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Transnational Regulation of the Pharmaceutical Industry

By JOHN BRAITHWAITE

ABSTRACT: While the pharmaceutical industry arguably has the worst record of serious corporate crime of any industry, international law evasion rather than outright law violation has been the biggest problem in the industry. To understand how these problems can be and are being brought under control, a legal-pluralist analysis is needed that decenters criminal enforcement by the state. Consumer and professional activism and a variety of levels of self-regulation in combination with state, regional, and international regulation are all important to understanding how progress is possible. Creative work within this web of controls can actually transform lowest-common-denominator regulation into highest-common-factor regulation and self-regulation when actors are capable of thinking strategically in world-system terms.

John Braithwaite is a professor in the Research School of Social Sciences, Australian National University. His books include Not Just Deserts: A Republican Theory of Criminal Justice *(with Philip Pettit) and* Responsive Regulation: Transcending the Deregulation Debate *(with Ian Ayres). From 1983 to 1987, he served as a member of Australia's Economic Planning Advisory Council, chaired by the Prime Minister.*

IN 1984, I published a book on the serious and rather widespread nature of corporate crime in the international pharmaceutical industry.[1] Since that book was published, there has been some improvement in the social control brought to bear against some of the problems I identified. The nature of this progress will be discussed in the present article. The interesting thing is that there has been little progress with criminal enforcement, which remains exceedingly rare in all nations of the world in spite of the fact that serious criminal conduct seems more common in the pharmaceutical industry than in perhaps any industrial sector in the world economy.[2] Implications of this situation for a legal-pluralist approach to the control of international corporate crime will be discussed. First, however, the nature of the problem must be described.

THE PROBLEM

In *Corporate Crime in the Pharmaceutical Industry*, I concluded that bribery is probably a larger problem in the pharmaceutical industry than in almost any other industry.[3] Of the 20 largest American pharmaceutical companies, 19 had been embroiled in bribery problems during the decade before the publication of the book. There was evidence of almost every conceivable type of actor who could strategically affect the interests of pharmaceutical companies receiving bribes from them: health ministers, government price control officials, purchasers for government pharmaceutical benefits systems, tax officials, police, customs officers, hospital administrators, health inspectors, physicians—and so the list went on. Product-safety offenses such as the sale of impure, overstrength, out-of-date, or nonsterile products were also shown to be widespread.[4] Antitrust offenses kept some of the postwar wonder drugs financially out of the reach of most of the world's population for many years, causing countless lives to be lost needlessly.[5] Misrepresentations in printed advertising and by word of mouth by sales representatives were common offenses in the pharmaceutical industry, with particularly serious consequences.[6] The pharmaceutical industry also had its share of tax offenders and fraudsters who duped shareholders and creditors.[7] But the most serious corporate crimes in the pharmaceutical industry were, and still are, in the safety testing of drugs.

Cases were documented of rats and monkeys in drug trials developing terrible symptoms like tumors and blindness and being replaced by healthy animals.[8] Cases of reincarnated rats were documented—rats that died reappeared later in the data as living animals. There were also many cases involving physicians who were paid handsomely to do clinical trials on humans for new drugs.

1. John Braithwaite, *Corporate Crime in the Pharmaceutical Industry* (London: Routledge & Kegan Paul, 1984).
2. Ibid., pp. 14-17.
3. Ibid., pp. 11-50.
4. Ibid., pp. 110-58.
5. Ibid., pp. 159-203.
6. Ibid., pp. 204-44.
7. Ibid., pp. 279-89.
8. Ibid., pp. 51-109.

Some had terrible misfortunes on the eve of Food and Drug Administration (FDA) audits of the quality of the data they had collected in support of new drug applications. For example, Dr. James Scheiner of Fairfax, Virginia, who did experiments for Johnson and Johnson, had his office vandalized the night before an FDA audit—the mindless vandals dumping the records relating to the studies to be audited into a whirlpool bath. Dr. Francois Savery, who had earned a fortune testing drugs for Hoffman-La Roche and other leading companies, suffered the catastrophe of accidentally dropping his data overboard while out in a rowboat. Unfortunately, a U.S. court did not believe him; he was sentenced to five years probation for felony fraud. Regrettably, however, safety-testing fraud remains a serious problem, with new allegations involving leading companies and leading researchers continuing to emerge repeatedly.

THE TRANSNATIONAL NATURE OF THE PROBLEM

The internationalized nature of corporate crime in the pharmaceutical industry makes criminal convictions difficult to obtain. The offenses we are discussing are complex to start with, before one adds the problem of international jurisdictional tangles. There is the complexity of the books—paper trails through the finances and the raw scientific data that are difficult to follow. Then there is the scientific complexity of cutting-edge technology. Not many of us are capable of understanding it, certainly not many Federal Bureau of Investigation officers. Then there is organizational complexity: everyone in the organization has a story as to why the slipups in the system were someone else's responsibility. All of these complexities are to some extent inherent in an international high-technology industry. But pharmaceutical industry informants have explained to me how the complexity is more contrived than inherent. For example, companies generally can get clearly defined internal accountability for things that matter to them. They define accountability clearly for internal purposes on matters like product quality, while setting forth a smokescreen of diffused and confused accountability for projection to the outside world. Three of the U.S. companies I visited a decade ago had "vice presidents responsible for going to jail." Incumbents in these positions explained to me how lines of accountability for purposes of official presentation to the outside world were drawn so that if a head had to go on the chopping block, it would be theirs. After a period of faithful service as the vice president responsible for going to jail, they would be rewarded with promotion sideways to a safe vice presidency.

