

Regulating Innovation

A Response to Ian Ayres and Amy Kapczynski, *Innovation Sticks: The Limited Case for Penalizing Failures to Innovate*, 82 U Chi L Rev 1781 (2015).

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INTRODUCTION

Professors Ian Ayres and Amy Kapczynski argue persuasively that threats to penalize private actors for failing to innovate can sometimes be more effective and efficient than either intellectual property rights or monetary incentives as mechanisms for inducing socially beneficial innovation.¹ This Essay suggests some modest adjustments of their analysis that might assist lawmakers when considering use of this important tool.

Part I summarizes (in terms slightly different from those used by Ayres and Kapczynski) the traditional theory of innovation economics and then situates their argument within that theory. Part II provides an example of the type of governmental intervention that Ayres and Kapczynski advocate: a mechanism that Professor Talha Syed and I have proposed as a way of improving the pattern of innovation in the pharmaceutical industry. Part III uses that example to offer a few modifications to Ayres and Kapczynski's analysis of the circumstances in which norms of this type would be appropriate.

I. INNOVATION ECONOMICS

The question of how governments could and should manage innovation has been addressed from four main angles.² Some

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¹ See generally Ian Ayres and Amy Kapczynski, *Innovation Sticks: The Limited Case for Penalizing Failures to Innovate*, 82 U Chi L Rev 1781 (2015).

² For discussions and comparisons of these four approaches, see William Fisher, *Theories of Intellectual Property*, in Stephen R. Munzer, ed., *New Essays in the Legal and Political Theory of Property* 168, 169–73 (Cambridge 2001); William W. Fisher III, *When Should We Permit Differential Pricing of Information?*, 55 UCLA L Rev 1, 20–37 (2007).

scholars and lawmakers, especially but not exclusively in common law jurisdictions, ask what forms of governmental action would best respect and enforce the natural rights of authors and inventors.³ Others, especially but not exclusively in civil law jurisdictions, ask what forms of governmental action would best protect the psychic bonds between artists (broadly defined) and their creations.⁴ Members of a third group ask what pattern of laws would most effectively foster a rich and diversified culture that offers all persons opportunities for human flourishing.⁵ Last but not least, many scholars and lawmakers, adopting a utilitarian perspective, seek to identify the pattern of laws that would most efficiently induce socially beneficial innovation and distribute the fruits thereof.⁶

For the most part, Professors Ayres and Kapczynski confine themselves to the utilitarian approach—and in this Essay I will do so as well. As they suggest, the heart of that approach is the proposition that “information is a public good; as such, it is both nonrivalrous and nonexcludable, and it is difficult to produce in competitive markets absent some form of government intervention.”⁷ They contend that most scholars who adopt this perspective concentrate on the relative merits of three tools that governments can employ to offset the tendency of information to be produced at socially suboptimal levels: intellectual property rights, grants awarded to potential innovators *ex ante* to induce them to innovate, and prizes awarded to successful innovators *ex post*.⁸ (They then lump grants and prizes together as “nontraditional carrots.”)⁹ Their principal thesis is that “innovation sticks” should be added to this quiver.¹⁰

The ways in which the four approaches have been brought to bear on copyright law are discussed in lectures 2, 4, and 10 of the CopyrightX lecture series. See *CopyrightX* (Harvard Law School, Jan 24, 2016), archived at <http://perma.cc/E7YH-CEK3>.

³ See, for example, Eric Maughan, *Protecting the Rights of Inventors: How Natural Rights Theory Should Influence the Injunction Analysis in Patent Infringement Cases*, 10 *Georgetown J L & Pub Pol* 215, 229–34 (2012).

⁴ See, for example, Gregory S. Alexander and Eduardo M. Peñalver, *An Introduction to Property Theory* 200–01 (Cambridge 2012).

⁵ See, for example, Molly Shaffer Van Houweling, *Distributive Values in Copyright*, 83 *Tex L Rev* 1535, 1548 (2005).

⁶ See Adam Moore and Ken Himma, *Intellectual Property* § 3.2 (Stanford Encyclopedia of Philosophy, Sept 22, 2014), archived at <http://perma.cc/TGU9-WNA5> (“In terms of ‘justification,’ modern Anglo-American systems of intellectual property are typically modeled as incentive-based and utilitarian.”).

⁷ Ayres and Kapczynski, 82 *U Chi L Rev* at 1790 (cited in note 1).

⁸ *Id.* at 1790–91.

⁹ *Id.* at 1790.

¹⁰ *Id.* at 1807–12.

