
The US-EU Mutual Recognition Agreements

Making Trade Policy

The mutual recognition agreements (MRAs) negotiated by the United States and the European Union highlight the role that standards and certification procedures can play in creating obstacles to trade. The case points to the possibilities of overcoming these obstacles without complete international harmonization. It raises questions about the pressures created by MRAs on domestic regulators, and it demonstrates how private-sector actors can form international coalitions to influence national trade policies. The case also underscores the institutional differences between the United States and the European Union and how these affect the transatlantic relationship.

Coverage

Should trade agreements include rules for regulatory standards? The introduction to the General Agreement on Tariffs and Trade (GATT) speaks of achieving both “the substantial reduction of tariffs and other barriers to trade” and the elimination of “discriminatory treatment in international commerce.” Even when tariffs and other border barriers are eliminated,

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however, international markets are not as integrated as national markets. One reason is that national regulations and standards often differ. Firms have higher market entry costs if they are required to adapt their products to meet different standards to sell products in another country. The testing and certification of compliance with these different national standards imposes additional costs. A particular concern in international trade is that such standards can be a cover for protectionism. In other words, a country may enact a regulation solely for the purpose of keeping outside firms from entering the domestic market. Thus, standards and product certification pose legitimate concerns to those seeking an open trading regime.

Depth

Under the original GATT rules, countries were expected to provide foreign goods with national treatment and to treat goods from all contracting parties equally (i.e., with most favored nation status).¹ As long as goods from all sources were treated equally, countries could set any standards they desired. During the Tokyo Round, concluded in 1979, negotiators developed codes for sanitary and phytosanitary standards and technical barriers to trade. These codes were extended in the Uruguay Round. Today, World Trade Organization (WTO) members are expected to follow certain basic principles when setting standards, avoiding any measure that restricts trade more than is necessary to achieve its objective. Countries are also encouraged, but not required, to use international standards. Members are allowed to adopt standards more stringent than the international norm, but their regulations must be based on sound science and risk analysis. Thus, while the WTO rules set certain constraints on regulation, countries are not required to adopt the same standards—a process known as harmonization.

Harmonization

The case for harmonizing standards internationally involves complex trade-offs and judgments. In principle, uniform international standards could make international markets more efficient and more easily contestable by reducing transactions costs and improving transparency. But the devil lies in the details. These positive outcomes are not guaranteed if the common standard is too stringent or is poorly designed. Such a stan-

1. National treatment applies only after a product, service, or item of intellectual property has entered the market. Therefore, charging customs duty on an import is not a violation of national treatment even if locally produced products are not charged an equivalent tax.

dard might reduce efficiency or, if it favors firms from a particular nation, actually hinder international competition. In addition, international standards restrict the choices of domestic governments. In national standards, countries can reflect their domestic institutions, values, and conditions more precisely. At the same time, however, domestic standards can enhance domestic monopolies and hinder international trade.

Choosing to harmonize standards leaves open the question of how these standards would be determined. One approach is to rely on negotiation, as was done in Europe until the early 1980s. Europeans originally sought to establish common standards through a process that required consensus among all members of the European Community—but because member countries had different interests, progress was extremely slow. Following complaints by European firms that these differences had dramatically increased their costs by preventing the creation of a single market, in the early 1980s a different approach was taken: mutual recognition.

Mutual Recognition

Mutual recognition served as a pillar in the EU92 initiative that sought to complete the internal European market. Under the European system, if a product met the standards of any one EC member country, then it could be sold throughout the Community. This approach avoided the problems inherent in negotiating universal standards, and it also introduced a new dynamic. If a firm could obtain access to the entire European market by meeting the standard of any EC member, it would choose the most attractive national standard. Therefore, competition existed between standards and between standards setters.

Despite these advantages of mutual recognition, the coexistence of several standards could also lead to confusion and impose information costs on consumers trying to understand them. Some also argue that competition in standards setting will lead to “a race to the bottom”—that is, it will encourage the continued weakening of standards. Because of such concerns, one country will not grant mutual recognition before it trusts the standards set by the other. Indeed, even within Europe, mutual recognition is sometimes accompanied by an agreement on minimum standards.

Mutual recognition does not automatically result in a race to the bottom, however. For example, suppose Germany has a more rigorous standard than France for sink faucets. Faucet manufacturers seeking to convince consumers that their products are superior might actually prefer to be certified in compliance with the German standard. On the other hand, if the regulation does not add value (or if it functions like a tax), the least costly would be the most attractive.

The US-EU MRAs did not seek full mutual recognition of standards but mutual recognition of inspection, testing, and certification requirements

for a range of traded products. While the United States and Europe would continue to set their own domestic standards, they would agree that producers could test in the United States to Europe's standards, and test in Europe to US standards. Therefore, the US-EU MRAs introduced competition between assessors. Such competition was familiar in Europe, where private firms had long provided certification, but was quite new for Americans, particularly the government agencies that had enjoyed a monopoly in providing certification in the United States. While some US officials believed that competition would lead to cheaper and more rapid certification, others worried about its implications for product safety.

Enforcement

Introducing competition into setting standards and assessing conformity also introduces pressure, which, some fear, might result in less meticulous enforcement. For example, a certifier could be deliberately lax as a way of attracting more firms. The need for mutual trust suggests that countries will be unwilling to sign MRAs without first extensively examining the procedures and integrity of the mechanisms that ensure continued compliance. In the United States, some products are assessed by private institutions; but many argue that health and safety concerns should preclude those products under the purview of the Food and Drug Administration (FDA) from being certified in a competitive environment.

Developing Countries

In general, mutual recognition is easier when countries are at similar levels of development, with similar standards. Understandably, such arrangements are particularly difficult to create between developed and developing countries. Developing countries with small markets would likely be forced to conform to the standards of countries with larger markets, because firms in the latter would be reluctant to cover the costs of certifying their standards. Indeed, developing countries may not have the capacity to establish standards at all, whether their own or others'. Developing countries are therefore unlikely candidates for MRAs, although certified laboratories in developing countries may be able to attest to conformity with European or US standards.

Participation

Should international trade agreements be negotiated multilaterally, bilaterally, plurilaterally, or at all levels simultaneously? The United States emphasized multilateralism through the early 1980s but then turned to a multitrack approach. Europe has followed both regional and multilateral

strategies. During the late 1980s, however, both major trading economies strengthened their regional focus, Europe with EU92 and the United States with the North American Free Trade Agreement (NAFTA). In 1994, agreements were made at the Asia Pacific Economic Cooperation group (APEC) summit in Bogor to achieve free trade and investment among members by 2010 for developed and 2020 for developing countries, and at the meeting of 34 nations from the Western hemisphere in Miami to conclude an agreement for free trade in the Americas.

These events naturally raised the question of whether the world's two largest economies should enhance their trading relationship bilaterally. They might negotiate a formal free trade agreement—but this approach had two problems. First, a US-EU bilateral agreement would inevitably be seen as a challenge to the multilateral system. Second, WTO rules required coverage of essentially all trade—including agriculture, which was extremely problematic for Europe. Accordingly, transatlantic dialogues took the place of a full-scale bilateral agreement. These dialogues led quite naturally to efforts to implement regional measures that could not be easily achieved multilaterally.

Winners and Losers

Europe's success in implementing MRAs internally suggested that they might be a potential area of agreement between the United States and the European Union. But full mutual recognition was a radical step that would have dramatically altered the role of regulators in the United States. In the area of pharmaceuticals, for example, firms wishing to sell products in the United States would have had only to meet European standards rather than undergoing the more taxing process of obtaining FDA approval. Instead, therefore, the parties took a smaller step: the mutual recognition of conformity assessment procedures. Thus, while continuing to set their own standards for domestic sales of goods and services, they agreed to allow European and American certifiers to verify compliance with both US and European standards—allowing firms to choose where they certified their products. The agreement reduced costs and improved efficiency, but it also reduced the traditional power of regulators and added to the options, and consequently the power, of the firms that needed such assessments. Moreover, the dialogues provided firms in the United States and Europe with new opportunities to form international coalitions and thus advance their agendas at home and abroad.

Governance

The MRA case points to the growing importance of nongovernmental actors in international economic relations and dramatizes the functional

pressures that are leading to deeper integration. The US and the EU governments helped to construct transatlantic dialogues between business, labor, consumer, and environmental groups. The MRA emerged from the business dialogue, clearly driven by the interests of firms on both sides of the Atlantic in greater efficiency in compliance certification. The virtue of this approach is that it allows private groups to consensually find mutually advantageous policy solutions to common problems. But although such alliances may yield better policies, they also affect the balance of power between the regulators and the regulated. Moreover, the agreements they reach may move policy in a direction considered unacceptable by parties who are not included in the dialogue. Participation by government officials is therefore crucial to ensure that a broad array of interests are considered and that trade-offs are made when consensus does not exist (a difficult task).

In short, mutual recognition has significant implications both for regulators and for those who are regulated. The competition created by MRAs may be useful in limiting the danger of one particular regulatory system being captured by special interests. At the same time, mutual recognition will curtail the ability of domestic governments to construct protectionist regulations. MRAs may also be viewed as undermining local (or national) control; alternatively, they may be viewed as expanding local or national jurisdiction, because decisions taken at that level will extend to other countries.

CASE STUDY: International Trade Meets Domestic Regulation—Negotiating the US-EU Mutual Recognition Agreements

In 1998, the United States and the European Union (EU) recognized each other's inspection, testing, and certification requirements for a wide range of traded products in a set of agreements known as mutual recognition agreements. The MRAs applied to nearly \$50 billion in transatlantic trade in six sectors: medical devices, pharmaceuticals, recreational craft, telecommunications, electromagnetic compatibility (EMC) testing services, and electrical equipment.² The Commerce Department estimated that the agreement would save US industries more than \$1 billion annually in testing and certification costs.³ According to Stuart Eizenstat, then

2. USTR, *1999 Trade Policy Agenda and 1998 Annual Report of the President of the United States on the Trade Agreements Program*, 1999, 217.

3. Charles Ludolph, deputy assistant secretary for Europe, US Department of Commerce, hearing before the House Subcommittee on Oversight and Investigations of the Committee on Commerce, "Imported Drugs: US-EU Mutual Recognition Agreement on Drug Inspections," 105th Congress, 2nd session, October 2, 1998, 24.

undersecretary for economics, business, and international affairs at the State Department, the MRAs proved that the United States could simultaneously protect its citizens, promote public health, and encourage trade. The MRAs “are a groundbreaking step in President Clinton’s policy to break down trade barriers, because they address the proliferation of requirements brought on by the growth in foreign trade,” said Eizenstat. “They cut red tape and save money for industry, consumers, and regulators and make the USA more competitive.”⁴

Champions of the MRA negotiations argued that the proliferation of differing standards, licenses, and certificates had created a formidable system of barriers to transatlantic trade. The MRAs were intended to eliminate duplicative testing, streamline procedures, lower costs, and decrease the time required to bring new products to market. Companies doing business internationally complained that they were often forced to retest their products at the border to standards that were very similar to those of the country of origin. For example, US companies exporting consumer electronics to Europe reported that the administrative burden alone of complying with double testing and certification cost them \$70 million each year.⁵ MRA proponents argued that performing all needed testing at one time would increase efficiency and reduce costs to consumers. “The basic concept behind the MRAs was the simple proposition that products could be tested once and considered to have been tested in both markets,” Eizenstat said.⁶

In addition to seeking changes that would streamline international trade, some industries hoped the MRA process would encourage domestic regulatory reform. The US medical device industry, for example, was frustrated that navigating the FDA approval process to bring a product to market took four years, on average. Industry observers hoped the MRA negotiations would help stimulate regulatory changes at the FDA modeled on the European approval system—a system viewed by industry as much more efficient. Champions of the MRAs also believed that the agreement would set a powerful precedent for increased international regulatory cooperation and future efforts to harmonize standards for traded goods. “The longer-term benefit that industry saw was a continued acceleration towards harmonization and standardization,” said one pharmaceutical executive. “Moving towards more harmonized standards is good for us. MRAs were a building block to that.”

4. Eizenstat, quoted in “US Industry Urged to Back MRAs with EU,” *Pharma Marketletter*, October 13, 1997.

5. Editorial, “The Strength of Dialogue,” *Journal of Commerce*, June 5, 1997, 6A.

6. Eizenstat, hearing before the Senate Foreign Relations Committee, “US-EU Cooperation on Regulatory Affairs,” October 16, 2003.

Industry played a key role in the MRA negotiations. Especially important was a new government-initiated organization of CEOs from Europe and the United States called the Transatlantic Business Dialogue (TABD). “This government-business dialogue is unique in the world, and has contributed immensely to the reduction of trade barriers across the Atlantic,” declared David Aaron, undersecretary of commerce for international trade. “No other forum has risen so rapidly to become as effective as the TABD.”⁷ But some observers, including consumer groups like Public Citizen, were suspicious of the TABD’s part in the MRAs. Was it appropriate for industry to be involved in negotiations over testing requirements for their own products? Why was there no comparable role for consumer and safety groups? Industry representatives noted that their participation was necessary since it was business that faced the inefficiencies and duplication in testing. Policymakers needed to have an understanding of the practical implications of any agreement, they said.

Though business played an important role, US and EU governments led the MRA negotiations. The talks presented a number of unprecedented institutional challenges to US and European officials. In Europe, the negotiation tested the relationship between the European Commission and the member governments of the European Union. In the United States, government agencies ordinarily uninvolved in trade discussions, such as the FDA and the Occupational Health and Safety Administration (OSHA), became central players—yet the idea of considering domestic regulatory and certification issues within the framework of a trade agreement made some participants uneasy. The primary mission of a regulatory agency, after all, is not to facilitate trade but to safeguard consumers. As Representative Henry Waxman (D-CA) put it, “There is no question that international agreements of this kind can enhance the efficiency of commerce, but it is equally clear that they can potentially depress American health and safety standards.”⁸ Such concerns made some regulators reluctant to participate in the MRA process.

Bilaterally, Europe and the United States had dissimilar ideas about how to structure the agreement; each was understandably eager to promote its own industries, cultural values, and institutions. In addition, differences in the way US and European businesses relate to government (and vice versa) affected the negotiations. Because of such challenges, completing the MRAs took four years of tough on-again, off-again talks, and implementation efforts continue.

7. Aaron, hearing before the House Ways and Means Committee, “Trade Relations with Europe and the New Transatlantic Economic Partnership,” 105th Congress, 2nd session, July 28, 1998.

8. Waxman, Hearing before the House Subcommittee on Oversight and Investigations, 4.

Background

What Is a Mutual Recognition Agreement?

The US-EU mutual recognition agreements aim to reduce what are technically known as *conformity assessment procedures*: the testing, certification, and inspection processes used to determine if a product meets specified standards and regulations. Ralph Ives of the office of the US Trade Representative (USTR), who served as lead US MRA negotiator, explains: “An MRA basically allows you to test [your products] in the US to Europe’s standards, and in Europe to US standards.”⁹ MRAs were negotiated on a sectoral basis; that is, separate talks were held for each industry sector.