International complexity is also both inherent and contrived. The bribe from a U.S. company to a Latin American health minister can be arranged so that it is paid in a third country by an intermediary from a fourth country through a Swiss (fifth country) bank account. This is using jurisdictional complexity to make lawbreaking harder to discover and punish. The more fundamental and insidious way that international jurisdictional complexity is used, how-

ever, is to evade laws instead of breaking them. International law evasion strategies have reached a high level of sophistication in the pharmaceutical industry.

The paradigmatic law evasion strategy is transfer pricing or profit shifting to avoid tax. A transnational corporation has massive intracorporate sales. Tax liabilities can be avoided by pricing low for intracorporate sales from a subsidiary located in a high-tax country to a subsidiary in a low-tax country and by pricing high when sales are from a low-tax to a high-tax nation. There have been cases where pharmaceutical transnationals have managed to run their worldwide operations at a loss except for a single obscure tax haven, in which massive profits are recorded.[9]

International law evasion in the pharmaceutical industry comes in both cruder and more sophisticated variants than profit shifting. An example of a cruder form of evasion is an impure or understrength product that is forbidden from sale in one country being dumped in another nation with looser laws.[10] With products where there is reason to believe that risks could be high during the experimental stage, initial testing can be done on Third World populations without a practical capacity to sue or to stir up public opinion in the firm's home country.[11] This strategy is often an element of a much more sophisticated international law evasion strategy whereby the firm develops an integrated plan of where it will do the early testing and where it will do its final testing; where it will seek marketing approval first, second, third, penultimately, and ultimately; and where it will locate manufacturing of the new product. While a remote jungle clinic may be ideal for initial testing, sophisticated final testing will have to be done by internationally reputable clinicians in the First World if the U.S. FDA is to be impressed. As far as marketing is concerned, after the initial testing in a Third World market, an Organization for Economic Cooperation and Development country with permissive standards for approval might be the next choice; Belgium was such a country at the time of my research a decade ago. Belgian approval might then be used to justify entry to a number of large Third World markets such as Brazil. The first manufacturing plant could be located in Belgium, so that Belgium could issue the certificate of free sale required by most Third World nations these days—a certificate indicating that the product is approved for marketing in the country of manufacture.[12] Then the firm might work its way up through First World markets with progressively more demanding registration requirements, using evidence from the safe and efficacious use of the products in the less sophisticated

9. Ibid., p. 285.

10. See David A. Bryan, "Consumer Safety Abroad: Dumping of Dangerous American Products Overseas," *Texas Tech Law Review*, 12:435-58 (1981).

11. Braithwaite, *Corporate Crime in the Pharmaceutical Industry*, p. 266.

12. Rosemary Pierce Wall, "International Trends in New Drug Approval Regulation: The Impact of Pharmaceutical Innovation," *Rutgers Computer and Technology Law Journal*, 10:129 (1984).

markets to gain entry to more sophisticated markets.

Hence using people in the Third World as guinea pigs is part of a rather complex totality. It is a complexity that manifests the rationality of the transnational corporation in finding the line of least resistance to early marketing through the complex jungle of the international regulatory nonsystem. Transnationals use system against nonsystem. While the transnational's worldwide goals are coherent, the goals of the regulatory agencies of the world are conflicting. So the transnational plays one off against the others. Corporations exploit the fact that regulatory goals have coherence only at a national level while corporate coherence is transnational. Transnational corporations also sometimes use—or turn a blind eye to—intermediaries who smuggle a product into countries where marketing approval has not been obtained. But such blatant lawbreaking is not the main game. In fact, it is a rather unimportant one for the transnational pharmaceutical corporation. The main game is the more subtle business of computer-assisted strategizing to find the path of least legal resistance through the international regulatory thicket. Instead of one nation's laws being viewed as an obstacle to be broken through by law violation, compliance with these laws becomes a resource for getting around the spirit of another nation's laws. In other domains of regulatory failure, we see the same paradigm of an international evasion strategy. The Bank of Credit and Commerce International (BCCI) used the laws of each country in which it operated to set itself up in such a way that it was effectively offshore in every country where it operated.[13] Compliance with the letter of some national laws can be used to avoid the spirit of all national laws.

SOME SOLUTIONS

When criminologists discover the great subtlety, sophistication, and power that enable transnational corporations to achieve their objectives with international law evasion strategies, the tendency is to evince a policy analysis of despair. National governments will be outmaneuvered every time by an adversary with a coherent international strategy in a game that is played in an international market. The alternative of an international regulatory agency is pie in the sky, so effective regulation in the public interest is hopeless.

This despair is warranted only if one's vision is restricted to national states as the sole regulators who matter. I will attempt to move to a legal-pluralist model of regulation that helps us to understand why prospects for protecting the public interest from exploitation by pharmaceutical transnationals are actually improving. My contention will be that we must view intervention to protect the public interest in safe and efficacious drugs as possible at a number of levels: national regulatory enforcement, regional regulatory cooperation, international regulatory

13. Albert Reiss, Jr., "Detecting, Investigating and Regulating Business Law-Breaking," in *The Future of Regulatory Enforcement in Australia*, ed. P. Grabosky and J. Braithwaite (Canberra: Australian Institute of Criminology, 1993).

coordination, intrafirm regulation through both individual executive consciences (for example, professional values) and organizational consciences (internal compliance groups), interfirm self-regulation through national and international industry associations as well as through the work of reforming individual firms, and private regulation by product liability suits and consumer activism.

