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Research, Development, and the Availability of Health Care Products: The Market, Regulation, and Legal Liability

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It is a reasonable public policy goal to promote health and avoid policies that frustrate health. To adopt the general goal of promoting health tells us nothing about what means should or may be used to promote health, what means will be most effective in promoting health, or how the goal of promoting health ranks relative to other public policy goals such as promoting security. Some ways public policy may promote health include: providing incentives for healthful practices or disincentives for practices known or thought to harm health; encouraging innovation and production of new health care products and services; encouraging social structures that promote access to health care products and services; deterring the development and dissemination of harmful products and services; and deterring over-use or inappropriate use of collapsing goods and services, such as antibiotics and emergency department treatment. In the light of Thomas Magnell's argument that innovation is an important means for responding to problems of collapsing goods and hence for promoting health, the general claim that it is a reasonable public policy goal to promote health, and the observation that throughout history the development of new health care products often has reduced morbidity and led people to live longer lives, it is reasonable public policy to encourage the development and availability of new health care products.[1] Developing and disseminating new products risks new and unforeseen harms or threats to health. It is reasonable, therefore, for us to use public policy to seek to promote innovation and safety as part of our overall goal of promoting health.[2] We consider some ways in which our economic, regulatory, and legal environments can affect and can be shaped to promote the development and production of safe and effective health care products, deter the distribution of harmful products, and promote the availability of health care products after they have been developed.

1. Promoting Innovation

Developing new health care products typically requires significant investments of money and time. Which expenses should be included in the calculation of such costs how costs should be calculated are matters of substantive debate. For example, the Pharmaceutical Manufacturers and Researchers of America estimates that on average it costs about $802 million to develop a new drug.[3] Others estimate that costs are lower, perhaps significantly lower.[4] Some analyses suggest that the average cost may be higher than $802 million.[5] It is indisputable that significant funds typically are required to develop new products. Generally, for persons with funds to make money available for the development of new products, they must see the opportunity as an investment, they must be forced to fund research, such as through taxation, or they must choose to make voluntary charitable donations. It is an open question whether research funded solely through tax dollars and charitable contributions would yield less, as much, or more, innovation and how such a system would compare to the current United States system overall on the goal of promoting health. Where the profit motive is eliminated or highly restricted, as in systems in which research and development is centrally funded and controlled, or where significant price controls are in place, we would expect to see far less innovation.[6] We have not seen sustained, significant innovation of health care products for a wide range of health conditions result solely from publicly funded and directed enterprises or from nonprofit organizations.

Although there is much debate about whether it is true that innovation would decrease if the United States imposed price controls on pharmaceuticals, much like Canada and other nations do, and whether we would see a lower, higher, or equal level of innovation if drug, device, and vaccine development were placed solely in the hands of the United States federal government, we do see that there is more innovation in health care products in the United States than elsewhere.[7] It is worth asking what aspects of the United States context of product development contribute to this, and acknowledging that we do not know what would happen if we adopted another approach. While publicly funded research has been critical to the development of many products, it is not clear that without the input of money, energy, and risk from private industry, many such products would have been developed and made available to patients. For all that private industry may depend on and, some would claim, take advantage of publicly funded research, it succeeds in using ideas and knowledge to produce goods or services people want or need. Generally, government entities lack the same level and type of incentive, and perhaps

the resources, that private companies have to use scientific knowledge to produce consumer products.

The prospect of profit seems to be an important factor motivating investors to fund the development of new products. Market mechanisms facilitate the exchanges that result in profit and loss, and when market mechanisms rather than artificial controls determine the magnitude of profits and losses, there is great incentive to develop useful and desired products that respond to a population's needs or desires. Assuming that the profit motive matters, we observe that to be highly effective in motivating the infusion of new research and development dollars as well as recruiting and retaining talent, the prospect of overall profits must outweigh the expected losses, and intellectual property and technology transfer policies should be used to secure the interests of those who develop new products while protecting public interests.[8] Thus one way public policy can promote innovation is by preserving the opportunity for profit to provide incentives to individuals and firms to develop new health care products.