The impetus to negotiate a US-EU agreement on conformity assessment procedures grew out of the mutual recognition of standards in Europe. Under full mutual recognition, if a product meets the standards of any one EC member country, then it can be sold throughout the European Community. Europe came to this practice of mutually recognizing standards after a failed attempt to pursue regulatory *harmonization*, which would have required all EC member countries to adopt the same standards.

Harmonization Efforts Within Europe

The free movement of goods within Europe was guaranteed in Articles 30–36 of the 1957 Treaty of Rome, which established the European Economic Community. Article 30 prohibited “qualitative restrictions on imports . . . between the Member States.” Article 36 allowed exemptions to this rule for reasons such as public security, protection of health and life, and the protection of national treasures. However, such permissible restrictions could not “constitute a means of arbitrary discrimination or a disguised restriction on trade between the Member States.”

The 1970s saw efforts in the Community to pursue regulatory harmonization, a move that would have made national barriers irrelevant by creating pan-European standards for products. But the process of creating such standards required consensus among all EC members, and directives for the harmonization became so detailed and technical that developing a standard could take 15 years. As a result, this effort, later dubbed the “Old Approach,” proved largely ineffective.

9. Unless otherwise noted, all quotes from Ralph Ives come from a November 1999 interview with Charan Devereaux.

The New Approach toward standards emerged from a series of cases at the European Court of Justice interpreting Articles 30–36. In an often-cited 1979 case (120/78), the court ruled that West Germany had violated EC free trade laws by banning a French liqueur on the grounds that it didn't have enough alcohol to be classified as a liqueur by German standards. The decision confirmed that goods should be allowed free circulation within the European market as long as they were safe and did not threaten public health or the environment.

Using such cases as a precedent, the European Commission adopted the principle of mutual recognition of standards based on essential safety requirements and ceased to pursue complete harmonization. It thereby avoided the complications inherent in negotiating universal standards. In 1985, the EC Council adopted a resolution titled "A New Approach to Technical Harmonization and Standardization." Mutual recognition of standards became a major element of Europe's Single Market Program, also approved in 1985. The governments of the 12 Community member countries, as well as the governments of 6 of the 7 members of the European Free Trade Association (EFTA), committed themselves to achieving mutual recognition by the end of 1992 in the Single European Act (SEA).

The New Approach directives were limited to essential safety and performance requirements for most manufactured products traded on the EC market.¹⁰ Under mutual recognition in Europe, if a product met the standards of any member country, then it could be sold throughout the Community. After products were issued a "CE" (Conformité Européenne) mark, they could be sold anywhere in Europe without undergoing further testing by individual countries.¹¹ Many New Approach directives required third-party certification before a manufacturer could affix the CE mark. As a part of this system, "notified bodies," or private third-party institutions to certify compliance, were developed. The Community also forbade the recognition or acceptance of most non-EC inspections and product certifications.

This decision not to recognize outside inspections required many non-EC manufacturers to retest their products at the borders of European member states. "Seen from the outside, the Community was perceived to be setting up a major obstacle to trade against third countries because our own products would be favored," says Karl Falkenberg, the European Commission's lead negotiator on the US-EU MRAs. "It was the origin of the debate about 'fortress Europe.'" The intent, Falkenberg argues, was

10. For some products, including food, automobiles, and airplanes, the Community continued to rely on the Old Approach.

11. The CE mark was an international symbol of quality management and product safety, earned after a manufacturer was inspected and audited by a "notified body" authorized under EU regulations. Once the mark was granted, the manufacturer could market its products throughout the European Union unregulated by individual countries.

not to create new barriers: “We were trying to liberalize as much as we could within Europe, but we were quite prepared to recognize any other country that would reciprocally recognize our standards or certification bodies.”¹²

The United States Organizes to Meet the Challenge

As the pursuit of a single market gained momentum in Europe, the US government became concerned about its implications for trade. The Europe-US trade and investment relationship was the largest in the world. Some experts predicted that a fortress Europe was indeed imminent and that EC-wide trade barriers would drive out US exports. The US Commerce Department was charged with the unenviable task of reviewing the proposed changes to European regulations.

In 1987, Charles Ludolph, director of the Commerce Department’s Office of European Community, became chair of the new US Interagency Working Group on European Standards and Regulatory Issues. In addition to drawing on such traditional players in trade as the Commerce Department, the State Department, and USTR, the working group also included officials from a wide spectrum of regulatory agencies such as the Federal Communications Commission (FCC), the FDA, the Environmental Protection Agency (EPA), the Federal Aviation Agency (FAA), the Department of Labor, OSHA, and the Department of Agriculture (USDA). Between 1987 and 1991, the group typically met at least once every six weeks.

Many regulators found that taking part in discussions led by the trade-related agencies was a relatively new experience. “We are not a trade agency,” explains Walter Batts, the FDA’s director of international relations. “Until very recently, there hasn’t been anything in our legislation that indicates we should be involved in these kind of things. . . . But at the same time, because we regulate such a wide range of products, we obviously have impact on trade.”¹³ Nor had regulators traditionally played much of a role in international trade talks. Trade negotiations had concerned themselves with “border barriers,” such as tariffs and quotas, as opposed to “beyond-the-border barriers” such as domestic regulation. Ludolph’s interagency group was therefore somewhat unusual.

Of particular concern to Ludolph were the implications of the new CE marks, which would be legally required for most manufactured goods distributed or sold within Europe’s single market. Between 1987 and 1992,

12. Unless otherwise noted, all quotes from Karl Falkenberg are from a November 1999 interview with Charan Devereaux.

13. Unless otherwise noted, all quotes from Walter Batts are from a 1999 interview with Charan Devereaux. The FDA regulates over \$1 trillion worth of products, which accounts for 25 cents of every consumer dollar spent in the United States each year (US Department of Health and Human Services, Food and Drug Administration, *Fiscal Year 2000 CFO’s Annual Report*, 2001, I-1).

“we stared at these 25 CE marking directives,” Ludolph recalls. “It was clear that no US manufacturers were prepared to send their products all the way to Europe to be tested and certified—the cost was too high—and that was what CE marking required.”¹⁴

The United States needed to find a different approach. Negotiating complete mutual recognition of standards between Europe and the United States was not feasible. For example, under full mutual recognition companies could sell pharmaceuticals in the United States after meeting European standards without first obtaining FDA approval. An agreement on testing and certification procedures was a smaller step, but appeared to be a more realistic goal. Through an MRA on conformity assessment procedures, the United States and Europe could continue to set their own domestic standards, but agree that producers could test in the United States to Europe’s standards, and test in Europe to US standards.

Ludolph was also interested in the efforts of telecommunications companies to address the same concerns. Some analysts believe that the MRAs were inspired by an agreement between the US and German telecom industries to facilitate trade in the face of the changes in how Europe treated standards. Subsequently, Lucent Technologies’ Chuck Berestecky and Nortel’s Vic Boersma encouraged the US government to address the issue with Europe more broadly.

In early 1992, drawing on the interagency working group discussions and the telecom industry efforts, Ludolph sent 400 letters to a range of US companies outlining his recommendations regarding the new European approach to standards. An alternative to having US products tested in Europe, Ludolph wrote, was an MRA—an alternative codified in the GATT Technical Barriers to Trade Agreement (TBT).¹⁵ “Under the TBT, there are fairly tough conformity assessment requirements,” Ludolph explains. “You either give national treatment to testing and certification services—which means you treat foreign producers the same as domestic producers—or if you deny national treatment you must offer MRAs. . . . I decided that MRAs were something we should recommend as an option to the business community.” Of the 25 business sectors Ludolph contacted, 11 expressed interest in MRAs.

That same year, the European Council empowered the European Commission to engage in MRA negotiations with a certain number of coun-

14. Unless otherwise noted, all quotes from Charles Ludolph come from one of several interviews conducted by Charan Devereaux in 1999 and 2000.

15. After years of negotiations at the end of the Tokyo Round in 1979, 32 GATT Contracting Parties signed the TBT. It laid down the rules for preparing, adopting, and applying technical regulations, standards, and conformity assessment procedures. The new WTO Agreement on Technical Barriers to Trade, negotiated during the Uruguay Round, strengthened and clarified the provisions of the Tokyo Round code (see www.wto.org).

tries. According to Giacomo Mattinò, an MRA negotiator from the Commission's Directorate-General for Enterprise, "The mandate identified MRAs as an instrument to achieve the objective of trade facilitation. The immediate cause was not the New Approach directives themselves. It was the overall perspective of broadening trade facilitation."¹⁶ In selecting the countries with which it would negotiate, the Commission weighed the volume of trade, the sectors in question, the types of legislation that were applicable, and the level of existing technical regulations. "It is easy to understand why the US was at the top of the list," adds Mattinò.

Later in 1992, Ludolph entered into "prediscussions" with European Commission officials to explore what an MRA would look like. "Those talks were totally useless," he says. Formal talks did not begin until October 1994. What caused the holdup? US observers say the European Commission had no incentive to enter into talks immediately. The New Approach directives were being phased in at different times for different sectors, and no real effects would be felt until January 1995. At that time, the Electromagnetic Compatibility Directive would be implemented, affecting all electronic products and at least \$13 billion worth of US computer exports.¹⁷ Ludolph wanted to have the MRAs in place and signed by 1995 to prevent any break in testing services. The main concern of the European Commission, in contrast, was simply to open negotiations early enough to avoid being brought before the WTO. If talks did not begin in a timely fashion, the United States could bring a case against Europe at the new trade dispute settlement body and penalties might result.

Getting to the Table

In 1994, an agreement was reached to begin MRA negotiations in earnest. In preparation, the Commerce Department took steps to directly involve the US business community. Ludolph approached a variety of trade associations and companies, asking them to "come together and advise us about how to proceed with the negotiations." The department formed advisory committees of businesspeople for each sector (except for recreational craft). The most active participants were those from the telecom industry, followed by representatives of the pharmaceutical and the medical devices industries.

16. Unless otherwise noted, all quotes from Giacomo Mattinò come from a December 1999 interview with Charan Devereaux. Since May 1998, Mattinò has been responsible for the overall coordination within DG Enterprise of the MRA dossier. Since January 2001, he has served as principal administrator at DG Enterprise. The views expressed are those of Giacomo Mattinò and do not represent any official view of the European Commission.

17. Interview with Ludolph.

Table 7.1 Bilateral trade in seven sectors under MRA negotiation, two-year average, 1994–95 (billions of dollars)

Sector	US exports to EU-15	US imports from EU-15
Sectors already deemed essential in agreement		
IT equipment and terminal telecommunications (telecom sector annex)	7.8	2.8
Aircraft, machinery, and appliances subject to FCC and/or OSHA requirements (electrical and electronic sector annex)	21.3	18.0
<i>Subtotal</i>	29.1	20.8
Sectors in which US-EU agreement is being sought		
Class I and II medical devices	2.3	1.0
Pharmaceutical GMPs	2.7	3.4
<i>Total</i>	34.1	25.2

FCC = Federal Communications Commission

GMPs = good manufacturing practices

OSHA = Occupational Safety and Health Administration

Source: Hearing before the House Subcommittee on Oversight and Investigations of the Committee on Commerce, 105th Congress, 2nd session, October 2, 1998, 75 (Commerce Department Analysis of Trade, 1996).

Telecommunications

“It was primarily the [US] telecommunications sector that thought the agreement would be useful,” says lead USTR MRA negotiator Ralph Ives—unsurprisingly, given its earlier enthusiasm. In 1994, the United States exported about \$7.8 billion in telecommunications equipment to the European Union while Europe sent only about \$2.8 billion to the United States (see table 7.1). As noted above, the industry’s attempts to streamline testing and certification processes preceded any formal government-led initiative.

Several US industry groups, including the Telecommunications Industry Association (TIA) and the American Council of Independent Laboratories (ACIL), approached the FCC (which regulated the industry) to express interest in the talks. “The Telecom Industry Association was a major part of what actually motivated the MRAs,” says the FCC’s MRA negotiator, Art Wall. “We [the FCC] got involved mainly because industry came to us, and because we saw the handwriting on the wall that change

was going to come. We also saw the handwriting on the wall that the FCC's resources were dwindling. If change was going to come about, it was better to be part of the process so that we could continue to monitor the things we cared about."¹⁸

The stakes were high for the telecom industry because the duration of any testing process directly affects the manufacturer's bottom line. "The objective of an MRA is to reduce the time and cost of bringing equipment to market," says Joanne Wilson, Lucent Technologies' director of global public affairs.

In order to get a product approved for sale, you often have to send the product to that country to be tested and have a conformity assessment body in that country do the testing. So this means that for every new market, you have another round of testing and you have another delay of getting the product into market. Product life cycles are getting shorter and shorter, and your profitability associated with the product depends on its life cycle. The more you delay getting to market, the shorter the lifetime of that product, which reduces its profitability. Particularly now in our computer-based products, the life cycle is getting very short. And so the only way to be profitable is to be able to get product into market very quickly.¹⁹

The FCC's Wall echoes her assessment: "The bottom line is that manufacturers need to get products to the market quicker. They can't wait three months for each country to do its product approvals, because the life cycle of some products is less than three months." Some also suspected that some delays had more to do with protectionism than with product approval. "That was definitely a real concern to the industry," said one industry representative.

European officials were less enthusiastic about pursuing an agreement in the telecom sector. "Europeans were initially somewhat cool to the idea," recalls Ives, USTR's lead MRA negotiator. "They saw trade being heavily in our favor. So the EC came back with a number of sectors they wanted to include, particularly pharmaceuticals, medical devices, and electrical safety. The package started to develop around those basic sectors." Falkenberg of the European Commission points out, "The package for us included, necessarily, pharmaceuticals and medical devices because we are large exporters of those products." For European negotiators, including these sectors in the talks was essential to balance the package.²⁰

18. Unless otherwise noted, all quotes from Art Wall come from a 1999 interview with Charan Devereaux.

19. Unless otherwise noted, all quotes from Joanne Wilson come from a December 1999 interview with Charan Devereaux.

20. The European Union was the world's largest producer and exporter of pharmaceutical products, with production totaling \$99.3 billion in 1993 ("Europe's Pharmaceutical Industry in 1993," *Pharma Marketletter*, October 24, 1994).