National regulatory enforcement

Criminal law enforcement to deal with the problems of corporate crime in the pharmaceutical industry has been practically nonexistent in every country in the world. This is a result of the technological, jurisdictional, legal, and organizational complexities discussed earlier. Given these realities, consistent criminal enforcement against known corporate lawbreaking is an impossible aspiration. An attraction of a legal-pluralist policy analysis is that the belief that there are constructive ways of solving problems of lawbreaking and evasion without recourse to the criminal law means that we can harbor our criminal enforcement resources for the rather small number of cases where criminal prosecution is the best way to have an impact on the problem. Policymakers who believe that the 100 criminal cases they know about should be investigated and prosecuted with an eye to criminal sanctions set themselves an impossible goal in the domain of complex corporate crime. Policymakers who believe that there are better ways of dealing with 99 out of 100 corporate crimes than taking them to court leave themselves with a superior capacity to concentrate their enforcement resources on the 1 case in 100 that they think is best handled by a criminal prosecution. Then when they score a major enforcement success by concentrating their scarce litigation resources on that 1 case in 100, this success strengthens their hand with the more negotiated approach they adopt toward the other 99 cases.[14]

Within the sphere of national criminal enforcement, there is a capacity for sanctioning that contains a rather more international reach than existing practice has. Brent Fisse and I develop this approach in a book we have almost completed on reforming corporate criminal law.[15] The book offers an approach to the problem of the limits of national law for dealing with conduct in international markets. The approach would force corporate offenders to use their private justice systems to take remedial action. Our accountability model proposes that, having proved the *actus reus* of the offense—for example, that the corporation distributed nonsterile products—the court would invite the corporation to prepare, perhaps with outside consultants, a report indicating the reasons for the offense, those responsible for its execution,

14. The enforcement-pyramid philosophy I am alluding to here is outlined and defended in much more detail in Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (New York: Oxford University Press, 1992), chap. 2.

15. This book is tentatively titled *Passing the Buck: Accountability and the Control of Corporate Crime.*

the organizational reforms to be taken to prevent recurrence, and the disciplinary measures to be taken against those responsible. If the package of measures proposed by the corporation in its self-investigation report is unsatisfactory to the court, the judge can allow the ax he or she has been holding over the corporate head to fall. If the package of measures is satisfactory to the needs of justice and community protection, then corporate sanctioning is withheld.

I will not attempt a detailed treatment of all the problems with the proposal and how these can be addressed. Instead, I want to emphasize one advantage of this approach that is relevant to the concern of this article—the limits of national enforcement for dealing with internationalized lawbreaking or law evasion. While the court or a regulatory agency cannot act directly against misconduct beyond its jurisdictional authority, our proposal allows it to hold a national threat over the head of an international corporation, which can use its private justice system to exert some international control. For example, if one reason for an offense occurring in the United States is certain actions of French executives at a French manufacturing plant, the self-investigation report to the U.S. court could recommend disciplinary action by the corporation against the French executives. While our accountability model does not enable an American court to put the French executives behind bars, it can lever private justice measures that cost them their jobs or their annual bonuses or can interrupt their career paths. These are not inconsequential levers, and national courts could use them against offenses that involve multiple offshore offenders within the employ of a transnational corporation.

There are many other measures that can be taken to improve national regulatory enforcement, but since I have discussed a number of these at length in the earlier book,[16] I shall not dwell upon them here. Rather, the purpose of this article is to show how this is only one of many control options from the perspective of a legal pluralist.

Regional regulatory cooperation

National governments do not have to harmonize their laws perfectly to prevent transnational corporations from playing one country's set of laws off against another's. Indeed, the practical economic constraints of law evasion are often such that a country that sets higher regulatory standards can effectively impose its higher standards on all other countries in a region. This is particularly so when the country is a large and powerful one such as the United States. But strategic government intervention even by small countries can change lowest-common-denominator regulation into highest-common-factor regulation. For example, a Central American regional director for a transnational pharmaceutical company explained to me that when Costa Rica banned a suspected carcinogenic additive in one of its prod-

16. Braithwaite, *Corporate Crime in the Pharmaceutical Industry*, pp. 290-383.

ucts, the company took the additive from all products being distributed in all Central American countries, since the cost of special production runs for the Costa Rican market was prohibitive. Similarly, Costa Rica has long ruled that all disclosures and warnings made on the drug packages and inserts in the country of origin should be identically made in Costa Rica. The same executive explained, "From our point of view, that means they all have to say what we say in [our home country] because the cost of having different packaging for the different Central American countries is too great."

Again, though, because of the capacity of the transnational to shift its activities around the world, there are limits to how high Costa Rica can push up all Central American standards. The same executive noted:

> Let me put it this way. It would not be in our interests to locate more of our manufacturing in the United States. For [one of the company's main products], our literature in Europe, Africa, Australia, South America, and so on claims some 10 indications for the product. In the U.S., the FDA approves only 3. We don't want to be forced by Costa Rica and others to suggest only three indications worldwide when we believe in 10.

