# *Etceteras . . .*

## Regulatory Harmonization: A Sweet-Sounding, Dangerous Development

Contemporary social and economic affairs take place within a bewildering complex of regulatory restrictions and requirements. Already profuse beyond comprehension, the labyrinth grows ever more extensive. In the United States, at the federal level alone, the four to five thousand new final rules put in place each year require some twenty thousand pages of the *Federal Register* for their official promulgation (Clyde Wayne Crews, Jr., *Ten Thousand Commandments: An Annual Policymaker's Snapshot of the Federal Regulatory State* [Washington, D.C.: Competitive Enterprise Institute, March 1999], 14–15). Simultaneously, the 50 states, 3,043 counties, 19,279 municipalities, and 16,656 townships crank out countless new regulations of their own (see *Statistical Abstract of the United States 1997,* 297, for the number of government units in 1992).

All of this regulatory activity, of course, occurs within a single nation-state. Elsewhere in the world, the regulators are not just sitting on their hands, and in certain countries—France springs immediately to mind—the bureaucrats would be outraged by the mere suggestion that the American regulators were surpassing them. Business firms that operate globally must deal with a vast variety of regulatory restrictions and requirements.

In general, complying with many different bodies of regulation costs more than complying with just one, or so it has often seemed to business people. Hence their inclination to support "regulatory harmonization."

### In the United States Historically

In the United States, business support helped to create the very first federal regulatory agency, the Interstate Commerce Commission, in 1887. As the historian Gabriel Kolko has remarked, in the locus classicus of this thesis, "The railroads realized long before 1900 that the federal regulation of railroads offered them protection, actual or potential, from harassment by the states"; and "it was this threat of state legislative attacks that kept the railroads solidly behind the I.C.C. and federal regulation" (*Railroads and*

*Regulation, 1877–1916* [Princeton: Princeton University Press, 1965], 164, 205; see also the section titled "National vs. State Regulation," 217–26).

Similarly, as Gary Libecap has shown, the shift of lobbying efforts by butchers and cattle raisers from the state legislatures to the U.S. Congress—not the complaints of consumers—played a crucial role in gaining passage of the Sherman Antitrust Act in 1890 ("The Rise of the Chicago Packers and the Origins of Meat Inspection and Antitrust," *Economic Inquiry* 20 [April 1992]: 242–62).

Along the same lines, Richard Sylla has argued that efforts toward regulatory harmonization underlay the widespread business support for big federal government that became so evident during the Progressive Era: "How much more efficient and less costly it must have seemed to the businessmen subjected to several state jurisdictions to create an administrative state at the federal level, and to have that state absorb some state activities and override others. That is what they tried to bring about—successfully" ("The Progressive Era and the Political Economy of Big Government," *Critical Review* 5 [Fall 1991]: 540). Reacting to an earlier, unpublished version of Sylla's article, I agreed that "the managers of the big firms, harassed by dozens of state governments and their rapacious politicos, . . . began to see the wisdom of federal regulation. Perhaps, they reasoned, they would stand a better chance of escaping the meddlesome, costly, and fluctuating congeries of state regulations if they could deal with a single national regulatory body" ("*Crisis and Leviathan:* Higgs Response to Reviewers," *Continuity: A Journal of History,* no. 13 [Spring–Fall 1989]: 95).

The story, however, did not end at that point. The businessmen who supported the creation of new federal regulatory agencies hoped, of course, to make their lives simpler and their costs lower. Better still, perhaps they could "capture" the agencies and make them serve, in effect, as cartel police, keeping maverick competitors in check and assuring higher rates of return to the cartel members. By no means did they always succeed in that quest (on the early ICC, for example, see Paul W. MacAvoy, *The Economic Effects of Regulation: The Trunk-Line Railroad Cartels and the Interstate Commerce Commission before 1900* [Cambridge, Mass.: MIT Press, 1965]). But, to the extent that they did succeed, consumers suffered as a result. No doubt George J. Stigler had just such outcomes in mind when he observed, "Regulation and competition are rhetorical friends and deadly enemies" (*The Citizen and the State: Essays on Regulation* [Chicago: University of Chicago Press, 1975], 183).