Ayres and Kapczynski's summary of the traditional utilitarian approach is entirely accurate so far as it goes, but it underplays two related aspects of that approach. First, many scholars have argued persuasively that the severity of the risk that innovation will be underproduced absent government intervention varies sharply by field. The risk is especially severe in contexts where:

- (a) innovation is especially costly;¹¹
- (b) the likelihood of failure is high;¹²
- (c) the marginal costs of producing embodiments of the innovation in question are low;¹³
- (d) innovations may be easily discerned by reverse engineering embodiments thereof;¹⁴ or
- (e) innovations have strong positive externalities.¹⁵

On the other side of the ledger, the risk is less severe (or altogether absent) in contexts where:

- (a) lead time or custom allows innovators to recover the costs of innovation before they must face competition;¹⁶

¹¹ See Will Rinehart, *Intellectual Property Underpinnings of Pharmaceutical Innovation: A Primer* (American Action Forum, July 29, 2014), archived at <http://perma.cc/X2PV-J56U>.

¹² See Marc Labonte, *The Size and Role of Government: Economic Issues* *13 (Congressional Research Service, June 14, 2010), archived at <http://perma.cc/WU6R-HDDH>.

¹³ See Thorsten Käseberg, *Intellectual Property, Antitrust and Cumulative Innovation in the EU and the US* 12 (Hart 2012) (noting that, absent IP laws, the incentive to innovate is inadequate in areas in which “the costs of copying or imitating” an innovation are low).

¹⁴ See Jon Chally, Note, *The Law of Trade Secrets: Toward a More Efficient Approach*, 57 Vand L Rev 1269, 1273–74 (2004) (noting that “benefits accruing to innovators . . . continue only as long as innovators [can] keep this information secret” and that, absent an expectation of maintaining secrecy, “[r]ational actors would be deterred from developing information at the rate it is currently developed”).

¹⁵ See Joshua C. Hall, *Positive Externalities and Government Involvement in Education*, 21 J Priv Enterprise 165, 165 (2006) (“[W]here [] production of a good produces positive externalities, the market price of the good will not reflect its true value and an underproduction of the good will occur.”); Jonathan M. Barnett, *Property as Process: How Innovation Markets Select Innovation Regimes*, 119 Yale L J 384, 400–01 (2009).

¹⁶ See Stephen Breyer, *The Uneasy Case for Copyright: A Study of Copyright in Books, Photocopies, and Computer Programs*, 84 Harv L Rev 281, 299–302 (1970).

- (b) self-help measures (such as secrecy, encryption, or private agreements¹⁷) enable innovators to increase the “excludability” of their innovations;¹⁸
- (c) nonmonetary motivations (for example, desires for prestige, fame,¹⁹ or academic tenure; the norms of scientific inquiry;²⁰ or the pleasures associated with creativity, either solitary or collaborative²¹) provide adequate incentives for innovation; or
- (d) innovation is supported by nongovernmental actors, such as aristocrats, philanthropists, or foundations.²²

To illustrate, all five of the exacerbating factors and none of the mitigating factors apply to the development of new pharmaceutical products (at least of so-called small molecules). It is thus not surprising that empirical studies attest to the importance of governmental intervention in that context.²³ Arguably, a similar combination of multiple exacerbating factors and minimal mitigating factors can be found in the context of automobile safety, the field addressed in the last part of Ayres and Kapczynski’s article.²⁴ By contrast, innovation in the contexts of computer software, recorded music, fashion, and trade books is characterized by fewer of the exacerbating circumstances and more of the mitigating circumstances.²⁵ The need for governmental intervention

¹⁷ See, for example, *Terms & Conditions of Use for the LexisNexis Services* §§ 1.1(f), 1.3 (LexisNexis, Sept 1, 2010), archived at <http://perma.cc/AWK3-PSNA>.

¹⁸ See Lee Kovarsky, *A Technological Theory of the Arms Race*, 81 Ind L J 917, 927–31 (2006).

¹⁹ See Michael Madow, *Private Ownership of Public Image: Popular Culture and Publicity Rights*, 81 Cal L Rev 125, 211–12 (1993).

²⁰ See John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 Emory L J 101, 134 (2001); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 Nw U L Rev 77, 92 (1999).

²¹ See generally Yochai Benkler, *Coase’s Penguin, or, Linux and The Nature of the Firm*, 112 Yale L J 369 (2002).

²² See F.M. Scherer, *The Innovation Lottery*, in Rochelle Cooper Dreyfuss, Diane L. Zimmerman, and Harry First, eds, *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* 3, 19 (Oxford 2001) (discussing payments received by classical music composers).

²³ See, for example, Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* *2 (NBER Working Paper Series, Feb 2000), archived at <http://perma.cc/SBB2-J86L>.

²⁴ See Ayres and Kapczynski, 82 U Chi L Rev at 1830–51 (cited in note 1).