Even though Costa Rica did not push this European company's standards up to those of the United States, the interesting thing is that they can push them up to some degree across the whole of Central America. Where international conventions fail, little Costa Rica can succeed in harmonizing minimum standards upward.

The Costa Rican situation illustrates the fact that within a region of the world, harmonization is possible. There are costs for transnationals in playing the international law evasion game—shuffling operations, product, and money around the world is never frictionless. A progressive nation does not always have to bring the whole world with it to defeat international law evasion in its region. The European Community and the European Free Trade Association provide various examples of this, though they also provide examples of nations with higher regulatory standards being pegged back to a regional norm.[17] The Benelux countries (Belgium, the Netherlands, Luxembourg) and the Andean Pact (Peru, Ecuador, Bolivia, Colombia, and Venezuela) both have made progress toward establishing some uniformity in drug regulation within their regions. The United States, like many other nations, has signed a number of bilateral memoranda of understanding. These memoranda bind the FDA and the foreign regulator to common standards for good laboratory practices and preclinical testing.[18]

Overall, the regional harmonization game can be a win-win game for the industry and its consumers. While harmonization cuts down possibilities for international law evasion by industry, having a single uniform set of regulatory requirements also reduces the costs of compliance. Even if consumers in some countries some of the time get products meeting lower standards under harmonized rules, they also get improved protection against products designed

17. Wall, "International Trends in New Drug Approval Regulation," p. 334.

18. Ibid., p. 335.

to meet much lower standards creeping into their market. And as we have seen, consumers in a lot of countries a lot of the time will get products that meet higher standards. This is because in regional regulatory forums, a captured or corrupt bureaucrat who wants to set standards well below the international average tends to be less persuasive than a crusading bureaucrat from a country that, because of a history of special problems with the product in his or her homeland, wants to set standards well above the international average.

International regulatory cooperation

The United Nations, preeminently the World Health Organization (WHO), provides a forum where more ambitious harmonization of laws is facilitated to thwart international law evasion strategies.[19] WHO's international drug adverse-reaction-reporting scheme does not work wonderfully well, but it effects some opening up of regulatory exposure in sophisticated markets for companies who test and dump in unsophisticated markets. The exposure is limited, however, because the unsophisticated markets are precisely those where problems are not reported into the scheme. Advocacy groups, as we will see later, have targeted their windows of exposure more effectively on these unsophisticated markets. The Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce is a successful harmonization project of the WHO. The large number of participating countries certify on request from another participant country that specified pharmaceutical exports meet the Good Manufacturing Practices Standards set down under the scheme, that the plants are subject to periodic inspection, and that the product is authorized for sale in the exporting country. Good Laboratory Practices are now becoming increasingly internationalized, thereby increasing the auditability of data from other countries and bringing the problem of fraud in the international safety testing of drugs under somewhat improved control. International regulatory cooperation on such matters under the auspices of the WHO and other international agencies has no panaceas to offer in a complex world, but it can effect limited improvements in international regulatory capability.

Professionalism and self-regulation

One of the analytical mistakes that scholars of white-collar crime repeatedly make is to assume that when an executive works for a criminogenic corporation, the executive's corporate identity is the only identity that matters to him or her. The 131 interviews I conducted with executives in the international pharmaceutical industry demonstrated clearly how executives have plural identities and multiple loyalties to multiple organizations. The Lilly research executive may have a loyalty to her research team that is more

19. Ellen N. Cohn, "International Regulation of Pharmaceuticals: The Role of the World Health Organization," *Virginia Journal of Transnational Law*, 23:331-61 (1983).

profound than the more remote loyalty to Lilly as a corporation. She may have a loyalty to her profession, to her patients if she is a doctor, and so on. The identity "Lilly executive" is just one of many identities.

An important conclusion from my earlier study was that the consumers of the world receive more protection from the higher standards that these competing identities bring into the firm than from enforcement of the law. This is particularly true with regard to the Third World. As many have demonstrated, drug companies have double and triple standards when it comes to marketing drugs in the Third World.[20] It is also true, however, that most, if not all, transnational pharmaceutical companies set much higher standards in the least regulated Third World markets than they are required to meet by the laws of those countries. They set higher standards because it would simply be intolerable to the professional standards of the people who work for them to stoop to the levels allowed by lax laws. There are other reasons that we will get to later. But in my fieldwork, and in my work as a consumer advocate, I have encountered many instances of responsible professionals within transnational corporations exposing the unethical conduct of certain of their own executives to the professional disapproval of their peers within the firm, and this in the firms that are among the worst lawbreakers in an industry with an unusually bad record for lawbreaking.[21]

Those in the best position to know about corporate wrongdoing are within the corporation. Those in the best position to understand whether organizationally and technologically complex corporate conduct actually amounts to wrongdoing are those imbued with an understanding of the organization, its technology, and the potential effects of that technology. The actors in the best position to mobilize informal sanctioning and disapproval that wrongdoers will care about are peers with whom they share a daily professional life. These are reasons why intracorporate self-regulation by employees with consciences is the form of regulation that almost certainly saves the greatest number of lives. If transnational pharmaceutical companies really did meet the minimum standards in the law of all the countries in which they operated, and never performed above those legal standards, the death toll from prescription drugs would be horrific. This observation points to the fundamental limitation of state law enforcement as a control strategy.

