EMEA brought a revolution in European pharmaceutical regulation (Garatinni and Bertele 2004). For the first time, the approval of a pharmaceutical product authorized centrally through the “centralized” procedure, would be binding for all EU member-states.

At the same time, the FDA, which as we saw was under increasing pressure in the 1980s, had already partially revised its policy on foreign data, adopted a policy of “on-going information sharing” with other regulatory authorities, and initiated a series of bilateral Memoranda of Understanding (MOUs) concerning mainly good laboratory practices and pre-clinical testing (Wall 1984). In the late 1980s, caught in the midst of the AIDS crisis, the FDA also turned to increased cooperation with foreign regulators, completing among other things a MOU for good manufacturing and laboratory practices with the EC in 1990, and co-sponsoring a trilateral conference with Canada and the EC on the harmonization of health care product names the next year (Vogel 1998).

At the same time, throughout the 1980s bilateral negotiations to reduce regulatory diversity were undertaken between the US and the European Community with Japan. These were motivated mainly by commercial considerations, and particularly the eagerness of the US and Europe to open up the large Japanese market.

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<sup>185</sup> In 2004, new legislation reinforced and streamlined the EMEA and its operations. The name of the agency has been changed to European Medicines Agency, but the acronym EMEA has been kept.

Japan, which is home to the second largest national pharmaceuticals market, is the only developed country who has been accused of using drug approval regulation as a non-tariff barrier to entry (Wall 1984; OTA 1991; Vogel 1998). Until 1975, a ban on foreign direct investment in pharmaceuticals in Japan helped to develop the local industry. Following the lift of the ban in 1975, foreigners could sell and manufacture their own drugs in Japan, but this required a complex approval procedure (Edelman 1988). Japanese authorities had developed a system of regulatory requirements that effectively resulted in total non-acceptance of foreign test data. This was justified on the grounds of racial differences, which was supported by evidence from an incident in the 1970s when a serious neurological side-effect's incidence had been much higher among the Japanese than any other national or racial group (Wall 1984). The complexity of the Japanese pharmaceutical regulatory system and its bias against foreign companies were specifically targeted during the Market-Oriented-Sector-Selected (MOSS) talks in 1985 with the US, which produced the first concrete results towards deregulation and national treatment of foreign companies, as the Japanese agreed to simplify the procedure for the transfer of licenses to foreign companies, and accept some foreign clinical data (Edelman 1988; OTA 1991). Europeans had already approached the Japanese regulators in 1984 in an effort to reduce the diversity of regulatory requirements and continued to have meetings with them throughout the 1980s (Griffith in D'Arcy and Harron 1992).

Given the momentum towards harmonization that was starting to build up at the time both in the European Community and in the United States, it was not surprising to see an effort going beyond regional, bilateral or unilateral initiatives towards a process of truly international harmonization. Indeed, the timing presented an opportunity for all three states/region to address many of their problems through international harmonization. In the EC the momentum towards European harmonization and the 1992 deadline gave the European Commission a unique opportunity both to take a lead in the international harmonization process and to use the latter to consolidate and complement the former. Indeed, regulation experts agree that the European Commission played a leading role in the inception and establishment of the ICH, taking advantage of its experience with the European

project (Vogel 1998; Braithwaite and Drahos 2000). At the same time, the completion of European harmonization was a prerequisite for negotiating global harmonization (Vogel 1998). This argument was used by the European Commission in its effort to push through European harmonization, as is evident from the fact that “the first three meetings of the ICH paralleled the EU’s progress in creating a single market for drugs in Europe” (Vogel 1998, p. 14).

In the United States, the climate was also ripe for a move towards international harmonization. As we saw above, during the 1980s, under growing domestic pressure, the FDA began cooperating closer with foreign regulators. However, this was not enough. The public confrontation with the AIDS patients in the late 1980s, the growing complaints about the drug lag, and perhaps most importantly, the deregulatory agenda of the Conservative Administration signaled the beginning of a more coordinated and comprehensive turn to harmonization in the context of an extensive FDA reform under the Bush Administration. As already mentioned, in November 1991, only a week after the first ICH conference, the Secretary of Health and Human Services Dr. Sullivan, announced a comprehensive reform of the FDA procedures in order to achieve shorter approval times for new drugs (Leary 1991). FDA’s reform had become a significant political issue (Jordan 1992; Vogel 1998). The reform was spearheaded by Vice-President Quayle, president of the White House’s Council on Competitiveness. A package of 11 major reforms of the FDA’s drug approval process were announced aiming to cut down drug review times by encouraging, among other things, greater use of external experts by the FDA, as well as greater cooperation between the FDA and the industry. Many of these reforms which were business friendly and aimed at reducing the regulatory burden on the companies, found their way in to new significant legislation passed in the early 1990s<sup>186</sup>, and changed the traditionally adversarial relationship between the FDA and the industry towards a more cooperative one (Wiktorowicz 2003). One of these 11 reforms was international harmonization, particularly in the context of the ICH (Jordan 1992; Contrera 1995). Vice-President Quayle confirmed the

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<sup>186</sup> A more detailed account about this new legislation will be presented in the next section of this chapter.

commitment of the Bush Administration to international harmonization at the highest political level, stating that one of the most important changes would be closer cooperation with the drug approval authorities of other countries, which would allow “quicker introduction of new therapies to other markets of the world”, while Secretary Sullivan stressed that “the development of common procedures would reduce ...duplication and speed the approval of drugs worldwide” (Leary 1991). To support this new direction, significant changes were made to the structures of the FDA, including the establishment in the early 1990s, of an Office for International Policy and an Office of International Affairs.

The Japanese regulators were also keen to progress to an international forum for harmonization. This was because first, for the Japanese, harmonization was viewed as a unique opportunity to continue the effort they had begun in the late 1970s to become a global pharmaceutical power. Harmonization would enable Japanese firms to use the results of tests conducted in Japan on their foreign applications, and thus enhance their ability to enter the US and European markets (Vogel 1998; Abraham and Reed 2001). As the Japanese Minister and Chargé d’Affaires of the Japanese mission to the European Community noted in his opening remarks in the first ICH Conference, “in the field of pharmaceuticals, maintenance and development of a free trade system is even more essential than in any other industry” (D’Arcy and Harron 1992, p. 7). Secondly, by helping to bring down R&D costs, harmonization could potentially contribute to a reduction of pharmaceuticals’ prices, which, as we have seen, was a major concern of the Japanese government.

This turn towards harmonization was also supported by the industry in all three jurisdictions. In the run up to the 1992 project, the EFPIA consistently argued for mutual recognition of regulatory bodies within Europe, and proposed “a single dossier for each product and a single assessment following a hearing open to the manufacturer of the medicine in consideration” (Orzack et al. 1992, pp.859-860). This idea also appealed to US and Japanese companies which had to file applications in fifteen different European jurisdictions, incurring considerable costs and regulatory uncertainty given the mistrustful and uncooperative attitude among European regulators (Orzack et al. 1992). At the same time European and Japanese companies

wanted to see American standards harmonized; the FDA traditionally required clinical studies to be performed in the US and generally considered foreign clinical data as cumulative or supportive if at all (Wall 1984). Finally, as we have already seen, European and American companies wanted to access the lucrative Japanese market, something the Japanese industry did not object, as long as harmonization reduced the regulatory burden for accessing the European and US markets as well.

Therefore, it is obvious that both public interest considerations and the private interests of the research-based pharmaceutical industry coincided in this case to a considerable degree, and drove regulators to international harmonization. It is also evident that, unlike the accounting harmonization case, harmonization in the pharmaceutical sector did not produce significant conflicts of interest among the dominant players. Therefore, the regulators' choice to set up the ICH as the forum for international pharmaceutical harmonization could not have been a forum-shifting strategy on the part of any of the three regulators. The only case that could be considered a case of redistributive cooperation, were the bilateral negotiations between the US and the EC with Japan. While the intention to pressure Japan into opening its market to foreign companies may have been part of the motivation behind international harmonization, it cannot explain on its own why harmonization initiatives could not continue on a bilateral basis, as had been the case throughout the 1980s, or why a hybrid forum was chosen over an international forum. Surely, the US and the EC would prefer either bilateral negotiations where they would enjoy a superior negotiating position, or an international forum, where Japan's negotiated commitments could potentially be stronger and have a higher degree of legal obligation. Moreover, the Japanese regulators surely preferred the ICH, where the same requirements would apply to all participating parties, to the bilateral negotiations with either the US and the EC, where the latter could negotiate from a position of superior market power. Indeed, the Japanese government, was quite supportive of the ICH initiative (D'Arcy and Harron 1992; 1994) and in 1992, the MHLW created "Pharma Dream 21", a \$10 million scheme to promote harmonization of drug regulation and fund joint international studies on racial differences' impact on clinical trials (Kanusky 1994).

Moreover, unlike the IASB, the ICH was created from the beginning with the participation and input of all three jurisdictions following a common decision taken at the 1989 WHO ICDRA in Paris. Domestic regulatory dilemmas and pressure from the industry in all jurisdictions created incentives for all three regulators to pursue harmonization. Even the unwillingness of the FDA to accept foreign clinical data and its long held attitude, expressed by an FDA Commissioner, as “harmonization is fine so long as the world harmonizes to us” (Braithwaite and Drahos 2000, p. 372), begun to change. Despite the fact that of the three founder members of the ICH the FDA was initially the most reluctant participant, often causing the irritation and discontent of the other participants in the early ICH stages (Abrahams 1991; D’Arcy and Harron 1994, Drahos and Braithwaite 2000), when confronted with the determination of the Conservative Administration to reform the FDA’s operation along the lines of market-friendly re-regulation, and the public outcry for its deteriorating drug approval record, the FDA’s resistance, dissipated. Any last hesitations it may have had were dissolved when pressed by the American industry to go ahead with the ICH (Braithwaite and Drahos 2000).

However, the absence of significant distributional conflicts and the fact that regulators had an incentive to pursue harmonization, do not explain their choice to do so in the context of the ICH. During the first ICH conference, the regulators of all three jurisdictions repeatedly argued that the ICH initiative was undertaken principally in the name of public health (D’Arcy and Harron 1992). However, as argued in chapter 3, when efficiency and/or effectiveness gains are the principal objective of international harmonization we would expect regulators to use international institutions and not a transnational regulatory forum. This would signal the strong commitment of the participating parties, would result in more binding legal agreements, which are likely to be more efficient and effective, and through the institutional safeguards of an international organization, would ensure transparency and easier access of the various stakeholders to the regulatory process, leading thus to a more comprehensive, inclusive and therefore readily accepted regulation, characteristics also associated with significant efficiency and effectiveness gains. The puzzle over the regulators’ choice becomes even greater in the case of pharmaceutical



harmonization, because there is already an international organization in the issue-area of health care with a clear mandate to pursue international regulation for pharmaceuticals, the WHO.

During the 1960s and early 1970s the WHO was quite active in the area of pharmaceutical regulation. The early WHO agreements were possible to a large degree due to the leadership of the United States (Braithwaite and Drahos 2000). During this period, the US sponsored International Conferences of Drug Regulatory Agencies and it was actively promoting harmonization through initiatives like the Good Manufacturing Practices agreement, which was in essence the globalization of US good manufacturing practices through the WHO (Braithwaite and Drahos 2000). However, following the adoption of the NIEO in 1974, things started to change. Given the importance of drugs for many developing countries facing acute public health problems, and the structure of the industry which was dominated by large MNCs, the pharmaceutical industry was a prime target for pressure by the developing countries. According to one commentator of the time “the pharmaceutical industry is destined to be a testing ground on which the future of this U.N. program [NIEO] will be decided” (Phelps 1982, p. 200). The tendency to focus on the pharmaceutical industry was reinforced by a number of unethical law evasion tactics by pharmaceutical MNCs, which often exported to developing countries products that were unlicensed or banned in the developed world or conducted high-risk experimental research in developing countries eschewing the safety testing standards of developed countries (Braithwaite and Drahos 2000). Consequently, the pharmaceutical industry became a target for analysis and action by many U.N. bodies and agencies (Cone 1983).

The US became worried over this new direction of WHO’s work and “carefully emphasized that... it opposes the kind of redistribution the NIEO invites” (Phelps 1982, p. 202). This concern marked a shift in the attitude of the US towards the WHO in the early 1980s. Two events were particularly important for this development. First, the coming to power of a conservative administration in the US which followed an anti-UN policy, limiting the interest, involvement and therefore influence of the US in the WHO (Braithwaite and Drahos 2000). The second was the

adoption by the WHO, of the International Code of Marketing of Breast-milk Substitutes in 1981 (Chetley 1990; Braithwaite and Drahos 2000). This Code came after many years of consumer campaigns following the well-supported documentation of health problems facing children in the developing world making use of breast-milk substitutes instead of breast-feeding (Cone 1983; Chetley 1990). As expected, this “interference with the operation of the free market was opposed by the Reagan administration in the US” (Abel-Smith 1994, p. 128). The United States was the only country to cast a negative vote in the World Health Assembly that approved the Code. Significant resistance also came from the industry, which argued that the WHO “should not be involved in efforts to regulate or control the commercial practices of private industry” (Silverman et al. in Abel-Smith 1994, p.128). According to an information paper from the Pharmaceutical Manufacturers Association (PMA), the breast-milk substitutes code “represents an unprecedented intrusion into corporate commercial operations...should this prove to be a precedent for pharmaceuticals, the impact on functioning, efficient private-sector drug distribution systems in many developing countries could be most harmful” (Cone 1983, p.335).

The confrontation between the developed states and the industry on the one hand, and the WHO on the other, soon intensified further. The success of the breast-milk substitutes code encouraged consumer groups and developing countries to argue for a WHO pharmaceuticals marketing code (Braithwaite and Drahos 2000). In 1981 the WHO’s Regional Office for Europe proposed the creation of an international U.N.-sponsored drug regulatory agency which would determine the safety, efficacy and quality of pharmaceuticals moving in international commerce, while WHO’s 1982-83 budget included a suggestion about the introduction of international regulations concerning the labelling and advertising of pharmaceutical products moving in international commerce (Cone 1983; Phelps 1982).

Predictably, these proposals provoked the industry’s reaction. The Chairman of the IFPMA set the tone in a speech to the federation’s assembly in 1981: “for this year and next, 70 percent of WHO’s budget will be paid by 13 industrialised countries...certainly this entitles the industrialised world to stand up to WHO. We must have the will to do so” (Dee in Chetley 1990, p.70). Nonetheless, in 1984 the

World Health Assembly called an examination of the industry's marketing practices, a call which resulted in the Ethical Criteria for Medicinal Drug Promotion in 1988. Unsurprisingly, the confrontation with the US reached a climax. In 1986 the US did not pay its financial contribution to the organization. In 1987 it paid off a small fraction of its previous debt for 1986 and 1985. By January 1988 the situation had reached a crisis: according to an editorial of *Science* the US was at that time in arrears of \$118 million which represented about 25% of WHO's annual budget (Chetley 1990). Although the situation was eventually alleviated, by 1988 the WHO was effectively abandoned by the US and therefore its power and legitimacy in creating international pharmaceutical regulation were severely undermined. Indeed, according to a former FDA official which played a significant role in the establishment of the ICH, the WHO was not considered an appropriate forum for dealing with developed countries' problems, such as the harmonization of technical requirements for the research-based industry<sup>187</sup>. In 1989 the regulators of the US, Europe and Japan decided to launch the ICH initiative.

The ICH initiative represented a joint government-industry effort to reduce unnecessary regulatory burden, diminishing development time and costs. Contrary to the ICH, the WHO initiatives aimed at increasing international regulation and giving more control to national governments. It is obvious therefore, that achieving an ICH-type agreement in the WHO was not possible. Even if developing countries agreed to reduce duplicate tests for the approval of new drugs, this would only be accepted in the context of an inter-governmental agency where developing countries would have significant influence. However, allowing developing countries to have a say in drug approval reviews could have significant political and economic implications for the incumbent governments in developed states. It would result in the loss of public confidence in a drug approval process where officials from countries without adequate expertise could play a potentially decisive role. Such an arrangement could not be accepted by developed states. Also, there is no doubt that in such a forum, developing countries would attempt to promote other regulatory goals, concerning for example the marketing of pharmaceutical products or essential drugs' procurement

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<sup>187</sup> Interview with author, 23/10/2007.

procedures and pricing. Such initiatives would be fiercely resisted by the industry. Therefore, the *compensatory costs* of giving partial control of an international drug approval procedure to developing countries (which lacked the necessary expertise) and of having to accept additional regulations for the industry were too high. These compensatory costs made the use of the WHO as the forum for international harmonization unlikely. The choice of a hybrid regulatory forum gave the “triad” the ability to exclude the developing countries from the harmonization talks altogether. Since having a significant pharmaceutical industry is a precondition for participating in a joint government-industry forum, the ICH has acted as a barrier to “regulatory entry” for developing countries.

However, the WHO’s association with high compensatory costs and the ICH’s function as a barrier to regulatory entry for developing countries, are still not enough to explain the regulators’ choice. As argued in chapter 3, when there is a harmony of interests among the dominant players and high compensatory costs associated with a particular international forum, the dominant players can exclude the parties that create the compensatory costs and benefit from the advantages of an international agreement (vs. transnational regulatory authority) by using or establishing an alternative international forum. In this case, when the divide is between developing and developed countries, the triad could have resorted to the OECD, instead of setting up the ICH. This would have minimized the costs they had to incur for setting up an organization from scratch (it took about two years of discussions and negotiations before the ICH was up and running), while taking advantage of already familiar and tested procedures, and limiting the harmonization process to almost the same set of countries that participated in the ICH. It is also worth mentioning that the OECD was already active, in a limited way, in the harmonization of some aspects of clinical testing. Why did the regulators of the three dominant players in the pharmaceutical industry choose the ICH over the OECD? The only answer, consistent with the evidence, is that the regulators chose to accommodate the requests of the industry.

#### 7.4.2 ICH and domestic redistribution

As we have seen, according to the economic theory of regulation in cases of redistribution, the winning constituencies tend to be small, well-organized and with a

high per capita interest in the promoted regulation. This condition is more than satisfied by the pharmaceutical industry in all three jurisdictions, but also internationally. The ability of the industry to influence the regulators has been boosted by its oligopolistic structure. Traditionally, when looking at the industry as a whole, the pharmaceutical industry has not been considered a highly concentrated industry (Statman 1983; McIntyre 1999). In 2004, the top ten companies accounted for 46.1% of the world market (ABPI 2004). While this degree of concentration clearly points to an oligopolistic market structure at an international level, there are other industries with higher concentration ratios (McIntyre 1999). This type of concentration ratio however, is not reflective of the true oligopolistic structure of the industry. The industry is separated in many distinct therapeutic categories, and products in these categories are poor substitutes for one another (Statman 1983; Schweitzer 1997; McIntyre 1999). Concentration ratios within these therapeutic categories therefore, are far more relevant for uncovering the true power of pharmaceutical companies<sup>188</sup>. Here concentration ratios are much higher, reaching in some instances, 80-90% of the world market for the top three or four companies, or even for just one company. Therefore, it is clear that specific companies dominate particular therapeutic classes and these companies have much more oligopolistic or even monopolistic power than the industry-wide ratios would lead us to believe. Moreover, this power is enhanced during the patent period when a company can literally enjoy a legally protected monopoly.

This level of concentration reveals the strong position of large multinational pharmaceutical companies. These companies, which are among the world's most profitable<sup>189</sup>, are able to coordinate in powerful and "politically active" associations which influence domestic and international regulatory arrangements. The PhRMA for example is a very active and well-organized association and considered one of the most powerful lobbies in Washington (Wiktorowicz 2003). The PhRMA consistently lobbies for the industry and makes large donations to influence members of Congress

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<sup>188</sup> See Appendix 5.

<sup>189</sup> The pharmaceutical industry has traditionally earned profits above the industrial average (Schweitzer 1997; McIntyre 1999). In 2001 the industry topped the Fortune 500 index of most profitable industries, while in 2006 it ranked fifth. For more details on the industry's profitability rankings in recent years see <http://money.cnn.com/magazines/fortune/fortune500/>, accessed, 3/2/2007.

and political parties. According to the non-partisan Center for Responsive Politics, in the 2002 Congressional elections, the pharmaceutical and health products industry spent about \$20 million, with three-quarters of that money going to Republican candidates and party committees (Pear and Oppel 2002). This contribution, while already putting the industry among the top donors, understates the industry's influence in Washington. According to Public Citizen, a consumer's organization, the industry spent approximately \$500 million on lobbying in the six years before the election, employing some 600 lobbyists including about two dozen former members of Congress (Pear and Oppel 2002). Canada's Research-based Pharmaceutical Companies (Rx&D) represents 63-brand names, mostly foreign-owned companies, that account for about 90% of prescription drug sales; "Rx&D is involved in the development and implementation of policy through its extensive committee structure, its ability to act on behalf of its members, and its capacity to bind member companies to its agreements (Wiktorowicz 2003, p.629). Similarly, the influence of the Association of British Pharmaceutical Industry (ABPI) on the UK's regulatory system has been considerable. The ABPI is considered "the most successful national association in term of its influence" (Permanand and Altenstetter 2004, p.48). These powerful national associations have also been able to cooperate at a regional and international level. The EFPIA, set up in 1978, has lobbied successfully on many issues (e.g. patent period extension), and has been able to play a central role in shaping the EU's regulatory framework (Permanand and Altenstetter 2004; Permanand 2006). In similar fashion, IFPMA has often played a significant role in representing the industry's interests at international fora (particularly the WHO) and, as we saw, played a critical role in the establishment of the ICH. It has become an invaluable institutional feature of the process by acting as ICH's Secretariat.

The influence of these associations is also reflected in the regulatory process of many developed countries. In most developed markets, the industry has a significant, and often, institutionally defined role in the regulatory process. This is particularly the case in Europe where the regulatory process has often been characterized by corporatist arrangements, which foster and encourage close cooperation between the industry and the regulators (Wiktorowicz 2003). In Britain

for example, the relationship between government and industry has been described as a case of “clientele pluralism” (Permanand and Altenstetter 2004, p.47)<sup>190</sup>. In France, the government-industry relationship is even closer, with the administration refraining from enforcing the detailed requirements of legislation; this is entrusted to professional or trade organizations with the government keeping a supervisory role over these associations (Hancher 1990). The close cooperation between regulators and industry in Europe is not limited to national markets alone. A striking feature of the EMEA is the fact that it is not based at the European Commission’s Public Health Directorate but rather at the General Directorate of Enterprises. As is the case with many national systems, the largest part of EMEA’s funding comes from fees charged to companies for the approval and authorization process. In 2002, 63.3% of EMEA’s budget came from industry fees (Garatinni and Bertele 2004, p.87). The result is that the EMEA effectively, has to compete with national agencies, since companies can follow either the centralized or a decentralized process (Garatinni and Bertele 2004). The latter procedure also forces national agencies to compete with each other for industry fees (Abraham and Lewis 1999). As is evident, this competition for fees among national and supranational regulators creates a dependence on the industry, with consequences on both the evaluation process itself and the regulatory measures that concern the authorization/registration process.

In Japan, the close relationship between companies and the government is not unique to the pharmaceutical industry. The regulatory process for most industries follows informal deliberations among government agencies, political parties and business, and legislation is pursued only after these parties have reached a consensus (Edelman 1988, p. 396). Industry committees draft the initial product standard and submit it to the appropriate ministry, although the reverse may also happen. In any case, “government and business insiders usually reach an agreement before a draft standard is presented for formal public comment” (Kanusky 1994, p.701).

Contrary to such corporatist practices, the US pharmaceutical regulatory system could be best characterized as pluralist (Wiktorowicz 2003). Industry, medical

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<sup>190</sup> Clientele pluralism refers to a situation where one narrow economic interest is involved in a process of joint policy formation, and decisions are taken to preserve and protect the structural bases of this interest (Wiktorowicz 2003, p.631).

organizations, consumer groups and the Congress have all had a significant impact on the FDA's regulatory work. Representation of the industry's interests is external, mostly based on public notice-and-comment procedures and judicial review, courses of action also available to other interest groups. Moreover, the fragmentation of the institutional power of the FDA through the oversight and intervention of Congress and the courts, have prevented the FDA from engaging more heavily with the industry; as we have seen, this type of oversight tends to direct the FDA towards an adversarial stance vis a vis the industry (Grabowski 1976; Jordan 1992; Wiktorowicz 2003). However, the "drug-lag" issue and competitiveness concerns, particularly in the 1980s, started to erode this attitude. This change, as we have seen, was encouraged and indeed promoted by gradual modifications of the regulatory framework through the deregulatory policies of consecutive Conservative, but also Democrat administrations. In 1987, new IND regulations encouraged communication between the FDA and the applicants throughout the review process, while in 1992, Congress passed the Prescription Drug User Fee Act (PDUFA), which introduced fees on the industry for the processing of applications; in 2002 these fees represented approximately 15% of the agency's budget (Garattini and Bertele 2004). The Food and Drug Administration Modernization Act (FDAMA) passed in 1997, enhanced cooperation between the FDA and the industry even further (Wiktorowicz 2003). The FDAMA renewed the PDUFA scheme, directed the FDA to use scientific advisory (external) committees for advice and recommendations on the clinical study and marketing approval of new drugs, and made the FDA-industry meetings during the review process mandatory (Merrill 1999). Under this new regime, the FDA is able to cooperate closer with the industry. However, this new relationship may have become a bit too close for comfort. In 2001, investigators of the House Government Reform Committee examined the work of the external committees because of claims of mismanagement and improper influence on their members (Gribbin 2001). The Committee found experts with ties to drug companies participating in meetings where they clearly had a conflict of interest (Wiktorowicz 2003). Moreover, it seems that the industry's influence is not limited to external committees. In a 1998 survey of the Centre for Drug Evaluation and Research (CDER) of the FDA, many drug application



reviewers revealed that they felt pressure to favour the desires of sponsors over science and public health, and that drug evaluation standards had fallen since the introduction of user fees in 1992 (Horton 2001).