One of the ways public policy can interfere with profits, as already has been mentioned, is price controls. A number of authors have argued that it has been possible for Canada to impose price controls without grossly compromising the availability of new health care products because other markets, most notably the United States, sustain profitability, and because selling to the Canadian market at controlled prices results in more profits than refusing to sell and risking compulsory licensing.[9] Price controls have been blamed by some observers for already slowing the pace of innovation.[10] In the United States we effectively have a federal price control on routine childhood vaccines because of the Vaccines for Children program, whereby the federal government buys about fifty-five to sixty percent of all vaccines and thus serves as a single payer who sets the price, much like the Canadian government does with pharmaceutical products. This de facto price control on vaccines has been cited as one of the reasons the profitability of making and selling vaccines has declined.[11] This, in turn, has been named as one reason so few companies produce and sell vaccines in the United States, a circumstance that has resulted in shortages in recent years.[12] Were all markets to control prices artificially as Canada does, some observers have argued, we could see dramatic decreases in the profitability of pharmaceutical and biotech investments and hence in research and development of new products.[13] Others disagree.[14]

Public policy also can affect the prospect of profit through the regulation of products, which can increase the costs of developing new products, bringing them to market, and keeping them commercially

available. This is not to claim that regulations are unnecessary or completely contrary to overall public policy goals, including the goal of promoting health, but instead that we should recognize the impact the regulatory burden may have on research and development costs and product pricing. The impact of United States regulations on profits has been cited as partially responsible for the high cost of medications.[15] It also has been cited as being partially responsible for a lack of interest in producing certain types of products, such as vaccines.[16] As will become clear, securing other public policy goals, such as maintaining safety and ensuring the availability of certain health care products, may warrant mechanisms that could compromise the opportunity for profit. In evaluating the impact of regulation, price controls, or other mechanisms aimed at securing public policy goals, we should consider the overall effect on our general public policy goal of promoting health.

In the United States, the principal body that regulates health care products is the Food and Drug Administration, which has jurisdiction over food other than meat and poultry, prescription and non-prescription drugs, medical devices, biologics and vaccines, animal drugs and feed, blood products, tissues for transplantation, products that emit radiation, and cosmetics, as outlined in the Food, Drug, and Cosmetic Act and its amendments. The Food and Drug Administration imposes different levels of control over product development, marketing, and labeling to promote and protect public health. Competing underlying values and priorities affect how we evaluate various regulations or other potential impediments to innovation. We could argue that the fact that sometimes new safety concerns are attributed to products approved by the Food and Drug Administration after they are marketed is evidence of the need for more stringent regulations. According to this view, approval of the Food and Drug Administration should give us confidence in the safety and efficacy of products. We also could argue that it would be better to promote product safety through litigation and avoid regulatory burdens that sometimes make products widely used elsewhere unavailable in the United States. Persons who are more concerned with the extent to which the burden of obtaining approval of the Food and Drug Administration delays or prevents altogether the availability of useful products rather than the possibility that some unsafe products will be sold might hold such a view.

Discussions of government market manipulation and regulation often focus on the negative effect that price controls and regulations have on profits and potentially on innovation. Governments might manipulate markets and regulatory requirements to increase innovation. Assuming that the profit motive can be effective in promoting innovation and that

where there is likely to be a very small market for a product coupled with a high regulatory burden and the possibility of significant loss through products liability litigation, the United States government developed in the mid-1980s a mechanism to create the potential for profit where little or none otherwise exists, but where new health care products are needed. The Orphan Drug Act refers to a series of amendments to the Federal Food, Drug and Cosmetic Act that aim to make the development and sale of so-called orphan drugs, generally an unprofitable venture, profitable and thus promote innovation. An orphan drug is a product meant to treat a rare disease or condition, which in the 1984 Orphan Drug Act amendment are defined as "any disease or condition which (a) affects less than 200,000 persons in the U.S. or (b) affects more than 200,000 persons in the U.S. but for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for such disease or condition will be recovered from sales in the U.S. of such drug."[17]

