International Trade Meets Domestic Regulation:

Negotiating the U.S.-EU Mutual Recognition Agreements

"This is about sovereignty, multinational corporations, the new post-cold war world, global standards, and international harmonization. These are very important issues. But it is like they are being dealt with in a closet somewhere and no one is watching."
-Former U.S. Trade Representative Mickey Kantor[1]

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 (MRAs). The MRAs applied to nearly $50 billion in transatlantic trade in six sectors: medical devices, pharmaceuticals, recreational craft, telecommunications, electromagnetic compatibility (EMC), and electrical equipment.[2] According to the Commerce Department, the agreement would save U.S. industries more than $1 billion annually in testing and certification costs.[3] According to Stuart Eizenstat, then Undersecretary for Economics, Business, and International Affairs at the State Department, the MRAs proved that the United States could protect its citizens, promote public health, and at the same time promote 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 differing standards, licenses, and certificates in each country had created a formidable system of barriers to transatlantic trade. The purpose of the MRAs was to eliminate duplicative testing, streamline procedures, lower costs, and decrease the time it took to bring new products to market. Companies complained that they were often forced to re-test their products at the border of another country to standards that were very similar to those of their country of origin. For example, U.S. consumer-electronics companies exporting to Europe reported that the administrative burden of complying with double testing and certification alone cost them $70 million each year. MRA proponents argued that it made more sense to perform all needed testing at one time, increasing efficiency and reducing costs to consumers.

In addition to seeking changes that would streamline international trade, some industries also pursued the MRA process in order to encourage domestic regulatory reform. The U.S. medical device industry, for example, was frustrated that it took an average of four years to navigate the Food and Drug Administration (FDA) approval process and bring a product to market. Industry hoped the MRA negotiations would help encourage regulatory changes at the FDA modeled on the European system – a system industry considered to be much more efficient.

Champions of the MRAs also believed that the agreement would be 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

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and standardization," said one pharmaceutical executive. "Moving towards more harmonized standards, more rational market behavior, is good for us. MRAs were a building block to that."

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," said David Aaron, Undersecretary of Commerce for International Trade. "No other forum has risen so rapidly to become as effective as the TABD."[5] 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?

Though business played an important role, the MRA negotiations were led by the U.S. and EU governments. The talks presented a number of unprecedented institutional challenges to U.S. and European officials. Government agencies ordinarily uninvolved in trade discussions, such as the FDA, the Occupational Health and Safety Administration (OSHA), and the Federal Communications Commission (FCC), became central players. However, the idea of looking at domestic regulatory and certification issues under the auspices 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 U.S. 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."[6] Due to such concerns, some regulators had reservations about participating in the MRA process. As one observer said, "To put it mildly, the FDA would have preferred not to be a part of this."

In Europe, the negotiation presented challenges to the relationship between the European Commission and the member governments of the EU. Bilaterally, Europe and the U.S. had different ideas about how to structure the agreement, each understandably eager to promote its own industries, cultural values, and institutions. The negotiations also highlighted differences in business-government relations in the United States and the European Union. Faced with such challenges, completing the MRAs took four years of tough on-again-off-again negotiations, and implementation efforts continue.

BACKGROUND

What is a Mutual Recognition Agreement?

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. An MRA would permit a U.S. exporter to have its products tested and certified to EU requirements by recognized bodies in the United States, and vice versa. "An MRA basically allows you to test in the U.S. to Europe's standards, and in Europe to U.S. standards," says lead U.S. MRA negotiator Ralph Ives of the U.S. Trade Representative (USTR).[7] MRAs were negotiated on a sectoral basis; that is, separate talks were held for each industry sector.

Harmonization within Europe

The seeds of the MRA negotiations were planted in Europe years before the talks were even conceived. The free movement of goods within Europe was guaranteed in Articles 30-36 of the 1957 Treaty of Rome that established the European Economic Community. Article 30 prohibited "qualitative restrictions on imports . . . between the Member States." Article 36 provided for exemptions to this rule for reasons such as public security, protection of health and life, and the protection of national treasures.

These restrictions, however, could not "constitute a means of arbitrary discrimination or a disguised restriction on trade between the Member States."

In the 1970s, there were efforts in the Community to pursue regulatory harmonization, a move that would make national barriers irrelevant by creating pan-European standards for products. Directives for the harmonization of standards were so detailed and technical, however, that it could take 15 years to develop a standard. This effort, later dubbed the "Old Approach," proved ineffective.

A new approach to standards emerged from a series of cases at the European Court of Justice interpreting Articles 30-36. In an often-cited 1979 case, 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.[8] 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 no longer pursued complete harmonization of standards. In 1985, the EC Council adopted a resolution entitled "A New Approach to Technical Harmonization and Standardization." Standards became a principal 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 six of the seven members of the European Free Trade Association (EFTA), committed themselves to achieving this goal by the end of 1992 in the Single European Act (SEA).

The "New Approach" directives were limited to essential safety and performance requirements for products traded on the EC market.[9] Products that met these standards would be issued a "CE" (Conformité Européenne) mark, and could be sold throughout Europe without undergoing further testing by individual countries. Many New Approach directives required third-party certification before a manufacturer could affix the CE mark; such third parties were called "notified bodies." The EU also forbade the recognition or acceptance of most non-EC inspections and product certifications.

This decision not to recognize outside inspections made it necessary for many non-EC manufacturers to re-test 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 U.S.-EU MRAs. "It was the origin of the debate about 'fortress Europe." As opposed to creating new barriers, Falkenberg argues, "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."[10] [11]

The U.S. Organizes to Meet the Challenge

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

In 1987, Charles Ludolph, Director of the Commerce Department's Office of European Community, became chair of the new U.S. Interagency Working Group on European Standards and Regulatory Issues. In addition to officials from traditional U.S. government trade players like the Commerce Department, State Department, and the U.S. Trade Representative, the working group also included officials from a wide spectrum of such regulatory agencies as the FCC, the FDA, the

Environmental Protection Agency (EPA), the Federal Aviation Agency (FAA), the Department of Labor, OSHA, and the Department of Agriculture (USDA). The group typically met at least once every six weeks between 1987 and 1991 to review proposed changes to European standards.

Involvement in discussions led by the trade-related agencies was a relatively new experience for many regulators. "We are not a trade agency," says 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."[12] [13] Nor had there traditionally been much of a role for regulators in international trade talks. Trade negotiations had concerned themselves with "border barriers" like tariffs and quotas, as opposed to "beyond-the-border barriers" such as domestic regulation. Therefore, Ludolph's interagency group was somewhat unusual.

Of particular concern to Ludolph were the implications of the new CE marks, which would be legally required for the distribution or sale of manufactured goods within the Single Market.[14] Between 1987 and 1992, "we stared at these 25 CE marking directives" Ludolph recalls. "It was clear that no U.S. 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."[15]

Ludolph was also interested in telecom industry efforts to address the same concerns. Some observers say that the MRAs were inspired by an agreement between the U.S. and German telecom industries to facilitate trade in the face of the changing European standards process. Subsequently, Lucent Technologies' Chuck Berestecky and Nortel's Vic Boersma encouraged the U.S. government to take on a broader effort with Europe.

In early 1992, based on the interagency working-group discussions, Ludolph sent 400 letters to a spectrum of U.S. companies outlining his recommendations with regard to the new European standards process. An alternative to having U.S. products tested in Europe, Ludolph wrote, was an MRA - an alternative codified in the GATT Technical Barriers to Trade Agreement (TBT).[16] "Under the TBT there are fairly tough conformity assessment requirements," Ludolph explained. "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." [17] Of the 25 business sectors Ludolph contacted, 11 expressed interest in MRAs.

The same year, the European Council empowered the European Commission to engage in MRA negotiations with a certain number of countries. "The mandate identified MRAs as an instrument to achieve the objective of trade facilitation," explains Giacomo Mattinò, an MRA negotiator from the Commission's Directorate General for Enterprise.[18] "The immediate cause was not the 'New Approach' directives themselves. It was the overall perspective of broadening trade facilitation." Selection of the countries the Commission would negotiate with was based on 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 U.S. was at the top of the list," says Mattinò.

