

Robert Schuman Centre for Advanced Studies

Managing U.S-EU Trade Relations through
Mutual Recognition and Safe Harbor Agreements:
"New" and "Global" Approaches to
Transatlantic Economic Governance?

Gregory Shaffer

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European University Institute
Badia Fiesolana
I – 50016 San Domenico (FI)
Italy

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BP Chair in Transatlantic Relations

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For further information:
BP Chair in Transatlantic Relations
Robert Schuman Center
European University Institute
Via dei Roccettini, 9
I-50016 San Domenico di Fiesole (FI)
Italy
E-mail: atlantic@iue.it
<http://www.iue.it/RSC/BP/>

ABSTRACT

A central goal in governing the interface of the economies of the United States and European Community (EC) is to reconcile the objectives of protective social regulation, on the one hand, and free competition facilitated through open trade policies, on the other. These policies can be both complementary and conflicted. This paper examines how these issues have been addressed bilaterally in a number of economic sectors through mutual recognition agreements and a hybrid form, the safe harbor principles on data privacy protection. The paper provides an overview and analysis of the 1997 Mutual Recognition Agreement and its six sectoral annexes, and the 2000 agreement on Safe Harbor Principles (for data privacy protection). The paper assesses what spurred these agreements, which actors participated in their negotiation, what constrains their implementation (in terms of both political and market forces), and, ultimately, what are the prospects and limits for their adoption in other areas. Although neither of these agreements directly prescribe harmonization of U.S. and EC laws or regulatory approaches, they have led to some de facto harmonization by regulatory authorities and firms. The paper concludes that, overall, transatlantic institutional adaptation has been slow (and often creeping), but where it has occurred, it has been rather unidirectional, and will likely continue to be so. Simply stated, the United States has made most of the changes, whether through adoption of international standards that mirror EC ones, through delegation of testing and certification responsibilities to private laboratories reflecting the EC's "global approach," or through coordination and oversight of these laboratories under a new U.S. national program analogous to those operating in the EC for over a decade.

I. INTRODUCTION¹

By the late 1990s, the value of trade between the United States and European Community (EC)¹ combined with sales of U.S. and EC affiliates in each other's markets had expanded to exceed \$1.7 trillion.² With this rise in transatlantic trade and investment, developments on one side of the Atlantic increasingly affect citizens, business enterprises and interest groups on the other, and, in turn, these groups' demands on their respective government representatives. With tariff rates at historic lows for most categories of goods, transatlantic trade issues increasingly have become regulatory ones—that is, divergent regulatory laws and procedures in themselves not only restrain trade, and thus transatlantic competition, but they can do so in an asymmetrical discriminatory manner. A central question facing national legislators, executives and administrative officials is how to govern transatlantic economic interdependence while maintaining social standards responsive to their respective constituencies' demands.

The United States and EC increasingly face the difficult task of reconciling the objectives of protective social regulation, on the one hand, and free competition facilitated through open trade policies, on the other. Depending on the context, these objectives can be complementary or in conflict. For example, the goals of domestic regulatory and free trade policies are both to protect and benefit citizen-consumers, in which sense they are complementary. Social regulatory policies, at least in their ideal form, are to protect consumers from the risk of market failures through state regulatory intervention. Open trade policies, at least in their ideal form, intend to offer consumers a wider selection of goods at lower prices, thereby expanding their consumption possibilities and increasing their standard of living.³

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Regulatory and trade policies, however, may conflict for two primary reasons. First, domestic lawmakers and regulators typically do not take account of the impact of domestic regulations on foreigners, primarily because foreigners do not have a voice in domestic political and regulatory processes.⁴ Even absent a discriminatory intent, regulatory requirements can be duplicative, redundant or otherwise disproportionately affect traded products, in part because domestic regulators do not take account of these impacts.⁵ In an economically interdependent world, domestic politics thus generates both input discrimination (from the lack of representation of foreigners in domestic political processes) and output discrimination (from the greater burden of duplicative regulations on cross-border traders).

Second, regulatory divergence reflects genuine difference in constituent preferences, and there is no reason why these differences must be harmonized or made compatible. Thus, the challenge confronting political leaders is to reduce redundant regulatory barriers to trade, where possible, without sacrificing democratic choice regarding the appropriate allocation of risks and the appropriate procedures for addressing them.⁶ The task is far from easy. To attempt to meet this challenge, U.S. and EC political leaders, under the aegis of the New Transatlantic Agenda,⁷ have begun to devise structures for transatlantic political and regulatory cooperation so that domestic regulatory processes are more likely to reflexively take account of the impact of domestic regulatory choices on non-constituents.

This Article provides an overview of how the tension between the goals of domestic regulatory protection and liberalized trade have been addressed by the United States and EC through transatlantic mutual recognition agreements and a hybrid form, the U.S. - EC safe harbor principles on data privacy protection. The Article assesses the prospects and limits, both politically and in the marketplace, of the U.S. - EC Mutual Recognition Agreement (MRA) and its six sectoral annexes (of 1997), the U.S. - EC Mutual Recognition Agreement on Marine Safety (initiated in June 2001), and the U.S. - EC understanding on Safe Harbor Principles for data privacy protection (of 2000). The analysis is based on a review of relevant documentation coupled with interviews of U.S. and EC representatives. The Article assesses what spurred these agreements, which actors participated in their negotiation, what constrains their implementation, and, ultimately, what are the prospects and limits for their adoption in other areas.

The Article advances four primary findings. First, transatlantic mutual recognition agreements need to be seen in the context of domestic and global business strategies to reduce regulatory compliance costs, to get new products quickly to market in a changing technological environment and thereby to enhance profits. Second, the agreements' implementation has been much more difficult than envisaged by business and government leaders on account of reactions in the marketplace and wariness of independent regulatory officials, particularly in the United States. Third, the agreements and understandings nonetheless have spurred some domestic regulatory change, as well as some mutual recognition of product approvals. They also could spur some *de facto* harmonization of regulatory approval procedures and substantive standards, thereby reducing the potential for intergovernmental conflict in these sectors. Fourth, and perhaps most controversially, where there has been convergence, the convergence has tended toward EC—and not U.S.—regulatory practices. As this Article will show, the EC now has a sustained record under its single market program of easing trade barriers among fifteen EC member states working in eleven different languages, while retaining relatively high regulatory standards. This practical experience, coupled with the EC's growing market power, has enabled EC regulators to put forward regulatory models that can be both attractive to firms and more pragmatic to adopt than their U.S. counterparts.

II. HARMONIZATION AND MUTUAL RECOGNITION: CAN THE EC'S "NEW" AND "GLOBAL" REGULATORY APPROACHES BE APPLIED TO THE TRANSATLANTIC MARKETPLACE?

There exist three primary options for easing regulatory barriers for trading firms: harmonization, mutual recognition and national treatment (albeit subject, of course, to multiple variants).⁸ Under a policy of harmonization, regulators in separate jurisdictions agree to adopt identical substantive standards and procedures.⁹ Such harmonization facilitates cross-border trade as well as cross-border regulatory cooperation because of regulators' greater comfort with similar standards. Under a policy of mutual recognition, regulators retain separate standards for internally-produced products, but agree to recognize the other jurisdiction's standards for products imported from it, albeit sometimes subject to significant conditions and controls.¹⁰ Mutual recognition agreements pose much greater challenges for regulatory cooperation because of regulators' unfamiliarity and unease with divergent foreign standards. Under a policy of national treatment, each jurisdiction maintains its own standards and is proscribed only from applying more stringent standards to foreign products. A national treatment regime removes fewer regulatory barriers, especially those that are non-discriminatory on their face, since regulators are not required to

“mutually recognize” the other’s standards.¹¹ These three policy options can be complementary, sometimes working in tandem.

A. Overview of the EC’s Coordination of National Regulatory Systems.

Since 1985, the EC has adopted what it terms “new” and “global” approaches to European regulation, under which EC institutions only legislate “essential requirements,” delegate the determination of more-detailed standards to quasi-public European standards organizations (the “*new approach*”), and then coordinate quasi-public national certification bodies to certify products produced in any one member state for sale throughout the EC market (the “*global approach*”).¹²

In 1985, the European Commission issued a bulletin that set forth its “new approach” to harmonization in response to the market-distorting and market-segregating impact of multiple national standards and the difficulty of appropriately overcoming them at the EC level, especially in light of rapidly changing technologies.¹³ Under this “new approach,” the Council of Ministers (the Council) enacts framework directives for technical standards covering “essential requirements.” The 1987 Single European Act modified voting rules for the enactment of EC internal market legislation to a “qualified majority” vote (as opposed to unanimity), thereby eliminating member state veto rights in the Council. This combination of qualified majority voting and the reduction of EC-prescribed standards to “essential requirements,” together with the EC’s highly-publicized push to “complete” an EC internal market by 1992, led to the adoption of a series of EC harmonization directives.¹⁴

Under this “new approach” to regulation, the Council delegates the task of drawing up more-detailed standards to industrial standardization bodies operating under the umbrella of three European standards organizations— CEN, CENELEC and ETSI.¹⁵ These European standards organizations are comprised of national standards bodies that, in turn, include representatives from government, industry and other social groups. The European standards bodies vote on a simple majority basis (following a first round of voting),¹⁶ facilitating the adoption of “non-essential” technical standards. These standards are not internally binding on the member states, so that member states retain some *de jure* autonomy. However, these standards have become *de facto* harmonized requirements for selling products within the EC on account of their importance in the marketplace.¹⁷

Under what is termed the EC’s “global approach” to regulation, products may be tested and certified within any member state in order to receive a “CE”

marking (which indicates that they comply with “*Communité Européen*” norms). All member states must recognize these certifications (i.e. mandatory mutual recognition), such that certified products may circulate freely throughout the EC market. In 1990, the member states formed the European Organization for Testing and Certification (EOTC) to coordinate national bodies engaged in the certification process and thereby help assure national authorities of the reliability of tests conducted in other member states.¹⁸ Each member state must approve and is responsible for overseeing the certification bodies within its jurisdiction and must notify the Commission’s Enterprise Directorate-General (DG) of its approvals. These testing and certification laboratories consequently are referred to as “notified bodies.”¹⁹ Member state authorities periodically meet and exchange information about the process’ operation through working groups and committees created pursuant to the respective directives. They thereby attempt to build and retain confidence in the system.²⁰ This EC system can be characterized as governance by coordinated cross-border public-private networks.²¹

Even though the CE marking alone is required for customs purposes, the trade names and trademarks of national notified bodies can remain advantageous for marketing purposes within member states. National distributors and suppliers sometimes prefer certification by national bodies within their own jurisdiction in order to reduce the risk of marketing products certified by a foreign body.²² Market barriers thus arise not only from government intervention and regulatory distrust, but also from the perceptions of private actors in the market. In short, the EC’s endeavors, while generally successful, have encountered setbacks, stalemates and ongoing challenges, despite the EC’s deployment of considerable institutional resources.²³

B. Harmonization and Mutual Recognition in the Transatlantic Context: Can the EC System Be Exported?

While there has been little effort to harmonize standards on a purely transatlantic basis, the United States and European member states have negotiated through international fora. In turn, such international standards can facilitate the negotiation of bilateral mutual recognition agreements because, where parties operate under common standards and procedures, they more easily understand and develop trust in each other’s regulatory practices. For example, the 1997 U.S. - EC Mutual Recognition Agreement is based largely on the mutual recognition of test results by “Conformity Assessment Bodies,”²⁴ which bodies, in turn, are evaluated pursuant to international standards set forth in ISO/IEC Guides. The international standard-setting bodies relevant to the sectors covered

by transatlantic mutual recognition agreements include the International Standards Organization (ISO) (for a broad range of standards); the International Electrotechnical Commission (IEC) (for testing and certification standards); Codex Alimentarius (for food-related standards)²⁵; the International Conference on Harmonization (for pharmaceutical standards)²⁶; the Global Harmonization Task Force (for medical device standards)²⁷; and the International Maritime Organization (for marine safety standards).²⁸

The EC has tended to look more favorably toward international harmonization efforts than the United States for two primary reasons. First, EC member states and European standards organizations have more experience in negotiating and implementing agreements with third parties in light of the EC's own internal market process.²⁹ Second, in international organizations where each country has one vote, the EC's fifteen member states can work collectively so that, overall, they are more likely to promote EC-based standards in multilateral fora. For example, two of the most widely known ISO standards, ISO 9000 and ISO 14000 were developed initially within Europe.³⁰

Mutual recognition agreements, in contrast, have been negotiated not internationally, but bilaterally or through regional fora. For example, the United States and EC have or are in the process of negotiating mutual recognition agreements under the auspices of APEC and CITEC, as well as with individual countries, such as Canada, Australia, Japan, New Zealand and Israel.³¹ The EC reports that it has concluded "six Mutual Recognition Agreements on conformity assessment between the European Community and third countries (which have) entered into force: on 1/12/98 with the United States, on 1/11/98 with Canada, on 1/1/99 with Australia and New Zealand, on 1/1/02 with Japan, and on 1/5/00 with Israel in the Sector of Chemicals Good Laboratory Practices (GLP)." See *Mutual Recognition Agreements*, (visited Feb. 26, 2002 <http://europa.eu.int/comm/enterprise/international/indexb1.htm#intro>). The EC's experience in harmonizing and coordinating fifteen national regulatory systems offers a model to be considered, and possibly exported, to these other contexts, including the transatlantic one. Yet, the EC's own experience also highlights the challenges that the United States and EC face in governing the interface of their economies. As this Article will demonstrate, there is even more distrust between regulators on either side of the Atlantic, there are greater challenges of political legitimacy, and the marketplace imposes even more severe constraints on the effective implementation of mutual recognition agreements in the transatlantic context.

III. THE 1997 U.S. - EC MUTUAL RECOGNITION AGREEMENT

A. What Gave Rise to the 1997 Mutual Recognition Agreement?

The issue of transatlantic standards became more important to firms engaged in transatlantic trade for two primary reasons. First, as transatlantic tariff barriers decreased, firms became more concerned with, what they termed, duplicative regulatory compliance costs.³² They pressed for their removal. This pressure increased with rising transatlantic investment, since divergent U.S. and EC standards and certification requirements most directly affect transatlantic corporate groups, and these groups more easily coordinate lobbying on both sides of the Atlantic. Subsidiaries of U.S. firms in the EC account for about one-third of EC imports from the United States, while subsidiaries of EC firms in the United States account for about 38% of U.S. imports from the EC.³³

Second, when the EC moved toward a single market, U.S. firms challenged that the EC was erecting a “fortress Europe” in which member states would use common “single market” standards and certification procedures to prejudice U.S. competition.³⁴ U.S. firms feared that they would be disadvantaged because, under the EC’s “global approach,” only notified bodies located within the EC could test and certify products for marketing in the EC.³⁵ Prior to the “global approach,” U.S.-based laboratories acted as subcontractors for the testing of products under member state standards, and firms feared that this option might be foreclosed.³⁶

In response to these developments, U.S. and EC authorities began to seriously address issues of regulatory coordination at the beginning of the 1990s. In May 1989, US Secretary of Commerce Robert Mosbacher and Commission Vice-President Martin Bangemann agreed to explore the possibility of transatlantic mutual recognition agreements, as well as mechanisms to grant U.S. firms greater access to EC standard-setting procedures.³⁷ In 1995, the United States and EC signed the New Transatlantic Agenda and its attached “Joint Action Plan” which contained a detailed list of items to address. At the NTA’s annual summits, negotiators were soon in search of “deliverables.”

Large businesses on each side of the Atlantic, working under the auspices of the Transatlantic Business Dialogue (TABD), promoted the concept of mutual recognition agreements, hoping to provide “deliverables” that met business needs.³⁸ Although the TABD’s formation was initiated by the U.S. Department of Commerce and the European Commission in the fall of 1995, TABD rapidly became a significant independent voice, identifying areas of concern and coordinating pressure on officials to set time tables for the signature

and implementation of mutual recognition agreements.³⁹ As Paula Stern, former chair of the U.S. International Trade Commission and advisor to TABD, states, “TABD quickly established the Trans-Atlantic Advisory Committee on Standards, Certification and Regulatory Policy (TACS) to formulate recommendations, organized on a sectoral basis, for the elimination of regulatory barriers between the two economies.”⁴⁰

U.S. and EC officials announced the 1997 MRA with fanfare as a “milestone” in U.S. - EC economic relations.⁴¹ Secretary Richard Daley of the U.S. Department of Commerce proclaimed that the MRA could save businesses over \$1 billion annually in unnecessary regulatory compliance costs.⁴² The Transatlantic Business Dialogue estimated that about half of \$110 billion of U.S. exports to Europe require some form of EC certification, which now could be accomplished in the United States. Officials announced plans for subsequent MRAs to cover an array of product and service sectors. The TABD estimated that a framework agreement for services would have an even greater impact in freeing up trade, affecting approximately \$130 billion in transatlantic commerce.⁴³ Yet, as will be seen, both transatlantic businesses and government officials have become less enamored with mutual recognition agreements in light of their experience with the 1997 agreement.

B. Transatlantic Business Practice before the 1997 MRA.

In order to understand the limited scope of the 1997 MRA, it is helpful to briefly review how businesses often had their products certified before its negotiation, and how many continue to operate. Still today, private testing bodies often test products in the manufacturer’s place of production on one side of the Atlantic in accordance with standards set on the other, and then have these test results certified by an accredited body in the importing jurisdiction. The domestic testing body operates under a sub-contracting arrangement with the responsible certification body in the importing jurisdiction.⁴⁴ For example, for the European market, laboratories in the United States can test U.S. products under EC standards and provide the paperwork to a “notified body” in Europe, which certifies them. In addition, large European notified bodies themselves have invested in the United States to provide these testing services in an integrated manner. Now that U.S. regulatory agencies increasingly recognize testing by private laboratories, U.S. laboratories too have entered into sub-contracting arrangements with European counterparts for product certification under U.S. standards. Large U.S. laboratories similarly have invested in Europe, and in some cases, themselves become EC notified bodies.⁴⁵ In consequence, the sectoral annexes to the 1997 MRA, assessed below, do not represent a

significant change for many businesses, but rather a slight extension of sub-contracting practices that have already adapted to regulatory and commercial developments. In fact, sub-contracting is specifically contemplated in some of the MRA's sectoral annexes, such as for telecommunications equipment, which provide that Conformity Assessment Bodies in one jurisdiction may sub-contract testing to laboratories in the other.⁴⁶

C. The 1997 MRA Negotiations.

U.S. - EC negotiators initially discussed negotiating mutual recognition arrangements in eleven sectors, but ultimately whittled this down to the following six: telecommunications equipment, electromagnetic compatibility, electrical safety, recreational craft, medical devices, and pharmaceutical good manufacturing practices. As with all trade negotiations, the EC and United States were concerned that the final results either favor their export industries or be "balanced." The United States wished to conclude an agreement on telecommunications equipment first, but the EC refused because it felt that U.S. firms would benefit more if the agreement covered only this sector. The EC used its political leverage by threatening not to sign any MRA involving telecommunications equipment without inclusion of MRAs covering medical devices and pharmaceutical good manufacturing practices.

