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FROM THE WRONG END OF THE TELESCOPE: A RESPONSE TO PROFESSOR DAVID BERNSTEIN

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INTRODUCTION

On the pages of this law review, in an article entitled *Uncertainty and Informed Choice: Unmasking Daubert*, the authors argued for the recognition of a new product liability cause of action when drug companies fail to warn about uncertain risks attendant to the use of non-therapeutic drugs whose purpose is to enhance lifestyle.¹ We noted that in the post-*Daubert* era, plaintiffs have faced increasing difficulty in proving that a given toxic agent was causally responsible for the injuries suffered after ingesting a drug.² That plaintiffs cannot overcome the barriers to proving injury causation does not mean that defendants have met their obligation to warn about the dangers associated with taking the drug. In many instances it is clear that drug companies failed to warn about known dangers or negligently failed to adequately test drugs for dangerous side effects.³ Even if plaintiffs cannot meet the high burden of proving injury-causation, we contend that plaintiffs

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1. Margaret A. Berger & Aaron D. Twerski, *Uncertainty and Informed Choice: Unmasking Daubert*, 104 MICH. L. REV. 257 (2005).

2. *Id.* at 260-267.

3. *Id.* at 267-270.

should be able to establish a cause of action for the failure of drug companies to provide the requisite information so that plaintiffs could make informed choices as to whether they wanted to expose themselves to the uncertain risk associated with the drug.⁴

We acknowledge that when plaintiffs cannot establish injury-causation, recovery for physical harm is inappropriate.⁵ However, a plaintiff deprived of informed choice has a legitimate claim for mental distress resulting from having lost the opportunity to refuse to subject herself to uncertain risk.⁶ In our article we set forth the template for this causation-free cause of action for the deprivation of choice.⁷

In a sharply worded rebuttal, Professor David Bernstein takes issue with our thesis.⁸ He considers our proposal to be "ill-conceived and dangerous."⁹ Bernstein argues that Bendectin, the drug we use to exemplify the need for a causation-free informed choice cause of action, has proven to be safe.¹⁰ From 1957 to 1983 Bendectin was a popular drug taken by women in the first trimester of pregnancy to reduce symptoms of nausea.¹¹ Though at first there was reason to believe that it might cause birth defects, two decades later, research has proven its safety.¹² Merrell-Dow, the manufacturer of Bendectin, withdrew the drug from the market because of the onslaught of litigation brought by parents who claimed that the drug was responsible for children born with limb reduction.¹³ Bernstein bemoans the withdrawal of this useful drug from the market because of a bogus scare created by avaricious plaintiff's lawyers.¹⁴ Bernstein argues that our proposal would deliver a new cause of action to an irresponsible plaintiff's bar based on a vague standard as to what qualifies to be a "material risk" deserving of an informed choice warning.¹⁵ Absent *Daubert* screening for reliability, Bernstein argues, juries will fall prey to plaintiffs' attorneys who are "masters at appealing to juries' emotions."¹⁶ Furthermore, he claims that informed choice drug litigation will deter doctors from prescribing safe drugs and patients

4. *Id.* at 270-275.

5. The authors do not challenge the received wisdom that a plaintiff must establish a causal nexus between the defendant's defective product and the physical harm suffered. *Id.* at 268.

6. *Id.* at 280-281.

7. *Id.* at 282-288.

8. David E. Bernstein, *Learning the Wrong Lessons from "An American Tragedy": A Critique of the Berger-Twerski Informed Choice Proposal*, 104 MICH. L. REV. 1961 (2006).

9. *Id.* at 1962.

10. *Id.* at 1963-67.

11. MICHAEL D. GREEN, *BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION* 91, 180 (1996).

12. Bernstein, *supra* note 8, at 1965-66.

13. GREEN, *supra* note 11, at 180.

14. Bernstein, *supra* note 8, at 1965.

15. *Id.* at 1969-70.

