

## Genomic Torts: A Response to Professor Feldman

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### I. INTRODUCTION

One point emerges above all others from Professor Feldman's presentation: to safeguard public health we need new constraints controlling the market-oriented, profit-maximizing pharmaceutical industry. That observation leads me to a question: Why do we hear so many lawyer jokes and so few jokes about drug companies? Which leads to my next question: Are the problems and fears that Professor Feldman levels at the pharmaceutical industry all that different from the fears and concerns that have been leveled at us?

Keeping these questions in mind, I have organized my response to Professor Feldman around three points: First, I question whether the pharmaceutical industry's preoccupation with marketing is necessarily a bad thing. Second, I question whether a "right to privacy" would be an appropriate check on marketing activities. And finally, I ask whether mass tort actions provide a suitable counterbalance to the pernicious market-oriented values — the MDM (market-driven manufacturing) — of the pharmaceutical industry.

### II. PHARMACEUTICAL INDUSTRY MARKETING

Professor Feldman is not the first person to be alarmed by the prospect of marketing drugs. Historically, states saw the risks of using advertising to influence consumer behavior with respect to prescription drugs and responded by banning all such advertisements.<sup>1</sup> The Court decisions, notably linked to decisions protecting advertisements by lawyers,<sup>2</sup> established a tie between commercial marketing and freedom of speech. I suppose that I am on this panel in part to recognize that tie and to speak up for the First Amendment.

The historical commercial speech cases were a mere prelude to contemporary concerns. When Congress recently exempted a particular category of compounded drugs from standard Food and Drug Administration (FDA) approval processes, it shifted the regulatory balance in favor of the drug industry.<sup>3</sup> As a quid pro quo, Congress imposed a marketing ban for promotion of drugs that had avoided

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1. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) (striking down a law providing that pharmacists were guilty of "unprofessional conduct" if they advertised the price of prescription drugs).

2. *See, e.g., Bates v. State Bar of Ariz.*, 433 U.S. 350 (1977).

3. Drug compounding allows a pharmacist or physician to combine drug ingredients to meet individual patient needs. *See* Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 353a (2000).

review.<sup>4</sup> I assume that congressional concerns motivating this legislation were similar to those of Professor Feldman.<sup>5</sup> The United States Supreme Court, however, struck down that limit on advertising, concluding that physicians can provide a more narrowly tailored safeguard against abusive marketing practices.<sup>6</sup> We are, after all, still talking about prescription drugs. What is the problem with advertising campaigns that end with the advice to “ask your doctor?” Why does this problem change in any principled manner when the campaigns are directed to individuals with specific genetic predisposition to disease? To continue with my legal profession analogy, what is the principled difference between targeted mailings to consumers regarding gene-related drugs and targeted mailings by lawyers to tort victims?

I also want to ask Professor Feldman whether marketing is more than a symptom of an underlying problem that infects our health care system. A more basic concern lies in our failure to resolve problems on the distribution side of the equation. Isn't the drug companies' preoccupation with marketing driven by our unholy dependence upon the private marketplace to deliver health care? What we need is broader access to prescription drugs, and until the government provides that access, we will be stuck with the dominance of private marketing as the lesser of alternative evils.

### III. PRIVACY INTERESTS

My second observation is closely related to the first. I assume that the privacy interests that concern Professor Feldman are those related to the use of genomic and genetic knowledge in “highly personalized MDM of genuceuticals.”<sup>7</sup> But why do these privacy interests warrant particular respect? How different are they from comparable concerns for privacy that have been rejected by the courts, at least when balanced against interests in free speech?<sup>8</sup> And how many times have we heard about zealous tort attorneys who im-

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4. *Id.* § 353a(c) (mandating that providers do “not advertise or promote the compounding of any particular drug, class of drug, or type of drug”).

5. The dissenting opinion of Justice Breyer emphasizes the problem of advertising to consumers who ask their physicians for drugs as a matter of convenience rather than as a medical necessity. *See* *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 379 (2002) (Breyer, J., dissenting).

6. *See id.* at 376-77.