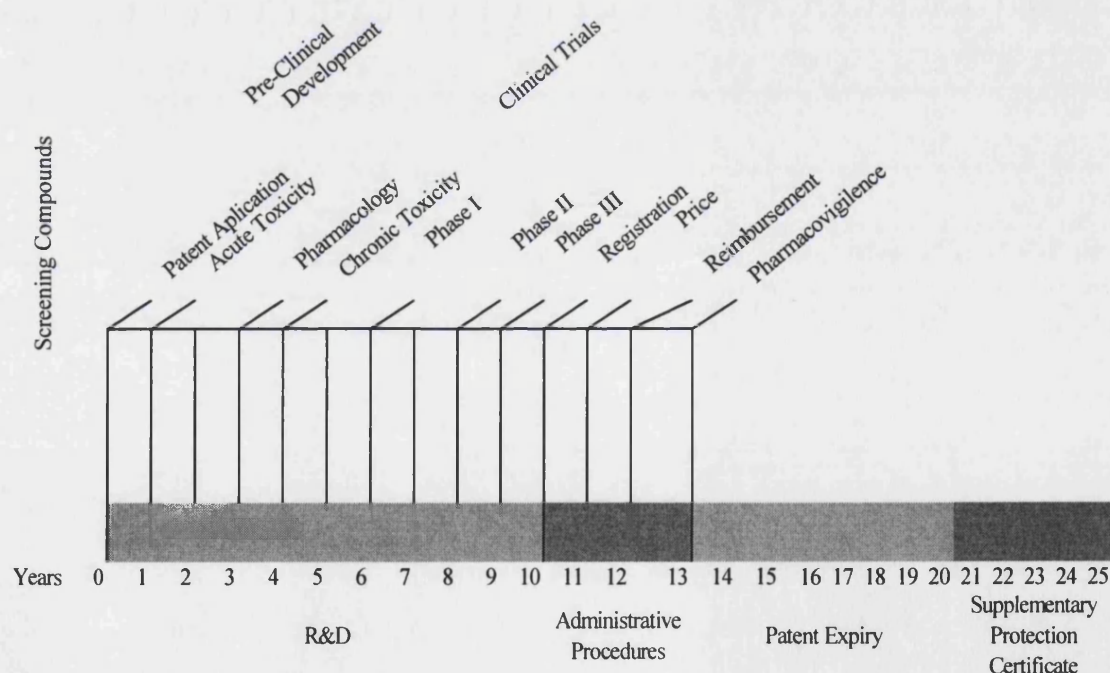
From the above discussion, it is evident that the industry had the power to influence regulators in all three jurisdictions to pursue regulation favourable to its interests. However, previously we argued that harmonization seemed to address to some degree, both the public interest considerations of the regulators, and the private interests of the industry. Therefore, why would the industry need to exert its influence over regulation that the regulators seemed willing to pursue anyway? The answer lies with the objective of the pursued harmonization. Prioritizing one of these two different sets of interests, leads to a different kind of harmonization. Focusing on the protection of public interest, would imply an agreement to harmonize “upwards” the existing diverse regulations, in terms of drug safety and effectiveness, while reducing unnecessary, duplicate requirements. On the other hand, focusing on the industry’s interests would mean prioritizing the reduction of the regulatory burden on companies, even if that meant operating in the context of a lowest-common-denominator agreement in terms of drug safety and/or effectiveness.

As we have seen, the duplicate testing required by the various jurisdictions entailed increasingly significant costs for the industry in terms of both time and money. Changes in the nature of the pharmaceutical industry only made things worse. The pharmaceutical industry is at the cutting edge of medical and scientific research, and the pharmaceutical R&D process is one of the most technically and scientifically complex subjects. It is worth noting that the pharmaceutical industry traditionally is one of the most innovative industries. Currently, it ranks second in Europe and the US and fourth in Japan in terms of its share to total industrial R&D expenditure (EFPIA 2006). Findings during the R&D process are often published in top academic journals of medicine, genetics, biology and chemistry and the leading scientists in companies’ research departments are often prominent academic researchers. In addition, research-based companies are engaged in a variety of collaborative research projects with universities and research institutes (Gambardella 1995; Kanavos 1998). Not only is pharmaceutical research extremely complex, but it has been changing at a fast pace as

the introduction of information technologies and new scientific knowledge, particularly in the field of biotechnology, have revolutionized the industry.

These developments have increased the knowledge requirements to such a degree, that not even large multinational pharmaceutical companies can satisfy them based solely on their own resources. Already since the 1980s, most companies have been forced to cooperate with a variety of actors at a global level, giving rise to transnational knowledge-based networks (Mytelka and Delapierre 1999). As a result of these developments, the cost of developing a new drug has increased from an average of \$2.5 million in the 1950s (Statman 1983) to \$259 million in 1990 (OTA 1993) to \$897 million in the 2000s (Di Masi et al. 2003). In addition, the time it takes to bring a new drug to the market has risen from 2-3 years in the 1950s (Statman 1983) to 12-13 years today (graph 7.5). Consequently, effective patent life today is about 8 years compared with the statutory protection period of 20 years.

**Graph 7.5 Phases of the R&D Process and Effective Patent Life**



Source: EFPIA 2006

The continuous rise in R&D costs and the erosion of the effective patent period, meant that the industry's priorities in a harmonization process were likely to

be dictated by a deregulatory outlook, aiming primarily to reduce the regulatory burden on companies: “companies hope for a system that could speed authorizations and allow quicker and easier access to the distribution of prescription drugs in multinational markets” (Orzack et al. 1992, p.852). Reducing drug evaluation and approval requirements would mean that part of the costs of health care provision would be transferred from the industry (extensive pre-marketing testing to ensure safety and effectiveness), to the public (increased monetary costs in both primary and secondary health provision due to the use of less effective and/or safe medicines).

Indeed, the industry’s view of what harmonization’s objective should be, was made clear early on. The comments of Dr. Griffin, Director of ABPI, at the first ICH conference, illustrate why harmonization was important for the industry:

where there are different regulatory requirements between national regulatory authorities,..., then valuable resources are being expended unnecessarily. Such resources expended by the innovative company are financial since new studies cost money. Resources are also consumed in the commitment of skilled personnel who could be better employed. Time is consumed and as time is consumed effective patent period is eroded. Erosion of patent time means lost revenue and lost revenue undermines the company’s ability to continue to invest in research.

(in D’Arcy and Harron 1992, p. 560)

In view of this situation, William Steere Jr., CEO of Pfizer Inc., was very straightforward in spelling out what he thought harmonization through the ICH should be aiming for: “the ICH process should be a means of streamlining burdensome regulatory requirements and regulators’ work so as to speed up new drug review” (in D’Arcy and Harron 1994, p.19).

Given the previous discussion on industry’s privileged position in national, regional and international, governance arrangements, in line with proposition (1) and condition (1a), we would expect the research-based industry to press hard and be able to persuade regulators to pursue business-friendly harmonization. Indeed, industry representatives, who were often present at the bilateral harmonization negotiations that took place during the 1980s, were also present at the EC-Japan meeting in 1988, where the idea for the ICH first originated (Contrera 1995). In the 1989 WHO regulators’ conference, the regulators of the three states/region met with IFPMA and

agreed the joint meeting of April 1990, which set the foundations of the ICH. That meeting was sponsored by IFPMA (Contrera 1995). The industry thus, participated actively in every step of the way towards the establishment of the ICH and as we saw in the chapter 6, has even assumed the operation of the ICH's Secretariat, which is based at the IFPMA headquarters in Geneva. It is obvious that industry was very committed in its aim to create and maintain such a harmonization procedure, even if it meant that it had to cover a substantial part of the expenses<sup>191</sup>. Indeed, it seems that the thrust of the whole initiative lay with the industry. As Dr. Doi, Director of New Drugs Division in the Japanese Ministry of Health and Welfare admitted in his remarks in the First International Conference on Harmonization: "the pharmaceutical industry has strongly urged that regulatory authorities promote global harmonization of the technical requirements for drug registration and the acceptance of foreign data" (in D'Arcy and Harron 1992, p.20). Officials from the FDA, the EC and the EMEA have acknowledged in interviews with the author that the industry lobbied hard for the ICH and was very important for its establishment and operation. One former FDA official, who was heavily involved in the establishment of the ICH, has admitted that it was the industry that came up to the regulators and convinced them of the need to pursue harmonization in the first place<sup>192</sup>. The pressure from the industry finally paid off and as the Financial Times reported following the first ICH conference in 1991:

for three years, the world's drugs industry has been trying to lighten the heavy financial burden of regulation by persuading national governments to standardise their rules...an ambitious initiative was announced this week after 18 months of tricky negotiations and sustained lobbying from pharmaceutical companies.

(Abrahams 1991)

As expected, the industry's view of harmonization was echoed by regulators involved in the design and establishment of the ICH process. According to the vice-President of the Commission, Martin Bangemann:

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<sup>191</sup> IFPMA is responsible for the preparation and documentation of the SC meetings as well as coordinating the preparations for EWG and Discussion Group meetings. It also provides administrative support for MedDRA and the Global Cooperation Group and is responsible for the technical documentation during Conferences (ICH website, <http://www.ich.org/cache/html/510-272-1.html>, accessed 17/01/2007).

<sup>192</sup> Interview with author, 23/10/2007.

The pharmaceutical industry is an innovatory one which spends a high proportion of its income on research. That is not to say that it should not be a profitable industry. Our joint effort here does not aim at maximizing profits but at reducing R&D costs in order to allow much better products to be introduced more rapidly on the world market.

(in D’Arcy and Harron 1992)

Similarly, Professor Strandberg, Director General of the Swedish Medical Products Agency, acting as representative of EFTA in the ICH, admitted that, “the need to increase cost-effectiveness is the driving force behind the harmonization and cooperation initiatives we have seen to date and which lie ahead” (in D’Arcy and Harron 1992, p. 30), while Dr. Doi, Director of New Drugs Division in the Japanese MHW, acknowledged in his remarks in the first International Conference on Harmonization that, “global harmonization will be extremely beneficial to pharmaceutical companies, especially in relation to global marketing and efficient recovery of the costs of R&D” (in D’Arcy and Harron 1992, p.20).

As a result, this approach has also informed the objectives of the ICH itself: “the Parties cosponsoring this Conference...re-affirmed their commitment to increased international harmonization, aimed at ensuring that good quality, safe and effective medicines are developed and registered in the most efficient and cost-effective manner”<sup>193</sup>. This harmony of purpose between the regulators and the industry has led critics to argue that the agenda of the ICH is to a large degree the regulatory agenda of the industry (Hodgkin 1996; Abraham and Reed 2001; WHO 2002). There has even been an admission to that effect by participants in the process. As the vice-president of international affairs at the IFPMA recounted:

The regulators’ attitude was “look, you’re the ones that have been telling us you’re wasting time and money because our requirements are all different and therefore you should be the ones who are identifying the problems, able to give us a concept paper which says, you know, this is the impact, this is the implication, this is the consequence” and certainly in the early days the main initiatives came from the industry.

(quote from interview, in Abraham and Reed 2001, p. 124)

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<sup>193</sup> “Statement by the ICH Steering Committee Tokyo”, October 1990, 1, in D’Arcy and Harron, Annex 3, 1992.

This mode of operation has also been confirmed to the author in an interview with a former FDA official, among the pioneers of the ICH initiative, who described how the regulators were depending on the industry both for the identification of the problems and for the proposed solutions<sup>194</sup>.

It is evident that, in line with our argument, the promoted harmonization was primarily designed to satisfy the industry's requirements. Nonetheless, the question remains: why was harmonization pursued in the context of the ICH and not in an international organization? According to propositions (2a) and (2b), we would expect regulators to shift the harmonization forum to a technically oriented, transnational non-state organization, in issue-areas with a high degree of technical and/or scientific complexity, when the issues being regulated, have a high potential to draw public attention. This can help regulators reduce the visibility of the whole harmonization process and exclude civil society organizations and other interested stakeholders from the discussion, hopefully reducing the risk of wide public awareness and reaction. The technical nature of the issue-area, particularly if expert representatives from civil society organizations are excluded from the negotiating process, means that the public is unlikely to learn or understand the content and significance of this harmonization process.

Indeed, the kind of cooperation described above, would not have been possible in an international regulatory forum where other stakeholders were also present. It is certain that regulators would prefer to avoid extensive public exposure of the harmonization process, given the high political risk involved in reducing pre-marketing registration procedures for drugs for human use. Pursuing harmonization in the context of an organization like the OECD would draw public attention and would enable various stakeholders (e.g. medical associations, consumer and patient associations, and health-related NGOs) to follow the process closely and offer their input. In this context, deregulatory measures seemed unlikely, since they could find opposition from other interest constituencies and spark a negative public reaction with potentially significant political consequences. The potential for such a negative reaction was very high. As we saw in chapter 6, literally all regulatory interventions

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<sup>194</sup> Interview with author, 23/10/2007.

in the 20<sup>th</sup> century were the result of public outcry in the wake of significant public health crises. Despite the technical nature of the issue-area, the political risk involved was significant, as the recent AIDS campaign in the US had made clear. The reforms demanded by the AIDS activists concerned the same kind of technical issues, pertaining to the drug evaluation and approval process. The significant publicity that the issue gained and the ability of the campaigners to reach the wide public through the media, showed that motivated and well-organized interest constituencies could deal significant political damage. The point was made eloquently by Dr. Poste of SmithKline Beecham:

the whole regulatory framework of not only the national research agenda, but certainly certain elements of regulatory strategy and posture in the United States, have been altered by the nature of the AIDS epidemic. A highly educated affluent, well-motivated community, unleashed to demand reform in regulatory process and I would argue dangerous precedents on occasion in terms of the nature of the review processes which have been adopted. The question we have to ask is, who is next?

(in D'Arcy and Harron 1992, p. 37)

The ICH structure has been very useful in keeping other stakeholders out of the regulatory process and as would be expected both the industry and the regulators have supported it fervently. Industry executives have repeatedly argued that exclusion of other actors such as consumer groups is justified because such organizations would not understand the ICH proceedings since they lack the technical expertise, they are not “scientific” enough (Abraham and Reed 2001). Regulators have also justified the shift to the ICH and the exclusion of other stakeholders on the same basis. Officials from the FDA, EMEA and EC have stressed in interviews with the author, that the guidelines developed in the context of the ICH deal with extremely technical issues, and that the required expertise lies primarily with the industry. Indeed, one of them argued that interest groups other than the industry do not have the required expertise<sup>195</sup>. However, this line of argument has two problems. First, it runs contrary to how the pioneers of the ICH themselves have characterized the process. According to the comments made by Martin Bangemann, EC Vice-President, at the inaugural ICH meeting regarding the objectives of the ICH, “this first Conference on

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<sup>195</sup> Interview with author, 13/04/2007.

Harmonization is no ordinary scientific conference, but combines the scientific and regulatory aspects against the background of increasing R&D costs” (D’Arcy and Harron 1992, p. 1). Secondly, such an argument cannot be easily supported given that some groups of outsiders, for example medical associations, obviously have the necessary expertise to participate meaningfully in the process, while others, such as consumer associations, often employ academic or other experts to represent their interests in a number of international fora. Indeed, representatives from the medical profession and international NGOs active in the health sector have repeatedly criticized the closed and opaque character of the ICH process (Hodgkin 1996; Abraham and Reed 2001). The WHO has also expressed its concern over this issue: “there is a perceived lack of sufficient consultation with academic scientists, health professionals, and societal forces such as consumer and patient groups” (2002, p. 16). The implausibility of this argument is further illustrated by the inability of regulators to provide a consistent and meaningful explanation for the structure of the ICH, which delegates regulatory authority to the pharmaceutical industry. The answer of Dr. Arlett, representative of the European Commission at the ICH Steering Committee is indicative of this:

why not have industry as advisers rather than actually at the table directly? Well, that is a perfectly valid perspective and I agree that you could design alternative models with industry advising but not deciding...it is a model for developing technical guidelines and there are other models, and I am fully aware that there are opinions out there in some stakeholder groups that think that industry should not be involved or directly involved in the development of guidelines that govern its own work; that is not the view of this Commission. This Commission does believe that industry has a very active role<sup>196</sup>.

There is no explanation, no specific argument about why the European Commission decided on this particular model, especially since there is an admission that other types of models could be used; it was simply the Commission’s choice that the industry should be involved.

Similarly, regulators could not provide a convincing answer to the author when asked why they did not pursue harmonization in the context of the OECD, which was already active in the harmonization of several technical aspects of

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<sup>196</sup> Interview with author, 15/05/2007. We should note however that Dr. Arlett was not part of the European team of regulators involved in the design and establishment of the ICH in the late 1980s.



pharmaceutical regulation at the time of the ICH establishment. An EMEA representative argued that the choice of the ICH was purely based on practical reasons, as the number of parties that participated should be limited in order to achieve progress<sup>197</sup>. This however does not explain why the industry should have voting rights in the process, or why the OECD, where approximately the same set of countries would participate, was not selected. His answer was that he did not know why the OECD was not chosen, while the answer of a former FDA official was that they simply did not think of it<sup>198</sup>. Surely, one would expect more detailed and clear explanations from public regulators, when justifying the choice of a regulatory structure as unique and consequential as the ICH, over an established international organization.

Finally, beyond excluding other stakeholders from participating in the regulatory work, reducing thus the visibility of the harmonization process, the structure of the ICH combined with the technical nature of the issues being regulated, have also served to reduce the visibility of the produced guidelines, as well as the ability of stakeholders to influence them even outside of the negotiating process. As we saw in the previous chapter, given the highly technical and quite advanced stage of development of the guidelines when they reach the public comment process, it is very difficult for other stakeholders to comment meaningfully on the guidelines (Goldman 1994; Booth 1997).

The weaknesses in regulators' defense of the ICH structure, and the redistributive aspects of the promoted harmonization, can be seen in the regulatory outcome of the ICH. There is evidence that suggests that the negotiations in ICH are more than strictly technical discussions about the best scientific solution to a highly complex issue, and that other regulatory parameters, about which other stakeholder groups should have a say, are also considered. Thus, critics have questioned a number of ICH's guidelines with regard to the claim that they are based on the best science available (Abraham and Reed 2001). For example, the ICH adopted a guideline for the duration of toxicity testing in animals (non-rodents) which recommends that

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<sup>197</sup>Interview with author, 13/04/2007. This official was also not involved in the design and establishment of the ICH in the late 1980s.

<sup>198</sup>Interviews with author, 13/04/2007 and 23/10/2007 respectively.

testing should last 9 months. Previously, in the EU 6 months were traditionally required prior to marketing approval, while in the US testing was required for 12 months. Despite the ICH's recommendation, which seems to be a compromise based more on political considerations rather than scientific evidence, the EC continues to accept testing for only six months, for reasons entirely irrelevant to best safety practices. The admissions of representatives from both the industry and the EC are illustrative (Abraham and Reed 2001, pp.121-122):

It isn't pure science. There you are in the US where drugs have always been tested with a year's toxicity and suddenly because of some negotiating with Europe, you're now reducing the safety margin on drugs being tested...I think the EU had to be very careful about the public reaction which says "hey wait a minute, all these years we've had drugs on the market which were only tested for 6 months" - you know- and that's why the EU absolutely have not said that drugs have to be tested for 9 months - they will accept 6 months. They will continue to accept 6 months.

(Vice-President of international affairs at IFPMA)

Europe was between a rock and a hard place on this one. There was no way politically that we could go to 9 months because we could potentially have undermined all the existing products on the market by saying that they were incorrectly tested.

(EC Official)

Similarly, there are considerable doubts that the harmonized guidelines regarding quality issues are driven by the best available science. According to the WHO (2002), ICH quality guidelines require high levels of expertise and considerable technological capabilities in order to be properly applied. This kind of harmonization, is to a large degree determined by the most recent technological developments in production, a process which puts less developed countries as well as smaller and generic companies in developed countries in a particularly difficult position: "smaller pharmaceutical companies, generic companies and many larger companies responsible for essential drug production in developing countries may be effectively squeezed out of drug manufacturing if ICH guidelines start to be interpreted as the only global standard" (WHO 2002, p.21). As the WHO (2002) notes, the benefits of incorporating these technological advances into new regulatory guidelines are only assumed and there are no tests which support their adoption. On the contrary, WHO argues that the quality assurances of pharmaceutical products established and maintained through its own

Expert Committee on Specifications for Pharmaceutical Preparations, are based on robust tests and that there is no new scientific data that suggests that the existing methods need tightening (2002, p.21-24). One could argue therefore that what drives, at least to a degree, harmonization in quality issues, are the advances in pharmaceutical production methods employed by the large global research-based industries, and not unbiased scientific evidence.

From the discussion presented above, it is evident that the pharmaceutical industry in all three jurisdictions has had both the ability and the motivation to press the regulators into harmonizing their drug registration requirements in a way favourable to their interests. Indeed, the research industry lobbied hard to establish the ICH, and succeeded in setting up a forum, which explicitly shares its view of harmonization, and affords it an institutionalized, privileged decision-making role, while excluding other stakeholders. As we would expect, in line with propositions (2a) and (2b), the technical nature of the issue-area and the politically sensitive nature of the harmonized regulations, provided regulators with an incentive to use ICH for domestic redistribution. Despite criticisms that often guidelines aim at the lowest common denominator or even reduce the standard of safety previously in force, occasional objections from national and international NGOs<sup>199</sup> about the lack of transparency and inclusiveness, and similar concerns raised by the WHO (2002), it has not been possible to raise significant public awareness about this issue and to unite the various stakeholders in an effort to address these issues. The highly technical nature of the guidelines has been used by both the regulators and the industry to defend the exclusion of other stakeholder groups, and has contributed to the low visibility of the ICH process, which has allowed the regulators to proceed rapidly with the agreement and adoption of over fifty guidelines.

#### **7.4 Justifying ICH's regulatory authority**

We saw previously that regulators were pressed both by the industry and other domestic interest constituencies to increase the efficiency of regulation by reducing duplicate tests, facilitating exchange of information, and harmonizing requirements,

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<sup>199</sup> See Scrip Magazine, 1963, 4th October 1994, pp.18-19 and Hodgkin 1996 respectively.

so that foreign pre-clinical and clinical data could be accepted without the need to re-examine them. While these efficiency gains have been linked to harmonization, as we saw above, the type of harmonization pursued through the ICH put the industry's interests before that of the consumers and the patients. The question that is interesting for this thesis is, how did the regulators justify their decision to pursue harmonization in the context of the ICH? How did they justify their decision to give the industry the power to co-decide with them both the issues targeted for harmonization and the substantive content of harmonization, while excluding other stakeholders?

We have already seen that the pharmaceutical industry is characterized by a high degree of scientific and technological complexity. Also, we have seen that scientific breakthroughs and technological innovation have made R&D even more complex and expensive. Consequently, the way the industry operates has changed and joint research projects across borders are replacing traditional in-house research departments leading to the creation of transnational knowledge-based networks. These characteristics of the issue-area have already been used to justify delegation of regulatory authority to the pharmaceutical industry in domestic regulatory systems. For example, a consequence of the continuous change in pharmaceutical research is that legislation cannot always be very precise in its stipulations of what the drug approval process should be looking for. In Canada the vagueness of the Food and Drug Act has been cited as one of the main reasons for the delegation of increased authority to Rx&D by the Therapeutic Products Directorate (TPD), in the development of guidelines for the inspection of manufacturing practices and the self-regulation of advertising claims (Wiktorowicz 2003). Moreover, lack of financial and therefore scientific resources has been identified as a major factor for the close relationship between the regulators and the industry, with the former often being dependent on the latter for expertise and information (Abraham 1995; Wiktorowicz 2003). As Wiktorowicz notes in his comparative study of pharmaceutical regulation:

while industrialized nations have established elaborate regulatory systems, they do not have complete independence in this policy area. Since they cannot conduct the clinical and preclinical trials necessary to determine the safety and efficacy of pharmaceuticals, governments must entrust the research and development of drugs, on which regulatory decisions are based, to private sector actors. Regulatory

authorities therefore rely on the technical capabilities and goodwill of industry and the cooperation of scientists in the research community to assess new drug products.

(2003, p.627)

This argument about the inadequacy of the traditional state regulation to provide adequate regulatory governance, has been employed even in the case of the FDA, which is the largest and best-resourced pharmaceutical regulatory agency in the world, the only one that reanalyzes clinical trial data on which product evaluations are based (Wiktorowicz 2003). It is worth noting that one of the reasons cited by the committee appointed by Health Secretary Sullivan for the FDA restructuring in the early 1990s, was that the FDA lacked qualified personnel and no longer had “the scientific ability to evaluate new drugs or to stay abreast of the revolutionary advances occurring in the biological and medical sciences” (Jordan 1992, p.487).