Pharmaceuticals

The US pharmaceutical industry as well as the European Commission was interested in pursuing an MRA. As matters stood, drug manufacturing facilities were inspected by each country that imported their products, resulting in much duplication of effort. The immediate goal of the industry was to streamline these testing procedures. Laura Peralta-Schulte, director of government affairs and public policy worldwide of Warner-Lambert (a company since merged with Pfizer), explains:

Industry was never saying we wanted to modify the Food, Drug, and Cosmetic Act. Nor did we want shoddy standards. We just wanted to modify the process so we could have one rather than multiple inspections with varying requirements and procedures because it is costly, time-consuming and slows the ability to get a product to market. That was short term. The longer-term benefit that industry saw was a continued acceleration towards harmonization and standardization. Moving towards more harmonized standards is good for us. MRAs were a building block to that. If we could get more of these issues under our belt, the thought was that at some point we could look towards a more harmonized transatlantic marketplace for other issues as well.²¹

This was not the first time that the United States and Europe had entered into regulatory discussions on pharmaceuticals. A conference of regulatory officials from Japan, Europe, and the United States, together with industry representatives, had laid the groundwork for the International Conference on Harmonization (ICH) in 1989.²² The ICH had two major goals. First, the participating countries and companies sought to harmonize the scientific requirements of pharmaceutical regulations in the United States, the European Community, and Japan. They hoped that if the various regulatory agencies required the same data, the differences in their approval processes would become less significant. Second, they wished to shorten the time from development to marketing of new drugs (Kidd 1996).²³

In addition, since the 1970s, the FDA had entered into memoranda of understanding, or MOUs, with Switzerland, Sweden, Canada, and Japan. In this MOU, foreign governments made a commitment that their regulated exports to the United States would meet FDA standards. The FDA

21. Unless otherwise noted, all quotes from Laura Peralta-Schulte are from a 1999 interview with Charan Devereaux.

22. The full title was the International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use.

23. The first ICH, held in Belgium in 1991, drew more than 1,000 government and industry representatives. The second ICH, in Florida in 1992, had 1,600 attendees. In 1995, some 2,400 delegates representing pharmaceutical companies and 40 governments took part in the third ICH in Japan (Kidd 1996).

also sent inspectors to certify that plants producing medications in those countries complied with FDA “good manufacturing practices,” or GMPs.²⁴ Since 1989, the FDA had been participating in discussions with the European Commission’s Directorate-General (DG) for Enterprise about entering into an agreement to exchange inspection information.²⁵

However, the mandate of the Commission’s trade directorate (DG Trade) to negotiate MRAs superseded DG Enterprise’s authority to pursue MOUs with the FDA. Any future discussions would therefore take place under the umbrella of the MRA. “FDA would have preferred to continue the bilateral MOU approach rather than getting sucked into the MRA,” admits Ives. Trade agencies were not involved in the MOU process.

FDA’s experience in trade-related negotiations was fairly limited. The agency first became involved in GATT negotiations during the Uruguay Round of trade talks (1986–94). “When the Uruguay Round negotiations began, it wasn’t something on our radar screen,” says the FDA’s Walter Batts. “The trade agencies didn’t actively seek out FDA in the early stages of the negotiations to be involved in establishing the US government position.” However, Batts explains, new items on the Uruguay Round agenda drew FDA into the process: “There was a totally new agreement being negotiated, the Sanitary and Phytosanitary [SPS] Agreement.²⁶ [As a result], a USDA representative contacted us and said, ‘Hey, we think you folks need to be aware and involved in this.’ We agreed and realized that we needed to be actively involved in the Technical Barriers to Trade negotiations as well.” In the latter part of the Uruguay Round, FDA therefore participated in negotiations for the SPS and TBT agreements. “We actually had people including myself and other FDA members as part of the negotiation teams,” Batts points out. “This was unprecedented for FDA.”

24. GMPs are practices and procedures for manufacturing, processing, and packing products to ensure their quality and purity. FDA investigators conduct both periodic and “for cause” inspections of manufacturers for compliance with GMPs (Horton 1998, 697).

25. During the MRA negotiations, DG Enterprise was known as DG III. The mission of DG III was to “promote the competitiveness of industry in the EU,” ensure the free movement of products as a “central role in the Internal Market Program,” promote innovation and R&D—particularly in information technology, and “ensure that other EU policies and activities contribute to improving industrial competitiveness.” (“Industry: European Commission Directorate-General Goes Public on Aims,” *European Report*, April 16, 1997.) In 1999, Europe ended the practice of numbering the DGs, and combined DG III, DG XXIII (Enterprise policy, tourism and SMEs), as well as parts of the DG XIII (telecommunications and information technology) to form DG Enterprise.

26. The Agreement on the Application of Sanitary and Phytosanitary Measures concerned the application of food safety and animal and plant health regulations. According to the WTO, the problem addressed in the agreement was “How do you ensure that your country’s consumers are being supplied with food that is safe to eat—‘safe’ by the standards you consider appropriate? And at the same time, how can you ensure that strict health and safety regulations are not being used as an excuse for protecting domestic producers?” (see www.wto.org).

Medical Devices

Even as the European Commission was pressing for the inclusion of the medical device sector in the MRA talks, the US medical device industry was gaining interest in the negotiations. As a part of the EC92 Single Market Program, the European Community had created a pan-European system intended to harmonize and streamline the regulation of medical devices, replacing the different standards of each different member country. The new system allowed manufacturers (a) to self-certify that low- and medium-risk devices met European requirements and (b) to employ third-party bodies to review and approve higher-risk devices. In short, the European regulatory system represented a public-private partnership in which the government established medical device requirements and private notified bodies actually approved the products. In the United States, Congress and the FDA established requirements and the FDA was responsible for approving the products. “The net result of the new European system,” according to a US Health Industry Manufacturers Association (HIMA) report, “is that European governments are able to approve advanced medical devices more than three times faster than FDA with only a small fraction of the staff that FDA has devoted to regulating devices” (HIMA 1997, 59). (In June 2000, HIMA changed its name to AdvaMed, the Advanced Medical Technology Association.)

The US industry considered the new European system to be much more modern, efficient, and highly developed than that of the FDA. The new system also freed US medical device manufacturers from having to meet a different standard for each individual country in the European Community. As a result, some US medical device companies moved their research facilities to Europe. A HIMA survey of 500 US medical device firms found that more than 45 percent of manufacturers and 55 percent of start-up companies were increasing their R&D activities in Europe. Many US companies were also introducing products into the European market earlier than the US market. When asked why, more than 90 percent cited the US process of product review, saying that they had to generate cash flow from European markets to fund the more costly and time-consuming US approval and commercial requirements (Wilkerson Group 1995). Guidant’s chief compliance officer, Michael Gropp, explains the implications:

If you look at companies such as Guidant, at any point in time, 50 to 60 percent of our revenue comes from products introduced in the preceding 12 months. So, for us, speed to approval of safe products is really important. At the time we started talking about the MRA, the gap between EU and US approval was much worse. So the idea was to find a way that you could go through a single approval process in one country and have it be accepted by authorities in another.²⁷

27. Unless otherwise noted, all quotes from Michael Gropp come from a 1999 interview with Charan Devereaux.

As in the pharmaceutical sector, efforts had been undertaken to pursue international harmonization in medical device regulation. The Global Harmonization Task Force (GHTF), founded in 1992, was an informal group that included regulatory and industry officials from the European Community, United States, Japan, Canada, and Australia. It defined its purpose as “encourag[ing] convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation and facilitating international trade.”²⁸ “The GHTF is FDA’s highest priority for international [medical] device activities,” declared the FDA’s Linda Horton in 1998 (Horton 1998, 720).

While an MRA would not harmonize standards, it would allow a body in the European Union to inspect a medical device to verify that it met US requirements, and vice versa. What analysts found particularly intriguing about this idea was that it introduced the notion of international competition between bodies tasked with conformity assessment. While the United States and Europe remained sovereign over their own standards, industry could choose to work with the most efficient body to certify that standard—be it the FDA or a private European notified body.

In addition, many in the medical device industry saw the MRA process as part of a broader effort to encourage the FDA to adopt what was considered a “more modern approach” to regulation through greater exposure to the European system. In the words of one industry representative:

First, the MRA would take steps towards eliminating duplicative regulatory requirements between Europe and the US. For example, instead of having two GMP inspections—one by FDA and one by a European notified body—you could have one inspection and it would suffice in both countries. Second, the Europeans had developed a new regulatory system that turned out to be very reasonable, providing for timely reviews and using very little in terms of government resources because it relied on third-party notified bodies. US industry saw that and said, “This is a good model for pushing the FDA reform process.” So ultimately, that is what the MRA negotiations turned into. A way to help us in our broader efforts to encourage FDA reform.

Domestic efforts were already being undertaken to encourage such changes, but the MRA talks were another venue for introducing that kind of thinking.

The MRA Negotiations

The First Two Years

Official MRA negotiations kicked off in 1994. The lead US negotiators were the Commerce Department’s Charles Ludolph and USTR’s Richard

28. Global Harmonization Task Force, “General Information,” November 17, 2004, www.ghtf.org.

Meier.²⁹ The rest of the US delegation was essentially the interagency working group on standards and certification that Ludolph had been meeting with for some time. He describes them as “the same group where people from FDA got to learn trade and people in USTR and Commerce got to know regulation.” Each sector had a regulator in charge of the technical negotiations who reported to Ludolph and Meier. For telecommunications, the negotiator was Art Wall of the FCC; for pharmaceuticals, Walter Batts of the FDA; and for medical devices, FDA’s Joe Levitt and Linda Horton. The MRAs progressed slowly, but Ludolph was relieved that at least negotiations had begun.

For the European Commission, DG Trade took the lead on the MRA negotiations; Karl Falkenberg was head of the unit, which was in charge of external relations and commercial policy with North America, the Far East, Australia, and New Zealand.³⁰ Officials from DG Enterprise also participated in the talks. Their unit’s key objective was to promote the competitiveness of European industry, and its responsibilities included coordinating regulatory and legislative activity in the European Union. “The Commission works very differently from a national government,” explains Falkenberg.

It particularly works very differently from the relationship between government and independent agencies in the United States. Within the Commission, we have different directors-general who have different prime responsibilities. But the Commission is working as a collective entity. We don’t have the sort of independence that you see in the States between, say, USTR on one hand and FDA on the other. Decisions here are made collectively at the level of the Commission with all the commissioners represented on all decisions.

Other fundamental differences between US and EU governmental structure were highlighted by the MRA initiative. DG Enterprise’s Mattinò points out, “In most cases, the US approach to regulation is that the conformity assessment organization intervenes directly—which means the public authority itself, such as FDA or OSHA, has to approve the products directly. Our approach, at least in sectors covered by the MRAs, is different. The public authority is not itself directly certifying products but entrusts this responsibility to third parties, independent certification organizations.”

The Commission also had an obligation to coordinate with the national governments of its member states. The coordinating body in trade negotiations was the 133 Committee. When the MRA negotiations were launched, the 133 Committee established an ad hoc MRA Committee to advise the

29. Ludolph was with the negotiations for their entire duration, from 1992 to 1998. Richard Meier was the lead negotiator for USTR until he retired. Ralph Ives became the lead USTR MRA negotiator after the TABD’s Chicago meeting in November 1996.

30. During the MRA negotiations, DG Trade was known as DG I.

Commission. “But 133 is a consultative committee,” Falkenberg emphasizes. “It can give views but it has no decision-making force.” According to Mattinò, the process of coordination and consultation with business and the member states was especially challenging because MRAs were a new idea:

The concept itself of an MRA in the format under negotiation between the EU and the US was so recently developed that this process of interrogating and receiving feedback from a number of economic operators was going hand in hand with a learning process where all the operators were trying to better understand what an MRA was. So on one hand we were asking for feedback from industry and on the other hand we were trying to explain exactly what an MRA could be. That’s sort of a strange situation, but that’s how it developed.

During the first two years, US and European negotiators met every six months, alternating between Brussels and Washington. “I think, in the beginning, it was a reasonable pace because we each had a lot of reading to do,” says lead European negotiator Karl Falkenberg.³¹ “We had to familiarize ourselves with certification procedures in the other market. We had to look into standards and understand which were mandatory standards and which were voluntary.” Many participants describe the initial phase of negotiations as a process of mutual education. Regulators from each side of the Atlantic presented the requirements of their respective markets, and business representatives were included in the discussion. As Commerce’s Ludolph explains: “We invited laboratories and manufacturers to accompany us on our negotiations and so every time we negotiated with the Europeans we brought a delegation of US companies and trade associations. Sometimes they were in the room and sometimes they were not in the room for the talks themselves.”

The Transatlantic Business Dialogue

As the MRA talks were getting under way, so too were efforts to organize a high-level dialogue between EU and US businesses. In December 1994, seeking ways to further facilitate trade between Europe and the United States, Commerce Secretary Ron Brown went to Brussels. While there, Brown outlined his vision of a business-to-business dialogue in a speech to the EU Committee of the US Chamber of Commerce. “He said that Europe and the US didn’t need a free trade agreement and there were plenty of government-to-government dialogues,” Ludolph remembers. “What was missing was a private-sector, high-level business dialogue.”

Initially, neither the European Commission nor European business representatives showed much enthusiasm for such discussions. In January 1995,

31. Falkenberg also was the Commission’s lead negotiator for MRAs with Canada, Japan, Australia, New Zealand, Switzerland, and countries in Eastern Europe.

Commerce Department officials proposed initiating a business-to-business dialogue in meetings with European Commissioner Sir Leon Brittan and other EC officials. Skeptical EC officials said they would wait to see if the European business community supported the idea.

Such support was by no means guaranteed. For one thing, as Ludolph explains, “the nature of the European business community is that they are much less connected to these kind of government initiatives.” For example, European business was not known for lobbying government. Instead, as one American business representative puts it, “they just took their lumps.” Over the years, according to some observers, European business had come to see its relationship with government as top-down. “The idea of the business community telling government to do something that they otherwise wouldn’t do was a novel concept,” Ludolph says. “There was not the kind of aggressive, pointed contact to influence the outcome of either the executive or the legislative branches anywhere in Europe” that there was in the United States. Falkenberg concurs: “In the US, aggressive lobbying is normal, so when US lobbying groups or large companies arrive in Brussels, the first thing they have to learn is to forget about their Washington ways, because they don’t work in Brussels. That’s part of the cultural difference.”

Another unusual feature of the Commerce Department’s proposal was that the point of contact for business would be the European Commission. Normally, the government officials with whom European businesses dealt were ministers from the 15 member states, who would then convey their thoughts and concerns to the Commission in Brussels. The idea of business working directly with the Commission was untested. Falkenberg also notes the differences between the advisory processes of the Commission and those of US agencies.

In the US, you have institutionalized advisory committees, where industry is used to working very directly with the administration. In Europe, our institutionalized counterpart is the member states—the 133 Committee, the Council of Ministers. Traditionally, the CEOs of industries were one step further away. That link existed between the CEOs and their national administration; the Commission was not used to involving us directly with individual enterprises and individual CEOs.

In light of these concerns, the Department of Commerce and the European Commission sent 1,400 US and European businesses and trade associations a survey accompanied by what one business recipient called “the three-B letter.” Signed by European Commission Vice President Sir Leon Brittan, Commissioner for Industry Martin Bangemann, and US Commerce Secretary Ron Brown, the letter asked how the Commission and the US administration could improve and deepen the transatlantic business relationship. The survey also asked whether there should be a US-EU business dialogue. According to the Commerce Department, approximately 80 percent of the respondents answered yes.