7. Heidi L. Feldman, *Pushing Drugs: Genomics and Genetics, the Pharmaceutical Industry, and the Law of Negligence*, 42 WASHBURN L.J. 575, 597 (2003) (explaining that “[a]s pharmaceutical companies gain genomic and genetic knowledge, they will be able to use this information to target people whose need for one drug suggests that they may have a predisposition for another”).

8. *See* *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983) (striking down a federal government ban on mailing unsolicited advertisements of contraceptives). Should a tort action have been allowed against Youngs Drug when they mailed pamphlets about “Condoms and Human Sexuality” or “Plain Talk about Venereal Disease?” It's worth noting that at the time

pinge upon the “right to privacy” of personal injury victims?<sup>9</sup> Is the behavior of the tort lawyer all that different from the behavior of the drug companies? Both deal with what Professor Feldman would describe as “extremely personal” information. At the very least, I need more guidance as to where and why these lines should be drawn.

Again, I see a relationship between privacy concerns and the lack of access to health insurance in general or to prescription drugs in particular. At least some of the fears regarding gene-specific marketing, and the invasion of privacy that could result, would be reduced if government played a more responsible role in providing health insurance and in distributing prescription drugs. Furthermore, meaningful protection from abuse of genetic information, including loss of employment or health or life insurance, will be better provided through legislation than through tort litigation.<sup>10</sup>

#### IV. TORT ACTIONS AND THE PHARMACEUTICAL INDUSTRY

The final question I want to raise is more complex. It involves Professor Feldman’s attack upon the obvious profit motives of the drug industry — the fact that “marketing considerations . . . continuously control every aspect and stage of a product’s life cycle.”<sup>11</sup> In assessing this issue, we should not lose sight of the fact that the pharmaceutical industry does not have monopoly control over medical research. The field of science benefits from an infusion of public as well as private dollars. The competition and cooperation that marked the relationship between the government-sponsored Human Genome Project and Celera’s private effort to map the human genome demonstrate the value of healthy public and private sector involvement.

We should also keep in mind the fact that the same kind of combination exists on the regulatory side of the ledger, as public government regulation is accompanied by private tort litigation to curb abusive pharmaceutical practices. The fact that lawyers seek to maxi-

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when the Supreme Court decided this case, claims were made that drug companies were motivated by profit and intruded upon private family decisions as a result.

9. See generally *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618 (1995) (allowing Florida to impose a thirty-day ban on targeted mail to accident or disaster victims or their relatives); *Shapiro v. Ky. Bar Ass’n*, 486 U.S. 466 (1988) (upholding the right of lawyers to make direct mail solicitation to potential clients so long as the information is not false or deceptive).

10. David Partlett argues that traditional tort remedies, including enforcement of confidentiality and fiduciary obligations, adequately protect parties injured by disclosure of private genetic information to employers or insurance companies. See generally David F. Partlett, *Misuse of Genetic Information: The Common Law and Professionals’ Liability*, 42 WASHBURN L.J. 535 (2003). But current law does not prevent an insurance company from asking applicants whether they have participated in genetic screening prior to establishing health or life insurance protection. Information “voluntarily” provided will not be subject to the tort protection Dean Partlett describes. Adjustment of insurance rates because of genetic predispositions undermines the fundamental risk distribution function that insurance should provide. Only legislative protection will address this problem.

11. Feldman, *supra* note 7, at 576.

mize benefits for their clients, and that for lawyers in litigation all other interests are subordinate, should not be grounds for discounting their contribution. These observations are simply part of the background for asking whether expanding the role of tort litigation would necessarily be in the best interests of the public. And when we address the interests of the public, we should keep in mind that compensating tort victims is not the highest value that we seek to preserve, especially in the context of health care. Much as successful tort litigation reinforces improvements in health care, so too are drug industry profits generally tied to advances in the prevention or cure of disease.

