EUROPEAN REGULATORY POWER: CAPACITY AND SEQUENCING IN INTERNATIONAL PHARMACEUTICAL AND COSMETICS GOVERNANCE

By

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Abstract

Over the last three decades, the pharmaceutical- and cosmetics industries have become increasingly global. To ensure product safety and consumer protection, regulators in leading markets have applied domestic rules extraterritorially and have joined forces to harmonize rules through transgovernmental cooperation. Yet whereas the United States has long been the dominant player in international market regulation of pharmaceuticals, the European Union has decisively shaped global rules for cosmetics. What explains differences in agenda setting across the two closely-related industries amidst the similar institutional evolution of governance? We compare and contrast the expectations of a realist account focused on market size and a liberal functionalist argument centered on the role of market friction with a historical institutionalist explanation stressing the relative sequential development over time of domestic regulatory capacity in leading markets. The empirical evidence shows that domestic regulatory institutions systematically shape international market regulation. Historical institutionalism provides an important complement to existing transgovernmental research, offering clear expectations for the origins of and terms of influence within such cooperation. More generally, it opens up a rich toolbox for the analysis of industry-level global market governance, which affect the daily lives of billions.

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Introduction

The global pharmaceutical- and cosmetics industries are worth close to $1 trillion and feature multibillion-dollar firms that trade, source, and invest around the world. In many respects, the two industries represent the vanguard of today's globalized economy. At the same time, pharmaceuticals and cosmetics are subject to stringent market access regulation to ensure safety and efficacy. In combination with intellectual property rules and public health policy, governance in this domain affects the cost and availability of life-saving drugs, not just in the industrialized world but also in emerging markets and developing countries (Elbe, 2008). Who shapes the regulation of international pharmaceutical and cosmetics markets, why, and how, are therefore important questions for International Political Economy (IPE).

Empirically, international market regulation of pharmaceuticals and cosmetics poses an intriguing puzzle.[i] In similar ways, the form of governance has shifted from occasional international spill-over of domestic rules to first deliberate extraterritorial imposition of domestic laws and subsequently to transgovernmental cooperation aimed at policy harmonization. Yet against this background of commonality, there is a sharp divergence when it comes to who shapes the policy agenda: in the case of pharmaceuticals, the United States has long been dominant and has only recently seen its leadership challenged by the European Union. In cosmetics, the EU has shaped international market regulation from the outset and the US has failed to make significant inroads. What explains the similar institutional evolution of international market regulation in the two fields and the differences in agenda setting between them?

We argue that the key to these questions lies in the relative sequential development over time of domestic regulatory capacity in leading markets. Regulatory capacity – the

ability of a jurisdiction to define and implement a set of market rules and to monitor firms' compliance with them – is largely institutionally-determined. It depends on the expertise of staff, the extent of statutory sanctioning authority vested in regulators, and the degree of centralization of regulatory authority over a market.[ii] Like other institutional characteristics of a political economy – the financial system, corporate governance, or industrial organization – it is the product of political processes slowly unfolding over time (Pierson, 2004, Büthe, 2002). Policymakers confronted with new regulatory challenges in the face of globalizing markets must rely on the institutional resources at their disposal. Yet the creation of these institutions usually predates the particular challenge at hand, constraining international initiatives. This means that reforms carried out with a purely domestic focus can have unintended consequences for international debates years later by either boosting or diminishing regulatory capacity.[iii] As regulatory capacity varies across countries, sectors, and time, disparities in regulatory capacity among leading markets are possible and to be expected. The relative sequential development of domestic regulatory capacity over time can thus be tracked and measured and, as this paper shows, systematically shapes international market regulation.

Employing the relative sequencing argument, we construct a causal typology, which offers expectations about the likelihood of transgovernmental cooperation, extraterritorial application of domestic law, or market governance. Robust transgovernmental cooperation requires capable and domestically-empowered regulators in all pivotal markets (Damro, 2006). A highly asymmetric distribution of regulatory capacity means international market regulation has to proceed through alternative governance modes. Extraterritorial application of domestic rules by the regulatory hegemon becomes likely in such instances (Fox, 1997). Lastly, if no jurisdiction has highly-developed regulatory capacity in a sector or those with

regulatory capacity choose not to exercise it, pure market coordination prevails internationally. This is the case for new markets at the technological frontier, for instance, where domestic regulation is often entirely lacking (Spar, 2001). Regardless of the form of governance, those regulators with significant regulatory capacity relative to others will be best positioned to shape the international policy agenda, i.e. the terms and conditions of standards and rules adopted by other countries and international institutions.[iv]

The paper makes contributions to three critical debates in IPE. First, it offers new insights on the relationship between domestic institutions and international cooperation. Much existing work has focused on a narrow set of domestic institutions and their role in formal intergovernmental bargaining (Frieden and Martin, 2002). Research has demonstrated, for instance, how the need for national legislatures to ratify international agreements shapes international trade policy (Putnam, 1988, Milner, 1997). But in many areas of global governance, the two-level game model picturing internationally-negotiating chief executives and domestically-ratifying legislatures no longer fits. We find a broader set of public policy institutions, including domestic regulators and other substate actors, who directly engage in international affairs and who autonomously incorporate internationally-coordinated rules into domestic policy. The growing international role of domestic institutions means that domestic initiatives, such as deregulation in the US or the Single Market project in Europe, can have significant – and often unanticipated – consequences for global governance.

Secondly, the paper expands on a growing literature on transgovernmental relations. Previous work has demonstrated the ability of transgovernmental networks among domestic regulators to resolve complex global governance challenges (Slaughter, 2004, Raustiala, 2002, Newman 2008). However, there are few models to predict the likelihood of

transgovernmental cooperation in a given area and even less is known about agenda setting power within such networks. A historical institutionalist focus on the importance of sequencing, unanticipated consequences, and the development of regulatory capacity over time sheds light on these questions and pushes this important agenda forward.

Third, and finally, the paper highlights to growing role of the European Union in international market governance. In issue areas from data privacy to chemicals, the EU has had growing influence in setting the rules of market competition. While scholars often point to the economic might of the single market, our research points to the equally important development of regulatory institutions. In particular, the growing coordination of market access coupled with technical expertise at the European level have altered the ability of the EU to leverage its market power.

The first section of the paper examines existing systemic theories of IPE, emphasizing market size and market friction as respective determinants of power- and institutional patterns in international governance. Section two develops a domestic institutional argument that explains changing patterns of international market regulation as a result of the sequential development of domestic regulatory capacity in leading markets. This is followed by two case studies on pharmaceuticals and cosmetics through which we evaluate the three arguments using process tracing. The final section discusses both positive and normative implications of the findings for the future of global governance.

