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Rethinking Global Pharmaceutical Policy

Chapter 10: Sticks

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The tools discussed in the preceding two chapters all attempt in some fashion to use financial incentives to change the behavior of pharmaceutical firms. This chapter considers a different approach. Instead of enticing firms to reorient their research and sales practices in ways that would help alleviate the global health crisis, we might require them to do so. In other words, we might use "sticks," rather than monetary "carrots," to achieve our ends.

The first section of the chapter argues for the legitimacy of this approach. The remaining sections examine a variety of regulatory systems that have been or might be employed.

A. Justifications for Regulation

Some readers are likely to balk at the threshold. As we have seen, pharmaceutical firms are already subject to an elaborate web of government regulations. A reform proposal that would tighten the fetters further may seem to some readers unpromising at best.

The response to their concern begins with the observation that many other industries have long been subject to intricate regulatory regimes. The best-known examples are: transportation industries (e.g., railroads, trucking); communication services (e.g., telephone companies); public utilities (e.g., electric companies, natural-gas providers, local cable-television systems); and financial services (e.g., residential mortgages, insurance).

To be sure, the *form* of the regulatory regimes to which most of these industries have been subject in the United States has changed dramatically over time. As Joseph Kearney and Thomas Merrill have pointed out, until 1975, each industry was typically managed by a separate federal government agency, which imposed upon member firms restrictions of the following sorts: obligations to offer customers specific packages of goods and services; ceilings on the prices the firms could charge for those goods and services (ceilings typically set through administrative proceedings that sought to prevent the firms from earning profits that were "excessive" in light of their past investments and current costs); limits on the entry of new firms into the industry; and encouragement (even requirement) of "cross-subsidies" to ensure that all potential customers had access to the firms' products or services. After 1975, in many industries this traditional regulatory model was displaced by a new regime. The key elements of the new strategy were: stimulation of competition, achieved by encouraging the entry of new firms; mandatory "unbundling" of packages of services; limits on the ability of firms in one sector of the industry to participate in other sectors; and duties to assist competitors by providing them

affordable "interconnection" services.[1] In short, the way in which these industries have been managed has evolved – and likely will continue to evolve. But the notion that governments may appropriately regulate how business is done in these fields – without establishing a causal connection between the firm's past conduct and the plights that the regulations are designed to alleviate – is rarely questioned.

Why? What underlies our acceptance of extensive governmental regulation in these (and similar) areas? Five related considerations – each of which seems especially salient in these fields – undergird both our historical practices and our attitudes.[2] First, we worry that firms that wield market power will employ it to earn higher profits than they deserve or need. Second, regulation seems especially appropriate when (to use an old phrase) businesses are "affected by the public interest" – either in the sense that they enjoy a "public grant of privileges" or in the sense that the good or service they supply is a necessity, rather than a luxury.[3] Third, regulation also seems especially appropriate when, in its absence, firms are likely to "discriminate" against vulnerable individuals or groups. Fourth, firms that enjoy strong informational advantages over their customers ought not be permitted to exploit those advantages. Fifth, in settings in which mistakes have permanent and serious costs, consumers should be prevented from making purchasing decisions inconsistent with their own long-term best interests. With the possible exception of the fifth proposition (which sometimes elicits the response that it represents illegitimate "paternalism"[4]), these principles are reasonably widely accepted in United States – and even more widely accepted in most other countries.

The relevance of these five principles to the pharmaceutical industry is probably apparent. First, for decades, the major pharmaceutical firms have earned remarkably high profits – substantially higher than firms in almost all other industries – and they continue to do so.[5] Second, those profits are derived in part from the firms' ability to exercise a "public grant of privileges" – specifically, the patent rights that (as we saw in Chapter 2) undergird their business models. In addition, the goods they provide – drugs, many of which are essential to life and health – are plainly "necessities," rather than luxuries. Third, as we saw in Chapter 4, the firms enjoy substantial power to engage in differential pricing of their products – and currently sometimes exercise that power in ways that, ironically, disadvantage poor individuals or countries. Fourth, like mortgage and insurance

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[1] See Joseph D. Kearney and Thomas W. Merrill, "The Great Transformation of Regulated Industries Law," *Columbia Law Review* 98 (1998).

[2] For a more extensive discussion of these five considerations, see William W. Fisher, III, *Promises to Keep: Technology, Law, and the Future of Entertainment* (Stanford University Press, 2004), 177-80.

[3] These phrases and arguments are derived from *Chas. Wolff Packing Co. v. Court of Industrial Relations of Kansas*, 262 U.S. 522, 535-38 (1923). The roots of the arguments are explored in Breck P. McAllister, "Lord Hale and Business Affected with the Public Interest," *Harvard Law Review* 43 (1930).

[4] See, e.g., William W. Fisher, III, "Reconstructing the Fair Use Doctrine," ibid.101 (1988): 1762-66.

[5] See, e.g., Richard Anderson, "Pharmaceutical Industry Gets High on Fat Profits," BBC News, November 6, 2014, http://www.bbc.com/news/business-28212223 ("Last year, five pharmaceutical companies made a profit margin of 20% or more -- Pfizer, Hoffmann-La Roche, AbbVie, GlaxoSmithKline (GSK) and Eli Lilly."); World Health Organization, "Pharmaceutical Industry," http://www.who.int/trade/glossary/story073/en/ ("The 10 largest drugs companies control over one-third of this market, several with sales of more than US$10 billion a year and profit margins of about 30%.").

companies, pharmaceutical firms typically know much more about the benefits and risks of their products than consumers. Finally, errors in purchasing drugs can be catastrophic. In short, if we are comfortable with extensive governmental regulation in the fields mentioned above, we ought to be willing at least to consider enhancement of the regulations that affect the pharmaceutical industry.

This brief tour, we hope, is sufficient to surmount the threshold objection to the regulatory approach and allow us to move on to the hard question: Which, if any, of the regulations of the pharmaceutical industry we might deploy would do more good than harm? The following sections consider five possibilities. They are arranged (roughly) from least to most promising.

B. Research Mandates

As we have seen, pharmaceutical firms currently devote fewer resources to research aimed at neglected diseases than would be socially optimal. The most direct regulatory response to this bias would be to require the firms to devote more.

This idea is not novel; several proposals of this general sort can be found in the relevant literature. For example, Hillary Clinton, as part of her Presidential campaign, advocated requiring "pharmaceutical companies that benefit from federal support to invest a sufficient amount of their revenue in R&D, and if they do not meet targets, boost their investment or pay rebates to support basic research."[6]

Adapting this general strategy to the research biases with which we are primarily concerned in this book, one might require all pharmaceutical firms to spend a specified percentage of their revenues on research intended to develop (a) breakthrough drugs, (b) vaccines, or (c) therapies aimed at specific diseases (which would be selected by a government agency on the basis of their global burdens and the lack of attention they are currently receiving).[7] Indeed, a list of such diseases already exists – developed by Congress and the FDA in conjunction with the priority-review-voucher program (discussed in the preceding chapter). The current version of that list is set forth below.[8]

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[6] See https://www.hillaryclinton.com/briefing/factsheets/2015/09/21/hillary-clinton-plan-for-lowering-prescription-drug-costs/. The penalties that Clinton would impose on firms that failed to comply are not entirely clear, but seem to include forfeiture of the right to take tax credits for the R&D expenditures that they do make. See Megan McCardle, "Clinton's Plan to Mess Up Prescription Economics," Bloomberg View, September 28, 2015, http://www.bloombergview.com/articles/2015-09-28/clinton-s-plan-to-mess-up-prescription-economics. This approach would have the troubling effect of punishing most severely the firms that come closest to regulatory target and least severely the firms that are most delinquent.

[7] Several proposals of this general sort are summarized and endorsed in Marcus Low (Treatment Action Campaign), "Submission to the United Nations High-Level Panel on Access to Medicines" (February 2016), http://www.unsgaccessmeds.org/inbox/2016/2/27/marcus-low.

[8] Source: Alexander Gaffney and Michael Mezher, "Regulatory Explainer: Everything You Need to Know About Fda's Priority Review Vouchers," *Regulatory Affaird Professional Society* (2015).

Eligible Diseases Under the Tropical Disease Priority Review Voucher System	
Malaria	Blinding trachoma
Buruli Ulcer	Cholera
Dengue/Dengue haemorrhagic fever	Dracunculiasis (guinea-worm disease)
Fascioliasis	Human African trypanosomiasis
Leishmaniasis	Leprosy
Lymphatic filariasis	Onchocerciasis
Schistosomiasis	Soil transmitted helminthiasis
Yaws	Tuberculosis
Added by Congress	
Cuevavirus	Ebolavirus
Marburgvirus	
Added by FDA Order	
Chagas	Neurocysticercosis

Although a requirement of this sort would likely stimulate some beneficial research, it would have four major disadvantages[9] (most of which parallel the disadvantages of the priority-review-voucher program itself). First, government agencies may have the information necessary to identify "neglected" diseases, but they lack the information necessary to determine the disease categories in which the greatest health benefits per dollar invested in research can be realized. Thus the list developed by the government is likely to be underinclusive and/or overinclusive from a social-welfare standard.

Second, the pharmaceutical firms that would be subject to such a regulation have much better information on this score than government agencies, but little incentive to use it – precisely because they stand to earn so little revenue from the drugs they are obliged to develop. Rather than identify and pursue the research path that offers the greatest social return, each firm is likely to invest (the minimum amount) in the path that offers the greatest benefit to the firm in terms of either favorable public relations or the likelihood of developing knowledge that would be of use in its primary markets.

Third, neither legislators nor government agencies are capable of determining how much (or what percentage) of the industry's total research expenditures ought, from a social-welfare standpoint, to be focused on neglected diseases. Picking the mandatory number in the first instance would thus be a shot in the dark. The government's aim is unlikely to improve much when it is called upon to adjust the mandatory number in response to changes in scientific opportunities, research costs, and so forth.

Finally, some firms are better positioned to develop drugs focused on neglected diseases than others. Compelling all to spend the same percentage of their revenues on such projects would thus be highly inefficient. In combination, these drawbacks seem sufficiently important that we will put this option to the side.

[9] Various other hazards associated with this general approach can be gleaned from Joseph A. DiMasi and Henry G. Grabowski, "Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D," (2004).

C. Foreign Filing Licenses

Some years ago, the late Professor Jean Lanjouw proposed an ingenious mechanism for increasing access to medicines aimed at so-called "global diseases" while preserving incentives for the development of new drugs, especially those aimed at neglected diseases. She summarized her proposal as follows:

> The basic structure of protection that is created with this proposal allows generic competition in poorer countries and gives increasingly broad protection in line with countries' market potential. The structure is illustrated in Figure 1 [below]. Countries are listed in increasing order of annual income per person on the vertical axis. Along the bottom are listed disease classes. These are sorted so as to begin on the left hand side with diseases for which pharmaceutical sales are relatively concentrated in developing countries (for example, malaria drugs). Furthest to the right are diseases that are prevalent everywhere but have almost all of their pharmaceutical market in the developed countries (for example, cancer drugs). Taking each disease class in turn, the policy would allow generic competition in a group of poor countries, up to the point where they together represent at most (say) 2% of the global sales in that class. The number of countries included for each disease class would thus depend directly on the size and location of the worldwide markets.