²⁵ See Breyer, 84 Harv L Rev at 306 (cited in note 16) (describing the optimal innovative environment in the trade books market).

to stimulate socially optimal levels of innovation in those areas is thus much less clear.²⁶

Next, the traditional model of innovation economics identifies two ways in which governments can (and do) respond to the risk of underproduction in addition to the three ways stressed by Ayres and Kapczynski. First, in some contexts, governments engage in innovation themselves. For example, in the United States, much research in the fields of space travel, improvements to agriculture, and mental health has been undertaken by government agencies. Second, governments sometimes stimulate innovation by reinforcing the self-help strategies that private innovators employ to increase the excludability of their creations. Examples of this approach include: trade-secrecy laws,²⁷ boat-hull protection laws, prohibitions on the circumvention of technological protection measures,²⁸ and interpretations of contracts in ways that disfavor nonpermissive uses of innovations.²⁹ The classic catalogue of governmental strategies thus includes five options: (1) governmental research, (2) grants, (3) prizes, (4) intellectual property laws, and (5) legal reinforcement of self-help practices.³⁰

As Ayres and Kapczynski observe, most scholars do not contend that any one of these strategies is best in all circumstances.³¹ Rather, each strategy has distinctive strengths and weaknesses that make it more or less appropriate in different settings.³²

²⁶ See generally Yochai Benkler, *The Wealth of Networks: How Social Production Transforms Markets and Freedom* (Yale 2006). See also Kal Raustiala and Christopher Sprigman, *The Piracy Paradox Revisited*, 61 *Stan L Rev* 1201, 1212 (2009); James Bessen and Robert M. Hunt, *An Empirical Look at Software Patents*, 16 *J Econ & Mgmt Strategy* 157, 170 (2007); Breyer, 84 *Harv L Rev* at 307 (cited in note 16).

²⁷ See generally, for example, Economic Espionage Act of 1996, Pub L No 104-294, 110 Stat 3488.

²⁸ See, for example, Digital Millennium Copyright Act § 103(a), Pub L No 105-304, 112 Stat 2860, 2863–76 (1998), codified as amended at 17 USC § 1201 et seq (providing penalties for circumventing copyright protection systems); Urs Gasser and Michael Girsberger, *Transposing the Copyright Directive: Legal Protection of Technological Measures in EU-Member States; A Genie Stuck in the Bottle? **6 (Berkman Center for Internet and Society at Harvard Law School, Nov 30, 2004), archived at <http://perma.cc/UKE2-PSDD>; *Trans-Pacific Partnership* ch 18, Art 18.68 (Office of the United States Trade Representative), archived at <http://perma.cc/FF64-SUMM>.

²⁹ See, for example, *ProCD, Inc v Zeidenberg*, 86 F3d 1447, 1453–55 (7th Cir 1996).

³⁰ See, for example, William W. Fisher III, *Promises to Keep: Technology, Law, and the Future of Entertainment* 199–201 (Stanford 2004).

³¹ See Ayres and Kapczynski, 82 *U Chi L Rev* at 1790–96 (cited in note 1).

³² See Nancy Gallini and Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, in Adam B. Jaffe, Josh Lerner, and Scott Stern, eds, 2 *Innovation Policy and the Economy* 51, 65–69 (MIT 2002); Amy Kapczynski and Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 *Yale L J* 1900, 1903 (2013) (arguing that some socially valuable “information goods [] are difficult to exclude even in

Against this backdrop, the best interpretation of the contribution made by Ayres and Kapczynski's article to the existing literature is as follows: when deciding how to stimulate innovation in a field in which some form of governmental intervention is warranted, lawmakers should consider, in addition to the five traditional options, a sixth approach—compelling actors to innovate in socially beneficial ways. This thesis is both convincing and important. The only respects in which Ayres and Kapczynski's argument could be improved concern the advantages and disadvantages of the approach they highlight, which affect its suitability for particular settings. Consideration of those advantages and disadvantages could be enhanced by an example, to which we now turn.

II. REORIENTING PHARMACEUTICAL RESEARCH

As mentioned above, the development of new pharmaceutical products is one of the fields of innovation in which governmental support is most necessary. It is thus not surprising that the governments of all developed countries attempt in some way to stimulate research in that area. In the United States, the federal government does so in three ways: It spends roughly \$3 billion per year on basic research conducted in government laboratories that is aimed at improving human health.³³ It makes grants totaling roughly \$24 billion per year to universities and other nongovernmental entities to support health-related research.³⁴ And through the use of patent law, data-exclusivity rules, and market-exclusivity rules, it enables pharmaceutical firms, for limited periods of time, to charge prices well above the marginal costs of producing new products—thus inducing the firms to engage in research intended to generate such products.³⁵ Exactly how much money the firms in fact spend on R & D is hotly contested, but the sum is almost certainly more than the roughly \$30 billion per year

the presence of patents” and thus that governmental support for the production of such goods should rely on other tools in the quiver).

³³ See *Extramural and Intramural Research Questions and Answers* (National Institute of Allergy and Infectious Diseases, Aug 11, 2015), archived at <http://perma.cc/TX3D-CZ65> (“Out of NIH’s approximately \$30.3 billion budget for FY 2015, about 10 percent was slated for intramural research.”).

³⁴ See *NIH Awards by Location & Organization* (National Institutes of Health, Dec 30, 2015), archived at <http://perma.cc/5FYB-Y3CD>.

³⁵ See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 *Mich Telecomm & Tech L Rev* 345, 359–60 (2007).

spent by the government.³⁶ In short, to enhance innovation in this field, the US government currently relies on a combination of the first, second, and fourth of the five approaches summarized in the preceding Part.