Observers suggest that promoting a business-to-business dialogue made sense for the Commerce Department from an institutional standpoint. In 1995, there were proposals from Republicans on Capitol Hill to eliminate the department as part of a plan to balance the budget. Commerce Secretary Brown denounced the idea, saying that it amounted to “suggesting unilateral disarmament in the battle for global competitiveness.”³² Initiating a transatlantic dialogue was one way to demonstrate the Commerce Department’s relevance and value, some said.

In addition to showing support for a US-EU dialogue, the responses to the three-B letter also indicated that businesses put a high priority on standards and regulatory issues. “When we got the survey back and tallied the results,” Ludolph recalls, “40 percent of all the respondents in Europe and the US said standards were the most important thing to the US-EU commercial relationship. The next-nearest thing was intellectual property at 8 percent. Standards just stood out as a huge issue.” Stephen Johnston, who later became the lead European staff person for the TABD, agrees: “Because of the success of the GATT, access to other nation’s markets was easy enough. The problems came once you were in the market.”³³

The Seville Meeting

The initial meeting of the TABD was scheduled to take place in Seville, Spain. Its goal was to make recommendations to participants in the December 1995 US-EU Summit about the US-EU economic relationship. The Commerce Department and the European Commission approached several key business executives to lead the TABD meeting. The two US co-chairs were two CEOs, Paul Allaire of Xerox and Alex Trotman of Ford. On the European side, the cochairs were BASF CEO Dr. Jürgen Strube and Chairman Peter Sutherland of Goldman Sachs International. Working groups on regulatory policy, multilateral issues, third-country issues, and investment were chaired by other CEOs. According to Selina Jackson, the US director for the TABD:

The notion behind the TABD was that the Cold War had ended, and the US government and the European Commission looked at their relationship and identified the key issues on which they should be focusing. And rightly, they identified business and economics as one of the key priorities for the transatlantic relationship. They thought to seek input from the business community, which is why they sent out this questionnaire and convened the Seville conference.³⁴

32. Martha M. Hamilton, Stephen Barr, “Brown Blasts Plan for Commerce Dept.; Elimination Would Hurt US Firms in Global Trade, Secretary Suggests,” *The Washington Post*, May 10, 1995, A5.

33. Unless otherwise noted, all quotes from Stephen Johnston come from a 1999 interview with Charan Devereaux.

34. Unless otherwise noted, all quotes from Selina Jackson are from a 1999 interview with Charan Devereaux. Jackson went on to work for United Parcel Service (UPS).

In September, a US steering committee began meeting daily at 8 A.M., hosted by the head of Xerox's Washington, DC, office. Jackson, a representative from Ford, and representatives of each of the TABD working groups attended these sessions. For example, because the CEO of Tenneco chaired Working Group 1 on standards and regulatory policy, a Washington staff person from Tenneco participated.

The Washington meetings focused on the logistics of the Seville conference and on drafting position papers. There were also some efforts to work with the group's European counterparts but Jackson notes, "there just weren't the relationships, because we had not met face-to-face." Though bilateral relationships began to develop at an October US-European full steering committee meeting at the staff level in Brussels, the preparations for the Seville conference were largely pursued separately.

In November 1995, the TABD held its conference. Commerce Secretary Brown addressed the group of European and US CEOs, encouraging their involvement in the trade negotiation process and declaring, "We should put the business 'horse' before the government 'cart.'"³⁵ The Seville meeting could not be called an overwhelming success, however. Attendance was modest, and a European observer frankly admits, "There weren't many high-quality European CEOs." Commission officials also note the lack of coordination between industry and the Commission.

But the conference did create some momentum for the MRAs. In the report published by the TABD, participating executives declared that they had come to Seville "not to negotiate between US and EU industry but to present joint recommendations" to government—in other words, to see what they could agree on. They stressed to political leaders that the transatlantic business relationship was one of the great successes of the postwar period, and business on both sides urged their governments to "eliminate, as soon as possible, the remaining obstacles to trade and investment" (TABD 1995, 1). Many of the US companies that sent representatives to Seville had also participated in Ludolph's advisory process for negotiating the MRAs. The final report for Working Group 1 on standards, certification, and regulatory policy recommended that the MRA talks be completed by January 1997.

The Dialogue Continues

Originally, the TABD was intended to last only three months; there were no plans to continue after the Seville meeting. Toward the close of the conference, however, Ford's Alex Trotman suggested that follow-up might be in order since some good first steps had been made. Ron Brown stepped forward to say that the United States would host the next TABD confer-

35. Brown quoted in Jeff Gerth, "Where Business Rules; Forging Global Regulations that Put Industry First," *The New York Times*, January 9, 1998, D1.

ence. The Americans knew that the US government was not prepared to underwrite such a meeting. “It was sort of funny,” recalls Jackson. “When Ron Brown said ‘We will host the conference,’ he was not committing the Commerce Department. He was committing the US business community.” It was agreed that the TABD would meet again the following year, but many executives were wary of creating yet another business organization. “A lot of the businesspeople didn’t want to set up another institution—there were quite a few already,” says European TABD director Stephen Johnston. The consensus was that the process should remain flexible.

An ongoing dialogue appealed to some members of the European Commission. There was a sense that continuing discussions could be an important element in reducing transatlantic trade tensions. According to Guidant’s Michael Gropp:

I think that there was an interest on the European side in trying to create some kind of forum that wouldn’t replace the GATT process, but where there could be a less argumentative approach in trying to resolve issues and build some consensus in ways that didn’t always lead to threats. The Europeans and the Japanese resented US trade policy and Super 301 threats. The European approach to these issues tends to be much less legalistic and much more one of consensus building. Partly that’s a cultural issue; partly it is the way that progress is made in the European Union. In many cases, disputes are not settled through legal channels as they are in the US, but through diplomatic initiatives, through consensus-building mechanisms. This of course frustrates some in the US industry and government, because it’s seen as slow and inefficient. But Europeans wonder if there isn’t a way to create a forum where you can achieve consensus in a more collegial manner without resort to threat and law.

Returning to the United States, Trotman tasked his Washington staff with figuring out what needed to be done to follow up on the Seville recommendations. Jackson calls the moment “really wide open—it was a tremendous opportunity.” On the European business side, there was a similar response. BASF’s Strube asked his vice president of international trade, Ilsa Stübinger, to take charge of the day-to-day running of the TABD. As a result, a small TABD office was opened on each side of the Atlantic. Selina Jackson was hired as director in Washington and Stephen Johnston was named her counterpart in Brussels.³⁶ And so the Transatlantic Business Dialogue was born.

The MRA Talks Gain Momentum . . . and Lose It

One month after the Seville conference, the MRA talks gathered new steam at the December 1995 US-EU Summit in Madrid, where US and EU presidents Clinton and Santer sought to expand transatlantic cooperation

36. Jackson had recently finished a graduate degree at Tufts University’s Fletcher School of Law and Diplomacy; Johnston had worked at the European Commission.

through an initiative called the New Transatlantic Agenda (NTA). The inauguration of the NTA marked the first time that the United States recognized the European Union as a major political institution. The centerpiece of the NTA's economic component was a commitment to create a New Transatlantic Marketplace (which later evolved into the Transatlantic Economic Partnership, or TEP), to be achieved by "progressively reducing or eliminating barriers that hinder the flow of goods, services, and capital" across the Atlantic.³⁷ Among those barriers were technical standards.

A few months later, in March 1996, US officials announced that a breakthrough in the MRAs was imminent, touting it as the first substantial fruit of the TABD's launch in Seville.³⁸ But the announcement was premature: The MRA talks broke down when European negotiators rejected a US proposal to drop two sectors where progress was lagging—pharmaceuticals and medical devices—refusing to delink them from the other areas still under negotiation. "There had been a lot of discussion about this concept of unbundling, of separating out the sectors," Falkenberg explains:

The Community had always said that these negotiations had to be a package, and that we would only conclude an MRA if there was an economic balance. That package for us included medical devices and pharmaceuticals because we are large exporters of those products, and because the obstacles we had identified in the US market because of the FDA were extremely burdensome, costly, and time-consuming. We needed those to be addressed.

The Debate over Pharmaceuticals

The pharmaceutical MRA would apply not to certification—any new drug still had to meet FDA standards—but to *production* of the drug once it had been approved. The US Food, Drug, and Cosmetic Act of 1938 (amended in 1993) aims to ensure that pharmaceuticals are safe and efficacious—that they actually do what their labels claim. The Act also seeks to guarantee that they are made safely, through regulations that govern so-called good manufacturing practices. GMPs are based on the premise that finished-product testing does not suffice, and that safety and quality must be built into products during their manufacture (Horton 1998, 697). Foreign firms were expected to comply with the same product requirements and the same GMP regulations as US domestic firms.

Typically, a company that wanted to export pharmaceutical products would invite the importing country to inspect its plant; once the manu-

37. *The New Transatlantic Agenda*, adopted December 3, 1995 at the EU-US Summit in Madrid, Spain.

38. Eurowatch, "Transatlantic Dialogue Spurs Progress on Mutual Recognition," April 15, 1996.

facturing process was deemed appropriate, the drug's importation would be allowed. For example, Europeans might visit Puerto Rico to inspect a US manufacturer's plant, which would also be inspected by the FDA to ensure that it met US GMPs. "The problem," Peralta-Schulte explains, "is that the ways different countries perform these inspections are different. Industry gets caught in between." Charles Ludolph's assessment is similar: "It is not standards, but the practice of the inspections that are different. If Europe does one process and the US does another, a company often got caught in between as to what standards they ought to be applying on a practical basis."

European MRA negotiators argued that EU and US testing bodies had comparable competence. It seemed reasonable to hope that facilities in the United States could test a product to European standards, and vice versa. But the FDA saw the situation differently. "Generally speaking, the EU took the position that US regulatory systems were good and acceptable to them," says the FDA's Walter Batts.

They were willing to accept our decisions on the marketability of products in return for us accepting their decisions. But from FDA's standpoint, we just couldn't accept that at all. We have a statutory requirement to review and approve certain products before they are marketed—including certain medical devices and pharmaceuticals. We can't delegate that authority to anyone else, to another government. We could not pursue an MRA on that basis.

FDA officials felt the need to educate US and European trade officials on the parameters of the Food, Drug, and Cosmetic Act, the central piece of legislation governing FDA operations. The agency wanted everyone to understand that any negotiations related to pharmaceuticals were constrained by the act's directives.

The FDA appeared to be in a tough position. As expanding international trade made growing demands on the agency, its resources had not increased comparably. Moreover, the problems of the FDA were symptomatic of a larger issue: conflicts caused by the distinct mission (and therefore the different priorities) of each federal agency. USTR and the Department of Commerce were pushing for MRAs as a trade issue. Meanwhile, the FDA insisted that inspections were regulatory matters that fell under its purview. The FCC and OSHA felt similarly about their sectors. And the State Department wanted a final say on any international pact.

As a result, European negotiators viewed the US government as unwilling to make any changes to its own procedures. This recalcitrance was especially frustrating in light of the US role in initiating the MRAs. As one European negotiator put it,

The US was saying that mutual recognition within Europe was creating trade barriers against the US and therefore, please do something about it. When we said we would be prepared to do something about it, but it implied some change in US legislation, the answer was, "No, no, no, that was not the deal." The deal was that

Europe should just recognize US certification procedures, but without any reciprocity, without any change to US legislation. That has been a major problem. We have developed recognition within the European territory. We have said that we are prepared to modify legislation and to extend this recognition to third countries, but on a reciprocal basis. Therefore, we can only accept recognizing third-country testing if those countries are prepared to recognize Community testing. And that has been the major problem, most vociferously argued by FDA. But we had similar concerns voiced by FCC and OSHA, really by all the agencies we talked to.

Some negotiators felt that European regulators had a head start in the MRA process because of the European Commission's New Approach directives. In Falkenberg's judgment,

The underlying issue is that every regulatory authority believes that it's the only entity that can do a job properly. These bodies believe that the only safe products are those tested by the agency itself—every foreign body is unfit. That attitude existed in Europe as it exists in the US, or anywhere else. In Europe, the New Approach to recognition within the EU basically broke this monopoly. Member states were forced to recognize what their Portuguese, Spanish, British, Swedish, French, or other colleagues were doing. In the US, we were still up against a complete monopoly. There was only the FDA. There was only the FCC. Our regulators had been forced inside the Community to recognize that someone else could do as good a job as they could themselves. For the US, this negotiation was the first exposure to that kind of thinking.

After some negotiation, the European Commission asserted that a series of FDA proposals for a system of equivalency in pharmaceutical plant inspections failed to constitute true mutual recognition in practice or in spirit (Gopal 1997, 38). According to several US observers, DG Trade was in effect saying to the departments of Commerce and State and to USTR, "You folks need to tell the FDA that this is not the kind of agreement we are going to have." The disagreement over pharmaceuticals held up the talks in all the other sectors. "It was such a divisive issue and nobody was thinking very creatively," admits Peralta-Schulte. "Both governments were basically at a standstill."

In early January 1996, the State Department's Stuart Eizenstat wrote FDA Commissioner David Kessler that "the [European] Commission has made it clear in its negotiations and to me personally that without the US-EU agreement on pharmaceutical GMPs, the Commission is not prepared to commit to agreements in another 4 to 5 sectors. Therefore I would like to ask you to personally look at these negotiations to help move the whole MRA process forward."³⁹

39. Quoted by Representative Ron Klink, Hearing before the House Subcommittee on Oversight and Investigations, *US-EU (European Union) Mutual Recognition Agreement on Drug Inspections*, 81.

Narrowing the Agenda

By August 1996, Charles Ludolph had concluded that, in his words, “the MRA talks were severely wounded.” He decided that he needed help to get them going again: “The European Commission wasn’t getting what they wanted in pharmaceuticals and I think they were very confused about what their business community *wanted* them to get. So in August of 1996, I went to the TABD and said, ‘These MRAs are going to die if I don’t get direct help, participation, and support from the pharmaceutical industry. And TABD has got to orchestrate that.’”

The US pharmaceutical company Warner-Lambert was “very responsive,” Ludolph says, and enlisted SmithKline Beecham to be the interlocutor on the European side. Both companies were members of the TABD. From August to November, the parties spent hours “in rooms arguing with each other” over the minimum that would benefit the pharmaceutical industry and the maximum that the FDA could give. “This was done at the expert level,” Ludolph emphasizes. “The CEOs provided the strategic umbrella and overall focus.” SmithKline Beecham and Warner-Lambert worked with other members of the pharmaceutical industry and with the trade association PhRMA (the Pharmaceutical Research and Manufacturers of America) to “help the European Commission and the FDA understand what the pharmaceutical industry needed at a minimum—what they couldn’t walk away from the MRAs without.” Ludolph adds, “It also gave an opportunity for the FDA and the European Commission to make their case directly to industry about what they were trying to get.”