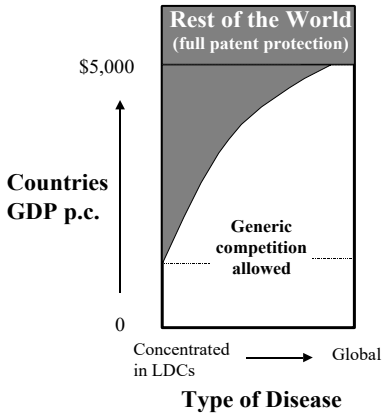

Figure 1: Along the horizontal axis are disease classes, starting with the classes where pharmaceutical sales are most concentrated in developing countries. On the vertical axis are countries listed in order of GDP per capita measured in constant US dollars. The white region indicates the area where generic competition would be permitted under the policy. The shaded region indicates the countries and diseases for which patent protection would be available to all inventors. In countries whose GDP per capita is above an upper threshold (here $5,000) the policy has no effect.

The resulting structure of protection would be as shown in the figure. For countries with incomes below the dotted line, there would effectively be no patent protection and thus no potential for patents to limit generic entry. As a country's

income increased, patent protection would widen, beginning first with new products treating diseases of specific importance in developing countries. The increasing breadth of protection at higher levels of income is shown as the gray area in the figure. For countries above the upper threshold (in the figure at $5,000) full protection is available on all pharmaceutical products.

This structure is achieved in a very innovative way. Although the effect occurs in developing countries it does not require those countries to do anything at all. In fact, their obligations under TRIPS would stay just as they are now. The policy is implemented through patent law in developed countries and is achieved as follows (described first for the U.S.). An inventor in the U.S. is currently required to obtain permission to file for patents overseas. The essence of the policy is simply to require that the patentee sign a declaration in order to obtain this permission. The declaration states that the permission being sought will not be used to prevent the sale of drugs in the countries, and for the diseases, shown as the white area of Figure 1. If the patent-owning firm later starts an infringement suit to prevent a competitor from selling a product in one of the proscribed markets, the firm would have falsified its declaration and in return would lose the ability to enforce the corresponding U.S. patent in respect of the product at issue in the infringement suit. Since the developed country market will almost invariably be vastly more valuable than the developing country market, the policy gives inventors a compelling reason to refrain from exercising their patent rights in the markets indicated in white.[10]

Assuming, for the moment, that Lanjouw's proposal could be implemented, it would have many advantages. As she suggests, it would simply and dramatically increase access in the developing world to drugs (patented after its adoption) that address AIDS, depression, heart disease, and so forth.[11] By contrast, it would avoid eroding patent-based incentives for the development of drugs that address schistosomiasis, leishmaniasis, elephantiasis, trachoma, and other diseases endemic in developing countries but (as yet) rare in developed countries.[12]

Unfortunately, the impediments to the adoption of this regime would be severe. As Lanjouw acknowledged, to be effective this mechanism would have to be adopted by most developed countries, not just the United States; otherwise pharmaceutical firms could and would evade it by relocating their laboratories to countries lacking such a rule.[13]

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[10] Jean O. Lanjouw, "Outline of the Foreign Filing License Approach," (2004), http://www.who.int/intellectualproperty/submissions/ForeignFiling.Lanjouw.pdf.

[11] For documentation of the misery that such diseases cause in developing countries, see Kevin Outterson, "Should Access to Medicines and Trips Flexibilities Be Limited to Specific Diseases?," *American Journal of Law & Medicine* 34 (2008).

[12] See Introduction, page 12, supra – available at http://cyber.law.harvard.edu/people/tfisher/Infection_Introduction.pdf.

[13] The reason that this maneuver would be effective is that the U.S. requirement that patentees obtain foreign-filing licenses only applies to drugs "made" in the United States. 35 U.S.C. § 184.

In addition, it probably violates the TRIPS Agreement. Article 27(1) of the Agreement (discussed in more detail in Chapter 3[14]) provides, in pertinent part: "[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[15] Lanjouw argued that her proposal could pass muster under this provision because it does not involve "de jure" discrimination, insofar as all applicants for foreign filing licenses would be obliged to make the representation in question.[16] To see the weakness of this argument, imagine that India adopted a statute requiring all patent applicants to renounce any intention to bring infringement actions against manufacturers or distributors of pharmaceutical products. Although formally nondiscriminatory, such a statute would surely be deemed to violate the Agreement. Thus, adoption of Lanjouw's proposal would require an amendment to Article 27. Thus its implementation would require a modification of the treaty – a formidable task.

Even if these barriers could be overcome, the mechanism would have a crucial limitation. By Lanjouw's admission, it would do little to increase access to drugs focused on the most neglected diseases – and would do nothing at all to augment incentives to develop new drugs for either "global" or neglected diseases.

For these reasons, we do not advocate pursuing this option. One aspect of it should, however, be borne in mind when considering other regulatory options: the potential it highlights for using pharmaceutical firms' dependence on the U.S. market to alter their treatment of the rest of the world.

D. Price Regulation

[Insert revised section on Price Regulation.]

E. Benefit Sharing

The drawbacks of the plans surveyed in the preceding three sections are troubling, but should not prompt us to abandon the regulatory strategy altogether. There exists at least two more variant of this general approach that merits serious consideration. Like all of the initiatives addressed in the book, neither is perfect. But both have more advantages and fewer disadvantages than any of the proposals considered thus far.

The first would augment the regulatory regimes that currently govern the subset of the drugs used to treat infectious diseases in developing countries that are derived from plants or other natural materials. Frequently, the developers of such drugs learn of the medicinal potential of the material by studying the traditional practices of indigenous groups. For example, in the seventeenth centuries, Spanish missionaries in Latin America learned that indigenous groups in the Amazon region had long used the bark of cinchona

[14] See pages ___, above.

[15] See https://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5.

[16] See Jean O. Lanjouw, "A New Global Patent Regime for Diseases: U.S. And International Legal Issues," *Harvard Journal of Law and Technology* 16, no. 1 (2002): 13.

trees to treat fevers. They brought samples back to Europe, where it became known as "Peruvian bark" and was successfully used to treat malaria. Eventually, two French chemists were able to distill from the bark the drug we know as quinine.

A more modern example, also involving both malaria and French scientists, involves the plant, *quassia amara*, sometimes known as bitterroot. In 2003, a group of researchers associated with the Institut de Recherche pour le Développement (IRD), traveled to French Guiana, a country where malaria is endemic but the death rate from the disease is unusually low, to determine which materials the residents had found most effective in treating the disease.[17] Of the 117 people they interviewed, 49 identified themselves as members of indigenous groups (either Paliku or Galibi); 7 were European by background; 14 were Brazilian; one was Hmong; and 46 were Creole.[18] The researchers found that most interviewees employed a combination of traditional and modern medicines to treat malaria, that twenty-seven different plants were used in the traditional medicines, and that, of those plants, *Quassia amara* (alone or in combination with other plants) was used most often and was thought to be the most effective.[19] After returning to France, they and their colleagues were eventually able to identify the crucial active ingredient in *quassia amara*, now known as Simalikalactone E.[20] Recognizing the potential economic value of this discovery, they then sought patent protection for the compound they had isolated. A U.S. patent was granted in 2013, and an EPO patent followed in 2015.[21] To date, no commercially viable drug has issued from this line of research. However, if (for the reasons identified in Chapter 1) resistance to artemisinin-based malaria treatments continues to grow, such a drug may prove both crucial in fighting the disease and valuable.

In recent years, a growing number of scholars and indigenous leaders have contended that, in situations of this sort, the group whose traditional knowledge contributed to the development of the drug deserves a share of the benefits of it. Four arguments are most often advanced in support of this claim. First, the labor that members of the group invested (often over centuries) to develop the knowledge at issue gives them a natural right to a portion of its fruits.[22] Second, allocating groups a share of the benefits will prompt them to take socially beneficial efforts to preserve and commercialize their knowledge.[23] Third, the groups are entitled to a share of the benefits as partial compensation for the brutal manner in which they were treated during the period of colonial conquest and

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[17] See M. Vigneron et al., "Antimalarial Remedies in French Guiana: A Knowledge Attitudes and Practices Study," *Journal of Ethnopharmacology* 98 (2005).

[18] See ibid., 354.

[19] See ibid., 357-59.

[20] See N. Cachet et al., "Antimalarial Activity of Simalikalactone E, a New Quassinoid from Quassia Amara L. (Simaroubaceae)," *Antimicrobial Agents and Chemotherapy* 53, no. 10 (2009).

[21] U.S. Patent No. 8,604,220 (filed June 17, 2010); Eur. Patent No. 2,443,126 (filed June 17, 2010).

[22] See, e.g., Joseph M Wekundah, "Why Protect Traditional Knowledge," *African Technology Policy Studies* (2012).

[23] See, e.g., Peter Drahos, "Towards an International Framework for the Protection of Traditional Group Knowledge and Practice," in *UNCTAD-Commonwealth Secretariat Workshop on Elements of National Sui Generis Systems for the Preservation, Protection and Promotion of Traditional Knowledge, Innovations and Practices and Options for an International Framework* (Geneva2004); Shubha Ghosh, "Globalization, Patents, and Traditional Knowledge," *Columbia Journal of Asian Law* 17 (2003).

exploitation.[24] Fourth, in virtually all countries today, the members of indigenous groups are more impoverished and suffer from more educational and social disadvantages than the members of all other races and groups; compensating them for uses of their traditional knowledge is one of the few ways in which we could mitigate their suffering.[25]

Beliefs of these sorts frequently prompt outcries when nonpermissive and uncompensated uses of traditional knowledge come to light. For examples, when Thomas Burelli (a legal scholar at the University of Ottawa) and Fondation Daniel Mitterand France Libertés (a nongovernmental organization devoted to the defense of human rights) learned of patents granted for the active ingredient in quassia amara, they publicly accused IRD of "biopiraterie."[26] IRD's conduct, they claimed, perpetuated colonial practices and was "both immoral and in conflict with intellectual property regulations."[27] Rodolphe Alexandre, the leader of the Organization of Indigenous Nations in Guiana, took up the call, contending that "l'IRD a abuse des connaissances de la population guyanaise . . . .".[28] Scientists associated with IRD initially sought to defend their conduct but eventually succumbed to the intensifying public criticism, agreeing to work with "authorities" in Guiana to develop a protocol that would guarantee a fair division of the benefits of any commercialization of IRD's patents and to ensure that the people of Guiana could obtain any drugs that grew out of the research at an affordable price.[29]

The same constellation of beliefs has now prompted the governments of several countries to adopt legislation governing permissible exploitation of traditional knowledge. Among the most forceful is a South African statute, which in turn has catalyzed several agreements in which companies have promised to make payments to indigenous groups upon whose knowledge the firms relied.[30] The beliefs have also spurred adoption of a growing list of multilateral agreements that attempt to compel member countries to grant

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[24] See, e.g., Waziyatawin, *Indigenous Knowledge, Anti-colonialism and Empowerment*, FED'N FOR HUMAN. & SOC. SCI. (Apr. 30, 2010), http://www.ideas-idees.ca/blog/indigenous-knowledge-anti-colonialism-and-empowerment.

[25] See Gillette Hall and Harry Patrinos, *Indigenous Peoples, Poverty and Development* (2010).

[26] Frances Libertés & Thomas Burelli, *Des Chercheurs Français S'approprient Des Avoirs Guyanais Ancestraux*, FONDATION DANIELLE MITTERRAND – FRANCE LIBERTÉS (Jan. 25, 2016), https://www.france-libertes.org/fr/des-chercheurs-francais-sapproprient-des-savoirs-guyanais-ancestraux/.