The total amount of research induced by this combination of strategies is formidable. However, the pattern of research that it generates deviates in several respects from the pattern that would be socially optimal. Relatively speaking, too many resources are devoted to generating so-called “me-too” drugs and modest improvements of extant drugs, while too few resources are devoted to drugs that take a long time to create or test (such as drugs that are focused on early-stage cancers or cancer prevention³⁷ and drugs that target diseases afflicting the central nervous system³⁸) and to vaccines or therapies aimed at infectious diseases common in developing countries but not in developed countries.³⁹

A growing body of literature proposes ways of reducing these biases. One of the most promising options is to make increased use of the third of the five approaches summarized above: awarding prizes to successful innovators.⁴⁰ A less traditional approach involves more deliberate efforts to manage the market for pharmaceutical products—which indirectly affects the capacity of intellectual property rights to stimulate research. The US government already does this clumsily—for example, by subsidizing

³⁶ See Richard Harris, *U.S. Funding of Health Research Stalls as Other Nations Rev Up* (NPR, Jan 15, 2015), archived at <http://perma.cc/JYS2-5ND2> (arguing that private medical-device, biotechnology, and pharmaceutical firms are spending roughly \$68 billion per year on R & D); *Extramural and Intramural Research Questions and Answers* (cited in note 33) (approximating the National Institutes of Health’s budget as \$30.3 billion for FY 2015).

³⁷ See Eric Budish, Benjamin N. Roin, and Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 *Am Econ Rev* 2044, 2080–82 (2015).

³⁸ See generally Dennis W. Choi, et al, *Medicines for the Mind: Policy-Based “Pull” Incentives for Creating Breakthrough CNS Drugs*, 84 *Neuron* 554 (2014).

³⁹ See William W. Fisher III and Talha Syed, *Infection: The Health Crisis in the Developing World and What We Should Do about It* Introduction at *18–20 (Stanford, forthcoming 2017), online at <http://cyber.law.harvard.edu/people/ffisher/Infection.htm> (visited Mar 6, 2016).

⁴⁰ See generally *Welcome to the Health Impact Fund* (Health Impact Fund), archived at <http://perma.cc/BSSA-RKX4>; James Love, *Prizes to Stimulate Innovation* (Knowledge Ecology International, Aug 12, 2009), archived at <http://perma.cc/V9SY-7BJV>; William W. Fisher and Talha Syed, *A Prize System as a Partial Solution to the Health Crisis in the Developing World*, in Thomas Pogge, Matthew Rimmer, and Kim Rubenstein, eds, *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* 181 (Cambridge 2010). See also Fisher and Syed, *Infection* ch 5 (cited in note 39). For criticism of this approach, see generally Benjamin N. Roin, *Intellectual Property versus Prizes: Reframing the Debate*, 81 *U Chi L Rev* 999 (2014).

private insurance plans (which increases the revenues that pharmaceutical firms can earn by generating the types of drugs sought by the subscribers to those plans) and by using its power as a monopsonist to drive down the prices of vaccines aimed at childhood diseases (which decreases incentives to develop new vaccines).⁴¹ As Rachel Sachs argues, the government could use its power in this regard much more precisely—for example, by increasing the rates at which Medicaid reimburses drug suppliers for types of drugs that are disfavored under the current regime.⁴²

Yet another approach would rely not on monetary incentives but on regulations to alter the pattern of research in more socially beneficial directions. In a forthcoming book, Professor Syed and I propose a regulation of this sort. In brief, it would work as follows: All pharmaceutical firms would be required (as a condition of permission to sell their products in the United States) to achieve each year a minimum social-responsibility index. Each firm's index would be a ratio, the numerator of which would consist of the aggregate health benefits (measured in "disability adjusted life years"—commonly known as "DALYs"⁴³) generated during the previous year through the distribution and consumption of the firm's products, and the denominator of which would consist of the firm's gross revenues (or some other measure of the firm's income). DALY "credits" would be both bankable and tradable.⁴⁴ Various penalties might be employed (separately or in combination) to encourage compliance with the requirement, including fines, an increase in the ratio that a delinquent firm must reach in the following year, and compulsory licensing of some of the firm's patents.

The information necessary to measure the numerators of these ratios could be obtained without undue difficulty by combining (1) the pharmacoeconomic data already generated by the British public health agency, the National Institute for Health

⁴¹ See Matt Baumann, *What's behind Vaccine Shortages?* (National Center for Policy Analysis, Apr 29, 2009), archived at <http://perma.cc/CS2V-H5J7>.

⁴² See Rachel E. Sachs, *Prizing Reimbursement: Prescription Drug Reimbursement as Innovation Incentive* *40–55 (unpublished manuscript, Nov 25, 2015) (on file with author).

⁴³ See *Metrics: Disability-Adjusted Life Year (DALY)* (World Health Organization), archived at <http://perma.cc/55TP-LW87>:

One DALY can be thought of as one lost year of "healthy" life. The sum of these DALYs across the population, or the burden of disease, can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability.

