

The Importance and Challenges of “Mutual Recognition”[†]

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I would like to thank Seton Hall Law School, and its Health Law & Policy Program in particular, for their invitation not only to participate in this morning’s symposium, but to spend this week as the Merck Visiting Scholar. For those of you who are close to the Seton Hall Health Law & Policy Program, it needs no introduction. It is, without question, one of the leading health law programs in the country. Those who created the program, or who have helped support it, should be very proud.

I want also to take the opportunity to express my pleasure at the presence of the Honorable Stuart Pollock, Justice of the New Jersey Supreme Court. He is one of the leading judicial thinkers in the field of health law in the United States. It gives me particular pleasure to note that, among his many accomplishments, he is a graduate of the University of Virginia’s Judges Program.

As Linda Horton represented a few moments ago,¹ I did indeed invite her to use as much of my allotted time as she wished. I learn something new every time I hear Ms. Horton talk, and so, I am sure, did you. Nobody in the United States is more knowledgeable than she about the international dimensions of food and drug regulation. She and I first met in 1975 when we both were working at the Food and Drug Administration (FDA or Agency) and laboring together to facilitate the enactment of the Medical Device Amendments to the Food and Drug Act.² And back then, just as now, no one knew more about the subject under discussion than Linda.

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¹ See Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 SETON HALL L. REV. 692-735 (1999).

² Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 15, 21 & 42 U.S.C. (1994)); Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938, 21 U.S.C. §§ 301-395 (1994).

I.

I hope to offer some perspectives that will place in broader context some of the points that Linda has already made. First, I will briefly discuss the institutional and commercial environments in which FDA must operate as it attempts to mesh domestic regulatory requirements with the practical realities of burgeoning international trade in food, drugs, and medical devices.³ Later, I will turn to the topic reflected in the title of my remarks: the domestic implementation of mutual recognition agreements.⁴ In this latter segment, I will speak from the perspective of a United States administrative lawyer. I will be concerned with the administrative procedures by which regulatory agreements made with our European and other trading partners will be made operational. Specifically, how will they get translated into the practices of FDA and the obligations of firms that do business in the United States? My thoughts about this issue are necessarily speculative. We do not yet have sufficient experience to afford a basis for firm conclusions. Congress has not provided clear statutory answers to any of the relevant questions and there are no judicial decisions directly on point.

II.

At the outset, I want to emphasize the importance of the subject under discussion, to which Ms. Horton's remarks provide such a rich introduction. In some ways we are, in 1998, at a stage of regulatory development comparable to that confronting Congress at the turn of the century. It was by then apparent that the production and marketing of food were no longer local activities. Meat packed in Chicago was being marketed in all of the nation's major cities. The same was increasingly true, but not so obvious, for the products of the fledgling pharmaceutical industry. Consumers could no longer rely exclusively, or indeed confidently, on local public health officials to protect their health and welfare. The enactment of the Pure Food and Drugs Act⁵ and the Meat Inspection Act⁶ in 1906 expressed

³ See *infra* Part II.

⁴ See *infra* Part III.

⁵ Federal Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 770 (1906), *repealed by* FFDCA. For a brief description of the background of the enactment of the 1906 Act, see PETER B. HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS* 996-97 (2d ed. 1991).

⁶ Federal Meat Inspection Act, Pub. L. No. 59-242, 34 Stat. 1260 (1907) (codified as amended at 21 U.S.C. § 603 (1988)). See *generally* UPTON SINCLAIR, *THE JUNGLE* (1906) (depicting conditions in the meat industry at the turn of the century, which led to pressure on Congress to pass regulatory measures).

Congress's judgment that, to be effective, regulation had to reach across state lines.⁷

Happily, an adaptable Constitution and, eventually, a sympathetic Supreme Court, provided the legal framework on which effective regulation of interstate markets could be built.⁸ The emergence of federal regulation did not mean that state and local regulation ceased to be important. With respect to many levels of the increasingly complex food production and marketing system — such as on-farm production, retail sale, and restaurant service — local monitoring and regulation have continued to be critical to this day.⁹ But the inexorable growth of interstate trade had shifted primary regulatory responsibility to the federal level before World War II, particularly for medical products.

At the end of the twentieth century, comparable practical challenges face policy-makers in the United States and across the world. International commerce in food and medicines has exploded in the last generation.¹⁰ Many of the major pharmaceutical firms are genuine multi-nationals. Medical devices firms generally owe their allegiance to a single country, but their customers, in increasing numbers, are distributed around the world. American consumers have come to depend on foreign sources for a substantial and rapidly growing portion of their foods, just as our remarkably efficient domestic producers of food look abroad for many of their customers.¹¹

⁷ See H.R. REP. NO. 59-2118, at 8-9 (1906) (quoted in HUTT & MERRILL, *supra* note 5, at 997).

⁸ See generally RONALD D. ROTUNDA & JOHN E. NOWAK, TREATISE ON CONSTITUTIONAL LAW: SUBSTANCE AND PROCEDURE §§ 4.1-7 (2d ed. 1992); Barry Cushman, *A Stream of Legal Consciousness: The Current of Commerce Doctrine From Swift to Jones & Laughlin*, 61 FORDHAM L. REV. 105 (1992).