In all firms, there are constituencies that are supportive of the intent of regulatory laws. In pharmaceutical companies, the office of the medical director and the quality assurance group are often such constituencies, and in some cases the general counsel's office is a constituency that also pushes for compliance with the law. Effective self-regulation depends to a considerable extent on

20. See, for example, Charles Medawar, *Insult or Injury?* (London: Social Audit, 1979); M.N.G. Dukes and B. Swartz, *Responsibility for Drug-Induced Injury* (Amsterdam: Elsevier, 1988); Milton Silverman, Philip R. Lee, and Mia Lydecker, *Prescriptions for Death* (Berkeley: University of California Press, 1982).

21. Marshall Clinard and Peter Yeager, *Corporate Crime* (New York: Free Press, 1980), pp. 119-22.

strengthening the hand of such offices. An example is the strategy, now widespread throughout the industry, of allowing decisions of quality control on batches of drugs to be overruled only by the signature of the chief executive. This eliminates much of the day-to-day nullifying of quality control by production managers who insist on meeting production targets when they deem attainment of specifications to be good enough. Such a management policy strengthens the hand of a pro-regulation internal constituency enormously.

Interfirm self-regulation

Interfirm regulation is one of the things that can constitute the intrafirm self-regulation that I concluded was so important in the last section—but so can it be constituted by state regulation, such as law requiring the signature of the chief executive when quality control is overruled, or by consumer activism. Interfirm regulation can occur at a number of levels. National industry associations can write and enforce self-regulatory codes, as can international industry associations. Then there is the work of single firms seeking to upgrade the standards of their corporate peers. Each of these levels of interindustry regulation will now be illustrated.

An example of national industry association self-regulation is the Australian Pharmaceutical Manufacturers' Association Code of Conduct.[22] The code relates primarily to the promotion of prescription drugs. Throughout the 1980s, I was a highly public advocate, along with leaders of the Australian consumer movement, of the view that self-regulation was not the way to go for the control of pharmaceutical advertising, that tougher government regulation was needed. I still believe that in principle this is an area in which government regulation ought to be more effective and efficient than self-regulation. In the aftermath of the total failure of such regulation during the 1970s and 1980s, however, the government decided to give a rejuvenated self-regulation scheme a three-year trial beginning in 1988. It turned out that self-regulation during this period was more effective in improving the integrity of pharmaceuticals promotion than the limp government regulation of the previous decade had been.[23] While Australian consumer activists such as myself who have been involved in a hands-on way with this issue do not doubt the finding that self-regulation worked better than the feeble government regulation that it replaced, we still believe that inappropriate marketing practices are widespread and unremedied. Nevertheless, improvement is improvement, and it warrants the concession that historical circumstances arise that result in self-regulation's working better than government regulation even in an area where in principle the reverse should be true. The reasons for the

22. Australian Pharmaceutical Manufacturers' Association, *Code of Conduct of the Australian Pharmaceutical Manufacturers' Association Inc.* (North Sydney: APMA, 1990).

23. See Trade Practices Commission, *Report by the Trade Practices Commission on the Self-Regulation of Promotion and Advertising of Therapeutic Goods* (Canberra: Trade Practices Commission, 1992).

success of this scheme were contingent; they included a substantial industry investment in prepublication monitoring of advertisements for compliance with the code, repeated postpublication surveys of the percentage of ads that complied that were conducted independently by the Australian Society of Clinical and Experimental Pharmacologists,[24] and knowledge that the self-regulation scheme would be evaluated by the Trade Practices Commission to determine if it should be replaced by government regulation.

This case illustrates that consumer advocates and regulatory strategists must avoid myopic rejection of strategies on the basis of theoretical dogma. Where self-regulation does outperform government regulation, pragmatism is needed to give credit where credit is due, rewarding improved protection for consumers in a plural regulatory order, so that improved protection may be achieved.

The International Federation of Pharmaceutical Manufacturers' Association (IFPMA) has also been in the business of self-regulation. Indeed, the Australian Pharmaceutical Manufacturers' Association code, discussed in the last two paragraphs, received part of its impetus from pressure for increased self-regulation from the IFPMA.[25] In turn, the fear of de facto international and national regulation by the WHO in conjunction with Third World governments in order to implement the WHO list of essential drugs—that is, to eliminate nonessential drugs from the market so that scarce health budgets could be concentrated on life-saving products—prompted the IFPMA in 1982 to start supplying essential drugs to a few pilot countries.[26] In countries such as Gambia and Sierra Leone, the initiative seems to have been responsible for some improvement in primary health care and in the availability of life-saving drugs.[27] By and large, however, one would have to say that the IFPMA efforts at self-regulation have been tokenistic and that it is only in a few countries such as Australia that they have been taken seriously because of extra pressure from professional and consumer constituencies.

An interesting more recent development in interfirm regulation has been at the level of a single firm—the Swiss giant Ciba-Geigy—that has sought to persuade its corporate peers to upgrade self-regulatory standards voluntarily. Ciba-Geigy was a pariah firm until the late 1980s as far as the international consumer movement was concerned.[28] It had done terrible things in product testing, such as spraying Third World agricultural workers with experimental chemicals from the air without their consent and aggressively

24. R.F.W. Moulds and L.M.H. Wing, "Drug Advertising," *Medical Journal of Australia*, 150:410-11 (1989).

25. The IFPMA introduced a code of pharmaceutical marketing in 1981. IFPMA, *IFPMA Code of Pharmaceutical Marketing Practices* (Geneva: IFPMA, 1987).