Expectations of Existing Theories: Market Size or Market Friction

Previous research in the realist and liberal tradition offers testable hypotheses about the causal factors and mechanisms that could account for observable governance patterns and changes within them.

Market Size

Realists, who focus attention on the critical role of state power, have recently applied this approach to international market regulation (Drezner, 2007). Power here is taken to be market power, which is commonly operationalized through market size. As Drezner (2005, 843) explains, "[s]tates are differentiated by their relative power" and "[p]ower is defined as the relative size and diversity of an actor's internal market." According to realists, dominant powers – those with the largest markets relative to others – can decisively shape international market rules, either through extraterritorial reach or within international bodies. Shifts in agenda setting should reflect changes in relative market size (Shambough, 1996, Vogel, 1995, James and Lake, 1989, Aggarwal, 1985). The US and EU, which have the largest markets in most sectors, should be the pivotal players. When they agree, de-facto global norms result. If they disagree, rival regulations promoted by the respective camps prevail, provided the two markets are roughly equal in size.

In terms of the form of governance, realist theory does not make clear predictions. Recent work by Drezner (2007) suggests that hegemons may look to non-traditional actors to obtain outcomes that they themselves find costly to achieve. Transgovernmental networks, for example, are expected to serve the dominant powers' national interests. But this merely shifts the question to why dominant powers would prefer one form of governance to another. There is no clear ex ante expectation of a shift from extraterritorial application of national laws to transgovernmental cooperation, for example.

Market Friction

Functionalist theories of international cooperation in a liberal tradition stress the underlying collective action problems, externalities, and inefficiencies that generate demand for international regimes (Keohane, 1984, Martin and Simmons, 1998). States supply regimes to reduce transaction costs associated with international interdependence. The states experiencing the greatest costs from market friction under the status quo are seen as most likely to press for and shape cooperation.

The form of governance will reflect the underlying collective action problem. Liberals expect greater centralization and delegation as transaction costs increase. Among the most important functions performed by international regimes are the provision of information and the facilitation of credible commitments among participating states (Abbott and Snidal, 1988). The former often requires the creation of a centralized coordination body, such as the Organization for Economic Cooperation and Development (OECD). But if information provision alone is the goal, no formal independence from participating states is necessary. However, if the institution is also to help states make credible commitments, it must have a measure of independence from its members, such as, for example, the World Trade Organization (WTO).[v]

The theory expects that given high levels of international interdependence, states seek institutional means to share information, promote reciprocal learning, and foster consensus-driven harmonization. In the case of international market regulation, where firms confront disparate national regulations across markets, states with large and diverse export sectors suffer the greatest burden. States should have little incentive to invest in international cooperation where national firms focus primarily on the domestic market.

Liberal functionalists assume that the institutional form chosen performs the required functions at the lowest cost. Network-based transgovernmental cooperation, for

example, would be most likely when there is demand for information provision and coordination but no need to make a mutual commitment credible (Kahler and Lake, 2003). A lack of cooperation suggests that any benefits of reduced transaction costs are outweighed by other costs. If transaction costs are sufficiently high to render pure market coordination inefficient, states might try to apply domestic rules extraterritorially.

Figure 1: Expectations of Existing Theories

	Realism	**Liberalism**
Form of Governance	determined by preferences of dominant power(s)	determined by nature of collective action problem, externalities, and inefficiencies
Agenda Setting	determined by distribution of power, which is reflected in relative market size	determined by relative transaction costs, which is shaped by extent of interdependence

Figure 1 summarizes the expectations of the earlier research streams. Following the domestic institutionalist argument below, we evaluate all three explanations empirically by process tracing the causal claims for the pharmaceuticals- and cosmetics cases.

Regulatory Capacity, Relative Sequencing, and International Market Regulation

Drawing on insights from historical institutionalism, we propose an alternative causal logic that explains evolving patterns of international market regulation through the relative sequential development over time of domestic regulatory capacity in leading markets. Consisting of a broader set of domestic institutions than those traditionally explored in IPE, regulatory capacity is a jurisdiction's ability to define, monitor, and enforce a set of domestic market rules. It encompasses the agencies or regulatory bodies that draw up and/or implement regulations, the expertise of staff working for these institutions, and the

overarching coordination of such institutions within the political economy. Clearly, regulatory capacity varies across sectors, policy areas, and time. A jurisdiction's regulatory institutions may be well-developed in the field of banking regulation, for example, but weak in competition policy. They are shaped by the specific political context in which they are created and adapted, opening the door to unintended consequences in later moments or different contexts (Pierson, 2004; Posner, forthcoming). We first elaborate the concept of regulatory capacity and explain how it bears on international market regulation, and then turn to sequencing.

Regulatory Capacity

Regulatory capacity has several dimensions joined together by institutional complementarities (Bach and Newman 2007, Mattli and Büthe, 2003, Gilardi, 2002). A jurisdiction's regulatory capacity in a given industry and point in time depends on its regulatory expertise, the coherence of regulation, and the extent of the regulator's sanctioning authority. To be effective, regulators need the staff and technical expertise to identify new challenges and to implement countervailing regulatory strategies. Regulatory authority also has to be coherent. Institutional fragmentation and/or poor coordination among regulatory sub-units undermine a jurisdiction's regulatory capacity. Lastly, regulatory capacity depends on the extent of a regulator's statutory sanctioning authority. Sanctioning tools range from public shaming through fines all the way to formal market exclusion. All else equal, regulators that are institutionally empowered to exclude from the domestic market have greater regulatory capacity than those that are not.

The temporal dependence of regulatory capacity does not mean it is static (Streeck and Thelen, 2005). The American progressive era, for example, saw a considerable expansion

of regulatory capacity, especially on the federal level (Skowronek, 1982). Similarly, the rise of the regulatory state in Europe in conjunction with the Single Market project has considerably augmented regulatory capacity in many sectors (Majone 1996). But such changes are generally quite slow (Thelen, 2004). When regulators confront new challenges at T=1, they must usually do so with institutional resources developed at T=0. With respect to international market regulation this means that regulators initially confront the challenges posed by globalization and market integration with regulatory tools developed for domestic settings. Moreover, the time lag means that national regulatory reform at T=0 can have unintended consequences for a jurisdiction's ability to engage in international market regulation at T=1.

International Implications

Regulatory capacity is the mechanism linking market size and power in international market regulation (Bach and Newman 2007, Newman 2008). A sizeable market alone does not confer the power to shape international market rules. To wield international influence, jurisdictions need capable and powerful domestic regulators that can identify new challenges posed by globalization, formulate countervailing strategies, and enforce rules where necessary even against foreign opposition. Jurisdictions with large markets rely on their institutional resources to make demands on foreign jurisdictions. Those, in turn, make domestic adjustments when the perceived costs of resisting are greater than adjustment costs. A critical source of power in international market regulation is thus the ability to unilaterally shift the reversion point for international bargaining. The reversion point describes the set of international market rules that prevail in the absence of a new international agreement (Richards, 1999). Domestic regulators that acquire new

competencies – competencies that enable them to unilaterally change aspects of the international market environment – wield additional power in formal or informal international bargaining.