Later in 1992, Ludolph entered into "pre-discussions" of what an MRA would look like with European Commission officials. "Those talks were totally useless," he says. Formal talks did not begin until October 1994.

What caused the hold up? U.S. observers say that the European Commission had no incentive to enter into talks so early. 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 (EMC) Directive would be implemented, affecting all electronic products and at least $13

billion worth of U.S. computer exports.[19] Ludolph wanted to have the MRAs in place, finished, and signed by 1995 so there would be no break in testing services. For the European Commission, however, according to U.S. observers, the only necessity was to begin talks early enough to avoid a case at the World Trade Organization (WTO). If talks were not started in a timely fashion, the United States could bring a case against Europe at the new trade dispute settlement body, possibly resulting in penalties.

GETTING TO THE TABLE

In 1994, an agreement was reached to begin MRA negotiations in earnest. In preparation, the Commerce Department took steps to involve the U.S. business community directly. 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.[20] The most active participants were those from the telecom industry, followed by pharmaceuticals and medical devices.

Telecommunications

Unsurprisingly, given its earlier interest, the U.S. sector that initially expressed the most interest in the MRAs was telecommunications. "It was primarily the telecommunications sector that thought the agreement would be useful," says Ralph Ives, the lead USTR MRA negotiator. In 1994, the United States exported about $7.8 billion in telecommunications equipment to the EU while Europe sent only about $2.8 billion to the United States (See Exhibit 1).[21] Industry efforts had already begun outside of any formal government–led initiative to streamline testing and certification processes.

Several U.S. industry groups including the Telecom Industry Association (TIA) and the American Council of Independent Laboratories (ACIL) approached the FCC, which regulated the industry, expressing 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."

The stakes were high for the industry because the duration of any testing process has a direct impact on its bottom line. "The objective of an MRA is to reduce the time and cost of bringing equipment to market," says Lucent Technologies' Director of Global Public Affairs Joanne Wilson.

> 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 lifecycle is getting very short. And so the only way to be profitable is to be able to get product into market very quickly.[22]

The FCC's Wall echoes this 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 lifecycle of some products is less than three months." The industry 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 Ralph 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 developed around those basic sectors." As Karl Falkenberg of the European Commission says, "The package for us included, necessarily, pharmaceuticals and medical devices because we are large exporters of those products." European negotiators wanted to ensure that these sectors were included in the talks in order to balance the package.[23]

Pharmaceuticals

Though pharmaceuticals were a key priority for the European Commission, the U.S. pharmaceutical industry also had interest in pursuing an MRA. Before the MRA, drug manufacturing facilities were inspected by every country that imported the drug, resulting in multiple inspections. The immediate goal of the industry was to streamline testing procedures for the manufacture of medicinal products. As Laura Peralta-Schulte of Warner-Lambert explains:[24]

> 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.[25]

This was not the first time that the United States and Europe had entered into regulatory discussions on pharmaceuticals. A 1989 conference of regulatory officials from Japan, Europe, the United States and members of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) had laid the groundwork for the International Conference on Harmonization (ICH).[26] The ICH had two major goals. First, the participating countries and companies wanted to harmonize the scientific requirements of pharmaceutical regulations in the United States, the EU and Japan. It was hoped that if the various regulatory agencies required the same data, differences in the approval processes would become less significant. The second goal of the ICH was to shorten the time from development to marketing of new drugs.[27]

In addition, since the 1970's, the FDA had entered into Memoranda of Understanding, or MOUs, with Switzerland, Sweden, Canada, and Japan. In an MOU, foreign governments committed that their regulated exports to the U.S. would meet FDA standards. The FDA also sent inspectors to certify that plants producing medications in those countries complied with FDA "Good Manufacturing Practices," or GMPs.[28] Since 1989, the FDA had also participated in discussions with the European Commission's Directorate General Enterprise, of entering into an agreement to exchange inspection information.[29]

However, the mandate of the trade directorate, DG Trade to negotiate MRAs superceded 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 U.S. negotiator Ralph Ives. Trade agencies were not involved in the MOU process.

FDA's experience in trade-related negotiations was limited. The first time the agency became involved in GATT negotiations was during the Uruguay Round (1986-1994). "When the Uruguay Round negotiations began, it wasn't something on our radar screen," says Walter Batts, the FDA's Director of

International Relations. "The trade agencies didn't actively seek out FDA in the early stages of the negotiations to be involved in establishing the U.S. 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.[30] [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 (TBT) negotiations as well.

In the latter part of the Uruguay Round, therefore, FDA became a participant in negotiations for the SPS and TBT. "We actually had people including myself and other FDA members as part of the negotiation teams," Batts points out. "This was unprecedented for FDA."

Medical Devices

Though the European Commission was pressing for the inclusion of the medical device sector in the MRA talks, the U.S. medical device industry also had motivations to get involved. As a part of the EC 1992 Single Market Program, the European Community had created a pan-European system for medical device regulation intended to harmonize and streamline regulations. Now instead of different standards for each different Member Country, there would be one system. The new system allowed manufacturers: (1) to self-certify that low-and medium-risk devices met European requirements and (2) to utilize third-party bodies for the review and approval of higher-risk devices. In short, the European regulatory system represented a public-private partnership where the government established medical device requirements and private notified bodies carried out product approval activities. In the U.S., the Congress and FDA established requirements and the FDA carried out the product approval activities itself. "The net result of the new European system," read a U.S. 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."[31]

It is noteworthy that the U.S. industry played an important role in the creation of the new European regulatory system, as well as the specific standards that were developed for medical devices. "At the beginning, anything could have happened," says one U.S. industry representative.

> There were the obvious concerns that new regulations could result in trade barriers. In addition, the U.S. industry felt the European medical device trade associations were each focused on a narrow component of the industry. There was also a certain degree of competition among them that kept them from working together in a completely coordinated way, and this could result in mixed messages coming from the device industry in lobbying at the policy level, even though the interests of both the European and American portions of the industry were largely aligned.

HIMA, which represented the entire U.S. device industry, became involved in encouraging the standards-based approach to device regulation in Europe. But HIMA realized that their Europeans industry counterparts would be more effective lobbyists, particularly in working directly with the European officials. So HIMA's goal was to coordinate loosely with the European associations, as well as with key EU officials on the broader policy issues, and then to have the European associations take the lead on the more detailed areas.

The U.S. industry considered the new European system to be much more modern, efficient, and state-of-the-art than that of the FDA. The new system also meant that U.S. medical device manufacturers no longer had to meet a different standard for each different country in the European Community. As a result, some U.S. medical device companies were reported to be moving research facilities to Europe. A HIMA survey of 500 U.S. 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.[32] Many U.S. companies

were also introducing products into the European market before doing so in the United States. More than 90 percent cited U.S. product-review requirements to explain the introduction of products overseas first, saying that they had to generate cash flow from European markets to fund the more costly and time-consuming U.S. approval and commercial requirements.[33] 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 U.S. 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.

As in the pharmaceutical sector, efforts had begun to pursue international harmonization in the regulation of medical devices. The Global Harmonization Task Force (GHTF), founded in 1992, was an informal group that included regulatory and industry officials from the EU, U.S., Japan, Canada, and Australia. The purpose of the GHTF was to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation, and facilitating international trade.[34] "The GHTF is FDA's highest priority for international [medical] device activities," declared the FDA's Linda Horton in 1998.[35]

While an MRA was *not* about the harmonization of standards, it would allow a body in the EU to inspect a medical device product to U.S. requirements and vice-versa. What was interesting about this idea, observers say, is that it introduced the notion of international competition between conformity assessment bodies. While the U.S. and Europe remained sovereign over their own standards, industry could choose work with the most efficient body to certify that standard - be it the FDA or a private European Notified Body. The U.S. medical device industry liked the idea of creating alternative pathways for inspections and product reviews.