⁴⁴ See Fisher and Syed, *Infection* at ch 6 (cited in note 39).

and Care Excellence, and similar organizations elsewhere in the world concerning the marginal health benefits of each drug (as compared to drugs already available when each drug was first introduced);⁴⁵ (2) data already collected by the World Health Organization and other institutions concerning the global burdens of the diseases targeted by each drug;⁴⁶ and (3) data supplied by the firms themselves and by health-care providers concerning the numbers of each of their products consumed by patients (not merely sold). The information necessary to measure the denominators could be obtained without undue difficulty from the firms' financial reports.

A firm could satisfy its obligation under this regime in any of a variety of ways: by supplementing its portfolio of R & D projects to include projects focused on products capable of generating large health benefits (for example, vaccines and therapies aimed at neglected diseases); by altering its business-development policies to acquire more companies that have developed such products; by lowering the prices and thus increasing the consumption of the firm's extant products that have large health benefits; by collaborating with public health agencies or NGOs in developing countries to ensure that the firm's products are effectively delivered to patients in those countries; by altering the formulations of its products to make them easier to distribute in countries lacking "cold chains"⁴⁷ or other modern distribution channels; or by purchasing DALYs from firms whose products have greater health benefits.

The regulation we advocate would have several advantages: It would capitalize on the informational advantages enjoyed by private firms by permitting each firm to select the most cost-

⁴⁵ See Michael Rawlins, David Barnett, and Andrew Stevens, *Pharmacoeconomics: NICE's Approach to Decision-Making*, 70 *Brit J Clin Pharmacology* 346, 347 (2010):

[The National Institute for Health and Care Excellence's] preferred measure of cost-effectiveness is the incremental cost-effectiveness ratio (ICER). This relates the increased marginal gain in health, expressed as the quality-adjusted life year (QALY), to the increased (or decreased) marginal costs less the savings attributable to the use of the product.

(citation omitted). See also Lesley Owen, et al, *The Cost-Effectiveness of Public Health Interventions*, 34 *J Pub Health* 37, 38–39 (2011).

⁴⁶ See *Global Health Observatory Data Repository: Burden of Disease* (World Health Organization), archived at <http://perma.cc/2HMP-P6DH>; *Global Burden of Disease (GBD)* (Institute for Health Metrics and Evaluation), archived at <http://perma.cc/7G7M-R8W6>.

⁴⁷ E.A. Haworth, et al, *Is the Cold Chain for Vaccines Maintained in General Practice?*, 307 *Brit Med J* 242, 242 (1993) (defining a cold chain as "a prescribed temperature range during distribution from manufacture to use").

effective way of meeting its obligations. It would be flexible, enabling firms to alter course whenever more-efficient ways of satisfying their obligations become apparent. The ability to buy or sell DALYs would ensure that the firms best able to contribute to public health would do so. Finally—stepping outside the utilitarian frame for a moment—the visibility of the price at which DALYs are traded in this regime would foster a culturally beneficial public conversation concerning the value that we, collectively, place on healthy human life.

To be sure, the proposed regulation would have drawbacks. In particular, the DALY metric is far from perfect as a way of estimating health benefits.⁴⁸ And the political will to increase the mandatory ratio to provoke additional health benefits would be hard to come by. But, in combination with some of the other strategies discussed above, it would have much to recommend it.

III. RECONSIDERING “STICKS”

As should be apparent, the proposal just summarized is an example of the general strategy advocated by Professors Ayres and Kapczynski. In much the fashion they urge, our proposal would impose on private parties obligations to innovate in socially beneficial directions—and it would penalize them for failing to do so. Indeed, our proposal was inspired by the (partial) success of the Corporate Average Fuel Economy (CAFE) regime—which also appears to have inspired their proposal. For that reason, our proposal lends additional credibility to Ayres and Kapczynski’s argument (at least if one is persuaded by our defense of the proposal).

However, our application of the approach they commend casts doubt on three aspects of Ayres and Kapczynski’s analysis of the contexts in which their approach might be more or less appropriate. The first such aspect concerns the complexity of the

⁴⁸ For discussion of its limitations, see Dominika Wranik, *Healthcare Policy Tools as Determinants of Health-System Efficiency: Evidence from the OECD*, 7 *Health Econ, Pol & L* 197, 205 (2012) (summarizing the literature that is critical of DALYs); Daniel D. Reidpath, et al, *Measuring Health in a Vacuum: Examining the Disability Weight of the DALY*, 18 *Health Pol & Planning* 351, 355 (2003) (attacking one of the technical assumptions of DALYs as “demonstrably flawed”); Trude Arnesen and Erik Nord, *The Value of DALY Life: Problems with Ethics and Validity of Disability Adjusted Life Years*, 319 *Brit Med J* 1423, 1425 (1999) (criticizing the DALY “valuation of human beings according to their functional capacity”); Sudhir Anand and Kara Hanson, *DALYs: Efficiency versus Equity*, 26 *World Dev* 307, 309–10 (1998) (“DALYs are an inequitable measure of aggregate ill-health and an inequitable criterion for resource allocation.”); Sudhir Anand and Kara Hanson, *Disability-Adjusted Life Years: A Critical Review*, 16 *J Health Econ* 685, 699–700 (1997) (identifying problems with “[r]esource allocation based on the DALY framework”).