⁹ See COMMITTEE TO ENSURE SAFE FOOD FROM PRODUCTION TO CONSUMPTION, INSTITUTE OF MEDICINE, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION 26-29 (1998) [hereinafter IOM REPORT]; see also Consumer Food Safety Act of 1998, H.R. 3676, 105th Cong., Title I § 106 (dealing with federal cooperation with the states regarding food safety); Safe Food Action Plan, H.R. 3148, 105th Cong. § 4 (1998) (calling for the creation of a Food Safety Rapid Response Team within the U.S. Department of Agriculture that would, among other duties, make recommendations to the Secretary on more effective cooperation with state and local agencies in response to food safety emergencies).

¹⁰ See U.S. GENERAL ACCOUNTING OFFICE, FOOD SAFETY: FEDERAL EFFORTS TO ENSURE THE SAFETY OF IMPORTED FOODS ARE INCONSISTENT AND UNRELIABLE 12-13 (April 30, 1998); see also John V. Flynn, Jr. et al., *Reasons for Rivalry*, PHARMACEUTICAL EXECUTIVE 88, June 1, 1998, at 88; *Special Section: Medical Industry Outlook 1998*, BIOMEDICAL MKT. NEWSL. (Biomedical Mkt. Newsl., Inc., Costa Mesa, CA), Jan. 31, 1998.

¹¹ See U.S. GENERAL ACCOUNTING OFFICE, *supra* note 10, at 13. Regarding U.S. agricultural exports, see U.S. GENERAL ACCOUNTING OFFICE, U.S. AGRICULTURAL EXPORTS: STRONG GROWTH LIKELY BUT U.S. EXPORT ASSISTANCE PROGRAMS' CONTRIBUTION UNCERTAIN 1-2 (1997).

The circumstances facing the United States and its trading partners today, however, differ in one obvious and important respect from those that confronted members of the United States Congress in 1906. If those turn-of-the-century Senators and Representatives were prepared, as a political matter, to create a cross-jurisdictional regulatory authority, they had a constitutional — that is, a legal — basis for doing so. By contrast, today the international legal order would not afford a firm anchor for a multinational regulatory authority even if there were support for one — which there surely is not. National regulatory requirements for medicines and foods — particularly foods — have long embodied diverse policies and served multiple goals. No country has been more determined to preserve its autonomy in setting and enforcing health protection standards than the United States. And no doubt many of our trading partners believe we have been as guilty as they of adopting standards whose real objective is to protect or advantage domestic producers.¹²

Accordingly, there are formidable obstacles to international harmonization of regulatory requirements for food and medical products. At the same time, there are mounting pressures on both producer and consuming countries to reach agreement on product and production standards. Even where harmonization does not seem possible, there are pressures — internally generated in part — to reach work-sharing arrangements that permit trading partners to make use of, and rely upon, the production-site activities of a partner's regulatory authorities.¹³ These latter pressures may prove irresistible simply because the alternatives to trusting the work of officials in other countries are unworkable — either accepting products based on physical examination or refusing their entry.

The recent Mutual Recognition Agreement with the European Community¹⁴ (EU MRA) is one expression of this reality. It is a cautious attempt by United States and European Union (EU) policy-makers to work out terms of reciprocal trust in which our regulatory officials accept the work, and sometimes the results, of their officials. The success of the venture — not yet demonstrated — will have important implications not only for international trade but also for protection of U.S. consumers.

¹² See, e.g., *EC Report Notes Differences in Sanitary Measures Approaches*, WORLD FOOD REG. REV., Sept. 1997, at 6; *Mexican Growers to Comply with New U.S. Tomato Size Rule*, WORLD FOOD REG. REV., Feb. 1998, at 9.

¹³ See U.S. GENERAL ACCOUNTING OFFICE, *supra* note 10, at 21-27 (noting that the lack of authority of the Food and Drug Administration (FDA) for requiring equivalent inspection systems in exporting countries diminishes its ability to protect consumers from unsafe foods).

¹⁴ AGREEMENT ON MUTUAL RECOGNITION BETWEEN THE UNITED STATES OF AMERICA AND THE EUROPEAN COMMUNITY, June 20, 1997, available at <<http://www.ustr.gov>> [hereinafter EU MRA].

III.

Turning to the content of this and other multi-national agreements, it is helpful to begin by defining terms. Linda Horton has made it clear that we are talking about two basic types of agreements.¹⁵ In a particular case it may be difficult to characterize an agreement as one calling for “mutual recognition” or one contemplating agreement on common standards, but it is surely possible to distinguish between their extreme or “pure” forms.¹⁶ And there is no doubt about what sort of agreement the EU MRA is.

Essentially, I view mutual recognition agreements, such as the one currently under discussion, as contracts for service. The United States enters into an agreement with a trading partner under the expectation that the trading partner will take steps to help FDA perform its primary function of applying domestic legal standards to products imported into the United States. The service contracted for may be the provision of information, such as sharing the report of an inspection, or it may be the evaluation of a medical device by a body recognized by the partner’s regulatory authorities. In both cases, the assumption is that U.S. law provides the standards that ultimately determine the acceptability of an inspected facility or an imported product. In such an agreement, the role of the trading partner is not that of law *maker* but rather that of information source or service provider.

An agreement to harmonize standards, by contrast, as Linda has suggested, contemplates the establishment of a single common rule of conduct or single common measure of product compliance, i.e., establishment of a single standard that is observed in both countries.¹⁷ If we keep these descriptions in mind, we will have a clearer grasp of the requirements for domestic implementation of any agreement into which the United States enters and a better appreciation of the pace at which we are moving toward internationalization of regulation.

IV.