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. In the words of one industry representative:

> First, the MRA would take steps towards eliminating duplicative regulatory requirements between Europe and the U.S. 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. U.S. 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.

While domestic efforts were already being undertaken to encourage such changes, the MRA talks were another venue to encourage that kind of thinking.

THE MRA NEGOTIATIONS

The First Two Years

Official MRA negotiations kicked off in 1994. The lead U.S. negotiators were the Commerce Department's Charles Ludolph and USTR's Richard Meier.[36] The rest of the U.S. delegation was essentially the interagency working group on standards and certification that Ludolph had met with all along. As he describes, it was "the same group where people from FDA got to learn trade and people in USTR and Commerce got to know regulations." Each sector had a regulator in charge of the technical

negotiations who would report 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 from Ludolph's perspective, at least negotiations had begun.

For the European Commission, DG Trade took the lead on the MRA negotiations and Karl Falkenberg was head of the unit. Officials from DG Enterprise also participated in the talks. DG Trade was in charge of external relations and commercial policy with North America, the Far East, Australia, and New Zealand. The key objective of DG Enterprise was to promote the competitiveness of European industry, and its responsibilities included coordinating regulatory and legislative activity in the EU.[3738] "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 Director Generals 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 U.S. and EU governmental structure were highlighted by the MRA initiative. As DG Enterprise's Mattinò explains:

> In most cases, the U.S. 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. In trade negotiations, the coordinating body was called the 133 Committee. When the MRA negotiations were launched, the 133 Committee established an ad-hoc MRA Committee to advise the 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 was especially challenging because MRAs were a new idea:

> The concept itself of MRA in the format under negotiation between the EU and the U.S. 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, U.S. 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 of DG Trade.[39] "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 mutual education process. Regulators from each side of the Atlantic presented the requirements of their respective markets. Business representatives were also included in the process. 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 U.S. 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 (TABD)

As the MRA talks were getting underway, so were efforts to organize a high-level dialogue between EU and U.S. businesses. In 1994, Commerce Secretary Ron Brown went to Brussels to investigate how to further facilitate trade between Europe and the United States. Brown outlined his vision of a business-to-business dialogue in a December 1994 speech to the EU Committee of the U.S. Chamber of Commerce. "He said that Europe and the U.S. 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 were enthusiastic. In January 1995, Commerce Department officials proposed initiating a business-to-business dialogue in meetings with European Commissioner Leon Brittan and other EC officials. EC officials were skeptical, however, and said they would wait to see if the European business community supported the idea.

A positive response from European business was not assured. For one thing, as Charles 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, some observers say, 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 [as there was in the U.S.]." DG Trade's Falkenberg expresses a similar view: "In the U.S., aggressive lobbying is normal, so when U.S. 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."

The Commerce Department's proposal was also unusual because the point of contact for business would be the European Commission. Normally, when European businesses interacted with government officials, it was with ministers from the 15 member states. The ministers would then communicate messages 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 U.S. agencies.

> In the U.S., 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 being involved directly with individual enterprises and individual CEOs.

Finally, the idea of a business-to-business dialogue was problematic because some Europeans saw it as one more way for the United States to force free trade on a rather recalcitrant Europe.

Despite all these reservations, the Department of Commerce and the European Commission sent a letter and a survey to 1,400 U.S. and European businesses and trade associations. One business recipient called it "the three-B letter" because it was signed by EC Commission Vice President Sir Leon Brittan, Commissioner for Industry Martin Bangermann, and U.S. Commerce Secretary Ron Brown. The letter asked how the Commission and the U.S. administration could improve and deepen the transatlantic business relationship. The survey also posed the question: should there be a U.S.-EU business dialogue? According to the Commerce Department, approximately 80 percent of the respondents replied that such a dialogue should be initiated.

Observers note that promoting a business-to-business dialogue also made sense for the Commerce Department from an institutional standpoint. "Remember that there was a serious proposal on Capitol Hill not too many years before to eliminate the Department of Commerce," says Guidant's Michael Gropp. "Someone at Commerce could say, 'This is a way we can expand what we're doing. It's to justify our existence. It's to do something of value for key corporate constituents.'"

The response to the three-B letter also indicated that standards and regulatory issues were a priority for business. "When we got the survey back and tallied the results," Ludolph recalls, "40 percent of all the respondents in Europe and the U.S. said standards were the most important thing to the U.S.-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 nations markets was easy enough. The problems came once you were in the market."

The Seville Meeting

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

> The notion behind the TABD was that the Cold War had ended, and the U.S. 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.[40]

In September, a U.S. steering committee began meeting daily at 8 a.m., hosted by the head of Xerox's Washington DC office. These meetings were attended by a representative from Ford, staff person Selina Jackson (later to become the TABD's director), and representatives of each of the working groups. For example, because the CEO of Tenneco chaired Working Group 1 on standards and regulatory policy, a Washington staff person from Tenneco attended the morning meetings.

The Washington meetings focused on the logistics of the Seville conference and on drafting position papers. Efforts were made to work with the group's European counterparts, but Selina Jackson notes that "there just weren't the relationships, because we had not met face to face." Bilateral relationships began to develop at an October U.S.-European full steering committee meeting at the staff level in Brussels. However, preparations for the Seville conference were largely pursued separately.

In November 1995, the TABD held its conference. Commerce Secretary Ron Brown addressed the group of European and U.S. CEOs, encouraging their involvement in the trade negotiation process. "We should put the business 'horse' before the government 'cart,'" he said. The Seville meeting could not be called an overwhelming success. For one, thing, the conference was modestly attended. A European observer frankly admits, "there weren't many high-quality European CEOs." Commission officials also note that there was little coordination between industry and the Commission.

But the conference did create some momentum for the MRAs. Participating executives emphasized that they had come to Seville, "not to negotiate between U.S. and EU industry, but to present joint recommendations" – in other words, to see what they could agree on.[41] Their central message to political leaders was that the transatlantic business relationship is one of the great successes of the post-war period, and business on both sides urged government to "eliminate, as soon as possible, the remaining obstacles to trade and investment."[42] Many of the U.S. 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 only intended to have a three-month life span; there were no plans to continue the dialogue after the Seville meeting. Towards the close of the conference, however, Alex Trotman of Ford Motor Company suggested that follow-up might be in order. Ron Brown stepped forward to say that the United States would host the next TABD conference. The Americans knew that the U.S. government was not prepared to financially support such a meeting. "It was sort of funny," says Selina Jackson. "When Ron Brown said 'We will host the conference,' he was not committing the Commerce Department. He was committing the U.S. 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 TABD Europe Director Stephen Johnston. The consensus was that the process should remain flexible.

An ongoing dialogue to address trade tensions appealed to some members of the Commission as well. 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 U.S. 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 U.S., but through diplomatic initiatives, through consensus-building mechanisms. This of course frustrates some in the U.S., 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, Ford's CEO Trotman tasked his Washington staff person Charlie Becher with figuring out what needed to be done to follow up on the Seville recommendations. "It was really wide open – it was a tremendous opportunity," Selina Jackson says. In Europe, there was a similar response. European Chair Juergen Strube the CEO of BASF, asked his Vice President of international trade Ilsa Stübinger to run the process on a day-to-day basis. 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.[43] 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 gained new momentum at the December 1995 U.S.-EU Summit in Madrid. At the summit, U.S. and EU Presidents Clinton and Santer sought to expand transatlantic cooperation through an initiative called the New Transatlantic Agenda (NTA). The inauguration of the NTA marked the first time that the U.S. recognized the EU as a political institution on a large scale. 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). This marketplace would be achieved by "progressively reducing or eliminating barriers that hindered the flow of goods, services, and capital" across the Atlantic. These barriers included technical standards.