Industry representatives worked to focus the scope of the talks. “I think where we were effective was in helping to narrow the focus to two issues,” says Warner-Lambert’s Laura Peralta-Schulte. “Once they were resolved, the other issues fell in line.” The two major issues were Good Manufacturing Practices and the public disclosure of inspection reports.

Manufacturing processes were actually subject to scrutiny at two points. The first was during the preapproval stage, when a pharmaceutical company was about to launch a new drug. As Peralta-Schulte notes, “A slowdown or miscommunication there can keep your product off the market until the issue has been resolved.” The second point was post-approval: Once a product was on the market, the manufacturer might change the production process in some way.

The US government position was that negotiations should focus on postapproval and not preapproval inspections. The Europeans believed that both stages should be within the scope of the agreement, and were supported by the pharmaceutical industry. “From a company standpoint, most problems are in the preapproval period,” explains Peralta-Schulte, “so to only focus on the postapproval stage and not on preapprovals, you are not solving the problem.” Industry suggested that the negotiations be staggered to address postapproval first, and then preapproval.

The second sticking point in the pharmaceutical negotiations concerned not the timing of inspections but their publication. While the US Food, Drug, and Cosmetic Act required disclosure of inspection reports to the public, the European negotiators believed that it was inappropriate for certain documents to be made public. US pharmaceutical companies recognized that the FDA could not ignore its legislated mandate, and therefore the TABD pharmaceutical representatives saw their role as explaining the US government position to European business and the Commission. As one US pharmaceutical representative says,

Europeans were coming at this from a place where there was not a thorough understanding of how important it was [in the United States] to maintain the Food, Drug, and Cosmetic Act. And quite frankly, that was the litmus test. We were not as an industry, or as the FDA, going forward to seek modifications to that act because any changes would take a lot of time. It was our theory that you could resolve these issues without going to that degree of activity.

Walter Batts sees the role of US industry in communicating the FDA's position to the European negotiators as important: "I think they were extremely helpful in that regard. They assisted the European Commission in understanding the US Constitution, FDA statutory authority, and the Food, Drug, and Cosmetic Act. [They also assisted the Commission in understanding] political reality in the US government. The US government cannot change its laws or policies on a whim."

In their efforts to move the talks forward, US pharmaceutical interests worked with several US agencies, but their major point of contact was the FDA. "Because the TABD process brought together various US departments and agencies, industry worked with the Commerce Department, USTR, the State Department, and numerous regulatory agencies," says Peralta-Schulte. "But no participant was more important than the FDA, because they were the ultimate decision maker on these issues."

The Search for Consensus

Before August 1996 the TABD was keeping an eye on the MRA talks, but the negotiations weren't a priority. "It wasn't really until that four-month exercise—from August to November—that things really got pointed up," says Charles Ludolph. In October, Ludolph, the FDA's Batts, and a State Department official visited "virtually everyone in Europe involved in pharmaceutical MRAs," including the health ministries of many of the EU member states, numerous European trade associations, and a number of companies active in the TABD. Ludolph continues, "By November 3, everybody in the business knew what the stakes were in the MRA and we brought the issues to their attention. At the same time, Warner-Lambert and SmithKline Beecham were getting companies to realize how important this was to their overall commercial agenda with US regulators."

Some MRA participants say it was this broader agenda with regulators that convinced pharmaceutical companies to exert effort on the MRA negotiations. One explains,

Mainly, they felt no matter how small the actual MRA was—because it only covered GMPs, which are a very small part of the total drug approval process—just getting the two regulatory communities to be exposed to each other’s procedures, and to be formally reporting to each other and exchanging information, was a huge accomplishment. Their goal was to get this improved dialogue between the two regulatory communities. And MRAs helped that. And so that’s why they were so willing to put so much into it.

As noted above, the medical device industry also had broader goals for participating in the MRAs: encouraging reform at the FDA. As one industry representative remembers:

FDA’s position was “We are the gold standard.” We could sit there and talk all day to them, saying, “How come you have 600 employees in the Office of Device Evaluation and it takes you five years to approve a device that’s been on the market for three years in Europe and there’s no evidence of safety problems?” But FDA really didn’t move until the trade agencies and other senior US officials, as well as the Europeans, began to put concerted pressure on them.

But industry’s hopes to keep pharmaceuticals and medical devices in the talks did not mean that its goals coincided with those of the European Commission. “The US industry had a slightly different interest,” notes DG Trade’s Falkenberg:

They were trying to effectively modernize FDA procedures through these MRAs, which was not necessarily what we wanted. We were not opposed to that, and we still favor that the FDA would review some of their burdensome procedures. But there was a bit of a danger for the negotiations because obviously it is much more difficult to modify existing domestic legislation than to seek recognition that a body in Europe could carry out existing procedures. Therefore, we were not necessarily supportive of these tactics.

Challenges persisted in other sectors as well. European negotiators were particularly dissatisfied with the negotiations on electrical safety. That issue was often bundled with the telecom and EMC sectors “because most of the products that are subject to legislation in one area are also subject to legislation in the other areas,” according to DG Enterprise’s Mattinò. But European negotiators felt they had no leverage in electrical safety. As Mattinò puts it,

US manufacturers already had full market access in Europe because they didn’t have to submit their products for certification to an independent organization. They could certify themselves, which meant they had direct responsibility and minor costs. What we wanted was to break what is regarded in Europe as the US monopoly by Underwriters Laboratories [UL]. We said to the US, “If you don’t accept terms we can live with in electrical safety, we will never accept the conclusion

of EMC or telecom.” But the EU and US telecom industries were so successful in lobbying they put pressure to conclude EMC and telecom. So from the perspective of a negotiation, we didn’t have anything to offer. We didn’t have any leverage.

At the same time, the negotiations over telecom were progressing more smoothly. The US Telecom Industry Association’s MRA task force met regularly with the two European telecom industry associations, ECTEL and EUROBIT.⁴⁰ “We held those joint meetings so that US and European industry were on the same page,” recalls Lucent’s Global Public Affairs Director Joanne Wilson. The TIA also worked with the US government on the substance of the agreement.

Of particular concern to industry were restrictive rules of origin. As Wilson notes, “We wanted the agreement to be strictly about conformity assessment, and not include issues related to where the product was sourced from, because we’re all global companies. So we were adamant about that. We wanted all parts of a piece of equipment to be covered under the scope of the agreement.” The Commission took the opposite position, initially seeking an agreement that would specify where a product could be manufactured. US negotiators attribute this stance to a hope of encouraging more manufacturing in Europe. In any case, the European telecom industry agreed with the US position that there should be no restrictions based on rules of origin. “The fact that the US [government] held a hard line on that issue and succeeded in keeping it out of the agreement is because the US and European industry made it very clear that it was a problem,” said one representative of the US telecom industry.

US industry representatives note that they and their European counterparts had different relationships with government. As one telecom industry executive observes,

We worked very closely with Commerce and USTR. They’d let us know how things were going in terms of their negotiations, the sticking points and so forth. We would give them feedback on our views, and the important points that we wanted them to dig their heels in on. We also shared with them areas where we could find some flexibility. It would have been easier had there been a closer working relationship between the Commission and companies in Europe. . . . The problem in general on the European side is that the Commission is not as easily influenced by industry. Because the Commission is appointed, they have much more autonomy [than the US government]. It is easier for the Commission to take positions that industry opposes than it is for the US government to do the same thing. I also think Europeans have a much more programmatic approach that expects more management by government of industry.

40. ECTEL is the Association of the European Telecommunications and Professional Electronics Industry. EUROBIT is the European Association of Manufacturers of Business Machines and Information Technology Industry.

The Chicago Breakthrough

While discussions continued in the various MRA sectors, the TABD was looking for a site—and, more specifically, a local organization that would help with expenses—for its next conference. The task fell to Alex Trotman and Ford's Washington office, and the Chicago Executive Club agreed to host the November 1996 meeting. As the conference approached, some believed that movement on the MRA talks had become the true test of the TABD's utility. "Breaking the long-standing MRA impasse has emerged as the clearest test of the TABD's potential to be a true catalyst for free and unregulated trade and investment, rather than simply a forum to discuss issues," declared one observer.⁴¹ As a result, according to USTR's Ralph Ives, "the TABD really dramatized the importance of the MRA. Basically, what the TABD was saying was, 'Look, we're a new organization. You, the government, encouraged us to do this. We haven't seen a lot of results for our efforts and we're putting in high-priced help here, CEOs of large companies. The MRA is a symbol for whether there is any utility to going to these meetings.'"

Nearly 70 CEOs from a cross section of American and European companies attended the Chicago conference, led by cochairs Alex Trotman and Simon DeBree, CEO of the Dutch petrochemicals firm DSM. Participants included Chrysler, Warner-Lambert, Xerox, and Sara Lee, as well as small and medium-sized businesses. Among the European participants were Ericsson, Daimler-Benz, Pirelli, and Pechiney (Breitfelder 1996, 22). Although the Chicago TABD meeting attracted more business representatives than did the first meeting in Seville, some European business leaders remained unconvinced of the forum's efficacy. "The people in Seville by and large came back," says European TABD director Stephen Johnston. "But a number of other European CEOs were still cautious. There was still a feeling that this was new and untested. And we weren't quite sure whether it was legitimate. Nobody wants to be caught out." The CEOs that did attend were particularly interested in the opportunity to speak face-to-face with government representatives.

Indeed, many participants remarked on the presence of high-level officials from the US government and the Commission. Mickey Kantor, who became commerce secretary after Ron Brown's death in an airplane crash, led the US delegation. On the European side, two commissioners, Sir Leon Brittan and Dr. Martin Bangemann, were in attendance. As Ives notes, "If you expect CEOs to be someplace, you have to expect cabinet-level officers to be at those meetings." Government, according to a TABD

41. "With No MRAs in Sight, TABD Participants Prepare for Second Annual Meeting," *Euro-watch* 8, November 1, 1996.

participant, had “a slight feeling of responsibility [for the TABD] because they had started it.”

Some analysts have observed that TABD involvement both raised the profile of the European Commission and provided the institution with information it could not otherwise have attained. The European member states did not play an active role in the TABD, and the Commission preferred it that way. One observer comments,

On the European side, there was always the issue that the Commission was not government, that they were not elected but the administrative arm of the common European institutions. The TABD raised the profile of Commission trade negotiations by giving them first-class information about what European business was asking for. It was useful to the Commission to be able to say to the member states, “We have a rather powerful, influential group of business people who want this agreement.”

Falkenberg echoes these sentiments: “The Commission welcomed the opportunity to speak with CEOs very much. It’s the member States who reacted jealously because it’s clear that direct contact between the Commission and individual national industrial interests weakened the position of the member states in the 133 and council advisory procedures. [Contact with industry] gave the Commission direct information that was otherwise filtered through the national administrations.”

A breakthrough on the MRAs came about on the second day of the conference, during the “Chairmen’s Breakfast.” The breakfast included the CEOs chairing the conference, the CEOs who would chair the following year, and key cabinet-level government officials. After some discussion, the group moved from the breakfast into the pharmaceutical breakout session. There Kantor, Brittan, and Bangemann joined several pharmaceutical industry CEOs—Warner-Lambert’s Lodewijk de Vink, Smith-Kline Beecham’s Jan Leschly, and Glaxo Wellcome’s Robert Ingram. Also present were the chief negotiators of the MRAs from Commerce, USTR, and DG Trade and regulators from the FDA and DG Enterprise. When Commerce Secretary Kantor walked into the room he reportedly said, “We’re going to make this happen. Let’s get this thing finished.”

The pharmaceutical industry understood that other sectors—especially telecom—were willing to throw pharmaceuticals overboard in order to reach an agreement. This understanding brought industry representatives to the table eager to work things out. On the subject of the pre- and post-approval of good manufacturing processes, one observer characterized US industry as “very supportive of the European position” that the agreement cover both. But the FDA continued to resist an agreement that addressed preapproval processes. In the end, negotiators decided to focus only on postapproval. Peralta-Schulte explains why industry conceded on this point: “The industry had to take a pragmatic standpoint. There is a cultural difference between government and industry. Industry lives by deliver-

ables, what can be accomplished in the near term. In working with government, however, we are often forced to accept incremental victories.”

On the second major stumbling block, the Commission declared that it could not support public disclosure of plant inspection reports because the European business community wouldn’t endorse it. But reportedly, the European CEOs of SmithKline Beecham and Glaxo Wellcome both contradicted this claim; in one observer’s paraphrase, they responded, “No, it’s OK. This is something we can live with.” In fact, they insisted, the European pharmaceutical industry was not as sensitive on this issue as the European Commission imagined. “It was quite compelling,” says one industry representative. “It is the difference between having someone unfamiliar with actual business practices articulate a point of view as opposed to someone who does this every day for a living.”

This discussion led directly to an agreement in principle between the United States and the European Commission. Europe conceded on the disclosure of inspection reports. In return, the FDA agreed to carry out second inspections of EU pharmaceutical imports only in special circumstances (Gopal 1997, 38). “Once these issues were discussed, not in a broad manner, but coming down to the central issues of concern,” says one observer, “you had reasonable people sitting together who could come to an agreement on how to move forward.”

Commerce Secretary Kantor declared that the MRA talks would be completed by January 1997—only two months away. “Mickey loved to establish deadlines,” says one observer. Though few saw this goal as reasonable, one participant asserts its importance: “For the first time, you had very high-level attention on the MRA negotiations.” Ralph Ives, the USTR lead negotiator, agrees:

For three or four years, the MRAs had been kind of floundering around, largely because nobody at high levels was paying attention to it. There were a lot of domestic political problems on both sides that people at my level just can’t overcome. So once you had leaders from both the US and EC saying, “We want this done within the particular period of time,” that gives a pretty good push. You know you’re going to have to report to these leaders every six months at the summit. It put a lot of pressure on both sides, both the US and the EC side, to try to reach an agreement.

The agreement in principle was considered a major breakthrough—“really the highlight of the conference,” says Johnston. One executive praised the effectiveness of the business-government session that advanced the MRAs, commenting that more real communication had taken place in two hours of dialogue than had occurred in the entire preceding year (Breitfelder 1996, 22). Another participant recalls Sir Leon Brittan telling the conference, “If business agrees on something on both sides of the Atlantic, it is up to the governments to say, ‘Why can’t it be implemented?’ ” But little is ever so simple. Charles Ludolph notes that the

TABD still was engaged in “making sure the consensus reached in Chicago was truly lived up to. And that was quite a job in itself. We still had several more months of negotiations where everyone was trying to slip out of that consensus.”

A Done Deal?