Regulatory capacity can also be used to persuade other jurisdictions of the potential benefits of adjustment. In addition to merely facilitating the provision of information, network-based cooperation provides leading regulators an opportunity to argue for their vision of sector best practices (Risse, 2000). Expert officials can use their knowledge of an issue area to shape the international agenda and to overcome objections by foreign authorities.

Domestic regulatory capacity develops over time, but it does so unevenly across jurisdictions.[vi] Interjurisdictional unevenness, which is not uncommon, can be dubbed the "Kissinger Effect." As US Secretary of State, Henry Kissinger underscored transatlantic asymmetry resulting from insufficient political integration in the Old World: "Who do I call if I want to call Europe?," he asked succinctly. Similar asymmetries profoundly affect international market regulation. If there is no institutionally-empowered counterpart to negotiate with, regulators in leading markets may have little choice but to apply domestic rules extraterritorially to safeguard the domestic status quo in the face of market globalization. Domestic early adopters thus often have a first-mover advantage when it comes to substantive international market rules, though they may be faced with the difficult task of unilaterally setting and enforcing rules.

The logic of relative sequencing implies that a first-mover advantage may not last forever. The domestic institutional perspective does not preclude change; it merely highlights that such change is historically-conditioned and the result of concrete domestic political processes. Follower jurisdictions may develop their own regulatory capacity, either as a

deliberate response to the first-mover's international assertion of authority or as an unintended consequence of domestic regulatory reform. In either case, the expansion of regulatory capacity in a key follower jurisdiction is a necessary condition for the development of more formal transgovernmental cooperation. International market regulation thus evolves, as transgovernmental cooperation complements or displaces unilateral moves. If both leading markets have insufficient regulatory capacity or are otherwise unwilling to assume an international role, pure market coordination prevails. Figure 2 summarizes the expected effects of the distribution of regulatory capacity on the form of international market regulation.

Figure 2: Domestic Regulatory Capacity and International Market Regulation

		A's Regulatory Capacity: Low	A's Regulatory Capacity: High
B's Regulatory Capacity	Low	Market Coordination	Extraterritorial Push A=>B
	High	Extraterritorial Push B=>A	Transgovernmental Cooperation

The domestic institutional argument leads to the following expectations about international market regulation. The domestic institutional status quo in leading markets just prior to the onset of international interdependence strongly shapes broad contours of international governance in a sector. If regulatory state-type institutions existed, we should expect domestic regulatory agencies to play leading roles in any evolving international framework. Pronounced asymmetry of domestic regulatory capacity – the "Kissinger Effect" – skews international governance towards unilateral mechanisms and hinders sustained international cooperation. Institutional reform over time in follower states, however, can

make the international distribution of regulatory capacity less lopsided, thus enabling transgovernmental cooperation.

Relative sequencing over time also affects who gets to shape the initial policy agenda. A regulatory first-mover with the ability to unilaterally shift the reversion point can obtain critical leverage over the evolving regime. While existing arguments focusing on market size predict opposing camps and rival rules when markets have equal size, we argue that discrepancies in regulatory capacity can decidedly tilt the balance toward one camp. This is because regulatory capacity can impose non-adjustment costs even on comparably large markets. Regulatory hegemony may thus result despite preference conflicts among dominant powers. Lastly, we would expect emerging markets with underdeveloped regulatory structures to be underrepresented in international debates, even as their market power grows.

Next, we develop expectations of the three arguments for international market regulation in pharmaceuticals and cosmetics, and then compare them to observable dynamics using process tracing.

International Market Regulation of Pharmaceuticals

Market Size

With respect to the realist focus on market size, the data for pharmaceuticals are unambiguous. The US is by far the world's largest pharmaceuticals market and US companies dominate the sector. This was not always the case, however. In 1990, the European Union accounted for 37.8 percent of the roughly €136 billion global market for pharmaceuticals. The US was in second place with 31.1 percent. During the 1990s, with the industry growing at an average annual rate of 4.6 percent in Europe, US annual growth was

more than double at 9.3 percent. By 2003, with a world market worth €412 billion, the US represented a whopping 49.1 percent compared to only 27.8 percent for the post-enlargement EU.[vii]

A similar trend is evident in data on the location of research expenditures, a key indicator as much pharmaceutical regulation focuses precisely on procedures for drug research, development, and testing. In 1990, the pharmaceutical industry spent about €8 billion on research and development in Europe as compared to only €5.3 in the US. A decade later, the picture was completely reversed with the industry investing €26.4 billion in research and development in the US and a mere €18 billion in Europe. Over the past decade, US firms have also consolidated their international leadership. In 1997, US firms accounted for 50.2 percent of global sales by the ten largest pharmaceutical firms, compared to 28.9 percent for European firms. These figures had risen to 51.4 percent for US firms and 32.7 percent for European firms by 2002.

Given global market trends, realists would expect a steady increase in US influence over international market rules. Similarly, the institutional make-up of international pharmaceutical governance should increasingly reflect US preferences as the US has clearly become the largest and most important market.

Market Friction

With respect to who is most affected by international interdependence, the key variable for liberal functionalists, the data clearly show that the global pharmaceutical market is highly concentrated in three regions. The ten largest importers of pharmaceuticals are the US, Japan, and eight European countries. These ten markets' overall share of imports has steadily increased, from 50.9 percent in 1980 to 61.8 percent by 1990 and 63.3 percent in

1999. Similarly, the US and nine European countries are the world's ten largest pharmaceutical exporters, accounting for 76.4 percent of global pharmaceutical exports in 1980, 73.7 percent in 1990, and 79.8 percent in 1999. Much pharmaceutical trade consequently occurs among the handful of leading markets. During this period, overall trade in pharmaceuticals has exploded, growing from a mere $5 billion in 1980 to almost $120 billion by 1999 in constant dollars.[viii] The relative economic stakes have also markedly increased with pharmaceutical trade more than doubling for the US, Germany, France, the UK, and Japan from 0.2 percent of GDP in 1980 to 0.48 percent by 1999.