A few months later, in March 1996, U.S. officials announced that a breakthrough in the MRAs was imminent, touting it as the "first substantial fruit" of the TABD's launch in Seville. But the announcement of a breakthrough turned out to be premature. The MRA talks broke down when European negotiators rejected a U.S. proposal to drop two sectors where progress was lagging - pharmaceuticals and medical devices. The Europeans refused to de-link these two sectors from the other 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 U.S. market because of the FDA were extremely burdensome costly, and time consuming. We needed those to be addressed.

As Laura Peralta-Schulte of Warner-Lambert observes, "There were sectors where the U.S. had a larger concern, particularly telecom, and there were sectors that were important to Europe, like pharmaceuticals."

The Debate over Pharmaceuticals

One underlying difficulty in the pharmaceutical and medical device sectors was the differing expectations on different side of the Atlantic. "Generally speaking, the EU took the position that U.S. regulatory systems were good and acceptable to them. They were willing to accept our decisions on the marketability of products in return for us accepting their decisions," said the FDA's Batts. "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."

European negotiators saw it differently. Testing bodies in developed countries have comparable competence, they argued. It seemed reasonable to hope that facilities in the United States could test a product to European standards and vice-versa. "The underlying issue is that every regulatory authority believes that it's the only entity that can do a job properly," says Falkenberg.

> 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 U.S., 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 U.S., 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 U.S., this negotiation was the first exposure to that kind of thinking.

European negotiators viewed the U.S. government as unreceptive to the idea of making any changes to its own regulatory rules. As one European negotiator put it,

> The U.S. was saying that mutual recognition within Europe was creating trade barriers against the U.S. 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 U.S. legislation, the answer was, "No, no, no, that was not the deal." The deal was that Europe should just recognize U.S. certification procedures, but without any reciprocity, without any change to U.S 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.

The U.S. medical device and pharmaceutical industries also hoped the FDA would have interest in changing some of their procedures. But the FDA initially wanted no part of these discussions, said one industry representative:

> 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 U.S. officials, as well as the Europeans, began to put concerted pressure on them.

Other U.S. observers commented that the FDA was in a tough position. Increasing international trade had put a great deal of pressure on the agency. For one, the demands on the FDA were growing without a comparable increase in resources.

A breakdown occurred in the talks when the EC 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.[44] DG Trade's reaction, according to several U.S. observers, was to look at the Department of Commerce and USTR and say, "You folks need to tell FDA this is not the kind of agreement we are going to have." The difficulty in the pharmaceutical negotiations held up the talks in all the other sectors. "It was such a divisive issue and nobody was thinking very creatively," says Warner-Lambert's Laura Peralta-Schulte. "Both governments were basically at a standstill."

In early January 1996, the State Department's Stuart Eizenstat wrote FDA Commissioner David Kessler to say that "the [European] Commission has made it clear in its negotiations and to me personally that without the U.S.-EU agreement on pharmaceutical GMP's [Good Manufacturing Practices], 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."[45]

Problems within the U.S. government were also slowing down the talks. FDA officials felt the need to educate U.S. trade officials on the parameters of the Food, Drug, and Cosmetic Act of 1938 (amended in 1993). The Act was the central piece of legislation governing FDA operations, and the FDA

wanted other U.S. agencies to understand that any negotiations related to pharmaceuticals were constrained by its directives. The problems of the FDA were symptomatic of a larger issue - the fact that each federal agency had a different mission and therefore it's own priorities. The U.S. Trade Representative and Department of Commerce were pushing for an agreement on pharmaceuticals as a trade issue. Meanwhile, FDA insisted that inspections and product approvals were regulatory matters that fell under FDA purview. The FCC and OSHA felt similarly about their sectors. And the U.S. State Department wanted a final say on any international pact.

Narrowing the Agenda

By August 1996, Ludolph 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 U.S. 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 was beneficial to the pharmaceutical industry and the maximum 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 PHaRMA (The Pharmaceutical Research and Manufacturers Association) 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 says. "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 (GMPs) and the public disclosure of inspection reports.

The pharmaceutical MRA would not apply to the certification of a new drug: any new pharmaceutical still had to meet FDA standards. What the agreement would apply to was *production* of the drug once it had been approved. The U.S. Food, Drug, and Cosmetics Act regulates drugs to ensure that they are safe and efficacious - that they actually do what their labels claim. The Act also aims to ensure that pharmaceuticals are manufactured in a safe manner. It is the latter regulations that govern so-called "good manufacturing practices" or GMPs.[46] GMP regulations are based on the premise that finished-product testing does not suffice, and that safety and quality must be built into products during manufacture. Foreign firms were expected to comply with the same product requirements and the same GMP regulations as domestic firms.

Typically, when a company wanted to export its pharmaceutical products, the importing country would inspect its plant. Europeans would visit Puerto Rico, for example, to inspect the plant of a U.S. manufacturer. Once the manufacturing process was deemed appropriate, the drug would be okayed for import. "The problem," Warner-Lambert's Laura Peralta-Schulte explains, "is that the ways different countries perform these inspections are different. Industry gets caught in between." Charles Ludolph characterizes the problem similarly: "It is not standards, but the practice of the inspections that are

different," he says. "If Europe does one process and the U.S. does another, a company often got caught in between as to what standards they ought to be applying on a practical basis."

There were actually two points in time when manufacturing processes were subject to scrutiny. At the pre-approval stage, when a pharmaceutical company was about to launch a new drug, the process by which it would be produced had to be approved. "A slow down or miscommunication there can keep your product off the market until the issue has been resolved," says Laura Peralta-Schulte. The second stage was post-approval: once a product was on the market, the manufacturer might change the production process in some way.

The U.S. government position was that negotiations should focus on post-approval and not pre-approval. The Europeans believed that both stages should be within the scope of the agreement, and had strong support from the pharmaceutical industry on this point. "From a company standpoint, most problems are in the pre-approval period," explains Laura Peralta-Schulte, "so to only focus on the post-approval stage and not on pre-approvals, you are not solving the problem." Industry suggested that the negotiations be staggered to address post-approval first, and then pre-approval.

The second sticking point in the pharmaceutical negotiations related to the disclosure of inspection reports. The U.S. Food, Drug, and Cosmetics Act required disclosure of inspection reports to the public. The European negotiators, however, believed that it was inappropriate for certain documents to be made public.

U.S. pharmaceutical companies recognized that the FDA could not ignore its legislated mandate. TABD pharmaceutical representatives, therefore, saw their role as explaining the U.S. government position to European business and the Commission. As one U.S. pharmaceutical representative says,

> Europeans were coming at this from a place where there was not a thorough understanding of how important it was to maintain the Food Drug and Cosmetic Act [in the U.S.]. 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 of the FDA noted that U.S. industry played an important role in communicating the FDA's position to the European negotiators:

> I think they were extremely helpful in that regard. They assisted the European Commission in understanding the U.S. Constitution, FDA statutory authority and the Food, Drug and Cosmetics Act. [They also assisted the EC in understanding] political reality in the U.S. government. The U.S. government can not change its laws or policies on a whim.

U.S. pharmaceutical interests worked with several agencies on the U.S. side in their efforts to move the talks forward, but the major point of contact was FDA. "Because the TABD process brought together various U.S. 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 Walter 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. "By November 3, everybody in the business knew what the stakes were in the MRA and we brought the issues to their attention," Ludolph says. "At the same time, Warner-Lambert and SmithKline Beecham were getting companies to realize how important this was to their overall commercial agenda with U.S. regulators."

Some MRA participants insist that it was this broader commercial agenda with regulators that convinced pharmaceutical companies to exert so much effort on the MRA negotiations. "They never thought the MRAs per se were the major reason to put effort into this," says one participant.

> There were more important deregulatory precedents that pharmaceutical companies wanted to establish, and working on the MRAs would help. So they had a larger game. They were frank in telling me that they were willing to put a lot of resources into this, because it helped with a lot of things they had been trying to do for a number of years toward deregulation. And 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.