These difficulties are bound to be even greater in the evaluation of new biotechnological products, since the regulatory framework itself will need continuous updating. This has already been realised by the regulators: “many of the guidelines in place for drug development do not encompass the new technologies, and thus new guidelines will have to be developed, an issue acknowledged by both the FDA and the EMEA” (Pirmohamed and Lewis 2004, p.288). Uncertainty over the new technologies will more likely lead to greater reliance on the industry for regulatory issues; already both the FDA and the EMEA, which support the introduction of new pharmacogenetics-based therapies, are meeting regularly with the industry to encourage “joint discussion of the meaning and interpretation of pharmacogenetics data” (Pirmohamed and Lewis 2004, p.288).

As anticipated by our framework, these types of arguments have also been employed by the regulators in the case of the ICH. First, in accordance with proposition (5), regulators participating in the ICH process have repeatedly stressed the increasing complexity of the R&D process due to scientific and technological developments. Thus, Professor Poggiolini, Chairman of the CPMP, noted in his opening remarks at the First International Conference on Harmonization the changes that started taking place in research strategies for the identification of new medicines:

Over the last ten years an important evolution took place in concepts applied to the planning of new drugs, principally by virtue of the progress achieved in the field of molecular biology. Research strategies are currently guided by knowledge acquired on cellular biochemical processes rather by chemical concepts...an extremely important role in the discovery of non-conventional drugs is played by the extraordinary progress made in that sector of molecular biology addressed to the study of genetic molecular material, and to the appropriate technologies for its modification, aimed at producing therapeutically useful substances...finally consideration should be given to the evolution of genetic engineering...

(in D'Arcy and Harron 1992, p.11)

What is more, regulators have acknowledged that these developments have created significant costs for the research-based industry<sup>200</sup>, which in turn transform the way the industry conducts research:

To accommodate the exorbitant costs of modern research, industry could take certain initiatives, such as strategic alliances. In fact, increased costs coupled with the drop in productivity, has already resulted in a tendency for pharmaceutical companies to seek collaboration in the research field. The number of strategic pharmaceutical alliances among companies consistently increased between the years 1986 and 1990...alliances in the biotechnology field... also greatly increased during the same period.

(Poggiolini in D'Arcy and Harron 1992, p.11)

These developments had consequences for the ability of regulators to provide governance:

We have, of course, to recognize the difficulty for regulatory authorities to depart from traditional ways in their national environment, in order to adapt to the new international dimension stemming from the global nature of pharmaceutical research.

(Sauer in D'Arcy and Harron 1992, p.556)<sup>201</sup>

These themes have been echoed by regulators throughout the operation of the ICH process. For example, many years later, in the context of the Sixth International Conference in 2003 in Osaka, the regulatory and scientific challenges due to new and advanced technologies, and due to the globalization of drug development, were identified as the two most significant future challenges for the ICH<sup>202</sup>.

In order to deal with these challenges, regulators of all jurisdictions have stressed the importance of pursuing harmonization on the basis of consensus founded

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<sup>200</sup> See for example the comments of Professor Poggiolini and Dr. Doi in D'Arcy and Harron 1992.

<sup>201</sup> Fernand Sauer was at the time Head of Pharmaceutical Unit at the EC.

<sup>202</sup> Sixth International Conference on Harmonization, New Horizons and Future Challenges, Summary Report, 13-15 November 2003, Osaka, Japan.

on the best available science and expertise<sup>203</sup>. Regulators from all three regions have repeatedly acknowledged the unique structure of the ICH<sup>204</sup>, but in accordance with proposition (4), have defended their choice on the grounds that the ICH has provided them with an ideal forum for this kind of technical/scientific harmonization:

The first international conference on harmonization provides a forum for the relaxed and open exchange of views, the cross-fertilization of positions and an eventual harmonised outcome...the advantage of a technically based conference such as this one, is that the real experts can express the true scientific needs and the regulators can can benefit from the clear unbiased views of these international experts.

(Bangemann in D'Arcy and Harron 1992, p. 4-5).

The first ICH developed into a unique opportunity and forum beyond many expectations...experts at the highest levels, representing their institutions throughout the world, both industry and regulators, have come together to communicate on scientific issues of common interest.

(Dr. Esber in D'Arcy and Harron 1992, p. 549)<sup>205</sup>

The role of the industry was particularly important in this process, as the expertise it possessed was necessary for the regulators trying address these challenges:

It would inappropriate not to acknowledge the valuable contribution of industry representatives in these activities. Not only has the industry provided a strong stimulus for these efforts and worked to identify the practical differences in requirements among the three regions, but has actively participated in the scientific deliberations and the collection of data to support the scientific discussions.

(Dr. Esber in D'Arcy and Harron 1992, p. 551)

This was particularly true for new areas of pharmaceutical research:

Biotechnology is, of course, a relatively new science whose technology is changing rapidly and whose innovative products are emerging from laboratories at a staggering pace. Because it is evolving so rapidly, biotechnology provides a forum where scientists from academia, industry and regulatory agencies can discuss issues based on scientific data without the constraints of ingrained policies or historic precedents.

(Dr. Kessler in D'Arcy and Harron 1994, p. 24)<sup>206</sup>

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<sup>203</sup> See the Proceedings of the first two conferences in particular (D'Arcy and Harron 1992, 1994).

<sup>204</sup> See for example some of the opening and closing remarks of regulators of all three regions in the International Conferences on Harmonization (D'Arcy and Harron 1992, 1994, 1996).

<sup>205</sup> Dr. Esber was at the time Associate Director for Research and Regulatory Coordination, CBER, FDA.

<sup>206</sup> Dr. Kessler was at the time the FDA Commissioner.

The ICH represented a complete break from traditional international cooperation mechanisms one ideally suited to the new regulatory environment. So much so, that it urged all regulatory authorities to reassess and change their own structures along the spirit of the ICH process:

The ICH process has prompted us to reassess FDA's current procedures, especially within the context of international peer review and the structure of the ICH process. These gains, I am sure, are shared also by our European and Japanese colleagues: we all have been compelled by ICH to take a fresh look at our approaches and policies, and adjust them in light of the latest science.

(Dr. Kessler in D'Arcy and Harron 1994, p. 24)

To be sure, both European and Japanese regulators echoed Dr. Kessler's comments<sup>207</sup>.

This public defence of the ICH process has been confirmed to the author in interviews with regulatory representatives from the three jurisdictions of the ICH process. All regulatory agencies' representatives interviewed by the author stressed the very specific and technical nature of the work conducted in the ICH<sup>208</sup>. According to Dr. Arlett of the European Commission, the expertise needed to understand and conduct this kind of work lies with the industry, and therefore its participation is essential:

The innovative pharmaceutical industry associations are at the table directly, and the justification for that at the beginning and the justification for that now is that the representatives of the industry have the expertise, and very valuable expertise; they are also best placed to judge disharmony because they are trying to access the three markets and therefore they are ideally placed to tell us where disharmony occurs<sup>209</sup>.

As we saw previously, similar remarks have been made by industry representatives who have justified the participation of the industry and the exclusion of other stakeholders, on the grounds that the industry alone holds the required expertise for the technical harmonization being pursued in the ICH (Abraham and Reed 2001).

Still, the choice of the ICH as the forum for pharmaceutical harmonization is surprising, when justified on grounds of protecting the public interest. This as we have seen, is due to the politically sensitive nature of the issue-area in question. While

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<sup>207</sup> See comments by Keith Jones and Tatsuo Kurokawa in D'Arcy and Harron 1994, pp. 536-537.

<sup>208</sup> Interviews with EMEA, EC and current and former FDA officials.

<sup>209</sup> Interview with author, 15/05/2007.



harmonization in the context of the ICH has targeted the “technicalities” of the approval process of commercial products, these products, medicines, are directly and inextricably related with the status of public health in any society, and its ability to treat disease. Indeed, it is for this reason that regulators have sought to justify their decision to participate in the ICH process, not only in terms of efficiency gains and technical expertise, but have stressed that these efficiency gains contribute significantly to the very purpose of their authority, that is, the protection of public health. At the opening session of the first ICH conference in 1991, the Vice-President of the European Commission argued that savings made by companies from harmonized regulations would further the delivery of innovative research, yielding therapeutic benefit to patients (Bangemann in D’Arcy and Harron 1992), while Vice-President Quayle argued that harmonization would save “millions of lives”(Leary 1991). This connection between efficiency and public health has been necessary, since “by representing it [the ICH] as being in the interest of public health, it became legitimate for governmental regulatory agencies, who are supposed to protect public health, to become its allies” (Abraham and Reed 2001, p.117). This argument has been also promulgated by the industry, eager to justify the ICH process in terms of public interest: “failure to achieve harmonization results in the repetition of studies to meet divergent regulatory requirements. Such repetition takes time, and therefore delays new therapeutic advances reaching patients. Speeding access of patients to new treatments can for many be life-saving” (Griffin, ABPI Director, in D’Arcy and Harron 1992).

In addition, the presence of public health risk, in line with condition (1b), has forced regulators to set up a hybrid regulatory structure where they retain a decisive role. In the ICH structure, regulators have retained voting rights that give them the power to control all ICH decisions. Final approval at step 4 is only achieved once the three regulatory authorities sign off the proposed guideline. This allows the regulators to argue that they retain the ultimate decision-making power in the ICH: “ICH is a harmonization process where there is then the final sign off...[the final sign off] is only amongst the regulatory partners at the ICH Steering Committee, so the final sign

off of the guidelines is only by the regulators”<sup>210</sup>. This is in contrast to the IASB, where the decision-making body is comprised solely by non-state actors. The structure of the ICH therefore, has a stronger intervention mechanism whereby the regulators participate in the development and approval of the actual regulatory work. This, I believe, reflects the heightened societal perception of risk related to medicines and therefore the correspondingly higher associated political costs.

## **7.5 Summary and conclusions**

Diverse national regulations for the registration procedures of medicines for human use create significant financial and time costs for multinational pharmaceutical companies, but also for patients, regulators, and governments. Harmonization, by cancelling duplicate tests, promoting mutual recognition of certain pre-clinical and clinical results and harmonizing the information necessary to acquire marketing approval in all countries, can reduce significantly the time and costs needed to put a new drug in the market. These benefits became particularly important for the industry during the 1980s, when the cost and time for developing new drugs and satisfying all the necessary pre-marketing regulations increased to levels that even multinational companies had a difficult time meeting. The industry pressed for harmonization of drug registration procedures aiming primarily to a reduction of the regulatory requirements of the drug approval process and lobbied for a hybrid, transnational regulatory forum.

The timing helped their cause. In Europe, institutional developments in the context of the 1992 project and frustration with past failures produced a strong impetus in favour of harmonization. At the same time, the financial burden of European health care systems, made regulators more receptive to the idea of harmonization as it held the promise of lower drug prices and therefore reduced health care costs. In Japan, concern over health care costs was also important, but equally significant was a desire to develop the growing Japanese pharmaceutical industry into a significant global player. In the US, it was the public outcry against the FDA’s inefficiency and a conservative administration (and later Congress)

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<sup>210</sup> Interview with Dr. Arlett, 15/05/2007.

promoting pharmaceutical market-friendly re-regulation that contributed to the FDA's decision to embrace harmonization.

The coincidence of industry pressures and domestic political circumstances favourable to harmonization gave added urgency to regulators' move towards harmonization. Nonetheless, harmonization did not have to occur in a transnational regulatory forum like the ICH. The WHO had a clear and legitimate mandate to develop international pharmaceutical regulation. However, the triad regulators did not see positively the type of harmonization promoted in the WHO and could not afford the compensatory costs associated with it. So, they used the absence of research-based pharmaceutical industry in developing countries to exclude them from a joint government-industry regulatory forum. Still, regulators could achieve the same result by using an alternative inter-state or inter-governmental forum comprising only developed states, like the OECD, particularly since a conflict of interests among the three regulators cannot be substantiated. The only explanation consistent with the evidence is that, in accordance with proposition (1), the regulators of the three states/region created the ICH as a means to effect domestic redistribution in favour of their research-based industries. The history, objectives, structure and regulatory output of the ICH provide support for this claim.

The large multinational companies that dominate the world pharmaceutical industry have traditionally been able to organize and lobby their governments, but also international and regional organizations, successfully. As per condition (1a), in the late 1980s they were able to lobby and persuade their respective regulators of the need to pursue technical harmonization, and to do so in the context of a hybrid regulatory forum like the ICH. According to propositions (2a) and (2b), we would expect regulators to use transnational regulatory authority for domestic redistribution in issue-areas with a high degree of technological and/or scientific complexity, when the issues being regulated have a high potential to attract public attention. Indeed, reducing regulatory requirements for the evaluation and approval of new drugs, is a highly sensitive political issue, despite its technical complexity, as made evident by the history of all significant regulatory interventions in the pharmaceutical industry and the recent AIDS' patients campaign in the US. Shifting harmonization to a

technically-oriented forum, which excluded “non-experts” could overcome these problems. As expected, the regulators agreed to the industry’s suggestion and decided to pursue harmonization in the ICH. The technically complex nature of the issue-area and the exclusion of other stakeholders from the process have allowed the ICH to proceed in its work without attracting significant social visibility.

The redistribution pursued in this case does not mean that the regulators in the three jurisdictions sacrificed the interests of the public to the interests of the industry. Rather, pharmaceutical harmonization is a case where the private interests of the industry coincide to a significant degree with the public interest. The point is however, that the industry’s interests seem to have been given a higher priority. As long as the public interest was served to a satisfactory degree, the industry’s preferred direction and mode of regulation was chosen. Transnational regulatory governance was chosen primarily for the private goods it created.

Finally, according to proposition (4) and (5), the inability of the state apparatus to provide adequate governance in this issue-area, in the context of significant scientific and technological developments that have transformed the way the R&D process take place, and the expertise of the private sector have been both cited by regulators as reasons for allowing the industry to participate as an equal partner in the context of the ICH. As we have seen, the industry was relied upon to identify the problems caused by the diversity of national registration requirements and also to propose the solutions for these problems. Moreover, given the politically sensitive nature of the issue-area in question, the regulators of the triad have also sought to justify their actions explicitly in terms of great benefits for public health, while also taking care to develop, as per condition (1b), an institutional mechanism for the approval and endorsement of the produced guidelines, that allows them to argue that they still retain the ultimate authority over the harmonization process.

## **Chapter 8**

# **Transnational Regulatory Authority and Global Economic Governance**

### **8.1 Introduction**

Following the examination of the IASB and the ICH through the lens of transnational regulatory authority, it is now time to return to our theoretical framework in order to evaluate its propositions in light of the case studies' findings. The summation and comparative evaluation of the evidence presented below will show that the propositions put forward in our theoretical framework have been given empirical support by our case studies. Of course, this verification does not translate in a final and conclusive validation of our framework. Nonetheless, I believe that it establishes a good starting point for a more thorough and analytically consistent investigation of transnational non-state governance. Following the overview of the evidence, we shall turn our attention to a number of issues that emerged from our research, and examine them in the context of the current literature debates on the nature, consequences and future of global governance. In this context, we shall also attempt to outline potential avenues for future research.

### **8.2 Explaining the emergence of transnational regulatory authority**

Transnational regulatory authority is a consequential new aspect of transnational non-state governance, one not explicitly identified and analysed as such until now. Its features transcend the traditional gulf between binding state authority and voluntary non-state governance. Invested with transnational regulatory authority, a non-state organization can issue rules that enjoy binding legal force. While setting it apart from other types of non-state governance, this distinctiveness of transnational regulatory authority also creates the puzzle of its emergence. In chapter 3, we posed three research questions in order to delineate this puzzle, and then offered a series of propositions and conditions to answer them. The principal argument of the thesis, as expressed in proposition (1), is that the use of transnational regulatory authority is the result of explicit redistributive regulatory strategies aimed at satisfying specific

domestic interest constituencies. In chapter 3, we put forward this argument after rejecting alternative hypotheses on theoretical grounds. Before proceeding to an evaluation of the propositions developed in our theoretical framework we shall begin the evaluation of our explanation of transnational regulatory authority by considering the alternative hypotheses examined earlier, based on the empirical findings of the two case studies.

The case studies' analysis has shown that the alternative theoretical explanations considered in chapter 3, are not supported by the empirical findings. In the IASB case, the evaluation of other hypotheses is particularly interesting, as we have seen that Simmons and Martinez-Diaz have offered alternative explanations for the emergence of the same organization. Simmons' analysis based on the power of the hegemonic financial centre, is not supported by the history of international accounting harmonization as presented in this thesis. Thus, Simmons' argument about a dominant regulatory innovator makes no sense, since the SEC made no new domestic regulatory innovation intended for export to a global scale. On the contrary, the SEC pressured from the forces of financial globalization, reacted by trying to keep its regulatory framework as intact as possible, either by achieving a favourable international agreement on harmonization, or failing this, by bringing about a de facto globalization of US GAAP, while blocking the progress of harmonization. While Simmons is right to emphasize the influence of the US markets and the SEC in the harmonization process, she overestimates the ability of the SEC to act unilaterally and enforce its own standards. As we have seen, SEC's tripartite proposal failed and the SEC was obliged to engage with the IASC in order to influence the future direction of harmonization, either by controlling IASC's work or by stalling its progress. The IASC, a transnational, non-state organization became an essential part of the SEC's strategy and indeed the only means to control international harmonization. Moreover, Simmons seriously underestimated the ability of the IASC/IASB to become a focal point for international accounting harmonization and thought that the G4+1 initiative would be a more probable forum for harmonization, and one, where Europeans would eventually be dragged on U.S.-U.K. terms. While it is true that the IASC/IASB's standards have been heavily influenced by the SEC and the FASB, Europe has

nonetheless, through its adoption of the IFRSs as national standards, changed the reversion point and acquired a voice of its own in the development of the standards, which as we have seen, becomes increasingly stronger. Today the IASB is the unquestionable forum for global accounting standard setting, while the G4+1 was disbanded in 2001.

Martinez-Diaz's account on the other hand, placed emphasis on the role of the IASC/IASB as an epistemic community. Nonetheless, as it became evident from the analysis in chapters 4 and 5, the IASC/IASB never really constituted a harmonious epistemic community, sharing a belief in common cause-and-effect relationships and common accounting principles. As we have seen, both internationally, and regionally in the context of the European harmonization programme, diversity of accounting standards and principles was so deeply ingrained in the practices of users and preparers of financial statements, that progress in accounting harmonization was extremely difficult, in both the UN and the EU, as well as in the context of the bilateral contacts between the EU and the US. Even in the early stages of the IASC, when it comprised solely accountants, disagreements were so strong that the usefulness and therefore endorsement of its standards were limited, given the number of options they allowed. Moreover, we have seen that since the early 1980s, a number of different constituents were included in the Board, which makes the characterization of the IASC/IASB, as an epistemic community, arbitrary. The manoeuvres of the SEC in order to influence the IASC's work, particularly in the context of the IOSCO, have demonstrated clearly the political nature of the standard-setting taking place in the IASC, while recent developments such as the adoption of the IASs/IFRSs by the EU, the establishment of a European endorsement mechanism that introduced two carve-outs, and the controversy about some of the new proposed IFRSs, have compromised the image of the IASB as an epistemic community beyond any doubt.

Finally, it is clear that an efficiency hypothesis does not stand up to the evidence either. As was clear from the critique of the SEC by highly prominent American experts, efficiency gains for small investors and US issuers did not necessarily derive from SEC's dismissal of foreign GAAPs. Certainly, the NYSE's proposal for a limited relaxation of the reconciliation requirement for a number of

quality global issuers would only bring benefits to both US investors and stock exchanges, as well as to big foreign issuers. Moreover, were efficiency gains the overriding objective, the SEC would surely have tried to negotiate an international agreement with the Europeans, who were extremely eager to promote harmonization, and would not limit its only international effort to a trilateral agreement, which would not solve the problem either for the majority of foreign companies, the American investors, or the US stock exchanges. On the other hand, Europeans refuge to mutual recognition, which only transferred the costs of assessing accounting differences to investors and generally users of financial statements, was obviously far from efficiency driven, given the deep disagreements among them. Similarly, mutual recognition with US GAAP, would benefit the “global issuers”, the constituency pushing hard for harmonization, at the expense of small investors and other constituencies (e.g. trade unions) trying to evaluate these companies’ accounts. Finally, the conduct of both the SEC and the EC in the context of their engagement with the IASC/IASB reveals that their decision was not based on efficiency grounds. This is well illustrated by the continuous interference and revisions introduced by the SEC during the core standards project, even for standards already judged as acceptable by the IOSCO and the unnecessary, from an efficiency point of view, diversion of resources away from IASC to the G4+1. Similarly, European efforts to gain influence in the IASC/IASB regulatory process, by allowing for example national interpretations consistent with IASs, at the expense of overall comparability of European statements, demonstrate that efficiency/effectiveness gains has not been the main driver of the European engagement with the IASC/IASB.

Similarly, in the ICH case alternative hypotheses do not stand up well against the evidence. Regarding the efficiency/effectiveness hypothesis, it is obvious that such an explanation cannot be easily reconciled with the nature and procedures of the ICH. As we have already argued, justifying the exclusionary set up of the ICH based on the argument that the necessary expertise can be found only in the private sector is a rather weak position to take. This is even more so for an efficiency/effectiveness argument, which is based on a premise of pursuit of the public interest. Reconciling the rather opaque structure of an organization where all interested stakeholders,



except for the industry, are excluded, with principles underlying a public interest argument is a challenging task, particularly when there have been criticisms that the ICH has not always taken up the opportunity to raise the harmonized standards or that occasionally it has even reduced their quality. Finally, one would be hard pressed to find any reasons why regulators acting on the basis of an efficiency and/or effectiveness maximizing rationale, would spend two years of preparations incurring time delays and monetary costs, in order to set up a new hybrid organization, when they could use existing international regulatory structures, such as the OECD, where pharmaceutical harmonization was already taking place, where approximately the same set of countries with the same regulatory concerns would participate, and where the resulting regulations could have a higher degree of legal obligation.

Concerning the epistemic communities argument, we have to admit that there seems to have developed a close working relationship between the regulators and the industry. Yet, this relationship developed over time and was not one of the factors that affected the establishment of the ICH. Indeed, as we have seen, in the case of the FDA, the relationship between regulators and the industry was characterized as adversarial before the establishment of the ICH and the deregulatory interventions of conservative US Administrations and Congressional majorities. Moreover, this relationship can hardly be said to possess the ambiance of an epistemic community. As we have seen, particularly in the early years, the regulators were depended on the industry to identify the problems, provide data for their analysis, and propose the solutions. This type of relationship can be more accurately described as a dependency relationship rather as an epistemic relationship based on equality and comradery. Finally, the very nature of the private sector participants, that is, manufacturers' trade unions do not fit the description of scientists operating in the context of an epistemic community, as their expertise is exercised under the overriding limitations and directions imposed by the commercial interests of the companies they represent. This commercial bias in the exercise of science prevents the development of a true epistemic community and as has been shown by empirical studies often runs contrary to well-established scientific practice and principles, particularly in the area of pharmaceutical research (Abraham 1995).

Finally, an explanation based on power does not make much sense in the ICH case either. The regulatory dilemmas faced by the regulators did not pit them against each other. There was no significant distributional conflict that drove a dominant power to impose some kind of agreement on the others. The ICH was the result of a tripartite agreement among the three dominant powers in pharmaceuticals. The commercial dispute with Japan is not enough to explain the emergence of the ICH or the type of harmonization it promotes. Were these commercial concerns the overriding driver of harmonization, the US and the EC would continue their bilateral negotiations from a position of asymmetrical power, as they had done in the 1980s, or pursue an international commercial agreement that would bind Japan more tightly, and would address trade obstacles and not technical harmonization. Finally, as we have seen, the FDA, which was the biggest regulatory agency, endowed with the most resources, was the one that was the least enthusiastic about this harmonization initiative in the beginning. Traditionally, the FDA did not consider foreign testing requirements as equivalent to its own and thought that harmonization should mean other jurisdictions harmonizing towards the FDA standards. The fact that the FDA followed in an initiative led, at least in its initial stages, by the EC, runs clearly contrary to the argument of a dominant regulatory innovator.

Since the empirical findings, do not support alternative explanations, we shall now turn our attention to evaluating the propositions put forward in this thesis. During the discussion of the two case studies, we showed that the empirical findings support these propositions. Here we shall summarize this evaluation and try to reinforce it by comparing and contrasting the evidence both across and within the case studies. The main argument of the thesis is that transnational regulatory authority is the result of an explicit redistributive strategy, employed by national regulators/politicians in order to satisfy specific domestic interest constituencies. This strategy can be used either to redistribute wealth among domestic constituencies or to transfer wealth from foreign to domestic constituencies. In any case, in accordance with the economic theory of regulation, and condition (1a), we expect the winning constituencies to be small, well-organized, and with a high per capita interest in the produced regulation. Nonetheless, as per condition (1b), we do not expect

regulators/politicians to delegate their regulatory authority away completely. We expect them to retain a role through an institutional mechanism, and thus the ability to control, to some degree at least, the regulatory outcome.

The analysis in chapter 7 has shown that the ICH case corresponds to a rationale of domestic redistribution. Duplicate and different testing and registration procedures created significant costs and time delays in the introduction of new medicines. The research-based industry, which was principally affected by the diversity of national regulatory procedures, agreed in all three states/region about the necessity of harmonization and lobbied politicians and regulators in the three jurisdictions to begin a harmonization process. The industry was helped by the timing, since the escalating costs of health care programmes and the inefficiency of existing national and regional registration procedures (and in the case of Japan industrial policy considerations) made governments even more receptive to industry pressure as harmonization looked like a promising way out of their problems.