[27] Jade Lindgaard, *Des Chercheurs Français Sur Le Paludisme Accusés De Biopiraterie*, MEDIAPART (Jan. 25, 2016), https://www.mediapart.fr/journal/france/250116/des- chercheurs-francais-sur-le-paludisme-accuses-de-biopiraterie.

[28] Erwann S, *Les Populations Autochtones S'agacent de la Biopiraterie,* KOTIDIEN (Jan. 29, 2016), http://lekotidien.fr/2016/01/29/les-populations-autochtones/.

[29] *See L'IRD va proposer aux autorités guyanaises un protocole d'accord conjoint pour le partage des avantages issus du brevet SkE*, INSTITUT DE RECHERCHE POUR LE DÉVELOPPEMENT (Feb. 5, 2016), https://www.ird.fr/toute-l-actualite/actualites/communiques-et-dossiers-de- presse/cp-2016/l-ird-va-proposer-aux-autorites-guyanaises-un-protocole-d-accord-conjoint-pour- le-partage-des-avantages-issus-du-brevet-ske/(language)/fre-FR.

[30] See R. Wynberg, "Making Sense of Access and Benefit Sharing in the Rooibos Industry: Towards a Holistic, Just and Sustainable Framing," *South African Journal of Botany* 110 (2017); Margo Bagley, "Toward an Effective Indigenous Knowledge Protection Regime; Case Study of South Africa," *Centre for International Governance Innovation* (2018).

and enforce enhanced rights to indigenous groups in situations of this sort. Most of those agreements have not fulfilled the hopes of their sponsors, but one of them is proving powerful. That agreement is the Nagoya Protocol on Access and Benefit Sharing. Its current membership is shown below.[31] (Conspicuously missing is the United States.)

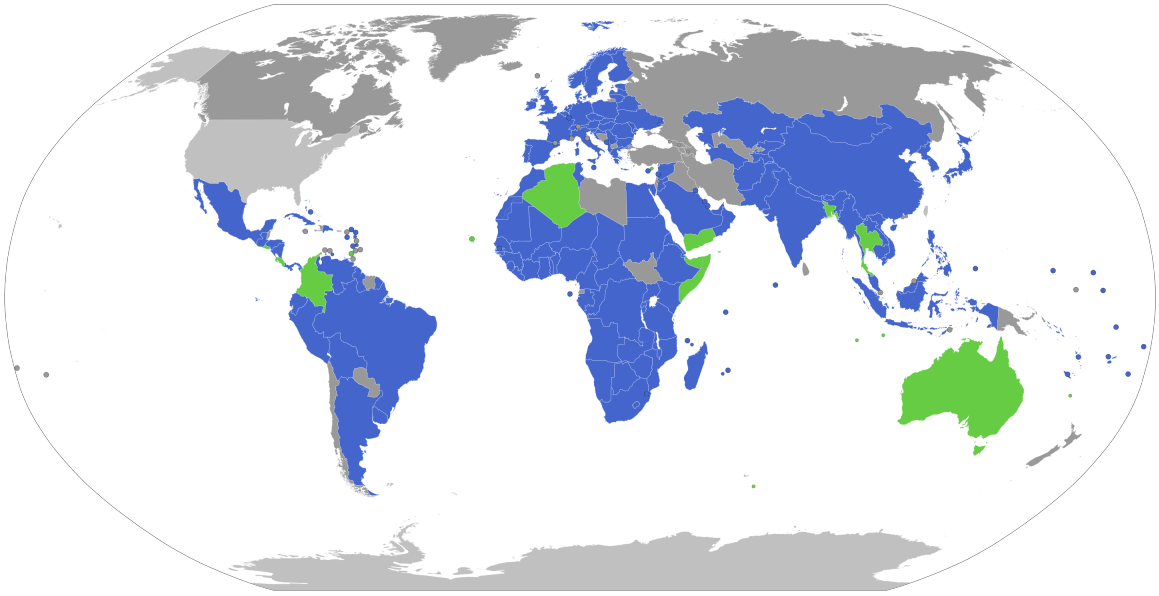

Figure 6: Membership in the Nagoya Protocol as of 2024
(Countries marked in blue are parties to the protocol;
countries marked in green have signed but not yet ratified it.)

In brief, the Nagoya Protocol works as follows: each member country must adopt a statute to ensure that biological resources and traditional knowledge located within its own territory are accessed only "with the prior and informed consent and approval and involvement of these indigenous and local communities, and [after] mutually agreed terms have been established."[32] All other countries adhering to the Protocol are obliged to adopt statutes — reinforced by appropriate penalties — ensuring that such resources and knowledge are "utilized" within their own jurisdictions only if the "domestic access and benefit-sharing legislation or regulatory requirements" adopted by the source country have been properly observed.[33]

In previous writings, one of us has expressed support for the fourth of the arguments commonly deployed in support of these statutes and agreements, but expressed skepticism

[31] [Check the map against the list of parties at: https://www.cbd.int/abs/nagoya-protocol/signatories.]

[32] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 1, Oct. 29, 2010, 1760 U.N.T.S. 79, Art. 7.

[33] *Id.* art. 16. For a helpful summary of the mechanics of this system, see JEROME S. REICHMAN, WHY THE NAGOYA PROTOCOL TO THE CBD MATTERS TO SCIENCE AND INDUSTRY IN CANADA AND THE UNITED STATES 7–8 (2018), https://www.cigionline.org/sites/default/files/documents/Paper%20no.158web.pdf. [Insert discussion of the agreement reached at COP16 (2024) pertaining to a fund pertaining to digital sequence information.]

concerning the other three.[34] We need not rehearse the debate here. For present purposes, less important than our own views concerning the strength of these arguments is their growing influence, not just among activists and indigenous leaders, but among the general populations of both developing and developed countries. The intensified concern with "benefit-sharing" provides a lever that might be used to help reduce the scourge of infectious diseases in developing countries. Before putting it to work, however, we suggest that the manner in which that concern is most often expressed could plausibly be adjusted in three ways.

The first concerns the kinds of "benefits" that ought to be shared. The type that figures most prominently in the academic debates – and in the modest number of agreements between pharmaceutical firms and indigenous groups that have thus far grown out of those debates – is money. Typically, the groups demand and the firms agree to pay a percentage of the revenues or profits that the firms earn from selling the drug at issue. Sometimes, such payments are supplemented with nonpecuniary benefits, such as funding for educational programs or other social services. Less common are agreements by the firms to employ members of the indigenous group (a variant that, with respect to cultural products, we strongly endorse). Oddly, as yet it has been rare for the firms to commit to providing members of the group access to the drug developed in part through their efforts and knowledge. (The promise made (under pressure) by the IRD researchers to provide to the Paliku and Galibi affordable access to malaria drugs derived from *quassia amara* is highly unusual.) For obvious reasons, our view is that access to the medicine itself should be included in the set of benefits to which an indigenous group is entitled.

The second adjustment concerns delineation of the group that is to receive these benefits. In controversies involving nonpermissive uses of traditional knowledge, a great deal of effort is often devoted to determining which indigenous group was the principal source of the knowledge in question – and is thus entitled to a return on it.[35] Among the reasons this is difficult is that, often, more than one indigenous group helped build the knowledge at issue – and that the members of some non-indigenous groups also contributed. In this respect, the racial and ethnic diversity of the set of people interviewed by the IRD researchers in French Guiana is representative. It would be both historically more accurate and morally more attractive to abandon the quest for a single ethnic source and instead to extend benefits to all of the residents of the country in question.

This suggestion dovetails with the first proposed adjustment. If the principal benefit to be shared were money, then enlarging the pool of recipients would diminish the amount payable to each. But if the principal benefit were affordable access to the drug at issue, the enlargement would not entail any such diminution. (This is yet one more manifestation of the "nonrivalrous" character of information about innovations.)

The third adjustment we suggest is analogous. In controversies of this sort, the plant in question frequently can be found in several countries – and, as a result, indigenous

[34] See William Fisher, "The Puzzle of Traditional Knowledge," *Duke Law Journal* 67 (2018).

[35] See, e.g., Wynberg, "Making Sense of Access and Benefit Sharing."

groups in several countries contributed to identification of its medicinal potential.[36] Limiting benefits to the particular country in which the pharmaceutical firm happened to conduct its ethnobotanical research produces morally arbitrary outcomes. Again, it would be more sensible, both from the standpoint of historical accuracy and from the standpoint of fairness, to include among the beneficiaries the residents of all of the countries in question.

To summarize, building upon growing public attitudes concerning the unfairness of unauthorized use of traditional knowledge, we advocate recognition of a duty on the part of pharmaceutical firms to ensure that the residents of countries from which the firms extract biological materials or traditional knowledge are provided access to the drugs generated through exploitation of those resources. The firms might satisfy that obligation in any of three ways: by producing the drugs and then providing them to the countries at issue; by licensing generic manufacturers to produce the drugs and provide them to the countries at issue; or, when technology transfer is required, by participating in joint ventures or apprenticeship programs designed to facilitate local production. (The last of these options was discussed in more detail in a different connection in Chapter 5.)

Turning finally to the law, how might such a duty be enforced? The most obvious path would be for the United States to ratify the Convention on Biological Diversity and then join and implement the Nagoya Protocol, after which it would be more likely for firms and groups negotiating ABS agreements to include in them provisions embodying our recommendations. However, this path is unpromising for two reasons. First, the hostility of pharmaceutical firms to the Protocol shows no signs of abating, and the US government has proven highly responsive to their views.[37] Second, because virtually all of the firms sell products in countries that have joined the Convention and Protocol, they are already subject to its dictates. Yet the compliance of most firms has been grudging and slow.

An alternative path would rely for enforcement, not upon the penalties contemplated by the Protocol (and the national laws implementing it) but on public opinion. In a related context, one of us has advocated adoption of labelling requirement for products rooted in traditional knowledge. Adapted to the present context, such a regime would work as follows: the seller of a drug whose development was based in significant part on biological materials or traditional knowledge found in a developing country would be required to disclose, in a label on all packages containing the drug (a) the fact of such reliance and (b) the arrangements made by the seller to ensure that the residents of developing countries had affordable access to the drug.

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[36] Examples: Hoodia; Rosy Periwinkle; Quassia Amara.

[37] See Catherine Klein, "New Leadership Needed: The Convention on Biological Diversity," *Emory International Law Review* 31 (2016).; Benji Jones, "Why the Us Won't Join the Single Most Important Treaty to Protect Nature," *Vox* (2021), https://www.vox.com/22434172/us-cbd-treaty-biological-diversity-nature-conservation; "Every Country Is Negotiating a Plan to Save Nature. Except the Us.," *Vox* (2024), https://www.vox.com/down-to-earth/379295/cop16-biodiversity-why-us-global-treaty-protect-nature.
(Adoption of the expansive interpretation of the firms' duties that we have advocated here would surely intensify their opposition.)

Such a requirement would be far from novel. The sellers of a variety of other products are already legally obliged to make analogous disclosures. For example, in the United States, institutions offering residential mortgages must present borrowers with detailed information concerning the nature of the financial obligations they are incurring; sellers of packaged food must reveal the contents thereof; sellers of clothes must include labels that indicate, among other things, the materials of which they are made and where they were manufactured; and last but not least sellers of prescription drugs must include in their packaging and advertisements warnings concerning the risks associated with their products.[38] In many of these settings, an administrative agency specifies the terms of the required disclosures and polices their accuracy. The same technique could be employed here.