The Orphan Drug Act is used to employ three mechanisms to promote innovation: "federal funding of grants and contracts for clinical trials of orphan products; tax credit of fifty percent of the clinical testing costs; and grant of an exclusive right to market the orphan drug for seven years from the date of FDA marketing approval."[18] Most people agree that it has succeeded in promoting innovation and the marketing of products to treat rare conditions, products that most likely would not have been developed and tested in its absence. The appropriateness of attempts to manipulate markets by artificially creating the possibility of profit and the extent to which they can succeed continue to be focus of substantive disagreement.[19] Moreover, some observers have criticized the Orphan Drug Act claiming that it can lead to excessive profits and high drug costs. For example, drugs that meet the criteria for the Orphan Drug Act may be useful in treating other, non-rare conditions making them highly profitable products whose manufacturers, some argue, do not deserve the special protections and advantages of the Orphan Drug Act.[20] Others contend that this problem is limited to only a few drugs and thus is not significant.[21] Nevertheless, the Orphan Drug Act demonstrates an awareness among policy makers in the United States that the potential for profit can promote innovation and of the impact legal, economic, and regulatory conditions can have on innovation. Mechanisms similar to the Orphan Drug Act have been recommended as means to encourage the development of new vaccines.[22]

A third factor that affects the overall potential for profit is products liability litigation. Litigation, or the threat of litigation, helps deter the development and dissemination of harmful products and also brings justice individuals who are harmed, as discussed below.[23] But, especially if

awards to plaintiffs do not appear to comport with the degree of injury or with the scientific evidence of causation, such litigation might hamper innovation. The extent to which such threats actually have slowed research and development of health care products in general is unclear. However, many have suggested that at least in certain markets, such as some vaccines, products liability litigation has hindered or could hinder the development of new products and the availability of already-developed products.[24] Others contest this claim.[25] To meet our public policy goal of promoting health, products liability systems should be structured to balance the interest of preserving the prospect of profit and our interest in deterring the development and dissemination of harmful products.

2. Maintaining Safety

Developing and disseminating new products carries the risk of harm to the people on whom they are tested in clinical research and the individuals who use them once they are marketed. As part of our overall goal of promoting health, we should aim public policy to aim at maintaining the safety of both groups of people. Efforts to maintain safety and identify risks impose costs that might serve as disincentives for innovation, raise the cost of products, or limit the availability of health care products. Nevertheless, in the light of our overall goal of promoting health, it would be unreasonable to abandon altogether the goal of maintaining safety. At the same time, efforts to promote health by maintaining safety must be considered in light of the effect they have on the possibility of promoting health through innovation and product availability.

The history of human research has taught us that human beings are capable of gross abuse and that ignorance and carelessness can result in grave harm to research participants. Both because of the overall goal of promoting health, including by maintaining safety, and because continued innovation of health care products depends on the willingness of humans to serve as research subjects, we have a public policy interest in protecting research subjects. In the United States, a series of requirements in the Code of Federal Regulations is used to protect the rights of persons to determine what will and will not be done to them, and to secure the relative safety of research subjects. In addition, the Office of Human Research Protections and the Food and Drug Administration routinely issue guidance on interpreting and applying the relevant sections of the Code of Federal Regulations. The regulations are not used to aim at maximally protecting subjects or at preventing any research that might result in harm to someone, because to do so would halt virtually all

biomedical research, making it impossible to evaluate the safety and efficacy of new products. This would subvert the overall goal of promoting health.

Such an approach has been subject to much criticism, including a concern that the Code of Federal Regulations does not offer sufficient protections.[26] There also is a concern that interpretations of it by institutional review boards are overly protective and restrictive, at least for certain types of research.[27] Judgments about the appropriateness of the United States system of human subjects protections, or any other system, depend on a number of factors, including what we believe persons may do to each other with and without permission, whether we hold that benefits to others justify risks to research subjects, what we believe competent adults may consent to, and what we believe may be done to non-competent human beings, such as children. Such judgments also depend on the priority we assign to the goals of promoting health through innovation and maintaining public safety.

Deterring the development and dissemination of harmful or dangerous products, products whose risks exceed their benefits, also is part of our general public policy goal of promoting health. Two principal mechanisms are employed to deter the development and dissemination of harmful products. The first is regulation of products to avoid bringing to market products that are considered too dangerous or not sufficiently effective, to ensure that the people have appropriate safety and efficacy information, and to restrict access to potentially dangerous but useful products. The second is litigation.