Regulators and the research-based industry came together in the context of the ICH, to promote the technical harmonization of drug approval guidelines. The available evidence suggests that the choice of the ICH was the result of a commonly agreed domestic redistribution strategy in all three jurisdictions. In line with condition (1a), the well-organized and well-funded national and international pharmaceutical manufacturers' associations, put their weight behind the idea of technical harmonization. The research-based industry lobbied hard not only for harmonization but also for a forum like the ICH, and assumed the costs of its operation. It played a significant role in every step of the establishment of the ICH, and gained a privileged, regulatory role alongside national/regional regulators, while other legitimate stakeholders were excluded from the process. While, in accordance with condition (1b), the three regulators developed a framework that granted them the final sign off of the tripartite guidelines, retaining thus an ultimate veto power, the objectives of the ICH have nonetheless followed closely the demands of the industry, which has often dictated both the issues in need for harmonization and the content of the new harmonized tripartite guidelines. The produced guidelines have often been criticized for aiming towards the lowest-common-denominator, favouring agreement over

“upwards” convergence, and for being decided on grounds other than the best available science. While public health undoubtedly stands to benefit from harmonization, the history, structure, procedures, and resulting guidelines of the ICH, clearly demonstrate that in choosing the ICH as the forum for pharmaceutical harmonization, regulators and politicians used the ICH as a means to reallocate some of the costs of health care from the industry to patients and consumers.

On the other hand, the analysis in chapter 5 has demonstrated that in the IASB case, the accounting harmonization debate developed into a dispute over the distribution of costs for issuers wanting to access international capital markets. The distribution of these costs was uneven, as European issuers have had to provide a quantified reconciliation to US GAAP for listing in the US capital markets, while their American counterparts could list their shares and bonds in European capital markets using their home accounting standards. This situation created a long-term, structural competitive disadvantage for European companies, since it often prevented them from accessing the US capital markets, the world’s most liquid and efficient capital markets. The EC therefore, faced a straightforward conflict of interests between big, global issuers with a large per capita stake in the harmonization process, and American interest constituencies. On the other hand, this situation also created a problem for the competitiveness of US capital markets, which were clearly lagging behind in terms of attracting foreign listings, compared to other international stock exchanges. The US stock exchanges pressed the SEC to abolish the reconciliation requirement, even if only for a few selected global issuers. The US issuers, but also SEC’s own regulatory establishment, were against such a move, since it would undermine the former’s competitive advantage and the latter’s extensive regulatory infrastructure. The SEC therefore, was caught in the midst of a more complex regulatory problem, whereby well-organized, wealthy constituencies with a high per capita stake in harmonization (including the SEC), were pitted against each other.

To satisfy both constituencies the SEC could either delay the harmonization of accounting standards, or failing that, ensure that the harmonized standards would be as close to the US GAAP as possible. In the first case, in the absence of an internationally agreed set of accounting rules, the attraction of the US capital markets,

the existence of a comprehensive and highly developed set of US accounting rules, and the reconciliation requirement, could lead to a gradual de facto adoption of US accounting standards in international listings. Such a development, if realized, would resolve SEC's domestic dilemma to the satisfaction of all sides, at the expense of foreign issuers, investors and regulators. Failing this, an international harmonization based on US GAAP, would at least transfer most of the adjustment costs to foreign constituencies. Indeed, the SEC sought to influence the development of the IASs so that they conformed closely to US GAAP. To achieve this objective and in line with condition (1b), it embedded its relationship with the IASC, in a working agreement between the IASC and IOSCO, over the work of which it exerted significant influence. Moreover, and in the context of a strategic manoeuvre not foreseen by our framework, the SEC effectively turned its engagement with the IASC into a forum-blocking strategy, consistently trying, from within, to delay the rise of the IASC as a global forum for accounting harmonization.

On the other hand the EC, tried to resolve its dilemma and overcome the SEC's resistance through mutual harmonization on an international set of accounting standards, particularly for the consolidated accounts of listed companies. This solution would ensure that European issuers did not have to incur extra costs for accessing the US capital markets, while avoiding tax implications and leaving intact most of the European accounting regulatory infrastructure. The engagement with the IASC had the potential to help the EC meet these objectives. This engagement became gradually closer and eventually led to the landmark decision to replace national accounting standards with the IFRSs. The strategy has succeeded, since the SEC has come to acknowledge that the future set of global accounting standards will be based on the IFRSs, and has agreed to abolish the reconciliation requirement. In addition, as per condition (1b), the EC embedded its relationship with the IASB, with a European endorsement mechanism, which has allowed it to increase its influence over the IASC's work. Still, the SEC's and FASB's influence, gained through their involvement with the IASC/IASB, have given them the ability to influence significantly the latter's work, converging, at least to a degree, the IFRSs to the US GAAP.

I believe that the discussion above has shown that both the IASB and ICH cases support proposition (1) and its accompanying conditions. This is all the more significant, because it is evident that several aspects of the regulatory dilemmas faced by the regulatory authorities, exhibit a significant degree of variation, not only between but also within the case studies. Thus, while the size, wealth and per capita interest of the winning constituencies in both cases conform to the economic theory's predictions, and therefore provide support to condition (1a), opposing constituencies, varied greatly, ranging from no opposition (IASB's case in Europe)<sup>211</sup>, to large, poorly organized constituencies (ICH's case), to significant and well-organized opposition (SEC's case). Also, the regulatory dilemma in the ICH case pitted domestic constituencies against each other, while in the IASB case, we had an international conflict of interests (EC's case), as well as a regulatory dilemma which pitted both domestic constituencies against each other and against foreign constituencies (SEC's case). The fact that, while the regulatory authorities in the two case studies faced different dilemmas, which created different types of coordination problems between them, still employed transnational regulatory authority in order to transfer wealth to specific domestic interest constituencies, provides additional support to proposition (1). Indeed, as is evident the two cases represent the two different types of redistribution described in proposition (1). Finally, condition (1b) has also been given support by both cases. The regulators in both cases embedded their relationship with the transnational regulatory fora, with an institutional mechanism that allowed them to influence and if possible control the regulatory process. What is more, in the IASB's case, both regulators employed such mechanisms, despite the significant differences in their institutional characteristics. Thus, the SEC engaged the IASC first through IOSCO, where it exerted significant influence and held the chair of the working group responsible for the cooperation with the IASC, and later also through the G4+1, taking advantage of the influence of the FASB as an accounting standard-setter. The EC on the other hand, tried first with

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<sup>211</sup> In the IASB case, European regulators and the EC did not have to deal with opposing constituencies. This is not surprising given that harmonization concerned only the consolidated accounts of listed companies and did not affect other constituencies significantly. More recent discussion about extending IFRSs requirements to other companies, e.g. SMEs, are not related to the initial decision to adopt IFRSs.

the development of a Contact Committee that would coordinate and transmit the European views to the IASC, and then through the creation of the endorsement mechanism, to influence the development of the IFRSs and prevent a wholesale adoption of US standards.

Propositions (2) and (3), sought to specify the conditions under which regulators and/or politicians have an incentive to use transnational regulatory authority as a redistributive strategy, compared to other international and/or transnational institutions. In the case of domestic redistribution, we would expect transnational regulatory authority to be the choice-strategy when it allows regulators/politicians to effect redistribution among domestic constituencies with lower political costs than through other alternatives. According to propositions (2a) and (2b), this is more likely to happen when, in issue-areas with highly complex scientific, technical, and/or technological content, the issues being regulated have a high potential to mobilize wide public opposition. On the other hand, when the aim is international redistribution, regulators/politicians may employ transnational regulatory authority, when in line with propositions (3a) and (3b), in an oligopolistic global market structure, there is a distributional conflict among the dominant market players, which cannot be resolved through international institutions. In this case, transnational regulatory governance may be used as a forum-shifting strategy.

The ICH case seems to verify conditions (2a) and (2b). The pharmaceutical industry is one of the most heavily regulated industries. This is understandable, given that the regulation of medicines is inextricably linked with the protection of public health. As such, pharmaceutical regulation more generally, and the regulation of drug approval procedures in particular, can have tremendous political consequences. As we have seen, most of the regulation governing this issue-area, has been the result of significant public reaction in the wake of public health crises. As a result, until recently national regulators guarded their sovereignty in these issues very closely, and did not accept foreign pre-clinical and clinical data, on safety grounds. More recently, the AIDS campaign in the US, has demonstrated that despite the very technical nature of the issues involved, well-organized and motivated constituencies can attract significant public attention. In this context, a forum like the ICH provided the only

mechanism where business-friendly harmonization aiming primarily at cost-effectiveness, could be sought without attracting significant public attention. The technical nature of the issue-area, has contributed to the low social visibility of the harmonization process. Despite the occasional reactions and criticism from national and international NGOs and indeed from the WHO itself, the ICH has remained for the most part invisible, opaque and exclusive, its character defended by both regulators and the industry as necessary for the conduct of purely technical and highly complex harmonization. In the course of a few years, the ICH has been able to adopt over fifty guidelines, without any significant public reaction.

Similarly, the IASB case also seems to lend support for propositions (3a) and (3b). We saw above, that the accounting harmonization debate turned into a conflict between the United States and the EU over the distribution of the listing costs on international capital markets. The US was clearly the dominant force in the world economy in terms of the significance and attraction of its financial markets. Also, as we saw above, it exerted significant influence on international harmonization due to SEC's reconciliation requirement and FASB's highly developed and detailed standard setting work. On the other hand, Europe's financial markets had also started to grow during the 1980s, and as we have seen, by the 1990s European financial transactions and market capitalization had grown significantly. Moreover, European financial markets had become particularly attractive destinations for big, international issuers. Finally, Europe's structural power in this issue-area was also boosted by the European accounting framework, which bound European jurisdictions and made it difficult for any single European regulator to make bilateral agreements with other states.

In these circumstances, the distributional conflict between the two major players was difficult to be resolved. The EC could not overcome SEC's resistance, as it did not possess the structural power required to change the reversion point. The troubled history and status of European accounting harmonization which had failed to produce a unified European accounting model, and the fact that most European jurisdictions already accepted US accounting standards for listing in their markets without any reconciliation requirement, weakened its negotiating position



significantly. Indeed, both the European Commission and European national regulators had tried to reach an international agreement on mutual recognition of accounting standards with the SEC, but the latter was not interested. On the other hand, while the SEC was clearly the dominant player, it could not unilaterally impose US standards. The SEC tried through a trilateral international agreement to force Europeans to harmonize towards the US GAAP. However, the European harmonization programme made the inclusion of the UK extremely difficult. Still, the SEC had enough structural power to resist any change in the status quo, which could gradually lead to the de facto prevalence of the US GAAP. As a result, there was a regulatory stalemate between these two major financial centres of the world economy.

As per condition (3b), it is exactly in cases like this that forum-shifting strategy may be employed to overcome the negotiating deadlock. Following the failure of the tripartite agreement, the SEC employed a transnational forum-shifting strategy, by engaging the IASC and promising transnational regulatory authority, that is the legal adoption of IASC standards, albeit in effort not to create transnational regulatory governance, but rather to control and if possible prevent it. On the other hand, following its failure to obtain an international agreement based on mutual recognition, the EC opted for a forum-shifting strategy gradually transferring the debate to the IASC. As was argued above, the IASC was the obvious choice, due to its high expertise profile and of course the agreement with IOSCO. As per our argument, with this move the EC was finally able to change the reversion point. It overcame the problems of the European harmonization project and created, by adopting the IFRSs, a set of rigorously enforced, comprehensive, high quality accounting standards to rival the US GAAP.

The discussion above showed that while propositions (2) and (3) were given support by our case studies' findings, in contrast to proposition (1) and its accompanying conditions, most of the propositions and/or variables included in these hypotheses cannot be compared across the two case studies. This is because the two cases represent two different types of redistributive strategies and therefore the propositions and/or variables involved in their articulation differ between them. Also, because these propositions set out the framework conditions for selecting

transnational regulatory authority as a redistributive strategy, they often refer to characteristics of the issue-area or industry where we would expect to see transnational regulatory authority. Obviously, this precludes, at least for such propositions and variables, variation within the cases. Thus, the degree of technical complexity of the issue-area or industry, as per proposition (2a), cannot vary among the three jurisdictions in the ICH case, since in all three jurisdictions we are examining the same industry. Similarly, the oligopolistic global structure of the industry in the IASB case is the same for all regulators. To achieve the optimum test for these propositions' validity, we should have at least two case studies for the same type of redistribution (domestic and international), where either additional cases of transnational authority could be compared for each type of redistribution, or test studies could be introduced to test the validity of the propositions. This however, would mean that we would have to have four case studies in total, something, which was not possible in the context of a resource-bound and time-limited doctoral thesis. It remains therefore for further research to validate further these propositions through comparative research with other cases. Still, for one proposition (3b), we can compare the regulators' behaviour within the IASB case. As we saw above, both regulators tried to use first international institutions to resolve their dilemma and only when these efforts failed, did they turn to transnational regulatory authority as a forum-shifting strategy. Despite the different use and objectives of the forum-shifting strategies of the two regulators, the fact that they both used transnational regulatory authority as a forum-shifting strategy, in order to redistribute wealth to their preferred domestic constituencies, strengthens the validity of proposition (3b).

While the arguments and empirical evidence presented above provide support for the propositions and conditions relating to the first two research questions, the third research question raised the normative dimension of transnational regulatory authority. According to propositions (4) and (5), we would expect national regulators/politicians that resort to transnational regulatory authority to justify their decision by arguing that it is necessary, because changes in scientific knowledge and/or technology have altered the nature of an issue-area or industry, thereby

hindering the ability of traditional state or inter-state mechanisms to provide an adequate standard of governance, on their own.

Indeed, despite the significant differences in the subject-matter of the two issue-areas discussed in this thesis, in both the IASB and the ICH cases, justification for the delegation of regulatory authority to non-state actors was based on an argument of necessity. Traditional state mechanisms were presented as inadequate given the rapid pace of technological change and the dramatic transformations that this change entailed for the structure and operation of industries and markets. In the case of accounting, the EC argued that the rapidly changing, instantaneous, global financial markets' environment created a new pressing need for increased comparability and flexibility of financial information, which the traditional EU mechanisms had proven unable to provide. A new more flexible and international accounting setting infrastructure was needed and the IASB provided just that. In the case of pharmaceutical harmonization, the expertise of the private sector was presented as necessary in order to identify regulatory differences burdening the operation of transnational enterprises in an increasingly global pharmaceutical market, and to address problems of extreme technical complexity in an environment of continuous technological and scientific change. In both cases recourse to the private sector was justified as necessary in order to achieve the regulatory authority's ultimate objective: to serve the public interest. In both cases, as proposed in the theoretical framework, endorsement mechanisms were set up to give the regulators some degree of leverage and control over the regulatory outcome. This allowed regulators to claim ultimate control over the regulatory process thus hoping to allay concerns over the legitimacy of their actions.

I believe that this brief evaluation of the case studies' empirical findings in relation to our hypotheses provides support for the theoretical framework put forward here. What is more, the discussion above, made clear that the comparative examination of these findings added to the credibility of this framework, and therefore justifies our decision to examine two case studies, one for each type of redistribution. While this research strategy limited to some degree the comparative examination of the framework conditions that could lead to the use of transnational

regulatory authority, it offered other advantages. First, it allowed us to examine both types of redistribution, thereby allowing us to test all framework conditions, even if only in the context of a single case study, something that would not be possible if we had selected two cases of the same type of redistribution. Moreover, the examination of our hypotheses for both types of redistribution provided a better test for the principal redistributive argument of the thesis, as well as for the justificatory hypothesis. Finally, this research design also allowed us to pursue a more holistic approach to case study analysis, an approach which was necessary, in order to address all the aspects, however different (e.g. interest-based vs. normative considerations), of a phenomenon as complex as transnational regulatory authority.

### **8.3 Transnational regulatory authority and the transformation of global economic governance**

While providing support for our framework's propositions, the synopsis presented above does not claim the final word on the issue of transnational regulatory authority and transnational non-state governance. On the contrary, the case studies' analysis has pointed to new research avenues arising out of the propositions put forward in this thesis, and has raised some issues, which merit further discussion in the context of current global governance debates. In this section, we shall identify these issues and offer some suggestions for potential avenues of future research.

#### **8.3.1 Privatizing and globalizing regulatory authority**

A basic feature of transnational regulatory authority, which was demonstrated clearly by our case studies, is the fact that it leads to the creation of new, and the alteration of existing regulatory structures at both the domestic, and the international/transnational level. These changes are not random. Two basic elements characterize them: a strengthening of the role of non-state actors and an increasing intertwining of domestic and transnational regulatory structures. Neither element is surprising. The strengthening and institutionalization of the role of non-state actors in the regulatory process is a constitutive feature of transnational non-state authority. The close cooperation between national and transnational governance arrangements was also anticipated given our argument about the establishment of an endorsement

mechanism by the regulatory authorities intending to use transnational regulatory authority. Our analysis of the IASB and the ICH cases however, has revealed not only close cooperation but rather an increasing integration of the domestic and transnational regulatory structures to a degree that was not expected.

In the IASB's case, following the decision to replace national standards with IFRSs, more than 7,000 European companies are obliged to use them for the preparation of their consolidated financial statements. This decision, implemented nationally, relocates to a transnational non-state organization a rule-making procedure that in most European countries was until recently under the auspices of the legislature. Instead of engaging in legislative work for the determination of the appropriate national financial reporting standards, national parliaments have now become integrated in a regulatory structure involving a series of transnational (IASB and EFRAG), transgovernmental (ARC) and supranational (EC, EP) institutional mechanisms, where they perform, as a last act, a largely ceremonial national ratification process, while national regulators have undertaken the task of implementing the standards adopted through this multi-level process. Although less publicized, the ICH's institutional impact is no less important. The tripartite guidelines agreed between industry and regulators have been incorporated in the official government medicinal rulebooks of the three jurisdictions participating in the scheme, complementing and often replacing other national pharmaceutical guidelines. The national regulatory procedure has been incorporated in the wider transnational regulatory procedure, with the draft guidelines being scrutinized under the normal, national regulatory consultation process in each of the three jurisdictions in step 3, before going back to the ICH for adoption in step 4, and finally becoming officially incorporated in each jurisdiction according to the national/regional procedures that apply to other regulatory guidelines in step 5.

It is obvious that the decision to delegate to non-state actors a regulatory role that produces legally binding results intended to be implemented nationally, has led, by necessity, to the partial incorporation of these transnational structures into domestic institutional regulatory frameworks. In this sense, transnational regulatory

authority could be conceived as an example of the denationalization process identified by Sassen:

particular institutional components of the national state begin to function as the institutional home for the operation of powerful dynamics constitutive of what we could describe as 'global capital' and 'global capital markets'...these types of dynamics unsettle the meaning of 'national' in institutional components of states linked to the implementation and regulation of economic globalization, and they do so within the law, not in violation of the law.

(2006, p. 412).

This conceptualization raises a number of issues that deserve to be examined further. A first set of questions has to do with the obvious political question: who gains by this transformation of the regulatory process? Are there particular constituencies/stakeholders that benefit from this rearrangement of the regulatory process? Do these constituencies/stakeholders share common characteristics across state borders? It is obvious from Sassen's definition above, that she considers that denationalization favours economic actors with a global or transnational outlook. Indeed, according to Sassen (2006) one of the driving forces of denationalization is the emergence of a number of specialized, globally-oriented assemblages which often re-organize institutional components of the state into new, globally-oriented organizing logics. This argument is similar to arguments made by scholars adopting a critical approach. Nölke, Overbeek and Van Apeldoorn (2007) for example, argue that recent changes in corporate governance regulation, including changes in the mode of regulation, are mainly driven (directly or indirectly through the political system) by global capital market actors, certain international organizations, and professions heavily engaged in transnational activities. In a similar vein, other critical scholars talk of transnational elites (e.g. Cutler 2003) which promote new forms of transnational governance along the neoliberal lines of a "new constitutionalism" (Gill 1995).

The framework developed in this thesis makes a redistributive argument based on the economic theory of regulation. There is nothing about redistribution that guarantees that constituencies more attuned to transnational preoccupations will dominate more domestically-oriented constituencies. Nonetheless, transnational regulatory authority, by its nature, is more likely to be used in order to satisfy

globally-oriented constituencies, since they would be more likely to have adequate incentives and capacities to engage meaningfully in a transnational regulatory forum. Indeed, in both cases examined here, it was global players that pushed the envelope of transnational regulatory authority. As we saw, in the case of the IASB, it was mainly big European “global issuers” claiming access to global capital, which drove EC’s effort of international harmonization, while in the US it was the stock exchanges wanting to attract large transnational issuers that were primarily in favour of abolishing the reconciliation requirement. In a similar vein, in the ICH case it was the major, transnational research-based pharmaceutical companies that were in favour of harmonization, and convinced regulators to pursue harmonization in the context of the ICH.

Another interesting avenue for research, which can also help us identify the winners and losers of this process, refers to the changes that transnational regulatory authority entails for the domestic regulatory framework. In the IASB case, it is evident that significant changes were made with new transnational and transgovernmental bodies being added (EFRAG, ARC) and a new regulatory process being put in place. A particularly interesting characteristic of this process, especially given the European tradition of Directives-based harmonization and the code-law approach to accounting standardization in many European jurisdictions, is the creation of the EFRAG, a private transnational body whose aim is to participate in the IASB process as a representative of European interests. The European accounting regulatory framework has been reconfigured to incorporate, as a crucial component, a private body along the lines of the Anglo-Saxon accounting tradition. This development represents a break with the previous accounting regulatory philosophy in a number of European states, affecting thus the established channels of pre-regulatory deliberation and thus the opportunities of the various stakeholders to access the regulatory process, and their potential to influence the regulatory outcome. As Perry and Nölke (2005) have shown, the technical, expert-dominated transnational deliberation process between EFRAG and the IASB is dominated by the Big Four accountancy companies and the highly globalized and mobile financial sector, while

there is a complete absence of labour unions or any other broad social interest groups, despite the fact that many of the issues addressed by IFRSs concern them directly.

In the ICH case, there were no significant new regulatory structures created, but rather the existing domestic and the new transnational regulatory procedures were incorporated in a new continuous process transcending national borders. One possible explanation for this difference in the two cases could be the different type of redistribution pursued in each case. Thus in the IASB case, the objective was to influence the standard-making process in favour of European positions. Therefore, a new transnational body was necessary to engage with the IASB process while the ARC was also necessary to address the legitimacy concerns stemming from this decision. On the contrary, in the ICH case the objective was domestic redistribution. As we have argued, the advantage of transnational regulatory authority is its depoliticized character and low visibility. It would seem logical therefore that the three regulatory authorities incorporated the new transnational regulatory process in the existing domestic procedures in order to avoid significant changes in the regulatory landscape which could draw public attention and spark public deliberation about the desirability and purpose of these changes. Nonetheless, this difference does not seem to limit the adverse effects of transnational regulatory authority on inclusiveness<sup>212</sup> observed in the IASB case. As we have seen, the incorporation of the national/regional procedures for public deliberation in the ICH process has not resulted in a significant strengthening of the voice of other stakeholders in the process. Even when an issue is of particular importance to certain interest groups (e.g. the generic industry), these are only invited occasionally to participate, and their presence is not formally institutionalized in the process.

Therefore, the institutional changes observed in the European accounting regulatory framework in the IASB case, but also the way that existing domestic regulatory mechanisms have been incorporated with transnational structures in the ICH case, seem to corroborate to some degree the proposition that large, transnational economic actors are likely to gain from a shift to transnational regulatory governance. Small-scale or domestically-oriented actors and interest groups are less likely to have

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<sup>212</sup> See Koenig-Archibugi (2006) for a discussion of the concept of inclusiveness in global governance.



the resources to participate meaningfully in the new transnational regulatory process. However, it should be made clear that this tentative suggestion, while in line with both Sassen's and critical theorists' positions, does not share their structural underpinnings. The fact that big, globally-oriented constituencies seem to be the winners of the redistributive strategies which employ transnational regulatory authority, does not mean that the latter is a phenomenon consistently promoted by certain globally-oriented assemblages or specific transnational classes of actors. The argument of this thesis is based on the economic theory of regulation. According to this approach, there is no general movement towards a predetermined direction, but in each issue-area or industry, depending on the configuration of interests and capabilities, one constituency or another, may or may not, be able to win the regulators' favour and promote regulation favourable to its interests. As was evident by the case studies, redistribution does not refer only to regulatory dilemmas pitting large, globally-oriented constituents against small, domestically-oriented ones, but could also refer to instances of big, globally-oriented constituencies pitted against well-resourced and well-organized primarily domestically-oriented constituencies (e.g. stock exchanges vs. domestic issuers and the SEC's establishment in IASB's case), or against other big, globally-oriented constituents (e.g. European global issuers against American global issuers in the IASB case). What is more, in these cases, big, global constituents were not always on the winning side.

Finally, a significant question, given the interlacing of domestic and transnational regulatory structures and the institutional changes, particularly in the IASB case noted above, is whether this process can be reversed or whether once these changes have taken place going back to purely national regulation is impossible. It is obvious that once engaged in a transnational regulatory forum, it is difficult for states to renege on their obligations. Although, as we have argued, backing out of the decision to participate in a transnational regulatory forum is probably not as costly as withdrawing from an international agreement, the element of legal obligation associated with transnational regulatory authority and the creation of an endorsement mechanism create significant "sunk" costs which cannot be easily overlooked by regulators. Non-state actors conscious of the significance of these costs may claim a

status of equality with state actors in the context of transnational regulatory governance.