In this globalizing market, the friction resulting from conflicting national regulations and duplicate efforts is considerable. Pharmaceutical companies must separately file for market approval in each market as national regulators reserve the right to act as local gatekeepers. Moreover, when regulators have different requirements, the information and supporting documentation required for market approval also varies, creating wasteful complexity and duplication. Applications can run in the thousands of pages and the approval process can cost several hundred million dollars if costs of clinical trials are included. The need to file separately based on inconsistent requirements slows down the overall time to market, depriving patients of needed medicines and pharmaceutical firms of vast potential revenues as valuable patent time ticks away.

With clearly growing international interdependence and considerable potential gains from harmonization, liberal functionalists would expect steadily expanding international cooperation. Neither mutual recognition nor the coordination of harmonized standards requires extensive delegation of powers to international institutions. The main role of institutions instead would be the gathering of information and facilitation of best practice development and diffusion. The US, EU, and Japan are, in this order, the three jurisdictions

with the greatest exposure to international markets and consequently with the most to gain from reducing market friction.

Regulatory Capacity

With respect to domestic regulatory institutions, we find that pharmaceutical market regulation has proceeded along very different paths in the US and Europe. Whereas US regulators confronted the period of market globalization with considerable regulatory capacity – manifested by significant expertise, regulatory coherence, and sweeping powers – Europe developed similar capacity much later.

Modern pharmaceutical regulation began when the 1906 Pure Food and Drug Act in the US established drug safety as a critical public policy goal. During the 19th century, the manufacture and marketing of medicines had been largely a local, artisan affair that was entirely unregulated. Scientific breakthroughs in medicine, the industrial chemicals revolution, and the prospect of mass production and -distribution considerably increased the stakes. The 1906 Act gave the US government a broad mandate to protect consumers by assessing drug safety. In 1938, during the height of the New Deal, Congress delegated authority over the industry to the Food and Drug Administration (FDA), an independent regulatory agency. The agency quickly and consciously built in-house technical expertise. To carry out its mandate, it got involved in many aspects of pharmaceutical research, -development, and -marketing, including oversight of laboratory conditions, testing methods, human trial protocols, and post-market safety. But its most fundamental task and principal source of power is its gatekeeper function. New drugs need FDA approval before they can be marketed, thus granting the agency sweeping market exclusion power. With a single agency in charge counting on expert staff and sweeping market exclusion power, the FDA

epitomizes extensive regulatory capacity (Wiktorowicz, 2003, Kulynych, 1999). The FDA's fundamental purpose is the protection of domestic consumers; it was not created with an eye towards global governance. Yet in building regulatory state-type institutions in the 1930s, US policymakers inadvertently laid the foundation for far-reaching US regulatory capacity when globalization raised the stakes for international pharmaceutical market regulation decades later.

In contrast to the early, relatively quick development of considerable regulatory capacity in the US, most industrial countries lacked a formal regulatory regime well into the 1960s. Britain and Germany, in keeping with their domestic regulatory traditions, relied on voluntary safety reporting systems run by industry. Companies and trade associations played the primary role in regulating product development and market entry, resulting in informal, decentralized governance structures.

A series of public health scandals put these informal systems under intense pressure. The thalidomide crisis of the early 1960s, in which a drug given primarily to pregnant women produced extreme birth defects, demonstrated the failure of informal drug approval regimes. The drug had been developed by a German company and was marketed in more than 40 countries without testing for effects on the health of the fetus. In the US, however, the FDA had rejected market approval citing concern for the safety of fetuses. The fallout from the scandal prompted both the UK and Germany to move toward the US model of formal governmental oversight by professional regulators, though it took decades to fully implement legislative reforms.

At the same time European countries accelerated the development of their own regulatory state-type institutions. The European Community entered the debate in 1965 in the immediate aftermath of the thalidomide crisis, adopting a directive requiring independent

regulation of pharmaceuticals. Implementation was left to member states, however, prompting the development of nationally-distinct regulatory systems. What followed was a thirty-year struggle to progressively harmonize and integrate European pharmaceutical regulation. In 1975, the European Commission introduced a procedure enabling drug companies to submit regulatory approval in one member state to authorities in other member states. This internal initiative responding to domestic regulatory failure, while long stalled and delayed by member states, ended up having far-reaching consequences for EU capacity to coordinate the European market.

The transnationalization of regulation took another important step in 1983 when the Commission created a standing committee of national regulators, the Committee for Proprietary Medicinal Products (CPMP), planting the seeds for an eventual pan-European regulator. Still, the European market remained fragmented among member state lines. The Commission identified lack of regulatory harmonization as a principal obstacle to greater market integration and pushed for even greater centralization. A 1993 directive transferred authority for the approval of innovative drugs to the CPMP, required national regulators to justify any deviation from a prior decision by another member state regulator, and created the European Agency for the Evaluation of Medical Products (EMEA). EMEA centralized regulatory expertise at the EU-level and became the institutional anchor for the CPMP network of national regulators (Feick, 2002).

By the early 1990s, the structure of European pharmaceutical regulation had undergone two fundamental transformations. First, informal industry-led governance had been replaced by formal regulatory state-type institutions at the national level. Secondly, the European Commission had begun to coordinate these consolidated regulatory institutions at the European level and increasingly centralized regulatory authority. The result was a marked

increase in European regulatory capacity over pharmaceuticals (Vogel, 1998, Kidd, 1996-1997, Braithwaite and Drahos, 2000). The professionalization and cross-national coordination of regulation greatly expanded regulatory expertise. Furthermore, Commission coordination and centralization of authority via CPMP and EMEA boosted regulatory coherence, giving Europe a single voice in international debates. Finally, the new institutions controlled access to the now-integrating European pharmaceutical market. A series of internal reforms, necessitated by the need to build the Single Market, thus significantly augmented Europe's regulatory capacity.

Table 3: Expectations for International Market Regulation of Pharmaceuticals

		1980	2008	Expected Dynamic
Market Size	US	Med	High	Agenda control shifts from Europe to the US; US increasingly shapes policy and form of governance according to its preferences
	EU	High	Med	
Exposure to Market Friction	US	Low	High	With growing stakes, cooperation becomes more likely; focus is a reduction in transactions costs, an interest that both US and EU share
	EU	Low	High	
Regulatory Capacity	US	High	High	Initial US dominance gives way to a transatlantic balance; growth of EU regulatory capacity enables shift from US unilateralism to transgovernmental cooperation
	EU	Low	High	

Table 3 summarizes the contrasting expectations of the three distinct approaches based on the underlying variables in question. The following section traces the actual evolution of international market regulation in the industry and assesses the three arguments.