The MRA negotiations required the involvement of multiple executive agencies since the negotiations comprised an overall framework agreement and six annexes covering the six separate sectors. The Office of the United States Trade Representative and the Commission's Trade Directorate-General (DG) led the negotiations of the MRA framework agreement.⁴⁷ Each of the annexes, however, was negotiated by the regulatory agency responsible for the sector concerned. On the European side, this was a simpler process on account of the centralization of the responsible agency officials within the Commission's DG Enterprise and these officials' long experience with coordinating the twin goals of regulatory protection and free trade within the single market. Because of this dual role, DG Enterprise officials are, in some ways, more analogous to the U.S. Department of Commerce than to independent U.S. regulatory agencies. On the U.S. side, in contrast, separate independent federal agencies negotiated the annexes. The Federal Communications Commission (FCC) handled the telecommunications and electromagnetic compatibility annexes; the Occupational Health and Safety Administration (OSHA), a division of the Department of Labor, negotiated the electrical safety annex; the Food and Drug Administration (FDA) negotiated the annexes for medical devices and pharmaceutical good manufacturing practices; and the Coast Guard oversaw the

recreational craft annex. These U.S. agencies traditionally have focused only on protecting public health and safety, and thus were less receptive to arguments concerning trade facilitation.

The involvement of both trade officials and regulatory officials resulted in *intra* - U.S. agency conflicts, as well as transatlantic ones. Trade officials more aggressively pushed for an agreement, and U.S. regulatory officials, in particular the FDA and OSHA, were reticent about accepting foreign certification of safety standards. Since these agencies are relatively independent compared to their EC counterparts, they obstructed agreement where they believed that their regulatory missions might be compromised. In the fall of 1996, negotiations almost broke down over inclusion of the medical device and pharmaceutical annexes.⁴⁸ Only Congress' intervention, following intensive lobbying efforts by private firms and the U.S. Department of Commerce, overcame FDA opposition to their inclusion. In November 1997, Congress passed the FDA Modernization Act, which specifically directed the FDA to "support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements."⁴⁹ The Act specifically encouraged mutual recognition agreements "between the European Union and the United States" in all product areas under FDA competence.⁵⁰

As the former EC Trade Commissioner Sir Leon Brittan states, "governments proved to be more eager than their agencies to cooperate."⁵¹ Ultimately, it was trade officials, spurred by business constituents, who drove the negotiations. High-level trade officials in two coordinating bodies within the NTA framework— the Senior Level Group and TEP Steering Group⁵² – identified goals, set deadlines and monitored progress. Nonetheless, the annexes required U.S. regulatory agency approval, which created delays, resulting in sharp and ongoing criticism from the Transatlantic Business Dialogue.⁵³

D. The 1997 Mutual Recognition Agreement.

The 1997 Mutual Recognition Agreement consists of a framework agreement and six annexes respectively covering telecommunications equipment, electromagnetic compatibility, electrical safety, recreational craft, medical devices, and pharmaceutical good manufacturing practices.⁵⁴ Each of the annexes is, in fact, a separate agreement for a separate sector covering defined categories and lists of products.

The 1997 MRA does not cover recognition of the adequacy or equivalency of transatlantic standards, but is rather much less ambitious. First, the EC and United States have not negotiated harmonized transatlantic standards for the concerned sector.⁵⁵ Second, although each annex is unique, each of them only addresses mutual recognition by certification bodies (called “Conformity Assessment Bodies”) located in the exporting jurisdiction in accordance with the importing party’s required standards and procedures. Since neither the United States nor the EC relinquish sovereign control over the substance of their standards, transatlantic trading firms still must meet the separate requirements of the world’s two largest markets.⁵⁶ Third, even these assessment evaluations are subject to varying pre-approval and post-approval conditions.⁵⁷ For example, in the case of medical devices, the relevant agencies need not accept the tests from foreign certification bodies if they find the reports deficient and delineate why, thus reducing businesses’ incentives to use these bodies. In the case of pharmaceutical good manufacturing practices, the tests are performed by regulatory bodies, and not private laboratories, and again, the agency in the importing jurisdiction may reject reports where it finds them deficient.

The MRA sets up a new transatlantic structure for overseeing its implementation. First, the MRA creates a Joint Committee, which consists of U.S. and EC trade officials who meet twice annually. Second, the annexes create Joint Sectoral Committees to oversee the annexes’ implementation. One would think that the Joint Sectoral Committees would be of greatest importance since they consist of the actual regulatory authorities who must oversee the protection of health and safety on each side of the Atlantic. However, members of the Joint Sectoral Committees for electrical safety have interacted primarily to argue over their interpretations of the United States’ obligations. The other Joint Sectoral Committees interact primarily via teleconference and e-mail.⁵⁸

1. Telecommunications and Electromagnetic Compatibility: Relatively Smooth Regulatory Cooperation.

The telecommunications and electromagnetic compatibility annexes should be viewed together because they both involve telecommunications equipment and their inclusion was sought by the telecommunications industry. These annexes’ complementarity is reflected structurally, in that the parties have formed a “Joint Sectoral Committee,” consisting of members of the U.S. Federal Communications Commission and the EC’s DG Enterprise to monitor the annexes’ implementation.⁵⁹ Under both annexes, the parties agree to recognize test reports and conformity assessment certificates issued by Conformity Assessment Bodies located in the exporting jurisdiction, “without any further

conformity assessment.”⁶⁰ As with all of the annexes, however, assessments are made in respect of the standards and in accordance with the procedures of the importing jurisdiction.

The responsible authority within each exporting jurisdiction (U.S. or EC member state) is to designate the Conformity Assessment Bodies located within it.⁶¹ These designations have been accomplished without controversy, unlike for other MRA annexes. As of June 2001, the United States had designated twenty-three Conformity Assessment Bodies for telecommunications equipment, and forty-three for electromagnetic compatibility.⁶² EC member states had designated a similar number of Conformity Assessment Bodies for electromagnetic equipment, but fewer for telecommunications equipment, in light of the shift in the EC toward self-certification (as described below).⁶³

Both annexes are now operational and, compared to the other annexes, their implementation has been relatively successful. However, the telecommunications annex has become less important for U.S. firms than when originally negotiated because, in 1998, the EC Council enacted a new directive concerning telecommunications equipment pursuant to which manufacturers now may self-certify that their equipment complies with EC requirements.⁶⁴ Under this directive, firms only need to consult with outside testing bodies. These bodies must maintain a record for post-market surveillance purposes, but they do not issue pre-market assessment certificates.⁶⁵ Similarly, in regards to electromagnetic compatibility, firms must prepare files on which EC “competent bodies” state “opinions,” but these bodies do not prepare assessment certificates.⁶⁶ Thus, the benefits of the MRA itself are relatively small for U.S. telecommunications firms, since the EC does not require any outside certification.⁶⁷ The EC’s move to manufacturer self-certification is much more dramatic for U.S. firms than the MRA itself, and U.S. firms now lobby U.S. authorities to adopt the EC’s decentralized system. For EC authorities, however, the two annexes relative success has been undermined by the United States’ failure (on account of OSHA) to implement the electrical safety annex, which, in the EC’s view, is also necessary for EC telecommunications firms to gain freer access to the U.S. market.

2. Electrical Safety: Regulatory Tensions.

EC negotiators insisted that the MRA include an annex concerning electrical safety standards because the EC market has long been relatively deregulated and thus more open to U.S. products. In contrast, the U.S. system calls for regulatory reviews and product approvals by OSHA, a division of the U.S. Department of

Labor. EC authorities, acting on behalf of EC firms, desired to ease the regulatory burden for EC imports into the U.S. market that required OSHA approvals.⁶⁸ They hoped to do so by having OSHA recognize product testing and certification, under OSHA standards, by Conformity Assessment Bodies located in Europe. In addition, at least certain sectors of the telecommunications industry, and in particular from the EC, desired an MRA that covered not only all aspects of telecommunications product approvals, but also might lead to adoption within the United States of a decentralized EC system. This annex has not been fully implemented, however, because of disputes with OSHA over the designation of European Conformity Assessment Bodies, as assessed below.

3. Recreational Craft: A Simple Annex.

The recreational craft annex was the simplest to negotiate and implement. In the United States, the applicable regulatory body, the U.S. Coast Guard, already permitted firms to self-certify their products, so that there was no need for any European conformity assessment bodies. In contrast, products must be certified by a “notified body” within the EC,⁶⁹ so that European recognition of U.S. Conformity Assessment Bodies could (at least in theory) reduce costs for U.S. firms. Nonetheless, it was much easier to implement this annex for the reasons assessed below.⁷⁰

4. Medical Devices: Disappointment and Delay.

As noted earlier, the United States and EC agreed to include the annexes for medical devices and pharmaceutical good manufacturing practices in the MRA only after the EC, U.S. trade officials, business lobbyists and Congress placed considerable pressure on a reticent FDA. Although the medical device annex was eventually included, the FDA insisted that the annex’s coverage be more limited, even though the parties only agreed to mutually recognize testing reports and not each other’s standards. First, the medical device annex only applies to less stringently regulated medical devices, subject to possible expansion based on an FDA “pilot program.”⁷¹ Second, designated Conformity Assessment Bodies are not selected by an authority of the exporting country, but rather by “joint assessment.”⁷² Third, implementation of the Annex was made subject to a three-year transition period (to have ended in December 2001), during which the FDA organized a “joint confidence building program.” However, in the fall of 2001, the parties agreed to extend this transition period for a further two years.⁷³ This confidence-building program includes mandatory seminars, workshops, joint training exercises and observed inspections, requiring a considerable investment by applicant laboratories. Fourth, designated

Conformity Assessment Bodies will not necessarily be permitted to perform all tests contemplated by the MRA, but only those in which the regulatory authority determines that they are competent.⁷⁴ Fifth, while the annex uses the terminology of “Conformity Assessment Bodies,” domestic regulatory bodies retain ultimate authority to recognize the testing results.⁷⁵ Thus, Conformity Assessment Bodies provide testing and systems evaluation services for regulatory authorities, but do not make definitive determinations for marketing purposes. Sixth, regulators must create a transatlantic “alert system” and exchange “post-market vigilance reports” as integral parts of the program.⁷⁶

5. Pharmaceutical Good Manufacturing Practices (GMPs): FDA Reticence.

The least ambitious and furthest from implementation of the six annexes is that for Pharmaceutical Good Manufacturing Practices. “Good manufacturing practices,” at least as defined by the EC, are those aspects “of quality assurance which ensures that products are consistently produced and controlled to quality standards.”⁷⁷

The parties’ intention in the pharmaceutical GMPs annex, the only annex not to rely on private Conformity Assessment Bodies,⁷⁸ is to permit regulatory authorities on one side of the Atlantic to rely on regulatory authorities on the other to conduct on-site visits of manufacturing facilities. After the inspection, the foreign regulatory authority is to provide an inspection report regarding the manufacturers’ compliance with good manufacturing practices.⁷⁹ These inspection reports should “normally be endorsed by the authority of the importing authority, except under specific and delineated circumstances” (article 12).

The pharmaceutical annex originally was, in large part, an agreement to agree, since many of the key provisions required further drafting. Initially, the parties could not even definitively agree on a definition of good manufacturing practices, noting definitions from each of their legislative texts and adding that “the US and EC have agreed to revisit this.” Similarly, the parties left open the content of their programs “for assessing equivalence” (article 6), as well as the content of the “information which must be present in inspection reports” (article 8). However, in each case, these issues apparently have been resolved, with the parties agreeing to retain their own inspection forms listing the items that the other party’s regulatory authority must evaluate and the information that it must provide.⁸⁰

The “cornerstone” of the pharmaceutical GMP annex is each parties’ determination of the equivalence of the regulatory system of the other party, which they “aimed” to conclude by December (1), 2001.⁸¹ The FDA, however, refused to recognize the equivalence of all but two member state systems, and thus the agreement was not implemented by the agreed date. The FDA faces a much more burdensome task to implement the MRA than do its European counterparts, who only need to adapt to one additional regulatory authority. In FDA’s view, to determine equivalence, it must review not only multiple EC directives and related EC documents, but also each member state’s implementing legislation, regulatory structures and regulatory practices.⁸² The FDA requires that it engage in joint training and joint inspections with regulatory officials in each member state before recognizing that state’s “equivalence.” The FDA claims that Congress has failed to allocate sufficient budgetary resources for the FDA to implement the 1997 mutual recognition agreement in a manner that ensures U.S. public safety.⁸³

6. One-sided Implementation of the Annexes.

As of January 2002, only the three annexes of greatest initial interest to U.S. negotiators were fully operational—those covering telecommunications equipment, electromagnetic compatibility and recreational craft.⁸⁴ In contrast, implementation of the annexes for electrical safety equipment, medical devices and pharmaceutical good manufacturing practices remain in dispute. The transitional period for the medical device annex was extended for two years. As for the pharmaceutical annex, the FDA maintained that it was willing to recognize the “equivalency” of two member state regulatory systems by the end of the 2001 transition period, but it set no fixed date for reviewing the others.⁸⁵ The EC, which must act on behalf of all fifteen member states, rejected this offer because it would prejudice manufacturers in the other thirteen member states, who would still be subject to duplicative EC and FDA inspections.⁸⁶

The EC’s negotiation stance has been somewhat complicated by the transition to a new U.S. administration and the fact that the U.S. executive has less control over the FDA and OSHA, as noted further below. The Commission, displeased that the unimplemented annexes are those that the EC initially imposed as conditions for the 1997 MRA, is reviewing its options.

E. New MRA for Marine Equipment: Initialed June 2001: Broadest in Scope.

On June 12, 2001, the United States and EC initialed an Agreement on Mutual Recognition of Certificates of Conformity for Marine Equipment. Unlike the

1997 Mutual Recognition Agreement and its six annexes, this new agreement provides for mutual recognition of each parties' standards and procedures as "equivalent" for purposes of certifications issued by conformity assessment bodies located in either parties' territory (Articles 3 and 4).⁸⁷ Although the initialed annex only covered five marine products, such as survival craft and lifesaving gear, the parties plan to expand this list before they submit the agreement for final adoption under their respective legislative and administrative procedures.⁸⁸

Pre-existing harmonization of standards in this sector, agreed under the auspices of the International Maritime Organization (IMO) in Geneva, made possible the parties' mutual recognition of the "equivalence" of each other's standards. This new mutual recognition agreement should be much easier to implement because testing bodies will not be certifying under separate standards and procedures and thus less training and information exchange is required. Moreover, the parties agreed up-front to recognize each other's existing certification bodies so that no application procedures are required for implementation (Article 6). Thus, while this agreement is relatively narrow in product coverage, it is much broader in scope.

IV. THE 1997 MRA IN CONTEXT: MULTI-LEVEL BUSINESS STRATEGIES, DIVERGENT REGULATORY CULTURES, UNEXPECTED MARKET BARRIERS

A. The 1997 MRA in the Context of Domestic Business Strategies.

Bilateral regulatory cooperation cannot be viewed, outside of domestic and global business strategies. At the domestic level, trading firms hope that the MRA will promote domestic adoption of harmonized standards, on the one hand, and deregulated certification requirements, on the other. Firms' main target has been U.S. independent regulatory authorities. They have had some success. Since 1998, the FCC has instituted a new program pursuant to which private testing laboratories may certify new telecommunications equipment, whereas formerly only the FCC could do so.⁸⁹ With business's encouragement, the EC has moved even further in some sectors, permitting manufacturer self-certification of most telecommunications equipment since 1998. Also since 1998, the FDA has instituted a program for private testing and certification of large categories of medical devices, starting with a pilot program that it plans to expand. As John Chai notes, U.S. manufacturers saw the EC system as a friendlier one to launch new products and urged Congress and the FDA to adopt many of its flexible features. Allegedly, some "U.S. manufacturers were moving their capital, resources, and facilities to Europe" as a result.⁹⁰ In response to

primarily domestic demands, the FDA Modernization Act expressly authorized the FDA to rely on private testing bodies in its oversight of medical devices.⁹¹

Although the original goal of the MRA annexes may have been to facilitate transatlantic trade, firms simultaneously focused on the deregulation of domestic product approvals.⁹² For example, deregulation of product marketing approvals is a core item on the Transatlantic Business Dialogues' agenda. TABD, in its 2001 Mid Year Report, called for a model "linked to a wider use of Supplier's Declaration of Conformity," and stressed the need for transatlantic adoption of the EC's global approach under the motto: "Approved Once, Accepted Everywhere."⁹³ Firms are primarily interested in reducing costs and getting new products to market in a rapidly changing technological environment.⁹⁴ A primary means to do so is to reduce pre-marketing regulatory requirements. The 1997 MRA annexes for telecommunications equipment and electromagnetic compatibility facilitated advancement of businesses' regulatory objectives. Many telecommunications firms continue to hope that the relevant U.S. agency, OSHA,⁹⁵ might relax its pre-market controls of electrical safety equipment by adopting a system of self-certification used in the EC since 1973.⁹⁶

As for Europe, U.S. firms hope to use transatlantic proposals for regulatory cooperation to change EC and member state legislative and regulatory procedures. In this case, firms would prefer that Europe adopt more of a U.S. procedural model, as set forth in U.S. administrative law.⁹⁷ As TABD argues, "A key element for further discussion between business and governments... is how to ensure transparency in the regulatory process... The rulemaking and implementation process must be open thereby permitting industry to participate meaningfully in the regulatory process."⁹⁸ TABD urges, in particular, "greater use of 'impact assessment' on regulations...(which) should include estimating the costs and benefits of regulation as well as any regulatory alternatives."⁹⁹ The United States, in this case, has taken up TABD's proposals in the negotiation of a U.S. - EC agreement on regulatory cooperation and transparency. In a 2001 draft, the United States proposed addressing "transparency" in regulatory processes through such mechanisms as "notice and comment rulemaking procedures," mandatory assessments of the "potential benefits, costs and other impacts for all parties, domestic and non-domestic," "public explanations... for the proposal and the alternatives," and "access to documents containing supporting research, data and analysis."¹⁰⁰

B. The 1997 MRA in the Context of Global Business Strategies.

Businesses also view transatlantic mutual recognition agreements in a global context. Firms, together with some government representatives, hope that transatlantic arrangements may be a stepping stone for reaching mutual recognition agreements with third countries, thereby offering increased access to lucrative Asian and South American markets. The WTO Agreement on Technical Barriers to Trade and the General Agreement on Trade in Services explicitly encourage and lend legal support to the expansion of transatlantic MRAs.¹⁰¹ Under WTO rules, countries that do not “give mutual satisfaction” to third countries offering “equivalent” procedures or standards are subject to WTO anti-discrimination claims under WTO most-favored nations clauses.¹⁰² While the prospect of these claims remains relatively remote, business organizations, such as the TABD, can use the WTO agreements as additional leverage.