Linda Horton has observed that the Federal Food, Drug, and Cosmetic Act (FFDCA) now contains express legislative authorization for

¹⁵ See Horton, *supra* note 1, at 692-735.

¹⁶ See *id.*

¹⁷ See *id.* See generally Sharon Smith Holston, *An Overview of International Cooperation*, 52 FOOD & DRUG L.J. 197 (1997) (discussing FDA’s efforts toward bilateral agreements and toward harmonization of standards). See also JERRY M. ROSENBERG, *DICTIONARY OF INTERNATIONAL TRADE* 155, 199 (1994); Margaret Gilhooley, *The Administrative Conference and the Progress of Food and Drug Reform*, 30 ARIZ. ST. L.J. 129, 137 (1998) (discussing FDA’s international harmonization efforts).

FDA to pursue certain types of international agreements.¹⁸ Indeed, Congress has sprinkled its authorization in a number of provisions,¹⁹ including two recently added by the FDA Modernization Act, passed in November 1997.²⁰ The Modernization Act added new language to section 203 of the FFDCa, setting forth Congress's expectations.²¹

Interestingly, the new provisions are framed as instructions to FDA to support the Office of the United States Trade Representative. Specifically, FDA is directed, in consultation with the Secretary of Commerce, to support the Trade Representative in two activities. One is to help in discussions with trading partners regarding ways to reduce the burden of regulations and harmonize regulatory requirements.²² There follows, however, this qualifying language: "[I]f the [FDA] determines that such harmonization continues consumer protections consistent with the purposes of this chapter."²³ Does this language mean, "so long as there is no net reduction in domestic U.S. regulatory requirements," or does it sanction a more expansive understanding of the content of "the protections consistent with the purposes of this Act?"²⁴

In another section, the amended FFDCa goes on to say that "[t]he [FDA] 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, perfume additives, color additives, and regulations governing good manufacturing practices (GMP).²⁵ Assuring compliance with GMP requirements and facilitating inspections to verify compliance seem to be of particular concern to Congress.²⁶ Other regulatory activities that might be the basis for international cooperation, and possible mutual recognition, are perhaps important but apparently less urgent.

The amended FFDCa adds an interesting geographic qualification to its instructions. FDA is specifically encouraged to reach mutual recognition agreements with the EU covering the regulation of all products within

¹⁸ See Horton, *supra* note 1, at 692-735.

¹⁹ See Richard A. Merrill, *FDA and Mutual Recognition Agreements: Five Models of Harmonization*, 53 FOOD & DRUG L.J. 133, 133-34 (1998). [hereinafter Merrill, *Harmonization*]

²⁰ Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified as amended in scattered sections of 21, 26, 35 & 42 U.S.C.).

²¹ See *id.*

²² See FFDCa, 21 U.S.C. § 383(c)(1) (1994).

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.* § 383(c)(2).

²⁶ See S. REP. No. 105-43, at 18-19 (1997).

the Agency's jurisdiction.²⁷ Congress is thus on record as recognizing that there are some partners with whom we are more interested in cooperating than others. Maybe this is simply a reflection of the commercial importance of the trans-Atlantic trade. It may also demonstrate congressional acceptance of the proposition that the regulators in EU countries are as capable and vigorous as our own officials.²⁸

V.

Before turning to the matter of implementation, I want to highlight three features of the regulatory "culture" at FDA. United States FDA officials not only have a strong tradition of tough-minded regulation, but many share — though they do not often express — a conviction that they are more thorough and rigorous about regulation than their counterparts in other countries. They believe that U.S. standards are higher and, just as important, that their means of assuring compliance with those standards are more reliable and certainly less trusting. In their view, FDA regulation represents the "gold standard."²⁹

²⁷ See FFDCFA, § 383(c)(2). The amended FFDCFA instructs FDA to work with the U.S. Trade Representative and the Secretary of Commerce "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." *Id.*

²⁸ See S. REP. NO. 105-43, at 18-19. Speaking about mutual recognition agreements and global harmonization efforts, the Senate Commerce Committee noted:

Only recently have we gotten good news that an important portion of the MRA which involves the *mutual recognition* of inspection reports for good manufacturing practices (GMP) for medical device and pharmaceutical products, and medical device review standards may be close to an agreement. It is important to recognize these efforts for what they are: these agreements would *not* make GMP inspection or product review necessarily uniform but would allow equivalent regulatory bodies to conduct a single review or inspection that would satisfy all of the criteria for all of the countries concerned, instead of conducting multiple inspections, often at great costs.

Id.

²⁹ See David A. Kessler, *Remarks by the Commissioner of Food and Drugs*, 51 FOOD & DRUG L.J. 207, 214-15 (1996). Speaking before the Food and Drug Law Institute's 38th Annual Educational Conference, FDA Commissioner David Kessler stated that "[t]hroughout the world, the FDA's process of rigorous evaluation has been considered the gold standard for new drug review. FDA approval often equates to automatically confirming a new drug's benefit in many foreign marketplaces. We are not going to sacrifice those standards." *Id.*; see also Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1784 n.97 (1996) (noting that "FDA dedicates more personnel to reviewing and regulating drugs than all other industrialized nations combined.") [hereinafter Merrill, *Architecture*]. Regarding FDA's investment in regulation, the General Accounting Office noted:

Under the Federal Food, Drug, and Cosmetics Act, as amended, FDA works to ensure that domestic and imported food products are safe, wholesome, and properly labeled. In fiscal year 1997, FDA spent approximately 463 staff

There is some evidence to support this self-assured view, but, whether or not it is fully justified, it is certainly genuine. This belief will almost certainly make harmonization more difficult and perhaps slow the drive toward mutual recognition. If United States regulatory officials start from the premise that FDA not only imposes the highest standards but also uses the most effective means for assuring compliance with those standards, “harmonization” appears to demand some relaxation of public health protection. At least it does so if other countries are not willing to adopt and enforce U.S. standards. This mindset may not ultimately impede FDA’s willingness to enter into agreements of the mutual assistance variety, but it surely will be an impediment to efforts to achieve agreement on substantive standards.