Tracing International Pharmaceuticals Regulation

Into the 1960s, there was very little international market regulation to speak of. Firms seeking access to a foreign market had to comply with existing requirements in that market, causing occasional regulatory spillovers. The thalidomide crisis alerted the FDA to the risk that weak foreign regulation posed to US consumers and triggered a more aggressive and deliberate extraterritorial application of US rules. According to Braithwaite and Drahos (2000, 375), "The US has been the most important actor in the globalization of drug regulation." The FDA used its control over market access to extend its de-facto reach far beyond its nominal jurisdiction, for instance, by conducting detailed inspections of overseas research labs and production facilities. Frequently, the international expansion of FDA influence was the by-product of domestic regulatory change. "The US as hegemon would introduce a new kind of regulation following domestic regulatory crises, such as Good Manufacturing Practices (GMP) in the early 1970s," Braithwaite and Drahos (2000, 375) continue, and the FDA would subsequently work with the World Health Organization (WHO) to "globalize these through mechanisms such as certification of GMP implementation (…)." To fulfill its mandate of ensuring domestic drug safety amidst a gradually globalizing industry, the FDA began to slowly become a global player, drawing on its unrivalled reputation and authority to push US rules and standards internationally (Wiktorowicz, 2003).

Three important changes transformed international pharmaceutical market regulation starting in the 1980s. First, while safety remained a key concern, regulatory efficiency emerged as an additional public policy focus. A wave of industry consolidation created a group of globally-operating pharmaceutical giants who pushed for international harmonization. In parallel, industry globalization fostered competition between jurisdictions

with respect to the quality, speed, and cost of approval processes (Vogel, 1998). How to meet demands for cross-national harmonization, greater speed, and lower cost while avoiding a race to the bottom that could jeopardize safety has become the principal challenge.

A second major change has been a striking shift in the form of governance toward transgovernmental cooperation. Starting in the 1990s, regulators began to forge bilateral partnerships codified in Memorandums of Understanding (MoU) to promote technical information sharing and coordination (Kelly and Bachorik, 2005). In parallel, regulators from the US, Europe, and Japan launched the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to standardize best practices. Working closely with industry representatives from the three regions, regulators have launched efforts in three areas: quality, safety, and efficacy.[ix] According to one observer (Lee 2005, 179-80),

> The accomplishments of the ICH have been impressive. Nearly sixty ICH Topics have become official Guidelines and reached the implementation stage as of 2003, meaning a harmonized text has been approved by all parties, including all three regulatory agencies. Many of these Guidelines pertain to uncontroversial matters in which much international agreement already existed. However, some represent meaningful progress in achieving harmonization.

ICH harmonization is based on a five-step process in which collaboration in joint working groups alternates with domestic consultation by each of the three regulators. Once ICH's governing bodies believe that consensus on an issue has been reached in the working group, each regulator gathers comments on the proposal in its domestic market. Results are again shared in the transgovernmental forum. Major domestic objections trigger the working group to make modifications and the consultation cycle begins anew. Conversely, if there are no important objections in any of the three major markets, ICH certifies the consensus as a

guideline and all three regulators enact the policy. In contrast to conventional international statecraft, no formal domestic ratification is necessary.

ICH's most important achievement is its adoption in 2000 of a Common Technical Document (CTD) that enables pharmaceutical firms to file for approval in the world's three largest markets with a standardized document. More recently, an electronic version, called eCTD, has further simplified the process. Industry credits the initiative with saving many millions of dollars and precious time. Many of the guidelines agreed to by the ICH, including the CTD, have been adopted by non-participant countries that see a benefit in joining a standard used in the dominant markets (Shani and Yahalom, 2008). As scholars of the process conclude, ICH is "a network of pharmaceutical industry and government scientists, who have, in effect, become the international regulatory power in setting safety standards for new medical drugs" (Abraham and Reed, 2001).

While cooperation has yielded impressive results, the achievements should be kept in perspective. Most efforts have aimed at harmonizing either regulatory processes or standards for the manufacturing of drugs; there has been only limited harmonization concerning market approval for new drugs. Pharmaceutical companies still need to file independently for market approval in the major markets, so transactions costs remain high.

EU and US policymakers experimented with a precursor to joint market approval in 1997 when they signed a Mutual Recognition Agreement (MRA) enabling regulators to certify some of their counterparts' evaluation procedures and findings. The idea was to allow European regulators to certify on a case-by-case basis that European exporters comply with US quality and safety standards and vice versa, eliminating the need for overseas inspections and dual filing. However, the FDA has largely failed to implement the accord and overseas inspections continue. As a consequence, European regulators acting on behalf of EMEA

have expanded their inspections of US manufacturers exporting to Europe and, in the words of one executive, EMEA audits "tend to be much harder than FDA" domestic audits.[x] Newly institutionally-empowered European regulators are thus leveraging access to the European market to exert influence internationally, taking a page out of America's playbook. The result is not full-fledged harmonization of market approval regulation driven by technical rationality but rather a growing tug-of-war between the still powerful, yet no longer omnipotent FDA, and its increasingly powerful European counterpart.

The growth of European regulatory capacity in pharmaceuticals over the last three decades has ended the previous lopsided distribution, enabling some limited but important transgovernmental cooperation. Compared to the past, European regulators are technically more capable, have greater authority and, perhaps most importantly, owing to intra-European coordination they can leverage access to the entire EU market and not just individual national markets (Feick, 2002). Europe's newfound ability to impose costs on US firms has effectively shifted the reversion point for international bargaining. In 2003, for example, the EU made the use of the CTD compulsory for any filing in Europe, whether by a European or foreign firm, and thus guaranteed the new standard a huge market. As EMEA has begun to impose its own rules extraterritorially, the FDA has begun to perceive cooperation as more appealing. According to observers, "the FDA had to join the [ICH] process to defend its position" in the face of Europe's growing international clout (Braithwaite and Drahos 2000, 372). As a result, there has even been some limited progress in the field of joint market approval: signaling an important US shift, the two sides agreed in 2007 to a joint approval process for orphan drugs, which target rare diseases with small markets. Consistent with liberal expectations, no powers have been delegated to international institutions as cooperation has focused on information sharing and voluntary

best practice development. But the shift to cooperation was not the result of an underlying change in functional demand, but rather made possible by the emergence of European regulators as capable and potent partners on which to anchor cooperation.