Regulation of health care products allows governments to prohibit widespread sale and use until it has been demonstrated that a product has a certain degree of efficacy, and until its safety profile has been established. It also enables governments to impose prescription requirements to restrict access to products and increase the likelihood that only persons for whom a product's benefits exceed its risks will use it. Prescription requirements also might prevent collapsing goods, such as the collapsing goods described by Magnell, from collapsing, thereby helping to foster overall health and safety in society.[28] For example, if prescription requirements can be used effectively to prevent the over-use of antibiotics, the development of antibiotic-resistant strains of bacteria may be slowed. A product's benefits must exceed its risks to individuals and society to meet our public policy goal of maintaining safety. The level and type of risks that are deemed acceptable and assessed as exceeding the benefits of a product depend to some extent on personal values and preferences as well as on the circumstances individuals face. For example, the Rotashield vaccine against rotavirus was withdrawn from markets in 1999 after one

year because it seemed that children who received the vaccine were at increased risk for intussusception, a condition in which portions of the bowel collapse or fold into each other, creating a bowel obstruction which is painful and life-threatening if not treated promptly. Some observers argued that perhaps Rotashield should have remained available for use in developing nations where the risk of death from vaccine-related intussusception was much lower than risk of death from rotavirus. The risk of intussusception associated with the vaccine was between one in four-thousand five-hundred and one in nine-thousand five-hundred in developed nations whereas the risk of death from rotavirus is approximately one in two hundred in developing nations. Rotashield had not been tested in developing nations and no safety and efficacy data were available for their populations. Because some vaccines have been found to be effective at different doses in developing versus developed nations, most notably oral polio, it could not be assumed that Rotashield data from developed nations could be transferred to developing nations.[29] Nor could it be assumed that the risks associated with the vaccine would be the same in a different population. Nevertheless, many observed that while the risks associated with Rotashield were not acceptable in developed nations, they might have been acceptable in developing nations because the risk of death from rotavirus is much greater there.

In evaluating the regulation of health care products, it is important to recognize that our goal of maintaining safety is a subset of our general goal of promoting health. If our primary aim in developing public policy were to maintain safety for safety's sake, we should impose extensive regulation and allow products to come to market only if and when they have been shown to have minimal risks associated with them.[30] Because our goal is to promote health, there is an interest in developing new health care products and making them available sooner rather than later, and not severely restricting product development and access through regulation. Similiarly, regulation can affect the potential for profit and hence the pace and scope of innovation. In our evaluation of regulatory schemes we should consider the effect of regulation on promoting and maintaining safety, as well as on innovation and product availability, all of which are aspects of our overall public policy goal of promoting health.

An important aspect of regulating health care products and determining which products may be brought to market, and when, is setting standards for how much testing must be done to establish the safety profile of a product. The more we value safety and the prevention of product-related injury over innovation, the more we will insist that clinical trials involve more subjects and last longer so that even rare risks and side effects can be identified.[31] As regulations are crafted and

implemented, policy makers should recognize that maintaining safety is only one aspect of our broader public policy goal of promoting health. As higher standards for ensuring safety are imposed, it is likely that the pace of innovation will be slower, that the development of new health care products will be more costly, and that useful new health care products may come to market more slowly, or may not become available at all.

Agents who produce and sell dangerous goods may be held liable for compensatory and punitive damages or may agree to settlements to avoid litigation. The prospect of significant economic loss through actual or threatened litigation might deter the development and dissemination of harmful products. It is difficult to determine the extent to which threats of liability effectively deter development and dissemination of harmful products or hinder innovation, or both, and there is disagreement among various parties, such as industry representatives and trial laywers, about the effect litigation has on innovation. There is evidence that sometimes the threat of liability is not an effective deterrent because corporations determine that it is more cost effective to pay for damages than to alter or withdraw a product from a market. In the 1970s, executives at Ford discovered that the Pinto model was at risk for fuel tank explosions in rear end collisions. Allegedly, they calculated that it would be more expensive to correct the problem than to pay for damages.[32] Nevertheless, there is reason to believe that concerns over liability do result in the dissemination of fewer harmful products; the immediate cost of compensating the injured and the long-term cost of losing public confidence sometimes will be significant.