26. Cohn, "International Regulation of Pharmaceuticals," p. 352.

27. Andrew Chetley, *A Healthy Business? World Health and the Pharmaceutical Industry* (London: Zed Books, 1990), pp. 133-34.

28. See Olle Hansson, *Inside Ciba-Geigy* (Penang: International Organization of Consumers' Unions, 1989).

marketing products such as clioquinol that had disastrous side effects, which were covered up. Ciba-Geigy also persisted in the marketing of products in the Third World after they had been demonstrated to be unsafe and had been withdrawn from First World markets. Cynics will say that it was the public relations setbacks associated with the consumer movement perception of Ciba-Geigy as a killer corporation, combined with the threat of an international consumer boycott, that caused the corporation to change its spots. Greater cynics will say that Ciba-Geigy has not altered its spots at all. My view is that Ciba-Geigy has changed, if not completely changed. At the end of 1986, the company initiated a program called the Risk Assessment of Drugs—Analysis and Response (RAD-AR). RAD-AR's goal is to get leading companies to be more open about the risk factors associated with their products and to foment a more constructive dialogue about the risks and benefits of particular pharmaceuticals, a dialogue in which industry critics take part.[29] RAD-AR's success has been patchy, varying from one part of the world to another. Representatives of many companies have attended RAD-AR seminars, but not many have acted to make their safety and efficacy data more genuinely open to their competitors and their critics. The U.S. company G. D. Searle, formerly a prominent practitioner of reincarnated rat research, is one organization that has moved significantly in the direction of greater openness about its products.[30] It is both interesting and theoretically significant that the companies that have taken the most determined steps toward greater openness and dialogue about the risks of an industry that markets tamed poisons have been those such as Ciba-Geigy and Searle that have been subjected, with good reason, to some of the strongest consumerist vilification.

29. An important forum for this discussion is the periodical *RAD-AR Report.*

Consumer activism

The interplay between interfirm regulation and consumer activism became clear in the last section. National and international industry associations have stepped up their self-regulatory activities when they have been put under pressure from consumer groups. The individual firms that have been preeminent in leading the industry in the direction of a more responsible regulatory culture[31] in recent decades have been firms that have been effectively targeted by the consumer movement. This self-regulatory improvement is in considerable part an attempt to fend off strengthened state and international regulation. And the threatened state and international regulation is itself a threat largely, or at least partly, because of the lobbying of national and international consumer groups. Another threat the industry fears is strengthened consumer product liability laws and class action legislation. Where this strengthening has

30. Chetley, *Healthy Business?* p. 139.

31. Regulatory culture includes firms, regulators, and public interest groups. I see regulatory culture as a very useful concept; see Errol Meidinger, "Regulatory Culture: A Theoretical Outline," *Law and Policy,* 9:355-86 (1986).

occurred, it largely has been through consumer movement activism. This in turn brings in another level of analysis to a legal-pluralist examination of the social control of drug risks, that concerned with private consumers punishing corporations in the courts for taking unjustified risks with their bodies. All these levels are interconnected, and very often interconnected in a way that suggests that an initial impetus from consumer movement activism was crucial. The industry itself recognizes this. Consequently, a new tactic in its appeals for partial deregulation of drug safety testing has been to work with gay and lesbian groups concerned about red tape holding up new drugs to combat acquired immune deficiency syndrome (AIDS).

In the United States, Ralph Nader's organization, Sidney Wolfe and the Health Research Group, and the Consumers' Union all have been important players in the drug regulation game, working hand in hand with sympathetic journalists such as Morton Mintz of the *Washington Post* and sympathetic legislators such as Edward Kennedy and Howard Metzenbaum. Internationally, the preeminently important group has been Health Action International, an arm of the International Organization of Consumers' Unions. These two groups now have a regional office structure that puts them on the battlefront of the worst abuses of the industry in the Third World.

In Australia, professional groups with strong links to the consumer movement have been particularly important in effecting change in industry practices. Dr. Ken Harvey has been a leading activist from the medical profession in promoting peer guidelines for the appropriate use of different drugs. Use of the guidelines within Australian hospitals has both reduced irrational prescribing and cut drug costs. The most interesting group in Australia has been the Medical Lobby for Appropriate Marketing (MLAM). The MLAM strategy has been relatively simple. Dr. Peter Mansfield, the inspiration behind MLAM, writes to a large number of doctors who are MLAM members around the world with information about a product that is being marketed inappropriately by a particular company in a particular country. These medical professionals then write to the company—generally at its world headquarters or in the country where the offense occurred or in their own country—demanding an explanation for the alleged inappropriate marketing practice. A naive strategy, hard-bitten advocates of state deterrence might say. Not really. It is a strategy that works enough of the time to make it an extremely cost-efficient method of social control for activists with scarce resources. Writing letters is cheap. Moreover, it is a decent method of social control based on a reasoned appeal to corporate and medical responsibility.[32] Sometimes MLAM decides that it wrongly assessed a situation and writes back to the company with an apology. Pharmaceutical executives, even some of the very worst of them, do have a better side, a re-

32. See Clifford Shearing, "A Constitutive Conception of Regulation," in *Future of Regulatory Enforcement in Australia*, ed. Grabosky and Braithwaite.

sponsible side, to which appeals to professional and corporate responsibility can be made. They have multiple selves that make it worth considering a strategy that encourages them to put their best self forward. When that does not work, there are other strategies available to advocacy groups—muckraking in the media and calls for state enforcement, for example, and in extreme cases threats of consumer or professional boycotts.

