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# Learning the Wrong Lessons from "An American Tragedy"

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**Abstract**

This paper is a critique of Margaret Berger and Aaron Twerski, "Uncertainty and Informed Choice: Unmasking Daubert," forthcoming in the Michigan Law Review. Berger and Twerski propose that courts recognize a cause of action that would allow plaintiffs who claim injury from pharmaceutical products, but who do not have sufficient evidence to prove causation, to recover damages for deprivation of informed choice. Berger and Twerski claim inspiration from the litigation over allegations that the morning sickness drug Bendectin caused birth defects.

Considering the criteria Berger and Twerski suggest for their proposed cause of action in the context of Bendectin, it appears that a pharmaceutical manufacturer could be held liable for failure to provide informed choice: (a) even when there was never any sound scientific evidence suggesting that the product caused the harm at issue, and there was an unbroken consensus among leading experts in the field that the product did not cause such harm; (b) when the product prevented serious harm to a significant number of patients, and prevented substantial discomfort to a much greater number, even when there were no available alternative products; (c) when a plaintiff claims that she would not have taken the product had she been informed of an incredibly remote and completely unproven risk; and (d) when the defendant is unable to prove a negative - that the product in question definitely did not cause the claimed injury.

No rational legal system would allow such a tort. Putting the Bendectin example aside, the informed choice proposal has the following additional weaknesses: (1) it invites reliance on unreliable junk science testimony; (2) it ignores the fact that juries are not competent to resolve subtle risk assessment issues; (3) it reflects an unwarranted belief in the ability of juries to both follow limiting instructions

and ignore their emotions; (4) it ignores the problems inherent to multiple trials - even if defendants were to win most informed choice cases, safe products could still be driven off the market by a minority of contrary verdicts; (5) it ignores the inevitable costs to medical innovation as pharmaceutical companies scale back on researching product categories that would be particularly prone to litigation; (6) to preempt litigation, pharmaceutical companies would overwarn, rendering more significant warnings less useful; and (7) FDA labeling requirements would arguably preempt the proposed cause of action.

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David E. Bernstein[1]

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[1] Professor, George Mason University School of Law; Visiting Professor, University of Michigan Law School, 2005-06. The author thanks Michael Abramowicz, Ted Frank, Michael Green, and Joseph Sanders for helpful comments, and Dr. Robert Brent for reviewing the accuracy of this article's discussion of the scientific evidence regarding Bendectin. Any remaining errors are the author's responsibility. The Law and Economics Center at the George Mason University School of Law provided funding for this Article.

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Margaret Berger and Aaron Twerski are among the leading scholars in their respective fields of Evidence and Products Liability. I have benefited from their work on many occasions.[2] Precisely because of the deserved respect and esteem in which Berger and Twerski are held—not to mention the prominence of their forum, the *Michigan Law Review*—their proposal to create a new "informed choice" cause of action in pharmaceutical litigation is likely to receive sympathetic attention. Because I believe that their proposal is ill-conceived and dangerous, I feel compelled (with some trepidation) to write this response.

Berger and Twerski propose that courts recognize an "informed choice cause of action" that would allow plaintiffs claiming injury from pharmaceutical products to recover damages for deprivation of informed choice when (1) the causal relationship between the toxic agent and plaintiff's harm is unresolved at the time of litigation and will likely remain unresolved; (2 ) the drug is not therapeutic but rather its purpose is to avoid discomfort or to improve lifestyle; (3) it is almost certain that a patient made aware of the risk that is alleged to be associated with consumption of the drug would have refused to take it; and (4) defendant drug company was aware of the potential risk or should have undertaken reasonable testing to discover the risk and failed to provide the requisite information to the physician or patient.[3]

These guidelines, however, are rather vague. Whether they are meant to be apply broadly or narrowly means the difference between a cause of action that would be available only in limited, perhaps even extraordinary, circumstances, and a cause of action that would open a Pandora's Box of litigation. Apparently, Berger and Twerski intend the scope of the "informed choice" action to be broad indeed. So broad, in fact, that if adopted it could lead to an

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[2] Among other things, I frequently refer to Professor Berger's Evidence treatise, and use Professor Twerski's casebook in my Products Liability class.

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unprecedented wave of litigation against pharmaceutical manufacturers, including lawsuits against products that are completely safe and effective.