I want to emphasize this point. With all due respect to the products liability lawyers who sustain the tort system, I have no more trust in their values or influences than I have in leaders of the pharmaceutical system. Both suffer from the same underlying devotion to private market mechanisms and concerns for maximizing gain. If we are to accuse the pharmaceutical industry of MDM, then maybe we need a comparable acronym to capture the mixed motives of lawyers promoting mass tort actions in response to new scientific developments. The label I suggest is DPDT for “deep pocket-driven torts.” Much as the pharmaceutical companies begin by creating a demand for new products, tort lawyers searching for deep pockets begin by inventing and promoting new theories of liability. Their work should be held to comparable levels of scrutiny.

The pharmaceutical industry has a “good” side — promoting drug-related improvements in health care — and our generation has witnessed the incredible benefits that come from their work. The tort industry has a “good” side as well — compensating some victims while providing a check on pharmaceutical decisions made to satisfy greed rather than science. But neither the corporate executives nor the plaintiffs’ lawyers are purely altruistic, and both may suffer at times from a similar underlying problem of seeking enrichment ahead of their science. Let me explain.

To understand the role of tort actions against the pharmaceutical industry, Professor Feldman suggests an analogy to drivers. “Just as drivers can act non-negligently or negligently, so too can practitioners of MDM.”<sup>12</sup> Consider an alternative. Instead of drawing a comparison to all drivers, focus on the errors made by drivers rushing to the hospital to save a dying passenger. In that context, we may want to excuse some use of high speed because there are other important interests at stake. In different words, while there is a real risk that gene-specific drugs will be rushed to market ahead of adequate testing because the industry is anxious to receive full benefits from their re-

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12. *Id.* at 576 n.4.

search prior to the expiration of their patents, other values might also be present. Individual patients may suffer or die while awaiting the results of prolonged drug testing and approval procedures.

With lawyers, the problem is even more complex. By professional mandate, they seek to maximize benefits for their injured clients. Almost by definition, injured plaintiffs present a sympathetic picture for jurors who are given the opportunity to provide relief at a relatively minimal expense to the evil pharmaceutical industry. Cutting-edge science, especially in the context of the drug reactions and multigenic traits described by Professor Feldman, necessitates difficult decision making and inevitable risks. With all of the advantages of hindsight, lawyers may be able to exploit that uncertainty by presenting arguments to a jury that survive judicial screening, generating huge rewards, even though the underlying merit of their claims may be questionable.<sup>13</sup>

Again, I want to be clear about the nature of my argument. I am not saying that this is a huge problem, or a problem that warrants reform of the tort system.<sup>14</sup> My primary point is that — given concerns about the underlying fairness and effectiveness of relying upon tort litigation for protecting public safety — I question the rush to expand the range of tort actions, particularly in the context of new scientific developments. This is especially true if heightened standards for compensation of patients injured by pharmaceutical products would significantly reshape the balance involved in moving helpful products to the market. When drug companies become deep pocket targets for injuries they did not cause, or that could not reasonably have been avoided, society may suffer from the failure to develop or market products that would provide significant beneficial results.<sup>15</sup>

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13. Consider the phenomenon of “phantom risk” litigation, for example claims that breast implants cause systemic diseases such as cancer or immune-system malfunctions, which have led to multi-billion dollar settlements and a major corporate bankruptcy. See David E. Bernstein, *The Breast Implant Fiasco*, 87 CAL. L. REV. 457, 502-05 (1999) (reviewing MARCIA ANGELL, *SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE* (1996)) (arguing that the tort system should be recognized for serving social goals other than compensation for injury and may justify relief from proof of negligent risk even in the absence of proof of causation of injury). The risk of litigation may lead to removal of valuable products from the market even in the absence of scientific evidence of harm.

14. Indeed, I think many efforts at “reform” have shifted the balance towards industry and away from injured consumers in an unwarranted fashion. Statutes imposing caps on non-economic harm, for example, punish the most severely injured plaintiffs while treating symptoms of a problem rather than treating the cause.