Not infrequently, however, business support for regulatory harmonization at the federal level gave birth to an unmanageable offspring. Like Dr. Frankenstein's monster, the newly created federal regulatory agencies often stopped heeding the voice of their business progenitors. Within twenty years, for example, the ICC had fallen under the sway of shipper interests, and, by refusing to approve reasonable rate increases, the commission proceeded to compress the railroad companies in a merciless cost-price squeeze (Albro Martin, *Enterprise Denied: Origins of the Decline of American*

*Railroads, 1897–1917* [New York: Columbia University Press, 1971]). So severely had the railroad firms suffered in the decade after 1906 that during World War I they collapsed, financially exhausted, into the loving arms of the U.S. Railroad Administration; and afterward, under the terms of the Transportation Act of 1920, they found themselves reduced to little more than regulated public utilities (Robert Higgs, *Crisis and Leviathan: Critical Episodes in the Growth of American Government* [New York: Oxford University Press, 1987], 152–53).

In similar manner, over the past century many a firm must have rued the day that business interests threw their weight behind the enactment of the Sherman Act and thereby gave rise to galling government harassment that epitomizes everything suggested by the phrase "arbitrary and capricious." Nor have consumers been well served by the rampaging federal trustbusters, as the contemporary case against Microsoft makes crystal clear once again (Richard B. McKenzie and William F. Shughart, "Is Microsoft a Monopolist?" *Independent Review* 3 [Fall 1998]: 165–97; and Stan J. Liebowitz and Stephen E. Margolis, *Winners, Losers, and Microsoft: Competition and Antitrust in High Technology* [Oakland, Calif.: Independent Institute, 1999]).

## On the International Scene Currently

As international commerce has grown in recent decades, more and more firms have found themselves butting up against the obstacles posed by the great variety of regulatory systems in place around the world. Seeking to mitigate the great cost of complying with diverse regulations, business people have lent their support to an accelerating movement toward international regulatory harmonization. Outstanding manifestations of this trend have appeared in the European Union and its predecessor organizations. As Manfred E. Streit has recently observed, "Almost throughout the whole process of European integration, harmonisation of national laws and regulations was considered a matter of course." There existed "a widespread prejudice . . . of assuming quite uncritically that a uniform legal system which covers a large area has a value on its own and that legal harmonisation will lead to the best possible system" ("Competition among Systems, Harmonisation and Integration," *Journal des Economistes et des Etudes Humaines* 8 [June–September 1998]: 239, 251). However one may characterize the course of economic activity in the EU, no one can deny that "business" has been brisk in Brussels.

Although I find myself in nearly complete agreement with the analysis of harmonization presented by Streit in the article just cited, I take issue with his particular conclusion that "taken together, the normative and positive evaluations suggest that harmonisation appears only advisable in those cases in which compelling reasons, *such as the prevention of hazard,* can be given" (250, emphasis added; the same exception for "health or safety" is adduced by Alan O. Sykes in his otherwise well-reasoned discussion, "The [Limited] Role of Regulatory Harmonization in the International Sys-

tem," working paper no. 96/97-23, University of California School of Law, Program in Law and Economics, Berkeley, 21, 24).

In large part, however, my disagreement springs from a recognition of certain tendencies noted by Streit himself, especially the following one: "Considering those regulations which have been introduced by harmonisation, it became obvious that in many cases they were more complex and comprehensive than those regulations which were previously in force in the member states" (252). Far from applying to the EU case alone, this statement tends to apply to the harmonization process wherever it occurs. That is, international harmonization of diverse national regulations tends to raise the severity of the regulations at least to the highest level previously reached by a member of the accord—there is, so to speak, a leveling up—and frequently to a higher, formerly untried level, so that even the previously strictest regulator becomes stricter still.

Now, it may seem counterintuitive that harmonization would be undesirable—even dangerous—in relation to regulations aimed at the prevention of hazard or the promotion of public health, but at least in certain pertinent areas I have studied in some detail, I am persuaded that such is the case.

## Medical Devices as an Example

In the United States, medical devices—thousands of distinct products that now range from bandages, syringes, and latex gloves to implantable defibrillators, CT scanners, and laser eye-sculpting machines—first became subject to regulation by the Food and Drug Administration (FDA) under the authority of the Food, Drug, and Cosmetic Act (FDC Act) of 1938. The scope and severity of the regulation became much greater under the authority of the Medical Device Amendments of the FDC Act, enacted in 1976, and later amendments, especially those of 1990. By the early 1990s, firms in the industry found themselves subject to excruciatingly detailed, unpredictable, very costly, and sometimes strangling regulatory strictures. Worse, consumers of the products—ultimately the patients themselves—suffered because of the regulation's destructive effect on technological development and because of the withholding of already developed products from the market while firms waited, often for years, to receive marketing approval from the FDA. (For a detailed account, see Robert Higgs, "FDA Regulation of Medical Devices," in *Hazardous to Our Health? FDA Regulation of Health Care Products,* edited by Robert Higgs [Oakland, Calif.: Independent Institute, 1995], pp. 55–95.)