problems that their approach is capable of managing sensitively. Ayres and Kapczynski suggest that grants and prizes “seem to have informational advantages [over sticks] when upper limits to performance are hard to define.”⁴⁹ They continue:

Put more generally, as [Professors Gerrit De Geest and Giuseppe Dari-Mattiacci] have noted in recent work, sticks may be best in “simple” settings, in which “citizens have more or less equal compliance costs and the lawmaker knows these costs and asks for equal efforts from all citizens.”⁵⁰

A mandatory social-responsibility index for pharmaceutical firms, of the sort Professor Syed and I have proposed, seems inconsistent with these assertions. Overcoming the existing biases (viewed from the standpoint of global social welfare) in the current pattern of innovation with respect to pharmaceutical products is plainly not a “simple” problem. Moreover, the costs of improving the aggregate pattern of research for the various firms operating in this setting are highly unequal, and lawmakers do not have good information concerning the magnitude of those costs. That none of these circumstances impairs the viability of our proposal undermines Ayres and Kapczynski’s (and De Geest and Dari-Mattiacci’s) analysis of the limitations of the approach.

A possible reason for Ayres and Kapczynski’s exaggeration of the impediments to the adoption of their own strategy stems from their comparative disinterest in variants of that strategy that permit some actors to pay other actors to satisfy their obligations. The bankable and tradable nature of DALYs in the regime that Syed and I propose is an illustration of that option—and helps to explain why it seems immune to this line of criticism.

A second respect in which Ayres and Kapczynski are skeptical concerning the applicability of their own argument also seems unpersuasive. They argue:

Innovation sticks would seem for one reason in particular to require more information than do nontraditional carrots: with sticks, the government needs good information about the potential set of innovators—but because people will not self-nominate for sticks, governments must identify potential innovators without their help.⁵¹

⁴⁹ Ayres and Kapczynski, 82 U Chi L Rev at 1803 (cited in note 1).

⁵⁰ Id, quoting Gerrit De Geest and Giuseppe Dari-Mattiacci, *The Rise of Carrots and the Decline of Sticks*, 80 U Chi L Rev 341, 345 (2013).

⁵¹ Ayres and Kapczynski, 82 U Chi L Rev at 1802 (cited in note 1).

This consideration would seem to limit application of their approach to industries dominated by a relatively small number of firms that can be reliably identified by regulators. The automobile industry, on which they concentrate, would seem to satisfy this requirement.⁵² By contrast, the pharmaceutical industry would not. To be sure, the set of major pharmaceutical firms is small (and shrinking).⁵³ But the set of potential innovators would also have to include the myriad biotechnology start-ups from which most new products now come.⁵⁴ Members of the latter group would be much harder to identify and monitor. The reason why this circumstance is not problematic is that, under our proposed regime, compliance with the social-responsibility index is a condition of access to the US pharmaceutical market. Because that market is roughly 40 percent of the global market for drugs,⁵⁵ we can expect most if not all firms (big and small) to comply. To generalize the point: if potential innovators must comply with a regulation in order to obtain access to something over which the government has control, then those innovators *will* self-identify and the informational problem suggested by Ayres and Kapczynski will not obtain.

The foregoing point leads to a terminological suggestion: Ayres and Kapczynski should consider calling the type of governmental intervention that they advocate something other than “sticks.” As they acknowledge, their preferred label is vulnerable to Professor Wendy Gordon’s objection that “[o]ne can verbally transform most benefit questions into ‘harms’ and vice versa by

⁵² See Benjamin Zhang, Mike Nudelman, and Skye Gould, *These 14 Giant Corporations Dominate the Global Auto Industry* (Business Insider, Feb 19, 2015), archived at <http://perma.cc/26BV-A7FQ>.

⁵³ See *The Role of Competition in the Pharmaceutical Sector and Its Benefits for Consumers* *7 (United Nations Conference on Trade and Development, Apr 27, 2015), archived at <http://perma.cc/4HDF-BU3A> (describing a recent “wave of mergers and acquisitions where large research and development-based transnational corporations are buying generic companies with potential new drug pipelines”).

⁵⁴ See *Fever Rising* (Economist, Feb 15, 2014), archived at <http://perma.cc/S94F-WH36> (describing large pharmaceuticals firms as dependent on the growing number of small firms for innovation and profitability); Max Nisen, *Forget the Tech Bubble. It's the Biotech Bubble You Should Worry About* (Quartz, Feb 19, 2015), archived at <http://perma.cc/5W7R-F7TP> (noting a precipitous increase in biotechnology initial public offerings). But see *Pharmaceutical and Life Sciences Deals Insights Quarterly: Q3 2015* *1 (PwC, Oct 2015), archived at <http://perma.cc/CF3P-TKVW> (describing consolidation as a “consistent theme” for the pharmaceutical and life sciences industry during 2015).