On December 16, 1996, at a press conference with Ireland’s Prime Minister Bruton and EC President Santer, President Clinton announced that the transatlantic commitment to reduce trade barriers was paying off:

Next month our negotiators will finish work on a set of mutual recognition agreements, which will abolish requirements that a broad range of products, including telecommunications and medical equipment, be reinspected and recertified for each other’s markets. This will remove barriers on \$40 billion worth of trade between the United States and the European Union, cutting red tape for our businesses and prices for our consumers. One standard, one test, one time.⁴²

Of course, the MRAs did not establish “one standard, one test, one time,” and some US negotiators were dismayed to hear these words. “Unfortunately he said it right after the US-EU Summit and it was not cleared with anybody,” says one negotiator. “My European counterparts would play it back to me, but what could we say?” President Clinton also thanked the Transatlantic Business Dialogue for its leadership in the MRA process, and asked the European and American co-chairs—Jan Timmer, former chairman of the Philips Electronics Corporation, and Dana Mead, chairman of Tenneco—to stand and be recognized.

To Create a Framework or Not to Create a Framework

Despite the president’s announcement, EU and US negotiators missed their January 1997 deadline for agreeing on the MRA package. One emerging problem centered on the concept of an overarching framework or umbrella agreement for the MRAs. While some Commission negotiators strongly favored it, “The US said, ‘We don’t need a framework agreement, for God’s sake,’ ” said one US negotiator. “We don’t need this big structure.’ But it became increasingly apparent to us that one reason the Europeans wanted this was largely for internal reasons—that is, to ensure that DG-1 [Trade] was in charge of all other DGs in the MRAs.”

In the United States, a specific regulatory agency (the FDA, FCC, etc.) had jurisdiction over each sectoral annex. Similarly, various Directorates-General in the Commission had responsibility for their respective sectors.

42. Press conference by President Clinton, Prime Minister of Ireland John Bruton, and President of the European Commission Jacques Santer, December 16, 1996, Washington, DC.

A framework agreement would put DG Trade in charge of the overall MRA. “In fairness to the Commission,” said one US participant, “there was probably a need for some type of a committee or structure to oversee all of this, particularly as you bundled more sectors into the package.” But if DG Trade was in charge on the European side, then USTR would be in charge on the US side. And that idea, according to Ives, created a dilemma:

The FDA has a much-deserved reputation as an independent regulatory authority, and this is something that the Europeans envy. It is an authority that has relatively little influence from outside trade or political influence. The downside of that for us, in negotiating something like the framework agreement, is FDA says, “Wait a minute. We have authority over regulating pharmaceutical products and medical devices, and you, USTR, can’t speak for us.” If you have a framework agreement where it’s clear that USTR is in charge, of course USTR could say in a meeting with the EC, “FDA will change that regulation.” But that carries absolutely no weight with FDA. I said to FDA, “It makes no sense that I would go into a meeting with the Europeans and say something that FDA won’t support.” But then it became largely a perception issue with the FDA and constituents, both on the Hill and public interest: does it look like USTR is speaking for FDA?

In addition, broader concerns were raised on the US side about the overall MRA effort. EPA officials organized a public hearing on the MRA to air worries about the agreement, though none of the sectors being negotiated were directly under its purview. Commerce’s Charles Ludolph characterizes the EPA’s efforts this way:

It took four years to do this thing [the MRA] and nobody really believes that something that takes four years is actually going to happen. But toward the end, when everybody saw it was really going to happen, agencies came out of the woodwork trying to stop it or influence it. The EPA essentially undertook a campaign to disengage completely from the MRA. There is solidarity among regulators in the US government. They seem to have an unspoken agreement to try and keep about the same policy positions, in a general way. The effect was that, when EPA had a problem, all of a sudden people who had been on board for four years suddenly had a problem. It was a hard thing for me to absorb.

Ives says the hearing failed to meet the EPA’s hopes because the public had little interest in the MRA negotiations and press coverage of the talks was sparse. As he describes it,

EPA saw the MRA as being this evil monster that was subjecting environmental concerns to trade concerns. Something that for the life of me—and we went through numerous interagency meetings—I just could not understand. I really couldn’t, because we assured FDA that there is nothing in this that was going to undermine their authority and we kept putting that in almost every other sentence of the MRA. But anyway, EPA had this public hearing, expecting that there would be a lot of public outcry. In fact, there was very little. There was just very little attendance. And very few call-in questions. So my point is, there has been throughout the process a number of attempts to elicit public comments, and there hasn’t been a lot of public interest in it. Nevertheless, FDA has a legitimate concern that it does not want the perception that its regulatory authority is being subjected to trade concerns.

Another factor that prolonged the process, according to industry executives, was European “culture shock” at the initiative taken by the private sector. “The Europeans had enormous problems with industry sitting at the table,” says telecom executive Vic Boersma of Nortel (quoted in Schick 1997, 18). European negotiators also balked at what they perceived to be the FDA’s intransigence. “The EU understands what’s at stake,” said the Commission’s Brittan. “Europe is prepared to go the last mile . . . but it is not prepared to become a sub-agency of the [US] Food and Drug Administration” (quoted in Journal of Commerce Staff 1997, 2A).

Finally, language surfaced as a problem. European negotiators insisted that the MRA be signed in all 11 official languages of the European Union. US negotiators countered that the agreement itself specified that the only authentic text was the English version. The Europeans agreed that the authentic MRA was in English, but remained adamant that all 11 versions had to be signed. US treaty lawyers refused to sign the 10 new versions until all were translated back into English and verified.

The Final Push

Senior US administration officials decided to push forward on the MRAs before they stalled under the weight of bureaucratic resistance. In May 1997, Secretary of State Madeleine Albright called EU President Santer to say that the time had come to resolve the remaining issues. Later that month, at a ministerial meeting of the Organization for Economic Cooperation and Development in Paris, USTR Charlene Barshefsky met with European Commissioner Sir Leon Brittan, but they failed to resolve all the outstanding issues. The next day, Barshefsky and Brittan met again with Jeff Lang, Stuart Eizenstat, Charles Ludolph, and Ralph Ives. Brittan put a new proposal on the table, and the leaders finally agreed on a deal. As Ives tells it,

This is where having high-level attention really helped. A combination of Jeff Lang and Stu Eizenstat calling various people—for example, the acting FDA commissioner at the time, Mike Friedman—and getting his staff involved in going through some of the new EC proposals. Then Charles Ludolph and I worked with FDA and came back with a counterproposal. The bottom line was: by the time we left Paris, over that three-day period, we had a text that both the US and EC negotiators could accept, and this was basically at the ministerial level. That meeting was a huge breakthrough.

The MRAs were initialed by all parties but not officially signed, because the translation-and-verification process still had to be completed. “This is a new way of doing business,” said Barshefsky. “The MRA package is an important breakthrough in the US-EU trade agenda. We could not have achieved this package without the Transatlantic Business Dialogue.” Sir

Leon Brittan of the European Commission added that the “massive red-tape-cutting” deal “will oil the wheels of transatlantic trade by cutting costs, shortening delays and reducing red tape in some of the most important sectors for the next century. With vital input from the TABD, it has assured that the US-EU relationship will bring real benefits to business and consumers.”⁴³ But because the agreement wasn’t signed, the game wasn’t quite over yet.

In November, Congress overwhelmingly passed the Food and Drug Administration Modernization Act of 1997 (FDAMA) with the goal of “improv[ing] the regulation of food, drugs, devices, and biological products” (Public Law 105-115). The legislation, meant to speed the FDA’s approval process for new drugs and medical devices, was the result of a three-year campaign by Republicans to reform the FDA. An attempt in 1996 to institute more sweeping changes had been blocked by Democrats. Health and Human Services Secretary Donna Shalala had threatened to recommend a presidential veto over provisions in the 1997 act on medical device approvals, but compromise language paved the way for President Clinton’s approval. Senator Edward Kennedy (D-MA) praised the legislation as a victory for public health saying, “the health of the American people will be enhanced through faster availability of pharmaceutical drugs and medical devices.”⁴⁴

Among the FDAMA’s provisions was a section on “mutual recognition agreements and global harmonization” (see appendix 7A) directing the FDA to support the efforts of Commerce and USTR to implement MRAs. The act also required that a plan be established within 180 days to achieve mutual recognition of pharmaceutical GMPs. Observers say that the inclusion of MRA language in the FDAMA was an important step toward finishing the agreement.

The FDAMA also made changes to the 1976 medical device amendments that also affected the MRAs—inadvertently. “Just as we were tying things up, of course, Murphy’s law kicked in,” jokes Charles Ludolph. As an unintended consequence of the law, four of the medical device products listed in the MRA could no longer be included (Horton 1998, 726). Negotiators were incredulous. “We had to amend the damned agreement,” says Ludolph, even though the agreement had already gone through the language-verification process. “Because we had already translated it, bureaucratically no one could figure out how to amend it.” But somehow the necessary changes were made.

43. Barshefsky and Brittan, quoted in “Transatlantic Business Dialogue Praises Conclusion of MRA,” US Newswire, June 13, 1997.

44. Mark Suzman, “Compromises Pave Way for FDA Reform: New Law Is Widely Hailed as a Victory for US Public Health,” *The Financial Times*, November 21, 1997, 7.

The Agreement

The MRAs were signed on May 18, 1998, by USTR Charlene Barshefsky, Commerce Secretary William Daley, European Commission Vice President Sir Leon Brittan, and European Commissioner for Industry Martin Bangemann (see appendix 7B).⁴⁵ The six sectors covered in the agreements were telecommunications, medical devices, pharmaceuticals, electromagnetic compatibility services, electrical equipment, and recreational craft.

For pharmaceuticals, the MRA governed good manufacturing practices and the exchange of inspection reports. Though the FDA ultimately agreed to include preapproval as well as postapproval GMP inspections, the agency prevailed in its demand for a three-year transition period—rather than the 18 months requested by the Europeans—to determine which EU inspection processes would be deemed equivalent to its own. Once the MRA was implemented, the FDA and its EU counterparts would each inspect domestic production facilities and make sure they were in compliance with the regulations of the country to which they were exporting.

The agreement also provided for the exchange of product evaluation reports by third parties in the United States and the European Union under the existing FDA pilot program for selected medical devices. These reports would be accepted and used by the receiving regulatory authority.

On electrical safety, European negotiators were dissatisfied. Giacomo Mattinò remarks that political pressure forced a bad outcome and was “detrimental to reaching fair and unambiguous conclusions.”

At the negotiating level, we were having a number of serious difficulties in the electrical safety sector. An important point about the TABD is that—at the time of negotiation—the most successful industry in lobbying on the issue was the big telecommunication industry on both sides, EU and US. They created such pressure to conclude the telecom and EMC sectors that basically we had to conclude electrical safety even though the terms were not what we were expecting. I personally would not have signed an agreement according to those terms. Even if that implied delaying an agreement in EMC and telecom.

Other observers heralded the innovative and precedent-setting role of the TABD. Ellen Frost, a senior fellow at the Institute for International Economics, told the House Ways and Means Committee’s Subcommittee on Trade: “This is the first time in the history of trade negotiations that a transnational business coalition has taken quite such a prominent and high-level initiative in defining an agenda of this kind. This makes sense

45. In 1998, the European Union comprised 15 countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

because these companies are most familiar with real-life transatlantic trade and investment and can identify the barriers most readily."⁴⁶

Some saw the TABD as part of an emerging trend, pointing out that with increased frequency, international trade initiatives are being spear-headed by business. Guidant's Michael Gropp comments:

I think [the TABD] is a reflection of a phenomenon. More and more, it is business that drives these multilateral initiatives because it's business that is forced to confront the inefficiencies and the duplication, more than governments. If you think about FDA, they deal with issues that come to them in the US, but they don't deal day-to-day with the problems of moving medical devices into markets or introducing pharmaceuticals around the world. These initiatives become even more important in view of pressures in most societies to reduce the growth of health care costs for aging populations.

But some saw this trend—and the TABD—as worrying. Public Citizen's Global Trade Watch, a US nonprofit consumer organization, was alarmed by the role of business in the MRA talks. If business groups were involved in determining how their own products were certified, wouldn't compromises in health and safety inevitably follow? In response to such concerns, the Clinton administration assured the public that the MRA would not jeopardize the safety of American consumers. One administration official declared that the MRA "in no way undermines the capacity of US regulatory agencies to inspect or test where they feel the health or safety of the American people is concerned."⁴⁷

TABD officials perceive these worries to be unfounded. "The dumbing-down of standards is not what we are about at all," says Selina Jackson, former director of the TABD. "The business community does not mind if there are high standards, they just want one standard. It is very difficult to conform to one standard in the United States and another in Europe. They would rather take the highest of standards, just as long as there is one. I am not sure consumer groups understand that." Some industry representatives also consider the suspicion of industry efforts a knee-jerk response, emphasizing that industry involvement was in fact necessary to reaching a final agreement. As Lucent's Joanne Wilson explains, "People think of lobbying as industry or interest groups just trying to have their way. But the reality is that those who are creating policy need to have an understanding of the implications of that policy in practice. It is a very valid and valuable process that industry plays to ensure that the policies are ones that are useful."

46. Frost, testimony before the House Subcommittee on Trade of the Ways and Means Committee, "New Transatlantic Agenda," 105th Congress, 1st session, July 23, 1997.

47. Dan Tarullo, assistant to the President for International Economic Affairs at the National Economic Council, White House press briefing, May 28, 1997.

The Commerce Department's Charles Ludolph sees no need to defend the idea of business and government working together, for such interactions are inevitable: "The US Commerce Department works with the business community. I would expect consumer groups to hope that the business community wouldn't be working with government, or vice versa. But in a democracy, in an open government, that is impossible to achieve. Every citizen, every interest group, has the right to work with the US government. If they don't want the government to talk to business anymore, that's clearly illegal."

But Public Citizen argued that while government was becoming more responsive to the concerns of business, it was becoming less responsive to the needs of consumers. For example, the White House had recently closed its Office of Consumer Affairs. In addition, even as government-initiated organizations like the TABD were being developed to improve dialogue with business, little effort had been made to include other constituencies, such as consumer and environmental groups, in discussions of international trade, Public Citizen noted. In response to such concerns, the Transatlantic Consumer Dialogue (TACD), an association of US and European consumer associations, was founded in September 1998.

Some business representatives claim that consumer groups could have been more active in the MRA process than they chose to be. "I don't remember any participation from consumer groups," says one pharmaceutical executive. "The FDA solicited public comment in the *Federal Register* and held hearings to seek input. The only thing I have seen from consumer groups has been post-MRA."

Concerns in Congress

As the MRAs were being completed, further concerns were raised in the US Congress, particularly over the pharmaceutical annex. For three years, the House Commerce Committee's Subcommittee on Oversight and Investigations had been studying the FDA's program of inspecting foreign drugs. "The amount of pharmaceutical products being imported into the US was exploding," explains the senior oversight counsel of the subcommittee, Alan Slobodin, "and there were concerns about the safety of these products."⁴⁸

In the summer of 1998, subcommittee staff traveled to Europe to meet with regulators and pharmaceutical industry representatives about the MRA. Staff members were trying to learn more about pharmaceutical GMP inspections in Europe. "We had very little information and we were trying to find some answers," says Slobodin. "No one seemed to know

48. Unless otherwise noted, all quotes from Alan Slobodin come from a 2000 interview with Charan Devereaux.

much about how these inspections took place. With 80 percent of the bulk pharmaceuticals used by US manufacturers being imported, this was a cause of great concern.”