The incident with the two European carve-outs in the IASB case illustrates the point. As made clear by the European Commission, these carve-outs were exceptional and always intended to be temporary pending changes in IAS 39<sup>213</sup>. They were supposed to be renegotiated in the deliberating process of the IASB through the EFRAG. Having decided to replace national accounting standards with the IFRSs, the EC and national European regulators could not introduce separate changes into the IFRSs to suit their reporting needs, since that would defeat the whole purpose of adopting an internationally acknowledged and expert-developed set of standards. Backing out of even a single standard became extremely difficult and working through the EFRAG and the IASB was the only option. The IASB knew this and seemed determined to press its advantage. This becomes obvious when we consider the reported statement of Paul Volcker, chairman of the IASC Foundation, who in reply to the EC Commissioner's warning that the EC would not be able to approve IAS 39 if differences were not resolved, commented that: "the IASB produces a standard-you take it or leave it"<sup>214</sup>.

### 8.3.2 Redistributing structural power among states

The double movement observed above from the national to the transnational and from the public to the private not only shifts the balance among various stakeholders, but also has the potential to alter the balance of structural power among states themselves to the degree that it affects their abilities to engage with the global economy and the global governance system. In this context, a number of interesting questions emerge: are there particular domestic institutional characteristics which reduce the costs and risks and/or raise the probabilities of success of using transnational regulatory authority? Do these institutional characteristics vary systematically across states? If this is the case, does the use of transnational regulatory authority change the balance of structural power in favour of certain states?

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<sup>213</sup> IASC Insight, July 2005, p.4.

<sup>214</sup> European Banker, April 30, 2004 p.1.

The IASB case study uncovered a complicated picture concerning the relation between domestic political and regulatory institutions and transnational regulatory governance. Undoubtedly, it was the EC's decision to replace national accounting standards with the IFRSs that effectively turned the IASB into a transnational regulatory authority. Determining a clear pattern of correlation between domestic institutions and the decision to delegate authority to the IASB however, is not an easy task. This is because the accounting regulatory framework in the EU has never been uniform. In countries following an Anglo-Saxon accounting tradition, the accounting profession has traditionally been accorded a significant role in the preparation of accounting standards. Indeed standard-setting itself is a feature associated with this particular tradition since in most Continental countries accounting regulation was part of the wider, corporate and commercial regulation and in many cases even legislation. Nonetheless, one pattern that was identified was that resistance to closer cooperation with the IASB and its predecessor, the IASC, came principally from Continental regulators which could not accept the wholesale delegation of regulatory authority to non-state actors. On the other hand, states with Anglo-Saxon accounting traditions argued in favour of closer cooperation with the IASC<sup>215</sup>. Although ultimately all states in the EU backed the decision to adopt the IFRSs, this decision, as we have seen, was a strategic move to overcome the SEC's resistance without jeopardizing the European accounting framework, rather than a shift in the accounting philosophy of Continental professionals and regulators.

This pattern could be viewed as providing support for a Varieties of Capitalism (VoC) argument (Hall and Soskice 2001). This approach is based on a distinction between coordinated market economies (CMEs) and liberal market economies (LMEs), defined in terms of their systematic institutional variation. Based on this distinction, a VoC approach would argue that states participating in international negotiations would try to promote policies that sustain and take advantage of their own institutional make-up (Hall and Soskice 2001). Examining transnational regulatory authority through the prism of VoC extends the basic VoC argument beyond the content, to the mode of regulation. The particular characteristics

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<sup>215</sup> See footnote 113, p.162.

of the institutional structure of a given state's political economy may provide it with a comparative institutional advantage not only in terms of economic activity and specialization as the VoC suggests, but also in terms of its ability to engage successfully in global economic governance structures. This is because the ability of a state to shift the *mode* of global economic governance in an issue-area to a mode of governance more compatible with the institutional characteristics of its domestic governance structure can be an extremely powerful negotiating tool. The availability of the relevant institutional infrastructure, the expertise in, and the experience of using a particular mode of regulatory governance, can and do confer a significant comparative institutional advantage in the context of international and transnational negotiations to the state that possesses them. This point has been stressed by Mattli and Büthe (2003) who have argued, that the institutional complementarities between domestic and international regulatory organizations are very important for the ability of a state to influence the international regulatory process.

Our analysis of the IASB case seems to support such a view. We have seen that it has been the US, which has been able to influence most effectively the work of the IASB. The SEC engaged the IASC from early on in what was in effect a forum-blocking strategy, in order to control or disable it from within. This in turn was possible because the SEC was uniquely placed among regulators, due to the make-up of the US accounting regulatory framework, to influence the work of a non-state organization like the IASC/IASB. According to Mattli and Büthe (2003) a state with well established, inclusive and hierarchical private sector standard-setting procedures will be in a better position to influence a non-state regulatory process at the transnational level and will thus have the advantage of the first mover. The existence of the FASB, which satisfies these criteria, allowed the American regulators to participate in significant preparatory work for the IASC from early on, and through the G4 +1 in the 1990s, and the convergence project in the 2000s, to take control of IASC's and IASB's agenda. On the other hand, it is obvious that the absence of a pan-European non-state standard-setting entity has hampered the ability of Europe to engage in the work of the IASC.

According to such a rationale then, it would be reasonable to expect states with Anglo-Saxon accounting traditions to push for a move towards an expert-dominated, non-state organization, mirroring their domestic regulatory frameworks. Indeed, as we have seen the SEC and the FASB pressed fervently during the restructuring of the IASC, and succeeded, in shaping the new transnational accounting standard-setting structure after the US accounting regulatory framework. A similar effort was launched by the EC, which however was unsuccessful. Following its failure to shape the IASB's governance structure according to its own preferences, the EC sought to adjust its own regulatory framework by incorporating of a non-state body (EFRAG), able to participate in the IASB process.

In the case of the ICH, we have seen that the corporatist regulatory environment of many European jurisdictions has allowed the European industry to play a significant domestic and regional regulatory role (Hancher 1990; Wiktorowicz 2003; Permanand and Altenstetter 2004; Permanand 2006). Similarly, pharmaceutical regulation in Japan is developed with the input of the industry, which also enjoys a privileged position in the regulatory process. On the other hand, the pluralist US system did not afford any privileged position to the US industry in the regulatory process, whereas the fragmented authority of the FDA, which was constantly under the supervision of the Congress, had created an often adversarial stance of the regulators towards the industry. Indeed as we have seen, of the three founder-members of the ICH the FDA was initially the most reluctant participant. The FDA's participation in the ICH was facilitated by the gradual change of the regulatory framework through the deregulatory policies of consecutive conservative administrations and congressional majorities. As we have seen, closer relations with the industry were encouraged through legislative measures and a major reform of the FDA included among other principal objectives, greater efforts towards harmonization.

From the above one could suggest that institutional characteristics associated with corporatist regulatory frameworks (e.g. business interest representation internal to the regulatory process, informal and accommodative stance vis a vis the industry,

or closed regulatory processes)<sup>216</sup> make the transition to transnational regulatory authority both a more likely policy option (due to industry's significant influence) and its implementation potentially an easier task for the regulators (given the existing delegation of regulatory authority at the domestic level). Indeed, it should be reminded that the initial proposal for the creation of the ICH came up in a bilateral EC-Japan meeting, where representatives of the both the European and Japanese industries were present. Moreover, as we have seen, the EC was strongly in favour of a wider harmonization process and played a leading role in the establishment of the ICH. We could therefore argue that the ICH case also supports an extended VoC argument in the sense that the ICH structure reflects the close, cooperative and often secretive relationship between regulators and the industry found in Europe and Japan and not the formal, external and often adversarial relationship between the FDA and the US pharmaceutical industry.

This discussion would again seem to support the argument of scholars investigating from a critical perspective the recent changes in the mode of global economic regulation affecting various aspects of corporate governance (Overbeek, Van Apeldoorn and Nölke 2007), that changes in the content and mode of international and transnational regulation are closely related. While, as we have shown above, this thesis also demonstrates that the mode and content of regulation are closely related, there is a significant difference in relation to critical theory's view. Critical theorists, position the changes in the global governance structure within the context of a greater transformation, taking place across issue-areas, which aims towards a marketization of the mode and content of regulation, along the lines of a neo-liberal project. As we argued above, the argument in this thesis is based on the economic theory of regulation, which suggests that regulation is a commodity for which there is a market with economic but also political characteristics, where winners and losers are determined by the configuration of interests and capabilities, in a given issue-area at a given time. Similarly, an extended VoC argument does not predict the direction of the institutional changes; it only suggests that states which

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<sup>216</sup> See Wiktorowicz (2003) for a detailed discussion and a comparative examination of these and other institutional characteristics and their application in pharmaceutical regulation.

exhibit complementarities between their national institutions and global governance structures will benefit from them in terms of negotiating power and influence. This becomes evident by examining our case studies.

According to Perry and Nölke (2006), the shift in global accounting standard-setting towards the IASB and the content of the standards promoted through the IASB could be seen as a wider structural shift of change and/or erosion of the Rhenish model of capitalism in favour of LMEs' model of capitalism. However, we have found no evidence of such a wide, politically driven, structural shift. On the contrary, the evidence we examined suggests that the adoption of the IASs was decided in the context of a forum-shifting strategy, and only following the failure of many years of efforts on the part of both European regulators and the EC to persuade the SEC to accept an international agreement, which would respect European accounting traditions. Had its proposals for a mutual recognition policy been accepted by the SEC, it is extremely unlikely that the EC would be upsetting this agreement by adopting the IFRSs. On the contrary, the attitude of the EC throughout the 1990s was quite adversarial towards both the SEC's insistence on reconciliation, and the Anglo-Saxon, capital market-oriented approach to accounting standard-setting (EC 1990; Van Hulle 1993), and as we have seen during the IASC restructuring process, it argued strongly in favour of a geographically representative and politically accountable Board, in contrast to the market-based, expert-driven Board advocated by the SEC (Van Hulle 1999). What is more, the new financial reporting strategy targeted only consolidated accounts of listed companies and therefore addressed the regulatory concerns of a specific interest constituency and did not represent a wholesale turn of accounting philosophy. Indeed, the European regulatory philosophy does not seem to have changed significantly, as is evident from the recent interventions and critique of the European Parliament, as well as ECOFIN's concerns and proposals regarding the IASCF/IASB's governance structure.

The distinction between our argument and critical theory's proposition becomes even clearer when we compare the findings of our two cases. Thus, it appears that the parties that pioneered the ICH initiative proposed a mode of regulation resembling their own domestic regulatory structure. Nonetheless, contrary

to the IASB case, this does not translate in a clear and identifiable shift in the mode of regulatory governance at the transnational level towards a traditional VoC category. The Anglo-Saxon/Continental categories are not so neatly defined in the case of pharmaceutical regulation. The pharmaceutical regulatory framework in countries such as the UK and Canada, usually identified as two of the most significant representatives of the Anglo-Saxon variety of capitalism, are clearly much closer to the corporatist arrangements found across Europe or in Japan than to the pluralist system of the United States. Both countries have been characterized as cases of “clientele pluralism”<sup>217</sup>. The picture may therefore be more complicated than a simple dichotomy along the VoC lines would have us believe and further research is needed before reaching safe conclusions on this issue.

The use of transnational regulatory authority changes the balance of structural power not only among developed states but also between developed and developing states. In chapter 3, we argued that transnational regulatory authority can serve as a barrier to regulatory entry to developing countries. Even if this is not the primary objective of the use of transnational regulatory authority, since a similar result can be achieved in inter-state forums like the OECD, the exclusion of countries with no significant presence in a given industry, serves as a *de facto* barrier to regulatory governance for these countries. What is more, these countries, even if they have no say in their design, are very likely to adopt the rules of a transnational regulatory authority, since these are legally endorsed by the leaders of the industry.

These imbalances can be observed in both case studies. During its lifetime, the IASC was dominated by accounting representatives from the developed world. As we have seen, even when representatives from developing countries were invited, they often declined the offer because they did not have the required expertise and resources (Cairns 1997). Similarly, on the initial IASB’s Board only one member from a developing country was appointed<sup>218</sup>. Despite this situation, we have seen that developing countries were often the first to adopt IASs and IFRSs. What is more, this

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<sup>217</sup> See Permanand and Altenstetter (2004) for the UK and Wiktorowicz (2003) for Canada.

<sup>218</sup> It is worth noting that the professional experience of this member had been gained for the most part in multinational companies originating from the developed world. See the IASB website at [www.iasb.org](http://www.iasb.org), for biographical details of the Board members.



has been the case even when it was obvious that many of the standards did not meet their accounting needs (Hove 1989; Wallace 1993; Abu-Ghazaleh 1999). Similarly, in the ICH case we have seen that developing countries have not been invited to the negotiating table. Despite the fact that increasingly consultation of external parties is encouraged, this occasional input has not been institutionalized. On the other hand, the Global Cooperation Group whose objective is to help developing countries to understand and implement the ICH guidelines, rather than to give them a voice in the regulatory process, has acquired distinct institutional identity and resources. Indeed, it is for this reason that the WHO (2002) has expressed fears that there is an effort on the part of the ICH establishment to turn the ICH guidelines into the de facto global marketing registration and approval guidelines.

### 8.3.3 Accountability, legitimacy and authority

In our theoretical framework, we argued that regulators and/or politicians do not operate in an institutional and normative vacuum. Their position as holders of *in* authority capable of issuing commands and directives expected to be enforced, places them under the scrutiny of the public eye and the political establishment and obliges them to respect several institutional and normative constraints when considering the delegation of part of their authority to a transnational non-state forum. In terms of the institutional constraints, we have argued that the delegation of authority needs to take place in a hierarchical fashion according to specific procedures, that the institutions receiving the grant of authority have to demonstrate some features reflective of the public character of their regulatory work (e.g. due process, increased transparency and inclusiveness), and that the state authorities have to retain some means of controlling the process. The two cases examined here have shown that the regulatory authorities engaged in transnational regulatory governance have followed these dictates. As we have seen, in the IASB case, the proposal to replace national accounting standards with IFRSs was forwarded, as required, to the European Council and the European Parliament where it was accepted without serious objections. Similarly, national parliaments, where necessary, have ratified the replacement of national accounting standards with IFRSs, again with no serious objections or delays. Moreover, we have seen that there was a new regulatory

mechanism put in place which included a political body, the ARC, which is placed above the private body, EFRAG, and retains the ultimate authority to decide on the adoption of the IFRSs. Also, the IASB has improved its due process and has increased the transparency and inclusiveness of its consultation procedures. Similarly in the ICH case, it was the competent regulatory authorities, which decided to set up and participate in the ICH. It should be reminded that these authorities are, in the case of Europe and Japan, supranational and governmental agencies with a clear authority to engage in such activities, while in the case of the FDA which is a Federal Agency operating under the auspices of the US Department of Health and Human Services, the Department and the higher echelons of the administration have clearly backed and encouraged the participation of the FDA in the ICH process. Moreover, these authorities participate directly in this forum retaining voting and veto powers and the ultimate authority to sign off the agreed guidelines. Finally, they have incorporated the national/regional procedures of consultation and comment in the ICH process, and following their adoption the guidelines are incorporated in the body of public regulation subject to the same enforcement mechanisms as other public regulations.

It seems therefore that the regulators engaged in transnational regulatory governance have followed the institutional provisions dictated by their position as holders of authority. As far as the substantive-normative assessment goes, we have seen that in both cases regulators employed an argumentation based on reduced state abilities to regulate, brought about by global changes, and have invoked the expertise and resources of the private sector to assist them achieve the purpose behind their authority: the protection and promotion of the public interest. It is obvious that this justification has for the most part been accepted, since both these institutions have been operating successfully in an authoritative regulatory capacity for a number of years without serious problems and social or political resistance.

Therefore, it would seem that at first sight, the regulators have done enough to ensure the legitimacy of the process of delegation and of the new transnational regulatory process itself. A closer look however may disrupt this impression. As we saw above, by introducing new and altering existing regulatory and political structures, transnational regulatory authority has the potential to change the balance

of power among various economic and social constituencies, among states, and between public and private actors. One of course could counter that since there are established institutional avenues of participating in and/or commenting on the regulatory process, any parties feeling disadvantaged by the proposed regulation could make use of them and oppose it, as would be the case with domestic regulation. As we saw in the previous sections however, the institutional safeguards put in place have proven inadequate to guarantee a truly inclusive regulatory process. This situation obviously raises a significant problem of inclusiveness in the regulatory process, which in turn undermines the legitimacy of the produced regulation. In the case of transnational regulatory authority this problem is particularly pressing due to the element of legal obligation which renders such transnational governance structures more influential and intrusive in the everyday operation of domestic economies and societies.

As we have seen, many of these problems have been cited by a number of analysts in both cases examined here. The question then is why the stakeholders that stand in the losing side of the shift to transnational regulatory authority have not reacted more strongly. There are two possible explanations. First, there is the possibility that they are not aware of the changes under way. Secondly, it is likely that they have not understood the impact of these changes on their interests. The first explanation is likely to be valid when the issues migrating to the transnational level are characterized by low social visibility. Zürn and Koenig-Archibugi (2006) have proposed that increased visibility through the movement of issues from sectoral, functionally defined publics, to broader publics, and from publics nationally fragmented to publics integrated across borders, is more likely to increase the significance of legitimacy concerns and consequently lead to changes in the governance arrangements. However, the ability to broaden the interested publics in an issue-area, as well as the ability of these publics to understand the consequences of the promoted regulation on their interests, depends to a large degree on whether there are obvious distributive implications, and on whether it is possible to communicate these implications in simple and appealing terms in the context of a discourse in the public domain. Both of these features in turn, are highly depended on the degree of

technical or scientific complexity of the underlying issues. Moreover, in order to integrate publics across borders a sense of transnational or global public interest needs to be identified that people from different cultures and socio-economic systems can relate to.

Neither is very likely in cases where we would expect to see transnational regulatory authority. In cases of domestic redistribution, according to propositions (2a) and (2b), the rationale behind the use of transnational regulatory governance is precisely to reduce visibility by transferring the issues under consideration to informal, expert-dominated and technically-oriented forums. Therefore, even though in this case nationally fragmented publics may indeed share a common interest, their ability to realize this is hampered by the technical nature of the issues selected for migrating to the transnational level, and the informal and technical nature of the transnational forum. This move contributes to a further de-politicization of these already complex issues making more remote the possibility of resistance and mobilization. In cases of international redistribution on the other hand, the interests of different publics often lie at opposite sides of the distribution equation or are simply indifferent. Thus, it is hard to imagine US or UK trade unions teaming up with German trade unions to stem the turn towards an Anglo-Saxon accounting model, associated with the work of the IASB.

These observations lend support for Zürn and Koenig-Archibugi's (2006, p.249) remark that higher levels of delegation do not always lead to politicization and demands for higher levels of inclusiveness and publicness in the governance arrangements, and that even if they do, institutional change is not guaranteed. The authors put forward Kerwer's (2006) hypothesis that the latter may occur when rule-setting and enforcement are undertaken by different actors, particularly when enforcement becomes the responsibility of transnational social actors. While this proposition may hold some explanatory power in the case of the IASB, where the EC enforces the standards developed by the IASB<sup>219</sup>, in the ICH case this is obviously not applicable. It is obvious that more research is needed in order to reach safer

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<sup>219</sup> This also needs to be further examined since Kerwer's hypothesis refers to voluntary standards primarily enforced by transnational societal actors and not public, mandatory enforcement of transnational standards as is the case of the IASB.

conclusions about the link between accountability, global governance and social resistance.

In any case, this situation raises significant concerns regarding the future of global governance, and ultimately through the process of denationalization, national government itself. As we have argued in chapter 3, technology permeates the operation of an increasing number of industries, often creating entirely new ones and fundamentally transforming others. This development has raised the level of technical and technological complexity necessary in the operation of many industries. Moreover, technological breakthroughs have made possible faster innovation rates, have limited significantly the obstacles of time and space in communication and transactions, and have contributed to an increasingly complex division of labour. All these changes are gradually turning the operation of the economy into a technologically and functionally complex transnational web of activities, whose governance necessitates a good understanding of the issues and technologies involved, awareness of the transnational aspects of economic transactions, and heightened reflexes to respond to the dramatic changes of the underlying economic reality. This in turn makes it easier for politicians and regulators, when they want pursue a redistributive strategy, to justify shifting the governance and regulation in a number of issue-areas and economic activities to expert-dominated, technically-oriented fora. The end-result is an increasing reliance on a transnational bureaucracy of experts for the governance of an increasingly globalizing economy.

This perspective in turn threatens the principles of democratic rule. This is because we are in danger of turning global governance into an epistemic project. Epistemic authority is different to epistemic authority (Ball 1987). The latter refers to *an* authority as defined in chapter 2. The former refers to the claim of a class or a group of people to rule others precisely because they are *an* authorities. This transforms the logic of an authority which, while founded on the possession of specialized knowledge, does not claim mandatory obedience. In this sense epistemic authority is conceptually parasitic upon epistemic authority: “epistemic authority attempts to assimilate political authority to the non-political epistemic authority of the technician or expert” (Ball 1987, p. 48). What is more, the

increasing reliance on experts and the increased levels of delegation of political authority to them is not the principle cause of concern. As Ball argues, the danger is not that we will come to concede too much authority to the experts but that we will come to conceptualize political authority exclusively in terms of expertise. This assimilation assumes that politics and ethics are activities in which there are experts, a development, which could justify the removal of the public not only from the exercise of global governance but also from government itself.

The considerations presented in this section, are not meant to offer an alternative account to that of the main thesis. They simply point out some of the intended and unintended consequences that the use of transnational regulatory authority can have for global governance, and offer a preliminary examination of these consequences, and a few tentative suggestions, based on the empirical analysis of the two cases. We do not argue that transnational regulatory authority is part of a wide-ranging, structural transformation of global governance, intentionally and consistently engineered, by particular states, transnational classes, or ideological movements. Rather we have shown that transnational regulatory authority is a tool in the economic diplomacy arsenal of national regulators and/or politicians, to be used for redistributive purposes, depending on the configuration of interests and capabilities in a given issue-area or industry at a given time.

#### **8.4 Epilogue**

While the case study analyses have provided support for the propositions we developed in the context of our theoretical framework, it is obvious that safe conclusions cannot be reached with the examination of only two case studies. As is evident from this concluding chapter, further research is needed in order to strengthen the empirical verification of these propositions (particularly the framework conditions relating to the second research question) and to provide answers to a number of new questions raised by this research exercise. In this sense, further research is needed to uncover other instances of transnational regulatory authority, but also to address cases of other types of transnational *in* authority, concerning implementation and adjudication functions. An obvious place to look for cases of transnational regulatory authority would be industries and issue-areas characterized by a high rate of

scientific, technical, and/or technological innovation and change, where as we have argued, the justification for the use of transnational regulatory authority can be persuasively made.

An example of an organization that seems to satisfy the conditions of transnational regulatory authority is the Internet Corporation for Assigned Names and Numbers (ICANN), which is a transnational, non-state, non-profit organization responsible for managing the Internet Domain Name System (DNS), the technical blueprint that allows access and use of the Internet. Within its structure: “governments and international treaty organizations work in partnership with businesses, organizations, and skilled individuals involved in building and sustaining the global Internet... consistent with the principle of maximum self-regulation in the high-tech economy, ICANN is perhaps the foremost example of collaboration by the various constituents of the Internet community”<sup>220</sup>. This transnational non-state body has developed specific institutional structures performing not only rule-making functions such as developing guidelines for the deployment of Internationalized Domain Names (IDN), but also managing the DNS, resolving technical problems, holding hearings on user complaints through its own ombudsman, and even developing a Uniform Domain Name Dispute Resolution Policy (UDRP), which has been used to resolve more than 5000 disputes over the rights to domain names<sup>221</sup>. A particularly interesting feature of this forum is that it exercises these functions on the basis of a Memorandum of Understanding (MoU) with the US Department of Commerce. Critics have argued that ICANN is effectively controlled by the US which has resisted calls to move the functions of the ICANN to an international forum (Bislev and Flyverbom 2008). Despite talks at various levels for a number of years, culminating in the Tunis World Summit of the Information Society (WSIS) in 2005, and the fact that the MoU between the US government and ICANN was set to expire in 2006, no progress was made as the US renewed the concession to ICANN, blocking thus the move to an international forum.

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<sup>220</sup> Available from ICANN's website, <http://www.icann.org/tr/english.html>, accessed 12/12/2007.

<sup>221</sup> Ibid.

In the same issue-area, an interesting case to investigate could also be the hybrid governance framework developed by the EU for its own top-level domain – dot eu. This framework is based on two pillars: the delegation of the responsibility for the governance of dot eu to the European Commission, which however works in collaboration with Eurid, a private, non-profit company charged with a series of tasks for the governance of dot eu, including the accreditation of registrar companies for the use of the dot eu domain, the development of principles and procedures for their accreditation and the terms of competition among them, as well as the creation of an alternative dispute resolution mechanism, whose function has been undertaken by the Czech Arbitration Court another non-profit organization (Christou and Simpson 2008).