Much more importantly than potential legal claims, each new mutual recognition agreement places pressure on third countries to enter into negotiations so that their firms are not disadvantaged—what Kalypso Nicolaidis refers to as a potential “contagion effect.”¹⁰³ Transatlantic and third country negotiations thereby have reciprocal effects. Each MRA provides leverage to domestic firms to demand new MRAs (with transatlantic or third country counterparts, as the case may be) to equalize market access. The telecommunications industry has sought MRAs for other lucrative markets in Asia and Latin America, which U.S. and EC authorities respectively have signed through APEC and CITES.¹⁰⁴ The EC has signed MRAs with Australia, Canada, Israel, Japan and New Zealand, in addition to those signed with the United States. The transatlantic MRA can, in this way, be seen as a step for the extension of MRAs globally, helping ensure that not only transatlantic markets, but also other foreign markets, will remain open to foreign competition.

The telecommunications industry, in particular, has promoted in global regulatory change toward the EC’s self-certification model. If the industry could spur regulatory change in the United States, it might use the transatlantic MRA as a catalyst for this global strategy.¹⁰⁵ The EC and United States are, in fact, in the process of implementing or negotiating a number of MRAs elsewhere in the world.¹⁰⁶

C. The Challenge of Implementation: Reconciling Regulatory Systems and Cultures.

The significant institutional asymmetries between the United States' and EC's respective regulatory systems and cultures creates a major challenge for transatlantic regulatory cooperation and the implementation of transatlantic mutual recognition agreements. Where regulators adopt similar regulatory structures and systems, and enact similar substantive standards, they more easily understand and accept each other's regulatory determinations. Regulatory symmetry facilitates regulatory trust and confidence, enabling regulatory cooperation to occur. For example, U.S. and EC regulatory authorities each have supported a more decentralized process for pre-marketing approvals of telecommunications equipment, which explains the relative ease of this annex's implementation.

Although the U.S. system is often characterized as fragmented and decentralized, its actual nature varies by sector. At times, the U.S. system is relatively highly centralized, as when Congress delegates regulatory authority to an independent federal regulatory body, such as the FDA.¹⁰⁷ At other times, the U.S. system is more fragmented, with regulation consisting of a patchwork of federal, state, and private voluntary standards with no overarching framework, as in the case of data privacy protection.¹⁰⁸ Significant for transatlantic mutual recognition agreements, U.S. private standard-setting bodies remain highly fragmented, since the American National Standards Institute (ANSI), which is the closest analogue to a U.S. national standards body, does not serve as an administrator or coordinator of private standard-setting.¹⁰⁹

While some commentators maintain that the United States grants private actors relatively more flexibility than in Europe,¹¹⁰ this stereotype is belied in practice by a number of the sectors covered by the 1997 transatlantic MRA. For example, the FCC certified all telecommunications equipment until the negotiation of the transatlantic mutual recognition agreement, at which time it adopted a more decentralized EC model. The U.S. Occupational Health and Safety Administration requires OSHA-accredited laboratories to certify all electrical safety equipment used in the workplace, whereas the EC has permitted manufacturers to self-certify the equipment's conformity with EC requirements since 1973. The U.S. Food and Drug Administration continues to certify most medical devices,¹¹¹ whereas EC authorities have permitted testing by private notified bodies since (1994).

U.S. and EC regulators work in different regulatory cultures, ones which (in the case of the MRA) makes EC institutional adaptation easier. EC and European national regulators operate under the dual mission of ensuring free trade within the internal market, on the one hand, while ensuring public safety through high product and process standards, on the other. They thus are quite accustomed to interacting with foreign regulators and testing bodies on an on-going basis. In consequence, the Commission's DG Enterprise and DG Trade units rarely tumbled when negotiating and implementing the 1997 Mutual Recognition Agreement. In contrast, the U.S. Food and Drug Administration traditionally has defined its role solely as that of protecting U.S. public health, and has not operated under a dual mission of also facilitating market exchange. Although FDA officials participate in the International Conference on Harmonization and although Congress expanded the FDA's mission in 1998 to include trade facilitation,¹¹² FDA authorities have developed U.S. standards and procedures over time in relative isolation from other regulators. FDA officials often consider their practices as superior, constituting what the FDA's General Counsel has characterized as "the gold standard."¹¹³ Because the FDA is an independent regulatory authority anxious to protect its regulatory autonomy, U.S. trade and commerce authorities encounter more difficulties in negotiating bilateral agreements concerning areas within the FDA's jurisdiction. Because of OSHA's and FDA's wariness of relinquishing regulatory controls, the U.S. and EC have so far been unable to implement the MRAs for electrical safety equipment, medical devices and pharmaceutical good manufacturing practices.

Implementation of transatlantic MRAs also has been much easier for the EC, because EC regulatory authorities only have to adapt to one new regulatory system (the United States') that is overseen in one language (English), whereas U.S. authorities must adapt to fifteen different regulatory structures operating in eleven different languages under the EC's umbrella. EC regulatory authorities already are accustomed to dealing with other national regulators in the context of the EC's single market. Simply as regards language, U.S. certification bodies submit their applications and testing report in English, a language with which EC and member state regulators are well-accustomed.¹¹⁴ Expansion of the EC system to include the United States is a less significant change. The EC's implementation of the recreational craft annex thus has been relatively simpler despite the fact that the EC has a more regulated system for this particular sector.¹¹⁵

OSHA

OSHA, for example, has found implementation of the MRA to be a "headache"¹¹⁶ as it believes that it is being pressed to accept, without significant

review, applications forwarded to it by fifteen different member state authorities, all or part of which may be in any one of the EC's eleven official languages. To ensure its regulatory mission, OSHA has insisted that it control the designation of European Conformity Assessment Bodies under the electrical safety equipment annex, rather than relying on European member state designations. OSHA has rejected a number of Conformity Assessment Bodies designated by member state authorities on different grounds, including on account of the language of the submission and the submission's incompleteness.¹¹⁷ In addition, OSHA has insisted that it conduct on-site reviews of these bodies. Finally, OSHA began charging an application fee in October 2000 because of the burden of the application process, which further raised tensions with European regulatory authorities. The Commission maintains that OSHA's assertion of control over the designation of European Conformity Assessment Bodies is in violation of the agreement's letter and spirit.¹¹⁸

The tensions between OSHA and the Commission's enterprise directorate-general stem, in large part, from differences in U.S. and EC regulatory structure and culture in this specific area. Since the EC's 1973 Council Directive on electrical safety equipment, EC member states permit manufacturers to self-certify their compliance with EC electrical safety requirements, subject to post-marketing member state surveillance and controls.¹¹⁹ The member states have agreed on the harmonization of approximately 600 standards for electrical safety equipment, which largely transpose international standards.¹²⁰ In contrast, all electrical safety equipment that may be used in the workplace in the United States must be approved by a laboratory recognized and overseen by OSHA.¹²¹

From the perspective of European regulators, the United States lacks the political will to provide for mutual recognition in this annex. As one Commission official states, "OSHA never wanted this annex and is not committed to it."¹²² OSHA officials indirectly concur, arguing that this annex was included as a "political gesture" to the Europeans and the telecommunications industry."¹²³ U.S. and EC regulatory authorities are now skeptical of the benefits of the electrical safety MRA. OSHA maintains that it already certifies foreign laboratories so that there is no need for an MRA. EC officials concur that if OSHA refuses to trust EC designating authorities, the MRA becomes superfluous. According to one Commission official, this MRA annex has been "counterproductive" for overall efforts at U.S. - EC regulatory cooperation. Another Commission official claims that the EC may exercise its right not to apply the other MRAs on account of OSHA's alleged violations of the agreement.¹²⁴

FDA

Similarly, implementation of even a relatively limited MRA program for medical devices has encountered serious obstacles. The primary difficulty lies in the wariness of the FDA, stemmed in large part by the very different nature of the U.S. and EC regulatory systems. The European regulatory system for medical devices is much more decentralized under the EC's "new" and "global" approaches. The relevant EC directives¹²⁵ only sets forth "essential requirements" that, in turn, are supplemented by voluntary standards set by standard-setting bodies. These standards bodies have agreed to a considerable number of harmonized standards, which facilitates the tasks of both regulators and testing laboratories. Accredited laboratories ("notified bodies") test and certify the products, and once certified, the products are only subject to post-market surveillance controls. Moreover, firms are offered a choice of how to meet the essential requirements, which choice varies depending on the product and its risk.¹²⁶

In contrast, the U.S. system is more heavily regulated, as the FDA often requires (depending on the product) both quality systems evaluations (which it terms "surveillance/post-market and initial/pre-approval inspection reports") and pre-market product evaluation reports (which it calls "510(k) reports").¹²⁷ Although the FDA is now working with private laboratories, its program is still in a pilot stage. Moreover, under the FDA's new program, FDA retains ultimate authority whether or not to accept laboratory reports or to require further information or testing, so that reliance on private laboratory certification (unlike FDA certification) is not automatic.

The FDA shows even more reticence concerning the annex for pharmaceutical good manufacturing practices. Because pharmaceutical products most directly bear on the FDA's mission of protecting U.S. public health, the FDA refuses to be forced to recognize member state equivalency until it is fully satisfied. In the words of one FDA official, FDA has "refused to compromise its mission of protecting public health for balance of trade purposes."¹²⁸ Because of the FDA's independence, there is little that the U.S. administration can do. Business has not been able to prevail over the FDA because the FDA also has allies among U.S. consumer advocates and Republican and Democratic Congressional representatives.¹²⁹ European representatives counter that the United States and its regulatory agencies must demonstrate their commitment to the 1997 MRA, and ultimately, show greater trust in the EC system, if transatlantic mutual recognition agreements are to work.

D. The Unexpected Challenge of Market Barriers to Implementation.

Transatlantic trade officials and businesses that first touted the benefits of U.S.-EC mutual recognition arrangements now realize their underestimation of the difficulties of implementation. These constraints involve not just regulators and regulatory cultures, but market forces as well. The market has not reacted favorably to the recognition of new Conformity Assessment Bodies under the 1997 MRA.¹³⁰ From the perspective of manufacturers, they typically develop long-term working relationships with certifying laboratories, which constitute a form of cost-effective firm-laboratory partnership. Because manufacturers invest in educating these laboratories about their products and manufacturing processes, and the relationship of these products and processes to applicable regulatory requirements, the cost of changing laboratories may be significant. Moreover, a laboratory's mark itself may be important in some markets, so that firms may continue obtaining formal certification from EC notified bodies for the EC market and U.S. laboratories for the United States. As a result, most firms may continue using the same laboratories even though these laboratories cannot directly certify products as Conformity Assessment Bodies, but must work through sub-contracting arrangements with accredited laboratories on the other side of the Atlantic.¹³¹

As for laboratories, they will not invest in the accreditation procedures required to become a Conformity Assessment Body if they fear that the benefits are limited or too uncertain. Accreditation costs can be substantial, involving seminars, workshops, training programs, audits and joint inspections with authorities across the Atlantic. While twelve European notified bodies initially applied to be recognized as Conformity Assessment Bodies under the medical device annex, two subsequently withdrew on account of costs.¹³² As a result, both manufacturing firms and private laboratories have become, in the words of one Commission official "a bit cool on the MRA."¹³³ This industry reaction, in turn, suits those regulators who were not enthusiastic about the MRA in the first place. The MRA's success, in consequence, may require considerable market promotion, including through government subsidies and promotional programs. As Commission representatives assert, "the MRA should contain sufficient commercial incentives for potential CABs (Conformity Assessment Bodies) and industry to show interest. Use of the MRA cannot be imposed."¹³⁴ The Transatlantic Business Dialogue supports such promotional efforts.¹³⁵

Some domestic firms, however, also benefit from domestic regulatory barriers to their transatlantic competitors. When there is no domestic constituency actively pressing for domestic regulatory change in a specific sector, implementation of the MRA faces greater hurdles. For example, there is

no dominant U.S. constituency pressing for implementation of the electrical safety MRA. As a Commission official points out, this is not a “balanced” MRA, since U.S.-based firms do not require conformity assessment to sell electrical safety equipment in the EC market. In addition, most U.S. producers allegedly encounter relatively less difficulty with OSHA’s program for their sales on the U.S. market, and thus may gain an advantage vis-a-vis European competitors because of their experience with OSHA-certified laboratories. Finally, laboratories already certified by OSHA have a relatively protected market and do not desire competition from laboratories newly certified by European authorities. Thus, there is little U.S. constituent pressure on OSHA to concede to the EC and recognize laboratories designated by EC member state authorities. Rather, the best hope for European firms may be that the change in U.S. administration could lead to deregulation of OSHA’s pre-market approval process by permitting manufacturer self-certification. If this occurs, however, the electrical safety annex’s provision of mutual recognition of testing bodies would have served little purpose other than (possibly) to help foment domestic regulatory change.

V. U.S. - EC UNDERSTANDING ON PRINCIPLES FOR DATA PRIVACY PROTECTION: MANAGING CONFLICT AND MAINTAINING FREE TRADE THROUGH HYBRID INSTITUTIONAL DEVELOPMENTS A LEVERAGING UP OF STANDARDS?

In July 2000, the United States Department of Commerce and European Commission formalized an agreement creating a set of “Safe Harbor Principles” (the Principles) on data privacy protection, under which U.S.-based firms may certify themselves in order to avoid European restrictions on data transfers to the United States.¹³⁶ The Principles constitute a unique development in the governance of U.S. - EC economic relations. To some, they represent the EC’s exercise of coercive market power in an extraterritorial fashion in an attempt to leverage up privacy standards within the United States.¹³⁷ To others, they represent a capitulation by EC trade bureaucrats to U.S. trading concerns through a weak agreement filled with loopholes.¹³⁸ And finally, to some, including this author, they represent a compromise through new institutional development pursuant to which free transatlantic information flows may be preserved while satisfying legitimate EC concerns about the use of personal information concerning EC residents in a technology-intensive, interdependent globalizing economy.¹³⁹

Unlike the mutual recognition agreements assessed above, the Safe Harbor Principles constitute a form of de facto *harmonization* of social standards. The Principles go beyond current regulatory requirements in the

United States, and thereby constitute a regulatory floor with which trading firms must comply if they wish to receive data from Europe without threat of challenge. This harmonization, however, is designed to affect only trading firms, and otherwise to create no legal obligations within the United States. The United States and EC may thereby claim that they formally retain autonomy to enact whatever privacy legislation they deem appropriate. However, any firm which engages in cross-border exchange is subject to pressure to abide by the Principles. In this way, Europe's regulatory approach may have spillover effects within the United States, leading to some convergence in data privacy practices, despite differing U.S. and EC regulatory systems.

Although the extent of the Safe Harbor Principles' implementation remains an open question, the U.S. - EC dispute and efforts at cooperation demonstrate the inherent interrelation between social regulation and open trade policies where regulation (or the lack thereof) has external effects. Alleged U.S. under-regulation can jeopardize the privacy interests of EC residents. Alleged EC over-regulation can limit the commercial operations of U.S. enterprises. In an interdependent transatlantic economy, U.S. and EC authorities attempt to manage the ensuing conflicts of norms and mesh, where possible, their divergent regulatory systems.

A. Pooled Sovereignty: The EC's Market Clout in an Interdependent Transatlantic Economy.

The U.S. - EC agreement was spurred by the creation of the EC single market, on the one hand, and the interdependent nature of the U.S. and European economies, on the other. The creation of the single market led to the EC's regulation of data privacy in the first place. Among the ironies inherent in the U.S. - EC dispute is that the original purpose of the EC's data privacy directive was not just to increase data privacy protection within the European Community. It was also to ensure the uninhibited flow of data within the EC from the threat of unilateral restrictions by individual EC member states on account of their differing data privacy protection regimes.¹⁴⁰ The interlinked nature of social protection and liberalized trade in a single European market gave rise to the Directive.

Similarly, data privacy protection became a transatlantic issue because of the growing interdependence of the U.S. and European economies and the rising importance of information technology. U.S. affiliates in Europe produce over a trillion dollars of goods and services annually, constituting "over half of all the foreign production of U.S. companies."¹⁴¹ These companies depend on information flows, not only with third party suppliers, customers, consultants,

marketers and other service providers, but also internally, within their complex networks of affiliates, joint ventures and partnerships.

The U.S - EC dispute over the adequacy of U.S. data privacy protection affects U.S. privacy policies and practices because the EC exercises political and market power. In a globalizing marketplace, the EC's single market initiative has reinforced the European Commission's position as a global actor.¹⁴² The EC's huge internal market enables the Commission to exercise considerable political clout in the negotiation of international and transatlantic rules, including harmonized rules governing firm behavior.

The shift of European regulation to the EC level has strengthened the EC's ability to represent the interests of its constituents vis-a-vis the United States. The EC member states have not simply "lost" sovereignty in working through centralized EC authorities. They have reallocated it in a manner which effectively enhances their negotiating authority (and in that way their autonomy) vis-a-vis the United States.¹⁴³ In pooling their sovereignty, EC member states now speak with a more powerful voice transatlantically. The timing of the United States' reaction to the threat of bans on data transfers from Europe demonstrates this. It was not until the EC's privacy directive went into effect that U.S. authorities drafted Safe Harbor Principles and increased pressure on companies to raise their internal privacy standards. When the threat moved to the EC level, the United States took the threat more seriously.

B. Overview of The EC Privacy Directive's Internal Requirements: Ex Ante and Ex Post Controls.

On October 24, 1998, Directive 95/46/EC on the Protection of Individuals with Regard to the Processing of Personal Data and the Free Movement of such Data¹⁴⁴ became effective. The EC, through its Directive, takes primarily a regulatory approach to data privacy protection, as opposed to private ordering through market processes. The Directive is noteworthy for its broad scope of coverage. Except for public security, criminal law and related exceptions, it covers all processing of all personal data by whatever means, and is not limited to action by government, business sector or field of use (arts. 2-3). The Directive prohibits data controllers from processing information unless the individual "unambiguously" consents to the processing and that consent is informed (arts. 7, 8, 10, 14). Information subject to the most stringent controls includes "personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life" (art. 8).

The Directive provides multiple means for enforcement. It requires member states to grant individuals a permanent right of access to obtain copies of the data about them and have it corrected or its use enjoined (arts. 12, 28). It obliges member states to provide a judicial remedy for infringements of data privacy rights, including the right to receive damages (arts. 22-24). To support effective enforcement, each member state must designate an independent public authority “responsible for monitoring the application within its territory” of the Directive’s provisions (art. 28). These supervisory authorities are to be granted significant powers, including the power to investigate processing operations, to deliver “opinions before processing operations are carried out,” to order “the blocking, erasure or destruction of data,” to impose “a temporary or definitive ban on processing,” and “to engage in legal proceedings” against violators of the rights guaranteed by the Directive (arts. 18, 28).