In Europe the situation contrasted markedly. Until recently, European countries imposed relatively little regulation on the producers of medical devices. Although the scope, detail, and cost of the regulation varied widely, no European country practiced the sort of rigid, elaborate, legislatively defined, centrally directed and enforced regulation imposed in the United States since 1976. The Europeans

relied more on the formulation of technical standards by professional organizations, leaving manufacturers free in most cases to comply or not comply with the established standards. Purchasers, of course, could insist that products meet certain standards, and in some countries major purchasers such as the national health service were either required or urged to do so. In the 1970s, the Europeans began to develop a more restrictive system of regulation, but the adoption of the new system proceeded slowly. Only in the 1990s did the member states of the EU begin to put in place a more systematic and demanding regulatory system. (For an account of the development of medical device regulation in Europe, see Robert Higgs, *How FDA Is Causing a Technological Exodus: A Comparative Analysis of Medical Device Regulation—United States, Europe, Canada, and Japan* [Washington, D.C.: Competitive Enterprise Institute, February 1995], 23–34.)

By the beginning of the twenty-first century, the European situation will have changed drastically, especially in countries that previously had little or no regulation. Notably, no evidence exists that European consumers in general have suffered because of the previous, relatively undemanding regulatory environment, and obviously many European patients have benefited by gaining quicker access to new, more effective devices ("FDA Slammed in Comparison with Europe," *Clinica* 694 [February 26, 1996]: 7; for many specific examples, see the evidence cited in Higgs, *How FDA Is Causing a Technological Exodus,* 48 n. 107). The recent, now nearly completed European changes have been driven not by safety concerns but by the need to make regulations uniform throughout the European Union in order to preclude their serving as trade barriers. As the desired uniformity is achieved, the common regulatory system will impose *more* regulation, even in countries such as France and Germany that already had relatively extensive regulation. Still, when the new EU system is fully in place, it will fall far short of FDA-type regulation, leaving European device manufacturers, purchasers, and patients much better off relative to their U.S. counterparts.

Because regulatory requirements still differ among the major market areas—the United States, the European Union, and Japan, not to speak of the rest of the world—producers continue to confront troublesome and costly regulatory diversity. Hence, they continue to press for even greater, ultimately global harmonization of the regulations ("Global Harmonisation is the Only Solution to Escalating Regulatory Costs, Says Industry Executive," *Clinica* 867 [July 19, 1999]: 5). The FDA Modernization Act of 1997 directs the FDA to meet with foreign governments to work out harmonization agreements. A Global Harmonization Task Force, including representatives of industry and regulators from the European Union, the United States, Australia, Canada, Japan, and other countries, was created in 1992 to chart a course toward that ultimate objective, and its four study groups have been busily emitting documents for potential official adoption by the appropriate government authorities ("Focus Moves from Mutual Recognition to Global Harmonisation," *Clinica* 815 [July 6, 1998]: 6).

A halfway house on the road to global harmonization is the mutual recognition agreement (MRA), a number of which have been reached by various pairs of countries and by the EU and various countries (Egid Hilz, "Mutual Recognition Agreements Set the Scene for Easier Trade," *Clinica Review 1998* [1999]: 10). On May 18, 1998, the United States and the EU signed an MRA, which is currently in the process of being implemented.

> Under the MRA, an EC CAB [European Community Conformity Assessment Body] could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected [lower-risk] devices based on FDA requirements. Similarly, a U.S. CAB could conduct quality system evaluations for all classes of devices and product type examinations and verifications for selected devices based on EC requirements. (*Federal Register* 63 [July 2, 1998]: 36247)

In effect, this MRA provides for harmonized regulatory reviews, rather than harmonized regulations; each country retains its own regulations within its own borders. In announcing the U.S.–EU agreement, however, the FDA declared that the MRA "may . . . enhance harmonization of U.S. and EC regulatory systems" (*Federal Register* 63, 36247).