In addition to corporate executives having a socially responsible self that can, surprisingly, often be brought to the fore, pharmaceutical companies have self-interested reasons to listen and respond seriously to rising ground swells of professional concern about their marketing practices. Pharmaceutical companies survive in the marketplace by persuading physicians to prescribe their products. In other words, they depend for success on convincing health care professionals that they are trustworthy. Sometimes they make the judgment that the best way to promote their long-term success is to actually be trustworthy, to admit a mistake and put it right. Five of 17 MLAM letters between January 1988 and June 1989 resulted in an agreement by the targeted company to alter claims or withdraw the product in question.[33] This strike rate increased to 5 of 9 for the period from July 1989 to June 1990.[34]

CONCLUSION

State regulation is very important for controlling corporate crime in the pharmaceutical industry. But inappropriate state regulation can deter innovation and push up the costs of drugs that are desperately needed in many parts of the world.[35] In this article, I have said very little about these crucial issues because they always are the focus in debates on the regulation of the pharmaceutical industry. Here I have sought to decenter the state. My argument has been that while the state is very important, its importance to market ordering and regulation of abuse is overrated. Underrated sources of regulation of abuse are market ordering by international organizations, mobilization of community disapproval by consumer and professional groups, intrafirm self-regulation at the level of individual executive professionalism, and interfirm self-regulation mobilized by national and international industry associations and individual firms, such as Ciba-Geigy.

All of these forms of social control may seem weak, but their weakness can be overstated if we fail to realize that their strength comes from the way they are interrelated. Pharmaceutical companies are not exactly enmeshed in a Foucauldian carceral archipelago,[36] but they are sur-

33. V. A. Wade, P. R. Mansfield, and P. J. McDonald, "Drug Company Evidence to Justify Advertising," *Lancet*, Nov. 1989, pp. 1261-64.

34. Peter R. Mansfield, "Classifying Improvements to Drug Marketing and Justifications for Claims of Efficacy," *International Journal of Risk and Safety in Medicine*, 2:171-84 (1991). Of course, with such data one can never be sure that the company would not have changed its marketing practices without the pressure from MLAM.

35. See, for example, Robert I. Chien, *Issues in Pharmaceutical Economics* (Lexington, MA: Lexington Books, 1979).

36. Michel Foucault, *Discipline and Punish: The Birth of the Prison*, trans. A. Sheridan (London: Allen Lane, 1977).

rounded by a web of controls that must be taken more seriously than any single strand of that web. Consumer groups might seem disorganized and weak. But when they can mobilize media assaults, sow seeds of professional distrust of the industry, foment consumer cynicism about the products the industry sells, heighten the threat of government regulation, nurture industry self-regulation to fend off the latter threat, and initiate mass tort litigation, the entire web of influences can change industry conduct. Most crucially, advocates engaging in a critical public dialogue with the industry flush out sympathizers within the industry. The pharmaceutical industry has within it thousands of public citizens who believe in corporate responsibility, who care about human health, and who have standards of professional integrity. In a pinch, some of these executives with a conscience will blow the whistle; at the drop of a hat, a good number of them will discreetly provide useful information to industry critics. Because the industry cannot exile its huge fifth column of responsible professionals, to a certain extent it actually listens to them and responds to their internal critiques. This is why intracorporate self-regulation is the main game. But it is a main game that gets a lot of its power from outside forces—consumerist critics, scientific journals, the popular media, professional societies, the professional socialization practices of universities, and, yes, criminal law. Criminal law must be seen, therefore, in proper perspective as one of the critical outside forces that empowers a web of market-ordering mechanisms. Criminal law is too clumsy and costly a device to be the frontline assault weapon that routinely strikes the blows that are decisive for winning the battle. Rather, criminal law has enormous importance as heavy artillery that provides the backing to push the frontline troops forward into hand-to-hand combat with the mercenaries.[37]

The United States is the country that is the heaviest user of criminal law as a control mechanism for regulatory problems in the pharmaceutical industry. Even so, criminal law is used in U.S. pharmaceuticals regulation with extreme rarity.[38] All nations should be using criminal law much more against the worst corporate crimes of the pharmaceutical industry. Although all nations have in common the fact that criminal law is rarely or never used against pharmaceutical transnationals, countries vary enormously in the levels of unwarranted risk that drug companies take with consumers' lives. A quick visit to a pharmacy in Guatemala and one in Sweden, neither country being one that uses criminal law against pharmaceutical companies, immediately communicates the enormous difference in the risk that consumers confront in these two societies. What accounts for the differences in drug morbidity and mortality is the total fabric of the web of controls I have outlined previously. Criminologists who eschew a legal-

37. See the enforcement-pyramid philosophy in Ayres and Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate*, chap. 2.

38. Braithwaite, *Corporate Crime in the Pharmaceutical Industry*.

pluralist analysis will never get to the bottom of what really protects the lives of consumers from corporate crime.