C. Overview of U.S. Data Privacy Protection vis-a-vis the Directive’s Criteria.

In contrast to the EC, the United States has stressed “self-regulation” by the private sector backed by regulation which tends to be sector-specific and less stringent. Congress’ targeting of specific sectors and concerns is reflected in the following statutory titles: The Driver’s Privacy Protection Act of 1994, the Video Privacy Protection Act of 1988, The Electronic Communications Privacy Act of 1986, the Cable Communications Policy Act of 1984, and The Fair Credit Reporting Act of 1971.¹⁴⁵ Overall, the U.S. approach is fragmented, involving standard-setting and enforcement by a wide variety of actors, including federal and state legislatures, agencies and courts, industry associations, individual companies and market forces.¹⁴⁶ To a certain extent, the United States’ handling of data privacy issues reflects Americans’ traditional distrust of a centralized government.¹⁴⁷ U.S. legislation provides citizens with significantly greater protection against the collection and use of personal information by government, in particular the federal government, than by the private sector.¹⁴⁸

Nonetheless, demands for privacy legislation covering the private sector within the United States have increased. In the fall of 1998, the Federal Trade Commission (FTC) successfully lobbied for greater online data privacy protection for children. *See* Pub. L. No. 105-277, 112 Stat. 2681 Title XIII (1998). In May 2000, a divided FTC, by a 3-2 vote, called for Congress to enact on-line privacy protection for all persons within the United States. Federal Trade Commission, *Privacy Online: Fair Information Practices in the Electronic Marketplace: A Report to Congress*, May 2000. With the change in the administration, the FTC has backed away from recommending legislation. The Bush administration nonetheless has implemented new medical privacy rules

adopted by the Department of Health and Human Services during the Clinton administration (although it did note that they could be revised or clarified to account for industry concerns). See Robert Pear, *Bush Accepts Rules to Guard Privacy of Medical Records*, NYT (April 13, 2001). Moreover, numerous privacy bills are pending in Congress.

D. The Directive's Extraterritorial Impact: Ban on Data Transfers to Countries Lacking Adequate Privacy Protection.

Article 25 of the Directive provides that member states shall prohibit all data transfers to a third country if the Commission finds that the country does not ensure “an adequate level of protection” of data privacy. Pursuant to article 29 of the Directive, an EC Working Party prepared a series of documents that identified core principles under which the adequacy of a country’s protections should be gauged.¹⁴⁹ These principles are in line with the EC’s internal requirements and include the following: processing must be limited to a specific purpose made known to the concerned individual, together with other information to ensure fair processing; the individual must have access to the data and the right to object to its processing; the individual must have procedural mechanisms available to effectively enforce the protections.

Since it appeared that the United States might not provide for “adequate” data privacy protection under the Directive’s criteria, U.S. and EC authorities engaged in intensive negotiations to avoid a ban on data flows to the United States, culminating in their agreement on Safe Harbor Principles. The Commission refrained from finding that the United States, as a whole, inadequately ensures data privacy protection while the parties negotiated the content of the Principles. Once signed, the member states formally recognized that U.S. firms’ adherence to these Principles would be sufficient to protect them from member state challenge. Member state authorities, however, may still challenge transfers to firms that do not adopt and comply with the Principles. Privacy rights associations can trigger these proceedings by filing claims with supervisory authorities.¹⁵⁰ Even before implementation of the Directive, data transfers to the United States were barred by British, French, German and Swedish courts and administrative authorities.¹⁵¹

E. The Safe Harbor Principles.

The U.S. Department of Commerce issued its first draft “Safe Harbor Principles” in November 1998, within a month of the Directive becoming effective. These were opened for comments within the United States and negotiated for almost twenty months with the Commission before they were

finalized and approved by the EC.¹⁵² The guidelines set forth seven core data privacy principles for industry to follow. Because the EC formally acknowledged the Principles as “adequate” under the Directive’s criteria, the Principles provide U.S. businesses with a “safe harbor.” The seven Principles are:

- (i) “Notice”: An organization must provide “clear and conspicuous” notice to individuals “about the purposes for which it collects and uses information about them, how to contact the organization with... complaints, the types of third parties to which it discloses the information, and the... means... for limiting its use and disclosure”;
- (ii) “Choice”: An organization must provide individuals with a “clear and conspicuous” choice to “opt out” of how their personal information may be used and to whom it may be disclosed; “for sensitive information (i.e, personal information specifying medical or health conditions, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership or information specifying the sex life of the individual), they must be given affirmative or explicit (opt in) choice if the information is to be disclosed to a third party or used for a purpose other than those for which it was originally collected or substantively authorized...”;
- (iii) “Onward Transfer”: To disclose information to a third party, an organization must apply the “Notice and Choice principles”;
- (iv) “Security”: Organizations must take reasonable measures to protect information from disclosure, misuse, alteration or loss;
- (v) “Data Integrity”: Organizations “may not process personal information in a way that is incompatible with the purposes for which it has been collected or subsequently authorized,” and “take reasonable steps to ensure that data is... accurate, complete and current”;
- (vi) “Access”: An organization must grant individuals access to personal information held about them and the opportunity to have it corrected, except where the burden would be disproportionate to the privacy risks in the case in question;
- (vii) “Enforcement”: There must be “mechanisms for assuring compliance” and “consequences” for non-compliance, which must include “readily available and affordable independent recourse mechanisms” and “sanctions (that) must be sufficiently rigorous to ensure compliance.”

The U.S. Department of Commerce and Commission supplemented the Principles with a document entitled “Frequently Asked Questions” (FAQs) designed to guide firms and authorities in the Principles’ application. Many of the FAQs specify the scope of exceptions, thereby providing some leeway to U.S. firms. Nonetheless, many firms find that the Principles require significant internal company adaptations.¹⁵³

Companies join the Safe Harbor program by annually certifying to the U.S. Department of Commerce that they will comply with the Principles. The Department of Commerce then places the company’s name on its web site list of certifying firms.¹⁵⁴ The firms’ primary benefit from certifying is that EC member states may not challenge them under member state law or otherwise condition any data transfers to them. Moreover, U.S. law applies to the Principles’ interpretation, and U.S. courts and administrative bodies hear all claims (although European courts and administrative bodies may still challenge the online collection of information from European residents by U.S.-based firms).¹⁵⁵

Self-regulatory organizations (such as BBB Online and TRUSTe, discussed below), backed by the U.S. Federal Trade Commission, offer the primary means for the Principles’ enforcement. In this way, the Principles’ application resembles the EC’s new and global approaches to internal market harmonization. As under the new approach, the Safe Harbor Principles set forth “essential requirements” that firms must meet. As under the global approach, firms self-certify their adherence, which certification is backed first by audits from self-regulatory organizations, and then (ultimately) by the authority of the state. If a company adopts the safe harbor principles and fails to comply with them, it subjects itself to challenge by the FTC for “using unfair or deceptive acts or practices in or affecting commerce.”¹⁵⁶ In a letter to the Commission date July 14, 2000, the FTC committed itself to “give priority to referrals of non-compliance with self-regulatory guidelines... (and) safe harbor principles” respectively referred to it from certifying organizations and EC member state authorities. As documented in this letter, the FTC has already brought enforcement actions against firms for failure to comply with their posted privacy policies.¹⁵⁷ In this backhanded way, the Directive informally shapes U.S. data privacy requirements, potentially becoming a baseline standard.¹⁵⁸ Yet, it does so in a relatively flexible manner that respects U.S. legal sovereignty and use of private oversight bodies.

F. Other Means to Comply with the Directive.

The Safe Harbor Principles should not be viewed in isolation, since the Directive provides other ways to comply with it, in particular through obtaining “unambiguous” consent from the “data subject” in Europe (art 7) and the signature of a “model contract” with data privacy authorities in member states (Article 26). In January 2002, the Commission approved standard contract clauses covering privacy protection that can be applied to all data transfers from the EC, regardless of a firm’s adherence to the Safe Harbor Principles.¹⁵⁹ U.S. financial services firms were particularly interested in the content of this model contract since they currently are ineligible for certification under the Safe Harbor Principles because no federal authority (such as the FTC) has competence to enforce them.¹⁶⁰ When a draft model contract went beyond Safe Harbor requirements, the financial services industry reacted vehemently, pressuring the Treasury and Commerce Departments to send a joint letter to the Commission in protest, albeit to no avail.¹⁶¹ Firms also can sign *ad hoc* contracts with individual member state data privacy authorities.¹⁶² In addition, firms can sign contracts with affiliates when transferring personal information, such as information contained in personnel files.

G. Implementation

The Safe Harbor Principles are still at an inchoate stage so that it remains too early to assess their impact. Some commentators questioned the effectiveness of the Principles given that only a few U.S. companies initially signed them. However, as practitioners point out, companies will not certify their procedures until their operations are in compliance. For large companies, this can involve considerable re-engineering of their information systems, creation of new internal policies, and training of personnel. Moreover, many companies waited to see the content of the Commission’s “model contract,” which turned out to be more stringent than the Safe Harbor Principles themselves. Finally, U.S. and EC officials had agreed on an implementation period during which firms would not be challenged, which period would be “reviewed in mid 2001.”¹⁶³ As the review deadline approached, more companies certified themselves, or publicly announced their intention to do so.¹⁶⁴ Although some companies initially hesitated certifying under the Safe Harbor Principles in order to avoid being subject to FTC challenge within the United States, most large companies receiving data from Europe will likely not reason in this manner. They would prefer to be in legal compliance with EC rules on both reputational and legal grounds, and the Safe Harbor Principles are the easiest way to proceed.

Companies engaged in transatlantic business operate in the shadow of the Directive's potential enforcement. As noted above, and as I have argued elsewhere, the EC Directive and Safe Harbor Principles contribute to a gradual convergence in data privacy practices. Data privacy regulation in Europe has informed not only the tenor and context of debates in the United States; it has shaped interest groups' appreciation of their options. Under the Directive, U.S. businesses face potential litigation before European courts and administrative bodies unless they adhere to the Safe Harbor Principles. Playing off the U.S. - EC regulatory conflict and its media coverage, privacy advocates have jacked up pressure on U.S. federal and state politicians, regulatory authorities and businesses. Even though privacy advocates have criticized the Safe Harbor Principles, privacy advocates will use them as part of their larger strategies. The context in which U.S. domestic debates over data privacy protection take place has been altered.

The Directive, in particular, has increased the demand for legal, consulting and other privacy services within the United States. The Center for Social and Legal Research, "a privacy think tank" based in Hackensack, New Jersey, works with multinational companies in drafting codes of conduct incorporating the Directive's requirements.¹⁶⁵ The Better Business Bureau OnLine created a privacy seal program which incorporates the Safe Harbor Principles, and was revised to track "safe harbor" negotiations.¹⁶⁶ The Electronic Frontier Foundation, a San Francisco-based public interest organization, has associated with information technology companies to launch a program named TRUSTe to rate the privacy protection of Internet sites, which program is certified under Safe Harbor.¹⁶⁷ Accountants, through their national organization, the American Institute of Certified Public Accountants (AICPA), created an analogous program entitled CPA WebTrust, under which they will evaluate web sites, conduct audits of firm's privacy practices and recertify participating firms.¹⁶⁸ As smaller companies find these certification programs costly, trade associations such as the Direct Marketing Association designed their own enforcement programs for their members to comply with Safe Harbor requirements.¹⁶⁹ Legislation, in this case foreign legislation, has helped raise the standards to be certified and spurred more companies to use seal programs with oversight and sanctioning mechanisms.

The Directive also has spurred the creation of a new corporate position—the chief data privacy officer in companies' human resources divisions. These company employees attend conferences on the Directive and U.S. privacy legislation,¹⁷⁰ write memoranda on privacy issues that they distribute within firms, and generally increase firm awareness of privacy issues. In formulating and overseeing the implementation of company policies, they foster company

compliance with applicable legal requirements. Finally, outside law firms increasingly provide advice to firms regarding the Directive and the Safe Harbor Principles, thereby again promoting adaptation of U.S. business practice. This conjunction of lawyer, consultant and “privacy officer” advice, rendered in the context of the Safe Harbor Principles, can lead to convergence of privacy policies over time, reducing the chance of a major transatlantic trade dispute over data privacy.

H. The Shadow of WTO Rules.

In an attempt to ward off EC action, U.S. officials implicitly threatened to challenge any ban imposed by the EC before the WTO’s Dispute Settlement Body.¹⁷¹ However, provided that the EC does not apply the Directive in a manner that discriminates against the United States, it arguably is in compliance with WTO rules.¹⁷² First, on its face, the Directive applies equally to EC and foreign-owned goods and services providers, and thus should not violate national treatment or most-favored nation clauses.¹⁷³ Second, WTO jurisprudence supports the EC’s position.¹⁷⁴ The WTO Appellate Body would likely refrain from engaging in a close balancing of trade and privacy interests, and rather review the process by which the EC takes account of foreign privacy protections. In compliance with the WTO Appellate Body’s approach in past jurisprudence, the EC has studiously assessed U.S. practices affecting the privacy of EC residents; U.S. authorities and companies have had access to EC officials to comment on the Directive and its applications; and the EC has engaged in prolonged, detailed discussions with U.S. representatives to examine “adequate” (as opposed to identical) data privacy safeguards which could be applied. Thus, in the case of the EC data privacy enforcement, WTO rules should shield the EC from a U.S. retaliatory threat. WTO rules thereby have reinforced pressure on the United States to negotiate a set of more stringent, data privacy requirements in the form of the Safe Harbor Principles.

I. Some Conclusions on Safe Harbor.

While the Safe Harbor Principles do not formally apply to purely domestic data processing operations, U.S.-based enterprises recognize that it will be difficult for them to use two sets of data privacy practices, one for EC residents (providing for greater privacy protection), and one for U.S. residents (providing for less). Business databases will often include information about EC and U.S. residents, in which case businesses will be pushed to comply with the EC’s more demanding requirements.¹⁷⁵ In addition, if businesses provide greater data privacy protection for EC residents than for U.S. residents, they may harm their public image. Privacy advocates have already exploited this argument,

proclaiming that U.S. citizens should not be treated as second class citizens in their own country.¹⁷⁶ This move toward convergence, in practice, should help relieve cross-border regulatory conflicts.

Most importantly, in a world of increased economic interdependence, the Safe Harbor Principles point to the importance of regulatory cooperation across borders involving public and private actors. Certification groups such as BBB OnLine meet with European data protection officials so that they become comfortable in the workings of an alternative U.S. approach. These private groups also negotiate contracts for joint seal programs in other jurisdictions, such as that concluded in 2001 between BBB OnLine and a Japanese counterpart.¹⁷⁷ In this way, on-line businesses can meet criteria in multiple jurisdictions without the need for drawn-out treaty negotiations. Government officials, including in Europe, realize that they do not have the resources to enforce the Directive's provisions solely on their own, and thus rely on public-private networks in an attempt to ensure better global practices affecting EC constituents. The regulation of data privacy in a global economy will require the meshing of different regulatory systems and a commitment from the various actors to sustained interaction to ensure trust and confidence in each other's efforts.

From a practical standpoint, the separate goals of protecting individual privacy, on the one hand, while ensuring trade liberalization, on the other, are inseparable. Regulation in a jurisdiction with less stringent data privacy controls has significant externalities, thereby affecting residents in other jurisdictions. The Safe Harbor Principles are an example of an instrument for reconciling these regulatory concerns with the goals of liberalized trade. They represent a form of compromise that recognizes different institutional approaches and social values, yet nonetheless sets baseline rules where domestic values are affected by trade. To make them work, however, will require sustained, cross-border cooperation. These new experiments in governance are a much preferred way to proceed than through litigation before a supranational court, such as the WTO's Dispute Settlement Body. New institutional development requires creative problem-solving and political will. The Safe Harbor Principles are an example of what—potentially—can be accomplished.

VI. CONCLUSIONS: THE PROSPECTS AND LIMITS OF U.S. - EC BILATERAL REGULATORY COOPERATION THROUGH MUTUAL RECOGNITION AGREEMENTS: MOVING TOWARD AN EC SYSTEM?

A. Reasons for Enhanced Bilateral Regulatory Cooperation.

Despite the significant difficulties of implementing the various U.S. - EC bilateral agreements, they have also created frameworks for interaction among regulatory officials who are responsible for protecting the health and safety of residents in an array of areas. Even if these transatlantic regulatory interactions result in tensions, blockages and obstacles, the concerned regulatory authorities also become more educated about each other's systems and are simultaneously initiating and pursuing various informal parallel programs which receive less attention than the conflicts, but may be more important in the long-term. Sustained regulatory encounters promoted by the various bilateral agreements ultimately are much more important than abstract undertakings to engage in regulatory cooperation.¹⁷⁸

This regulatory interaction can lead to more protective social regulation *and* greater trade facilitation, both to consumers' benefit. First, regulatory exchange can spur improved social regulation, as authorities compare experiences and learn from each other's best practices. FDA and member state regulatory officials, for example, meet to study their different evaluations of new products and the reasons why one authority may grant and the other withhold approval. They complement their reviews of market approvals with new joint alert and safeguard systems to more rapidly notify each other of risks that they encounter, and better coordinate procedures to address them.¹⁷⁹ Through these information exchanges, regulatory officials learn to build on each other's separate experiences, avoiding duplicative efforts so that they can target resources for other challenges.

Second, regulatory exchange can lead to harmonized standards and procedures, which can help facilitate and spur further regulatory cooperation because officials more easily understand each other's systems and activities. In addition, harmonized standards can facilitate trade and competition by reducing production costs, since firms no longer need different product lines and product evaluation controls for multiple jurisdictions. For example, increased interaction between the FDA and European regulators may facilitate transatlantic and international harmonization through the Global Harmonization Task Force.¹⁸⁰ These harmonization efforts reciprocally could facilitate implementation of the medical devices MRA by easing the FDA's review of European products and

procedures.¹⁸¹ Individuals, in turn, could have more rapid access to new products and greater product choice at lower prices.

Harmonization, of course, is not an end in itself, and diversity is also a core value.¹⁸² Regulatory diversity can reflect differences in constituent values, environmental conditions and other contexts. Nonetheless, in an increasingly interdependent transatlantic economy in which choices in one jurisdiction may have significant impacts on constituents in others, regulatory decisions are more informed – and more inclusive – when made in the context of sustained regulatory exchange. Again, the central normative goal of transgovernmental regulatory cooperative efforts is to create frameworks that conduce national regulators to reflexively take into account the impact of their actions on affected, but otherwise unrepresented, foreign constituents, while remaining deferential to disparate national values and priorities.