Another particularly interesting case of delegation of regulatory authority to non-state actors is “Basel II”, the new capital adequacy accord developed under the auspices of the Basel Committee on Banking Supervision. This new framework, developed in close collaboration with the global financial and banking community, has transformed the credit-risk evaluation process by effectively delegating to banks and financial institutions the responsibility for assessing their own capital adequacy levels. Supervision of the process is again performed in a close cooperative relationship with the supervised institutions. All in all, some analysts have judged the new Basel Accord as “the perfect example of regulatory and supervisory capture” (Tsingou 2008, p.61). What is more, Basel II assigns a central role to the private credit rating agencies as it dictates that several risk measurements should be provided by them.

The examples above illustrate the variety of different governance functions performed by hybrid public-private, or purely non-state transnational organizations. As we saw above, some of these organizations have taken over not only rule-making tasks, but also adjudication procedures and implementation/administration duties. This in turn reminds us the limitations of this research exercise. The theoretical framework presented in this thesis, does not claim wide application to all types of non-state authority. Our framework operates within the context of certain scope conditions, which limit its applicability and clarify its purpose. Therefore, we cannot



claim that the propositions developed here for the delegation of regulatory authority to transnational non-state actors, will be equally applicable for the delegation of adjudication or implementation functions. Thus, perhaps the delegation of both of these functions may be explained more consistently on the basis of an efficiency argument, rather than a redistributive argument that was the case for the delegation of regulatory authority. What is more, it is often the case that in the delegation of implementation functions in particular, the non-state actors receiving the grant of authority, are not private sector actors but national or international NGOs, which may be motivated not by economic interest, but by ideological and ethical criteria. This brings us in turn, to another condition, which refers to the fact that the argument we have developed here does not apply to all instances of non-state authoritative governance. Our redistributive argument is based on the economic theory of regulation, an interest groups' approach with regard to economic regulation. Obviously, there exist other types of regulation and legislation, which refer to the governance of issues without a significant or pre-dominant economic component (e.g. civic rights and duties, human rights, internal and/or external security, ethical and religious issues, several types of social regulation). In these cases, our framework may not apply, since the economic theory of regulation, on which it is based, may be irrelevant. This does not mean that interest group politics are necessarily absent from the regulation of such issues, but it means that both the interest groups involved and the regulators/politicians may be motivated by incentives other than strictly individual economic interests, which cannot be accounted for by an economic theory of regulation. In this context, it should also be made clear that, our framework aims to explain the delegation of *in* authority entrusted to state authorities, operating in the context of a democratic liberal society. It applies neither to totalitarian regimes nor to other non-state types of authority (e.g. religious authority).

Notwithstanding these scope conditions, we have to emphasize the political but also symbolic significance of transnational regulatory authority and the potential impact it may have on global governance, but also on national politics. To the degree that transnational regulatory authority and transnational *in* authority more generally, embed transnational non-state structures in domestic political economies through

institutionalization and legalization, they make the reversal of this impact less probable. For this reason, I believe that further research along the lines developed in this thesis is needed, in order to identify and address the economic, political and ultimately normative implications of transnational *in* authority.

## **Appendix 1**

### **List of Interviewees**

#### **IASB Case Study**

1. David Cairns, 11/05/2006 (IASC Secretary-General, 1985-1994).
2. Sir Bryan Carsberg, 15/03/2007 (IASC Secretary-General, 1995-2001).
3. Thomas E. Jones, 08/05/2007 (IASB Vice-President).
4. Tony Cope, 07/06/2007 (IASB Member, 2001-2007).
5. Karel Van Hulle, 08/06/2007 (Former Head of Unit for Accounting Standards, for Financial Reporting and Company Law, and for Accounting and Auditing, European Commission, Directorate-General “Internal Market and Services”, 1984-2004).
6. Sue Bielstein, 14/06/2007 (Director of Major Projects and Technical Activities, FASB).
7. Mary Tokar, 08/05/2007 (Head of the KPMG International Financial Reporting Group. Former Senior Associate Chief Accountant, International, SEC’s Office of the Chief Accountant, 1997-2000. Chair of Working Party No. 1 on multinational Disclosures and Accounting, IOSCO, 1999-2000).
8. Saskia Slomp, 22/05/2007 (Technical Director, Fédération des Experts Comptables Européens).

#### **ICH Case Study**

1. Dr. Peter Arlett, 15/05/2007 (Member of the ICH Steering Committee, Principal Administrator Pharmaceuticals Unit, European Commission).
2. Dr. Spiros Vamvakas, 13/04/2007 (ICH Technical Coordinator for EU, (EMA), Principal Scientific Administrator, Scientific Advice and Orphan Drugs Sector, EMA).
3. Dr. Elaine Esber, 23/10/2007 (Executive Director, Medical Affairs International, Merck Vaccine Division, Chair of the IFPMA Biologics and Vaccines’ Committee. Former Associate Center Director for Medical and International Affairs, CBER, FDA. Former ICH Steering Committee Member (FDA representative) 1990-2001).

4. Dr. Joseph F. Contrera, 13/08/2007 (written reply to list of open-ended questions. Informatics and Computational Safety Analysis Director, Office of Pharmaceutical Science, CDER, FDA).
5. Dr. Christine-Lise Julou, 17/07/2 (Member of the ICH Steering Committee, Manager, Scientific Technical Regulatory Affairs, EFPIA).
6. Dr. Lembit Rägo, 27/04/2007 (WHO Observer on the ICH Steering Committee, Department of Medicines Policy and Standards, WHO).

## Appendix 2

### Trends in European Financial Markets' Growth

#### Market Capitalization of European Stock Exchanges (USD millions)

	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Italy	149	159	124	145	186	210	257	345	566	728
Deutsche Börse	355	392	347	461	499	577	665	825	1087	1432
Euronext Brussels	65	71	64	78	84	102	119	139	244	184
Euronext Amsterdam	120	136	135	183	225	287	375	469	600	695
Euronext Paris	312	373	350	455	452	500	587	676	985	1497
London	850	986	928	1151	1145	1347	1643	1996	2373	2855
Spanish Exchanges (BME)	111	127	99	119	124	151	241	290	400	432
Stockholm	92	97	78	107	131	173	240	265	279	373
Swiss Exchange	158	174	189	271	285	398	400	575	702	693
Vienna	26	26	22	28	31	33	34	37	36	33

Source: Haller (2002) and Standard and Poor's Global Stock Market Factbook (2004)

#### Cross-border Transactions in Bonds and Equities in Major Continental Economies (% of GDP)

	1980	1985	1990	1991	1992	1993	1994	1995	1996	1997
France	5	21	54	79	122	187	197	187	258	313
Italy	1	4	27	60	92	132	207	253	470	672
Germany	7	33	57	55	85	170	158	172	199	253

Source: Bank for International Settlements Annual Report (1998)

### Appendix 3

#### Country breakdown of amounts raised by privatisation<sup>1</sup> (USD millions)

	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Austria <sup>2</sup>	32	48	49	142	700	1035	1302	2438	2537	70	2086
Belgium	-	-	-	956	548	2745	1222	1848	2288	10	-
France	-	-	-	12160	5479	4136	3096	10105	13596	9478	17438
Germany <sup>3</sup>	11	351	-	73	678	191	1421	3125	11357	2754	1750
Greece	-	-	-	35	73	44	558	1395	3960	4880	1384
Italy <sup>4</sup>	-	-	759	3039	9077	10131	11230	23945	15138	25594	2653
Netherlands	716	179	-	780	3766	3993	1239	842	335	1481	310
Portugal	1092	1002	2206	422	1123	2362	3001	4909	4299	1620	3256
Spain	172	-	830	3222	1458	2941	2680	12532	11618	1128	1079
United Kingdom <sup>5</sup>	4219	5346	7923	8114	4632	5648	2426	4500	-	-	-

Notes:

.. Not available.

– Nil or insignificant.

1. The amounts shown are gross proceeds from direct privatizations. These do not necessarily correspond to the net amount available to the government. The figures are on a calendar year basis and they may not add up to published budget figures.

2. Statistics refer only to privatizations by the central government.

3. Up to 1997, information on trade sales is not available.

4. Including indirect privatizations since 1996-2000 raising million USD respectively 2,325; 2,018; 3,235; 5,791; 9,244.

5. Debt sales for years 1990-97 (fiscal years) amounting to GBP 5,347 million, GBP 7,924 million, GBP 8,189 million, GBP 5,453 million, GBP 6,429 million, GBP 2,439 million, GBP 4,500 million, respectively. All the figures are provided in fiscal years.

Source: OECD Financial Market Trends, No. 82, June 2002.

## Appendix 4

### Differences in Shareholders' Equity from Reconciliation to U.S. GAAP for Foreign MNCs

Company	Year	Domestic	U.S.-Adjusted	Difference	% Change
Ericsson (Sweden)	1995	Skr 34,263 m	Skr 37, 878 m	Skr 3,651 m	+11
	1996	Skr 40,456 m	Skr 44,921 m	Skr 4,465 m	+11
	1997	Skr 52,624 m	Skr 57, 364 m	Skr 4,740 m	+9
Benetton (Italy)	1995	Lit 1,657 bn	Lit 1,779 bn	Lit 122 bn	+7
	1996	Lit 1,821 bn	Lit 1,905 bn	Lit 129 bn	+7
	1997	Lit 2,030 bn	Lit 1,824 bn	Lit (206 bn)	-10
Daimler-Benz (Germany)	1993	DM 18,145 m	DM 26,281 m	DM 8,136 m	+45
	1994	DM 20,251 m	DM 29,435 m	DM 9,184 m	+45
	1995	DM 13, 842	DM 22,860 m	DM 9,018 m	+65
Glaxo Wellcome (UK)	1995	£ 91 m	£ 8,168 m	£ 8,077 m	+8,876
	1996	£ 1,225 m	£8,153 m	£ 6,928 m	+556
	1997	£ 1,843 m	£ 7,882 m	£ 6,039 m	+328
British Airways (UK)	1997	£2,984 m	£ 2,400 m	£ (584 m)	-20
	1998	£3,321 m	£ 3,044 m	£ (277 m)	-8

Source: Nobes and Parker 2000, p.3

## Appendix 5

### World Market for Ethical Pharmaceuticals by Therapeutic Class (1991/92 market shares in selected therapeutic sub-markets)

Therapeutic Class/ Indication	Cardiovascular		Gastro-intestinal		Cancer Treatment
	ACE-inhibitors	CA-antagonists	H2-antagonists	Proton-pump inhibitors	Immunomodulators
	1991	1991	1992	1992	1992
Drug (top company)	Vasotec (Merck)	Cardizem (MMD)	Zantac (Glaxo)	Losec (Astra)	Intron-A (Schering –Plough)
% market share	41%	18%	57%	85%	31%
Drug (2 <sup>nd</sup> company)	Capoten (BMS)	Procardia (Pfizer)	Tagamet (SKB)		Roferon-A (Roche)
% market share	38%	17.3%	15.4%		22%
Drug (3 <sup>rd</sup> company)	Zestrill (Zeneca)	Adalat (Bayer/ Takeda)	Gaster (Yamanouchi)		Krestin (Sankyo)
% market share	9.4%	16.5%	5.5%		19%
Drug (4 <sup>th</sup> company)		Calan (Monsanto)			
% market share		10%			
Total	88.4%	61.8%	77.9%	85%	72%

Source: Kanavos (1998)



## **Appendix 6**

### **International Accounting Standards Committee Foundation**

#### **Criteria for IASB Members**

(Annex to the IASC Foundation Constitution (July 2005)).

The following would represent criteria for IASB membership:

- 1. Demonstrated Technical Competency and Knowledge of Financial Accounting and Reporting.** All members of the IASB, regardless of whether they are from the accounting profession, preparers, users, or academics, should have demonstrated a high level of knowledge and technical competency in financial accounting and reporting. The credibility of the IASB and its individual members and the effectiveness and efficiency of the organisation will be enhanced with members who have such knowledge and skills.
- 2. Ability to Analyse.** IASB members should have demonstrated the ability to analyse issues and consider the implications of that analysis for the decision-making process.
- 3. Communication Skills.** Effective oral and written communication skills are necessary. These skills include the ability to communicate effectively in private meetings with IASB members, in public meetings, and in written materials such as accounting standards, speeches, articles, memos and correspondence with constituents. Communication skills also include the ability to listen to and consider the views of others. While a working knowledge of English is necessary, there should not be discrimination in selection against those for whom English is not their first language.
- 4. Judicious Decision-making.** IASB members should be capable of considering varied viewpoints, weighing the evidence presented in an impartial fashion, and reaching well-reasoned and supportable decisions in a timely fashion.

**5. Awareness of the Financial Reporting Environment.** High quality financial reporting will be affected by the financial, business and economic environment. IASB members should have an understanding of the global economic environment in which the IASB operates. This global awareness should include awareness of business and financial reporting issues that are relevant to, and affect the quality of, transparent financial reporting and disclosure in the various capital markets worldwide, including those using International Financial Reporting Standards.

**6. Ability to Work in a Collegial Atmosphere.** Members should be able to show respect, tact and consideration for one another's and constituents' views. Members must be able to work with one another in reaching consensus views based on the IASB's objective of developing high quality and transparent financial reporting. Members must be able to put the objective of the IASB above individual philosophies and interests.

**7. Integrity, Objectivity and Discipline.** The credibility of members should be demonstrated through their integrity and objectivity. This includes intellectual integrity as well as integrity in dealing with fellow IASB members and constituents. Members should demonstrate an ability to be objective in reaching decisions. Members also should demonstrate an ability to show rigorous discipline and carry a demanding workload.

**8. Commitment to the IASC Foundation's Mission and Public Interest.** Members should be committed to achieving the objective of the IASC Foundation of establishing international accounting and financial reporting standards that are of high quality, comparable, and transparent. A candidate for the IASB also should be committed to serving the public interest through a private standard-setting process.

## Appendix 7

### Compendium of FSF Standards

Area	Standard	Issuing Body
<b>Macroeconomic Policy and Data Transparency</b>		
Monetary and financial policy transparency	Code of Good Practices on Transparency in Monetary and Financial Policies	IMF
Fiscal policy transparency	Code of Good Practices in Fiscal Transparency	IMF
Data dissemination	Special Data Dissemination Standard/ General Data Dissemination System <sup>1</sup>	IMF
<b>Institutional and Market Infrastructure</b>		
Insolvency <sup>2</sup>		World Bank
Corporate governance	Principles of Corporate Governance	OECD
Accounting	International Accounting Standards (IAS) <sup>3</sup>	IASB <sup>4</sup>
Auditing	International Standards on Auditing (ISA)	IFAC <sup>4</sup>
Payment and settlement	Core Principles for Systemically Important Payment Systems Recommendations for Securities Settlement Systems	CPSS/IOSCO
Market integrity	The Forty Recommendations of the Financial Action Task Force/ 8 Special Recommendations Against Terrorist Financing	FATF
<b>Financial Regulation and Supervision</b>		
Banking supervision	Core Principles for Effective Banking Supervision	BCBS
Securities regulation	Objectives and Principles of Securities Regulation	IOSCO
Insurance supervision	Insurance Core Principles	IAIS
<ol style="list-style-type: none"> <li>1. Economies with access to international capital markets are encouraged to subscribe to the more stringent SDDS and all other economies are encouraged to adopt the GDDS.</li> <li>2. The World Bank is co-ordinating a broad-based effort to develop a set of principles and guidelines on insolvency regimes. The United Nations Commission on International Trade Law (UNCITRAL), which adopted the Model Law on Cross-Border Insolvency in 1997, will help facilitate implementation.</li> <li>3. Relevant IAS are currently being reviewed by the IAIS and IOSCO.</li> <li>4. The International Accounting Standards Board (IASB) and the International Federation of Accountants (IFAC) are distinct from other standard-setting bodies in that they are private sector bodies.</li> </ol>		

## Bibliography

- Abbott, Kenneth W., Robert O. Keohane, Andrew Moravcsik, A. M. Slaughter, and Duncan Snidal. "The Concept of Legalization." *International Organization* 43, no. 3 (2000): 401-19.
- Abbott, Kenneth W., and Duncan Snidal. "Hard and Soft Law in International Governance." *International Organization* 54, no. 3 (2000): 421-56.
- Abel-Smith, Brian. *An Introduction to Health: Policy, Planning and Financing*. London and New York: Longman Group Limited, 1994.
- Abraham, John. *Science, Politics and the Pharmaceutical Industry*. London: UCL Press, 1995.
- Abraham, John, and Jim Reed. "Trading Risks for Markets: The International Harmonization of Pharmaceuticals Regulation." *Health, Risk and Society* 3, no. 1 (2001): 113-28.
- Abrahams, Paul. "A Tricky Balancing Act for Regulators." *Financial Times*, November 15, 1991, 19.
- Abu-Ghazaleh, Talal. "Comments on the Discussion Paper 'Shaping IASC for the Future'." *IASC Insight* June (1999): 13.
- Agrawal, Madhu. *Global Competitiveness in the Pharmaceutical Industry*. New York: Pharmaceutical Products Press, 1999.
- Akehurst, Michael. *A Modern Introduction to International Law*. 6th ed. London: Allen & Unwin, 1987.
- Alexander, D., and S. Archer. "On the Myth of 'Anglo-Saxon' Financial Accounting." *International Journal of Accounting* 35, no. 539-557 (2000).
- Amerasinghe C., F. *Principles of the Institutional Law of International Organizations*. Cambridge: Cambridge University Press, 1996.
- Andersson, F. "The Drug-Lag Issue: The Debate Seen from an International Perspective." *International Journal of Health Services* 22 (1992): 53-72.
- Αριστοτέλης. Πολιτικά 1. Αθήνα: Κάκτος, 1993.
- Anscombe, G. E. "On the Source of the Authority of the State." In *Authority*, edited by J. Raz. Oxford: Basil Blackwell, 1990.

- Archer, Clive. *International Organisations*. London; New York: Routledge, 1992.
- Archer, S., P. Delvaille, and S. McLeay. "The Measurement of Harmonisation and the Comparability of Financial Statement Items: Within-Country and between-Country Effects." *Accounting and Business Research* 25, no. 98 (1995): 67-80.
- Arendt, H. "What Was Authority?" In *NOMOS I: Authority*, edited by C. J. Friedrich. Cambridge: Harvard University Press, 1958.
- Association of British Pharmaceutical Industries. *Facts & Statistics from the Pharmaceutical Industry: A Global Industry 2006* [cited 17/01/2007]. Available from <http://www.abpi.org.uk/statistics/section.asp?sect=1>.
- Averch, M., and L. Johnson. "Behaviour of the Firm under Regulatory Constraint." *American Economic Review* 92 (1962): 1052-69.
- Baldwin, Robert, and M. Cave. *Understanding Regulation*. Oxford: Oxford University Press, 1999.
- Baldwin, Robert, Scott Colin, and Christopher Hood, eds. *A Reader on Regulation*. Oxford: Oxford University Press, 1998.
- Ball, R., and P. Brown. "An Empirical Evaluation of Accounting Income Numbers." *Journal of Accounting Research* 6 (1968): 159-77.
- Ball, T. "Authority and Conceptual Change." In *NOMOS XXIX: Authority Revisited*, edited by J. R. Pennock and J. W. Chapman. New York and London: New York University Press, 1987.
- Barker, R. *Political Legitimacy and the State*. Oxford: Clarendon Press, 1990.
- Basedow, Jurgen, Isaak Meier, K. Schnyder Anton, Talia Einhorn, and Daniel Girsberger, eds. *Private Law in the International Arena - Liber Amicorum Kurt Siehr*. The Hague, The Netherlands: T.M.C. Asser Press, 2000.
- Basel Committee on Banking Supervision. "Report to G7 Finance Ministers and Central Bank Governors on International Accounting Standards." April 2000.
- Baumol, William J., and J. Burton Malkiel. "Redundant Regulation of Foreign Security Trading and U.S. Competitiveness." *Journal of Applied Corporate Finance* 5, no. 4 (1993): 19-27.

- Bay, Wolf, and Hans-Georg Bruns. "Multinational Companies and International Capital Markets." In *International Accounting*, edited by Peter Walton, Alex Haller and Bernard Raffournier. London: Thompson Learning, 2003.
- Bayles, M. D. "The Justification of Administrative Authority." In *NOMOS XXIX: Authority Revisited*, edited by J. R. Pennock and J. W. Chapman. New York and London: New York University Press, 1987.
- Beaver, William H. *Financial Reporting: An Accounting Revolution*. Third ed. New Jersey: Prentice-Hall, Inc., 1998.
- Becker, Garry S. "A Theory of Competition among Pressure Groups for Political Influence." *The Quarterly Journal of Economics* Vol. XCVIII, no. 3 (1983): 371-97.
- Biddle, G. C., and S.M. Saudagaran. "The Effects of Financial Disclosure Levels on Firms' Choices among Alternative Foreign Stock Exchange Listings." *Journal of International Financial Management and Accounting* 1, no. 1 (1989): 55-87.
- Biener, Herbert. "What Is the Future of Mutual Recognition of Financial Statements and Is Comparability Really Necessary?" *The European Accounting Review* 3, no. 2 (1994): 335-42.
- Bislev, Sven, and Mikkel Flyverbom. "Transnational Private Governance of the Internet: The Roles of Business." In *Transnational Private Governance and Its Limits*, edited by Jean-Christophe Graz and Andreas Nölke. London; New York: Routledge, 2008.
- Black, J. "Constitutionalising Self-Regulation." *The Modern Law Review* 59, no. January 1996 (1996): 24-55.
- Booth, Paul M. "FDA Implementation of Standards Developed by the International Conference on Harmonisation." *Food and Drug Law Journal* 52 (1997): 203-23.
- Botosan, C. "Disclosure Level and the Cost of Equity Capital." *The Accounting Review* 72 (1997): 323-50.
- Braithwaite, John, and Peter Drahos. *Global Business Regulation*. Cambridge, UK: Cambridge University Press, 2000.

- Breyer, S. *Regulation and Its Reform*. Cambridge, MA: Harvard University Press, 1982.
- Breyer, S. G. *Administrative Law and Regulatory Policy: Problems, Text, and Cases*. 4th ed. New York: Aspen Law & Business, 1998.
- Briston, R.J., ed. *Introduction to Accountancy and Finance*, 1981.
- Brown, V. H. "Commentary on Accounting Standards: Their Economic and Social Consequences." *Accounting Horizons*, September (1990): 89-97.
- Brownlie, I. *The Rule of Law in International Affairs, International Law at the Fiftieth Anniversary of the United Nations*. The Hague: Kluwer Law International, 1998.
- Burchell, Stuart, Colin Clubb, and Anthony G. Hopwood. "Accounting in Its Social Context: Towards a History of Value Added in the United Kingdom." *Accounting, Organizations and Society* 10, no. 4 (1985): 381-413.
- Burchell, Stuart, Colin Clubb, Anthony G. Hopwood, and Chris Hughes. "The Roles of Accounting in Organizations and Society." *Accounting, Organizations and Society* 5, no. 1 (1980): 5-27.
- Burstall, M. L. "Europe after 1992: Implications for Pharmaceuticals." *Health Affairs*, no. Fall (1991): 157-71.
- Cairns, D. "The Conceptual Framework-the International Experience." David Cairns International Financial Reporting, 2001b.
- . *International Accounting Standards Survey 2000*. Henley-on-Thames: International Financial Reporting, 2001a.
- Cairns, David. "The Future Shape of Harmonization: A Reply." *The European Accounting Review* 6, no. 2 (1997): 305-48.
- Cairns, David with, Brian Creighton, and Anne Daniels. *Applying International Accounting Standards*. 3rd ed.: Tolley LexisNexis, 2003.
- Campos, Roel C. *The Global Marketplace and a Regulatory Overview* 2004 [cited 10/05/2006. Available from <http://www.sec.gov/news/speech/spch091704rcc.htm>.
- Cauchon, Dennis. "FDA Advisers Tied to Industry." *USA Today*, September, 25 2000, 1A.
- Cecchini, Paolo. *The European Challenge, 1992*. Adershot: Wildwood House, 1988.

- Cerny, Philip G. "The Deregulation and Re-Regulation of Financial Markets in a More Open World." In *Finance and World Politics: Markets, Regimes and States in the Post-Hegemonic Era*, edited by Philip G. Cerny. Aldershot: E. Elgar, 1993.
- . "Globalization and the Changing Logic of Collective Action." *International Organization* 49, no. 4 (1995): 595-625.
- Chaderton, Robertine, and Taylor P. J. "Accounting Systems of the Caribbean." *Research in Third World Accounting* 2 (1993): 45-66.
- Charles River Associates. "Innovation in the Pharmaceutical Sector: A Study Undertaken for the European Commission." 2004.
- Checkel, Jeffrey T. "The Constructivist Turn in International Relations Theory." *World Politics* 50 (1998): 324-48.
- Chetley, Andrew. *A Healthy Business? World Health and the Pharmaceutical Industry*. London and New Jersey: Zed Books Ltd, 1990.
- Choi, Frederick .D. S., Hisaaki Hino, S. K. Min, S. O. Nam, J. Ujiie, and A. I. Sotonehill. "Analyzing Foreign Financial Statements: The Use and Misuse of International Ratio Analysis." *Journal of International Business Studies*, no. Spring/Summer (1983): 113-31.
- Choi, Frederick .D. S., and Gerhard G. Mueller. *International Accounting*. New Jersey: Prentice-Hall International Inc., 1984.
- Choi, Frederick .D.S., ed. *International Finance and Accounting Handbook*. Third ed. New Jersey: John Wiley & Sons Inc., 2003.
- Choi, Frederick .D.S., and R. M. Levich. "International Accounting Diversity and Capital Market Decisions." In *Handbook of International Accounting*, edited by Frederick .D.S. Choi, 7.1-7.28. New York: John Wiley & Sons, Inc., 1991.
- Choi, Frederick D.S., ed. *Handbook of International Accounting*. New York: John Wiley & Sons, Inc., 1991.
- Christou, George, and Seamus Simpson. "Limitations to Transnational Private Governance of the Internet: The Dot Eu Top-Level Domain." In *Transnational Private Governance and Its Limits*, edited by Jean-Christophe Graz and Andreas Nölke. London; New York: Routledge, 2008.