A policy analysis of despair is no longer warranted in the face of the reality of international law evasion strategies, as deep and deadly as the problem remains. International harmonization efforts are slowly moving forward, particularly in a European Community that is increasingly setting the international agenda. Guarded support for these harmonization moves is coming from the industry and many national regulators and consumer and professional groups who see some prospect for win-win change. More striking, there is a new view gaining momentum in the industry that the international law evasion game is not the way to go. This view is succinctly summarized in the advice of Harvard Business School guru Michael Porter in his paradigm-shattering book, *The Competitive Advantage of Nations*.

Establish norms exceeding the toughest regulatory hurdles or product standards. Some localities (or user industries) will lead in terms of the stringency of product standards, pollution limits, noise guidelines, and the like. Tough regulatory standards are not a hindrance but an opportunity to move early to upgrade products and processes.[39]

Find the localities whose regulations foreshadow those elsewhere. Some regions and cities will typically lead others in terms of their concern with social problems such as safety, environmental quality, and the like. Instead of avoiding such areas, as some companies do, they should be sought out. A firm should define its internal goals as meeting, or exceeding, their standards. An advantage will result as other regions, and ultimately other nations, modify regulations to follow suit.[40]

Firms, like governments, are often prone to see the short-term cost of dealing with tough standards and not their longer-term benefits in terms of innovation. Firms point to foreign rivals without such standards as having a cost advantage. Such thinking is based on an incomplete view of how competitive advantage is created and sustained. Selling poorly performing, unsafe, or environmentally damaging products is not a route to real competitive advantage in sophisticated industry and industry segments, especially in a world where environmental sensitivity and concern for social welfare are rising in all advanced nations. Sophisticated buyers will usually appreciate safer, cleaner, quieter products before governments do. Firms with the skills to produce such products will have an important lever to enter foreign markets, and can often accelerate the process by which foreign regulations are toughened.[41]

Here we have an intriguing emerging international dynamic. Firms that have upgraded their safety standards early because of their location in states that are early movers to higher standards have an interest in getting other states to follow the lead. There is thus a connected strategy for those of us who are active in the international consumer movement. It is to persuade targeted national governments to be first movers to up-

39. Michael Porter, *The Competitive Advantage of Nations* (London: Macmillan, 1990), p. 585.

40. Ibid., p. 588.

41. Ibid., pp. 648-49.

grade regulatory standards through the argument that they can actually benefit their national economy by doing so. Porter supplies many examples of nations that constructed important competitive advantages by being first to establish tougher health and safety standards.[42] Then home-base transnationals from those first nations can be recruited to support upgrading standards in other nations, thus setting back their competitors from laggard nations.

Porter's way of thinking about the constitution of competitive advantage is gaining wider acceptance in business and regulatory communities. Pharmaceutical companies can see that it is actually a competitive disadvantage to have as a home base an Eastern European country that might have cheap labor costs and minimal regulatory standards. The absence of demanding regulators and demanding consumer groups gives companies from these countries totally inadequate preparation for competing in sophisticated markets.

What is it that is generating this shift among some industry strategists from an interest in seeking the lowest possible standards to finding the highest standards? It is "sophisticated buyers . . . [who] . . . appreciate safer . . . products before governments do." To the sophisticated buyers we might add sophisticated health care professionals, sophisticated corporate insiders, and sophisticated industry association leaders. Shifts toward a search for the highest standards are caused by the web of influences that has been the subject of this article. Increasingly one does meet pharmaceutical industry executives who are actively committed to shooting for the highest regulatory standards in the way Porter commends. Shifts away from lowest-common-denominator regulation in the world system toward highest-common-factor regulation can be a result of the web of interconnections among regulatory, self-regulatory, and consumerist actors in a plural international ordering of markets. Comparatively poorly resourced players of

42. Empirically, it is simply not the case that it is the countries with weak business regulations that are flourishing in the world economy. The toughest environmental or consumer protection legislation in the world on any given hazard will usually be found in the United States, Japan, or Germany. Porter provides an account of some of the reasons why this is the case. Australia's BHP spent a 9-figure sum during the 1980s on new doors to reduce the hazardous emissions from its coke ovens. The doors were bought from Japan. Why? Japan was the leader in tightening regulatory controls over coke oven emissions, and as a consequence it was Japanese steelmakers that developed the control technology and sold it to the rest of the world. The Japanese Energy Conservation Law of 1979 set demanding standards for energy saving in air conditioners, refrigerators, and cars, resulting in a variety of product improvements that have benefited Japan's international position. America more than Japan has historically led the world in the export of pollution-control equipment and services as a result of its tough environmental regulation. However, when certain deregulatory tendencies in the United States allowed Germany, Sweden, and Denmark to move ahead of the United States on some environmental standards, these countries increasingly came to supply world markets for the relevant technologies. Sweden led the world in regulations requiring special access and aids for handicapped persons. Consequently, Swedish companies dominate world markets in technology to aid the disabled.

the regulatory game, such as consumer groups, need not be powerless actors if they are smart. To be smart, they must have an internationalist strategy that recognizes and works with the plural sources of market ordering.[43]

43. For a sophisticated discussion of the theoretical foundations for a pluralist analysis of market ordering see Shearing, "Constitutive Conception of Regulation."