I should not leave the impression that FDA officials are alone in their belief that their Agency enforces the most demanding standards of product safety. With regard to some subjects, our trading partners claim to be more protective of their consumers than we are of ours. For example, several members of the EU continue to insist that, by sanctioning the use of growth-promoting hormones in livestock production, FDA — and U.S. agriculture — has exposed American consumers to a significant risk of cancer.³⁰ Similarly, most EU countries have displayed far greater skepticism than FDA officials about the supposed risks associated with use of genetic engineering in food production.³¹ The more accurate message, perhaps, is that in just about any country a putative food hazard can elicit an extreme regulatory response that may be oblivious to the scientific facts and prove resistant to compromise, which harmonization ultimately requires.

Another feature of the institutional culture at FDA is the widely-held conviction — or realization — that the Agency is over-extended and under-resourced. The job that FDA has traditionally assumed is getting harder, not easier. In its efforts to assure the safety of food, for example, the Agency confronts organisms that it cannot detect, which pose risks that it cannot assess.³² The task of monitoring food shipments and inspecting

years (inspectors, laboratory staff, and support staff), at a cost of approximately \$35.1 million, to ensure the safety of about 2.7 million imported food shipments.

U.S. GENERAL ACCOUNTING OFFICE, *supra* note 10, at 14.

³⁰ See Samuel S. Epstein, *The Chemical Jungle: Today’s Beef Industry*, 20 INT’L J. HEALTH SERVICES 277, 277-80 (1990) (assessing the cancer risks posed by the use of hormones in cattle); see also Neil Buckley, *EU Defends Ban on Hormone-Treated Beef*, FIN. TIMES, Nov. 4, 1997, at 3.

³¹ See generally Nyaguthii Chege, Comment, *Compulsory Labeling of Food Produced From Genetically Modified Soya Beans and Maize*, 4 COLUM. J. EUR. L. 179 (1998); Christopher Wyeth Kirkham, *Novel Foods and Food Ingredients*, 3 COLUM. J. EUR. L. 317 (1998); *EC Aims for Coherent Policy on Labeling on GMO Products*, WORLD FOOD REG. REV., Sept. 1997, at 5-6.

³² See IOM REPORT, *supra* note 9, at 2-37.

food producers has grown larger because the number of suppliers of food has mushroomed in the last decade.³³ In the medical products area, FDA has recently taken on responsibility for overseeing research in gene therapy and the recovery and processing of human tissue used in surgery — in both instances without new legislative authority or appropriations.³⁴ Until the Clinton administration called for a significant increase in resources for food safety, the Agency's only recent significant funding increases had come through ear-marked user fees collected from the manufacturers of new prescription drugs³⁵ and a special allocation for tobacco.³⁶

The realization that resources have not kept pace with workload, much less public expectations, helps explain the seriousness with which FDA officials seem prepared to entertain proposals for mutual recognition. If you can get other people to help you perform *your* functions — functions that you view as essential — this may help spread the cost of assuring compliance.

Another distinctive tradition has been reflected in the statute that FDA is responsible for administering. It can be described as paternalistic. Many U.S. officials — perhaps more in Congress than at FDA — have long contended that American firms regulated by FDA should not be able to market overseas products they cannot market in the United States.³⁷ This conviction stems from language in the 1938 FFDCA, which FDA later interpreted as prohibiting the export of “new drugs” until they received FDA approval.³⁸ FDA's policy made it impossible for a U.S. manufacturer to ship a drug overseas that FDA had not approved — even if the drug had not been rejected for approval here and would be or had been ap-

³³ See *id.*

³⁴ See Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53,248 (1993); Human Tissue Intended for Transplantation, 62 Fed. Reg. 40,429 (1997) (to be codified at 21 C.F.R. pts. 16, 270); see also Michael A. Friedman, *Remarks of the Lead Deputy Commissioner of the Food and Drug Administration*, 53 FOOD & DRUG L.J. 19, 21 (1998) (“How can the agency continue to manage a twelve percent annual average increase in the total number of all types of applications it receives and continue to produce performance gains of seventeen percent a year, if FDA's budget grows at an annual rate of 1.3 percent in constant dollars?”).

³⁵ See Merrill, *Architecture*, *supra* note 29, at 1794-96.

³⁶ See *House/Senate Appropriations Conference Winds Up . . . Generic Office Gets Extra \$1 Million, FDA Gets Full Tobacco Request*, INSIDE WASHINGTON'S FDA WEEK, Sept. 19, 1997, at 5 (reporting the allocation of \$34 million in fiscal year 1998 to FDA for its tobacco initiative); *If Tobacco Pact, New User Fees Fail, FDA Budget is Millions Short*, INSIDE WASHINGTON'S FDA WEEK, Feb. 6, 1998, at 1 (reporting on congressional debates over FDA's request for \$134 million for fiscal year 1999 for its tobacco programs).