The purpose of this duty is probably apparent. As noted above, in the United States and in most other developed countries, popular skepticism concerning the pricing practices of pharmaceutical firms is growing. A substantial subset of the population believes that the firms should do more to ensure that poor people have access to their products, particularly if doing so would not reduce the availability of the drugs in developed countries. This sentiment is especially strong in circumstances in which the drugs were derived in some way from the countries in which such people live. Awareness of this sentiment and a desire to assuage it would put pressure on the firms to agree to ABS deals of the sort we have described.

To be sure, adoption of such laws would solve only a portion of the problem addressed by this book. At most, it would increase the availability and affordability in developing countries of drugs for which incentives are already adequate and that are derived in part from materials and traditional knowledge from such countries. But this modest intervention would save many lives.

F. The Social Responsibility Index

Before presenting our final proposal, we will sketch the two regulatory systems that have inspired it. Following this path will require some patience from the reader, because it will take us far afield of global health. But it should enhance understanding of our own proposal.

1. Analogues

[38] See *State Required Disclosure Matrix— External Version*, LOANDEPOT WHOLESALE (Nov. 9, 2017), https://portal.ldwholesale.com/portaldocs/yoda/wholesale/State_Specific_Disclosure_Matrix_EXTERNAL.pdf; Mary E. Kremzner & Steven F. Osborne, *An Introduction to the Improved FDA Prescription Drug Labeling*, FDA, https://www.fda.gov/downloads/training/ forhealthprofessionals/ucm090796.pdf; Textile Fiber Products Identification Act (Textile Act), 15 U.S.C. §§ 70–70k (2012); Wool Products Labeling Act of 1939 (Wool Act), 15 U.S.C. §§ 68–68j (2012); Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938), the Fair Packaging and Labeling Act, Pub. L. No. 89-755, 80 Stat. 1296 (1966), and the Nutrition Labeling and Education Act of 1989, Pub. L. No. 101-535 104 Stat. 2353 (1990).

In 1975, stung by the shock to the U.S. economy caused by the "Arab Oil Embargo," Congress adopted an unusual regulatory regime in hopes of increasing the fuel economy of automobiles in the United States. The Energy Policy and Conservation Act required the Department of Transportation to establish and enforce Corporate Average Fuel Economy Standards ("CAFE Standards," for short), which would oblige all companies selling automobiles in the U.S. to achieve in each model year an overall average fuel-economy level in their fleets of vehicles. A company that failed to meet the target would pay a substantial fine. The Department of Transportation delegated responsibility to set the mandatory levels to the National Highway Transportation Safety Administration (NHTSA). In 1978, the NHTSA set the initial level for cars at 18 miles per gallon; in 1979, it introduced a new standard for "light trucks," and set it at 17.2 mpg for two-wheel-drive versions and 15.8 mpg for four-wheel-drive versions. In subsequent years, the agency raised the standards to reflect advances in technology that made increased fuel economy feasible.

Automobile manufacturers could comply with this new regime in any of a variety of ways. The most obvious option was to develop and install in their cars and trucks new gas-saving technology. But they could also raise their overall fuel-economy averages by reducing the size of their engines (which, other things being equal, would make them less powerful but also cause them to use less gasoline); reducing the weight of their vehicles (thus reducing the amount of fuel necessary to push them up hills); or by increasing the price differential between their smaller cars and their larger cars (thus increasing sales of the former and reducing sales of the latter – and thereby improving the average fuel efficiency of their fleets). In one of these ways or another, the large majority of manufacturers met their targets, but a few (mostly makers of sports cars) chose to pay fines instead.[39]

Overall, the program has been highly successful in two ways. First, since 1975, the average fuel economy of the automobiles sold in the United States has increased sharply – more than would have been true in the absence of the CAFE standards.[40] Second, by leaving the companies free to decide how to meet their targets, the regime has achieved this social benefit relatively efficiently.

To be sure, the program has flaws – some of which, unfortunately, are getting worse. First, the NHTSA has not increased the targets as much or as fast as changing technology would have allowed – or as the relevant statute seems to require. As a result, the progress achieved by the regime has been highly uneven. The fluctuations in regulatory vigor are apparent from the graph below.[41]

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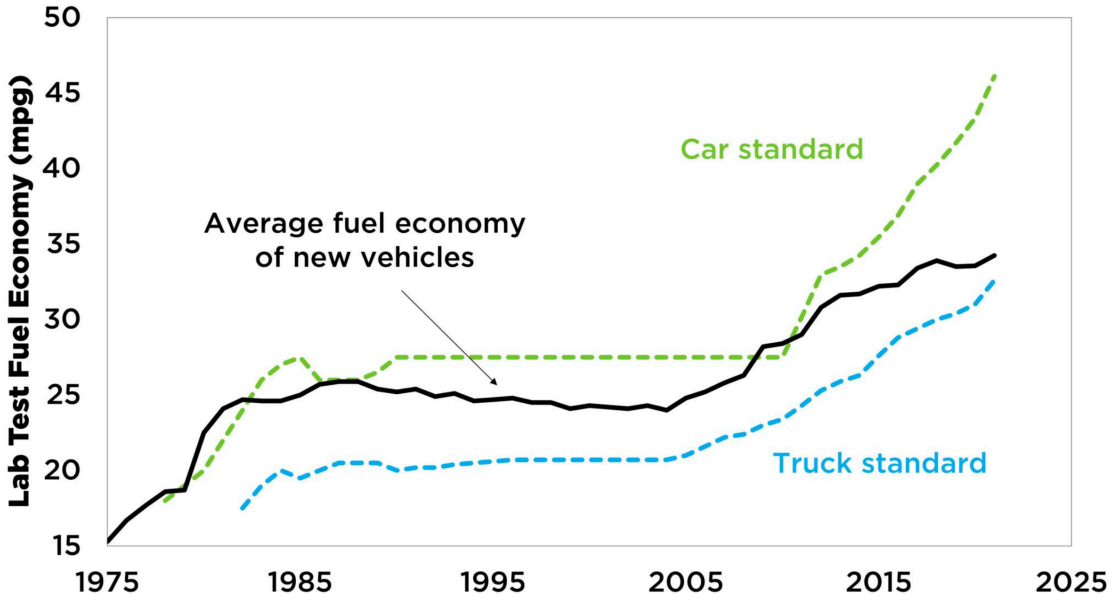
[39] For data concerning the magnitude of the fines collected, see Summary of Corporate Average Fuel Economy (CAFE) Fines collected: CAFE Program Page (August 2015), https://catalog.data.gov/dataset/summary-of-corporate-average-fuel-economy-cafe-fines-collected-summary-of-cafe-fines.

[40] See National Academy of Sciences, "Effectiveness and Impact of Corporate Average Fuel Economy (CAFE) Standards," National Academies Press (2002), http://www.nap.edu/catalog/10172/effectiveness-and-impact-of-corporate-average-fuel-economy-cafe-standards.

[41] Source: "Driving Efficiency: Cutting Costs for Families at the Pump and Slashing Dependence on Oil," Whitehouse.gov, https://www.whitehouse.gov/sites/default/files/fuel_economy_report.pdf.

Figure 2: CAFE Standards and Achieved Fuel Economy[42]



Second, because the standards for cars and light trucks are separate – and (as the graph reveals) the former has always been stricter than the latter – manufacturers could (and did) evade the rules to some extent by shifting their production and marketing away from cars and toward "sport utility vehicles," which are classified as trucks. This not only undermined the overall benefits of the regime, but also contributed to the blight of "SUVs" on American roads.[43]

Third, the regime puts no pressure on consumers to drive less. Thus, it fails to incentivize a mechanism for reducing overall fuel consumption that might be, at least at the margin, more socially efficient than the changes made by the automobile manufacturers.

Fourth, the reduction in the average weight of cars seems to have increased highway injuries and fatalities.[44] (This side-effect may have been exacerbated by the second, insofar as fatalities are especially common when small cars collide with SUVs.)

Finally, some of the efficiency advantages of permitting the manufacturers to decide for themselves how to meet their targets were forfeited by details lurking in the

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[42] Source: Union of Concerned Scientists, "Stronger Fuel Economy Standards Are Needed to Clean up Combustion Vehicles," (2024).

[43] Related distortions arise from an adjustment to the regime, first introduced in 2011, that imposes less stringent requirements on vehicles with larger "footprints." See Whitefoot & Skerlos, "Design incentives to increase vehicle size created from the U.S. footprint-based fuel economy standards," *Energy Policy* 41 (2012): 402-411.

[44] See "Vehicle Weight, Fatality Risk and Crash Compatibility of Model Year 1991-99 Passenger Cars and Light Trucks," NHTSA Technical Report, DOT HS 809 662 (October 2003); Diane Katz, "CAFE Standards: Fleet-Wide Regulations Costly and Unwarranted," http://www.heritage.org/research/reports/2011/11/cafe-standards-fleet-wide-regulations-costly-and-unwarranted.

regime that incentivized them to adopt particular technologies, rather than to adopt the measures they deemed most cost-effective.

Most of these defects, however, are not inherent to the CAFE approach. Rather, they reflect or reveal mistakes in the way in which the regime has been implemented. And even with its warts, the regime offers intriguing hints concerning how we might alter the behavior of pharmaceutical firms.

The second of the two regulatory regimes that can help guide us is the "cap-and-trade" approach to the reduction of air pollution that is now being employed by a growing set of states and countries. To see the potential relevance of that approach requires a bit of background:

As most readers will be all too aware, "greenhouse gases" (GHGs) increase the overall temperature of the earth, causing climate change and reducing the overall welfare of the earth's (human) inhabitants. The enterprises that emit most GHGs currently have insufficient incentives to reduce their emissions. Governments thus must intervene in some way to change their behavior.

There are four main ways in which governments might do so. First, they might apply or modify tort law to make the enterprises liable to the persons injured by their emissions. Second, they might regulate the enterprises' conduct directly – for example, by requiring them to install GHG-reduction technologies or compelling them to use fuels that cause fewer noxious emissions. Third, governments might impose on the enterprises a tax – ideally, a tax on each unit of GHGs emitted by an enterprise equal to the marginal social harm that the unit causes. Fourth, governments might forbid enterprises to emit more than prescribed amounts of GHGs.[45]

The first of these approaches, although theoretically sound, is highly impractical – for reasons sufficiently obvious that we can put it to one side. The second, though more feasible, is inefficient, for reasons that should by now be apparent: government officials are poorly equipped to determine what changes in behavior (in general or by specific enterprises) would most efficiently reduce emissions. The real choice thus comes down to options 3 and 4: taxes and quantity limits.