16. *Id.* at 1975.

from taking them even when necessary.¹⁷ And if all this were not enough, adding this new drug cause of action will burden the scientific community with endless discovery requests that amount to harassment.¹⁸ Bernstein concludes that our regime will deter innovation and ultimately result in a surfeit of useless warnings.¹⁹

I. FROM THE WRONG END OF THE TELESCOPE

A. A Different Perspective on Bendectin

Well over half of Professor Bernstein's rebuttal concerns Bendectin. Despite his suggestions to the contrary, we do not dispute his conclusion that by the 1980s Bendectin was shown not to pose actionable harm to the children of women who had taken the morning-sickness remedy. His discussion and conclusion are, however, totally irrelevant to our thesis. For us, the significant date is not the moment when a scientific consensus was reached that Bendectin was, at most, a mild teratogen with undetectable effects. For us the significant date is 1974, when Betty Mekdeci took Bendectin to counter the nausea she experienced while pregnant with her son David.²⁰ Professor Bernstein does concede, albeit in footnotes, that "[t]o the extent that physicians reportedly told patients that Bendectin was proven 'totally safe' before the 1980s, this information was inaccurate."²¹

In text, Professor Bernstein tries to move the significant date back to 1977—the year Mekdeci instituted suit²²—a date that is equally irrelevant to our hypothesis that plaintiff is entitled to a meaningful informed choice before taking a lifestyle drug. Professor Bernstein argues that fourteen epidemiological studies had been performed by 1977 finding no association and that “no serious doubts” had been raised about “[Bendectin’s] safety in the scientific or medical community.”²³ This statement is somewhat disingenuous. We are most fortunate that two excellent books exist about the Bendectin litigation written by two eminent law professors, Michael Green and Joseph Sanders.²⁴ Both books document that there were “signals” pointing to possible adverse outcomes and that there was no basis in 1974 for concluding that the drug was safe.

17. *Id.* at 1976–77.

18. *Id.* at 1977.

19. *Id.* at 1978–79.

20. GREEN, *supra* note 11, at 1.

21. Bernstein, *supra* note 8, at 1964 n.8; *see also id.* at 1968 n.50.

22. *See id.* at 1963; text accompanying notes 4 and 5.

23. *Id.*

24. GREEN, *supra* note 11; JOSEPH SANDERS, *BENDECTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION* (1998).

Professor Sanders could find no indication that any research had been conducted on Bendectin before it was marketed in 1956.²⁵ He found nine epidemiological studies that were conducted prior to 1974, and although none found an association between Bendectin and birth defects, Professor Sanders critiques them as having little scientific value—most contained no statistical analyses, failed to focus on Bendectin, and had a limited ability to detect small defects.²⁶ One of the studies was done so badly that plaintiffs later used it to show “Merrell’s lack of concern about the safety of the drug.”²⁷

And there were adverse signals. Physicians sent adverse reaction reports to Merrell and then were pressured by Merrell to reclassify them as inquiries so that they did not have to be reported to the FDA (Food and Drug Administration).²⁸ A 1963 unfavorable animal study by a Merrell employee was not submitted to the FDA for three years, and then only after the data were modified and the author’s recommendations for further studies were deleted.²⁹ But no research was done by Merrell. According to Professor Sanders, “[a]t the end of 1984 one would have concluded that the in vivo research cast doubt on the safety of Bendectin.”³⁰ Professor Green’s conclusion is equally telling: “[t]he five juries that awarded punitive damages against Merrell did not concoct out of thin air their findings of recklessness or wanton disregard, required for awarding punitive damages.”³¹

It doesn’t matter to Professor Bernstein that in 1974 Merrell had no basis for opining that its drug was safe. The results he fears from our suggested cause of action are so horrendous that he is willing to impose on the plaintiff all the uncertainty about the safety of the drug and all the costs and burdens of jumping through the *Daubert* trilogy hoops. He fails to acknowledge that many of the horrors that he foresees would not occur if pharmaceutical companies would advise physicians about possible risks associated with lifestyle drugs so that they can counsel their patients appropriately. If Mrs. Mekdeci and other pregnant women had elected not to take Bendectin, the results Professor Bernstein envisions would not materialize. Of course, if women refuse to take the drug in question, the pharmaceutical company may end up without a marketable drug as happened with Bendectin. But if this occurs, the pharmaceutical company should blame itself

25. SANDERS, *supra* note 24, at 62. After the Thalidomide disaster, Congress required the Food and Drug Administration to examine for efficacy all drugs marketed prior to 1962. Because of enormous backlogs it was not until 1975 that the FDA required Merrell to conduct additional studies. *Id.* at 4. Now, of course a drug could not be marketed without FDA approval. But just because a drug has passed safety and efficacy trials does not mean that it is incapable of causing problems that cannot be detected during the clinical trials. See Berger & Twerski, *supra* note 1, at 261.