Third, the MRA could save firms the costs of multiple inspections. For example, EC pharmaceutical manufacturers exporting to the United States currently are inspected for GMP compliance by both member state and FDA officials. These dual inspections may take up to (six weeks). Similarly, U.S. pharmaceutical manufacturers exporting to the EC must have each batch/lot of their products tested and certified by an EC importer in accordance with specifications and controls set forth in EC directives. The EC importer also must be a licensed pharmaceutical manufacturer subject to GMP reviews by the member state authority. For certain new products, European member state authorities sometimes conduct inspections at manufacturers' facilities within the United States.¹⁸³ For U.S. manufacturers, the MRA would eliminate the additional costs of these importer batch/lot tests, certifications and inspections. Again, reducing redundant product inspections permits products to get to market faster at a lower price.¹⁸⁴

Fourth, in an age of limited government resources for the oversight of rapidly changing, expanding and interacting economies, regulators also could save costs through enhanced cooperation with foreign regulatory officials and decentralizing product certification systems. FDA simply does not have the resources to adequately conduct all testing itself, especially where testing involves significant foreign travel.¹⁸⁵ By permitting an “over-extended and under-resourced” FDA¹⁸⁶ to outsource testing and evaluation of medical devices to private bodies, FDA can reallocate its resources to areas of higher concern, while retaining high product and process standards and post-market surveillance controls. In particular, FDA officials are more concerned by medical devices produced in jurisdictions other than Europe, so that the transatlantic MRA could free up resources for it to address these other areas. Similarly, FDA officials

admit that they are already unable to conduct annual pharmaceutical GMP reviews of foreign manufacturers as they would prefer, and thus the MRA could ensure more consistent oversight of foreign manufacturers' practices.

B. Need for Regulatory Resources: Limits to Transatlantic Regulatory Coordination.

Irrespective of the potential benefits to firms and regulators, and irrespective of political pressure for regulatory adaptation, transatlantic regulatory cooperation remains by no means a foregone conclusion. While the New Transatlantic Agenda and Transatlantic Economic Partnership create various frameworks for regulatory coordination, significant obstacles remain, whether on account of institutional asymmetries, market contexts or differences in culture and values. The challenges of implementing the 1997 Mutual Recognition Agreement and 2000 Safe Harbor Principles so demonstrate. Where existing regulatory structures, cultures and standards mesh, then regulatory coordination becomes easier. Both the FCC and the FTC's have dual missions focused on assuring consumer protection and open competition, so that they have been relatively more open to cooperating with trade authorities under the 1997 MRA and 2000 Safe Harbor Principles. However, where regulatory agencies, such as the FDA and OSHA, experiment for the first time with delegating functions to private testing bodies, and, even more importantly, where these agencies are wary of new EC-like approaches, building and retaining the requisite trust and confidence requires considerable time and resources. Institutional learning curves are steep. Where the issues involve differences in complex regulatory systems, such as those covered by the 1997 medical device annex, independent agency interests more likely prevail because political pressure from the executive and legislative branches is more difficult to sustain.¹⁸⁷

As noted above, transatlantic mutual recognition agreements potentially could save costs for regulatory agencies. However, it remains unclear whether governments actually will save costs while ensuring consumer safety, at least in the short term. Cross-border regulatory interaction is not free, and thus the net benefits for regulators of the MRA remains an open question. Regulators on both sides of the Atlantic have had to dedicate considerable resources to implement the MRA, especially during the transition period.¹⁸⁸ Just to start, the effort entails considerable up-front negotiation costs and the costs of regulators learning and becoming comfortable with each other's systems.¹⁸⁹ For example, to implement the medical device annex, FDA has trained foreign private bodies in its methods, conducted joint inspections, and assessed detailed dossiers. A number of the European applicants submitted documents in a foreign language, which FDA returned for translation. Even after translation (at the Commission's

expense), some applications were drafted in a broken English, again complicating FDA's task.¹⁹⁰ The FDA estimated that it already had expended over \$10 million dollars by June 2001 to implement the annex.¹⁹¹ EC officials have been even further behind schedule, citing a lack of resources. By mid-2001, they had yet to conduct any joint tests or training of U.S. certification bodies' for the testing of medical devices.¹⁹² Similarly, FDA maintains that it does not have the resources to verify the equivalence of all fifteen member states' systems for implementation of the pharmaceutical GMP annex.¹⁹³

C. Moving Toward an EC Model?

Overall, transatlantic institutional adaptation has been slow (and often creeping), but where it has occurred, it has been rather unidirectional, and will likely continue to be so.¹⁹⁴ Simply stated, the United States has made most of the changes, whether through adoption of international standards that mirror EC ones, through delegation of testing and certification responsibilities to private laboratories (reflecting the EC's "global approach"), or through coordination and oversight of these laboratories under a new U.S. national program analogous to those operating in the EC for over a decade.¹⁹⁵ For example, because the United States lacked a coordinated system of accredited testing and certification laboratories, European officials were concerned about the ability of U.S. regulators to guarantee the competence and quality of U.S. conformity assessment bodies. In response, the U.S. National Institute of Standards and Technology, a division of the Department of Commerce, created a new U.S. program (named the National Voluntary Conformity Assessment Program). Taking from the EC model, the U.S. program aims to coordinate and oversee U.S. conformity assessment bodies, and thereby provide greater confidence to regulatory officials, whether domestic or foreign.

Unlike their U.S. counterparts, EC regulatory authorities have operated for over a decade under a dual mission of ensuring public safety, on the one hand, and ensuring free movement of goods within the EC's single market, on the other. They consequently are more experienced in managing the coordination of distinct national regulatory systems than their U.S. counterparts.¹⁹⁶ The EC experience thus offers a model to be considered, and possibly adapted, for the transatlantic context, although U.S. and EC regulators avoid formally acknowledging this on account of U.S. political sensitivities.

Yet, regardless of the model's appropriateness, the EC exercises significant market leverage in determining transatlantic standards and regulatory structures required to implement mutual recognition policies on account of the size of its single market, which is already larger than the United States'. This

leverage will only increase as the EC potentially expands its borders to encompass up to thirteen additional nations within the next decade. Firms desiring access to the EC market place pressure on their national officials to adapt their own systems to accommodate reciprocal trading arrangements. As the EC enters into mutual recognition agreements with other OECD countries, such as Japan, Australia, New Zealand, Switzerland and Canada, and as these countries adapt their systems to interact with the EC model, the pressure on the United States to adapt its own regulatory structures should augment. The same process occurs as the EC negotiates with other countries regarding the adequacy of their data privacy protection laws, and as these countries adapt by enacting new legislation affecting the export of data to the United States. Consciously or unconsciously, the EC steadily is exporting its system globally. The 1997 Mutual Recognition Agreement and the 2000 Safe Harbor Principles so attest. In pooling their sovereignty at the EC level, European member states collectively exercise much more leverage in transatlantic and international negotiations over common regulatory standards and procedures.

D. Legitimacy: Ensuring Public Health and Safety while Retaining Open Markets; the Need for Political Will and Resources to Build Transatlantic Regulatory Trust and Confidence; The Limits of Unfunded Mandates.

Assessing the legitimacy of enhanced bilateral cooperation raises questions of both substance (outputs) and procedure (inputs). From a substantive perspective, bilateral cooperation cannot be accomplished on the cheap or it could result in deregulatory measures with little oversight. This would lead to challenges that the system benefits only producer, and not consumer interests, and thus that regulatory outcomes are substantively illegitimate. From a procedural perspective, citizens justifiably fear that they will have less control and access to regulatory decision-making made outside of their own borders, raising issues of procedural legitimacy.¹⁹⁷

A number of consumer advocates, such as Public Citizen, distrust new transatlantic mutual recognition arrangements.¹⁹⁸ The transatlantic push for regulatory coordination and reform arguably has led to increased delegation of traditional public services to private testing bodies. U.S. consumer advocates, in particular, distrust the adoption of the EC's decentralized approach based on manufacturer self-certifications and certifications by private laboratories. In part, this distrust could stem from the perception that, in the U.S. context, private actors lack the tradition of cooperating with regulatory authorities that exists in more corporatist, state-directed European systems.¹⁹⁹ There is, however, no necessary link between private certification and increased risk to public health

and safety, *provided* that these certification processes are based on high health and safety standards and are complemented by significant regulatory oversight and controls.²⁰⁰ While there may well be a growing role for new governance mechanisms based on private monitoring and information exchange,²⁰¹ these mechanisms will unlikely be successful unless backed by the prospect of state regulatory intervention.²⁰²

Building a transatlantic marketplace requires reconciliation of the twin goals of social protection and competition through open trade. These twin goals only can be reconciled through increased regulatory cooperation, which, in turn, will require sustained political will, institutional adaptation, and significant regulatory resources. EC member states have sustained such political will and dedicated such resources over decades in order to create the single market. And even so, they too have encountered significant setbacks and obstacles.²⁰³ While it is far too early to pre-judge the 1997 MRA, it nonetheless is fair to question whether the requisite political will exists on each side of the Atlantic to ensure that regulatory resources are made available.

Regulators engaged in this process must gain and sustain trust and confidence in each other's decisions, in particular in areas affecting public health and safety where they are asked to rely on testing, certifications and accreditations by foreign laboratories and officials. Regulatory officials on both sides of the Atlantic complain that they simply do not have the resources to engage in the seminars, workshops, joint testing, inspections, and information exchange prescribed in the MRA, and necessary for its proper implementation. The Commission's DG Enterprise confirms that it has yet to locate the resources to properly implement the medical devices MRA. The FDA asserts that the MRA annexes under its responsibility constitute "unfunded mandates," because Congress has instructed FDA to cooperate with trade officials in the negotiation and implementation of mutual recognition agreements, but has not provided it with the requisite resources. FDA officials are frustrated by what they view as "political pressure" from trade officials that "complicates our regulatory mission."²⁰⁴

This involves a curious reversal of arguments used by fiscal conservatives within the United States. Whereas it was the Congress of the "Gingrich Revolution" that decried "unfunded mandates" without cost-benefit analysis and the provision of adequate federal funding to state authorities to implement Congressional dictates, now consumer advocates and federal regulators decry unfunded mandates for cross-border regulatory coordination. Consumer advocacy groups go even further, arguing that businesses, not taxpayers, should pay these costs.²⁰⁵ Regardless of how the necessary regulatory resources are

obtained, the MRA's proper implementation requires them. Without such resources, mutual recognition agreements could put consumer health and safety at greater risk, calling into question the substantive legitimacy of these arrangements. Given the United States' traditionally more inward-looking approach, and now that a new Republican administration is lodged in Washington bent on tax cuts and trimming back government, whether adequate resources will be dedicated to transatlantic regulatory cooperation remains in doubt.

Gregory Shaffer
University of Wisconsin Law School
gshaffer@facstaff.wisc.edu

ENDNOTES

¹ The term EC is used in this Article instead of EU (or European Union) because it is EC institutions that enter into bilateral agreements with the United States under the “first pillar” of the Treaty of European Union (TEU) of 1992. The TEU changed the name of the European Economic Community to the European Community to denote that the European Community had integrated beyond purely economic matters. The TEU also created three separate pillars of activities for the regional block. The first pillar concerned all traditional EC matters, as expanded by the TEU to cover, in particular, European economic and monetary union. The 1997 U.S.-EC Mutual Recognition Agreement thus refers to the EC as a party, and not to the EU. Commentators, however, often use the term EU because it is broader in scope, covering all three pillars of activities.

² Mark Pollack and Gregory Shaffer, *Transatlantic Governance in Historical and Theoretical Perspective*, in *TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY* 3, 4 (eds. Mark Pollack and Gregory Shaffer, 2001) (citing Anthony Gardner, *A New Era in U.S.-EU Relations? The Clinton Administration and the New Transatlantic Agenda*, viii (1997)). The value of US/EU trade (i.e. not including sales by affiliates) was \$379.2 billion in 2001 and \$385.1 billion in 2000. *See* (visited March 7, 2002) <http://www.census.gov/foreign-trade/balance/c0003.html>.

³ Many proponents also maintain that free trade policies protect consumers from domestic oligopolistic practices and domestic rent-protectionist protectionist legislation. *See e.g.* MELVYN KRAUSS, *HOW NATIONS GROW RICH: THE CASE FOR FREE TRADE* (1997); John McGinnis & Mark Movsian, *The World Trade Constitution: Reinforcing Democracy Through Trade*, 114 *HARV. L. REV.* 511 (2000).

⁴ As Miguel Maduro writes, “National polities have a twofold deficit: on the one hand, they do not control many decision-making processes which impact on those national polities but take place outside their borders; on the other hand, national polities exclude from participation and representation many interests which are affected by (their) decisions.” Miguel Poiares Maduro, *Europe and the Constitution: What if this is As Good as it Gets*, in *RETHINKING EUROPEAN CONSTITUTIONALISM* (eds. J. Weiler & M. Wind: 2001).

⁵ Whereas products intended solely for domestic markets need comply only with domestic testing, certification and related regulatory requirements, exported products need comply with those of the producing and importing jurisdictions.

⁶ As Christian Joerges writes, “risks, especially those caused by internationally produced and marketed products, cannot be meaningfully attributed to just one legally defined territory and the political confines of nation-states.” Christian Joerges, *Law, Science and the Management of Risks to Health at the National, European and International Level— Stories of Baby Dummies, Mad Cows and Hormones in Beef*, 7 *COLUMBIA J OF EUROPEAN L.* 1, 3 (2001)

⁷ *See* discussion in POLLACK AND SHAFFER, *TRANSATLANTIC GOVERNANCE*, *supra* note, at 14-17.

⁸ *See* Kalypso Nikolaidis, *Regulatory Cooperation and Managed Mutual Recognition: Developing a Strategic Model*, in *TRANSATLANTIC REGULATORY COOPERATION* 596 (ed. George Bermann 2001).

⁹ On the limitations of harmonization policies, *see* David Leebron, *Lying Down with Procrustes: An Analysis of Harmonization Claims*, in *FAIR TRADE AND HARMONIZATION: ECONOMIC ANALYSIS* 393 (Jagdish Bhagwati & Robert Hudec eds., 1996). Some commentators point out how harmonization tends to demand more than mutual recognition

agreements, although, as will be seen, the negotiation and implementation of mutual recognition agreements also demand significant resources. See Michelle Egan, *Mutual Recognition and Standard Setting: Public and Private Strategies for Governing Markets*, in MARK POLLACK AND GREGORY SHAFFER, *TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY* 179, 195 (2001).

¹⁰ See Kalypso Nicolaidis, *Regulatory Cooperation and Managed Mutual Recognition: Developing a Strategic Model*, in *TRANSATLANTIC REGULATORY COOPERATION* 596 (ed. George Bermann 2001). As Nicolaidis' work, this Article focuses on the alternative of mutual recognition determined through political negotiation, as opposed to judicial decision. See Kalypso Nicolaidis, *Mutual Recognition of Regulatory Regimes: Some Lessons and Prospects*, in *REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS*, 171, 173-174 (OECD 2001)(contrasting judicial mutual recognition under the Cassis de Dijon approach in the EC).

¹¹ Nicolaidis refers to "policed national treatment" as a third approach. See Kalypso Nicolaidis, *Mutual Recognition of Regulatory Regimes: Some Lessons and Prospects*, in *REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS*, 171, 173 (OECD 2001). A narrow interpretation of national treatment permits for considerable regulatory diversity and, in consequence, a greater likelihood of regulatory barriers to trade. However, courts have ruled against regulations that provide for national treatment on their face where the regulations lack a "scientific" basis or cover foreign production processes (as opposed to product characteristics). Such judicial oversight can lead to controversial outcomes, as in the WTO shrimp-turtle case (concerning an import ban imposed on account of foreign production processes) or the WTO meat-hormones case (concerning an import ban imposed without conducting a sufficient risk assessment). Just as mutual recognition policies, such judicial challenges facilitate regulatory competition through which consumers implicitly choose among production processes when they purchase products on the market.

¹² Guide to the Implementation of Directives Based on the New Approach and the Global Approach. (visited Feb. 25, 2002)
http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf

¹³ Technical Harmonization and Standards: A New Approach: Bull. EC 1-1985.

¹⁴ Egan notes the adoption of 21 "new approach" harmonization directives between 1985-2000 covering a wide range of industries and giving rise to 2,905 standardization acts ratified or in the process of preparation or approval by standards organizations as of June 1997. See MICHELLE EGAN, *CONSTRUCTING A EUROPEAN MARKET: STANDARDS, REGULATION AND GOVERNANCE* 166-167 (2001)

¹⁵ CEN is the acronym for the Comité Européen de Normalisation (founded in 1961); CENELEC for the Comité Européen de Normalisation Electrotechnique (founded in 1959); and ETSI for the European Telecommunications Standards Institute (founded in 1988).

¹⁶ See MICHELLE EGAN, *CONSTRUCTING A EUROPEAN MARKET: STANDARDS, REGULATION AND GOVERNANCE* 154-158 (2001) (noting two rounds of voting before decision by a majority vote, as well as other preliminary procedures).

¹⁷ See Giandomenico Majone, *International Regulatory Cooperation: A Neo-Institutionalist Approach*, in *Regulatory Cooperation and Managed Mutual Recognition: Developing a Strategic Model*, in *TRANSATLANTIC REGULATORY COOPERATION* 596 (ed. George Bermann 2001) ("the voluntary standards produced by the European organizations become, de facto,

binding”). As stated in the Commission’s 1985 Bulletin, “the authorities in the Member States will be obliged to recognize that products manufactured in accordance with harmonized standards (set by private bodies)... are presumed to conform to the ‘essential requirements’ laid down in the Directive; this means that any manufacturer will be free to produce goods which do not meet the standards, but the burden of proof that his products meet the essential requirements of the Directive will then fall upon him.” See *Technical Harmonization and Standards: A New Approach*, (art. 1.3.3(iv)), *supra* note...

¹⁸ Michelle Egan, *Mutual Recognition and Standard Setting: Public and Private Strategies for Governing Markets*, in MARK POLLACK AND GREGORY SHAFFER, *TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY* (2001), at 190.

¹⁹ The overall process is called the “global approach” because once a notified body certifies that a product meets EC standards, the product may be marketed in all fifteen member states.

²⁰ Firms and laboratories also remain subject to post-marketing member state regulatory controls, as well as market-reputational constraints.

²¹ See Renaud Dehousse, *Regulation by networks in the European Community: the role of European agencies*, 4 J. OF EUROPEAN PUBLIC POLICY 246 (1997); Egan, *Constructing a European Market*, *supra* note..., at 12. See also R.A.W. Rhodes, *The New Governance: Governing without Government*, 44 POLITICAL STUDIES 652 (1996) (theoretical background on governance through networks).

²² See *infra* notes.

²³ See EGAN, *CONSTRUCTING A EUROPEAN MARKET*, *supra* note, at 229 (“Firms continue to experience difficulties in persuading other economic operators or suppliers to accept the results of conformity assessment from bodies they do not know, or to accept national standards and marking arrangements that they are not familiar with.”); and DAVID VOGEL, *BARRIERS OR BENEFITS: REGULATION IN TRANSATLANTIC TRADE* (1997), at 4. See also John Chai, *Medical Device Regulation in the United States and the European Union: A Comparative Study*, 55 FOOD & DRUG L.J. 57, 72 (2000) (noting that “no member state was able to meet the deadline” for implementing the 1993 Active Implantable Medical Devices Directive and “most member states were not able to designate their [notified bodies] in time”).

²⁴ “Conformity Assessment Bodies” are the transatlantic analogue of “notified bodies” operating within the EC market in the context of the EC’s “global approach.”