Soon after the trip, several ranking members of the subcommittee and the full committee—including Subcommittee Chair Joe Barton (R-TX), John Dingell (D-MI), Henry Waxman (D-CA), and Ron Klink (D-PA)—wrote to the FDA requesting more information about the MRAs. One observer called this letter, signed by John Dingell, “the Dingell-gram from Hell,” since the FDA was not eager to be the subject of congressional investigation. In October 1998, the subcommittee convened a hearing titled “Imported Drugs: US-EU MRA on Drug Inspections.” Opening the session, Chairman Joe Barton declared: “The Congress is open-minded about this MRA and we are very supportive of the FDA cooperating with foreign health authorities. However, this agreement raises serious questions that Congress must address. As my mentor Ronald Reagan has stated so elegantly regarding international relations, ‘Trust, but verify.’”⁴⁹

Committee members voiced their questions and concerns to Charles Ludolph, Ralph Ives, Walter Batts, and FDA Deputy Commissioner for External Affairs Sharon Smith Holston. “We are already experiencing a severe negative trade balance in drug products with the EU,” asserted Commerce Committee Chairman Tom Bliley. “In the last six years, this trade balance has become over 24 times larger, amounting to a negative trade balance of \$4 billion.”

Waxman, coauthor of the 1984 Waxman-Hatch Act on pharmaceuticals, also expressed reservations. “There is no question that international agreements of this kind can enhance the efficiency of commerce. But it is equally clear that they can potentially depress American health and safety standards.” Klink ruminated,

It only makes sense to reduce the number of duplicative inspections and processes that manufacturers have to go through to get their products on the market. But . . . during the negotiations, I fear that the FDA—the agency most responsible for protecting the health and safety of our citizens—may have been reduced to a large poker chip in a game of high stakes trade worth tens of billions of dollars.

Along those lines, one committee member read an internal FDA e-mail in which a former member of the FDA’s MRA negotiation team suggested that the agency should consider withdrawing from the talks.

Some observers and participants saw the congressional hearing as proof that the US political process was working—that federal agencies were held accountable and asked to explain their reasoning and decisions.

49. All quotations from House members in this passage are drawn from the Hearing before the House Subcommittee on Oversight and Investigations of the Committee on Commerce, “US-EU (European Union) Mutual Recognition Agreement on Drug Inspections” October 2, 1998.

In the end, the MRA remained intact, though the subcommittee asked the General Accounting Office (GAO)—now the Government Accountability Office—to keep it informed on the FDA’s progress in devising a means to assess the EU GMPs. According to the GAO’s John Hansen,

The biggest concerns were what criteria FDA was going to use to measure equivalency, and how those criteria were going to be applied to the respective inspection programs of each of the EU member states. What the FDA was telling Congress was very general. In order to learn more about FDA’s plans, members of Congress asked us to look into how FDA intended to implement the MRA in more detail.⁵⁰

Though an agreement had been signed, the story clearly was not over.

Implementation

Negotiation of the MRAs was just the beginning of the process—next came implementation. Many issues required further discussions to determine their terms. “The tough issues in negotiation became the tough issues in implementation,” says Lucent’s Joanne Wilson. Some called the negotiation of the MRA elementary compared to the challenge of implementing the agreement. According to DG Enterprise’s Giacomo Mattinò, “The MRA often implies regulatory changes that the responsible parties on the internal front are not always ready to put in place, have not conceded to, or did not expect would come so quickly. I think some have been taken by surprise.” Another negotiator says, only half-joking, “It’s never over. As far as I’m concerned, we will have to be vigilant the rest of our lives.”

Events in Europe during the MRA negotiations had underscored the importance of protecting public safety, heightening public awareness of controversies over trade and public health. A Commission official explains:

In Europe there’s been a series of problems—for example the mad cow experience, the problem in Belgium with Coke—that attracted the attention of the wide public, pointing out how particular attention should be given to protecting public safety. GMOs [genetically modified organisms] and the beef hormone case can also be seen in the same perspective. On one hand there is trade liberalization, and on the other hand the fact that public safety must be safeguarded appropriately. We are trying to promote an appropriate approach to those issues with the ultimate objective of overall deregulation. But again, not deregulation just for the sake of deregulation.

Though some concerns about health and safety were legitimate, regulators were keenly aware of the frequent use of standards and certification

50. Unless otherwise noted, all quotes from John Hansen come from a 2000 interview with Charan Devereaux.

as trade barriers. As a European Commission staff member notes, “conformity assessment has traditionally been used everywhere as an instrument for each state to be somewhat protectionist.”

The ultimate long-term relevance of the MRAs was also debated. Some, including Michael Gropp, saw the MRAs as a step along the way toward further harmonization of standards:

My view is that the work of the Global Harmonization Task Force will eventually eclipse MRAs, but that’s a long time down the road. In my mind, the bigger game and the better outcome would be harmonization, not a growing web of bilateral MRAs, because they become difficult to manage. I think that five to ten years out, we could have harmonization in the leading markets in the world, and maybe even some of the smaller markets. If that’s the case, then I expect that the MRAs would essentially drop by the wayside as being superfluous.

The suggestion that MRAs were a temporary fix raised concerns that too great a proportion of scarce regulatory agency resources were being devoted to a project that might have limited use. Others worried that perceived lack of success in negotiating and implementing MRAs might jeopardize future international agreements on regulatory issues. One negotiator gave voice to that view: “They say, ‘after all, MRAs are a little part of a bigger idea. If this little part is not successful then why should we try for a more ambitious one?’” Finally, some suggested that success in implementing the MRAs could make future regulatory reform more difficult. Charles Ludolph explains, “One of the criticisms which has been said of the MRAs is that they tend to freeze the regulatory situation of each party instead of pushing them to change. If you accept my legislation as such and I accept yours, then probably we don’t have an interest in changing anything in the future.”

Though disagreement over these broad questions remained, implementation was under way. The telecommunications section of the MRAs took effect in December 2000, as planned, and the US-EU MRA became the pattern for future telecom agreements. The US industry later entered into MRAs with the 17 nations of APEC and then with the Inter-American Commission of Telecommunications. “The real benefit was not so much the agreement itself, it was the process,” says one industry official. “It became a model. What’s happening in various countries—not just in Europe, but around the world—is that the regulatory agencies are changing their product approval programs to accommodate the MRAs.”

Other sectors did not enjoy such obvious success. The three-year confidence-building period for the medical device sector of the MRAs began in December 1998. Industry continued to hope that the United States and Europe would agree to a joint implementation plan with action steps and benchmarks. “You may have an agreement signed,” says Bernie Liebler, HIMA’s director of technology and regulatory affairs, “but until

you actually have a plan, it's difficult to move forward."⁵¹ For example, when it began conducting routine European inspections in 1999, the FDA asked medical device companies if they wanted to include a European Conformity Assessment Body (CAB) as part of the MRA process. When Europeans wondered how the FDA could move forward with joint audits in the absence of a joint implementation plan, the FDA countered that it was just trying to move forward. "There's been some miscommunication," admits Liebler. "As a result, the process has been slow to get under way." The United States and the European Union therefore agreed to defer implementation in the medical device sector until November 2003.

The biggest problems in implementing the MRAs arose in the electrical safety and pharmaceutical sectors. In a letter to USTR Charlene Barshefsky written in October 2000, EU Trade Commissioner Pascal Lamy accused the United States of "being hardly within the letter and even less in accordance with the cooperative spirit of the MRA." Efforts to implement the agreement were "drifting dangerously," he wrote.⁵² The European Union believed that US regulatory agencies—particularly OSHA and the FDA—were undermining the deal by refusing to recognize European product safety testing as equivalent to tests in the United States. Some business leaders were especially frustrated by the holdup because they had made the MRAs a top priority. In a document presented to both EU and US governments, the TABD noted that failure to implement the MRAs by the December 2000 deadline "will have far-reaching negative consequences for both the governments and industry. . . . Full implementation of the agreement is essential to maintain the credibility of these processes and future EU-US trade negotiations" (TABD 2000, 23). The TABD called on the governments to apply the group's objective of "Approved Once, Accepted Everywhere" (TABD 2001, 4).

OSHA maintained that it had sole authority to determine whether EU electrical safety inspection labs met US standards. The European Union disagreed, arguing that authorities in the 15 member states should certify these European labs. Three European testing laboratories went ahead and applied directly to OSHA for approval to certify products for the US market; two of these applications received no consideration because they were made in French and Spanish, not English. "We are a domestic health and safety agency," said Steven Witt, the director of technical support at

51. Unless otherwise noted, all quotes from Bernie Liebler are from a 2000 interview with the author.

52. Pascal Lamy, letter to US Trade Representative Charlene Barshefsky, October 20, 2000; reprinted in *Inside US Trade*, November 10, 2000.

OSHA. “We don’t do translations.”⁵³ In the pharmaceutical sector, the European Union proposed extending the implementation period for the pharmaceutical GMPs annex to 2003, but the FDA was hesitant to set any firm deadline. EU officials also considered increasing the pressure on the US government by suspending or terminating portions of the MRAs (such as the telecom agreement) that were of key interest to US industry.

Ultimately, the European Union withdrew entirely from participation in the MRA electrical safety agreement when the European Council suspended the annex in January 2003. The impasse over implementing the MRA’s pharmaceutical annex continued as well. As a result, some characterized the MRAs as a failure. “The efforts that we’ve made to date—the MRA process for example—are, I think, failures or seen as failures by authorities and the business community,” said Jean-François Boittin, minister for economic and commercial affairs at the French embassy in Washington. According to Boittin, the lack of progress showed that the United States and European Union had failed to find “the right framework” for discussing and resolving regulatory issues in a way that facilitates trade.⁵⁴

Not all officials shared his assessment. Assistant USTR for Europe and the Mediterranean Cathy Novelli observed that although the United States and European Union “have not figured out all the pieces” of solving regulatory problems, “to me, that doesn’t mean we simply cease and desist and say this is a failure. . . . I take a less dim view of the efforts we’ve had to date, because we are trying to work our way through this difficult period.” She suggested that progress on regulatory issues tends to be slow: “For now at least, we are doomed to incrementalism in terms of thinking about this.”⁵⁵ Perhaps the most important aspect of the MRA process, some said, was learning more about the other side. As Mattinò notes,

I would say a good half of the negotiating process was spent exchanging information. This is one of the good things that came out of the MRA. It made an incredible contribution, surprisingly, to a better understanding between the regulatory communities. I say it’s surprising because I’m surprised myself that people didn’t have the chance to get more familiar with procedures in different countries before. But in fact it is the truth that the MRAs have greatly contributed to the experts at the same level from each side of the Atlantic talking to each other. In the end this will hopefully lead us to greater confidence in each other.

53. Witt, quoted in Edward Alden, “Mismatch on Product Safety Puts Accord on Danger List: The European Union Is Accusing the US of Undermining Their Deal on Mutual Recognition of Tests and Standards,” *The Financial Times*, November 9, 2000, 23.

54. Boittin, quoted in “US, EU Seek Way Ahead on Stalled Regulatory Cooperation Agenda,” *Inside US Trade*, March 21, 2003.

55. Novelli, quoted in “US, EU Seek Way Ahead.”

Despite their setbacks in dealing with pharmaceutical good manufacturing practices, medical devices, and electrical safety, at a June 2003 summit meeting the United States and European Union agreed to regulatory cooperation in five more areas: cosmetics, automotive safety, nutritional labeling, food additives, and metrology. European officials characterized the agreement as involving no detailed commitment on any particular regulation, serving instead as a promise to cooperate on new regulatory issues and to look for ways to coordinate rule making between US and EU agencies.⁵⁶ In February 2004, the United States and the European Union signed an MRA on marine safety equipment covering \$150 million to \$200 million annually in two-way trade. "Regulatory cooperation between us is the way forward to foster trade and investment," said the Commission's Pascal Lamy.⁵⁷

Negotiation Analysis of the Case

When the MRA talks are viewed through the lens of negotiation analysis, it is clear why they proved to be so challenging. The rationale for pursuing MRAs is easy to understand: Companies were often forced to retest their products in different countries to similar standards, a costly and time-consuming requirement. But when the process of international trade met the process of domestic regulation and certification, challenges inevitably arose. In the MRA talks, US and European officials confronted unprecedented institutional issues. Government regulatory agencies, ordinarily uninvolved in trade discussions, became central players. Their involvement complicated the negotiations, for their primary mission was to protect public safety, not to facilitate trade. The reluctance of some FDA officials to participate in the process was an obvious sign of this tension. One lesson that can be drawn from the MRA story is that new issues in trade necessarily draw new players into trade negotiations, leading to new complexities in the negotiating dynamic.

In the face of such challenges, participants in the MRA talks sought to advance the negotiations by engaging in a number of classic game-changing moves. One such move was the creation of the Transatlantic Business Dialogue (TABD). By leveraging this unofficial negotiating forum, business and government representatives were able to move the official MRA negotiations forward. The MRA talks can also be seen as part of a longer-term strategy of certain export industries to achieve greater harmonization in international standards and to increase pressure on domestic US regulatory agencies (notably the FDA, the FCC, and OSHA) to change how they regulate their sectors.

56. "Lamy Spells Out Areas for US-EU Regulatory Cooperation," *Inside US Trade*, June 20, 2003.

57. Lamy quoted in European Commission press release no. 33/04, "EU-US Sign Mutual Recognition Agreement on Marine Equipment," February 27, 2004.

Element #1: Organizing to Influence

The evolution of the MRA negotiations was strongly shaped by two initiatives originating in the US Commerce Department. The first effort, spearheaded by Charles Ludolph in 1987, supported and launched MRA negotiations between the United States and Europe. Anticipating the impact of the introduction of CE marks by the European Union, Ludolph and his interagency working group surveyed US industries to gauge interest in negotiating MRAs. When a critical mass of industry sectors expressed support, Ludolph initiated a dialogue with the European Commission that eventually led to the MRA negotiations. He also created supporting business advisory groups for each industry sector.

The second MRA organizing effort, begun in 1994, resulted in the creation of the TABD. The brainchild of Commerce Secretary Ron Brown, the concept of the TABD initially met with a cool response from EC officials, who wanted evidence of interest on the part of European business. Secretary Brown and his staff involved the European Commission by convincing the EC to undertake a joint survey of European and US business interest in the idea. Positive results and subsequent success in engaging business leaders on both sides of the Atlantic led to the first TABD event in Seville.

Element #2: Selecting the Forum

Arguably the most interesting aspect of the MRA case, like the Multilateral Agreement on Investment (MAI) case, is the effort to create a new negotiating forum. A key difference, of course, is that the MRA negotiations ended in an agreement (though tenuous in some sectors), in part because the TABD forum played a constructive role in helping the negotiators to overcome significant barriers to reaching a deal.