26. SANDERS, *supra* note 24, at 70 (summarizing the results in a chart).

27. *Id.* at 69.

28. *Id.* at 8.

29. GREEN, *supra* note 11, at 128–29.

30. SANDERS, *supra* note 24, at 63.

31. GREEN, *supra* note 11, at 334.

rather than greedy lawyers—in order to show that the uncertain risks pose no real dangers it could have done the studies that Merrell chose not to do until litigation was well under way. Our solution will provide inducements for pharmaceutical companies to divulge and to develop information when problems first surface.

B. *The Parlodel Saga*

Professor Bernstein levels his guns at Bendectin and gives only scant attention to Parlodel, the second example we use to support our thesis that a causation-free informed choice cause of action is necessary to support patient autonomy. Bernstein has good reason to avoid the discussion of Parlodel for unlike Bendectin he cannot support his attack based on scientific evidence that supports its proven safety. Parlodel was approved by the FDA in 1980 for the prevention of postpartum lactation (PPL) in women who could not or chose not to breast-feed.³² By 1985, there were enough reports of adverse reactions to Parlodel that the FDA requested that the manufacturer, Sandoz Pharmaceuticals, warn about adverse reactions such as seizures, strokes, and heart attacks.³³ Sandoz initially resisted the request but agreed over the years to make labeling changes and finally to notify doctors in writing about the potential dangers of using Parlodel for PPL. However, throughout, Sandoz did everything it could to undermine the warnings. First, it mailed the “Dear Doctor” letters to only a small fraction of the doctors registered in the college of obstetricians and gynecologists.³⁴ Sandoz only distributed the letters to a wider audience when forced by the FDA.³⁵ In 1987, Sandoz issued an internal memo to its sales force explaining that, while it had modified the Parlodel package insert to reflect the adverse reactions, “this issue should not be mentioned unless a discussion is initiated by the physician.”³⁶

In 1989, the FDA Fertility and Maternal Health Drugs Advisory Committee found that given the uncertain risk of serious adverse reactions, routine use of Parlodel for PPL was unwarranted since use of common analgesics and breast support was equally if not more effective.³⁷ The FDA adopted the committee’s recommendation in 1989 and asked all the manufacturers of lactation suppression drugs to voluntarily state that these drugs

32. See *Eve v. Sandoz Pharm. Corp.* No. IP 98-1429-C-Y/S, 2001 U.S. Dist. LEXIS 4531, at *10 (S.D. Ind. Mar. 7, 2001). For an extensive listing of the appellate cases dealing with Parlodel, see Berger & Twerski, *supra* note 1, at 269 n.69. The *Eve* case contains the most comprehensive description of the conduct of Sandoz throughout the years that the drug was used for anti-lactation purposes.

33. *Eve*, 2001 U.S. Dist. LEXIS 4531, at *12–18.

34. See *Sandoz Pharm. Corp. v. Gunderson*, Nos. 2004-CA-001536-MR, 2004-CA-001537-MR, 2005 WL 2694816, at *8 (Ky. Ct. App. Oct. 21, 2005) (as modified on denial of rehearing).

35. *Id.* at *9.

36. *Eve*, 2001 U.S. Dist. LEXIS 4531, at *19–20.