- Clarke, M. *Regulation: The Social Control of Business between Law and Politics*. Basingstoke, Houndmills, Hampshire and London: Macmillan, 2000.
- Cochrane, James L. "Helping to Keep U.S. Capital Markets Competitive: Listing World-Class Non-U.S. Firms on U.S. Exchanges." In *International Capital Markets in a World of Accounting Differences*, edited by Frederick .D. S. Choi and R. M. Levich. Burr Bridge; New York: Irwin Professional Publishing, 1994.
- Commission of the European Communities. "The Future of Harmonization of Accounting Standards within the European Communities." 1990.
- . "Press Release : EC, USA and Japan Ready to Reduce Pharmaceutical Product-Testing and Animal Tests Dramatically." IP:1008, 1991, November, 13.
- Commission on Global Governance. *Our Global Neighbourhood : The Report of the Commission on Global Governance*. Oxford: Oxford University Press, 1995.
- Commission on Transnational Corporations. "Report of the Group of Experts on International Standards of Accounting and Reporting." United Nations, 1977.
- Cone, Ellen N. "International Regulation of Pharmaceuticals: The Role of the World Health Organization." *Virginia Journal of International Law* 23 (1983): 331-61.
- Cone, Margaret. "Sixth International Conference on Harmonisation, New Horizons and Future Challenges, 13-15 November 2003, Osaka, Japan Summary Report." 2003.
- Connolly, W.E., ed. *Legitimacy and the State*. Oxford: Basil Blackwell, 1984.
- . "Modern Authority and Ambiguity." In *NOMOS XXIX: Authority Revisited*, edited by J. R. Pennock and J. W. Chapman. New York and London: New York University Press, 1987.
- Contrera, Joseph. "Comment: The Food and Drug Administration and the International Conference on Harmonization: How Harmonious Will International Pharmaceutical Regulations Become?" *The Administrative Law Journal* 8 (1995): 927-60.

- Cummings, Joseph P. "Forging International Accounting Standards." *Tax Executive* XXVII, no. 4 (1975): 352-59.
- Cutler, A. C. "Private Authority in International Trade Relations: The Case of Maritime Transport." In *Private Authority and International Affairs*, edited by A. C. Cutler, Virginia Haufler and Tony Porter. Albany: State University of New York Press, 1999.
- Cutler, A. C., Virginia Haufler, and Tony Porter. "The Contours and Significance of Private Authority in International Affairs." In *Private Authority and International Affairs*, edited by A. C. Cutler, Virginia Haufler and Tony Porter. Albany: State University of New York Press, 1999.
- . "Private Authority and International Affairs." In *Private Authority and International Affairs*, edited by A. C. Cutler, Virginia Haufler and Tony Porter. Albany: State University of New York Press, 1999.
- Cutler, A. C., Virginia Haufler, and Tony Porter, eds. *Private Authority and International Affairs*. Albany: State University of New York Press, 1999.
- Cutler, A. C. *Private Power and Global Authority*. Cambridge: Cambridge University Press, 2003.
- D'Arcy, P.F., and D.W.G. Harron, eds. *Proceedings of the First International Conference on Harmonisation Brussels 1991*: International Federation of Pharmaceutical Manufacturers Associations, 1992.
- , eds. *Proceedings of the Second International Conference on Harmonisation Orlando 1993*: International Federation of Pharmaceutical Manufacturers Associations, 1994.
- , eds. *Proceedings of the Third International Conference on Harmonisation Yokohama 1995*. Belfast: International Federation of Pharmaceutical Manufacturers, 1996.
- David, René', and John E.C. Brierley. *Major Legal Systems in the World Today : An Introduction to the Comparative Study of Law*. 3rd ed. London: Stevens, 1985.
- Davis, E.P., and Benn Steil. *Institutional Investors*. Cambridge, Mass.: MIT Press, 2001.

- De Bruyne, D. "Global Standards: A Tower of Babel?" *Financial Executive* 48, no. 2 (1980): 30-37.
- De George, Richard T. *The Nature and Limits of Authority*. Kansas: University Press of Kansas, 1985.
- De Jouvenel, B. "Authority: The Efficient Imperative." In *NOMOS I: Authority*, edited by C. J. Friedrich. Cambridge: Harvard University Press, 1958.
- Denman, John H. "The OECD and International Accounting Standards." *CA Magazine* 113, February (1980): 56-59.
- Dewing, Ian, and Peter Russell. "The Role of Private Actors in Global Governance and Regulation: US, European and International Convergence of Accounting and Auditing Standards in a Post-Enron World." In *The Transnational Politics of Corporate Governance Regulation*, edited by Henk Ovebeek, Bastiaan Van Apeldoorn and Andreas Nölke. London; New York: Routledge, 2007.
- Di Masi, Joseph A, Ronald W Hansen, and Henry G Grabowski. "The Price of Innovation: New Estimates of Drug Development Costs." *Journal of Health Economics* 22 (2003): 151-85.
- Di Masi, Joseph A, and Cherie Paquette. "The Economics of Follow-on Drug Research and Development." *Pharmacoeconomics* 22, no. Suppl. 2 (2004): 1-14.
- Diggle, G., and Christopher W. Nobes. "European Rule Making in Accounting: The Seventh Directive as a Case Study." *Accounting and Business Research* 24, no. 96 (1994): 319-33.
- Dillman, John Patrick. "Prescription Drug Approval and Terminal Diseases: Desperate Times Require Desperate Measures." *Vanderbilt Law Review* 44 (1991): 925-51.
- Donaldson, William H. *Remarks before the International Organization of Securities Commissions* 2004 [cited 10/05/2006. Available from <http://www.sec.gov/news/speech/spch102804.htm>.
- Easton, David. *The Political System: An Inquiry into the State of Political Science*. New York: Knopf, 1953.
- Economist, The. "Drug Regulation: Radical Change." November 16, 1991, 84.

- Edelman, Peter B. "Japanese Product Standards as Non-Tariff Trade Barriers: When Regulatory Policy Becomes a Trade Issue." *Stanford Journal of International Law* 24 (1988): 389-446.
- Edwards, Franklin R. "Listing of Foreign Securities on U.S. Exchanges." *Journal of Applied Corporate Finance* 5, no. 4 (1993): 28-36.
- EMA. "Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework." (2005).
- Emenyonu, E.N., and Sidney J. Gray. "EC Accounting Harmonisation: An Empirical Study in Measurement Practices in France, Germany and the UK." *Accounting and Business Research* 22 (1992): 49-58.
- Ess, Silvia M., Sebastian Schneeweiss, and Thomas D Szucs. "European Healthcare Policies for Controlling Drug Expenditure." *Pharmacoeconomics* 21, no. 2 (2003): 89-103.
- Esty Daniel, C., and Damien Geradin, eds. *Regulatory Competition and Economic Integration*. Oxford: Oxford University Press, 2001.
- European Commission. "Contact Committee on the Accounting Directives." 1996.
- European Federation of Pharmaceutical Industries' Associations. "The Pharmaceutical Industry in Figures." 2006.
- Evans, T.G., and M.E. Taylor. "Bottom Line Compliance with the IASC: A Comparative Analysis." *International Journal of Accounting*, Fall (1982): 115-28.
- Fell, Lindsay. *An Introduction to Financial Products and Markets*. London and New York: Continuum, 2000.
- Financial Accounting Standards Board. *Statements of Financial Accounting Concepts*. 2002/2003 ed. New York, Chichester: Wiley, 2002.
- Fiorina, Morris P., and Roger G. Noll. "Voters, Bureaucrats and Legislators." *Journal of Public Economics* 9 (1978): 239-54.
- Fitzgerald, Richard D. "International Harmonization of Accounting and Reporting." *The International Journal of Accounting* 17, no. 1 (1981): 21-32.
- Flathman, R. E. *The Practice of Political Authority: Authority and the Authoritative*. Chicago and London: The University of Chicago Press, 1980.

- Florini, Ann M. "Who Does What? Collective Action and the Changing Nature of Authority." In *Non-State Actors and Authority in the Global System*, edited by Richard Higgott, Geoffrey R.D. Underhill and Andreas Bieler. London: Routledge, 2000.
- Flower, John. *European Financial Reporting*. New York: Palgrave Macmillan, 2004.
- . "The Future Shape of Harmonization: The EU Versus the IASC Versus the SEC." *The European Accounting Review* 6, no. 2 (1997): 281-303.
- Flower, John, and Gabi Ebbers. *Global Financial Reporting*. New York: Palgrave Macmillan, 2002.
- Freund, William C. "That Trade Obstacle, the SEC." *The Wall Street Journal* (August 27, 1993): A6.
- Friedman, R. B. "On the Concept of Authority in Political Philosophy." In *Authority*, edited by J. Raz. Oxford: Basil Blackwell, 1990.
- Friedrich, C. J. "Authority, Reason and Discretion." In *NOMOS I: Authority*, edited by C. J. Friedrich. Cambridge: Harvard University Press, 1958.
- , ed. *NOMOS I: Authority*. Cambridge: Harvard University Press, 1958.
- . *Tradition and Authority*. London: Pall Mall, 1972.
- Gambardella, Alfonso. *Science and Innovation*. Cambridge: Cambridge University Press, 1995.
- Gambardella, Alfonso, Luigi Orsenigo, and Fabio Pammolli. "Global Competitiveness in Pharmaceuticals: A European Perspective." European Communities, 2000.
- Garattini, Silvio, and Vittorio Bertele. "The Role of EMEA in Regulating Pharmaceutical Products." In *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality*, edited by Elias Mossialos, Monique Mrazek and Tom Walley. Maidenhead, England: Open University Press, 2004.
- Gernon, Helen, S. E. C. Purvis, and Michael A. Diamond. "An Analysis of the Implications of the IASC's Comparability Project." School of Accounting, University of Southern California, 1990.

- Gessner, Volkmar, and Ali Cem Budak, eds. *Emerging Legal Certainty: Empirical Studies on the Globalization of Law*, Onati International Series in Law and Society. Brookfield, USA; Aldershot, UK: Ashgate, Dartmouth, 1998.
- Getzen, Thomas E. *Health Economics: Fundamentals and Flow of Funds*: John Wiley and Sons, Inc., 1997.
- Gill, Stephen. "Globalization, Market Civilisation, and Disciplinary Neoliberalism." *Millenium: Journal of International Studies* 24, no. 3 (1995): 399-423.
- Gilpin, Robert. *U.S. Power and the Multinational Corporation: The Political Economy of Foreign Direct Investment*. New York: Basic Books, 1975.
- . *War and Change in World Politics*. New York: Cambridge University Press, 1981.
- Gladwell, M. "FDA Streamlining Approval Process for Cancer Drugs." *Washington Post*, June, 4 1991, A21.
- Glaum, Martin. "Bridging the GAAP: The Changing Attitude of German Managers Towards Anglo-American Accounting and Accounting Harmonization." *Journal of International Financial Management and Accounting* 11, no. 1 (2000): 23-47.
- Glautier, M. W. E., and B. Underdown. *Accounting Theory and Practice*. Seventh ed. Harlow, England: Pearson Education Ltd., 2001.
- Goldman, Patti. "The Democratization of the Development of United States Trade Policy." *Cornell International Law Journal* 27 (1994): 631-97.
- Grabowski, H. G. *Drug Regulation and Innovation*. Washington, D.C.: American Enterprise Institute for Public Policy Research, 1976.
- . "Regulation and the International Diffusion of Pharmaceuticals." In *The International Supply of Medicines: Implications of US Regulatory Reform*, edited by R. B. Helms. Washington, D.C.: American Enterprise Institute for Public Policy Research, 1980.
- Grabowski, H. G., and J. M. Vernon. "Innovation and Invention - Consumer Protection Regulation in Ethical Drugs." *American Economic Review* 67 (1977): 359-64.

- Graham, Cosmo. "Self-Regulation." In *Administrative Law and Government Action: The Courts and Alternative Mechanisms of Review*, edited by Hazel Genn and Genevra Richardson. Oxford: Clarendon Press, 1994.
- Gray, Sidney J. "The Impact of International Accounting Differences from a Security-Analysis Perspective: Some European Evidence." *Journal of Accounting Research* 18, no. 1 (1980): 64-76.
- Gray, Sidney J., J. C. Shaw, and L. B. McSweeney. "Accounting Standards and Multinational Corporations." *Journal of International Business Studies*, no. Spring/Summer (1981): 121-36.
- Graz, Jean-Christophe, and Andreas Nölke, eds. *Transnational Private Governance and Its Limits*. Abingdon and New York: Routledge, 2008.
- Green, Daniel. "Survey of Pharmaceuticals." *Financial Times*, April, 25 1995, 37.
- Gribbin, August. "House Investigates Panels Involved with Drug Safety; Mismanagement Claims Spur Action." *The Washington Times*, June, 18 2001, A1.
- Haas, Ernst B. *Beyond the Nation-State Functionalism and International Organization*. Stanford: Stanford University Press, 1968.
- Haas, Peter M. "Do Regimes Matter? Epistemic Communities and Mediterranean Pollution Control." In *International Organization: A Reader*, edited by Friedrich V. Kratochwil and Edward D. Mansfield. New York: HarperCollins College Publishers, 1994.
- . "Introduction: Epistemic Communities and International Policy Coordination." *International Organization* 46, no. 1 (1992): 1-35.
- Hall, J. "Authority and the Law." In *NOMOS I: Authority*, edited by C. J. Friedrich. Cambridge: Harvard University Press, 1958.
- Hall, Peter A., and David Soskice, eds. *Varieties of Capitalism*. Oxford; New York: Oxford University Press, 2001.
- Hall, Rodney Bruce, and Thomas J. Biersteker, eds. *The Emergence of Private Authority in Global Governance*. Cambridge: Cambridge University Press, 2002.

- Haller, Alex. "Financial Accounting Developments in the European Union: Past Events and Future Prospects." *The European Accounting Review* 11, no. 1 (2002): 153-90.
- . "International Accounting Harmonization: American Hegemony or Mutual Recognition with Benchmarks?" *The European Accounting Review* 4, no. 2 (1995): 2235-248.
- Haller, Alex, and Peter Walton. "Country Differences and Harmonization." In *International Accounting*, edited by Peter Walton, Alex Haller and Bernard Raffournier. London: Thompson Learning, 2003.
- Hancher, Leigh. *Regulating for Competition*. Oxford: Clarendon Press, 1990.
- Harden, I., and N. Lewis. *The Noble Lie: The British Constitution and the Rule of Law*. London: Hutchinson, 1986.
- Hardin, Russell. *Collective Action*. Baltimore: Johns Hopkins University Press, 1982.
- Hartley, Keith, and Maynard Alan. "The Regulation of the UK Pharmaceutical Industry: A Cost-Benefit Analysis." *Managerial and Decision Economics* 3, September (1982): 122-30.
- Hasenclever, Andreas, Peter Mayer, and Volker Rittberger. "Integrating Theories of International Regimes." *Review of International Studies* 26 (2000): 3-33.
- Held, David. *Democracy and the Global Order*. Cambridge: Polity Press, 2004.
- Held, David, and Mathias Koenig Archibugi, eds. *Global Governance and Public Accountability*. Oxford: Blackwell, 2005.
- Held, David, Anthony McGrew, David Goldblatt, and Jonathan Perraton. *Global Transformations*. Cambridge: Polity Press, 2000.
- Hendel, C. W. "An Exploration of the Nature of Authority." In *NOMOS I: Authority*, edited by C. J. Friedrich. Cambridge: Harvard University Press, 1958.
- Herdman, Robert K. *Moving toward the Globalization of Accounting Standards* 2002 [cited 10/05/2006. Available from <http://www.sec.gov/news/speech/spch554.htm>].
- Hermes, Niels, and Robert Lensink, eds. *Financial Development and Economic Growth*. London: Routledge, 1996.
- Higgott, Richard, Geoffrey R.D. Underhill, and Andreas Bieler, eds. *Non-State Actors and Authority in the Global System*. London: Routledge, 2000.



- Hodgkin, Catherine. "International Harmonisation - the Need for Transparency." *International Journal of Risk and Safety in Medicine* 9 (1996): 195-99.
- Holston, Sharon Smith. "The Implications of Harmonization: Viewpoint from the USA." In *Proceedings of the Third International Conference on Harmonization*, edited by P. F. D'Arcy and D. W. G. Harron. Belfast: IFPMA, 1996.
- Hopwood, Anthony G. "The Archaeology of Accounting Systems." *Accounting, Organizations and Society* 12, no. 3 (1987): 207-34.
- . "Some Reflections on the Harmonization of Accounting within the EU." *The European Accounting Review* 3, no. 2 (1994): 241-53.
- Horton, Linda R. "The Food and Drug Administration's International Harmonization, Enforcement, and Trade Policy Activities." *Fundamentals of Law and Regulation* (1997): 99-159.
- Horton, Richard. "Commentary: Lotronex and the FDA: A Fatal Erosion of Integrity." *The Lancet* 357, no. May (2001): 1544-45.
- Hove, Mfandaizda R. "The Inappropriateness of International Accounting Standards in Less Developed Countries: The Case of International Accounting Standard Number 24- Related Party Disclosures-Concerning Transfer Prices." *International Journal of Accounting* 24 (1989): 165-79.
- Howells, Peter, and Keith Bain. *Financial Markets and Institutions*. Second ed. New York: Longman Publishing, 1994.
- Hurd, Ian. "Legitimacy and Authority in International Relations." *International Organization* 53, no. 2 (1999): 379-408.
- International Accounting Standards Committee. "IASC/IFAC Mutual Commitments." In *Objectives and Procedures, IASC/IFAC Mutual Commitments, Appendix 3*. January 1985, 1982.
- . "International Accounting Standards Committee Constitution." In *Objectives and Procedures, IASC/IFAC Mutual Commitments, Appendix 2*. January 1985, 1982.
- . "Statement of Intent, Comparability of Financial Statements." July 1990.

- International Accounting Standards Committee Foundation. *IASC Foundation Constitution* July 2005 [cited 14/01/2006. Available from <http://www.iasb.org/about/constitution.asp>.
- International Organization of Securities Commissions. "IASC Standards - Assessment Report." May 2000.
- Jack, Andrew. "No Headache Cure for Costly Drug Regulation: Testing Procedures Vary Greatly between the Us, Europe and Japan. Wyeth Says the System Must Be Harmonised." *Financial Times*, April, 15 2005, 13.
- Japan Pharmaceutical Manufacturers Association. *Pharmaceutical Administration and Regulations in Japan* 2006 [cited 23/01/2007. Available from <http://www.jpma.or.jp/english/parj/0607.html>.
- Jarrell, Gregg A. "Sec Crimps Big Board's Future." *The Wall Street Journal* (June 19, 1992): A10.
- Jarrold, Wiener. *Globalization and the Harmonization of Law*. London; New York: Pinter, 1999.
- Jensen, M., and W. H. Meckling. "Theory of the Firm: Managerial Behaviour, Agency Costs and Ownership Structure." *Journal of Financial Economics* 3 (1976): 305-60.
- Joos, Peter, and Mark Lang. "The Effects of Accounting Diversity: Evidence from the European Union." *Journal of Accounting Research* 32 (1994): 141-68.
- Jordan, David W. "International Regulatory Harmonization: A New Era in Prescription Drug Approval." *Vanderbilt Journal of Transnational Law* 25 (1992): 471-507.
- Josselin, Daphne, and William Wallace, eds. *Non-State Actors in World Politics*. Basingstoke: Palgrave, 2001.
- Kanavos, Panos. "Determinants of Market Structure in the International Biopharmaceutical Industry." In *Economic Aspects of Biotechnologies Related to Human Health. Part II: Biotechnology, Medical Innovation and the Economy: The Key Relationships*, edited by Directorate for Science Working Party on Biotechnology, Technology and Industry. Paris: OECD, 1998.

- Kanusky, Rosemarie. "Pharmaceutical Harmonization: Standardizing Regulations among the United States, the European Economic Community, and Japan." *Houston Journal of International Law* 16 (1994): 665-707.
- Katz, Eric M. "Europe's Centralized New Drug Procedures: Is the United States Prepared to Keep Pace?" *Food and Drug Law Journal* 48 (1993): 577-87.
- Keohane, Robert O. *After Hegemony : Cooperation and Discord in the World Political Economy*. Princeton, N.J.: Princeton University Press, 1984.
- . "Global Governance and Democratic Accountability." In *Taming Globalization*, edited by David Held and Mathias Koenig-Archibugi. Cambridge: Polity Press, 2003.
- Kerwer, Dieter. "Governing Financial Markets by International Standards." In *New Modes of Governance in the Global System*, edited by Mathias Koenig-Archibugi and Michael Zürn. New York: Palgrave Macmillan, 2006.
- Kidd, Dan. "The International Conference on Harmonization of Pharmaceutical Regulations, the European Medicines Evaluation Agency, and the FDA: Who's Zooming Who?" *Indiana Journal of Global Legal Studies* 4 (1997): 183-206.
- King, Gary, Robert O. Keohane, and Sidney Verba. *Designing Social Inquiry*. Princeton: Princeton University Press, 1994.
- Kitchen, R. L. *Finance for the Developing Countries*. Chichester: John Wiley & Sons, 1986.
- Kline, John M. *International Codes and Multinational Business: Setting Guidelines for International Business Operations*. Connecticut: Quorum Books, 1985.
- Knill, Christoph, and Dirk Lehmkuhl. "Private Actors and the State: Internationalization and Changing Patterns of Governance." *Governance: An International Journal of Policy, Administration, and Institutions* 15, no. 1 (2002): 41-63.
- Kobrin, Stephen J. "Economic Governance in an Electronically Networked Global Economy." In *The Emergence of Private Authority in Global Governance*, edited by Rodney Bruce Hall and Thomas J. Biersteker. Cambridge: Cambridge University Press, 2002.

- Koenig-Archibugi, Mathias, and Michael Zürn, eds. *New Modes of Governance in the Global System*. New York: Palgrave Macmillan, 2006.
- Krasner, Stephen D. "Global Communications and National Power: Life on the Pareto Frontier." *World Politics* 43, no. 3 (1991): 336-66.
- . "State Power and the Structure of International Trade." *World Politics* 28, no. 317-347 (1976).
- Kratochwil, Friedrich. *Rules, Norms, and Decisions: On the Conditions of Practical and Legal Reasoning in International Relations and Domestic Affairs*. Cambridge: Cambridge University Press, 1989.
- Krieger, L. "The Idea of Authority in the West." *The American Historical Review* 82, no. 2 (1977): 249-70.
- Lafferty, Michael, David Cairns, and James Carty. *1979 Financial Times Survey of 100 Major European Companies Reports and Accounts*. London: The Financial Times Business Publishing Ltd, 1979.
- Lang, M., and R. Lundholm. "Corporate Disclosure Policy and Analyst Behaviour." *The Accounting Review* 71 (1996): 467-93.
- Lasagna, Louis, and W. M. Wardell. "The Rate of New Drug Discovery." In *Drug Development and Marketing*, edited by Robert B. Helms. Washington D.C.: American Enterprise Institute for Public Policy Research, 1975.
- Le Pen, Claude. "European Drug Prices: Old and New Models." In *Health Care Reforms and the Role of the Pharmaceutical Industry, Proceedings of a European Workshop: Pharmaceutical Partners for Better Healthcare*, 1995.
- Leary, Warren E. "FDA Announces Plan to Speed Process for Approving New Drugs." *The New York Times*, November, 13 1991, B13.
- Leuz, Christian, Dieter Pfaff, and Anthony Hopwood. *The Economics and Politics of Accounting*. Oxford; New York: Oxford University Press, 2004.
- Levine, Michael E., and Jennifer L. Forrence. "Regulatory Capture, Public Interest, and the Public Agenda: Towards a Synthesis." *Journal of Law, Economics, and Organization* 6, no. Special Issue (1990): 167-98.
- Lincoln, B. *Authority: Construction and Corrosion*. Chicago and London: The University of Chicago Press, 1994.