15. This risk may be especially great in the context of the negligent MDM tort that Professor Feldman describes. By definition, such litigation would focus upon the profits of the pharmaceutical industry, giving juries a virtual blank check to raid the corporate coffers. This litigation context sounds almost too good to be true from a plaintiff’s perspective. Promotion of such a tort action without thorough study of the social impact, however, strikes me as a potential example of negligent DPDT. Professor Feldman has previously noted the importance of “investigation into the empirical effects . . . as to the relative merits of ensuring safety and dampening innovation” prior to shifting the balance in tort litigation. Heidi L. Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 46 (1995). I question, however, the use of

I do not mean to suggest that plaintiffs' lawyers should back away from their commitment to maximize benefits for their clients. Today, however, when we address issues of ethics and public policy, we need to be sure that we are not behaving like bad drug companies, rushing our new product to market before we are sure that it will not cause more harm than good. MDM should not be trumped by DPDT without careful, critical examination of potential consequences.

Contradictions that appear within the sweeping scope of Professor Feldman's arguments heighten this concern. She acknowledges, but appears to give little weight to, the value of hastening discoveries that may lead to disease prevention or cure. The "satire" Professor Feldman chooses to introduce her article displays her skeptical view of the pharmaceutical industry. Her characterization of the "rapidly decreasing difference between a pharmaceutical manufacturer and an automobile maker"<sup>16</sup> further demonstrates this skepticism. She also makes a sweeping assertion that "drugs the companies are ready to patent now are not in any way critical to health."<sup>17</sup> After basing much of her criticism on this derogatory depiction of the pharmaceutical role, however, Feldman leaps to an assumption that new tort theories are needed to constrain future genetic research that may "pave the way to more effective therapies and preventive measures" implicating "many major disabling and fatal diseases including heart disease, Alzheimer's, epilepsy, stroke, diabetes, and several kinds of cancer."<sup>18</sup> Even if one accepts Feldman's comparison of current drug production to making automobiles, it does not follow that new tort constraints should burden the production or promotion of "effective therapies and preventive measures" related to ailments that may be susceptible to genomic treatment.<sup>19</sup>

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the common-law tort system to adjust that balance rather than alternative legislation that might also provide appropriate regulatory reform and broader distribution of health care to those in need.

16. Feldman, *supra* note 7, at 575.

17. *Id.* at 580. In the illustrative tale that Professor Feldman uses to relate her concerns about pharmaceutical marketing, she notes that "Pfizer would be much better positioned to defend itself . . . if it had not engaged in such heavy duty MDM for Neurotin." *Id.* at 598. The same could be said in response to Professor Feldman's article: She would have been better positioned to support her claims for new tort constraints if she had not engaged in such a "heavy duty" assault on the pharmaceutical industry to introduce (or market?) her argument.

18. *Id.* at 596.

19. *Id.* Professor Feldman recounts problems with the off-label promotion of products like Neurontin to support her argument, but we do not need new tort theories to challenge intentional marketing of a drug for uses that have not been approved by the FDA. Current tort law limits protection from strict liability to drugs "properly prepared, and accompanied by proper directions and warning." RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). Given the account described by Professor Feldman, off-label promotion of Neurontin should not qualify for this protection, and existing theories of products liability adequately address these issues. Because the example Professor Feldman used to state a case for expanding tort liability relied in significant part on negligent conduct that is actionable under current law, we are left to wonder whether she could state an effective case without relying upon such evidence.

## V. CONCLUSION

Professor Feldman has focused on injury from abusive marketing practices and suggests mass tort actions as a response. In her oral remarks, she described the “marketing mix” as the “tail that wags the dog.” But can we be sure that the search for new tort actions against the deep pockets of the pharmaceutical and insurance industries will not be vulnerable to the same criticism? At the very least, I would suggest that Professor Feldman’s focus on challenging marketing practices is symptomatic of limitations inherent in the world of torts. Tort actions work when it comes to looking intensively at a unique injury and developing an injury-specific cure. Once we commit ourselves exclusively to this framework, however, we risk losing sight of the big picture.

The picture we should be talking about is health care, and our primary concern should be with the entire universe of people in need of that care. A focus on compensation for victims of abusive MDM creates the risk of inappropriate DPDT. We should not allow preoccupation with these concerns to divert us from the more fundamental tasks of restructuring the delivery of health care services. In making this distinction, we need to be sure that we do not confuse injury with blame, and that we do not rely on a system that funnels compensation only when we are able to attach blame while, in the process, neglecting those who suffer and die without treatment.