37. *Id.* at *26–27.

are not indicated for PPL.³⁸ All the manufacturers complied with the exception of Sandoz.³⁹ Not only did it not comply, it instructed its sales force to sell Parlodel aggressively.⁴⁰ One sales representative testified that “Parlodel was . . . receiving a lot of heat in the journals and from the FDA and . . . we needed to bleed every dollar that we could get out of Parlodel before the FDA just put a stop to it.”⁴¹ Only when faced with FDA proceedings in 1994 to withdraw approval of Parlodel for PPL did Sandoz “voluntarily” withdraw the Parlodel indication for the prevention of lactation.⁴²

Plaintiffs who have suffered from the adverse reactions associated with ingestion of Parlodel have, with rare exception, not prevailed because defendants have maintained successful *Daubert* challenges to plaintiffs’ expert testimony.⁴³ As noted in our earlier article, we are agnostic as to the wisdom of *Daubert* and whether it is being appropriately applied. When a drug company, however, behaves in a manner that does not adequately portray the risks and indeed downplays them to squeeze every last dollar from the drug before bowing to FDA demands,⁴⁴ plaintiffs who would have avoided taking the drug if informed of the potential risks and who have suffered injuries from the very risks that they should have been warned against have a legitimate claim for the deprivation of informed consent. Plaintiffs deprived of the requisite information as to whether to take a drug that has no therapeutic benefits have a right to mental distress damages arising from the deprivation of choice. Bernstein cannot claim that Parlodel has been proven safe for lactation suppression. It has not. The risks are real. Sandoz continued to tell doctors that it was useful in the teeth of clear evidence to the contrary to protect profits from a drug that one of its salespeople dubbed a “cash cow.”⁴⁵

38. *Sandoz Pharm. Corp. v. Gunderson*, 2005 WL 2694816, at *9.

39. *Id.*

40. *Eve*, 2001 U.S. Dist. LEXIS 4531, at *27–28.

41. *Id.* at *28.

42. *Id.* at *11.

43. See Berger & Twerski, *supra* note 1, at 269 n.69, for an extensive listing of cases.

44. The conduct of Sandoz was so egregious that the court in *Sandoz Pharmaceuticals Corp. v. Gunderson*, 2005 WL 2694816, at *13, found that it was reasonable to find that the behavior amounted to a “wanton or reckless disregard for the safety of women” and entitled the plaintiff to punitive damages. The court did, however, vacate the jury award of \$11.25 million for punitive damages and remanded for a new trial because the trial judge failed to instruct the jury that it was not to punish Sandoz for conduct that occurred outside of Kentucky. The court affirmed jury awards of compensatory damages of \$3 million apiece to each of the decedent’s children for loss of consortium and \$1.848 million to the decedent’s estate for loss of services and lost earnings. *Gunderson* is a rare case that has survived challenges to the admissibility of expert testimony on the issue of whether Parlodel causes strokes.

45. *Eve*, 2001 U.S. Dist. LEXIS 4531, at *28.

II. BERNSTEIN'S SLIPPERY SLOPE ARGUMENTS

A. *Informed Choice Warnings Are Not Worthless*

Bernstein argues that our contention that the vast majority of patients would refuse to take a lifestyle drug when warned that it presents uncertain risks is incorrect.⁴⁶ He claims that it depends on how the warning is articulated. With regard to Bendectin he admits that if pregnant women had been told that there was an uncertain risk of birth defects then we would be correct.⁴⁷ If, however, it were portrayed more accurately as "We can never guarantee with absolute certainty that a drug will not cause birth defects, but Bendectin has been used safely for over twenty years, the FDA and the scientific community believe that it is the only drug safe and effective for treating NVP (morning sickness), and there is no reputable evidence to the contrary" the vast majority of women would have decided to take Bendectin to relieve NVP.⁴⁸ The problem with Bernstein's proposed warning is that it does not reflect an honest evaluation of the uncertainty during most of the years that Bendectin was on the market. A more appropriate warning would have read: "We have yet to do reliable testing as to whether Bendectin causes birth defects. Not only can we not opine that it is safe, we have yet to confirm adverse reaction reports that suggest that it may be a teratogen. Until further research establishes its safety, Bendectin should be used only in cases of severe nausea." The problem with the honest warning is that Bendectin would not have been the huge moneymaker that it was. It would have had a small market niche. Merrell would certainly not have sold thirty-six million prescriptions during the twenty-seven years it was marketed. When one seeks to huckster drugs as if they were M&M's, brutal honesty is called for.