²⁵ Codex Alimentarius, a joint undertaking of the World Health Organization and the Food and Agricultural Organization, is relevant to the U.S.-EC Veterinary Equivalence Agreement. This latter agreement is not yet operational and is not covered in this Article.

²⁶ The International Conference on Harmonization is a program that “harmonizes requirements and guidelines for testing drugs and biologics.” Its members are the Commission, the European Medicines Evaluation Agency, EC member state regulators, Japan’s health ministry and U.S. European and Japanese pharmaceutical trade industry associations. See Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 SETON HALL L. REV. 692, 717-718 (1998)

²⁷ The Global Harmonization Task Force consists of regulators from the US, EC, Canada, Japan and Australia, although the Task Force now admits observers from many other countries.

²⁸ In addition, the United States and EC have worked through organizations such as the OECD, regarding the criteria of “good laboratory practices” in pharmaceutical production, and the UN Economic Commission for Europe, regarding certain car manufacturing standards

(the latter involving cooperation since 1984 in the context of a 1958 UN-ECE agreement). See Michelle Egan, *Mutual Recognition and Standard Setting: Public and Private Strategies for Governing Markets*, in MARK POLLACK AND GREGORY SHAFFER, *TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY 200* (2001).

²⁹ As Vogel writes in respect of harmonization of pharmaceutical guidelines and standards, “the experience the Europeans gained in harmonizing regulations among the EU’s member states has both enabled and encouraged it to play a leadership role in promoting international regulatory cooperation.” See David Vogel, *The Globalization of Pharmaceutical Regulation*, 11 *GOVERNANCE* 1, 14 (Jan. 1998).

³⁰ Egan, *Mutual Recognition and Standard Setting*, *supra* note, at 201

³¹ APEC is the Asia Pacific Economic Cooperation forum “is the primary international organization for promoting open trade and economic cooperation among 21 member ‘economies’ around the Pacific Rim.” See *United States APEC Index* (visited Feb. 28, 2002) <http://www.apec.org/>. CITELE is “an entity of the Organization of American States, is the main forum in the hemisphere in which the governments and the private sector meet to coordinate regional efforts to develop the Global Information Society according to the mandates of the General Assembly of the Organization and the mandates entrusted to it by Heads of State and Government at the Summits of the Americas.” See *CITELE* (visited Feb. 28, 2002) <http://www.citel.oas.org/>.

³² Firms engaged in cross-border sourcing of products particularly are concerned with disparate standards. See also MARIA GREEN COWLES, *THE LIMITS OF LIBERALIZATION: REGULATORY COOPERATION AND THE NEW TRANSATLANTIC AGENDA*. 3 (1997).

³³ Pollack and Shaffer, *Transatlantic Governance in Historical and Theoretical Perspective*, *supra* note, at 14.

³⁴ See Egan, *Mutual Recognition and Standard Setting*, *supra* note, at 186-187. Although firms have largely been assuaged that EC harmonization would not be used as a weapon to discriminate against U.S. firms, they would still prefer not to have to meet multiple U.S. and EC standards.

³⁵ Under the EC’s “global approach,” testing and certification of products for meeting a defined standard may take place in the member state home country, provided that the certifying body is a “notified body” recognized in Brussels. See discussion in *supra* note ___ and accompanying text.

³⁶ However, as noted below, sub-contracting continues today, so that again, firms’ fears of the EC “global approach” have largely been assuaged.

³⁷ See DAVID VOGEL, *BARRIERS OR BENEFITS: REGULATION IN TRANSATLANTIC TRADE*, at 9 (1997).

³⁸ The Transatlantic Business Dialogue was launched in 1995 roughly at the time as the creation of the New Transatlantic Agenda. As documented by Cowles, the TABD consists of CEOs of over 100 of the largest firms on each side of the Atlantic. See Maria Green Cowles, *The Transatlantic Business Dialogue: Transforming the New Transatlantic Dialogue*, in POLLACK AND SHAFFER, *TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY* (2001), at 215.

³⁹ To give one example of TABD’s work, *see.e.g.* Mutual Recognition of the Food and Drug Administration and European Community Member State Conformity Assessment Procedures; Pharmaceutical GMP Inspection Reports, Medical Device Quality System Evaluation

Reports, and Certain Medical Device Pre market Evaluation Reports, 63 Fed Reg. 17,744, 17,747 (Apr. 10, 1998) (noting views of TABD).

⁴⁰ See Paula Stern, *The Trans-Atlantic Business Dialogue: A New Paradigm for Standards and Regulatory Reform: Sector by Sector*, in OECD PROCEEDINGS: REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS 155, 156 (1996).

⁴¹ See e.g. statement of Charles Gaylord from the Office of International Programs in the FDA at a public meeting on the 1997 Mutual Recognition Agreement in Rockville, Maryland, Dec. 8, 1999: "When the Mutual Recognition Agreement was signed last year, it was a significant milestone that was the culmination of years of hard work by many people both within the EU and the FDA." (visited March 12, 2002) <http://www.fda.gov/oia/dec8transcript/opening.html>.

⁴² Gary Yerkey, *U.S., EU Conclude Standards Pact on Testing and Certification, Officials Say*, 14 INT'L TRADE REP. 1068 (June 18, 1997) (citing Secretary of Commerce William Daley). Daley was likely taking his figures from industry. For example, ITI, which led "the efforts of information technology firms in the United States to press government for closure of talks in telecommunications and information technology," estimated that a transatlantic "MRA on telecommunications and information technology products would save over \$1.1 billion in costs for US manufacturers and consumers each year." See John Sullivan Wilson, *Eliminating Barriers to Trade in Telecommunications and Information Technology Goods and Services: Next Steps in Multilateral and Regional Liberalisation Efforts*, in OECD PROCEEDINGS: REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS 131, 141 (1996). See also Stern, *The Trans-Atlantic Business Dialogue*, *supra* note, at 161 (citing same figure from TABD). Other estimates were more modest, but still considerable. See e.g. DAVID VOGEL, *BARRIERS OR BENEFITS: REGULATION IN TRANSATLANTIC TRADE* (1997), at 12 (citing figure of \$172 million saved); and Egan, *Constructing a European Market*, *supra* note (citing a figure of \$47 billion in transatlantic trade affected by 1997 MRA).

⁴³ See Rebecca Steffenson, *Regulating the Transatlantic Marketplace: The EU-US Mutual Recognition Agreements*, paper prepared for ECSA Conference 2001, at 2.

⁴⁴ See Egan, *Mutual Recognition and Standard Setting*, *supra* note 29, at 187-188. In June 1991, the Commission and U.S. Department of Commerce signed an agreement in principle to allow specified US certification laboratories to test the conformity of US products to Community standards." See GEORGE BERMANN, ROGER GOEBEL, WILLIAM DAVEY, ELEANOR FOX, *EUROPEAN COMMUNITY LAW* 446 (1993).

⁴⁵ Underwriters Laboratory, the largest U.S. private laboratory, acquired a number of European laboratories in the 1990s. In 199-, a UK subsidiary of Underwriters Laboratory became a notified body in the United Kingdom. Cites

⁴⁶ See e.g. Section VII of the Telecommunication Equipment Annex.

⁴⁷ See Rebecca Steffenson, *EU-US Mutual Recognition Agreements*, *supra* note 44, at 12 (concerning the role of different actors in the negotiations).

⁴⁸ See Gary P. Yerkey, *U.S. Official Accuses Europeans of Stalling Progress on MRAs*, 13 INT'L TRADE REP. (BNA) 1246 (July 31, 1996). Gary P. Yerkey, *U.S., EU Still Have "Serious Difficulties" to Overcome in MRA Discussions, Aide Says*, 14 INT'L TRADE REP. (BNA) 490 (March 12, 1997). See also Egan, *Mutual Recognition and Standard Setting*, *supra* note, at 191.

⁴⁹ Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified as amended in sections of 21U.S.C. § 301-394 (supp. 1997)) See in particular FFDCA, sec. 383(c). Even earlier, "the Safe Medical Device Act of 1990 called for the

establishment of the Office of International Relations (within FDA) to promote, inter alia, mutual recognition.” John Chai, *Medical Device Regulation in the United States and the European Union: A Comparative Study*, 55 FOOD & DRUG L.J. 57, 75 (2000). See also Egan, *Mutual Recognition and Standard Setting*, *supra* note at 191.

⁵⁰ See FFDCa, sec. 383(c)(2). Nonetheless, under a Memorandum of Understanding between USTR and FDA, “FDA speaks for the government on discussions relating to FDA’s regulatory responsibilities and authority, in both the Joint Committee under the umbrella agreement and in the Joint Sectoral Committees for drugs and devices.” Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 SETON HALL L. REV. 692, 735 (1998)

⁵¹ Sir Leon Brittan, *Transatlantic Economic Partnership: Breaking down the hidden barriers*, in TRANSATLANTIC REGULATORY COOPERATION (George Bermann, et al. eds., 2000), at 13.

⁵² TEP is the acronym for the Transatlantic Economic Partnership, a follow-up to the New Transatlantic Agenda signed in May 1998. The Senior Level Group was responsible for overseeing EC-U.S. relations and consisted of The TEP Steering Group took primary responsibility for trade and investment issues and consisted of... See POLLACK AND SHAFFER, TRANSATLANTIC GOVERNANCE, *supra* note..., at 16.

⁵³ See e.g. Gary Yerkey, *Standards: U.S., Europe Near Agreement on Plan to Boost Trade in Marine Safety Equipment*, 19 INT’L TRADE REP (BNA) 313 (Feb. 21, 2002) (citing October 2001 TABD report).

⁵⁴ A single product may be covered by more than one annex. For example, some telecommunication equipment may be subject to the annexes on telecommunication equipment, electromagnetic compatibility, electrical safety.

⁵⁵ The sole minor exception to date is the mutual recognition agreement on marine equipment initialed in June 2001. Although the United States and EC signed a Veterinary Equivalency Agreement in 1998 which sets a framework under which authorities may accept each other’s standards as equivalent, this agreement has yet to be put into operation. The Veterinary Equivalence Agreement is more accurately viewed as a framework for future dialogue so that regulators may gain trust in each other’s systems and decisions. Interview with Commission official in DG Consumer Affairs, Brussels, June 15, 2001 (official attends meetings of the management committee of this agreement).

⁵⁶ The advantage for firms under the 1997 MRA is that once a product is certified in the exporting country to conform to the standards set by the importing country, it need not be re-certified after importation. In theory, this could save testing, shipping and packaging costs and perhaps lead to mutual recognition of substantive standards.

⁵⁷ For example, Section VII.2 of the Telecommunications equipment annex provides for post-market surveillance (including via labeling and numbering requirements) and border and internal checks, provided that the latter are not done in a discriminatory manner. See also *infra* note... (re controls under the pharmaceutical GMP annex).

⁵⁸ Confirmed by representative of OSHA concerning the electrical safety annex, telephone interview on June 7, 2001, and by officials in DG Enterprise, June 15, 2002, Brussels.

⁵⁹ Different units of DG Enterprise are responsible for implementation of all internal “single market” directives concerning industrial products, so that DG Enterprise is the European counterpart of U.S. regulatory authorities in these domains.

⁶⁰ In addition, under the telecommunications annex, both parties agree to recognize quality assurance certificates of the other body. This function is not included in the Electromagnetic Compatibility Annex since it is not required in Europe. Telephone interview with Joe Dhillon,

of the National Institute for Standards and Technology (NIST) of the U.S. Department of Commerce, June 7, 2001. See compare list of functions in Section III of both annexes.

⁶¹ Each EC member state has identified a ministry or delegated body which acts as the designating authority for Conformity Assessment Bodies located within it. The U.S. designating authority is the National Institute for Standards and Technology (NIST) of the U.S. Department of Commerce, which works in conjunction with the FCC for these annexes. Telephone interview with Mary Sanders of NIST, June 6, 2001.

⁶² Interview with Joe Dhillon, *supra* note..., June 7, 2001.

⁶³ See list available at *Mutual Recognition Agreements* (visited March 7, 2002) <http://europa.eu.int/comm/enterprise/international/indexb1.htm#intro>.

⁶⁴ Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity, and interpretation thereof.

⁶⁵ See e.g. Annex IX of the 1998 Telecom Directive, *supra* note...

⁶⁶ Competent bodies are similar to notified bodies, but issue only opinions as opposed to assessment certificates. They are likewise accredited pursuant to member state procedures. In the context of the U.S.-EC MRA, U.S. Conformity Assessment Bodies may perform the roles of “competent bodies” for U.S. products marketed in the EC, on account of the electromagnetic compatibility annex.

⁶⁷ Nonetheless, as Majone points out, a well-functioning market in telecoms will nonetheless still require institutional adaptations. See Majone, *International Regulatory Cooperation: A Neo-Institutionalist Approach*, *supra* note... at 135.

⁶⁸ One Commission official, for example, characterizes OSHA’s system as “antiquated.” Interview with Commission official from DG Enterprise, June 15, 2001 in Brussels.

⁶⁹ Products must receive such certification in order to receive the “CE mark” and thereby be freely marketed within the EC. See *supra* note...

⁷⁰ See *infra* note...

⁷¹ Appendix 2 of the medical device annex specifies that the agreement only covers class 1 products (such as bandages) and certain listed class 2 products. FDA can expand this list following its review of a “pilot program,” although in no case does the agreement cover “any US Class II-tier 3 or any Class 3 product.” FDA categorizes medical devices under three classes, while the EC divides them into four. See John Chai, *Medical Device Regulation in the United States and the European Union: A Comparative Study*, 55 FOOD & DRUG L.J. 57-60 (2000) (providing an overview of these classification systems).

⁷² This is unlike any of the other annexes, subject to one’s interpretation of the Electrical Safety Annex. In particular, the FDA is concerned by what it finds to be laxer conflict-of-interest rules in Europe in a context in which private bodies henceforth will be paid by the manufacturing firms that they are testing, and on whose data the FDA is to rely. See Chai, *Medical Device Regulation*, *supra* note..., at 65. FDA officials also note some problems within Europe based on approvals by notified bodies in one jurisdiction resulting in harm in another, such as in regards to breast implants. FDA thus remains more wary than the FCC and Coast Guard in respect of annexes under its authority. Telephone interview with FDA official, June 8, 2001.

⁷³ See Gary Yerkey, *Standards: U.S., Europe Near Agreement on Plan to Boost Trade in Marine Safety Equipment*, 19 INT’L TRADE REP (BNA) 313 (Feb. 21, 2002).

⁷⁴ (Although the FDA has trained and inspected Conformity Assessment Bodies in conducting

U.S. quality system evaluations, FDA had yet to train them to conduct pre-market 510k approvals by mid-2001. However, FDA may do so in the future, pending results of its pilot program. Telephone interview with FDA official, June 8, 2001.)

⁷⁵ Articles 11 and 12 of the annex provide that “reports prepared by the CABS listed as equivalent will normally be endorsed by the importing Party, except under specific and delineated circumstances” (listing a number of examples).

⁷⁶ See Article 20 of the medical device annex.

⁷⁷ This is the EC’s definition, taken from Council Directive 91/356/EEC and included in article 1.3 of the annex. The United States’ definition is more verbose, and covers “the requirements found in the respective legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.” Both of these definitions are included in article 1.3 of the annex, with the indication “The US and EC have agreed to revisit these concepts,” which indication has since been eliminated.. Interview with Commission official from DG Enterprise, June 18, 2001. Linda Horton of the FDA provides a more succinct version of the U.S. description of GMPs as follows: “GMPs are practices and procedures for manufacturing, processing, and packing... products to ensure their quality and purity.... GMP regulations are based on the premise that finished product testing cannot suffice and that safety and quality must be built into products.” Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 Seton Hall L. Rev. 692, 697 (1998). The parties already have harmonized, to a certain extent, their practices in respect of GMPs. See e.g. 1990 U.S.-EC Memorandum of Understanding, discussed in David Vogel, *The Globalization of Pharmaceutical Regulation*, 11 GOVERNANCE, 1, 10 (Jan. 1998).

⁷⁸ The pharmaceutical GMP annex is the only annex not to be based on the use of private Conformity Assessment Bodies, since public authorities alone certify pharmaceutical manufacturers’ GMPs on each side of the Atlantic under relevant U.S. and EC legislation. Thus, the annex provides for “inspection reports generated by authorities” (i.e. public ministries), provided that the parties deem them to be equivalent “in terms of quality assurance of the products and consumer protection” (article 6).

⁷⁹ These could be “pre-approval inspections” (i.e. before a product is first marketed) or “post-approval inspections” (i.e. after a product is first marketed).

⁸⁰ Interview with Commission official from DG Enterprise, June 18, 2001.

⁸¹ See article 2 (Purpose). In other words, the agreement itself does not recognize the “equivalence” of the parties’ regulatory systems for purposes of evaluating “good manufacturing practices,” but rather provides for a three-year transitional period during which the parties’ regulatory authorities aimed to make this determination.

⁸² The member state implementing legislation was translated for FDA at the Commission’s expense. Interview with Commission official in DG Enterprise, June 18, 2001.

⁸³ Telephone interview with FDA official, June 7, 2001.

⁸⁴ See *Enterprise Policy* (visited Feb. 23, 2002) http://europa.eu.int/comm/enterprise/enterprise_policy/index.htm.

⁸⁵ The two targeted states were the United Kingdom and Ireland, with some indication from FDA that France and Germany would be reviewed next.

⁸⁶ Article 11 of the annex does contemplate that FDA may not approve all member state

systems as “equivalent,” at least by the end of the transition period, in which case FDA agreed to “accept for normal endorsement... inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent,” provided further that enforcement of the inspections’ findings would be guaranteed. However, as Commission officials state, the EC did not contemplate that one or two member state regulatory authorities would engage in all fifteen member states. Interview with Commission official in DG Trade, June 13, 2001.

⁸⁷ The relevant EC legislation is Council Directive 96/98/EC of 20 December 1996 on marine equipment, as amended by Commission Directive 98/85/EC. This directive is based on the “new approach” and “global approach.” The relevant U.S. legislation is 46 U.S.C. 3306, as implemented in 46 CFR Parts 159-165. The relevant regulatory authorities are the U.S. Coast Guard and the relevant agencies in the fifteen member states.

⁸⁸ Interview with Commission official in DG Trade on June 13, 2001 in Brussels.

⁸⁹ Since the MRA telecommunications and electromagnetic compatibility annexes rely on recognition of foreign Conformity Assessment Bodies, the United States (at a minimum) needed to adopt a program permitting the use of private testing laboratories were it to enter the MRA.

⁹⁰ See John Chai, *Medical Device Regulation in the United States and European Union: A Comparative Study*, 55 Food & Drug L. J. 57, 60 (2000). See also MICHELLE EGAN, CONSTRUCTING A EUROPEAN MARKET: STANDARDS, REGULATION AND GOVERNANCE 195 (2001) (“many multinational firms are pursuing a Europe-first marketing strategy” because “European governments are able to approve advanced medical devices more than three times faster than the FDA)..