The TABD is an example of a particular type of game-changing move: the use of “track two” diplomacy. The creation of a parallel forum allowed informal discussions to take place that helped advance the formal negotiations. Because the TABD’s status as an MRA negotiating forum was unofficial, the key parties could talk without the pressure of committing themselves to specific positions. The TABD forum also provided government negotiators with an important channel for learning about business perspectives on standards issues. This learning function was especially helpful in Europe, where businesses had traditionally worked with national governments, not the Commission. Through the TABD, European business and EC officials could communicate directly.

The case also illustrates the implications for regulatory agencies of negotiating standards and certification issues in a multisector trade forum. Before the MRA negotiations began, the FDA was engaged in focused bi-

lateral talks with Europe's DG Enterprise to complete a memorandum of understanding that would have committed EU countries exporting drugs to the United States to meet FDA standards. But because the MRAs superseded the MOU process, the FDA was pulled into a new negotiating forum, where multiple sectors were being dealt with in the context of a broader trade relationship. The parallel negotiations made cross-sector trades feasible—a possibility that understandably made the issue-focused US regulatory authorities quite nervous.

Moreover, the involvement of the FDA in the MRA negotiating forum advanced the interests of the medical device industry. The US industry preferred the European regulatory process, which it found less costly and time-consuming than the FDA's. By broadening awareness of the differences in the two systems, the MRAs helped to create pressure within the US government to reform the regulation of medical devices.

Element #3: Shaping the Agenda

Rather than seek a broad agreement to completely harmonize regulatory standards, a goal that they realized was probably unreachable, the organizers of the MRA negotiations decided to focus narrowly on mutual recognition. By concentrating on the modest objective of recognizing each other's testing and certification processes, the negotiators had a fighting chance of finding a zone of agreement. The deal structure also established precedents that would help to create momentum toward future regulatory agreements.

European and US officials engaged in "prenegotiations" over which industry sectors would be included in the talks. Negotiators sought to identify a package of sectors that both represented a reasonable aggregate balance of trade between the United States and European Union and provided sufficient potential for creating value through cross-sectoral trades. The US telecommunications industry was very interested in negotiating an MRA with Europe, for example, but European Commission officials refused to include telecom unless pharmaceuticals, medical devices, and electrical safety (strong export industries for Europe) were added to the package. The United States agreed to include these sectors, in part because the US pharmaceutical and medical devices industries believed that they could advance their own agendas through negotiating an MRA. In this way, mutually beneficial trades shaped the agenda.

Negotiators also made the important decision to narrow the agenda when disagreement in the pharmaceutical sector threatened to derail the whole process in 1996. When the FDA objected to preapproval inspections of pharmaceutical manufacturing processes, the MRA negotiators—believing that an agreement, however modest, that advanced the harmonization agenda was key—avoided breakdown by agreeing to focus only

on postapproval inspections. In fact, the FDA eventually accepted preapproval inspections.

Finally, the parties needed to decide whether the MRAs should be placed into a broader, longer-term negotiation framework. After initially opposing such a framework, which might seem to confirm the perception that the trade agencies were “in charge” of the regulatory agencies, US negotiators realized that the real issue was intra-European bureaucratic politics. DG Trade was trying to solidify its control over the other EC directorates-general in the administration of the MRAs. Its maneuvers, as well as the FDA’s discomfort with domestic regulatory issues being moved onto the trade agenda, illustrate how government bureaucracies incorporate agenda setting into their efforts to win internal competitions for policymaking influence.

Element #4: Building Coalitions

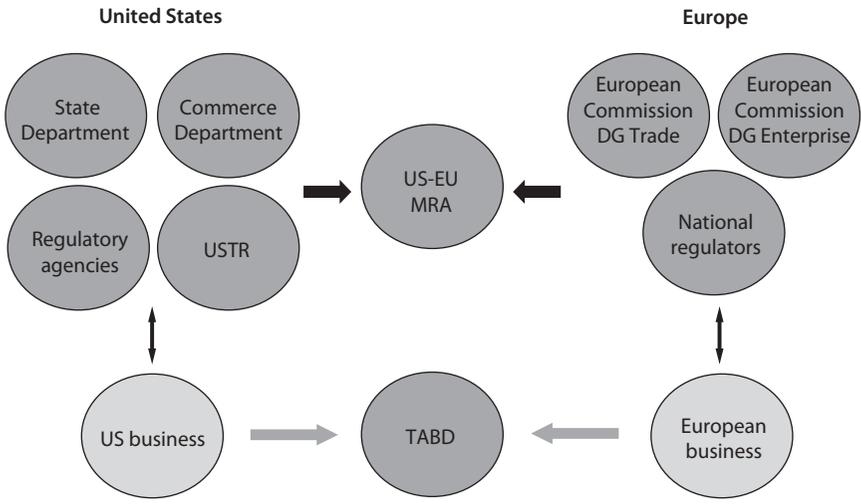
The organizers of the TABD sought to support the MRA process by fostering coalition building between US and European businesses. Traditionally, the US and EU business communities had influenced trade negotiations by cooperating on an ad hoc, issue-specific basis (as seen, for example, in the case of the Agreement on Trade-Related Aspects of Intellectual Property Rights). The TABD provided a new institutional structure that broadened and formalized transatlantic business cooperation (see figure 7.1).

The TABD also provided a forum for direct dialogue between European business and the European Commission. Through the TABD, business interests could explore common interests and better educate negotiators on their positions. For example, European negotiators initially believed they were acting in the interests of their pharmaceutical companies by demanding that plant inspection reports remain confidential; but when direct dialogue between US and EU CEOs and government officials revealed it to be a nonissue, the roadblock in the pharmaceutical negotiations was removed.

Element #5: Leveraging Linkages

As illustrated in figure 7.2, the MRA negotiations were linked to a number of prior sets of talks. These included the negotiations in Europe that created the CE marking process in 1985 and an agreement between US and German telecommunications companies. The efforts of companies to negotiate common positions in forums such as the International Conference on Harmonization (for the pharmaceutical industry) and the Global Harmonization Task Force (for the medical device industry) also helped to shape the MRA negotiations.

Figure 7.1 The TABD and coalitions in transatlantic trade negotiation



DG = director-general
 MRA = mutual recognition agreement
 TABD = Transatlantic Business Dialogue
 USTR = US trade representative

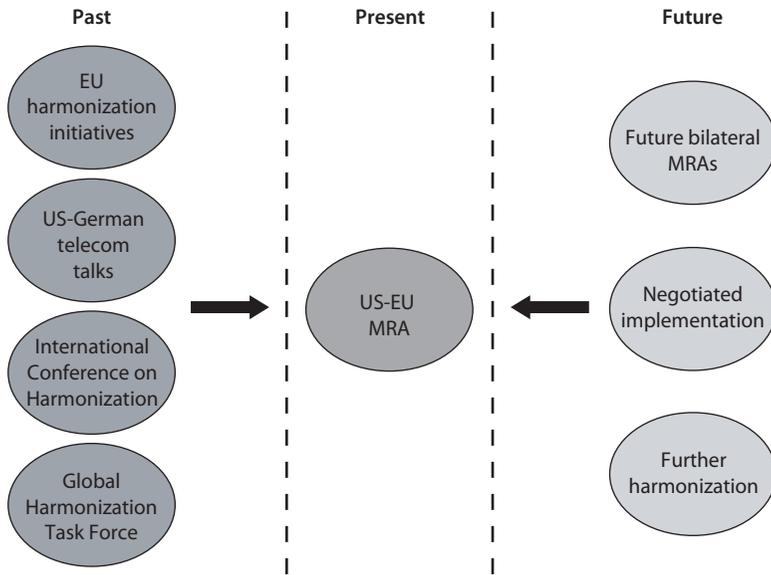
The negotiators also were bargaining in the shadow of future talks. They knew that an MRA would establish important precedents for reaching future bilateral agreements on standards. In fact, the US-EU MRA in the telecommunications sector became the template for later agreements both between the United States and APEC and between the United States and the Inter-American Commission of Telecommunications.

In addition, the MRA negotiations set the stage for subsequent (and problematic) linked negotiations over the agreement’s implementation. Difficulties were especially acute in electrical safety and pharmaceuticals. When negotiations over the rules are problematic, it should come as no surprise if negotiations over implementation are equally fraught with difficulty.

Element #6: Playing the Frame Game

While framing played a limited role in the MRA negotiations, there are some notable examples of the use of this tactic. One is found in the argument that the talks were an important step in creating momentum in the direction of harmonization of standards, which helped to increase the support of pharmaceutical companies for the MRA negotiations. Another

Figure 7.2 Linkages in MRA negotiations



MRA = mutual recognition agreement

is Ron Brown’s statement, “We should put the business ‘horse’ before the government ‘cart,’” which framed business as playing a central role in the process.

The EPA tried to play the frame game at the end of the process by holding a public hearing intended to undermine the MRA process. But it didn’t work. Some in Congress, with similar lack of success, tried to frame the agreement as threatening the integrity of domestic regulation. Perhaps the technical nature of the negotiations provided opponents with limited raw material to create a compelling frame, or perhaps those opponents were somewhat lacking in focus or creativity.

Element #7: Creating Momentum

In both Europe and the United States, action-forcing events created momentum in the MRA negotiating process. The European Union’s move to create new pan-European standards and testing procedures, the CE marks, together with its prohibition on non-European testing organizations, spurred US interest in negotiating MRAs. The negotiations showed limited movement until 1994, however. The Europeans felt little urgency, because the first standard on electromagnetic compatibility would not come

into force until 1995. The deadline for implementing that standard, another action-forcing event, eventually goaded the European side into action; they had to initiate talks with the United States in a timely manner or face the likelihood of a US challenge at the WTO.

The Commerce Department skillfully used surveys as action-forcing events that progressively pushed MRAs onto the trade negotiation agenda—an example of step-by-step involvement. Charles Ludolph's early survey of US businesses regarding the US-EU trade relationship clearly identified regulation as their biggest concern. The survey also demonstrated that many sectors had substantial interest in pursuing an MRA. The joint survey of US and EU businesses undertaken by the Commerce Department and the European Commission likewise proved a potent tool for establishing a critical mass of support to create the TABD.

As the negotiations progressed, key meetings of TABD and high-level government officials helped to maintain momentum. After the negotiations in the pharmaceutical sector bogged down in 1996, for example, the TABD meeting in November was instrumental in achieving a breakthrough. Similarly, the final high-level meetings between USTR Charlene Barshefsky and European Commissioner Sir Leon Brittan facilitated high-level agreement on some remaining difficult issues, while at the same time spurring the bureaucracies on both sides to bring the process to closure.

The FDA unsuccessfully tried to slow momentum by arguing that the Food, Drug, and Cosmetic Act constrained what it could agree to. This argument was undercut when Congress included provisions in the FDA Modernization Act of 1997 that directed the FDA to support the MRAs. The act also gave the FDA a 180-day deadline for presenting a plan to achieve mutual recognition of good manufacturing practices inspections.

Though enough momentum was created to successfully reach agreement, some was lost in the MRA implementation phase, as seen in the European Union's decision to cancel altogether its participation in the electrical safety sector. Struggles over implementation might indicate that more guidelines, deadlines, and high-level government participation in the negotiations are needed to ensure follow-through.

Conclusion

Reaching an agreement is by no means the end of the story: Further talks are necessary to bring an agreement into force. As noted above, while the US administration was successful in garnering support for the MRAs, significant problems emerged in implementing their terms. Challenges in implementing the MRAs were principally due to continuing (and understandable) reluctance in the US regulatory agencies to recognize European safety standards and testing as equivalent to those of the United States. Some believed that the MRAs required too much too soon. To repeat the

words of one European negotiator, “The MRA often implies regulatory changes that the responsible parties on the internal front are not always ready to put in place, have not conceded to, or did not expect would come so quickly.” Though the prospects for full implementation remain unclear, the MRAs are one link in a larger ongoing process of dealing with the significant challenges of domestic regulation in a globalizing economy.

Appendix 7A

Excerpt from the FDA Modernization Act of 1997

Section 410: Provisions for Mutual Recognition Agreements and Global Harmonization

- (c)(1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonization regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act.
- (2) The Secretary shall 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 relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices between the European Union and the United States.
- (3) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements.
- (4) The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.
- (5) Paragraphs (1) through (4) shall not apply with respect to products defined in Section 201(ff).

Appendix 7B

Agreement on Mutual Recognition Between the European Community and the United States of America (1998)

Framework

The EUROPEAN COMMUNITY, and the GOVERNMENT OF THE UNITED STATES OF AMERICA, hereinafter referred to as “the Parties,”

CONSIDERING the traditional links of friendship that exist between the United States of America (US) and the European Community (EC);

DESIRING to facilitate bilateral trade between them;

RECOGNIZING that mutual recognition of conformity assessment activities is an important means of enhancing market access between the Parties;

RECOGNIZING that an agreement providing for mutual recognition of conformity assessment activities is of particular interest to small and medium-sized businesses in the US and the EC;

RECOGNIZING that any such mutual recognition also requires confidence in the continued reliability of the other Party’s conformity assessments;

RECOGNIZING the importance of maintaining each Party’s high levels of health, safety, environmental and consumer protection;

RECOGNIZING that mutual recognition agreements can positively contribute in encouraging greater international harmonization of standards;

NOTING that this Agreement is not intended to displace private sector bilateral and multilateral arrangements among conformity assessment bodies or to affect regulatory regimes allowing for manufacturers’ self-assessments and declarations of conformity;

BEARING IN MIND that the Agreement on Technical Barriers to Trade, an agreement annexed to the Agreement establishing the World Trade Organization (WTO), imposes obligations on the Parties as Contracting Parties to the WTO, and encourages such Contracting Parties to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other’s conformity assessment;

RECOGNIZING that any such mutual recognition needs to offer an assurance of conformity with applicable technical regulations or standards equivalent to the assurance offered by the Party's own procedures;

RECOGNIZING the need to conclude an Agreement on Mutual Recognition (MRA) in the field of conformity assessment with sectoral annexes; and

BEARING in mind the respective commitments of the Parties under bilateral, regional and multilateral environment, health, safety and consumer protection agreements.

HAVE AGREED AS FOLLOWS: . . .

ARTICLE 2 PURPOSE OF THE AGREEMENT

This Agreement specifies the conditions by which each Party will accept or recognize results of conformity assessment procedures, produced by the other Party's conformity assessment bodies or authorities, in assessing conformity to the importing Party's requirements, as specified on a sector-specific basis in the Sectoral Annexes, and to provide for other related co-operative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the Parties with regard to conformity assessment for all products covered under this Agreement. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the Party alleging its market access has been denied may, within 90 days of such consultation, invoke its right to terminate the Agreement in accordance with Article 21.