The medical device industry also had broader goals for participating in the MRAs, namely encouraging reform at the FDA.

But industry's eagerness to keep pharmaceuticals and medical devices in the talks did not mean that its goals coincided with that of the European Commission. "The U.S. industry had a slightly different interest," said 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. Electrical safety was often bundled with the telecom and electromagnetic compatibility 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 Europeans negotiators felt they had no leverage in electrical safety. As Mattinò puts it,

> U.S. 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 monopoly in the United States by Underwriters Laboratories (UL). We said to the U.S., "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 U.S. telecom industries were so successful in lobbying, they put such 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.

Meanwhile, the negotiations over telecom were progressing more smoothly. The U.S. Telecom Industry Association (TIA) MRA task force met regularly with the two European telecom industry associations, ECTEL and Eurobit. "We held those joint meetings so that U.S. and European industry were on the same page," recalls Lucent's Global Public Affairs Director Joanne Wilson. The TIA also worked with the U.S. Government on the substance of the agreement. "We got the text every time they had a new draft," Wilson says. "We went through it and proposed changes in the language in order to accommodate our interests. We took very specific positions about what we wanted to see and what we didn't want to see in the agreement."

One thing that industry did not want to see was restrictive rules of origin specifying where a product could be manufactured. "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," says Joanne Wilson of Lucent. "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, however, initially wanted to include rules of origin in the agreement. U.S. negotiators attribute this stance to hope of encouraging more manufacturing in Europe. In any case, the European telecom industry ultimately agreed with its U.S. counterpart that there should be no restrictions based on rules of origin. "The fact that the U.S. [government] held a hard line on that issue and succeeded in keeping it out of the agreement is because the U.S. and European industry made it very clear that it was a problem," said one representative of the U.S. telecom industry.

U.S. industry representatives note that their relationship with government differed from that of European industry. 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 U.S. government]. It is easier for the Commission to take positions that industry opposes than it is for the U.S. government to do the same thing. I also think Europeans have a much more programmatic approach that expects more management by government of industry.

The Chicago Breakthrough

While discussions continued in the various MRA sectors, the TABD was looking for a site for its next conference. It fell to Alex Trotman and Ford's Washington office to find a city where a local organization would help with expenses. Ultimately, 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 longstanding 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.[47]

Nearly 70 CEOs from a cross-section of American and European companies attended the Chicago conference, led by co-chairs Alex Trotman, CEO of Ford Motor Company, and Simon DeBree, CEO of the Dutch petrochemicals firm DSM. Participants included Chrysler, Warner-Lambert, Xerox, and Sara Lee, as well as CEOs from small and medium-sized businesses. European participants included companies such as Ericsson, Daimler-Benz, Pirelli, and Pechiney.[48] The Chicago TABD meeting attracted more business representatives than the first meeting in Seville, but 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 CEO's that did attend were particularly interested in the opportunity to speak face-to-face with government representatives.

The government delegations to the TABD Chicago conference consisted of high-level officials from numerous agencies. The U.S. delegation was led Mickey Kantor, who had been appointed Commerce Secretary after Ron Brown's death in an airplane crash. On the European side, Commissioners Sir Leon Brittan and Dr. Martin Bangermann were both in attendance. Many participants remarked on the presence high-level officials from the U.S. government and the Commission. As Ralph 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 participant, had "a slight feeling of responsibility [for the TABD] because they had started it."

For the Europeans, according to observers, involvement with TABD raised the profile of the Commission as an institution and provided otherwise unattainable information. The European member states did not play an active role in the TABD, and the Commission preferred it that way. As 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 very 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 which was otherwise filtered through the national administrations.

The TABD was eager to make progress on the MRAs in Chicago, in part because the negotiations had become a measure of the TABD's usefulness. "The TABD really dramatized the importance of the MRA," says USTR's Ralph Ives,

> 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."

A breakthrough on the MRAs came about on the second day of the conference, during the Chairman's Breakfast. "It was a very small room," recalls one participant, "with just the leaders of the conference - the CEOs who were chairing it, the CEOs who were going to chair the following year, the key Cabinet-level government officials, and the TABD staff people." After some discussion, the group moved from the breakfast into the pharmaceutical breakout session. At the breakout session, Kantor, Brittan, and Bangermann joined several pharmaceutical industry CEOs – Warner-Lambert's Lodewijk de Vink, SmithKline Beecham's Jan Leschly, and Glaxo Wellcome's Robert Ingram.[49] Also present were the chief negotiators of the MRAs from Commerce, USTR, DG Trade, and regulators from FDA and DG Enterprise. When Commerce Secretary Mickey Kantor walked into the room he reportedly said, "We're going to make this happened. 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 apparently brought industry representatives to the table eager to work things out. As Laura Peralta-Schulte puts it, "This was an important agenda item for us and our goal was to see . . . if there was any way to bring our thinking to the table, to help clarify the situation . . . It was a problem solving role."

In terms of the pre- and post- approval of good manufacturing processes, one observer characterizes the U.S. industry as "very supportive of the European position" which covered both processes. The FDA, however, continued to be unsupportive of covering pre-approval processes in the agreement. Ultimately, negotiators decided to focus only on post-approval. 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 deliverables, what can be accomplished in the near term. In working with government, however, we are often forced to accept incremental victories.

As for plant inspection reports, the Commission declared that it could not support public disclosure of these reports because the European business community wouldn't endorse it. Reportedly, however, the European CEOs of SmithKline Beecham and Glaxo Wellcome both responded, in one observer's paraphrase, "No it's OK. This is something we can live with." In fact, they insisted, the European pharmaceutical industry was not as sensitive to disclosure of inspection reports 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 everyday for a living." "From then on out," another U.S. participant notes, "the Commission did not have their smoking gun, if you will, so there was a breakthrough. The Commission was thinking that they were supporting what their business community wanted, when in fact this was not the case at all."

This discussion led directly to an agreement in principle between the United States and the European Commission. Europe conceded on FDA's insistence on disclosure of inspection reports for pharmaceuticals. In return, the FDA agreed to carry out second inspections of EU pharmaceutical imports only in special circumstances.[50] "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 Mickey Kantor set a deadline for the completion of the MRA talks by January 1997, only two months away. "Mickey loved to establish deadlines," says one observer. Kantor wanted the MRAs to be completed by January 1997 - only two months away. Though few saw this deadline as a reasonable goal, one participant asserts that "the importance of it was that, for the first time, you had very high-level attention on the MRA negotiations." As USTR lead negotiator Ralph Ives puts it:

> 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 U.S. 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 U.S. 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 TABD European Director Stephen Johnston. Commenting on the effectiveness of the business-government session that advanced the MRAs, one executive observed that more real communication had taken place in two hours of dialogue than had occurred in the entire preceding

year.[51] 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 there were still challenges left to address. "After that, it was just a question of the TABD keeping its hand in and making sure the consensus reached in Chicago was truly lived up to. And that was quite a job in itself," says Charles Ludolph. "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.

Of course, the MRAs did not establish "one standard, one test, one time," and U.S. negotiators were dismayed to hear these words. "Unfortunately he said it right after the U.S.-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 Framework or Not to Framework

Despite the president's assurances, the EU and U.S. negotiators missed their end-January 1997 deadline for agreeing on the MRA package. One problem that surfaced was the concept of an overarching framework or umbrella agreement for the MRAs, which some Commission negotiators strongly favored. "The U.S. said, 'We don't need a framework agreement, for God's sake," said one U.S. 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, the appropriate regulatory agency had jurisdiction over each sectoral annex. For example, FDA was in charge of medical devices and pharmaceuticals and the FCC was in charge of telecom. Similarly, various Directorate Generals in the Commission had responsibility for their respective sectors. A framework agreement would put DG Trade in charge of the overall MRA. "In fairness to the Commission," said one U.S. 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 the concept of a framework was particularly problematic for the FDA. If DG Trade was to be in charge on the European side, USTR would be in charge on the U.S. side. Ralph Ives remembers the resulting 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 to specific U.S. concerns about a framework agreement, concerns were also raised on the U.S. side about the overall MRA effort. Officials from the EPA organized a public hearing on the MRA to air concerns about the agreement. 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 U.S. 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.