³⁷ See Alan H. Kaplan, *Fifty Years of Drug Amendments Revisited: In Easy-to-Swallow Capsule Form*, 50 FOOD & DRUG L.J. 179, 193 (1995).

³⁸ See Sheila R. Shulman et al., *The Drug Export Amendments Act of 1986: Is It All It Was Intended To Be?*, 49 FOOD & DRUG L.J. 367, 368 n.6 (1994).

proved by foreign authorities.³⁹ The same premise was later incorporated in the somewhat weaker controls imposed on the export of unapproved medical devices by the 1976 Medical Devices Amendments to the FFDCA.⁴⁰

Congress relaxed these restrictions on the export of unapproved products in 1996.⁴¹ But it would still be incorrect to say that, under U.S. law, it is lawful to export any product that a receiving country is prepared to accept. Further relaxation of U.S. restrictions on exports will continue to excite opposition, as demonstrated by the debate over a possible “global” tobacco settlement. One of the many issues in this debate has been whether domestic law should prevent the tobacco companies from exporting products overseas that it may no longer sell without restriction in the United States.⁴²

In short, FDA has historically been viewed by Congress — and has come to view itself — as having responsibility to protect citizens of other countries as well as citizens of our own. This tradition, too, may impede harmonization efforts, particularly if they appear to contemplate any relaxation of U.S. standards.

VI.

I want to devote the remainder of my time to addressing what I call the “domestic implementation” of the EU MRA — and other similar agreements. My interest is in the procedures FDA must follow to translate the commitments and understandings embodied in such agreements into internal obligations that the Agency must fulfill or into duties that it may enforce against private parties.

I start from the premise that, whatever its status under international law, the EU MRA does not automatically have legal effects within the United States. Its terms would not provide the basis for suit against FDA, and they provide FDA no basis for action against any private party. Indeed, on its face, the EU MRA is an agreement to negotiate future agree-

³⁹ See HUTT & MERRILL, *supra* note 5, at 1096-98, 1101.

⁴⁰ See *id.* at 1098.

⁴¹ See FDA Export Reform and Enhancement Act of 1996, Pub. L. No. 104-134, Title II, ch. 1A, 110 Stat. 1321-313 to 1321-320 (1996) (codified at 21 U.S.C. §§ 301 note, 331, 381, 382; 42 U.S.C. § 262 (1994)). See generally Ansis M. Helmanis, *The FDA Export Reform and Enhancement Act of 1996: The FDA's New Extraterritorial Authority Over Labeling and Promotional Practices*, 51 FOOD & DRUG L.J. 631 (1996).

⁴² See *Interagency Group Weighs Trade Implications of Tobacco Strategy*, INSIDE WASHINGTON'S FDA WEEK, Sept. 5, 1997, at 10; see also Mohammad Akhter, *Expanding a Deadly Export Business*, WASH. POST, Sept. 11, 1997, at A15; Peter Hardin, *State Officials Wary at Prospect of Controls on Tobacco Exports*, RICHMOND TIMES-DISPATCH, Apr. 29, 1998, at A1.

ments with respect to particular classes of products or, possibly, with respect to particular trading partners.

A threshold question, therefore, is whether the terms of the EU MRA need somehow to be made part of the domestic law that FDA administers. Reportedly, the Agency is, as we speak, preparing a proposal to domesticate the terms of the EU MRA. Apparently this is being done on the advice of the Agency's Chief Counsel's office.⁴³ Most likely, then, a document will soon appear in the Federal Register — a description of the commitments made in the EU MRA on which members of the public may offer comments. Presumably, FDA will later announce that it has read the comments and will publish, as regulations, the commitments that are embodied in the EU MRA.⁴⁴

It is unclear to me what kinds of comments would be in order. Objections that the United States should not have entered into the EU MRA would seem rather beside the point, for the deed has been done.⁴⁵ Conten-

⁴³ See *Device MRA Implementation Agreement By FDA/USTR Nearing Completion*, GRAY SHEET, Mar. 16, 1998, available in 1998 WL 9544717.

⁴⁴ On November 6, 1998, FDA issued a final rule regarding the implementation of the EU MRA. See *Mutual Recognition of Pharmaceutical Good Manufacturing Practice Inspection Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports Between the United States and the European Community*, 63 Fed. Reg. 60,122 (1998) (codified at 21 C.F.R. pt. 26) (effective Dec. 7, 1998). The Background section of this final rule states:

At the conclusion of negotiations, the United States and the EC submitted the text of the MRA to their respective authorities to complete the necessary procedures for approval and implementation. For FDA, the procedures include publishing this proposed rule that was published in the Federal Register of April 10, 1998 (63 FR 17744). The proposed rule was based on the provisions contained in the two FDA sectoral annexes and the "framework" agreement of the MRA concluded on June 20, 1997. FDA received comments from 14 persons in response to this proposed rule. Many of these comments supported the proposed rule. Some comments raised significant issues but none that, in FDA's view, necessitated any substantive changes to the proposed rule. On May 14, 1998, FDA informed the Office of the U.S. Trade Representative (USTR) that it supported the signing of the MRA. The MRA was signed in London on May 18, 1998. The MRA was signed in London on May 18, 1998. Provisions of the MRA are between the United States and EC, and do not create rights in third parties.

Id.

Regarding the comments submitted to FDA on the proposed rule, see *MRA Confidence Building Period Will Be "Entirely Open," FDA Says*, PINK SHEET, June 22, 1998, available in WL 8441497. The article stated, in part:

In comments on the proposed rule, Public Citizen maintained that "mechanisms for the public to participate in the equivalence determination process" are "crucial" and a "key feature" missing from the proposal. "At a bare minimum," the group stated, "the factual basis for a determination of equivalence should be publicly available and clearly understood."