Had Merrell provided the suggested warning, Bernstein would not be wringing his hands today that an effective and safe drug was removed from the market thus depriving women who truly need the drug of its availability. Bendectin was pursued by plaintiffs' lawyers for good reason. Adverse reaction reports, *in vivo* studies, and Bendectin's chemical similarity to known teratogens suggested that there might be a problem.⁴⁹ Until litigation forced its hand, Merrell did little to dissipate its ignorance about the drug. Plaintiffs who blindly took it on the drug manufacturer's good faith and who should have been given a choice to do otherwise have a legitimate right to recovery for the distress that they suffered. Warnings about inadequate testing do not lead us down a slippery slope to useless warnings, at least not for non-therapeutic drugs.

46. Bernstein, *supra* note 8, at 1968.

47. *Id.*

48. *Id.*

49. See SANDERS, *supra* note 24, at 4-5.

B. *Bypassing Daubert Will Not Lead
to Unreliable Expert Testimony*

In our proposal we acknowledge that a causation-free informed choice cause of action places heavy emphasis on defining material risk.⁵⁰ When a material risk has not been warned against and the plaintiff later suffers from the risk that should have been warned against, a cause of action for mental distress for the denial of informed choice accrues. In deciding whether a risk is material, we argue that a broad range of evidence may be considered. Sources such as animal studies, chemical-structure analysis, in vitro studies, preliminary but not yet determinative epidemiological studies, and adverse reaction reports are all relevant as to whether a risk is material. These sources are often excluded in *Daubert* screening since each alone is not determinative on the issue of causation and courts have been unwilling to aggregate them to support a finding of causation. Bernstein argues that hired gun experts and outliers who hold views far outside the mainstream of their professions will have a field day with a cause of action that allows them to testify as to such a broad mosaic of evidence.

We would ask Bernstein: if our proposal for risk assessment is not correct, what would he propose in its stead? How is materiality of risk to be assessed if not from the composite of all sources that, taken together, tell us that a risk is of sufficient moment that it deserves a warning? Bernstein would answer that a jury ought never to evaluate the composite picture of risk. Only if each slice of evidence standing alone is sufficient to make out causation under the strictures of *Daubert* will a jury ever see the panoply of sources relevant to the determination of whether a risk is material.⁵¹ That strikes us as manifestly unfair. A jury will rarely be privy to all the relevant data to determine whether a warning should have been given. Bernstein's answer seems to be to preempt the warning case on *Daubert* causation grounds and no one will ever know the better of it.

Our approach is the very opposite. Let the judge and jury hear the full story on risk assessment and causation. If the judge believes that the testimony in its totality does not meet *Daubert* standards, the judge is free to direct a verdict on the issue of causation. Furthermore, if the judge believes that the composite information does not meet *Daubert* standards as to the existence of material risk the judge is free to direct a verdict for the defendant on the informed choice cause of action. But we ought not to willfully blindfold both the judge and the jury from the evidence that supports a finding that a material risk was not warned against.

Finally, Bernstein ignores our view that the standard for material risk ought not to be based on a "reasonable person standard" that is used by most courts in determining informed consent in medical malpractice cases but

50. Berger & Twerski, *supra* note 1, at 275-80.

51. *Id.* at 279-80.

rather on a “reasonable physician” standard.⁵² Only the kind of risks that reasonable physicians (not outliers) would want to have revealed to them so that they can decide whether to prescribe the drug to their patients need be warned against. Physicians live with risk on daily basis. They do not seek information about remote risks that have no practical significance. A trial judge utilizing the substantive “reasonable physician” standard and applying the evidentiary *Daubert* standard should be able to screen out unworthy cases that do not constitute a material risk.