Observers say that EPA did not elicit the public response it hoped for from the public hearing. There seemed to be little interest in the MRA negotiations, and press coverage of the talks was sparse even as the MRA neared completion. Negotiator Ralph Ives describes the EPA event:

> FDA held a number of public hearings on the MRA, but got relatively little attendance. EPA, despite the fact that it did not have an interest in any of the sectors being negotiated, insisted on having a public hearing on the entire MRA. 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 inter-agency 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 it's regulatory authority is being subjected to trade concerns.

Industry executives say that another factor that prolonged the process 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.[52] European negotiators also balked at what they perceived as FDA's intransigence. "The EU understands what's at stake," said European Commission Vice President Leon Brittan. "Europe is prepared to go the last mile . . . but it is not prepared to become a sub-agency of the [U.S.] Food and Drug Administration."[53]

Finally, language surfaced as a problem. European negotiators insisted that the MRA be signed in all 11 official languages of the European Union. U.S. 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. U.S. treaty lawyers refused to sign the ten new versions until they were all translated back into English and verified.

The Final Push

Senior U.S. administration officials decided that the MRAs must be pushed forward before bureaucratic inertia got in the way. In May 1997 Secretary of State Madeline 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 (OECD) in Paris, USTR Charlene Barshefsky met with European Commissioner Leon Brittan, but failed to resolve all the outstanding issues. The next day, Barshefsky and Brittan met again with Jeff Lang, Stuart Eizenstat, Ludolph, and Ralph Ives. Sir Leon Brittan put a new proposal on the table and the leaders ultimately agreed on a deal. As Ives recalled:

> 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 counter-proposal. The bottom line was: by the time we left Paris, over that three-day period, we had a text that both the U.S. 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 U.S. Trade Representative Charlene Barshefsky. "The MRA package is an important breakthrough in the U.S.-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 U.S.-EU relationship will bring real benefits to business and consumers."[54] But because the agreement wasn't signed, the game wasn't quite over yet.

In November, Congress passed the FDA Modernization Act of 1997 (FDAMA) with the goal of "improv[ing] the regulation of food, drugs, devices, and biological products."[55] The Act outlined provisions for "Mutual Recognition Agreements and Global Harmonization." (See Exhibit 2) and directed the FDA to support Commerce and USTR "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." The Act also provided that, no later than 180 days after the enactment of the FDAMA, a plan had to be established to achieve mutual recognition of good manufacturing practices inspections (GMPs). The FDA was mandated to meet all FDAMA requirements with no increase in its budget, but with a projected doubling of its workload over the next six years.

Observers say the inclusion of such language in FDAMA was an important step toward finishing the agreement. But who pushed for it? Aids in the drafting process say that the pharmaceutical and medical device industries lobbied strongly for its inclusion.

In addition to the MRA language, FDAMA made changes to the 1976 medical device amendments. However, these regulatory changes impacted the MRAs. "Just as we were tying things up, of course, Murphy's law kicked in," says Charles Ludolph. As a result of the FDAMA, four of the medical device products listed in the MRA could no longer be included.[56] Negotiators were incredulous. "We had to amend the damned agreement," says Ludolph. This was a particular problem because 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 the necessary changes were made.

The Agreement

The MRAs were signed on May 18, 1998 by USTR Charlene Barshefsky, Commerce Secretary William Daley, and the European Commission's Vice President Leon Brittan and Commissioner for Industry Martin Bangermann.[57] The six sectors covered in the agreements included telecommunications, medical devices, pharmaceuticals, electromagnetic compatibility (EMC), electrical equipment, and recreational craft.

In terms of pharmaceuticals, the MRA governed Good Manufacturing Practices and the exchange of inspection reports. Though the FDA initially wanted to limit the agreement to post-approval GMP inspections, ultimately the agency agreed to include pre-approval inspections as well. But the FDA prevailed in its demand for a three-year transition period to determine which EU inspection processes would be deemed equivalent to its own, rather than 18 months as the Europeans had requested. Once the MRA was implemented, 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 export.

In the medical device sector, the agreement provided for the exchange of product evaluation reports by third parties in the United States and the EU 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 the political pressure that forced completion of the agreement was "detrimental to reaching fair and unambiguous conclusions " in electrical safety:

> 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 any time of negotiation - the most successful industry in lobbying on the issue was the big telecommunication industry on both sides, EU and U.S. 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. As 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 because these companies are most familiar with real-life transatlantic trade and investment and can identify the barriers most readily.[58]

Some saw the TABD as part of an emerging trend. More and more, some observers point out, international trade initiatives are being spearheaded 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 multi-lateral 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 U.S., 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 not all participants and observers were completely enthusiastic about the role of the TABD in the MRAs. DG Enterprise's Mattinò believes that the pressure from the TABD forced an agreement to be signed that was unsatisfactory in certain sectors, for example in electrical safety. "The TABD plays a very important role in indicating what the strategic objectives of trade liberalization shall be," Mattinò acknowledges, "But in my opinion, this pressure was counterproductive to the EU interests during the finalization of the U.S.-EU MRAs."

Some groups had deeper concerns about the role the TABD. The consumer group Public Citizen's Global Trade Watch was alarmed by the role of business in the MRA talks. If business groups were involved in determining the certification processes for their own products, couldn't that lead to compromises in health and safety? In light of such concerns the Clinton Administration assured the public that the MRA would not jeopardize American consumer safety. As one administration official noted, the MRA "in no way undermines the capacity of U.S. regulatory agencies to inspect or test where they feel the health or safety of the American people is concerned."[59]

TABD officials note that they were not interested in lowering standards. "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 U.S. and another in Europe. They would rather take the highest of standards, jus as long as there is one. I am not sure consumer groups understand that.

Some industry representatives also consider it a knee-jerk response to suspect industry efforts when, in fact, industry involvement was necessary to the process of creating 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.

The Commerce Department's Charles Ludolph does not see a need to defend the idea of business and government working together: "The U.S. 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 U.S. 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 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, while 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 international trade discussions. In September 1998, the Trans Atlantic Consumer Dialogue (TACD) was founded, largely in response to the "one-sided input in trade dialogue by the Transatlantic Business Dialogue."[60]

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 U.S. 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 foreign-drug-inspection program. "The amount of pharmaceutical products being imported into the U.S. was exploding," explains the Subcommittee majority's senior oversight counsel, Alan Slobodin, "and there were concerns about the safety of these products." In March 1998, the General Accounting Office (GAO) had reported to the Subcommittee that "unless corrected, problems in FDA's foreign-inspection program could lead to the importation of adulterated and low-quality drugs that could pose serious health risks to Americans."[61]

In summer 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 much about how these inspections took place. With 80 percent of the bulk pharmaceuticals used by U.S. manufacturers being imported, this was a cause of great concern."[62]

Soon after the trip, several ranking members of the Subcommittee and the full Committee including Subcommittee Chair Joe Barton (R-Texas), John Dingell (D-Michigan), Henry Waxman (D-California), and Ron Klink (D-Pennsylvania), wrote to the FDA requesting more information about the MRAs. One observer calls this letter "the Dingell-gram from hell," since the FDA was not eager to be the subject of Subcommittee investigation. In October 1998, the Subcommittee convened a hearing on "Imported Drugs: U.S.-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.'"

Committee members addressed a number of questions and concerns, often harshly worded, 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 the Chairman of the Commerce Committee, 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."

Commerce Committee Democrat Henry Waxman, co-author of the 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." Waxman cited "serious problems in practice with harmonizing inspection standards under other trade agreements," referring specifically to changes wrought by the North American Free Trade Agreement (NAFTA).[63]

Subcommittee Democrat Ron 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 today, we're talking about an agreement that deals with products that have life-and-death consequences for the consumers who use them. . . . 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 email where a former member of the FDA MRA negotiation team wrote that the FDA should consider withdrawing from the talks.