In many respects, these two strategies are similar. Both are much more practicable than #1, and neither imposes upon governments the extreme informational demands that beset #2. At first blush, taxes appear more efficient than quantity limits, insofar as the former will induce each enterprise to reduce emissions only up to the point beyond which further reductions would cost more than the taxes saved, whereas the latter presumptively require all firms to reduce emissions by the same amount (or by amounts proportional to the firms' sizes), regardless of differences in their costs of doing so. However, this contrast disappears if the firms subject to the quantity limits are permitted (or required) to buy the limited set of emission permits – either from the government (at auctions) or from each

[45] For the most influential explication of these options, see Ronald Coase, "The Problem of Social Cost," reprinted with commentary in Kennedy and Fisher, *The Canon of American Legal Thought*.

other. So, in this crucial respect, taxes and quantity limits fare equally well. Likewise, they are equally subject to criticism on the ground that they fail to respond sensitively to temporal fluctuations in technological options for reducing emissions or the social costs of emissions – but are also equally capable of deflecting this criticism by allowing the "banking" and "borrowing" of permits.[46]

Choosing between taxes and quantity limits is rendered even more difficult by the fact that each strategy can be (and sometimes is) tempered in ways that cause it to incorporate elements of the other. For example, the rigidity of a quantity limit (and the associated hazard that it will force enterprises to adopt extremely costly measures to comply with its obligations) can be mitigated by adding a so-called "safety valve" – under which the government stands willing to sell an unlimited number of additional emission permits at a specified price (a price higher than the price at which the government expects those permits to sell in the initial auction or to trade in the "private" market). The more that firms avail themselves of such a valve, the more that a regime based on quantity limits comes to resemble a tax regime.[47]

That said, taxes and quantity limits are not identical. The most important difference between them is that the latter, unlike the former, require government officials to decide the aggregate level of emissions that would be socially optimal. The likelihood that they will set the levels too high or too low (or will fail to adjust them at optimal rates) causes most economists to argue that taxes are superior to quantity limits in most circumstances.[48] However, the political impediments to the imposition of taxes have prompted the overwhelming majority of jurisdictions to opt for (tradeable) quantity limits instead as the principal mechanism by which they seek to curb air pollution. Most economists think that not much has been sacrificed by this choice.

So how have those quantity limits fared in practice? For the most part, very well indeed. For example, the regional carbon trading program used by nine Northeastern states in an effort to curb acid rain is generally regarded as a major success. It has both sharply reduced injuries from acid rain in the vulnerable eastern (downwind) states in the region and, through emission-permit auctions, raised considerable funds for the participating states.[49] Similarly, the Emissions Trading Scheme employed in the European Union and

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[46] See Brian C. Murray, Richard G. Newell, and William A. Pizer, "Balancing Cost and Emissions Certainty: An Allowance Reserve for Cap-and-Trade," *Resources for the Future* July 2008 (2008); Richard G. Newell and Nathan E. Wilson, "Technology Prizes for Climate Change Mitigation," ibid. (2005).

[47] See ___. Cf. Adele Morris, et al., "Time for a Price Collar on Carbon," *Politico* (July 24, 2009), available at http://www.politico.com/news/stories/0709/25346.html.

[48] See, for example, Reuven S. Avi-Yonah and David M. Uhlmann, "Combating Global Climate Change: Why a Carbon Tax Is a Better Response to Global Warming Than Cap and Trade," *Stanford Environmental Law Journal* 28 (2009); Jonathan S. Masur and Eric A. Posner, "Toward a Pigouvian State," *University of Pennsylvania Law Review* 164 (2015); Michael Wara, "Instrument Choice, Carbon Emissions, and Information," *Michigan Journal of Environmental & Administrative Law* 4, no. 2 (2015). But cf. Newell and Wilson, "Technology Prizes for Climate Change Mitigation."; Lawrence H. Goulder and Andrew R. Schein, "Carbon Taxes Vs. Cap and Trade: A Critical Review," (2013), http://ssrn.com/abstract=2308219.(arguing for the superiority of modified quantity limits under some circumstances).

[49] See Jared Kaltwasser, "As N.J. Leaves RGGI, Study Says Program Added $1.6 B to Region's Economy," NJBIZ (Nov. 15, 2011), available at http://www.njbiz.com/article/20111115/NJBIZ01/111119893/As-NJ-

the similar program employed in California to reduce GHGs are generally regarded as successes.[50]

To be sure, like the CAFE standards, all extant cap-and-trade systems have flaws. For example, the California regime has been justifiably criticized on the ground that, in practice, it enables utilities to shift the burden of greenhouse gases to other states, rather than to reduce their overall emissions,[51] and that it is regressive in impact, unfairly burdening poor consumers more than rich ones.[52] But most such problems are generally (and properly) regarded as the fruits of mistakes in design or implementation, not inherent to the general approach of quantity limits.

2. Tradeable Obligations to Enhance Health

The regulatory system that we advocate to address the global health crisis seeks to capitalize on the lessons of the two ongoing regulatory experiments described above. Here's how it would work: Each pharmaceutical firm would be required to achieve, each year, a ratio, which we will call the social-responsibility index (SRI). The numerator of this index would be the total number of Disability Adjusted Life Years (DALYs) saved as a result of the distribution and consumption of the firm's products during the year. The denominator would be a measure of the firm's size, presumptively its global gross revenues during the year.[53]

Who would manage and enforce such a regime? The simplest approach would be for Congress to adopt a statute instituting such a requirement as a condition for the right to distribute pharmaceutical products in the United States. Because the U.S. market for drugs constitutes roughly 40% of the global market, few firms, regardless of where they are based, could or would refuse to comply. Most likely, Congress would delegate responsibility for implementing the system to an administrative agency – either the Food and Drug Administration or a new agency. (Other possible ways of implementing the regime will be considered shortly.)

Like GHG emission permits, the DALYs in this regime would be both tradeable and bankable. Thus, a firm that, in a given year, failed to earn enough DALYs to meet its target could purchase DALYs from a firm that had a surplus. For example, a firm specializing in so-called "lifestyle" products (such as erectile-dysfunction drugs, sales of

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leaves-RGGI-study-says-program-added-$16B-to-region's-economy; Eleanor Stein, in Gerrard & Freeman, eds., *Global Climate Change and U.S. Law* (2d ed. 2014), Chapter 9.

[50] See Larry Parker, "Climate Change and the Eu Emissions Trading Scheme (Ets): Looking to 2020," *Congressional Research Service. R41049* (2010); Tseming Yang, "An Introduction to California's Greenhouse Gas Emission Trading Program," *Journal of Jiangsu University, Social Science Edition* (2013), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2281821.

[51] See Danny Cullenward, "Leakage in California's Carbon Market: Preliminary Trading Is Consistent with Expected Impact of Regulatory Changes," (2014).

[52] See David Gamage and Darien Shanske, "Using Taxes to Improve Cap and Trade, Part I: Distribution," *State Tax Notes* (2015).

[53] Alternative measures that might be less subject to evasion or more sensitive for our purposes would include (a) gross profit; or (b) earnings before income, taxes, depreciation, and amortization.

which are lucrative but result in only modest health benefits) could buy DALYs from a firm specializing in vaccines or drugs efficacious in preventing or treating more serious diseases or conditions. Alternatively, a firm that, in a given year, earned more that enough DALYs to satisfy its obligations, instead of selling the surplus could apply it to the firm's account for the following year.

Like the CAFE standards, our proposed regime would permit each firm to decide how it could most efficiently comply with its obligation. A firm at risk of missing its target would have (at least) the following options:

1) It could reduce the prices charged in developing countries for drugs already in its portfolio, thereby increasing the number of persons able to afford the drugs and earning more DALYs.
2) It could alter the formulations of drugs already in its portfolio so that they could be distributed more easily in developing countries – for example, by making them more heat resistant and thus easier to distribute in areas without reliable "cold chains."[54]
3) It could increase its investment in research projects that promise to generate drugs with large health benefits (for example, vaccines for infectious diseases).
4) It could alter its business-acquisition policies to acquire more "startup" biotechnology companies that have developed products that offer large health benefits.
5) It could collaborate with governments or NGOs in developing countries to improve the distribution systems for its drugs, thereby getting them into more mouths.
6) It could, as mentioned above, buy DALYs from other firms better positioned to improve public health.
7) Finally, it could reduce the prices of some or all of its products, thereby lowering the denominator of its ratio. (For obvious reasons, this is the option the firm is least likely to adopt.)

The system would be introduced gradually. During the first year of its operation, the responsible administrative agency would estimate the total number of DALYs saved throughout the globe during the preceding year as a result of the consumption of all pharmaceutical products, divide that number by an estimate of the global gross revenues of the pharmaceutical industry, and set the mandatory ratio slightly higher. The announcement of the ratio would prompt firms to begin trading DALYs, along the lines sketched above. If the agency's estimates were roughly accurate, the equilibrium price for DALYs during this first year would be very low. In each subsequent year, the agency would increase the ratio. The equilibrium price for DALYs would rise as a result, and the financial pressure on the pharmaceutical industry as a whole to redirect its aggregate energies toward improvements in global health would increase correspondingly.

[54] See EA Haworth et al., "Is the Cold Chain for Vaccines Maintained in General Practice?," *British Medical Journal* 307 (1993).

A system of this sort would have many advantages. Most fundamentally, it would address simultaneously what we have been describing as the "access problem" (the inability of poor countries and residents to afford the drugs they need) and the "incentive problem" (the inadequacy of the financial motivations to develop new drugs). Most reform proposals – and most of the regulatory regimes considered earlier in this chapter – address only one of the dimensions of the global health crisis and either leave the other dimension untouched or exacerbate it. By contrast, the social-responsibility index would lead both to lower prices in poor countries for existing drugs and to increased investment in new vaccines and drugs for neglected diseases.

Those incentives would radiate through the pharmaceutical industry. An illustrative example can be derived from the grim (and nearly catastrophic) recent outbreak of Ebola Hemorrhagic Fever.[55] The existence of the Ebola virus and the hazard it poses to human health have been known for decades. Since 1976, there has been an outbreak of the disease on average every three years. But until 2013, pharmaceutical firms devoted minimal resources to the development of a cure or vaccine. Two aspects of the most recent outbreak prompted a surge of interest in the disease: its scale (all previous outbreaks had killed fewer than 300 people; the new one killed over 11,000); and the fact that, for the first time, persons outside of West Africa were infected. There are now ten separate projects underway to develop an Ebola vaccine and 12 projects focused on developing therapies for the disease.[56] Most likely, we will soon have drugs that enable us to combat at least the most virulent strain of the disease. But – and here is the key point – very few of these promising research initiatives have been undertaken by major pharmaceutical firms; most have been undertaken by small companies (typically supported with government grants). In explaining why they turned their attention to Ebola, many of the executives in those small firms have indicated that their principal motivation (aside from the obvious humanitarian considerations) was, by demonstrating their research capacities, to attract the interest of the major pharmaceutical companies, which might then fund their other projects. Adoption of our proposed regulatory system would increase sharply the incentives of such small companies (buoyed by public or private investment) to address neglected diseases – because it would increase the incentives of the major firms to buy them and/or their products. (Recall option #4, above.) The result would be to increase the likelihood that we will have vaccines for Ebola's cousins (the Marburg, Machupo, Junin, Lassa, and Lloviu viruses[57]) before, rather than after, they kill thousands (or millions) of people.

The second major advantage of the regime we propose is that, like a prize system and unlike a grant system, it would capitalize on the informational advantages of the pharmaceutical firms. Their scientists and executives know better than government officials which of the seven paths enumerated above would generate, in a given year, the biggest health benefits for the least cost. By setting a target but not telling the firms how to hit it, our proposed regulatory regime would enable them to use that knowledge. The result, of course, will be increased efficiency in alleviation of the global health crisis.

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[55] Additional background on Ebola is available in Appendix 5.

[56] For summaries of these projects, see ibid., pp. 13-38.

[57] For the risks posed by these viruses, see ibid., pp. 41-42.

Similar efficiency gains would result from the market in DALYs. The firms best positioned to improve global health would do so – relying partly on funds provided by firms less well situated.