Id.

⁴⁵ See *Device MRA Implementation Needs Industry Input Early In Process*, GRAY

tions that FDA has misinterpreted certain provisions of the EU MRA could be advanced, I suppose, but would the Agency be within its rights if it were to change its view of what this bilateral instrument means based on comments from domestic constituencies? What if FDA, in its final “regulations,” were to take a position about a particular provision of the agreement with which representatives of the EU disagreed, would the EU have grounds for legal objection under international law? These are puzzles about which FDA’s attorneys have presumably thought and to which they may have convincing answers, but those answers have not yet been provided as we meet today.

Perhaps FDA expects this imminent “rulemaking” to provide standards for it to follow in negotiating future agreements with respect to particular products or with specific countries. If so, what the Agency contemplates seems, on first glance, to be similar to the procedure that the Nuclear Regulatory Commission (NRC) followed when, several years ago, it decided to codify the criteria it would apply in evaluating license applications for nuclear power plants.⁴⁶ In substance, the NRC announced: “We are going to establish, through rulemaking, standards for assessing the safety precautions — for fuel storage and disposal and reactor operations — that future applicants for operating authority must satisfy.” If this is a plausible analogy, what FDA contemplates would at first glance seem quite logical. By publishing and explaining the EU MRA, the Agency would be setting the standards it will apply in negotiating specific agreements in the future. This strategy could make sense if the Agency wished, in the future, to avoid relitigation — or, in this context, renegotiation — of the issues purportedly resolved by the standards; and, of course, so long as it was prepared to live with the results those standards dictated.

But I am not convinced that the NRC example is the appropriate administrative law analogy. The NRC engaged in rulemaking to establish, in one proceeding and for adherence in all future proceedings, the environmental effects of the nuclear fuel cycle. Each of the “future proceedings” that would be governed by the rule was to consider the qualifications of a single licensee to operate a particular facility. In short, the NRC saw rule-

SHEET, May 11, 1998, available in 1998 WL 9545906; see also *EU/US: New Trade Plan Launched at Summit*, EUR. REP., May 21, 1998, available in 1998 WL 8802118.

⁴⁶ See *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519 (1978). In this case, the Nuclear Regulatory Commission (NRC) sought to use the opportunity of considering the granting of an operating license to the Vermont Yankee nuclear power plant to engage in rulemaking that would set out environmental criteria that future applicants would have to meet to obtain an operating license. See *id.* at 528-30. In this way, the NRC, rather than relying on lengthy and expensive adjudicatory processes for each future operating license application, could rely instead on a set of rules setting forth the environmental criteria that would be incorporated into a cost/benefit analysis of each application. See *id.* at 538.

making as a means of simplifying and expediting a series of inevitably complex adjudications. This analytical framework does not appear to fit the task facing FDA. As I interpret the EU MRA, it sets FDA's agenda for a series of future actions that, if they resemble any conventional administrative proceeding, look more like proceedings to establish rules for classes of products, groups of trading partners, or both.

Accordingly, I have searched for another analogy. And one occurs to me, drawn from a different arena of government regulation: the Clean Air Act.⁴⁷ Under the Clean Air Act, the Environmental Protection Agency (EPA) is under an obligation to review (and if acceptable, approve) each state's "implementation plan" (SIP) for achieving compliance with the air quality standards EPA has previously established.⁴⁸ A state implementation plan typically embodies a series of limitations and controls that the state will impose on stationary and mobile sources of air pollution within the state. The "plan" is in essence a collection of rules that may be enforced according to state law, and the plan itself looks more like a "rule" than an adjudicatory order. Inevitably, while the Clean Air Act prescribes criteria that EPA must consider in approving state plans and while most state plans share many common elements, each SIP is unique.

The statutory procedure for EPA review and approval of state plans under the Clean Air Act resembles rulemaking more than adjudication. Each state must afford interested persons an opportunity to comment on a state's plan before it is adopted by the state and submitted to EPA.⁴⁹ In addition, EPA's decision to approve an SIP is reviewable in court. A state's entire plan never appears in the Federal Register; such documents are too voluminous and are continuously being revised and reapproved. The statutory procedure, however, is designed to permit what I will call "second tier" public involvement in setting the rules for air pollution control within the state.

Will the specific agreements contemplated by the EU MRA more closely resemble state air pollution plans or NRC approvals of specific power generation facilities? Since we have no examples to study, it is not possible to say with confidence. My speculation, however, is that these agreements will cover more than one class of products from several countries or several classes of products from one country. In either case, each one will describe procedures for determining the compliance status of nu-

⁴⁷ Clean Air Amendments of 1970, Pub. L. No. 91-604, 84 Stat. 1676 (codified as amended in scattered sections of 42 U.S.C. (1994)).

⁴⁸ See 42 U.S.C. § 7410(a)(1)-(2) (1994).

⁴⁹ See *id.* § 7410(a)(2) (this section amends the language from the 1970 Clean Air Amendments and is from the Clean Air Act Amendments of 1990, Pub. L. No. 101-549, 104 Stat. 2399).

merous products or producers. They will, in short, resemble rules in their generality and prospectivity.