- Lindemann, Eric. "Importing AIDS Drugs: Food and Drug Administration Policy and Its Limitations." *George Washington Journal of International Law and Economics* 28 (1994): 133-69.
- Lukes, S. "Perspectives on Authority." In *NOMOS XXIX: Authority Revisited*, edited by J. R. Pennock and J. W. Chapman. New York and London: New York University Press, 1987.
- Majone, G. "The Rise of the Regulatory State in Western Europe." *West European Politics* 17, no. 77 (1994).
- Malanczuk, P. *Akehurst's Modern Introduction to International Law*. 7th rev. ed. London; New York: Routledge, 1997.
- Marsh, Peter. "A Suitable Case for Treatment." *Financial Times*, August, 22 1990, 17.
- Martin, Lisa L. "Interests, Power, and Multilateralism." *International Organization* 46, no. 4 (1992): 765-92.
- Martinez-Diaz, Leonardo. "Strategic Experts and Improvising Regulators: Explaining the IASC's Rise to Global Influence, 1973-2001." *Journal of Business and Politics* 7, no. 3 (2005).
- Mattli, Walter, and Tim Büthe. "Setting International Standards: Technological Rationality or Primacy of Power?" *World Politics* 56, no. October (2003): 1-42.
- Maurer, Reed P. "Restructuring the Japanese Pharmaceutical Industry." *Scrip Magazine*, May 1994, 38-40.
- McIntyre, Ann-Marie. *Key Issues in the Pharmaceutical Industry*. Chichester: John Wiley and Sons Ltd, 1999.
- McKee, David L., and Don E. Garner. *Accounting Services, the International Economy, and Third World Development*. Westport: Praeger Publishers, 1992.
- McKinnon, S. M., and P. Jannell. "The International Accounting Standards Committee: A Performance Evaluation." *International Journal of Accounting*, Spring (1984): 19-34.
- Merrill, Richard A. "Modernizing the FDA: An Incremental Revolution." *Health Affairs* 18, no. 2 (1999): 96-111.

- Miles, S., and Christofer Nobes. "The Use of Foreign Accounting Data in UK Financial Institutions." *Journal of Business Finance & Accounting* 25, no. 3 & 4 April/ May (1998): 309-28.
- Milner, Helen V. "Rationalizing Politics: The Emerging Synthesis of International, American, and Comparative Politics." *International Organization* 52, no. 4 (1998): 759-86.
- Mitrany, D. "The Functional Approach to World Organization." *International Affairs* 24, no. 3 (1948): 350-63.
- . *The Functional Theory of Politics*. London: Robertson [for the] London School of Economics and Political Science, 1975.
- . *A Working Peace System*. Chicago: Quadrangle Books, 1966.
- Mossialos, Elias, and J. Le Grand. *Health Care and Cost Containment in the European Union*. Aldershot: Ashgate, 1999.
- Mossialos, Elias, Tom Walley, and Monique Mrazek. "Regulating Pharmaceuticals in Europe: An Overview." In *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality*, edited by Elias Mossialos, Monique Mrazek and Tom Walley. Maidenhead, England: Open University Press, 2004.
- Muchlinski, Peter. *Multinational Enterprises and the Law*. Oxford; Malden, Massachusetts: Blackwell, 1995.
- Mytelka, Lynn K., and Michel Delapierre. "Strategic Partnerships, Knowledge-Based Networked Oligopolies, and the State." In *Private Authority and International Affairs*, edited by A. Claire Cutler, Virginia Haufler and Tony Porter. Albany, NY: SUNY Press, 1999.
- Nair, R. D., and W. G. Frank. "The Harmonization of International Accounting Standards." *International Journal of Accounting*, Fall (1981): 61-77.
- Neuer, Jürgen. "Binding Territoriality and Functionality? Globalization Meets the Law." In *Emerging Legal Certainty: Empirical Studies on the Globalization of Law*, edited by Volkmar Gessner and Ali Cem Budak. Brookfield, USA; Aldershot, UK: Ashgate, Dartmouth, 1998.

- Nikolaisen, Donald T. *Remarks before the IASB Meeting with World Standard-Setters* 2004 [cited 10/05/2006. Available from <http://www.sec.gov/news/speech/spch092804dtn.htm>].
- . *A Securities Regulator Looks at Convergence* April 2005 [cited January 27, 2006. Available from <http://www.sec.gov/news/speech/speecharchive/2005speech.shtml#staff>].
- Nobes, Christofer W., ed. *International Accounting - General Issues and Classification*. Cheltenham, U.K.: Edward Elgar Publishing Ltd., 1996.
- , ed. *International Accounting and Comparative Financial Reporting*. Cheltenham, U.K.: Edward Elgar Publishing Ltd., 1999.
- . *Interpreting European Financial Statements*. Second ed. London, Dublin and Edinburgh: Butterworths, 1994.
- . "On the Myth of 'Anglo-Saxon' Financial Accounting: A Comment." *The International Journal of Accounting* 38 (2003): 95-104.
- Nobes, Christofer W., and Robert Parker. *Comparative International Accounting*. Harlow, England: Pearson Education Ltd., Prentice Hall, 2000.
- Nobes, Christopher W. "Compliance by US Corporations with IASC Standards." *British Accounting Review* 22 (1990): 41-49.
- . "The True and Fair View Requirement: Impact on and of the Fourth Directive." *Accounting and Business Research* 24, no. 93 (1993): 35-48.
- Nölke, Andreas, Henk Ovebeek, and Bastiaan Van Apeldoorn. "Marketization, Transnationalization, Commodification, and the Shifts in Corporate Governance Regulation: A Conclusion." In *The Transnational Politics of Corporate Governance Regulation*, edited by Henk Ovebeek, Bastiaan Van Apeldoorn and Andreas Nölke. London; New York: Routledge, 2007.
- Nölke, Andreas, and James Perry. "Coordination Service Firms and the Erosion of Rhenish Capitalism." In *The Transnational Politics of Corporate Governance Regulation*, edited by Henk Ovebeek, Bastiaan Van Apeldoorn and Andreas Nölke. London; New York: Routledge, 2007.
- Noll, Roger G., ed. *Regulatory Policy and the Social Sciences*. Berkeley: University of California Press, 1995.

- Oakeshott, Michael. *On Human Conduct*. Oxford: Clarendon Press, 1991.
- Oatley, Thomas, and Robert Nabors. "Redistributive Cooperation: Market Failure, Wealth Transfers, and the Basle Accord." *International Organization* 52, no. 1 (1998): 35-54.
- O'Brien, Richard. *Global Financial Integration: The End of Geography*. London: Pinter Publishers, 1991.
- Ogus, A. "Rethinking Self-Regulation." *Oxford Journal of Legal Studies* 15 (1995): 97-108.
- Olson, Mancur. *Mancur the Logic of Collective Action: Public Goods and the Theory of Groups*. Cambridge MA: Harvard University Press, 1965.
- Orzack, Louis H., Kenneth I. Kaitin, and Louis Lasagna. "Pharmaceutical Regulation in the European Community: Barriers to Single Market Integration." *Journal of Health Politics, Policy and Law* 17, no. 4 (1992): 847-68.
- Ovebeek, Henk, Bastiaan Van Apeldoorn, and Andreas Nölke, eds. *The Transnational Politics of Corporate Governance Regulation*. London; New York: Routledge, 2007.
- Page, Alan C. "Self-Regulation: The Constitutional Dimension." *The Modern Law Review* 49, no. 2 (1986): 141-67.
- Parsons, T. "Authority, Legitimation and Political Action." In *NOMOS I: Authority*, edited by C. J. Friedrich. Cambridge: Harvard University Press, 1958.
- Pauly, Louis W. "Global Finance, Political Authority, and the Problem of Legitimation." In *The Emergence of Private Authority in Global Governance*, edited by Rodney Bruce Hall and Thomas J. Biersteker. Cambridge: Cambridge University Press, 2002.
- Pear, Robert, and Richard A. Oppel, Jr. "Results of Elections Give Pharmaceutical Industry New Influence in Congress." *The New York Times*, November, 21 2002.
- Peltzman, Sam. *The Economic Theory of Regulation after a Decade of Deregulation, Brookings Papers on Economic Activity*. Washington D.C.: Brookings Institution, 1989.



- . *Regulation of Pharmaceutical Innovation: The 1962 Amendments*. Washington D.C.: American Enterprise Institute for Public Policy Research, 1974.
- . "Towards a More General Theory of Regulation." *Journal of Law and Economics* 19 (1976): 211-40.
- Pennock, J. R., and J. W. Chapman, eds. *NOMOS XXIX: Authority Revisited*. New York and London: New York University Press, 1987.
- Permanand, Govin. *EU Pharmaceutical Regulation*. Manchester and New York: Manchester University Press, 2006.
- Permanand, Govin, and Christa Altenstetter. "The Politics of Pharmaceuticals in the European Union." In *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality*, edited by Elias Mossialos, Monique Mrazek and Tom Walley. Maidenhead, England: Open University Press, 2004.
- Perry, James, and Andreas Nölke. "The Political Economy of International Accounting Standards." *Review of International Political Economy* 13, no. 4 (2006): 559-86.
- Perry, James, and Andreas Nölke. "International Accounting Standard Setting: A Network Approach." *Business and Politics* 7, no. 3 (2005): 1-32.
- Pharmaceutical Research and Manufacturers of America. "Value of Medicines, Facts and Figures 2006." Washington D.C., 2006.
- Phelps, James R, Esq. "The New International Economic Order and the Pharmaceutical Industry." *Food Drug Cosmetic Law Journal* 37 (1982): 200-11.
- Pilling, David. "Europe's Fledgling Drugs Safety Agency Wins Its Spurs: The EU's Medicines Regulator Has Cut Approval Times." *Financial Times*, January, 27 2000, 10.
- . "Trials and Tribulations: Getting a New Drug to Market Can Take Years." *Financial Times*, April, 22 1999, 11.
- Pirmohamed, Munir, and Graham Lewis. "The Implications of Pharmacogenetics and Pharmacogenomics for Drug Development and Health Care." In *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity, Quality*, edited by

- Elias Mossialos, Monique Mrazek and Tom Walley. Maidenhead, England: Open University Press, 2004.
- Putnam, Robert D. "Diplomacy and Domestic Politics: The Logic of Two-Level Games." *International Organization* 42, no. 3 (1988): 427-60.
- Puxty, A. G., H. C. Willmott, D. J. Copper, and T. Lowe. "Modes of Regulation in Advanced Capitalism: Locating Accountancy in Four Countries." *Accounting, Organizations and Society* 12, no. 3 (1987): 273-91.
- Radebaugh, Lee H., and Sidney J. Gray. *International Accounting and Multinational Enterprises*. Fourth ed. New York: John Wiley & Sons, Inc., 1997.
- Raffournier, Bernard, and Peter Walton. "Accounting Differences and Financial Statement Analysis." In *International Accounting*, edited by Peter Walton, Alex Haller and Bernard Raffournier. London: Thompson Learning, 2003.
- Raghavan, Anita, and Michael R. Sesit. "Financing Boom: Foreign Firms Raise More and More Money in the U.S. Markets." *The Wall Street Journal*, October 5th 1993, A1, A8-A9.
- Rappaport, A. "Statements in Quotes." *The Journal of Accountancy*, May (1977): 89-99.
- Raz, J., ed. *Authority*. Oxford: Basil Blackwell, 1990.
- . *The Authority of Law: Essays on Law and Morality*. Oxford: Clarendon Press, 1979.
- Reekie, Duncan W. "Barriers to Entry and Competition." In *Economics and Innovation in the Pharmaceutical Industry*, edited by George Teeling-Smith. London: Office of Health Economics, 1969.
- Reekie, Duncan W., and Michael H Weber. *Profits, Politics and Drugs*. London and Basingstoke: The MacMillan Press Ltd, 1979.
- Reinicke, Wolfgang H. *Global Public Policy*. Washington D.C.: Brookings Institution Press, 1998.
- Reis-Arndt, E. "New Pharmaceutical Agents 1961-1973." *Drugs Made in Germany* 18, no. 3 (1975): 123-30.

- Reis-Arndt, E., and Elvers D. "Results of Pharmaceutical Research - New Pharmaceutical Agents 1961-1970." *Drugs Made in Germany* 15, no. 3 (1972): 134-40.
- Richards, John E. "Toward a Positive Theory of International Institutions: Regulating International Aviation Markets." *International Organization* 53, no. 1 (1999): 1-37.
- Roberts, Clare, Paul Gordon, and P. Weetman. *International Financial Accounting: A Comparative Approach*. London: Prentice Hall, 2002.
- Rosenau, James M. "Governance, Order and Change in World Politics." In *Governance without Government: Order and Change in World Politics*, edited by James M. Rosenau and Ernst-Otto Czempiel. Cambridge; New York: Cambridge University Press, 1992.
- Rosenau, James M., and Ernst-Otto Czempiel, eds. *Governance without Government: Order and Change in World Politics*. Cambridge; New York: Cambridge University Press, 1992.
- Rosenblum, N. L. "Studying Authority: Keeping Pluralism in Mind." In *NOMOS XXIX: Authority Revisited*, edited by J. R. Pennock and J. W. Chapman. New York and London: New York University Press, 1987.
- Ruggie, John G. "Territoriality and Beyond: Problematizing Modernity in International Relations." *International Organization* 47, no. 1 (1993): 139-74.
- . "What Makes the World Hang Together? Neo-Utilitarianism and the Social Constructivist Challenge." *International Organization* 52 (1998): 855-85.
- Salter, Stephen B., and Timothy S. Doupnik. "The Relationship between Legal Systems and Accounting Practices: A Classification Exercise." *Advances in International Accounting* 5 (1992): 3-22.
- Samuels, J.M., and A.G. Piper. *International Accounting: A Survey*. London and Sydney: Croom Helm, 1985.
- Sarrett, L. H. "FDA Regulations and Their Influence on Future R&D." *Research Management*, March (1974): 18-20.
- Sassen, Saskia. *Territory, Authority, Rights: From Medieval to Global Assemblages*. Princeton and Oxford: Princeton University Press, 2006.

- Saudagaran, S. M. *International Accounting: A User Perspective*. Cincinnati, United States: South-Western College Publishing, Thompson Learning, 2001.
- Saudagaran, S. M., and G. C. Biddle. "Financial Disclosure Levels and Foreign Stock Exchange Listing Decisions." *Journal of International Financial Management and Accounting* 4, no. 2 (1992): 106-48.
- . "Foreign Listing Location: A Study of MNCs and Stock Exchanges in Eight Countries." *Journal of International Business Studies* Second Quarter (1995): 319-41.
- Schuetze, Walter P. "What Is the Future of Mutual Recognition of Financial Statements and Is Comparability Really Necessary?" *The European Accounting Review* 3, no. 2 (1994): 330-34.
- Schultz, Joseph J., Jr., and Thomas J. Lopez. "The Impact of National Influence on Accounting Estimates: Implications for International Accounting standard-Setters." *The International Journal of Accounting* 36, no. 3 (2001): 271-90.
- Schweitzer, Stuart O. *Pharmaceutical Economics and Policy*. New York: Oxford University Press, 1997.
- Scott, William R. *Financial Accounting Theory*. Third ed. Toronto: Pearson Education Canada, Inc., 2003.
- Sell, Susan. "Multinational Corporations as Agents of Change: The Globalization of Intellectual Property Rights." In *Private Authority and International Affairs*, edited by A. C. Cutler, Virginia Haufler and Tony Porter. Albany: State University of New York Press, 1999.
- . *Private Power, Public Law*. Cambridge: Cambridge University Press, 2003.
- Simmonds, A., and O. Azières. *Accounting for Europe- Success by 2000 AD?* London: Touche Ross, 1989.
- Simmons, B. "The International Politics of Harmonization: The Case of Capital Market Regulation." *International Organization* 55, no. 3 (2001): 589-620.
- Sinclair, Timothy. "Bond-Rating Agencies and Coordination in the Global Political Economy." In *Private Authority and International Affairs*, edited by A. C. Cutler, Virginia Haufler and Tony Porter. Albany: State University of New York Press, 1999.

- Sir Benson, Henry. "The Story of International Accounting Standards." *Accountancy*, July (1976): 34-39.
- Slatter, Stuart St. P. *Competition and Marketing Strategies in the Pharmaceutical Industry*. London: Croom Held Ltd, 1977.
- Slaughter, A. M. "Governing the Economy through Government Networks." In *The Role of Law in International Politics*, edited by Michael Byers. Oxford: Oxford University Press, 2000.
- . *New World Order*. Princeton, NJ.: Princeton University Press, 2004.
- Slingsby, Brian T, Noriko Nagao, and Akira Akabayashi. "Administrative Legislation in Japan: Guidelines on Scientific and Ethical Standards." *Cambridge Quarterly of Healthcare Ethics* 13 (2004): 245-53.
- Snidal, Duncan. "Coordination Versus Prisoners' Dilemma: Implications for International Cooperation and Regimes." *The American Political Science Review* 79 (1985): 923-42.
- Solomons, D. "The Politicization of Accounting." *The Journal of Accountancy*, November (1978): 65-72.
- Spar, Debora L. "Lost in (Cyber)Space: The Private Rules of Online Commerce." In *Private Authority and International Affairs*, edited by A. C. Cutler, Virginia Haufler and Tony Porter. Albany: State University of New York Press, 1999.
- Spencer, M. E. "Weber on Legitimate Norms and Authority." *The British Journal of Sociology* 21, no. 2 (1970): 123-34.
- Spiro, H. J. "Authority, Values and Policy." In *NOMOS I: Authority*, edited by C. J. Friedrich. Cambridge: Harvard University Press, 1958.
- Spivey, Richard N., Albert I. Wertheimer, and Donald T. Rucker, eds. *International Pharmaceutical Services*. New York; London; Norwood: Haworth Press, 1992.
- Statman, Meir. *Competition in the Pharmaceutical Industry, American Enterprise Institute Studies in Health Policy*. Washington D.C. and London: American Enterprise Institute for Public Policy Research, 1983.
- Stein, A. A. "Coordination and Collaboration: Regimes in an Anarchic World." *International Organization* 36, no. 2 (1982): 299-324.

- Stigler, George J. "The Theory of Economic Regulation." *Bell Journal of Economics and Management* 2 (1971): 3-21.
- Stigler, George J., and Claire Friedland. "What Can Regulators Regulate? The Case of Electricity." *Journal of Law and Economics* 5 (1962): 1-16.
- Strange, Susan. *States and Markets*. 2nd ed. London: Pinter Publishers, 1994.
- . *The Retreat of the State: The Diffusion of Power in the World Economy*. New York: Cambridge University Press, 1996.
- Streeck, P., and P. Schmitter. *Private Interest Government: Beyond Market and State*. London: Sage, 1985.
- Street, D.L., and K.A. Shaughnessy. "The Evolution of the G4+1 and Its Impact on International Harmonization of Accounting Standards." *Journal of International Accounting, Auditing and Taxation* 7, no. 1 (1998): 132-61.
- Teubner, Gunther, ed. *Global Law without a State*. Brookfield, USA; Aldershot, UK: Dartmouth, 1997.
- Thomas, Barbara S. "Increased Access to United States Capital Markets: A Brief Look at the SEC's New Integrated Disclosure Rules for Foreign Issuers." *Journal of Comparative Business and Capital Market Law*, 5, 129-135 (1983).
- Tsingou, Eleni. "Transnational Private Governance and the Basel Process: Banking Regulation and Supervision, Private Interests and Basel II." In *Transnational Private Governance and Its Limits*, edited by Jean-Christophe Graz and Andreas Nölke. London; New York: Routledge, 2008.
- Tweedie, David. "Report of the Chairman of the IASB." In *IASC Foundation: Annual Report 2004*. London: IASC Foundation, 2004.
- U.S. Congress, Office of Technology Assessment. "Biotechnology in a Global Economy, OTA-BA-494." Washington, DC: U.S. Government Printing Office, October 1991.
- . "Pharmaceutical R&D: Costs, Risks, and Rewards, OTA-H-522." Washington, D. C.: US Government Printing Office, 1993.
- U.S. Securities and Exchange Commission. *2004-2009 Strategic Plan* 2004 [cited 7 April 2007. Available from <http://www.sec.gov/about/secstratplan0409.pdf>.
- . "Statement Regarding International Accounting Standards." 1996.

- UNCITRAL. "Arbitration Rules." UN Doc. A/31/17.
- . "Model Law on International Commercial Arbitration." UN Doc. A/Conf. A/40/17, reprinted in UNCITRAL Yearbook 1986, 16:393.
- Underhill, G. R.D. "Keeping Governments out of Politics: Transnational Securities Markets, Regulatory Cooperation and Political Legitimacy." *Review of International Studies* 21, no. 3 (1995): 251-78.
- Underhill, Geoffrey R.D., and Xiaoke Zhang, eds. *International Financial Governance under Stress: Global Structures Versus National Imperatives*. Cambridge; New York: Cambridge University Press, 2003.
- United Nations. "Conclusions of the Intergovernmental Working Group of Experts on International Standards of Accounting and Reporting." 09/02/1988.
- . "Convention on the Recognition and Enforcement of Foreign Arbitral Awards." UN Doc. A/Conf. 9/22 reprinted in ILM (1968):1,042-62, June 10, 1958.
- Van Apeldoorn, Bastiaan, and Laura Horn. "The Transformation of Corporate Governance Regulation in the EU: From Harmonization to Marketization." In *The Transnational Politics of Corporate Governance Regulation*, edited by Henk Ovebeek, Bastiaan Van Apeldoorn and Andreas Nölke. London; New York: Routledge, 2007.
- Van Hulle, K. "Harmonisation of Accounting Standards in the EC - Is It the Beginning Or the End?" *The European Accounting Review* 2, no. 2 (1993): 387-96.
- . "Harmonisation of Accounting Standards: A View from the European Community." *The European Accounting Review* 1, no. 1 (1992): 161-72.
- Vogel, David. "The Globalization of Pharmaceutical Regulation." *Governance: An International Journal of Policy and Administration* 11, no. 1 (1998): 1-22.
- Wall, Rosemary Pierce. "International Trends in New Drug Approval Regulation: The Impact on Pharmaceutical Innovation." *Rutgers Computer and Technology Law Journal* 10 (1984): 317-40.

- Wallace, Olusegun R. S. "Development of Accounting Standards for Developing and Newly Industrialized Countries." *Research in Third World Accounting* 2 (1993): 121-65.
- Walton, Peter. "Harmonization of Accounting in France and Britain: Some Evidence." *Abacus* 28, no. 2 (1992): 186-99.
- Walton, Peter, Alex Haller, and Bernard Raffournier, eds. *International Accounting*. Second ed. London: Thompson Learning, 2003.
- Wardell, W. M. "The Drug Lag Revisited: Comparison by Therapeutic Area of Patterns of Drugs Marketed in the United States and Great Britain from 1972 through 1976." *Clinical Pharmacology and Therapeutics* 24 (1978): 499-524.
- . "Introduction of New Therapeutic Drugs in the United States and Great Britain: An International Comparison." *Clinical Pharmacology and Therapeutics* 14 (1973): 773-90.
- Watts, J. *Accounting in the Business Environment*. Second ed. London: Pitman Publishing, 1996.
- Watts, R. L. "Corporate Financial Statements, a Product of the Market and Political Processes." *Australian Journal of Management* 2, April (1977): 53-75.
- Watts, Ross L., and Jerold L. Zimmerman. *Positive Accounting Theory*. New Jersey: Prentice Hall International, Inc., 1986.
- Wechsler, Jill. "Washington Vs. The World?" *Pharmaceutical Executive*, February 1996, 16-20.
- Weetman, P., and Sidney J. Gray. "A Comparative International Analysis of the Impact of Accounting Principles on Profits: The USA Versus the UK, Sweden and the Netherlands." *Accounting and Business Research* 21, no. 84 (1991): 363-79.
- Weetman, P., E. A. E. Jones, C. A. Adams, and Sidney J. Gray. "Profit Measurement and UK Accounting Standards: A Case of Increasing Disharmony in Relation to Us GAAP and IASs." *Accounting and Business Research* 28, no. 3 (1998): 189-203.



- Weingast, Barry R. "Regulation, Reregulation, and Deregulation: The Political Foundations of Agency Clientele Relationships." *Law and Contemporary Problems* 44, no. 1 (1981): 148-77.
- Wendt, Alexander E. "Anarchy Is What States Make of It: The Social Construction of Power Politics." *International Organization* 46 (1992): 391-425.
- Wendt, Henry, and Brian Abel-Smith. "Introduction." In *Health Care Reforms and the Role of the Pharmaceutical Industry, Proceedings of a European Workshop: Pharmaceutical Partners for Better Healthcare*, 1995.
- Wiktorowicz, Mary E. "Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain and France." *Journal of Health Politics, Policy and Law* 28, no. 4 (2003): 615-58.
- William, Bratton, Joseph McCahery, Sol Picciotto, and Colin Scott, eds. *International Regulatory Competition and Coordination*. Oxford: Clarendon Press, 1996.
- Williams Oliver, F, ed. *Global Codes of Conduct*. Notre Dame, Indiana: University of Notre Dame Press, 2000.
- World Health Organization. "The Impact of Implementation of ICH Guidelines in Non-ICH Countries." Geneva, 2002.
- Wyatt, A. "Commentary Accounting Standards: Conceptual or Political?" *Accounting Horizons*, September (1990): 83-88.
- Wygall, Donald E., David E. Stout, and James Volpi. "Reporting Practices in Four Countries." *Management Accounting*, December (1987): 37-42.
- Yin, Robert K. *Case Study Research: Design and Methods*. 3rd. ed. Thousand Oaks; London; New Delhi: Sage Publications Inc., 2003.
- Zeff, S. A. "The Rise of Economic Consequences." *The Journal of Accountancy*, December (1978): 56-63.
- Zünd, Andre. "Endeavours Towards the Harmonization of Standards of Accounting and Reporting in the OECD and UNO: A Critical Appraisal." In *Accounting Standards Setting: An International Perspective*, edited by Michael Bromwich and Anthony G. Hopwood. London: Pitman Books Ltd., 1983.
- Zürn, Michael, and Mathias Koenig-Archibugi. "Conclusions II: The Modes and Dynamics of Global Governance." In *New Modes of Governance in the*

*Global System*, edited by Mathias Koenig-Archibugi and Michael Zürn. New York: Palgrave Macmillan, 2006.