Some observers and participants see the Subcommittee hearing as proof that the U.S. political process was working – that federal agencies were held accountable and asked to explain their reasoning

and decisions. In the end, the MRA remained intact, though the Subcommittee asked the GAO to keep it updated on the progress of FDA's assessment process for equivalency of the EU GMPs. According to the GAO's John Hansen:

> The biggest concerns were what criteria FDA was gong 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.[64]

Though an agreement had been signed, it was clear that the process was not over. Next would come the specifics of implementation.

IMPLEMENTATION

Negotiation of the MRAs was just the beginning of the process. Many issues remained open and required further discussions to determine the terms of implementation. "The tough issues in negotiation became the tough issues in implementation," says Lucent's Joanne Wilson. Some characterized negotiation of the MRA as an elementary task 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."

For one, US regulatory agencies, particularly the FDA, remained somewhat uneasy about the purpose of the MRAs. "They still have not settled in their own mind the question: is this primarily a trade agreement or primarily a technical agreement to facilitate safety?" one source notes. "That question is not easily settled even today." As Guidant's Michael Gropp puts it:

> FDA fundamentally views itself as a law enforcement and consumer protection agency. Commerce views itself as an agency intended to promote trade. I think that part of the difficulty in moving the MRA process forward, both in the negotiation and implementation, is that there are two different views of the world in the two agencies.

Events in Europe during the MRA negotiations had also reinforced the importance of protecting public safety in the EU. Europeans had become quite familiar with controversies over trade and public health. As one Commission official notes:

> 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 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.

Despite concerns about health and safety, regulators were keenly aware that standards and certification were often used as trade barriers. As one source in the European Commission notes, "conformity assessment has traditionally been used everywhere as an instrument for each state to be somewhat protectionist."

There was also debate over the ultimate long-term relevance of the MRAs. For some, the MRAs were seen as a step along the way toward further harmonization of standards. As Guidant's Michael Gropp described:

> My view is that the work of the Global Harmonization Task Force (GHTF) 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.

As the long-terms relevance of MRAs was questioned, more concerns surfaced about the overall process. Negotiating and implementing MRAs used scarce regulatory agency resources. Should those resources be given to a project that might have limited use? Another concern was that if MRA negotiation and implementation was not seen as successful, it could jeopardize future international agreements on regulatory issues. As one negotiator said, "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 worried that implementing the MRAs would make future regulatory reform more difficult. As Charles Ludolph puts it:

> 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 such broad questions remained, implementation was underway. The telecommunication section of the MRAs took effect in December 2000 as planned. For the telecom industry, the U.S.-EU MRA turned out to be a model for future. The U.S. telecommunications industry later entered into MRAs with the 17 nations of the Asia Pacific Economic Community (APEC) and then the Inter-American Commission of telecommunications. "The real benefit was not so much the [MRA] 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."

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," said Bernie Liebler, HIMA's Director of Technology and Regulatory Affairs, "but until you actually have a plan, it's difficult to move forward." For example, when beginning to conduct 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. 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," reflects Liebler. "As a result, the process has been slow to get underway." Both the U.S. and the EU agreed to put off implementation in the medical device sector until November 2003.

The biggest problems in MRA implementation arose in the electrical safety and pharmaceutical sectors. In November 2000, EU Trade Commissioner Pascal Lamy wrote USTR Charlene Barshefsky accusing the United States of "being hardly within the letter and even less in accordance with the co-operative spirit of the MRA."[65] Though implementation was scheduled to start on December 3rd, 2000, the EU accused U.S. regulatory agencies - particularly OSHA and the FDA – of undermining the deal by refusing to recognize European product safety standards and testing as equivalent to those in the United States.

For example, OSHA maintained that it had sole authority to determine whether EU electrical safety inspection labs met U.S. standards. The EU disagreed, saying that these European labs should be certified by authorities in the 15 EU member states. Three European testing laboratories went ahead and applied directly to OSHA for approval to certify products for the U.S. market. Two of these applications were not considered because they were made in French and Spanish instead of English. "We are a domestic health and safety agency," said Steven Witt, the director of technical support at OSHA. "We don't do translations."[66] In the pharmaceutical sector, the EU proposed extending the implementation period for the pharmaceutical good manufacturing practices annex to 2003, but the FDA balked at accepting any firm deadline whatsoever.

Corporate leaders were frustrated by the hold up – especially after making the MRAs a top priority. The TABD presented a document to both EU and U.S. governments noting that failure to implement the MRA by the December 3rd, 2000 deadline "will have far-reaching negative consequences for both the governments and industry."[67] The TABD called on the governments to apply the TABD objective of "Approved Once, Accepted Everywhere."[68]

However, the stalemate continued over implementation of the pharmaceutical and electrical equipment sectors.[69] The summer of 2002 found the EU considering whether to continue, suspend, or terminate the MRAs altogether. The US regulatory agencies continued to refuse to recognize European product safety standards and testing as equivalent to those in the United States. EU officials also considered suspending or terminating the portions of the MRAs that were of key interest to US industry, such as the telecommunications sector, in order to increase the pressure.

Ultimately, despite the challenges, negotiators hope that the MRA experience would facilitate further efforts to streamline trade. Perhaps the most important aspect of the process, some say, was learning more about the other side. As Mattinò noted,

> 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.

Exhibit 1

Bilateral Trade in Seven Sectors
Under MRA Negotiations
Two Year Average 1994-1995
Billions of dollars[70]

Sector	U.S. Exports to EU 15	U.S. Imports from EU 15
(Telecom Sector Annex) ITE and Terminal Telecommunications	$7.8	$2.8
(Electrical and Electronic Sector Annex) Aircraft, machinery and appliances subject to FCC and/or OSHA requirements	$21.3	$18.0
Subtotal of sectors already deemed essentially in agreement	$28.1	$20.8
Sectors in which U.S.-EU agreement is being sought		
Class I and II Medical Devices	$2.3	$1.0
Pharmaceutical GMPs	$2.7	$3.4
Total of above	$33.1	$25.8

The seven sectors currently under active negotiation are:

- ITE and telecommunications terminal equipment
- All products subject to EMC requirements
- All products subject to electrical requirements
- Recreational craft
- Veterinary Biologics
- Low and medium risk Medical Devices (Certain Class I and II medical devices, but not IVD or AMID devices)
- Pharmaceuticals – including both basic materials like hormones, alkaloids, and ephedrines as well as processed pharmaceuticals. These estimates do not include Recreational Craft and veterinary biologics, but could represent about $200 million in two way trade.

Exhibit 2

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 established a framework for achieving mutual recognition of good manufacturing practices inspections.

Exhibit 3

AGREEMENT ON MUTUAL RECOGNITION
BETWEEN
THE EUROPEAN COMMUNITY
AND THE UNITED STATES OF AMERICA

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 (U.S.) 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
U.S. 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 cooperative 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.