If my speculation is plausible, the imminent rulemaking proceeding that FDA contemplates may be just the first stage in a two-stage process. And if each component of the second stage — agreements with respect to designated classes of products or with named countries — requires rulemaking to implement, one wonders what FDA will have gained by inviting comment on the terms of the EU MRA itself. One answer, of course, is that the proceeding will afford members of the public, including, in particular, critics of the entire enterprise, an opportunity to ventilate their views on the public record and alert FDA to the kinds of objections it may confront when it proceeds to make or elicit specific commitments with trading partners. Having these views on the record may strengthen the Agency's position in negotiations with other parts of the government that may apply pressure on FDA to relax its own demands in the negotiating process.

One cannot say, in the abstract, whether the specific agreements contemplated by the EU MRA will require rulemaking to implement domestically. The answer will depend on what commitments an agreement embodies and what obligations it imposes on FDA and on private parties. It is easier to explain why the answer to this question could matter.

First, if rulemaking is legally required, it will take FDA longer to implement — i.e., to domesticate — any agreement that it enters. Any significant FDA rulemaking involves review by the Office of the Secretary of Health and Human Services and by the Office of Management and Budget.⁵⁰ I never met an FDA employee who thought that this process would prove simple, even for uncontroversial rules.

Second, if the Agency dispenses with rulemaking, it will surely hear objections to its failure to allow public participation in the formulation of domestic regulatory policies. The focus of such policies may be activities overseas, but it is their domestic legal status that is being determined.

Finally, if any legal instrument takes the form of a rule under the Administrative Procedure Act (APA), it will be harder to modify or abandon at a later time. And it may be staff concern about the difficulty of getting top level approval and about the formal impediments to changing poli-

⁵⁰ Regarding Health and Human Services review, see *Raising the Level of Rulemaking Authority of the Food and Drug Administration in Matters Involving Significant Public Policy*; Response to Executive Order, 46 Fed. Reg. 26,052 (1981), *modified by* 47 Fed. Reg. 16,010 (1982) (codified at 21 C.F.R. pt. 5). Regarding Office of Management and Budget (OMB) review, see JERRY L. MASHAW ET AL., *ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM: CASES AND MATERIALS* 241-65 (3d ed. 1992) (presenting a discussion of presidential oversight of regulatory policy and the role of OMB); *see also* Exec. Order No. 12,866, 3 C.F.R. 638 (1993).

cies embodied in regulations that have stimulated FDA interest in what officials hope could be a one-step process for domesticating the EU MRA.

VII.

At a recent program sponsored by the Food and Drug Law Institute, I offered an analytical framework for determining whether implementation of specific agreements should require rulemaking.⁵¹ I propose to recapitulate that analysis here. In it, I categorized under five headings the agreements that seemed to me likely to emerge from future negotiations. I should add, here, that any international agreement, with the EU or with a single trading partner, could embody elements of all five types or “models.” Thus, it is important to read any agreement carefully to determine what commitments have been made.⁵²

The first type of agreement I call the “agent in place” model.⁵³ An example would be an agreement to exchange inspection reports. The object of the agreement, from FDA’s perspective, is to get the trading partner to share information that its regulatory authorities have collected about a company operating within its borders or a product produced there. Any such agreement is likely to be reciprocal: “We will send our inspection reports to you; you agree to send yours to us.” The key point is that such an agreement makes no change in the legal standards by which compliance is measured. For all products shipped from the trading partner into this country, the legal requirements are as they were before the agreement was signed. The agreement simply puts FDA in a better position to determine whether those requirements are met.

This sort of agreement ordinarily would not require rulemaking, unless — and this would be unlikely, indeed implausible — FDA had previously promulgated regulations specifying the sources of information on which it would rely in monitoring imported foods and the regulation’s excluded use of inspection reports from exporting countries.

My second type of agreement I call the “enforcement discretion” model.⁵⁴ What I envision here is an agreement in which FDA says to a trading partner’s counterpart authority: “We are persuaded that you do

⁵¹ See generally Merrill, *Harmonization*, *supra* note 19.

⁵² The critical inquiry is whether an agreement calls for steps designed to help assure compliance with existing legal standards or contemplates some adjustment or change in those standards. Agreements that contemplate a change in the applicable law presumptively require rulemaking. See Administrative Procedure Act (APA), 5 U.S.C. §§ 553, 556, 557 (1994); see also KENNETH CULP DAVIS & RICHARD J. PIERCE, JR., *ADMINISTRATIVE LAW TREATISE* § 6.4 at 248-50 (3d ed. 1994) (distinguishing between procedural and substantive rules).

⁵³ See Merrill, *Harmonization*, *supra* note 19, at 135.

⁵⁴ See *id.* at 135-36.

such a good job in inspecting your local producers to assure compliance with *your* sanitation requirements that, when their products are imported into this country, we will, as a matter of discretion, subject them to less rigorous scrutiny than we ordinarily would apply.” Such an agreement would commit FDA to indulge a (presumably weak) presumption that the trading partner’s products will comply with U.S. requirements.

Law enforcement agencies exercise this sort of discretion all the time. Most highways are posted 55 miles an hour, yet some — though not all — witness average speeds of 65 miles an hour. Highway patrolmen are responsible for combating dangers on the highway, but they also have other law enforcement duties that often rank higher in importance. How closely a particular stretch of road is patrolled will depend, in part, on official judgments about the likelihood that the posted speed will be exceeded if patrolling is light — as well, of course, on assessments of the importance of competing functions. But no one believes that all highways posted 55 m.p.h. are policed with equal intensity. It does not seem to me fundamentally different for FDA to say to its counterparts in the United Kingdom: “We have such confidence in your efforts that when we see food bearing the U.K. label entering the United States, we are quite likely to give it a pass.” The governing legal standards are still FDA standards, and not those of the U.K. FDA’s decisions about how rigorously to monitor foods from the U.K. to assure compliance with U.S. standards simply take into account our understanding of — and, in my example, agreements with — the regulatory officials of a familiar trading partner.