The third major change in international market regulation of pharmaceuticals concerns agenda setting. Until the 1990s, the US was the sector's undisputed regulatory hegemon. "The FDA has long provided the public health gold standard for the world," said FDA Commissioner Jane E. Henney in 2001.[xi] According to Braithwaite and Drahos (2000, 361), "In the 1970s, manufacturers were (…) required in Western nations, then progressively in developing countries, to comply with Good Manufacturing Practices regulations, written by the US Food and Drug Administration then promulgated by the World Health Organization." Since at least the 1990s, however, there has been a clear shift toward a more balanced situation (Molzon, 2005). While the FDA continues to exert considerable influence over the international regulatory agenda, the European Commission and the EMEA have become powerful voices. As Braithwaite and Drahos (2000, 375) explain, "US leadership was pre-eminent from the Pure Food and Drugs Act to the election of President Regan in 1981. Today the EU is more hegemonic, or perhaps there is a tregemony of the EU, US and Japan." This observation runs exactly counter to realist expectations. Data on market size, market share, and R&D patterns uniformly predict growing, not diminishing US power. Instead, US regulators have increasingly had to make important concessions. Consider just four examples:

- after long resisting, the FDA has begun to accept, in some cases, data of clinical trials conducted on non-US subjects and under the supervision of foreign regulators;[xii]

- on issues such as the reporting of adverse drug reactions, carcinogenicity testing, and the duration of toxicity testing, the FDA has agreed to ICH compromises that have lowered existing standards (Abraham, 2004);
- with the compromise on joint market approval for orphan drugs, the FDA has for the first time opened the door to yielding market access control to a foreign entity; and
- after decades of refusal, the FDA has responded to domestic pressure and has adopted the European model of outsourcing part of the review process to private firms, rather than just relying on in-house experts.

While the FDA remains a leading global player, the one-way street of regulatory export of the previous era is no more (Kidd, 1996-1997, Kulynych, 1999).

While the realist focus on market size fails to predict observable patterns, they match those predicted by the domestic institutional account stressing the sequential development over time of regulatory capacity. US international dominance into the 1990s stemmed from unrivalled US regulatory capacity in the industry. During this period, the simplest response to the challenge of dissimilar national regulation amidst market integration was the extraterritorial application of US law (Braithwaite and Drahos (2000, 376). Yet market integration exposed US firms to foreign approval systems, many of which had improved considerably since the 1960s while maintaining quick approval times. The difference between the systems became a political issue in the 1980s when US drug makers decried a "drug lag" which they claimed challenged their international competitiveness. The result was growing pressure on the FDA to abandon unilateralism and to start looking abroad for new ideas. At the same time, European regulatory capacity had increased considerably as a result of domestic institutional reforms and pan-European coordination and centralization of

regulatory authority. These domestic reforms had a largely unanticipated effect on international regulatory dynamics: "Once European regulation unified, the US was no longer the biggest player," argue Braithwaite and Drahos (2000, 376), "smaller countries followed Europe more than the US." The picture captured by the "Kissinger Effect" thus gave way to a more symmetrical distribution of regulatory capacity with Europe increasingly able to give the US a taste of its own medicine. The stage was thus set for an institutional shift in international market regulation, away from pure unilateralism and towards regulatory cooperation.

International Market Regulation of Cosmetics

The motivation and public policy justification for cosmetics regulation closely resemble the case of pharmaceuticals, focusing on product safety and consumer protection. However, ethical issues, especially efforts to reduce or eliminate animal testing, increasingly matter as well. While not as stringent as pharmaceutical regulation, rules for the cosmetics sector nevertheless have considerable distributional implications.

Market Size

Applying a realist lens reveals relative size parity between the largest two markets. Western Europe has the largest single regional market for cosmetics with 29 percent of the global $270 billion market in 2006. North America, however, was closely behind with 21 percent. Both regions have seen their share of the world market fall since the 1990s from 31 percent and 25 percent respectively. During this entire time, the US has had the largest single national market.[xiii]

Turning closer attention to dynamic market changes, the data point to a role that emerging markets might play in international cosmetics regulation. Recent sector growth is centered in Latin America and Asia, not Europe or the US where annual industry growth rates were only 3 percent and 2 percent respectively between 2001 and 2006. While the US, Japan, France, Germany, the United Kingdom, and Italy represented the six largest national markets in 2003, Brazil has surpassed France as the third largest and China has moved passed Italy to become the seventh largest market in 2006.[xiv] Realists would expect Europe and the US to have historically dominated regulatory dynamics in the industry. In case their substantive preferences were aligned, the two should be expected to have set global standards. In case of substantive divergence, given the rough parity in size, the most likely scenario are rival standards between regional camps. Reflecting recent market trends, emerging powers, especially Brazil and China, should increasingly challenge transatlantic leadership in this domain.

Market Frictions

With respect to international interdependence, we find that the EU and US have long been net exporters of cosmetics and are each other's largest export market (Global Insight, 2007). In terms of foreign sales and asset dispersion, European and US firms are similarly integrated into world markets. In 2003, over 20 percent of sales for the largest European and American cosmetics firms happened in each other's markets and a similar percentage of assets were located in the respective other's jurisdiction. These firms recorded roughly 17 percent of their sales in Japan, bringing foreign sales to roughly 40 percent of the total. The Japanese sector is much less integrated into the global economy. Japanese companies control some 70 percent of their home market. In 2003, the largest Japanese

firms were much more dependent on their domestic market with only 8 percent of sales coming from Europe and the US combined and only 13 percent of assets located in those other two regions (Oh and Rugman, 2006).

Given these economic patterns of interdependence with the US and EU highly integrated and Japan relatively independent, liberals would expect the former two to lead international harmonization efforts. Japan should be less engaged. As in the case of pharmaceuticals, liberals would expect rather informal institutions at the international level. However, given the relatively low level of interdependence overall, there is a real chance of no institutionalized cooperation at all and that the industry features only ad-hoc coordination.

Regulatory Capacity

Examining regulatory capacity, we find that transatlantic cosmetics markets exhibit a significant "Kissinger Effect", though in the opposite direction from the pharmaceuticals case: US regulatory capacity is weak owing to fragmentation and insufficient statutory authority; Europe, by contrast, boasts powerful regulatory state institutions and strong coordination at the EU-level. The origins of these disparities date back multiple decades and regulatory institutions in the two largest cosmetics markets have developed along very different trajectories. Owing to domestic political maneuvering, the US Food, Drugs and Cosmetics Act of 1938 required that cosmetics be safe but failed – with the exception of colorants – to provide the FDA with pre-market approval power. The consequence of this purely domestic political decision was that US regulatory capacity in cosmetics paled in comparison to the parallel case of pharmaceuticals. It was not until 1976 that the Cosmetic, Toiletry & Fragrance Association organized the Cosmetics Ingredient Review as a voluntary,

self-regulatory scheme. To this day, the FDA has in practice no formal authority to control market access and has comparatively little expertise in cosmetics, relying instead on industry-led ingredient review. The US market, in short, has a weak regulatory structure with limited government monitoring and enforcement (Termini and Tressler, 2008).