Product liability litigation has been the subject of frequent, heated debates in the popular press and academic literature.[33] Cases in which products have been directly connected to harms, such as with DES, have stirred less controversy than those in which has been less evidence to support claim that a product caused a particular injury, such as with Bendectin.[34] The character of a products liability system reflects a balancing of competing goals and can affect the extent and pace of innovation. Product liability helps fulfill our public policy goal of maintaining safety by deterring the dissemination of harmful products as well as our goal of bringing justice to injured parties. There are a number of elements of a product liability system, such as the rules of evidence adopted, standards of proof to which parties are held, and whether and how the system limits awards, that reflect various priorities and goals. For example, if we hold that deterring the distribution of dangerous products or compensating the injured is sufficiently important that we are willing to risk hindering innovation and the availability of other new health care products, we will favor a product liability system in which we adopt a

lower standard of proof of causation and injury and permits higher awards. If our only or cardinal public policy goal is to deter the distribution of dangerous products or compensate the injured, or both, then it would make sense to craft a products liability system that overwhelmingly favored plaintiffs. If we frame our public policy to aim solely at promoting innovation, then a product liability system should impose a very high standard of proof of injury and causation and limit awards. Some proponents of innovation might wish to discourage or disallow litigation altogether, perhaps relying on something akin to the Vaccine Compensation Fund as the only means of recourse for persons injured by health care products.

Evaluating and reforming a product liability system involves the balancing of a series of competing goals, several of which are aspects of our general goal of promoting health, namely promoting innovation and availability of health care products and deterring the development and dissemination of harmful products. In addition, there is an interest in bringing justice to injured people. We should aim at crafting a products liability system that balances these goals and avoids extremes that subvert the general goal of promoting health.

3. Promoting Production and Availability of Health Care Products

In addition to encouraging innovation and deterring the distribution of harmful products, a third way in which we can use public policy to promote health is by promoting the availability of health care products once they have been developed. If useful products are developed but are not produced in sufficient quantities, or for some other reason are not commercially available, they do not contribute to our general goal of promoting health. There are multiple ways in which public policy can be crafted to create conditions that would encourage the production of goods and avoid disincentives for production and product distribution. Some of the factors that affect innovation also affect product availability, such as the potential for profit, the regulatory burden associated with making and selling a product, and potential liability. For example, if a company will not recover its costs or will do little more than break even by producing and selling a product because the costs of maintaining the license to make and sell it are high, or because of price controls, the company in question might determine that it is not worth it to make it at all, or in large quantities. Some analysts have argued that what amount to government price controls on vaccines in United States through the federal Vaccines for Children program, coupled with heavy regulation,

are to blame for recent vaccine shortages in the United States.[35] In addition, through compulsory licensing governments sometimes may require patent holders to allow others entities to make and sell a product that is not available in sufficient quantities or, in some cases, that is not available at a price the government deems acceptable. Compulsory licensing is controversial and companies typically try to avoid being forced to allow others to manufacture and distribute their products. The threat of compulsory licensing might motivate companies to increase production or lower prices, or both. In recent years, compulsory licensing has been the focus of discussions about access to a number of products, including antiretrovirals, Cipro, Tamiflu, and Xalatan. Inasmuch as compulsory licensing, or the threat of it, might promote the availability of products that already have been invented, there is a danger that it can undermine our overall goal of promoting health by creating a disincentive to innovate. This most likely would be the case if compulsory licensing were used often. In crafting public policy regarding compulsory licensing, policy makers should recognize that encouraging the availability of health care products is one aspect of the general goal of promoting health. The impact of mechanisms aimed at fulfilling each aspect of our goal of promoting health on other aspects of this general goal should be considered.