I do not believe that this form of agreement should require rulemaking to implement because it does not purport to alter the substantive legal standards that govern producers or products. Of course it is possible, but unlikely, that FDA may have adopted a regulation that would, unless changed, foreclose such an exercise of enforcement discretion. In that rare circumstance, rulemaking would be required to modify the restrictive regulation.

My third prototype agreement I call the “deputy sheriff” model.⁵⁵ What I visualize is an agreement in which the United States, on behalf of FDA, would say to the other party: “Here are our requirements. We want your officials to tell us whether they believe that a product or a manufacturer is meeting our requirements. We will rely on them, following their procedures, to confirm compliance — but applying FDA’s substantive standards. For our part, FDA will provide equivalent service for your officials.” While my hypothetical assumes that each party is content to leave it to the other to determine its own methods for verifying compliance, it is

⁵⁵ See *id.* at 136.

entirely conceivable that such an agreement might also prescribe the methods to be used.

This caricature exemplifies many of the mutual recognition agreements that the United States is likely to enter into with the EU or with individual EU members. In principle, I do not believe that implementation of such an agreement should require FDA to engage in rulemaking. The agreement does not contemplate any change in the substantive standards applicable to imported products; it merely calls for a change in the means FDA uses to verify compliance.

I must, however, attach a caveat at this point. It is conceivable that FDA has adopted regulations that specify how it ordinarily will go about verifying compliance with applicable domestic standards. If FDA has said in regulations: "We always use our own inspectors," or "inspectors assigned by another U.S. agency," then an agreement to rely on inspectors employed by a trading partner would represent a change in established practice that could require rulemaking. There would surely be persons interested in commenting on the wisdom of "deputizing" foreign inspectors, and FDA might, in any case, wish to allow them the opportunity. If the Agency were not so inclined, it might argue that any regulations describing its usual procedures for verifying compliance were "rules of agency practice or procedure" exempt from the rulemaking requirements of the Administrative Procedure Act (APA).⁵⁶

I call my fourth prototype the "equivalence" model.⁵⁷ An example of such an agreement would be one in which the United States and other signatories say to each other, in substance: "While our standards are not identical in text or in detail, we believe and agree that they provide equivalent public health protection. Accordingly, if the officials of country A affirm that a product meets country A's standards, we will permit its entry into and marketing in the United States as meeting our domestic standards."

I believe that implementation of an agreement of this sort would ordinarily require rulemaking. Among the prototypes discussed to this point, such an "equivalence" agreement represents a determination by FDA that a different approach than the one it has previously demanded will satisfy the requirements of United States law. This model would change FDA's historical interpretation of what measures the FFDCA requires. The Agency is, in effect, agreeing that there are two ways to satisfy the statute, where before there was but one. The agreement thus effects a change in the substantive law.

⁵⁶ 5 U.S.C. § 553(b)(A) (1994); *see also* MASHAW ET AL., *supra* note 50, at 481-85.

⁵⁷ *See* Merrill, *Harmonization*, *supra* note 19, at 136-37.

It is possible, I suppose, that FDA could respond: “We have always acknowledged that there was more than one approach to meeting the FFDCAs substantive requirements; now we are simply recognizing that, e.g., the U.K. approach, is one of them.” If such a response were a plausible historical account, FDA’s agreement would simply represent a formal recognition of what had always been the law.

My final prototype is the “harmonization” model.⁵⁸ An agreement to harmonize standards is an agreement to apply the same legal standards in both or all participating countries. Only in instances where the agreed-upon common rule was the established FDA rule — all other signatories agreed to “harmonize toward” the United States — could rulemaking be avoided. Only then could FDA plausibly say that the agreement did not effect a change in U.S. law. If any change in the applicable legal standards is contemplated, rulemaking would be required to accomplish it.

VIII.

The foregoing analysis suggests that FDA may be able to achieve significant and close collaboration with our major trading partners through international agreements whose main purpose is labor saving rather than law changing. Even where an agreement contemplates some change in applicable substantive standards for products or processes, the change might not be controversial and the burden of rulemaking to effect the change therefore could be modest. Of course, FDA could assume a larger procedural burden than the APA itself mandated by agreeing to undertake rulemaking even though not obligated to do so. A desire to educate producers or assuage concerns of consumers might prompt the Agency, as a matter of discretion, to provide for greater public participation than the APA prescribes.

My focus in the latter part of this Article has not been on the most critical issues that FDA confronts as it attempts to grapple with the increasing internationalization of the markets for food and medical products. The first issue that FDA must always consider is whether its standards for domestic production and marketing are protective, legally defensible, and administrable. Only then does it become necessary to worry about the special challenge of assuring the safety and utility of imported products. That challenge can, however, be formidable, particularly as FDA shifts from requirements enforced primarily through physical inspection and chemical analysis of products to requirements that emphasize process design and adherence. This shift is a palpable and increasingly important feature of regulation across all areas of FDA’s jurisdiction and will continue to force

⁵⁸ See *id.* at 137.

the Agency to find ways to cooperate with our trading partners and allocate regulatory responsibility more efficiently.