⁵⁵ The figure of roughly 40 percent can be inferred from the fact that the United States accounts for 94 percent of pharmaceutical sales in North America, which in turn accounts for about 46 percent of global pharmaceutical sales. See Kristina M. Lybecker, *The Economics of Access to Medicines: Meeting the Challenges of Pharmaceutical Patents, Innovation, and Access for Global Health*, 53 Harv Intl L J Online 25, 27 (2011).

juggling the baseline from which effects are measured.”⁵⁶ But they contend that this observation can be neutralized by focusing on the ways in which norms of different sorts are viewed by the actors who are subject to them:

We readily acknowledge that whether something is seen as a carrot or a stick depends on the baseline framing, which can, in some instances, be malleable. Then again, it is the rare mousetrap manufacturer who views the failure of the government to grant a twenty-year monopoly on a new product as a punishment for not coming up with a better trap. And it is the rare automobile manufacturer who views a CAFE fine as the absence of a reward. . . . [P]otential inventors volunteer for carrots—for example, when they apply for a patent. Potential inventors who ultimately fail are unlikely to self-nominate to bear the pain of the stick.⁵⁷

The mandatory social-responsibility index that Syed and I have proposed, an example of the type of norm that Ayres and Kapczynski advocate, suggests that Gordon’s objection cannot be so readily evaded. Adoption of our proposal would be unlikely to discourage a significant number of pharmaceutical firms from “self-nominating”—that is, from seeking permission to market their products in the United States. Although the imposition of the regulation could be expected to diminish somewhat the revenue of a subset of firms (specifically, those that must either alter their business practices or buy DALYs from other firms), the diminution would not be so great as to prompt many (if any) of the existing players to exit the market—or to discourage new firms from entering. The reason, of course, is that the profits available in the pharmaceutical industry are high.⁵⁸ In turn, the reason that those profits are high is that the intricate combination of laws that govern the industry in the United States—a special version

⁵⁶ Ayres and Kapczynski, 82 U Chi L Rev at 1784 (cited in note 1), quoting Wendy J. Gordon, *Of Harms and Benefits: Torts, Restitution, and Intellectual Property*, 21 J Legal Stud 449, 451 (1992).

⁵⁷ Ayres and Kapczynski, 82 U Chi L Rev at 1784–85 (cited in note 1).

⁵⁸ See Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits* (BBC, Nov 6, 2014), archived at <http://perma.cc/5BHQ-VBVR>; *Pharmaceutical Industry* (World Health Organization), archived at <http://perma.cc/DT7L-653E> (“The 10 largest drug[] 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%.”).

of the patent system,⁵⁹ a set of safety and efficacy regulations intertwined with the patent system,⁶⁰ renunciation of the kind of price regulation employed by most European countries,⁶¹ prohibitions on Medicare using its bargaining power to drive down the price of drugs (when combined with generous formulary requirements), and so forth—affords industry participants generous opportunities to earn money. The regulation we propose thus functions less as a penalty than as a condition of access to this lucrative regulated industry.

Generalizing from this example, I suggest that a better label for the type of norm that Ayres and Kapczynski highlight is “regulation.” That term describes more fairly than “sticks” efforts by governments to stimulate innovation through mandates rather than through either monetary incentives (grants or prizes) or legal protections against competition.

The principal purpose of this suggestion is to enhance precision in future scholarly analysis of the strategy that Ayres and Kapczynski have highlighted. But the change in nomenclature might also have some practical implications. To see those implications requires a bit of background. As Ayres and Kapczynski acknowledge, the valence of legal norms in the minds of persons subject to them matters. For instance, they argue, plausibly, that “[i]f actors are subject to loss aversion, . . . then sticks may be more powerful motivators than carrots, even if the fines and benefits are otherwise equivalent.”⁶² But how norms are perceived can have other effects as well. For example, actors are likely to regard a “stick” as more punitive than a condition placed on access to benefits or privileges—and thus are more likely to resent

⁵⁹ The primary reason that it is “special” is the Hatch-Waxman Act. See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food & Drug L J 187, 189–91 (1999).

⁶⁰ See Eisenberg, 13 Mich Telecomm & Tech L Rev at 347–48 (cited in note 35).

⁶¹ See Patricia M. Danzon and Michael F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries* (Health Affairs, Oct 29, 2003), archived at <http://perma.cc/YW6B-525J>.

⁶² Ayres and Kapczynski, 82 U Chi L Rev at 1800 (cited in note 1). Later in their article, the authors buttress and then refine this suggestion as follows: “[W]hen there are pervasive externalities or when the targets are nonmarket actors, sticks are likely to be a better innovation tool than nontraditional carrots.” Id at 1807–12.

it.⁶³ The latter effect might cause a norm seen as a stick to generate negative psychic externalities⁶⁴ that overwhelm its behavioral benefits.