The system we recommend would also prompt firms to respond rapidly both to scientific advances and to changes in the landscape of diseases. When scientific breakthroughs exposed new paths to the creation of efficacious drugs or when new diseases appeared (or old diseases suddenly became more virulent[58]), the firms would alter course immediately. They would not need to wait for government officials to detect the changes and to adjust accordingly the regulatory regime or the pattern of government subsidies for research.

Finally, the system would stimulate public discourse concerning the global health crisis as a whole. An indirect effect of the market for DALYs is that it would reveal the price that society as a whole places upon a year of healthy human life. Public discussion of the plight of the poor in developing countries is currently impeded by the difficulty of grasping the scale of the problem or the feasibility of solutions to it. By exposing, simply and accurately, the marginal cost of saving a year of someone's healthy life, the system would facilitate reflection and debate concerning our collective moral obligations to do more – or less. That debate would help guide the administrative agency that managed the system when determining whether (or how fast) to turn up the SRI dial. More broadly, it would strengthen the global moral community.

The principal disadvantage of our proposed system is that, to operate well, it would require an enormous amount of information. To be sure, some of the data necessary to implement it has already been developed for other purposes. For example, the World Health Organization already collects and publicizes annual mortality and morbidity data broken down by country and disease.[59] And government agencies in Australia, Canada, France, Germany, New Zealand, Sweden, and the United Kingdom have already developed considerable data concerning the relative clinical effectiveness of the various drugs that target each of those diseases.[60] Other data essential to the operation of the system could be provided by the pharmaceutical firms themselves. For example, to demonstrate achievement of the SRI, the firms could be obliged to submit, not just financial information necessary to calculate the denominators of their ratios, but also verified data concerning the distribution (and consumption) of each of their drugs during the preceding year. But,

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[58] See, for example, Donald G. McNeil Jr., Simon Romero, and Sabrina Tavernise, "How a Medical Mystery in Brazil Led Doctors to Zika," New York Times, February 6, 2016, http://www.nytimes.com/2016/02/07/health/zika-virus-brazil-how-it-spread-explained.html.

[59] See "Global Health Observatory Data Repository," http://apps.who.int/gho/data/node.main.BURDENOFDISEASE?lang=en. Cf. Institute for Health Metrics and Evaluation, "Global Burden of Disease," http://www.healthdata.org/gbd.

[60] See Matthew D. Adler, "Qalys and Policy Evaluation: A New Perspective," *Yale Journal of Health Policy, Law and Ethics* 6 (2006); Karin H. Cerri, Martin Knapp, and Jose-Luis Fernandez, "Decision Making by Nice: Examining the Influences of Evidence, Process and Context," *Health Economics, Policy and Law* 9 (2014); Corinna Sorenson and Kalipso Chalkidou, "Reflections on the Evolution of Health Technology Assessment in Europe," ibid.7 (2012): section 2.5; Tom Walley, "Drugs, Money and Society," *Journal of Clinical Pharmacology* 70, no. 3 (2010).

to run system accurately and fairly, the administrative agency would need to supplement these data with additional information. That would be both difficult and expensive.

This drawback could, however, be mitigated by asking universities (in particular, faculty in medical schools and schools of pharmacy) and other nongovernmental organizations, to augment their ongoing pharmacoeconomic evaluations of drugs. That such data would not only have global social benefits (of the sorts we have outlined) but would also enhance the ability of individual doctors to prescribe the right treatments for their patients might also prompt foundations to fund increased research of this sort.

3. Variations on the Theme

The version of the social-responsibility index outlined above is the most straightforward. But modified versions are readily imaginable. Some would advance our goals more precisely than the basic model; others might be more politically palatable. A few of them are described and assessed below.

(a) Safety Valves

One of the advantages of the SRI is that, unlike quantity limits (such as the "caps" on GHG emissions), it does not expose either the regulated firms or society at large to serious risks caused by government officials misestimating social benefits and harms. As we have explained, during the first year of its operation, the system would require firms to achieve a ratio only slightly higher than the industry-wide ratio of DALYs saved to global revenues – the calculation of which would be time-consuming but not difficult. In subsequent years, the mandatory ratio would be gradually increased, subjecting firms to slowly strengthening obligations. This incremental approach would pose little danger of forcing firms suddenly to make large – and potentially socially excessive – expenditures to meet their regulatory obligations. As a result, our proposed system would not need a "safety valve" – the principal purpose of which is to mitigate that danger.[61]

Adding such a valve to the system would, however, be simple. The government or agency administering the regime would offer to sell each year an unlimited number of (virtual) DALYs at a specified price – a price somewhat higher than the price at which the agency expected DALYs to trade on the private market. If the market price rose above this level, delinquent firms could and would purchase from the government (rather than from other firms) the number of DALYs they needed to hit their targets.

There are two reasons why it might make sense to add this feature to the system. First, the availability of the safety valve might reduce pharmaceutical firms' opposition to the adoption of the regime. The executives of such firms are likely to have less faith in the expertise of government officials than we do. Assurance that, if worse came to worst, they could purchase DALYs at a set price might reassure them.

[61] See the text accompanying note ___, supra.

Second, a beneficial side-effect of the use of the valve would be to provide the government a source of money that it could use to fund (through grants or prizes) additional research on neglected diseases. And why, exactly, would that be a good idea? A full answer to that question must await the following chapter, where we will consider "blends" of the various reform options examined in this book. But, in brief, it would enable the government to channel funds toward research projects that promised long-term benefits but not short-term gains – and thus to offset the tendency of the pharmaceutical firms to favor (somewhat) investments that enable them to "make their numbers" each quarter.[62]

(b) Refining Measures of Health Impacts

In two ways, the mechanism we have outlined for measuring the health benefits secured through the distribution of drugs could be refined. First, as we saw in Chapter 2, the DALY metric, although widely and successfully used, is imperfect. To review, its flaws include: (a) it presumes that the suffering caused by a given condition does not vary by country (e.g., that being blind in the United States is no more and no less burdensome than being blind in Ethiopia[63]); (b) the weight it assigns to a year of lost or impaired life varies with the age of the person in question (in ways that are difficult to defend); (c) it uses a 3% discount factor to compare future harms and benefits with current harms and benefits; and (d) it implicitly treats interventions that save the lives of disabled people as less important than interventions that save the lives of healthy people.[64] Because the incentives generated by our proposed system are tied to DALYs, the system would sometimes result in a pattern of pharmaceutical research and development that (although vastly better from the standpoint of social welfare than the current pattern) would fail to align exactly with our moral intuitions. This problem could be avoided by instructing the agency charged with running the system to develop and apply a new metric that addressed the legitimate criticisms that some philosophers and public-health experts have directed at the DALY scale. If the considerable cost of developing a new metric (and then using it to re-measure the health benefits secured by each drug) discouraged us from making this adjustment, the result would not be catastrophic. The imperfections of the DALY metric are just that – not fundamental defects. To eschew our proposal because of our awareness of them would be to succumb to what Harold Demsetz once described as the "nirvana fallacy."[65]

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[62] For this point, we are indebted to Jeff Kindler, the former CEO of Pfizer, Inc..

[63] For one of the major causes of the disproportionate incidence of blindness in Ethiopia, see Yermane Berhane et al., "Prevalence of Trachoma in Ethiopia," *Ethiop. J. Health Dev.* 21, no. 3 (2007).

[64] For discussion of these and other limitations of the DALY metric, see Sudhir Anand and Kara Hanson, "Disability-Adjusted Life Years: A Critical Review," *Journal of Health Economics* 16 (1997); Sudhir Anand and Kara Swanson, "Dalys: Efficiency Vesus Equity," *World Development* 26, no. No. 2 (1998); T Arnesan and E Nord, "The Value of Daly Life: Problems with Ethics and Validity of Disability Adjusted Life Years," *British Medical Journal* 319 (1999); DD Reidpath et al., "Measuring Health in a Vacuum: Examining the Disability Weight of the Daly," *Health Policy Plan* 18, no. 4 (2003); Dominika Wranrik, "Healthcare Policy Tools as Determinants of Health-System Efficiency: Evidence from the Oecd," *Health Economics, Policy and the Law* 7 (2012).

[65] See Harold Demsetz, "Information and Efficiency: Another Viewpoint," *Journal of Law and Economics* 12 (1969). ("The view that now pervades much public policy economics implicitly presents the relevant choice as between an ideal norm and an existing "imperfect" institutional arrangement. This nirvana approach

Second, the calculations used to determine the mandatory ratio for a given year could be adjusted to improve the distributional impact of the system. The regime we have outlined thus far employs a purely utilitarian criterion. It measures – and thus would nudge the pharmaceutical industry toward maximization of – overall human welfare (measured by the values that people place on life and good health). As we pointed out in the previous chapter, when discussing the analogous aspect of a prize system, such an approach has the effect of giving equal weight to drugs designed to alleviate minor ailments that afflict large numbers of people and drugs designed to alleviate serious ailments that afflict small numbers of people.[66] If, for the reasons addressed in Chapter 5, we wished to tilt the pattern of incentives more toward serious ailments, we could adjust the way that the numerator of the SRI is calculated. For example, before multiplying the number of DALYs saved per person through the consumption of a given drug by the number of people to whom it had been administered, we could apply an exponential function to the number of DALYs saved per person (and then of course modify the mandatory ratio to maintain the overall pressure the system exerted on the industry). Such an adjustment would accommodate our moral intuition that, if the total misery caused by two diseases is equal, and they are equally susceptible to prevention or cure, more resources should be devoted to research aimed at the disease that causes acute pain to a few people than to the one that merely irritates many people. Although this particular possible adjustment is (to us) morally attractive, it would have a significant disadvantage: It would undermine the capacity of our proposed regime to stimulate public discourse concerning the global health crisis – because the price at which DALYs traded in the modified system would no longer reveal so clearly the value we collectively place on a year of healthy human life.

(c) Offset Credits

Another possible adjustment of the regime would permit pharmaceutical firms to count, for the purposes of satisfying their obligations, benefits (for which they are responsible) other than those arising out of consumption of their products. To be sure, even the basic form of our model would accommodate a wide range of health benefits. For example, the administration of a vaccine to one person generates a benefit, not just to the person vaccinated, but also to everyone else with whom that person might come into contact. The resultant "positive externality" would certainly be included in the calculation of the DALYs saved through the administration of the vaccine. Another example: For reasons not yet apparent, it appears that the efficiency of the transmission of malaria parasites from people to mosquitos (an essential step in the life cycle of the parasite) increases as the incidence of malaria in a given region declines.[67] This makes especially important the development and deployment of drugs that would impede such

differs considerably from a comparative institution approach in which the relevant choice is between alternative real institutional arrangements.")

[66] See Chapter 5, pages 24-27, supra – available at http://cyber.law.harvard.edu/people/tfisher/Infection_Prizes.pdf.

[67] See Thomas Churcher, Jean-Francois Trape, and Anna Cohuet, "Human-to-Mosquito Transmission Efficiency Increases as Malaria Is Controlled," *Nature Communications* 6 (2015).

transmissions.[68] Consumption of such a drug would confer no immediate benefits on the consumers thereof, but would benefit their neighbors. That benefit would be added to the account of the drug's developer.