Implementation of the U.S.–EU MRA has not been smooth sailing. Once the agreement went into force in December 1998, the FDA threw up a series of obstacles, and European observers concluded that "the FDA only intended to follow through with the MRA on its own terms":

> The FDA believed it would be able to use the mutual recognition agreement (MRA) to reinforce the European device regulatory system, which it considers too weak, by ensuring more stringent and more frequent controls on European manufacturers at little extra cost to itself. The FDA also hoped to retain the ultimate say in market authorisation. (Amanda Maxwell, "European Industry Fears the US Is Playing a Cat and Mouse Game with Mutual Recognition Agreement," *Clinica* 843 [January 25, 1999]: 3)

For some Europeans involved in the process, the FDA's insistence on dominating the implementation of the U.S.–EU MRA rendered the arrangement "little more than a charade" (Maxwell, "European Industry Fears," 3).

European industry representatives have begun to view the MRAs as failures and to characterize them as detours from, rather than way stations on, the road to global harmonization. According to Ian Cutler, the director of regulatory affairs at Smith & Nephew, "As a result of these initiatives the regulatory scene is becoming too complex and there does not appear to be any effective control. This excessive regulation will stifle and retard medical device development, increase the costs of market entry, discourage investment in industry and ultimately deny patients the potential benefits" (Zoë McLeod, "Tide of European Industry Opinion Moves against Device MRAs

and Global Harmonisation," *Clinica* 853 [April 12, 1999]: 4). Most likely, however, such grumbling reflects little more than the frustrations normally associated with constructing any elaborate regulatory arrangement involving many interested parties in many different countries. The trend toward global regulatory harmonization in the medical device industry seems unalterable, if only because so many government bureaucracies around the world have committed themselves to it.

It has been noted that "regulatory harmony, like motherhood and apple pie, is difficult to argue against" (Helen Gavaghan, "Harmony and Regulation Yield to the Need for Payment," *Clinica Review 1996* [1997]: 3). Especially for the bureaucratic mind, enforcing one set of regulations seems to make more sense than enforcing many. Business people always resent the costs associated with regulatory multi-compliance. With the affected business interests demanding regulatory harmonization and the world's legislators and regulators willing to supply it, who will oppose it? The answer, all too often, is no one.

The absence of organized, vocal, political opposition, however, does not signify that regulatory harmonization harms no one. On the contrary, it holds the potential to harm multitudes. For regulatory harmonization is a species of cartelization, and just as successful cartelization in ordinary markets harms the consumers, so successful cartelization across regulatory jurisdictions tends ultimately to harm all those whose freedom of peaceful, voluntary action the regulations restrain.

During the first half of the 1990s, when the FDA became even more outrageous than usual in its regulation, many people fled to Europe to gain access to the medical devices to which the FDA denied them legal access in the United States. Medical device companies began to shift their operations, especially their clinical trials, from the United States to Europe (Higgs, "FDA Regulation," 73–77). In those days, Americans had somewhere to seek refuge from intolerably harmful regulation. Their pathetic flight served as important evidence when, after the 1994 elections, certain members of the Republican-led Congress took the FDA to task, causing it to moderate its most outrageous actions—a reactive "reinvention" eventually codified in the FDA Modernization Act of 1997.

Once global regulatory harmonization has been achieved, however, the FDA's victims will have nowhere to run. They will have no choice but to suffer in silence, or, should they incline toward expressing their political "voice," to plead pitiably for the mercy of their governmental overseers. For the most part, the victims will remain unaware of the relation between their plight and the worldwide cooperation of those who claim, counterfactually, that they are only protecting people's health and safety. The costs of regulatory harmonization will have to be counted not only in dollars but in freedom, physical well-being, and life itself (see Robert Higgs, "Should the Government Kill People to Protect Their Health?" *Freeman* 44 [January 1994]: 13–17).

Even the critics of regulatory harmonization make an exception for regulations affecting the public health and safety. In so doing, they are turning matters upside down. Whereas the public can endure the costs of, say, securities regulation or cable TV regulation, the costs of government regulation of medical goods are far greater. It has been said that war is too important to be left to the generals. Likewise, people's health and survival are far too important to be left to officeholding politicians and their smiley-faced henchmen.

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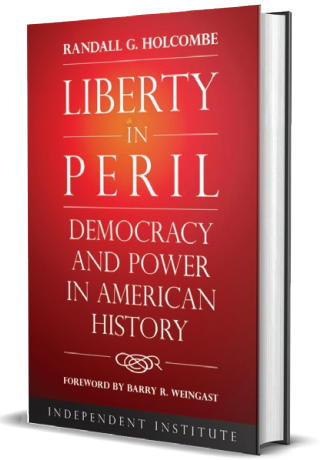


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