4. Conclusion

The general public policy goal of promoting health can be advanced by promoting innovation, deterring the dissemination of harmful products, and promoting the availability of products, which are influenced by economic, regulatory, and liability conditions. In crafting public policy, the effect of each of these areas on meeting the particular goals of promoting innovation, deterring the distribution of harmful products, and encouraging availability of health care products should be considered in assessing their role in meeting the ultimate goal of promoting health. Policy makers, and those who evaluate and choose them, should not lose sight of the fact that efforts to fulfill one aspect of health promotion, such as deterring the availability of dangerous products, can hinder fulfillment of other goals related to health promotion, such as promoting innovation and encouraging the availability of health care products. We should not presume that we may, for example, provide maximum security from exposure to harmful products through regulation and litigation without compromising innovation or product availability. Similarly, it is not possible to increase dramatically the pace of innovation without

increasing the costs of health care products or the possibility that some unsafe products will be marketed. We should craft our policies to aim at striking a balance among the goals that contribute to our overall goal of promoting health.[36]

Notes

1. See Thomas Magnell, "Collapsing Goods in Medicine and the Value of Innovation," *Journal of Value Inquiry*, Vol. 40, Nos. 2–3 (2006).
2. See Sandra H. Johnson and Ana S. Iltis, "Risk, Responsibility, and Litigation," in H.T. Engelhardt, Jr. and J. Garrett eds., *Ethics, Profits, and Medical Innovation* (Salem, Mass.: M&M Scrivener, 2007).
3. See J.A. DiMasi, R.W. Hansen, and H.G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22 (2003).
4. See Marcia Angell, *The Truth About Drug Companies: How They Deceive Us and What to Do About It* (New York, N.Y.: Random House, 2004).
5. See Christopher Adams, and Van V. Brantner, "Estimating the Cost of New Drug Development: Is it Really $802 Million?" *Health Affairs* 25 (2006).
6. See Richard Epstein, "Does America Have a Second Drug Problem?" in H.T. Engelhardt, Jr. and J. Garrett eds., op cit.
7. See Henry Grabowski, Y. Richard Wang, "The Quantity and Quality of Worldwide New Drug Introductions, 1982–2003," *Health Affairs* 25 (2006).
8. See Baruch Brody, "Public Goods and Fair Prices," *Hastings Center Report* 26 (1996).
9. See John R. Graham, "Perils of Parallel Trade: Reimporting Prescription Drugs from Canada to the U.S.," in H.T. Engelhardt, Jr. and J. Garrett eds., op cit.; J. Somberg, "Therapeutics, Drug Pricing, and Innovation," *American Journal of Therapeutics* 10 (2003).
10. See Somberg, op. cit.
11. See Paul Offit, "Why are Pharmaceutical Companies Gradually Abandoning Vaccines?" *Health Affairs* 24 (2005).
12. See Offit, op. cit.; Margaret S. Coleman, Nalinee Sangrujee, Fangjun Zhou, and Susan Chu, "Factors Affecting U.S. Manufacturers' Decisions to Produce Vaccines," *Health Affairs* 24 (2005).
13. See Graham et al, op. cit.
14. See Donald W. Light, and Joel Lexchin, "Will Lower Drug Prices Jeopardize Drug Research? A Policy Fact Sheet," *American Journal of Bioethics* 4 (2004); Angell, *op. cit*.
15. See Adams and Brantner, *op. cit*.; Henry I. Miller. "The Cost of Medicine," *Washington Times* 1 September 1997.
16. See Offit, op. cit.
17. Orphan Drug Act, 1984, P.L. 98–551.
18. David Duffield Rohde, "The Orphan Drug Act: An Engine of Innovation? At What Cost?" *Food and Drug Law Journal* 55 (2000): p.128.