But some kinds of health interventions would fall outside the model as we have described it thus far. Suppose, for example, that a pharmaceutical firm developed and deployed an improved technology, of the sort we discussed in Chapter 4, for monitoring drugs in the distribution chain and thereby detecting (and enabling patients to avoid) counterfeits.[69] The resultant increase in the consumption of authentic versions of the firm's products would cause a rise in firm's SRI. But, if the numerator of the fraction included (as we have suggested) only health benefits attributable to consumption of the firm's products, the benefits accruing from the concomitant increase in the consumption of authentic versions of other firms' products made possible by the new technology would not be counted when determining whether the innovator firm had met its regulatory obligation. Including such ancillary gains from innovations other than the creation of new drugs would add to the complexity of our proposed regime, but would improve the pattern of incentives it sustained.[70]

A possible objection: But appropriate incentives to develop supplementary technologies like the anti-counterfeiting system that figures in our hypothetical case are already provided by the patent regime. The ability of the developer of such a technology to obtain either a product patent on the technology itself or a process patent on the method of using it – and then demanding license fees from other pharmaceutical firms – already provides a carrot sufficient to induce the creation of such things. A partial answer to this objection is that some initiatives that would lead to ancillary health benefits (such as an educational program that prompted people in developing countries to seek medical care earlier in the progression of diseases) would not be patentable – or even if patentable in principle, would not be "excludable" in practice.[71] A more fundamental answer is that permitting such ancillary benefits to be "counted" in the numerator of the SRI of the innovator firm, while permitting other firms to benefit from the innovation without paying license fees (which in turn would force them to raise the prices of their drugs), would,

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[68] Promising candidates for these purposes are described in Martin Enserink, "Drug Could Kill Mosquitos When They Feast on Human Blood," *Science*, October 27, 2015 2015; Cassandra Willyard, "Malaria Eradication: Blocking Transmission to Mosquitos," *The Pharmaceutical Journal*, January 7, 2015.

[69] See Chapter 4, pages ___, supra – available at http://cyber.law.harvard.edu/people/tfisher/Infection_Differential_Pricing.pdf.

[70] Support for this adjustment might be gleaned from the analogous provision for "offset credits" in the current version of the California system for reducing GHGs. As explained by Tseming Yang: "In addition to regular allowances, offset credits may also be used to fulfill up to 8% of a facility's emission compliance obligations. Such offset credits can be generated by GHG emission reductions or carbon sequestration projects involving forestry, urban forestry, elimination of methane from manure, and destruction of ozone-depleting substances. Offset projects are subject to rigorous independent verification requirements and must be located within the United States, though international offset projects are anticipated in the future. Yang, "California's Greenhouse Gas Program". 4.

[71] See Amy Kapczynski and Talha Syed, "The Continuum of Excludability and the Limits of Patents," *Yale Law Journal* 122 (2014).

unlike the patent regime, incentivize socially beneficial innovation without at all curtailing public access to its fruits.

The pattern of incentives generated by the system could be further refined by recognizing, in the form of offset credits, the health benefits that arise from firms' donations of their intellectual property to patent pools or similar collaborative ventures. Suppose, for example, that when Pfizer, AstraZeneca, Novartis and Zertex all decided recently to shut down their research programs on tuberculosis,[72] each of them contributed the patents, trial data, and know-how they had already acquired in the field to the TB Alliance, a nonprofit product-development partnership that coordinates research on new TB drugs.[73] Suppose further that those donations helped the TB Alliance develop a new combination therapy for MDR-TB, which in turn reduced the number of deaths (currently 190,000 per year) from that variant of the disease. Each of the pharmaceutical firms might be given a credit toward its SRI for the number of DALYs saved each year as a result of the firm's donation of intellectual property. (To be sure, allocating such credits among the donor firms would require estimation of the relative importance of the sets of patents they had contributed. That would not be easy, but commercial patent pools already routinely make similar estimates when determining the royalties paid to each of their members.[74]) Incorporating calculations of this sort in the SRI would increase sharply the willingness of firms to donate their patents and associated know-how to collaborative, nonprofit ventures better positioned than they are to address some public-health needs.

(d) Global Management

Plainly, the government of the United States is not the only entity under whose auspices such a system could be implemented. In many ways, a global institution with expertise in the field of public health would be better positioned. The World Health Organization, if it could correct the problems exposed by its clumsy response to the Ebola crisis,[75] would be especially well situated to take on the job.

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[72] See Grania Brigden & Katy Athersuch (MSF), "Submission to the United Nations High-Level Panel on Access to Medicines" (February 2016), http://www.unsgaccessmeds.org/inbox/2016/2/27/grania-brigden-and-katy-athersuch; Mike Frick (Treatment Action Group), "Submission to the United Nations High-Level Panel on Access to Medicines" (February 2016), http://www.unsgaccessmeds.org/inbox/2016/2/28/mike-frick.

[73] See http://www.tballiance.org/about/mission.

[74] For a survey and assessment of the various techniques employed by commercial patent pools when making such determinations, see Michael Mattioli, "Power and Governance in Patent Pools," *Harvard Journal of Law and Technology* 27, no. 2 (2014): 439-55.

[75] As the WHO itself acknowledges, its response to the 2014 Ebola outbreak was inadequate. Médecins Sans Frontières (MSF) has persuasively criticized the WHO for ignoring its early warnings about the unprecedented nature of the Ebola epidemic. See "Pushed to the limit and beyond," March 23, 2015, available at: http://www.msf.org/article/ebola-pushed-limit-and-beyond. MSF sounded the alarm as early as March 2014, calling for urgent action to halt the epidemic, but its calls were labeled unnecessary and alarmist. It was not until August 2014 that the WHO declared an international health emergency. See Brooks, C. "MSF Blames WHO for Vast Ebola Deaths," *Clapway,* March 23, 2015, available at: http://clapway.com/2015/03/23/msf-blames-who-for-vast-ebola-deaths123/. The leaders of the WHO have themselves admitted that the organization was "too slow to see what was unfolding before us" and have proposed a strengthened team of epidemiologists for detecting disease and a network of other providers to allow responders to reach "surge capacity." See Worland, J. "WHO Chief Unveils Reforms After Ebola

The principal obstacle to implementation of the regime through a global institution like the WHO is that none of the plausible candidates currently has adequate legal authority. Investing one of them with the necessary power would require a treaty – perhaps facilitated by the World Intellectual Property Organization (WIPO). Adopting such a treaty would be difficult and time-consuming. WIPO has struggled unsuccessfully for decades to create a general framework for the recognition and enforcement of the rights of indigenous groups to the "traditional knowledge" that frequently facilitates efficient exploitation of genetic resources.[76] Negotiation of an agreement that would enable the WHO (or one of its cousins) to administer a regulatory regime of the kind we have outlined would face even more resistance – and thus likely take even longer. But if it could be achieved, such a reform would probably lead to a system more responsive to the needs of both firms and patients located outside the United States than the model we have described thus far.

(e) Enlisting the Firms

A final possible variation on our plan is procedural, rather than substantive. Perhaps, instead of imposing a regime of this sort upon reluctant pharmaceutical firms, it could be developed with their assistance and support. As we saw in Chapter 2, the major pharmaceutical firms are currently under considerable pressure to adjust their business practices to address the global health crisis. Some, as we saw in Chapters 3 and 4, have already voluntarily initiated major programs designed either to develop new vaccines and drugs or to lower the prices for their products in developing countries. They are hobbled, however, by the competitive nature of the industry; the scale of their voluntary initiatives is limited by fear of losing ground to rivals that focus exclusively on commercially promising projects. Under such circumstances, all of the firms could benefit from a regulatory regime that bound them all. Perhaps, recognizing this, the executives of the firm could be persuaded to help build and implement it.

A procedure of this sort would not be unprecedented. On occasion, the major firms in other industries confronting analogous crises have come together to help craft – and then subject themselves to – regulatory regimes. For example, in the United States in the late nineteenth and early twentieth centuries, the major railroads helped create a federal regulatory regime.[77] More recently (and relevantly) the major pharmaceutical firms participated in the crafting of the Affordable Care Act, which reshaped their businesses in enormous ways. Even more recently, most automobile manufacturers worked closely with the Obama Administration in developing the detailed regulations underlying the sharp increase (discussed above) in the CAFE standards – to which all manufacturers will be subject in the coming decades.[78]

Response Criticized," *TIME*, January 25, 2015, available at: http://time.com/3681696/who-ebola-changes/. The Organization's much more rapid response to the spread of the Zika virus suggests that it means to make good on this promise.

[76] See Ruth Okediji, "When Should We Invent International Intellectual Property Rights" (2016) (forthcoming).

[77] See Gabriel Kolko, *Railroads and Regulation, 1877-1916* (1970).

[78] See National Highway Traffic Safety Administration, "President Obama Announces Historic 54.5 mpg Fuel Efficiency Standard" (July 29, 2011),

The obvious danger of this approach is "industry capture"; the resultant regime may serve the firms' interests more than the interests of the public at large. The histories of railroad regulation and insurance regulation contain many cautionary tales on this score. But the process that generated the recent revisions of the CAFE standards suggests that, if the relevant government officials participating in the planning process are vigilant, sacrifice of the public interest can be avoided.

Adoption of such an approach would make management of the system by a global organization (discussed in the preceding subsection) more realistic. If the major pharmaceutical firms were engaged in the planning of the regulatory regime, they might consent to its implementation by the WHO or a similar institution. After all, many of them are based in countries other than the United States. For various reasons, both symbolic and practical, they are likely to prefer that such a comprehensive regulatory system be managed by an institution more attuned to their needs than the U.S. Food and Drug Administration. If so, their support would increase sharply the likelihood that a treaty giving the WHO the necessary authority could be negotiated in a reasonable period of time.

The successful negotiation of the Marrakesh Treaty for the Visually Impaired[79] provides grounds for encouragement on this score. The principal negotiators of that agreement consulted extensively the businesses whose conduct it would regulate (principally, the publishers of educational materials) in addition to the representatives of the participating countries and the representatives of the persons who would benefit from it. The contributions of the leaders of the industry associations to the design of the system

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http://www.nhtsa.gov/About+NHTSA/Press+Releases/2011/President+Obama+Announces+Historic+54.5+mpg+Fuel+Efficiency+Standard.: "President Obama today announced a historic agreement with thirteen major automakers to pursue the next phase in the Administration's national vehicle program, increasing fuel economy to 54.5 miles per gallon for cars and light-duty trucks by Model Year 2025. The President was joined by Ford, GM, Chrysler, BMW, Honda, Hyundai, Jaguar/Land Rover, Kia, Mazda, Mitsubishi, Nissan, Toyota and Volvo – which together account for over 90% of all vehicles sold in the United States – as well as the United Auto Workers (UAW), and the State of California, who were integral to developing this agreement." For manifestations of the support the new standards have received from most manufacturers, see, e.g., "BMW Group supports Obama Administration's Proposal on Future National Fuel and Green House Gas Regulations," Press Release, July 29, 2011, https://www.press.bmwgroup.com/usa/pressDetail.html?title=bmw-group-supports-obama-administration's-proposal-on-future-national-fuel-and-green-house-gas&outputChannelId=9&id=T0118606EN_US&left_menu_item=node__2213; Andrew Ganz, "Marchionne: 54.5 mpg 'very doable' for Chrysler; will step down by 2016," Left Lane, August 3, 2011, http://www.leftlanenews.com/marchionne-54-5-mpg-very-doable-for-chrysler-but-will-step-down-by-2016.html; "Toyota Issues 2011 North American Environmental Report," November 9, 2011, http://corporatenews.pressroom.toyota.com/releases/toyota+issues+2011+north+american+environmental+report.htm; "GM Outlines Progress on Environmental Priorities," GM Corporate Newsroom, Press Release, July 11, 2013, http://media.gm.com/media/us/en/gm/news.detail.html/content/Pages/news/us/en/2013/Jul/0711-sustainability-rpt.html. By contrast, as one might expect, representatives of the oil industry were sharply critical of the tightened standards. See, e.g., Jude Clemente, "Higher CAFE Standards: 'There's No Such Thing as a Free Lunch,'" August 31, 2012, http://oilprice.com/Energy/Energy-General/Higher-CAFE-Standards-Theres-No-Such-Thing-as-a-Free-Lunch.html.