III. ADMINISTRATIVE CONTROLS WILL NOT WORK

In his conclusion, Bernstein concedes the gravity of the problems we seek to address—the inability of premarketing testing to ensure the safety of a newly marketed drug, and the ineffectiveness of postmarketing surveillance.⁵³ Bernstein offers no solutions. But in contrast to ours, which he terms “the least attractive possible response,”⁵⁴ he praises a recent article by Professor Catherine Struve.⁵⁵ One aspect of her proposal according to Bernstein is that it “takes determination of the scientific merits of claims that a company is concealing a hazard away from random panels of lay jurors and gives them to scientific experts at the FDA.”⁵⁶ Although it is true that Struve explores this option in some detail, she ends up by rejecting it. She concludes that “recent experience provides strong reason to question the wisdom of giving the FDA (as currently structured and funded) and its advisory panels (as currently staffed) a dispositive role in products liability actions.”⁵⁷

The recent experience to which Struve alludes is undoubtedly the Vioxx debacle which revealed an underfunded FDA, riddled by internal strife, devoid of postmarketing surveillance capacity, and subject to industry control and political pressure. Although the FDA is exploring ways in which to restructure itself, it is highly unlikely given current budgetary constraints, political reality, and the clout of the pharmaceutical industry that the agency will emerge with sufficient power and independence to become a viable candidate for resolving postmarketing issues about drugs that it initially approved. Our proposal recognizes the weaknesses of the FDA regulatory scheme and the strength of an independent judicial system. It is not the litigation system that is at fault. The Vioxx episode demonstrates—as did Bendectin and Parlodel—that current tort law does not provide adequate incentives for pharmaceutical companies to supply physicians with enough

52. Bernstein's concern is that juries will be duped by “outlier experts” and “hired guns” who will make a mockery of the judicial process. Bernstein, *supra* note 8, at 1969.

53. *Id.* at 1979.

54. *Id.* at 1979–80.

55. Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 587 (2005).

56. Bernstein, *supra* note 8, at 1980.

57. Struve, *supra* note 55, at 668.

information so that they can notify their patients of the risks they run when taking a drug that offers little or no therapeutic benefits, especially when the drug is producing billions in profits.⁵⁸ We believe that the courts have adequate tools to curb irrational juries and to reduce excessive awards. What the courts do not have is a rule of substantive law that will deter behavior inimical to public health and that will fairly compensate victims who have not been provided with an informed choice. It is time for tort law to respond.

CONCLUSION

Professor Bernstein has it wrong. Under the cover of *Daubert* he is willing to allow drug manufacturers blanket immunity from negligent and even reckless failure to warn about risks that should have been brought to the attention of patients before they decide whether they wish to imbibe non-therapeutic drugs. *Daubert* has become more than a hoary rule of evidence. That it has blocked recovery for physical harms that cannot be made out under its strict standard for the admissibility of expert testimony may be defensible. But, that courts have not focused on the need to protect the right of informed choice is not. Bernstein does not respond to our argument that the right of informed choice deserves protection. His only response is to list a parade of horrors that might eventuate if our proposal is accepted. Those cries have accompanied every proposal for the expansion of tort law. A cause of action allowing pure mental distress damages is not likely to run amok. Courts have been quite willing to ride tight herd on the mental distress cause of action. The specter of drug manufacturers refusing to test for fear that information they develop may be detrimental or what is worse secreting information that may deter patients from taking non-therapeutic drugs cannot go unaddressed. We share some of Professor Bernstein's concerns but not his conclusion. He has sadly left unanswered our question as to what happened to the right of autonomy for patients who unwittingly take drugs that they would not have taken if presented with the uncertain risks attendant to their use. They are doomed to live their lives with the pain and anguish of knowing that their lives or those of their children might not have been compromised if they had been given the choice deservedly due them. That injury is real and warrants legal recognition.

58. The International Committee of Medical Journal Editors became so incensed about the failure of drug companies to furnish information about ongoing clinical trials that it announced in September 2004 that its journals would not publish the results of any trials that had not been registered in a public registry by September 13, 2005. An article recently examined compliance with this requirement. It found that registrations by academic and governmental institutions were universally completed in a meaningful fashion but that some commercial entities were still playing games by not providing the names of the drug being studied or not providing details about the trial's primary outcome as required. See Jeffrey M. Drazen & Alastair J.J. Wood, *Trial Registration Report Card*, 353 *NEW ENG. J. MED.* 2809 (2005).