The EU, by contrast, adopted formal regulation with clear lists of accepted, restricted, and prohibited ingredients with the passage of the Cosmetics Directive in 1976. An early initiative of the Internal Market project, the directive aimed to guarantee product safety, while facilitating the free flow of goods within the European market. Over the following three decades, the EU has built its regulatory expertise and control over market access. In terms of expertise, the EU created the European Centre for the Validation of Alternative Methods (ECVAM) in 1991 to study alternatives to animal testing and approve procedures for EU use. In 1997, the EU created the Scientific Committee on Cosmetic Products, renamed the Scientific Committee on Consumer Products (SCCP) in 2004. Comprised of experts from the member states, the committee analyzes the safety of ingredients and makes recommendations to the Commission about which ingredients should be placed on a negative list that effectively bans products containing them from the European market. This network of scientific experts has greatly enhanced the level of expertise available to the Commission as it reviews individual products, just as ECVAM provides the Commission with critical technical information on testing (Risk and Policy Analysts 2004).

In terms of market access, successive reforms have expanded EU control. Starting with the 6th Amendment to the Cosmetics Directive in 1993, the EU prohibited the marketing of cosmetics that contained ingredients that had been tested on animals. In 2003, the EU adopted the 7th Amendment to the Directive, which further enhanced European

regulatory capacity by extending the ban to include not only ingredients but also finished products that have been tested on animals. The Amendment set 2009 as the final deadline for implementation and empowered ECVAM to monitor and enforce the provisions under Commission oversight and coordination. The 7th Amendment also enhanced the consumer protection aspects of the regime. Most important, the reform significantly expanded the list of ingredients that were considered prohibited or restricted. Substances containing category 1 and 2 carcinogens were banned. As a result, the number of prohibited ingredients has doubled to nearly one thousand and the scope of ingredients analyzed by the SCCP has similarly grown (Risk and Policy Analysis 2004).

In sum, the cosmetics industry shows a lopsided distribution of regulatory capacity. Whereas Europe's already considerable expertise and authority in this domain has further increased since the late 1990s as part of the Single Market process, owing to domestic political decisions in the first half of the 20th century the US has little formal regulatory capacity. The domestic institutionalist account for international market regulation thus expects unrivalled European leadership and limited cooperation. Combining a large and attractive market with sweeping regulatory capacity, the EU will deliberately apply European rules extraterritorially and actively promote their export. Table 4 compares these expectations with those from the two rival approaches.

Table 4: Expectations for International Market Regulation of Cosmetics

		1980		2008	Expected Dynamic
Market Size	US	High		Med	Initially either joint US-EU dominance or transatlantic stalemate, depending on interest configuration; over time, agenda power shifts away from US-EU and toward emerging markets
	EU	High		Med	
Exposure to Market Friction	US	Low		Med	Initially a low-salience issue that is unlikely to trigger cooperation; cooperation becomes more likely over time, with US and EU equally likely to lead international efforts
	EU	Low		Med	
Regulatory Capacity	US	Low		Low	EU issue dominance that strengthens over time; considerable extraterritorial application of EU rules and limited or no cooperation
	EU	Med		High	

Tracing International Cosmetics Regulation

The evolution of international cosmetics regulation mirrors the parallel case of pharmaceuticals. Domestic regulation, often with extraterritorial reach, constitutes a first important pillar of governance. The EU in particular has enacted binding regulations for the sector that strictly regulate which ingredients are acceptable, restricted, or outright prohibited. In addition to ingredient safety, the EU has passed legislation banning the importation of cosmetics products tested on animals. In both cases, product- and process regulations have had international spillover effects for non-European cosmetics firms in global markets.

Mirroring pharmaceuticals, transgovernmental cooperation between domestic regulatory agencies has emerged alongside unilateralism. Regulators from four leading markets – the US, Japan, Canada, and the EU – engage in information sharing under the Cosmetics Harmonization and International Cooperation (CHIC) framework. Meetings have taken place three times since 1999. The group initially focused on the exchange of

information about their respective regulatory approaches, safety concerns, and alternative testing methods. Initiatives currently under discussion include the establishment of an international rapid alert system to enhance consumer protection. This process produced minimal results and was considered defunct until the original CHIC members reinvigorated their efforts in 2007 and 2008 with the start of the International Cooperation on Cosmetics Regulation (ICCR). At the same time, the European Commission and the FDA have agreed to a bilateral exchange of letters establishing procedures for information sharing on draft legislation, market defects, scientific opinions, and inspection reports. When compared to transgovernmental cooperation in pharmaceuticals, however, regulatory cooperation in the cosmetics field is much more limited.

Importantly, transgovernmental cooperation has been most successful in the one area where US policymakers managed to augment US regulatory capacity. In response to European efforts on alternative testing, the US established an agency to oversee the scientific certification of such techniques, the US Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (Donnellan, 2007). As the deadline for the first alternative-testing ban approached, regulators from the EU, US, Japan, and Canada intended to diffuse regulatory tensions. The absence from newly reinvigorated transgovernmental cooperation under the ICCR-framework of China and Brazil, both of which have large markets but weak regulatory institutions in this field, further strengthens the claim about the importance of domestic regulatory capacity. Additionally, the breakdown of previous, more ambitious transgovernmental cooperation under the CHIC framework supports the relative sequencing argument as the FDA has insufficient regulatory capacity over cosmetics.[xv] In sum, while there is little institutionalized cooperation to speak of, this is not the result of insignificant benefits from harmonization as liberal functionalists would

argue but rather because the lopsided distribution of regulatory capacity among the major markets impedes cooperation.

Despite some similarities in the institutional evolution of governance, the two sectors sharply diverge when it comes to agenda setting power. In cosmetics, Europe is the undisputed regulatory hegemon. Mercosur countries including Argentina, Brazil, Paraguay, and Uruguay have all adopted legislation in the late 1990s that includes the European definition of cosmetics and that empowers regulatory agencies to oversee positive and negative lists. The ten members of ASEAN adopted legislation in 2003 that essentially copies European rules and incorporates the positive and negative ingredient lists maintained by the European Commission into binding local regulation.[xvi] Japan reformed its legislation in 2001 and moved towards the European model. Similarly, the state of California enacted tough legislation in 2006 inspired by European rules. Lastly, in 2007, China formally banned many substances on the European negative list. Not only has the US never been a match for the EU in this domain despite market size parity, observable patterns further defy realist expectations as Europe's worldwide influence has grown since the 1990s despite losing global market share to emerging economies.

The development of regulatory capacity has been central to the extraterritorial export of European rules. In order to facilitate uptake, the EU has conducted capacity building exercises in other countries. In the case of ASEAN, the European Commission even sent a group of technical experts to the region to help in their development of cosmetics directives. Indeed, the ASEAN directive reflects the intense EU involvement. It incorporates the substantive list of banned substances in Europe and creates an ASEAN Cosmetics Scientific Body, which has as one of its mandates the active review of developments in the EU. Since the directive's 2003 adoption, experts from Brunei, Cambodia, Indonesia, Lao, Malaysia,

Philippines, Singapore, Thailand, and Vietnam have traveled to Europe for Commission-sponsored trainings. Minutes of the ASEAN Cosmetics Scientific Body routinely reference input from the European Commission and deference to its expertise.[xvii] The Commission has conducted similar capacity building exercises in Latin America, including meetings in Venezuela and Chile to promote its ingredient list system.