⁹¹ See 21 U.S.C.A. 360(m). See also Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 SETON HALL L. REV. 692, 707 (1998) (providing overview of FDA pilot program and its codification and expansion under the FDA Modernization Act. Nonetheless, as Horton points out, FDA continues to decide which devices are eligible, accredits the participating bodies, and makes final approval decisions in all cases. *Id.* As Chai states, “The utilization of private third parties is limited to their role in the preliminary assessment of low- and medium-risk devices. FDA gives the manufacturers the option of engaging qualified third-parties in the 510(k) submissions of the applicable devices.” John Chai, *Medical Device Regulation in the United States and the European Union: A Comparative Study*, 55 FOOD & DRUG L.J. 57, 63 (2000).

⁹² Interview with FCC official, June 8, 2001. EC officials state that deregulation was likely not the initial goal with the MRA, but agree that this goal has become more central for firms. Interview with two officials from DG Enterprise, June 15, 2001, in Brussels.

⁹³ TABD, *2001 Mid Year Report*, at 2 and 14. (visited March 10, 2002) www.tabd.org/recommendations/MYM01.pdf

⁹⁴ Firms, of course, also maintain that such regulatory flexibility, in turn, benefits consumers on account of enhanced innovation and competition.

⁹⁵ OSHA has long been challenged by U.S. business which has been partially successful in preventing OSHA from efficiently doing its job. As Terry Moe writes, “Interest groups representing business actually did participate in the design of OSHA,... (and) OSHA is an administrative nightmare, in large measure because some of its influential designers fully intended to endow it with structures that would not work.” Terry Moe, *The Politics of Structural Choice: Toward a Theory of Public Bureaucracy*, in ORGANIZATION THEORY, 116

(ed. Oliver Williamson: 1990).

⁹⁶ See Council Directive 73/23/EEC of February 1973 as amended by Directive 98/13/EC of the European Parliament and of the Council.

⁹⁷ On differences between the U.S. Administrative Procedure Act and EC administrative law, see e.g. Martin Shapiro, *Codification of Administrative Law: The US and the Union*, 2 EUROPEAN L. J. 26 (March 1996); and Francesca Bignami, *The Democratic Deficit in European Community Rulemaking: A Call for Notice and Comment in Comitology*, 40 HARVARD INT'L L. J. 451 (1999). Other U.S. legislation of interest to business includes the 1993 Government Performance and Results Act and the 1995 Unfunded Mandates Act. The Unfunded Mandates Act creates procedural hurdles for Congress to impose new requirements on local regulators without providing federal funds. The Government Performance and Results Act requires agencies to justify funding that they receive, with the implied threat that funding will be reduced if they do not perform efficiently (a form of agency cost/benefit analysis).

⁹⁸ TABD, 2001 Mid Year Report, *supra* note..., at 14.

⁹⁹ *Id.*, at 16 (also adding “Business consultation and the consultation of other interested stakeholders should be part of the assessment process”). In addition, TABD proposes that all regulation be subject to a separate “‘trade impact statement’ at the cost-benefit analysis phase of regulatory activities and in the development of legislation.” 2001 Mid Year Report, *supra* note..., at 8.

¹⁰⁰ Draft agreement on file with author.

¹⁰¹ See Kalypso Nicolaidis, *Mutual Recognition of Regulatory Regimes: Some Lessons and Prospects*, in OECD PROCEEDINGS: REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS 171, 191 (1996).

¹⁰² See David Leebron, *Mutual Recognition: Structure, Problems and Prospects*, in OECD PROCEEDINGS: REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS 205, 215 (1996).

¹⁰³ See Kalypso Nicolaidis, *Managed Mutual Recognition: The New Approach to Liberalization of Professional Services* at ¶ 97 (visited March 11, 2001) <http://www.ksg.harvard.edu/prg/nicolaidis/managemr.htm#IV>.

¹⁰⁴ See *supra* note... The transatlantic MRA, of course, was also signed in the context of these other negotiations.

¹⁰⁵ Firms view self-certification as an even more important goal in countries where regulatory certification requirements result in significant delays or protection for domestic competitors.

¹⁰⁶ See *supra* note...

¹⁰⁷ See Mark Pollack and Gregory Shaffer, *The Challenge of Reconciling Regulatory Differences: Food Safety and GMOs in the Transatlantic Relationship*, in TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY 156 (2001).

¹⁰⁸ On data privacy protection, see *infra* notes..., and Gregory Shaffer, *Globalization and Social Protection: The Impact of EU and International Rules in the Ratcheting Up of U.S. Privacy Standards*, 25 YALE J. INT'L L. 1 (2000). For service sectors, U.S. state regulation is often more significant than federal regulation, adding further complications.

¹⁰⁹ See Egan, *Mutual Recognition and Standard Setting*, *supra* note..., at 199.

¹¹⁰ It is sometimes maintained that the U.S. provides greater flexibility for firms to set standards through self-regulation or through the competitive market place, subject to *ex post* review under tort law, while the EC takes a more precautionary *ex ante* approach, setting

more stringent standards overseen by regulatory bodies. *See e.g.* Michelle Egan, *Constructing a European Market: Standards, Regulation and Governance* 131 (2001) (calling the EC system more “state-directed” and the U.S. system more “market-oriented”). The divergent approaches of the United States and EC to data privacy protection, genetically modified foods and hormone-injected beef also reflect this perception. *See* Shaffer, *Ratcheting Up U.S. Privacy Standards*, *supra* note; Mark Pollack and Gregory Shaffer, *Food Safety and GMOs in the Transatlantic Relationship*, *supra* note...

¹¹¹ See discussion of new FDA pilot program in *supra* note...

¹¹² *See* Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 SETON HALL L. REV. 692, 708 (1998) (noting the 1998 FDA Modernization Act, calling on FDA to “participate... with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements”).

¹¹³ Richard Merrill, *The Importance and Challenges of “Mutual Recognition,”* 29 SETON HALL L. REV. 736, 743 (1998). Similarly, Linda Horton of the FDA writes, “it is the opinion of the author that no other country has a drug or medical device approval system as rigorous as that of FDA.” Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 SETON HALL L. REV. 692, 706 (1998).

¹¹⁴ In contrast, even if European regulatory bodies submit documents to U.S. regulatory authorities in English, the texts can be far from fluent.

¹¹⁵ In fact, only one U.S. laboratory, Underwriters Laboratory, has applied to be a U.S. Conformity Assessment Body under this annex, primarily because there is, in fact, little market demand for new notified bodies in this sector. Telephone interview with Joe Dhillon, *supra* note..., June 7, 2001. U.S.-based firms have long used U.S.-based laboratories operating under sub-contracting arrangements with EC notified bodies, which the EC permits. Firms prefer to enter into long-term relationships with a laboratory that understands their products and thus are not interested in changing current arrangements if they function effectively. In addition, in some cases, the commercial mark of the EC notified body may remain important for marketing purposes.

¹¹⁶ OSHA simply has not wished to be forced to accept, without significant review, applications forwarded to it by fifteen different member state authorities, all or part of which may be in any one of the EC’s eleven official languages. Telephone interview with OSHA official, June 7, 2001.

¹¹⁷ Of the initial proposals only three remain, one each submitted by Germany, France and the UK.

¹¹⁸ The Electrical Safety annex reads that European member state authorities (defined as “EC Designating Authorities,” of which there is one for each state) “shall designate conformity assessment bodies located in the EC” and that “OSHA shall rely on (these EC designating authorities) for conducting on-site reviews at the respective Member States’ conformity assessment bodies.” The same article provides, however, that OSHA shall “give notice of its consent or objection to a proposed conformity assessment body... within 120 business days,” implying that OSHA has the final say over these bodies’ designation. Section VI of the Annex further provides that OSHA shall determine “whether the proposal is complete... and give notice of its consent or objection.” OSHA returned all three applications on the grounds that they were insufficient, either because they needed to be translated, or because more information was required. Once OSHA accepts an EC-designated conformity assessment body, that body “shall have NRTL status in the US” for U.S. regulatory purposes. Similarly, a

U.S.-designated conformity assessment body “shall have Notified Body status within the EC.”

¹¹⁹ EC member state regulatory authorities coordinate a system of post-market surveillance in which they interact via periodic meetings and regular e-mail and telephone interaction. For example, they exchange information to implement sales bans of at least three hundred electrical safety products per year. EC authorities believe that member state regulators interact at least as much as local OSHA representatives in the U.S. context. Interview with representative of DG Enterprise, June 13, 2001.

¹²⁰ Approximately 90% of these standards are set by the International Electrotechnical Commission (IEC). Interview with Commission representative in DG Trade, June 13, 2001.

¹²¹ This laboratory is called a Nationally Recognized Testing Laboratory (or NRTL), meaning that it has been recognized by OSHA. Under the MRA, EC Conformity Assessment Bodies are to be recognized as NRTLs.

¹²² Interview with official in DG Enterprise, June 15, 2001 in Brussels.

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ The directive covering most medical devices is Council Directive 93/42 EEC of 14 June 1993 concerning medical devices. In addition, the EC has adopted two specific directives, Council Directive 90/385/EEC of 20 June 1990 relating to active implantable medical devices, and Council Directive 98/79/EC on In Vitro Diagnostic medical devices. See John Chai, *Regulation of Medical Devices in the European Union*, 21 J. LEGAL MED. 537 (Dec. 2000).

¹²⁶ Increasingly, EC firms appear to choose quality systems evaluations pursuant to which notified bodies evaluate the overall manufacturing process, and not specific products. Interview with Commission official from DG Enterprise, June 16, 2001 (pointing out that enterprises producing a range of products tend to prefer a quality system evaluation approach. Since quality system evaluations are also based on international ISO 9000 standards, firms selling in foreign markets may also benefit from them. Those manufacturers that produce only a single product line predominantly for the EC market may continue to prefer what the EC refers to as “type examination and verification reports.”). Chai notes that “Mandatory individual device review under the EU system is necessary only for the devices with the highest risk potential.” Chai, *Medical Device Regulation*, *supra* note.. , at 68.

¹²⁷ As Chai notes, “Most Class II devices are subject to the 510(k) premarket notification— the process to verify the substantial equivalence of a product to a predicate device in terms of its safety and effectiveness.” John Chai, *Medical Device Regulation in the United States and the European Union: A Comparative Study*, 55 FOOD & DRUG L.J. 57, 58 (2000). Similarly, as Linda Horton writes, “the review of the 510(k) looks principally at whether the device is substantially equivalent to one marketed already.” Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 SETON HALL L. REV. 692, 707 (1998). The agreement also covers a third set of reports called “post-market vigilance reports” (article 3). See description in Horton, at 732.

¹²⁸ Telephone interview with FDA official, June 7, 2001.

¹²⁹ See e.g., *U.S.-EU Mutual Recognition Agreement (MRA)- Congressional Hearing* (visited March 11, 2002) <http://www.citizen.org/trade/harmonization/MRA/articles.cfm?ID=6156>.

¹³⁰ Telephone interviews with officials from FDA, OSHA and NIST on June 7. Interviews with Commission officials in Brussels from DG Enterprise, June 15, 2001.

¹³¹ Firms and laboratories have adapted over time to differing U.S. and EC regulatory

requirements through entering into sub-contracting arrangements. Some U.S. manufacturers state that it is cheaper for them to use a notified body, with testing conducted through a sub-contracting arrangement, than to use a Conformity Assessment Body. Moreover, firms continue to predominantly use free FDA inspections in the United States, even though they now are authorized to use private testing bodies. Interview with FDA official, June 8 2001.

¹³² Interview with Commission official from DG Enterprise, June 15, 2001 in Brussels (concerning medical devices).

¹³³ Interview with official from DG Enterprise, June 15, 2001, in Brussels.

¹³⁴ Minutes from the Thirteenth US/EU MRA Medical Device Annex Stakeholders Teleconference (Nov. 7, 2001) (on file with author). The need for promotional efforts also confirmed in interviews with Commission officials in DG Enterprise, June 2001. Commission officials also confirm that they will likely subsidize some efforts to promote some of the MRA annexes, in particular those in which they feel U.S. regulators are cooperating.

¹³⁵ See e.g. TABD Mid Year Report, at 43.

¹³⁶ The agreement was formalized through an exchange of letters between Robert LaRussa, the Acting Secretary of the Department of Commerce and John Mogg, the Director of DG Internal Market (formerly DG XV) in the European Commission. See Joel R Reidenberg, *E-Commerce and Trans-Atlantic Privacy*, 38 HOUSTON L. REV. 717, 739 (2001).

¹³⁷ See e.g. Aaron Lukas, *Safe Harbor or Stormy Waters? Living with the EU Data Protection Directive* 16 Trade Briefing Papers (CATO Institute Center for Trade Policy Studies), Oct. 30, 2001; and Mark Cutler, *Information Technology: Lawyers Say U.S., EU on Collision Course over E-commerce as Competitiveness Issues*, 18 INT'L TRADE REP (BNA) 1868 (Nov. 22, 2002) (arguing that EU laws "inhibit the ability of U.S. companies to compete within the EU"). See generally Greg Shaffer, *Globalization and Social Protection: The Impact of EU and International Rules in the Ratcheting Up of U.S. Privacy Standards*, 25 YALE J. INT'L. L. 1, 70-78 (2000) (citing U.S. business reactions to the Directive).

¹³⁸ See e.g., Joel R Reidenberg, *E-Commerce and Trans-Atlantic Privacy*, 38 HOUSTON L. REV. 717, 743-746 (2001).

¹³⁹ Some commentators have distinguished an EC state-based approach to a U.S. market-based approach. See e.g. Egan, *Constructing a European Market*, supra note..., at 131. Yet, this is an overstatement, for as shown above, the EC itself has adopted novel institutional means to reconcile free movement of goods and social protection through the EC's new and global approaches to harmonization, which include self-certification and oversight by self-regulatory organizations.

¹⁴⁰ The Directive was negotiated within the context of the threat of data transfer bans from certain member states with protective data privacy laws (such as France and Germany) to other member states with less stringent laws (such as Italy). By requiring similar data privacy protection throughout the European Union, the Directive concurrently removed the threat to unhindered data flows between member states. To ensure the economic benefits of trade liberalization through the creation of a single market, EC member states collectively agreed to guarantee more stringent protections of data privacy. See Greg Shaffer, *Globalization and Social Protection: The Impact of EU and International Rules in the Ratcheting Up of U.S. Privacy Standards*, 25 YALE J. INT'L. L. 1 (2000).

¹⁴¹ The above figures are from the prepared testimony of Assistant Secretary of Commerce Franklin Vargo before the House Committee on International Relations. See 'Issues in U.S.-European Union Trade: European Privacy Legislation and Biotechnology/Food Safety

Policy,' *Federal News Service* (May 7, 1998).

¹⁴² The United States increasingly negotiates with the EC as an independent political institution apart from its fifteen member states. As Assistant Secretary of Commerce Franklin Vargo states, the New Transatlantic Agenda signed between the U.S. and EC in December 1995 "marks the first time that we are dealing with the EC as a political institution on a large scale." *Id.*

¹⁴³ As Joel Trachtman states, "(s)overeignty, viewed as an allocation of power and responsibility, is never lost, but only reallocated." A "loss" of sovereignty "may be viewed as a question of what is received, and by whom, in exchange for a reduction in the state's sovereignty, rather than simply a question of whether sovereignty is reduced." Joel Trachtman, '*Reflections on the Nature of the State: Sovereignty, Power and Responsibility*,' 20 CAN.-U.S. L. J. 399 (1994).

¹⁴⁴ See Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L 281) 1 (hereinafter Directive).

¹⁴⁵ In many cases, Congress has simply reacted to public scandals. In passing the Fair Credit Reporting Act, it responded "to consumer horror stories of dealings with credit reporting agencies." It enacted The Video Privacy Protection Act after the video rental records of Judge Robert Bork were published by a news reporter in the course of a campaign against his Supreme Court nomination.

¹⁴⁶ The fragmented, decentralized nature of the U.S. regulatory process is described in STEVEN VOGEL, *FREER MARKETS, MORE RULES: REGULATORY REFORM IN ADVANCED INDUSTRIALIZED COUNTRIES*, 217 (1996).

¹⁴⁷ See Robert Kagan, *How Much Do National Styles of Law Matter*, in *REGULATORY ENCOUNTERS: MULTINATIONAL CORPORATIONS AND AMERICAN ADVERSARIAL LEGALISM*, (Robert Kagan & Lee Axelrod eds.2000), at 11.

¹⁴⁸ The Privacy Act of 1974 is the only federal omnibus act that protects informational privacy. Yet despite the legislation's broad title, the Privacy Act only applies to data processing conducted by the federal government, not by state governments or private entities. The vast majority of states lack omnibus privacy acts, and rather offer scattered statutes applying to specific sectors or concerns.

¹⁴⁹ In July 1998, the Working Party incorporated earlier papers in a Working Document entitled *Transfers of personal data to third countries: Applying Articles 25 and 26 of the EU data protection directive*.

¹⁵⁰ Privacy International, a London-based privacy organization, has threatened to file claims against American Express and EDS for failing to provide adequate data privacy protection. See 'Will Amex and EDS Face Privacy Lawsuits in Europe?,' *Computergram Int'l*, July 2, 1998.

¹⁵¹ See Fred Cate, *The EU Data Protection Directive, Information Privacy, and the Public Interest*, 80 IOWA L. REV. 431, 438 (1995) (citing prohibitions on data transfers to the U.S. from Britain (involving sales to a direct mail organization) and France (involving patient records)); David E. Kalish, 'U.S. Firms Fear Impact of EU Privacy Law,' *The Record* (Bergen County, NJ) Oct. 29, 1998 (concerning American Airlines appeal of a Swedish court ruling that bars it from transferring data from Sweden to its U.S. electronic reservation system without first obtaining customer consent); Christopher Kuner, *Beyond Safe Harbor: European Data Protection Law and Electronic Commerce*, 35 INT'L LAWYER 79,84 (2001) (concerning

Spain's fine levied on Microsoft Iberica SRL).

¹⁵² The Safe Harbor Principles were approved by the Council of Ministers, but rejected by the European Parliament. However, under applicable EC law, Parliament's rejection did not affect the EC's acceptance of the Principles through the Commission's final decision.

¹⁵³ Telephone interviews with Barbara Wellbery of the law firm Morrison & Forester (previously with the Department of Commerce) and Robert Gellman (independent privacy consultant), June 5, 2001.

¹⁵⁴ See *US Department of Commerce: Safe Harbor* (visited April 2, 2002) <http://www.ita.doc.gov/ecom>.

¹⁵⁵ To the extent U.S.-based firms gather information on-line from web sites in Europe, they may be subject to enforcement in Europe under the Directive despite their signing onto the Safe Harbor Principles, an issue about which U.S. and EC authorities have argued, but which remains unresolved. See Joel R Reidenberg, *E-Commerce and Trans-Atlantic Privacy*, 38 HOUSTON L. REV. 717, 743 (2001) (citing inter alia EC Article 29 working group report maintaining that EC authorities have jurisdiction over such activities).