[1] Jeff Gerth, "Where Business Rules; Forging Global Regulations That Put Industry First," *The New York Times*, (9 January 1998), p. D1.
[2] Figure of "nearly $50 billion" comes from the *USTR 1998 Annual Report*, p. 217.
[3] Charles Ludolph, Deputy Assistant Secretary for Europe, U.S. Department of Commerce, testimony before the House Subcommittee on Oversight and Investigations of the Committee on Commerce, 105th Congress, 2 October 1998, p. 24.
[4] "U.S. Industry Urged to Back MRAs with EU," *Marketletter*, 13 October 1997.
[5] Testimony before the House Ways and Means Committee, July 1998.
[6] Hearing before the House Subcommittee on Oversight and Investigations of the Committee on Commerce, 105th Congress, 2 October 1998.
[7] Unless otherwise noted, all quotes from Ralph Ives come from a November 1999 interview.
[8] Case 120/78
[9] In some areas such as food, automobiles and airplanes, the EU continued to rely on the "Old Approach."
[10] DG Trade was known as DG-I for most of the length of the negotiations.
[11] Unless otherwise noted, all quotes from Karl Falkenberg are from a November 1999 interview.
[12] Unless otherwise noted, all quotes from Walter Batts are from a 1999 interview.
[13] 25 cents of every dollar of products sold in the U.S are regulated by the FDA
[14] To gain a CE mark, a manufacturer was inspected and audited by an authorized "notified body" under EU regulations. The CE mark was an international symbol of quality management and product safety. Once the CE mark was received, the manufacturer could market its products throughout the EU without undergoing individual country regulation.
[15] Unless otherwise noted, all quotes from Charles Ludolph come from one of several interviews conducted in 1999 and 2000.
[16] After years of negotiations at the end of the Tokyo Round in 1979, 32 GATT Contracting Parties signed the Agreement on Technical Barriers to Trade (TBT). The Agreement laid down the rules for preparation, adoption, and application of 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 Standards Code. Source: www.wto.org
[17] *National treatment* means that imported and locally-produced goods should be treated equally. 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.
[18] Unless otherwise noted, all quotes from Giacomo Mattinò come from a December 1999 interview. 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.
[19] Charles Ludolph
[20] Except for recreational craft
[21] These figures are for the telecommunications equipment ultimately covered by the MRA. U.S. Commerce Department, Bilateral Trade in Seven Sectors Under MRA Negotiations, published in Hearing before the House Subcommittee on Oversight and Investigations of the Committee on Commerce, 105th Congress, 2 October 1998, p. 75.
[22] Unless otherwise noted, all quotes from Joanne Wilson come from a December 1999 interview.
[23] The EU was the world's largest pharmaceutical market, accounting for more than $70 billion in 1993. "Europe's Pharmaceutical Industry in 1993," *Marketletter*, 24 October 1994.
[24] Warner-Lambert merged with Pfizer Inc. in 2000.
[25] Unless otherwise noted, all quotes from Laura Peralta-Schulte are from a 1999 interview.
[26] The full title was the International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use
[27] The goals of the ICH summarized in Dan Kidd, "The International Conference on Harmonization of Pharmaceutical Regulations, the European Medicines Evaluation Agency, and the FDA: Who's Zooming Who?" *Indiana Journal of Global Legal Studies*, Fall, 1996. The first ICH, held in Belgium in 1991, drew over 1000 government and industry representatives. The second ICH, in Florida in 1992, was attended by 1600

people. In 1995, some 2400 delegates representing pharmaceutical companies and forty governments took part of the third ICH in Japan.

[28] The Food, Drug and Cosmetics Act charged FDA with ensuring not only that a product was safe, efficacious, and it did what the label says it did, but also that the product was manufactured in a safe manner.

[29] DG-III's main responsibilities included: (1) coordinating regulatory and legislative activity in the EU (particularly related to the internal market for products); (2) promoting research and innovation by instigating and supporting projects aimed at developing and applying new technologies; (3) promoting industrial co-operation and dialogue both within the EU and with partners in third countries; and (4) providing accurate and up-to-date analyses of performance and economic trends in the main industrial sectors. DG-III also has specific responsibilities for the steel industry in the framework of the European Coal and Steel Community Treaty of 1952. Source: http://europa.eu.int/comm/dg03/mission_en.htm

[30] The Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) concerned the application of food safety and animal and plant health regulations. According to the World Trade Organization (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?" Source: www.wto.org

[31] HIMA, *1997 Global Medical Technology Update*, p. 59.

[32] The Wilkerson Group for the Health Industry Manufacturers Association, "Forces Reshaping the Performance and Contribution of the U.S. Medical Device Industry," 1996.

[33] Ibid.

[34] Source: www.ghtf.org

[35] Linda Horton, "Sixth Annual Health Law Symposium: Pharmaceuticals and Medical Devices: International Harmonization and Mutual Recognition Agreements," *Seton Hall Law Review*, 1998

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

[37] www.europa.eu.int

[38] Interestingly, however, several U.S. participants described DG-I as the rough equivalent to USTR, and DG-III as the rough equivalent to FDA or other regulatory bodies. But the mission of DG-III is to promote industry, not to protect consumer health, safety, or welfare.

[39] Falkenberg also was the lead negotiator for Canada, Japan, Australia, New Zealand, Switzerland and Eastern European MRAs.

[40] Unless otherwise noted, all quotes from Selina Jackson are from a 1999 interview.

[41] TABD 1995 Seville Report

[42] Ibid.

[43] Jackson had recently finished a graduate degree at the Fletcher School of Law and Diplomacy. Johnston had worked at the European Commission.

[44] Kevin Gopal, "Discordant Voices," *Pharmaceutical Executive*, 17 (May 1997): 38.

[45] Quoted by Representative Ron Klink at hearings before the House Subcommittee on Oversight and Investigations of the Committee on Commerce, 105th Congress, 2 October 1998, p. 81.

[46] 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. Linda Horton, *Seton Hall Law Review*, 1998.

[47] "With No MRAs in Sight, TABD Participants Prepare for Second Annual Meeting," *Eurowatch*, 8 (1 November 1996).

[48] Summarized from Matt Breitfelder, "The Transatlantic Business Dialogue: Chicago conference exceeds expectations and confirms the TABD as a major force for a more open Transatlantic Market," *Business America*, (November 1996): 22.

[49] On December 27, 2000, Glaxo Wellcome and SmithKline Beecham merged to form GlaxoSmithKline

[50] Kevin Gopal, "Discordant Voices," *Pharmaceutical Executive*, 17 (May 1997): 38.

[51] Summarized from Breitfelder, "The Transatlantic Business Dialogue."

[52] Shane Schick, "Canada, Europe in mutual recognition agreement deadlock," *Computer Dealer News,* 13(3 November 1997) p. 18.

[53] "US, EU Race to Meet Looming Deadline for Products Standards," *The Journal of Commerce*, (8 May 1997), p.2A.
[54] "Transatlantic Business Dialogue Praises Conclusion of MRA," U.S. Newswire, (13 June 1997).
[55] Public Law 105-115 [S. 830] (21 November 1997), *Food and Drug Modernization Act of 1997.*
[56] Linda Horton, *Seton Hall Law Review*, 1998.
[57] In 1998, the EU comprised 15 countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.
[58] House Subcommittee on Trade, July 23, 1997
[59] Assistant to the President for International Economic Affairs at the National Economic Council Dan Tarullo, White House Press Briefing, May 28, 1997.
[60] TACD Press Release, December 17, 1998. (www.tacd.org)
[61] GAO, Report to the Chairman, House Subcommittee on Oversight and Investigations, Committee on Commerce, 105th Congress, "Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program," March 1998, p. 2.
[62] Unless otherwise noted, all quotes from Alan Slobodin come from a 2000 interview.
[63] Hearing before the House Subcommittee on Oversight and Investigations of the Committee on Commerce, 105th Congress, 2 October 1998.
[64] Unless otherwise noted, all quotes from John Hansen come from a 2000 interview.
[65] Pascal Lamy, letter to US Trade Representative Charlene Barshefsky, d/3120, October 20, 2000. Reprinted in *Inside U.S. Trade*, November 10, 2000.
[66] 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, page 23.
[67] 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, page 23.
[68] TABD*, Transatlantic Business Dialogue 2001 CEO Report*, page 4.
[69] As of June 2002, the European Commission was still deciding whether to cancel participation in the electrical safety portion of the MRAs. (Source: *Inside US Trade*, "EU Still Weight Withdrawal from MRA, will raise it This Month," June 14, 2002)
[70] Source: In 1996, the Department of Commerce prepared an analysis of trade related to the MRAs. Hearings before the House Subcommittee on Oversight and Investigations of the Committee on Commerce, 105th Congress, 2 October 1998, p. 75.