Against this backdrop, renaming as “regulations” norms of the sort considered by Ayres and Kapczynski is potentially liberating. Recognition that such norms are not *inherently* sticks highlights the power that lawmakers may sometimes enjoy to influence the ways in which norms are perceived—both by the actors subject to them and by the public at large. In some cases, it may be better to characterize them as “sticks,” but in other cases, it may be more efficacious or appropriate to characterize them in some other way.⁶⁵

The way in which the Obama administration first secured and then publicized the recent revision of the CAFE standards for automobiles provides a suggestive illustration. The administration might have chastised automakers for continuing to produce gas-guzzlers and depicted the new standards as necessary to force them to stop degrading the earth’s climate. Instead, government agencies collaborated closely with the automakers when developing the new standards, and the administration announced the new standards with the automakers’ support. The press release revealing the standards made this posture explicit:

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

⁶³ See James Andreoni, William Harbaugh, and Lise Vesterlund, *The Carrot or the Stick: Rewards, Punishments, and Cooperation*, 93 Am Econ Rev 893, 901 (2003) (noting that the combination and availability of carrots and sticks “alter[] the ideals that they enforce” and that sticks may be perceived as “harsher conditional punishments when rewards are also available”).

⁶⁴ See Frank I. Michelman, *Property, Utility, and Fairness: Comments on the Ethical Foundations of “Just Compensation” Law*, 80 Harv L Rev 1165, 1214–15 (1967) (examining the role of psychic externalities, or “demoralization costs,” in influencing human action).

⁶⁵ Analogously, it is sometimes possible for a seller to craft and characterize a differential-pricing scheme either as a discount or as a surcharge, which affects the willingness of consumers to accept it. See Fisher, 55 UCLA L Rev at 13 (cited in note 2) (“[A] scheme that charges everyone a high standard price, but then gives some people a discount . . . is perceived as much less unfair than a functionally identical scheme that charges everyone a low standard price and then imposes on some people a surcharge.”); Daniel Kahneman, Jack L. Knetsch, and Richard Thaler, *Fairness as a Constraint on Profit Seeking: Entitlements in the Market*, 76 Am Econ Rev 728, 739 (1986) (“Discounts have the important advantage that their subsequent cancellation will elicit less resistance than an increase in posted price. A temporary surcharge is especially aversive because it does not have the prospect of becoming a reference price, and can only be coded as a loss.”).

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.

“This agreement on fuel standards represents the single most important step we’ve ever taken as a nation to reduce our dependence on foreign oil,” said President Obama. “Most of the companies here today were part of an agreement we reached two years ago to raise the fuel efficiency of their cars over the next five years. We’ve set an aggressive target and the companies are stepping up to the plate. By 2025, the average fuel economy of their vehicles will nearly double to almost 55 miles per gallon.”⁶⁶

In sum, the new standards were depicted not as “sticks” but as embodiments of collaboration between government officials and private actors. To be sure, the automakers’ participation in this depiction⁶⁷ most likely was not fully sincere; at least some of them probably sought to put a good face on a set of regulations they would have preferred to avoid. But they may have also seen in the new regime both practical advantages (increased latitude to develop—and charge for—new technologies) and an opportunity to improve their reputations. Whatever the reason, they helped popularize a conception of the new regime as a collaborative effort to address a social problem, rather than as a cattle prod.

⁶⁶ *President Obama Announces Historic 54.5 mpg Fuel Efficiency Standard* (National Highway Traffic Safety Administration, July 29, 2011), archived at <http://perma.cc/X7FB-LEQA>. See also *Remarks by the President on Fuel Efficiency Standards* (The White House, July 29, 2011), archived at <http://perma.cc/MX9F-JCHX>.

⁶⁷ See, for example, *GM Outlines Progress on Environmental Priorities* (General Motors, July 11, 2013), archived at <http://perma.cc/2HXG-FWSV>; *Toyota Issues 2011 North American Environmental Report* (Toyota, Nov 9, 2011), archived at <http://perma.cc/W3N9-2VKL>; Andrew Ganz, *Marchionne: 54.5 mpg “Very Doable” for Chrysler; Will Step Down by 2016* (Left Lane, Aug 3, 2011), archived at <http://perma.cc/5EDA-2WLL>; *BMW Group Supports Obama Administration’s Proposal on Future National Fuel and Green House Gas Regulations* (BMW Group, July 29, 2011), archived at <http://perma.cc/9J2X-ME3J>. By contrast, as one might expect, representatives of the oil industry were sharply critical of the tightened standards. See, for example, Jude Clemente, *Higher CAFE Standards: “There’s No Such Thing as a Free Lunch”* (OilPrice, Aug 31, 2012), archived at <http://perma.cc/S3HX-KTJS>.

The general point latent in this illustration is that lawmakers may have some degree of power over whether regulations designed to stimulate innovation are seen as “sticks,” as adjustments of systems of governmental benefits, or as something else. They should exercise that power thoughtfully when using this important tool.