19. See Rohde, op. cit.; Thomas Maeder, "The Orphan Drug Backlash," *Scientific American* 288 (2005).
20. See United States. Subcommittee on Antitrust, Monopolies, and Business Rights of the Senate Judiciary Committee. *Anticompetitive Abuses of the Orphan Drug Act: Invitation to High Prices*. Hearing, 21 January 1992. 102nd Cong., 2nd Sess.; Rohde, op. cit.
21. See David B. Clissold, "Prescription for the Orphan Drug Act: The Impact of the FDA's 1992 Regulations and the Latest Congressional proposals for Reform," *Food and Drug Law Journal* 50 (1995); Sheila R. Shulman, Brigitta Bienz-Tadmor, Pheak Son Seo, Joseph A. DiMasi and Louis Lasagna, "Implementation of the Orphan Drug Act: 1983–1992," *Food and Drug Law Journal* 47 (1992); Rohde, op. cit.
22. See Henry Grabowski, "Encouraging the Development of New Vaccines," *Health Affairs* 24 (2005).
23. See Johnson et al, op. cit.
24. See Coleman et al., op. cit.; Offit, op. cit.; Somberg, op. cit.; Philip Boffey. "Vaccine Liability Threatens Supplies." *New York Times* 26 June 1984, p. C1; J.P. McMenamin, "Does Products Liability Litigation Threaten Picture Archiving and Communication Systems and/or Telemedicine?" *Journal of Digital Imaging* 11 (1998).
25. See American Trial Lawyers Association. "Liability Concerns are not Affecting Vaccine Production," Fact Sheets and Resources, 2005 .
26. See National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants* (Bethesda, Md.: Government Printing Office, 2001).
27. See Institute of Medicine, *Ethical Considerations for Research Involving Prisoners* (Washington, D.C.: National Academies Press, 2006); American Association of University Professors, "Protecting Human Beings: Institutional Review Boards and Social Science Research," *Academe* 87 (2001); Joan Sieber, Stuart Plattner, and Philip Rubin, "How (Not) to Regulate Social and Behavioral Research," *Professional Ethics Report* 15 (2002).
28. See Magnell, op. cit., pp. 155–157.
29. See Roger I. Glass and Umesh D. Parashar, "The Promise of New Rotavirus Vaccines," *New England Journal of Medicine* 354 (2006); Charles Weijer, "The Future of Research into Rotavirus Vaccine; Benefits of Vaccine May Outweigh Risks for Children in Developing Countries," *British Medical Journal* 321(2000).
30. See Offit, op. cit.
31. See ibid.
32. See *Grimshaw v. Ford Motor Co*., 119 Cal. App. 3d 757 (4th Dist. 1981); Gary Schwartz, "The Myth of the Ford Pinto Case," *Rutgers Law Review* 43 (1991).
33. See Johnson et al, op. cit; Marcia Angell, "Shattuck Lecture – Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion," *New England Journal of Medicine*, 334 (1996); Doug Bandow. "Many Torts Later, the Case Against Implants Collapses," *Wall Street Journal* 30 November 1998, p. 23; Alexander M.Capron, "Daubert and the Quest for Value-Free 'Scientific Knowledge' in the Courtroom," *University of Richmond Law Review* 30 (1996); David S. Caudill and Lewis H. LaRue, "Why Judges Applying the Daubert Trilogy Need to Know About the Social, Institutional, and Rhetorical – and Not Just the Methodological – Aspects of Science," *Boston College Law Review* 45 (2003); Edward Cheng, "Changing Scientific Evidence," *Minnesota Law Review*

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34. See E.K. Senekjian, R. K. Potkul, K. Frey, A. L. Gerbst, ''Infertility Among Daughters Either Exposed or Not Exposed to Diethylstilbestrol,'' *American Journal of Obstetrics and Gynecology* 158 (1988); D.C. Paterson, ''Congenital Deformities Associated with Bendectin,'' *Canadian Medical Association Journal* 116 (1977); D.C. Paterson, ''Congenital deformities,'' *Canadian Medical Association Journal* 101 (1969); D. Donnai and R. Harris, ''Unusual Fetal Malformations After Antiemetics in Early Pregnancy,'' *British Medical Journal* 9 (1978); J.E. Fisher, S. J. Nelson, J. E. Allen, and R. S. Holzman, ''Congenital Cystic Adenomatoid Malformation of the Lung. A Unique Variant,'' *American Journal of Disabilities in Children* 136 (1982); K. Frith, ''Fetal Malformation After Debendox Treatment in Early Pregnancy,'' *British Medical Journal* 9 (1978); C.J.G. Menzies, ''Fetal Malformation after Debendox Treatment in Early Pregnancy,'' *British Medical Journal* 1 (1978).
35. See, Offit, op. cit.
36. I thank Sandra Johnson for stimulating conversations about the relationship among free markets, regulation, and legal liability that shaped this paper.