In contrast to some of the other major non-EU markets, the US has so far resisted European convergence pressure at the federal level. However, EU regulations have nevertheless affected US cosmetics as compliance with EU regulations is a prerequisite for entering the lucrative EU markets as well as a growing number of markets in Latin America and Asia. Many US firms have therefore voluntarily adopted EU standards throughout their global operations (Carvajal, 2007). Moreover, in a few cases where cosmetics firms refused to remove ingredients in products for the US market even though these had been banned in Europe, US consumer organizations mobilized and eventually forced product changes for the US market as well.[xviii] The EU has thus extended its de-facto regulatory reach around the world, including to the US.

Conclusion

Regulatory institutions in the US and Europe have significantly shaped global markets for pharmaceuticals and cosmetics, affecting the everyday lives of billions. This has occurred largely outside the purview of treaty-based international organizations or regimes; instead, global governance has emanated from extraterritorial extensions of national law and growing transgovernmental coordination. Dominant IPE theories stressing market size and market friction struggle to explain both the form of governance and shifting agenda power within it. This paper offers an alternative account based on the relative sequential

development over time of domestic regulatory capacity in leading markets. The empirical evidence obtained from two industry case studies offers preliminary support for our domestic institutional argument and opens up a new research perspective for those interested in international market regulation.

Having said that, the domestic institutional approach is likely to complement rather than to replace existing theories. The evidence suggests that both realist and liberal functionalist perspectives have merit. Realism correctly focuses attention on the critical role of the largest markets in the US and Europe. Similarly, as liberals would expect, reducing transactions costs through harmonization has motivated cooperation, especially in pharmaceuticals. But both accounts leave important aspects of international market regulation unexplained; filling these gaps requires taking the analysis to the domestic institutional level.

The identification of domestic regulators and regulatory institutions as key drivers of evolving patterns of international market regulation has several important implications. First, the findings speak to the importance of internal regulatory developments for global governance. Domestic reforms can boost a jurisdiction's standing in international debates or diminish it. Since domestic reforms are usually driven by national political agendas, they can have unintended consequences for international market regulation. While transatlantic dominance of global economic governance is usually attributed to the combined size of America's and Europe's economies, our argument suggests that size is not everything. The US may be an economic giant in cosmetics, for example, but it has been a dwarf when it comes to shaping international cosmetics rules. Europe's steadily growing clout in international pharmaceutical regulation, finally, shows that regulatory capacity can be built

over time and how domestic reforms, such as regulatory harmonization as part of the Single Market initiative, can have significant unanticipated international effects.

Secondly, this study adds to a growing literature about the international role of unelected domestic bureaucrats in global governance (Slaughter, 2004; Börzel 1998). Interestingly, the transgovernmental initiatives examined show how global rules can strengthen domestic regulators in participating countries even though cooperation may, at times, lower standards. For advocates of consumer safety, transgovernmental efforts therefore present a mixed bag. In terms of third countries, however, these initiatives universally raised the regulatory bar. Clearly, leading regulators in Europe and the US shape international agendas according to their own preferences and their mandates do not require them to take concerns of foreign entities into consideration, raising questions of accountability and legitimacy (Singer, 2007). That the imposition of ICH guidelines creates a burden for producers in developing countries is not a key concern to FDA and EMEA regulators, for instance.

Finally, the findings lend powerful support to the argument that a broad set of domestic public policy institutions are central to understanding dynamics of international market regulation. Historical institutionalists have long argued that countries differ in their regulatory capacities, that such capacities vary internally across sectors and time in part due to the unintended consequences of earlier reforms, and that these difference can help explain cross-national policy patterns. But so far this insight has not been applied systematically to international politics. In contrast to debates about "strong" and "weak" states or legislative veto points, this study examines the relative distribution of institutional resources and connects the insights with more systemic conceptualizations of power. By borrowing another historical institutionalist concept – the notion of sequencing – we can get

considerable traction on the empirical record in the cases of pharmaceuticals and cosmetics. Future research should dive deeper into the mechanisms at play, examine cases where a larger number of countries are influential, and theoretically integrate preference formation and bargaining strength. What is clear already though is that historical institutionalism offers a rich analytic toolbox that can fuel new scholarship on economic globalization and global governance for years to come.

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Notes

[i] Many issues shape international markets for pharmaceuticals and cosmetics. This paper focuses on the fundamental decision of whether to allow a product to enter the consumer market and the safety standards that producers must follow during production.

[ii] This argument draws on historical institutional work such as Zysman, 1994 and Thelen, 2004.

[iii] Jurisdictions can consciously build-up regulatory capacity, as happened during the period of telecommunications liberalization, but such build-up does not happen overnight. See Vogel, 1996 and Gilardi, 2002.

[iv] The paper focuses on structural power embodied in regulatory capacity and not the underlying preferences of the lead regulators. For an examination of preferences see Singer, 2007.

[v] A growing rationalist literature on the design of international institutions considers these questions. See Koremenos, Lipson & Snidal, 2001.

[vi] This transposes sequencing arguments developed in the comparative setting to international issues. See (Pierson, 2004).

[vii] IMS Health, 2004. IMS World Review. Norwalk, CT.

[viii] *The World Health Situation*. Geneva: World Health Organization. Chapter 3.

[ix] See www.ich.org.

[x] See "EMEA inspections growing, get tougher than FDA audits, Wyeth exec says," *Warning Letter Bulletin*, 12 July 2004.

[xi] See Henney, 2001.

[xii] International Accord on Drug Testing Standards Will Delete LD50 Animal Testing Requirements, F-D-C REP. ("The Blue Sheet"), Nov. 20, 1991, at 9.

[xiii] Data are taken from presentations made in April 2004 and April 2007 by Euromonitor.

[xiv] Data are taken from presentations made in April 2004 and April 2007 by Euromonitor.

[xv] Author interview with an industry spokesperson. Brussels, 2007.

[xvi] See Shefali Srinivas, "Tougher Regulations for Cosmetics Next Year." *Straits Times,* November 22, 2007.

[xvii] See the ASEAN Cosmetics Association at http://www.aseancosmetics.org/default.

[xviii] See Laurel Naversen Geraghty, "Should You Worry About the Chemicals in Your Makeup?," *The New York Time*, July 7, 2005.