¹⁵⁶ See Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(6). The Safe Harbor Principles provide that where "an organization relies in whole or in part on self-regulation, its failure to comply with such self-regulation must also be actionable under Section 5 of the Federal Trade Commission Act." Cf Joel R Reidenberg, *E-Commerce and Trans-Atlantic Privacy*, 38 HOUSTON L. REV. 717, 740-741 (2001) (questioning whether FTC has jurisdiction to protect foreign consumers).

¹⁵⁷ In the fall of 1998, the FTC brought an enforcement action against Geocities, which has "one of the most popular sites on the Web," for having suggested that GeoCities was collecting personal information, when the personal information was rather going directly to third parties. In 1999, the FTC announced a second enforcement action against Liberty Financial Companies, Inc., operator of the Young Investor Web site, for falsely representing that information collected would be maintained anonymously. Another complaint was brought by the FTC against the online auction site ReverseAuction.com, which resulted in a consent agreement in January 2000. A description of these cases is set forth in Letter from the FTC to John Mogg, Director of DG Internal Market (formerly DG XV) of the European Commission, dated July 14, 2000.

¹⁵⁸ The drafting, reception of public comments, and revisions of the Safe Harbor Principles are analogous to negotiated rule making in U.S. administrative law. Yet here, the negotiated rule making was of a peculiar variety. The Safe Harbor Principles are not intended, on their face, to affect U.S. law, but rather to provide a "safe harbor" to companies in respect of a foreign law, the EC Directive. Domestic parties, however, are aware of the spill-over effects these principles will have on data privacy policy and practice in the United States. While U.S. companies are not—technically—forced to adopt them, most large businesses take them into account even if they do not formally certify that they are adopting them, in order to avoid EC restrictions on data transfers. Moreover, large businesses generally do not wish to be found in violation of law, since they are concerned about reputational effects in the product and capital markets.

¹⁵⁹ See Anandashankar Mazumdar, *European Commission Gives Final Approval to Model Clauses to Protect Personal Data*, 19 INT'L TRADE REP (BNA) 187 (Jan. 31, 2002). The Commission will likely supplement this universal model contract with other models tailored for transfers of specific types of information. Interview with Fabrizia Benini, DG Internal

Market, June 13, 2001, in Brussels.

¹⁶⁰ FTC jurisdiction does not cover the financial sector, so that other U.S. federal agency, such as the Office of the Comptroller of the Currency, would have to have the authority to make a similar commitment to the Commission to give priority attention to referrals. *See e.g.* Joel R Reidenberg, *E-Commerce and Trans-Atlantic Privacy*, 38 HOUSTON L. REV. 717, 743 (2001) (concerning FTC's limited competence).

¹⁶¹ The content of the model contract ended up going far beyond both the relevant U.S. legislation (under the Gramm-Leach-Bliley Act) and the Safe Harbor Principles. *See* Joe Kirwin, *EC Dismisses U.S. Worry that 'Model Contract' Will Hurt Safe Harbor Talks*, 18 INTL. TRADE REP (BNA) 537 (April 5, 2001).

¹⁶² These contracts also place ongoing pressure on U.S. firms because it means that, in order to comply with the model contract, either they will treat EC citizens more favorably than U.S. residents (subjecting themselves to political criticism) or they will have to harmonize upwards their privacy policies within the United States.

¹⁶³ *See* Letter from Robert LaRussa of the U.S. Department of Commerce to John Mogg, Director of DG Internal Market (formerly DG XV) of the European Commission, dated July 17, 2000 at *US Department of Commerce Safe Harbor* (visited April 2, 2002) <http://www.export.gov/safeharbor>.

¹⁶⁴ *See e.g.* announcement of Microsoft... As of June 13, 2001, fifty two companies had certified. As of February 23, 2002, the number of certifications had expanded to one hundred fifty six. *See US Department of Commerce: Safe Harbor* (visited February 23, 2002) <http://www.export.gov/safeharbor>.

¹⁶⁵ *See* PETER SWIRE & ROBERT LITAN, NONE OF YOUR BUSINESS, WORLD DATA FLOWS, ELECTRONIC COMMERCE, AND THE EUROPEAN PRIVACY DIRECTIVE 170 (1998).

¹⁶⁶ Telephone interview with Gary Laden, Director BBB OnLine Privacy Program, April 21, 1999.

¹⁶⁷ The Electronic Frontier Foundation's web site is located at <http://www/eff.org>. The TRUSTe web site is at <http://www.truste.org>.

¹⁶⁸ *See Web Trust: Online Businesses* (visited April 2, 2002) <http://www.cpawebtrust.org/online.htm>.

¹⁶⁹ Telephone interview with Charles Prescott, Direct Marketing Association, June 6, 2001 (noting that their survey showed that about half of their catalogue companies (representing 500 companies) worked with overseas orders, meaning that they would need to take account of the Directive and Safe Harbor Principles). *See also* Commission Staff Working Paper, *The application of Commission Decision 520/2000/EC of 26 July 2000 pursuant to Directive 95/46 of the European Parliament and of the Council on the adequate protection of personal daata provided by the Safe Harbour Privacy Principles and related Frequently Asked Questions issued by the US Department of Commerce*, SEC(2002) 196 (Feb. 13, 2002) (referring to the Direct Marketing Safe Harbour Program).

¹⁷⁰ To give just one example, at a symposia on data privacy organized by Westin's group, the Center for Social and Legal Research, in the fall of 1998, over 170 people, primarily from corporate human resource departments, attended. Interview with Peter Swire in Washington D.C., March 26, 1999.

¹⁷¹ For example, Ira Magaziner, formerly responsible for U.S. discussions on electronic commerce issues, including privacy protection, stated that, "In general, we in the U.S. don't recognize an extra-territorial attempt to shut down the electronic flow of data between

countries. According to principles of international trade, I think that's a violation of WTO rules." Kenneth Cukier, 'U.S. Under Fire over 'Aggressive' Net Tax Stance,' *Comm. Wk. Int'l*, March 2, 1998.

¹⁷² For a fuller analysis, see Shaffer, *Globalization and Social Protection*, *supra* note..., at 46-55.

¹⁷³ For a brief assessment of whether the GATS or GATT would apply to this issue, see Shaffer, *Globalization and Social Protection*, *supra* note...

¹⁷⁴ See e.g., *Communication from The Appellate Body: United States – Import Prohibition of Certain Shrimp and Shrimp Products available in Westlaw*, 1998 WL 716669 (W.T.O).. Another relevant factor is that, under the Directive, individual companies meeting EC requirements may still transfer data to the United States despite the imposition of a general ban. For an overview and analysis of the Appellate Body shrimp-turtle decision, see Gregory Shaffer, *United States-- Import Prohibition of Certain Shrimp and Shrimp Products*, 93 AM. J. INT'L L. 507 (April 1999).

¹⁷⁵ As Kagan notes in his summary of case studies involving multiple industries, there is "evidence for a dynamic toward trans-national 'corporation-level' harmonization of regulatory compliance routines in multinational companies, keyed to compliance with the most stringent national standards (sometimes with a margin of error)." See Robert Kagan, *Consequences of Adversarial Legalism*, in REGULATORY ENCOUNTERS: MULTINATIONAL CORPORATIONS AND AMERICAN ADVERSARIAL LEGALISM, 374 (Robert Kagan & Lee Axelrod eds)..

¹⁷⁶ See Comments of Mark Silbergeld on the Department of Commerce, Draft Safe Harbor Principles on behalf of a number of privacy advocate organizations, at <http://www.ita.doc.gov/ecom/com1abc.html#silbergeld>.

¹⁷⁷ The Japanese counterpart is named JIPDEC, a public-private body working with the Japanese Ministry of Trade and Industry. Telephone interview with Gary Laden, Director BBB OnLine Privacy Program, June 6, 2001. The fifteen members of the Article 29 working group (of national data privacy authorities) came and met with BBB OnLine to see how self-regulation works within the U.S. setting. This, combined with the FTC's commitment to expeditiously pursue complaints referred to it by European authorities, helped seal the Safe Harbor deal.

¹⁷⁸ Such abstract undertakings are reflected in the NTA, the TEP and their action plans, as well as the draft U.S.-EU Guidelines/Principles on Cooperation and Transparency in Establishing Technical Resources which has been negotiated for years.

¹⁷⁹ Interview with official in DG Enterprise, June 15, 2001, Brussels.

¹⁸⁰ The Global Harmonization Task Force has created four study groups that respectively cover regulatory systems, postmarket vigilance, quality systems and auditing. To give one example the Global Harmonization Task Force has adopted an "Essential Principles of Safety and Performance of Medical Devices on a Global Basis" See Chai, *Medical Device Regulation*, *supra* note..., at 78. A Commission official confirms that this document is based on EC "essential requirements" set forth in the 1993 EC medical devices directive. Interview with Commission official in DG Enterprise, June 16, 2001.

¹⁸¹ This goal is specifically envisioned by the annex, which confirms the parties' intention to continue to participate in the Global Harmonization Task Force and to review whether the Task Force's work is "applicable to the (MRA's) implementation" (article 18).

¹⁸² See e.g. David Leebron, *Lying Down with Procrustes: An Analysis of Harmonization*

Claims, in 1 FAIR TRADE AND HARMONIZATION: ECONOMIC ANALYSIS 41 (Jagdish Bhagwati & Robert Hudec eds., 1996); and Daniel Esty in REGULATORY COMPETITION AND ECONOMIC INTEGRATION (Daniel C. Esty & Damien Geradin eds., 2000); and Daniel Esty, *Revitalizing Environmental Federalism*, 95 MICH. L. REV. 595 (1996).

¹⁸³ Some member state authorities perform on-site GMP inspections on behalf of all EC member states, in which case they are reimbursed by the EC. Their inspections are usually limited to new products that raise more concern, such as some biologicals. Interview with Commission official from DG Enterprise, June 18, 2001, Brussels.

¹⁸⁴ The key issue, of course, will be whether such products, on balance, pose more of a risk to consumers because of reduced regulatory oversight or offer greater health benefits on account of their more rapid availability.

¹⁸⁵ FDA officials also note that by freeing the FDA from having to conduct tests in Europe, FDA can allocate more resources to products produced elsewhere, such as “surgical gloves produced in Malaysia.” Telephone interview with FDA official, June 8, 2001.

¹⁸⁶ Merrill, *Challenges of Mutual Recognition*, *supra* note, at 744 (further noting “that resources have not kept pace with workload”). For example, the value of EC pharmaceuticals and medical devices imported into the United States nearly doubled in just three years between 1994 and 1997, resulting in only one FDA inspection for every \$60 million of imports. Sharon Smith Holston, *An Overview of International Cooperation*, 52 FOOD & DRUG L.J. 197, 198 (1997). Ms. Holston was FDA Deputy Commissioner for External Affairs.

¹⁸⁷ Comment of Ambassador David Aaron, formerly head of the international trade division of the U.S. Department of Commerce, Fiesole, Italy, July 6, 2001.

¹⁸⁸ Some regulators believe that these transition costs will be more than recouped, although others remain skeptical. In addition, the MRA’s impact on public safety remains an open question, as its implementation remains at an early stage. However, there has been no evidence of a threat to public health on account of the EC’s single market program, which arguably should also be the case with the transatlantic MRA. Nonetheless, considerable resources have been expended to implement the EC single market program, and the United States is so far unwilling to dedicate such resources to the MRA.

¹⁸⁹ Negotiation of both the 2000 Safe Harbor Principles and 1997 Mutual Recognition Agreement required considerable personnel time and government expense. The 1997 MRA magnifies these costs, since both parties retain separate standards and procedures and thus must train each other’s regulators and testing bodies in these standards and procedures. In the case of member state authorities and certification bodies from non-English speaking countries, especially from southern Europe, language issues create additional obstacles.

¹⁹⁰ Telephone interview with FDA official, June 7, 2002.

¹⁹¹ See Steffenson, *The EU-US Mutual Recognition Agreements*, *supra* note., at 22; See e.g. TACD Bruce Farquhar and Alex Donahue, Briefing Paper on Mutual Recognition Agreements 20 (September 2000) (on file with author) (citing U.S. General Accounting Office reports).

¹⁹² The EC training and approval process will involve a working group of (four) member state regulatory officials and representatives of DG Enterprise. Interview with Commission official from DG Enterprise, June 15, 2001.

¹⁹³ However, EC officials are unclear if the FDA is “merely playing games” with its assertions about resource constraints. EC officials point out that the EC has also signed an MRA on

pharmaceutical GMPs with Canada, and Canada has completed evaluation of all fifteen member state regulatory systems within a shorter transition period. The EC has signed MRAs concerning pharmaceutical GMPs with Australia, New Zealand, Canada, Switzerland and Japan. Unlike the MRA with the United States, under these MRAs the inspection reports are usually included by the manufacturer with its batch/lot certificate. Thus, the system will work in a more fluid manner, without direct exchanges of inspection reports between regulatory officials in most cases, although regulatory officials will retain the power to make such requests. Interview with Commission official, June 18, 2001, Brussels.

¹⁹⁴ There is, however, some move on the EC side to create independent regulatory authorities, such as the European Medical Evaluation Agency and a new European food authority, although these agencies will typically not have independent regulatory authority, at least to anywhere near the extent of their U.S. counterparts. However, EC political bodies have delegated much more limited powers to them. *See e.g.* Renaud Dehousse, *Regulation by networks in the European Community: the role of European agencies*, 4 J. OF EUROPEAN PUBLIC POLICY 246, 258 (1997) (“powers delegated to agencies are extremely limited”); Pollack and Shaffer, *Food Safety and GMOs in the Transatlantic Relationship*, in TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY, *supra* note..., at 159-160 (concerning new European food authority).

¹⁹⁵ *See* EGAN, CONSTRUCTING A EUROPEAN MARKET, *supra* note..., at 255. Similarly, the European Commission helped forge a “European Organization for Testing and Certification” (EOTC) in 1990 in order to “(1) coordinate testing and certification practices to prevent firms from having to undergo multiple market entry and approval requirements, and (2) develop a common European framework to encourage mutual confidence and trust in member countries regulatory and self-regulatory testing and certification practices.” *See e.g.* EGAN, CONSTRUCTING A EUROPEAN MARKET, *supra* note..., at 152.

¹⁹⁶ Although the United States is a federalist system under which states may retain separate regulatory regimes unless preempted by federal legislation, the areas covered by the 1997 Mutual Recognition Agreement largely have been federalized, with federal regulatory agencies overseeing federal regulations, a much different approach than the multi-level coordinative ones used in the EC.

¹⁹⁷ The inadequacies of regulation at the purely domestic level have already been noted. *Supra* note... However, participation in democratic decision-making at the national level is of a much higher quality because of the closer relation between the citizen and the state, the consequent reduced costs of organization and participation, and the existence of a sense of a common identity and of communal cohesiveness— that is, of a *demos* (a people). This Article does not address the design of procedural mechanisms to insure adequate monitoring of and input into transatlantic regulatory networks. Nonetheless, the Article highlights the central questions of identifying the appropriate balance between domestic and international decision-making processes, and designing international decision-making processes to enhance and not undermine democratic participation, oversight and control.

¹⁹⁸ *See e.g.* *U.S.-EU Mutual Recognition Agreement (MRA)- Congressional Hearing* (visited March 10, 2002)

<http://www.publiccitizen.org/trade/harmonization/MRA/articles.cfm?ID=6156>. Mary Bottari, Peter Lurie & Sidney M. Wolfe, *Public Citizen Comments on Pharmaceutical Annex to U.S.-EU Mutual Recognition Agreement* (visited March 10, 2002) <http://www.publiccitizen.org/trade/harmonization/MRA/articles.cfm?ID=4302>.

See also Steffenson, *Regulating the Transatlantic Marketplace*, *supra* note, at 22 (concerning reactions of the Transatlantic Consumer Dialogue (TACD) and of the Transatlantic Environment Dialogue (TAED). The TACD and TAEC consist of non-governmental organizations from both sides of the Atlantic. See Francesca Bignami and Steven Charnovitz, *Transatlantic Civil Society Dialogues*, in *TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY*, 255 (Pollack and Shaffer, eds. 2001).

¹⁹⁹ See e.g. EGAN, *CONSTRUCTING THE EUROPEAN MARKET*, *supra* note..., at 131 (noting that, in the United States, “the public and private sector have remained much more distinct,” and the policy style is less “state-directed;” and Kagan, *Regulatory Encounters*, *supra* note, at 3 (noting the much more “legalistic” and adversarial” regulatory style in the United States).

²⁰⁰ It is important to distinguish between deregulation of standards and deregulation of regulatory pre-market approvals. Arguably, the EC aims to raise substantive standards and deregulate procedural authorizations. Thus, a deregulation of product approvals does not necessarily mean that standards will be lowered. Rather, as with the experience of the EC’s internal market, standards may be raised. There is, in fact, little evidence that firms and private laboratories have conspired in any way to put public safety at risk in the EC, or that EC residents are subjected to more product safety risks than U.S. residents under more traditional U.S. approaches. See Michelle Egan and Dieter Wolf, *Regulatory Oversight in Europe: The Case of Comitology*, in Christian Joerges & Ellen Vos (eds.), *EU COMMITTEES: SOCIAL REGULATION, LAW AND POLITICS* 253 (1999); and DAVID VOGEL, *TRADING UP: CONSUMER AND ENVIRONMENTAL REGULATION IN A GLOBAL ECONOMY* 50-55 (1995).

²⁰¹ See e.g. Anne-Marie Slaughter, *Agencies on the Loose? Holding Government Networks Accountable*, in *TRANSATLANTIC REGULATORY COOPERATION* (George Bermann et al, eds.), *supra* note..., at 521-535 (providing proposals for enhancing the accountability and legitimacy of governance through transgovernmental networks); and ARCHON FUNG, DARA O’ROURKE & CHARLES SABEL, *CAN WE PUT AN END TO SWEATSHOPS?* (2001).

²⁰² The need for back-up of state intervention is often referred to as the “shadow of hierarchy.” See e.g. MICHELLE EGAN, *CONSTRUCTING A EUROPEAN MARKET: STANDARDS, REGULATION AND GOVERNANCE* 130 (2001); and Michelle Egan, *Mutual Recognition and Standard Setting*, *supra* note..., at 205-206.

²⁰³ See EGAN, *CONSTRUCTING A EUROPEAN MARKET*, at 7 (“The task of market creation is extremely difficult given variations in the historical timing of regulatory development, in national institutional structures, and national legal traditions.”)

²⁰⁴ Telephone interview with FDA official, June 7, 2001.

²⁰⁵ See Steffenson, *Regulating the Transatlantic Marketplace*, *supra* note..., at 22 (citing Transatlantic Consumer Dialogue, Principles of Harmonization, TACD Trade Document, issued February 2000). Some regulators agree, as demonstrated by OSHA’s initiation of fees for applications from testing laboratories. Yet, given the current market reaction to implementation of the 1997 Mutual Recognition Agreement, fee schemes, such as that imposed by OSHA, could further reduce the MRA’s prospects.