[79] The full title of the agreement is: *Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled*, http://www.wipo.int/treaties/en/ip/marrakesh/.

helps explain why it (in contrast to a treaty on traditional knowledge) emerged from the WIPO maelstrom fairly rapidly.[80] If we are able to produce an international agreement that, by modestly curbing copyrights, will help millions of visually-impaired persons, perhaps we could, by following a similar path, produce an international agreement that, by modestly curbing patent rights, would help tens of millions of people currently suffering from infectious diseases.

[80] This is not to suggest, of course, that negotiation of the treaty was easy. Quite the contrary. For an examination of some of the impediments and complexities, see William New, "Negotiators, Stakeholders Tell Tale of Wipo Marrakesh Treaty Negotiation, Look to Implementation," http://www.ip-watch.org/2013/09/20/negotiators-stakeholders-tell-tale-of-wipo-marrakesh-treaty-negotiation-look-to-implementation/., and the videotape of the conference described in that article, available at http://www.pijip-impact.org/events/marrakesh/. (A forthcoming book, edited by Justin Hughes, will describe the negotiation process in more detail.) Nor is it to suggest that ratification by the necessary number of countries is inevitable. See "Wipo Marrakesh Treaty in Force by Early 2016? Now Part of Bigger Un Process," http://www.ip-watch.org/2015/06/12/wipo-marrakesh-treaty-for-blind-readers-in-force-in-early-2016-now-part-of-bigger-un-process/. But the history of the agreement suggests that a free-standing treaty curbing intellectual-property rights for the benefit of a vulnerable global population is at least possible.

References

Adler, Matthew D. "Qalys and Policy Evaluation: A New Perspective." *Yale Journal of Health Policy, Law and Ethics* 6 (2006): 1.

Anand, Sudhir, and Kara Hanson. "Disability-Adjusted Life Years: A Critical Review." *Journal of Health Economics* 16 (1997): 685-702.

Anand, Sudhir, and Kara Swanson. "Dalys: Efficiency Vesus Equity." *World Development* 26, no. No. 2 (1998): 307-10.

Arnesan, T, and E Nord. "The Value of Daly Life: Problems with Ethics and Validity of Disability Adjusted Life Years." *British Medical Journal* 319 (1999): 1423-25.

Avi-Yonah, Reuven S., and David M. Uhlmann. "Combating Global Climate Change: Why a Carbon Tax Is a Better Response to Global Warming Than Cap and Trade." *Stanford Environmental Law Journal* 28 (2009): 3-.

Bagley, Margo. "Toward an Effective Indigenous Knowledge Protection Regime; Case Study of South Africa." *Centre for International Governance Innovation* (2018).

Berhane, Yermane, Alemayehu Worku, Abebe Bejiga, Liknaw Adamu, Wondu Alemayehu, Amir Bedri, Zegeye Haile*, et al.* "Prevalence of Trachoma in Ethiopia." *Ethiop. J. Health Dev.* 21, no. 3 (2007): 211-15.

Cachet, N., F. Hoakwie, S. Bertani, G. Bourdy, E. Deharo, D. Stien, E. Houel*, et al.* "Antimalarial Activity of Simalikalactone E, a New Quassinoid from Quassia Amara L. (Simaroubaceae)." *Antimicrobial Agents and Chemotherapy* 53, no. 10 (2009): 4393-98.

Cerri, Karin H., Martin Knapp, and Jose-Luis Fernandez. "Decision Making by Nice: Examining the Influences of Evidence, Process and Context." *Health Economics, Policy and Law* 9 (2014): 119-41.

Churcher, Thomas, Jean-Francois Trape, and Anna Cohuet. "Human-to-Mosquito Transmission Efficiency Increases as Malaria Is Controlled." *Nature Communications* 6 (2015): doi:10.1038/ncomms7054.

Cullenward, Danny. "Leakage in California's Carbon Market: Preliminary Trading Is Consistent with Expected Impact of Regulatory Changes." (2014).

Demsetz, Harold. "Information and Efficiency: Another Viewpoint." *Journal of Law and Economics* 12 (1969): 1.

DiMasi, Joseph A., and Henry G. Grabowski. "Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D." (2004).

Drahos, Peter. "Towards an International Framework for the Protection of Traditional Group Knowledge and Practice." In *UNCTAD-Commonwealth Secretariat Workshop on Elements of National Sui Generis Systems for the Preservation, Protection and Promotion of Traditional Knowledge, Innovations and Practices and Options for an International Framework*. Geneva, 2004.

Enserink, Martin. "Drug Could Kill Mosquitos When They Feast on Human Blood." *Science*, October 27, 2015 2015.

Fisher, William. "The Puzzle of Traditional Knowledge." *Duke Law Journal* 67 (2018).

Fisher, William W., III. *Promises to Keep: Technology, Law, and the Future of Entertainment.* Stanford University Press, 2004.

———. "Reconstructing the Fair Use Doctrine." *Harvard Law Review* 101 (1988 1988): 1661.

Gaffney, Alexander, and Michael Mezher. "Regulatory Explainer: Everything You Need to Know About Fda's Priority Review Vouchers." *Regulatory Affaird Professional Society* (July 2, 2015 2015).

Gamage, David, and Darien Shanske. "Using Taxes to Improve Cap and Trade, Part I: Distribution." *State Tax Notes* (2015).

Ghosh, Shubha. "Globalization, Patents, and Traditional Knowledge." *Columbia Journal of Asian Law* 17 (2003).

Goulder, Lawrence H., and Andrew R. Schein. "Carbon Taxes Vs. Cap and Trade: A Critical Review." (2013). http://ssrn.com/abstract=2308219.

Haworth, EA, R Booy, L Stirzaker, S Wilkes, and A Battersby. "Is the Cold Chain for Vaccines Maintained in General Practice?". *British Medical Journal* 307 (1993): 242-44.

Jones, Benji. "Every Country Is Negotiating a Plan to Save Nature. Except the Us." *Vox* (2024). Published electronically October 30, 2024. https://www.vox.com/down-to-earth/379295/cop16-biodiversity-why-us-global-treaty-protect-nature.

———. "Why the Us Won't Join the Single Most Important Treaty to Protect Nature." *Vox* (2021). Published electronically May 20, 2021. https://www.vox.com/22434172/us-cbd-treaty-biological-diversity-nature-conservation.

Kapczynski, Amy, and Talha Syed. "The Continuum of Excludability and the Limits of Patents." *Yale Law Journal* 122 (2014): 1900.

Kearney, Joseph D., and Thomas W. Merrill. "The Great Transformation of Regulated Industries Law." *Columbia Law Review* 98 (1998): 1323.

Klein, Catherine. "New Leadership Needed: The Convention on Biological Diversity." *Emory International Law Review* 31 (2016): 135.

Kolko, Gabriel. *Railroads and Regulation, 1877-1916.* 1970.

Lanjouw, Jean O. "A New Global Patent Regime for Diseases: U.S. And International Legal Issues." *Harvard Journal of Law and Technology* 16, no. 1 (2002).

———. "Outline of the Foreign Filing License Approach." (2004). http://www.who.int/intellectualproperty/submissions/ForeignFiling.Lanjouw.pdf.

Masur, Jonathan S., and Eric A. Posner. "Toward a Pigouvian State." *University of Pennsylvania Law Review* 164 (2015): 93.

Mattioli, Michael. "Power and Governance in Patent Pools." *Harvard Journal of Law and Technology* 27, no. 2 (2014): 421-65.

McAllister, Breck P. "Lord Hale and Business Affected with the Public Interest." *Harvard Law Review* 43 (1930): 759.

Murray, Brian C., Richard G. Newell, and William A. Pizer. "Balancing Cost and Emissions Certainty: An Allowance Reserve for Cap-and-Trade." *Resources for the Future* July 2008 (2008).

New, William. "Negotiators, Stakeholders Tell Tale of Wipo Marrakesh Treaty Negotiation, Look to Implementation." Published electronically September 20, 2013. http://www.ip-watch.org/2013/09/20/negotiators-stakeholders-tell-tale-of-wipo-marrakesh-treaty-negotiation-look-to-implementation/.

———. "Wipo Marrakesh Treaty in Force by Early 2016? Now Part of Bigger Un Process." Published electronically June 12, 2016. http://www.ip-watch.org/2015/06/12/wipo-marrakesh-treaty-for-blind-readers-in-force-in-early-2016-now-part-of-bigger-un-process/.

Newell, Richard G., and Nathan E. Wilson. "Technology Prizes for Climate Change Mitigation." *Resources for the Future* (2005).

Outterson, Kevin. "Should Access to Medicines and Trips Flexibilities Be Limited to Specific Diseases?". *American Journal of Law & Medicine* 34 (2008): 317-38.

Parker, Larry. "Climate Change and the Eu Emissions Trading Scheme (Ets): Looking to 2020." *Congressional Research Service. R41049* (2010).

Reidpath, DD, PA Allotey, A Kouame, and RA Cummins. "Measuring Health in a Vacuum: Examining the Disability Weight of the Daly." *Health Policy Plan* 18, no. 4 (2003): 351-56.

Scientists, Union of Concerned. "Stronger Fuel Economy Standards Are Needed to Clean up Combustion Vehicles." 2024.

Sorenson, Corinna, and Kalipso Chalkidou. "Reflections on the Evolution of Health Technology Assessment in Europe." *Health Economics, Policy and Law* 7 (2012): 25-45.

Vigneron, M., X. Deparis, E. Deharo, and G. Bourdy. "Antimalarial Remedies in French Guiana: A Knowledge Attitudes and Practices Study." *Journal of Ethnopharmacology* 98 (2005): 351-60.

Walley, Tom. "Drugs, Money and Society." *Journal of Clinical Pharmacology* 70, no. 3 (2010): 342-45.

Wara, Michael. "Instrument Choice, Carbon Emissions, and Information." *Michigan Journal of Environmental & Administrative Law* 4, no. 2 (2015): 261-302.

Wekundah, Joseph M. "Why Protect Traditional Knowledge." *African Technology Policy Studies* (2012).

Willyard, Cassandra. "Malaria Eradication: Blocking Transmission to Mosquitos." *The Pharmaceutical Journal*, January 7, 2015.

Wranrik, Dominika. "Healthcare Policy Tools as Determinants of Health-System Efficiency: Evidence from the Oecd." *Health Economics, Policy and the Law* 7 (2012): 197-226.

Wynberg, R. "Making Sense of Access and Benefit Sharing in the Rooibos Industry: Towards a Holistic, Just and Sustainable Framing." *South African Journal of Botany* 110 (2017): 39-51.

Yang, Tseming. "An Introduction to California's Greenhouse Gas Emission Trading Program." *Journal of Jiangsu University, Social Science Edition* (2013). http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2281821.