Berger and Twerski suggest that the paradigmatic example of why courts need to adopt the informed choice cause of action is the failure of plaintiffs claiming that the morning sickness drug Bendectin caused their children's birth defects to achieve recovery for causation, or for anything else. As demonstrated below, if the proposed informed choice tort's boundaries are broad enough to encompass the Bendectin plaintiffs, then they are extraordinarily, dangerously, broad.

**Criterion 1**: *The causal relationship between the toxic agent and plaintiff's harm is unresolved at the time of litigation and will likely remain unresolved.*

Neither pioneering Bendectin plaintiff Betty Mekdeci—whose "anguished cry" Berger and Twerski say they are responding to[4]— nor any of the subsequent Bendectin plaintiffs ever had sound reason to believe that Bendectin caused limb reduction birth defects, the main focus of the Bendectin litigation. In 1977, when Mekdeci brought her lawsuit, fourteen epidemiological studies of varying strength and quality had examined the relationship between Bendectin and birth defects and found no association.[5] While these studies were not powerful enough to rule out some connection between Bendectin and birth defects, they certainly provided no cause for alarm. Bendectin had been on the market since 1956 with no serious doubts raised regarding its safety in the scientific or medical community. Nor did Bendectin contain suspiciously toxic

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[3] Manuscript at 2.

[4] Manuscript at 35.

[5] JOSEPH SANDERS, BENDECTIN ON TRIAL 70 (1998).

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ingredients: one active ingredient of Bendectin was a simple B vitamin, and the other was an ingredient used in a popular over-the-counter sleeping pill.

Meanwhile, Mekdeci's evidence that Bendectin did cause birth defects was "remarkably thin."[6] Many chemicals are known not to be teratogens in humans, so the mere fact that pregnant women ingested a pharmaceutical product such as Bendectin did not mean there was an inherent risk. Beyond the mere fact that she ingested Bendectin during pregnancy and later gave birth to a child with a limb reduction birth defect, Mekdeci's evidence of causation consisted primarily of eighty-six reports to the FDA of other women had also given birth to children with limb reduction defects after taking Bendectin.[7] These reports are the direct source of Mekdeci's complaint, implicitly endorsed by Berger and Twerski, that Bendectin's manufacturer should have warned of a possible association with birth defects.[8]

Berger and Twerski acknowledge that "[t]he mere fact that a child was born with a limb reduction to a mother who had ingested Bendectin did not necessarily point to Benedictin as the

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[6] *Id*. at 7.

[7] MICHAEL GREEN, BENDECTIN AND BIRTH DEFECT 106, 124 (1997).

[8] Mekdeci said: "I feel like there were certainly enough [adverse reactions of limb reduction in children born after their mothers had taken Benedictin to alleviate symptoms of nausea] reported, given our bad reporting system,...to have warranted some kind of acknowledgment of this on the labeling and to physicians." Quoted in manuscript at 1.

Putting the case reports aside, should Ms. Mekdeci and others similarly situated have been warned about potential birth defects, given that Bendectin had not been adequately tested to rule out the possibility that it was a relatively weak teratogen? To the extent that physicians reportedly told patients that Bendectin was proven "totally safe" before the 1980s, this information was inaccurate. But given that there was no particular reason to believe that Bendectin caused birth defects, and, as noted above, some reason to believe it didn't, Bendectin was logically in the category of many pharmaceuticals prescribed to pregnant women today, with regard to which doctors say "we can't absolutely guarantee it's safe, but any risk is minimal."

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cause of the birth defect."[9] In fact, the mere fact that *dozens* or even *hundreds* of children were reported to have been born with limb reductions after their mothers ingested Bendectin doesn't, by itself, even *suggest* a risk. Approximately thirty million women took Bendectin, and by chance alone there would be ten thousand limb reduction defects among children born to these women.[10]

Berger and Twerski apparently see the issue of whether Bendectin caused birth defects as "unresolved" at the time of litigation. As noted above, when the Bendectin litigation began, the relevant research was not strong enough to rule out the possibility that Bendectin caused a small increase in birth defects, but there was no reason to rule in that possibility, either. There was *never* any valid scientific evidence supporting the proposition that Bendectin was a teratogen.

As interest in the teratogenicity of Bendectin increased due to the litigation, evidence quickly piled up that Bendectin was safe. No animal studies using doses equivalent or even substantially above human therapeutic doses showed teratogenicity.[11] Most epidemiological studies produced no statistically significant findings.[12] The few positive studies[13] each found an

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[9] Manuscript at __.

[10] Robert L. Brent, *Bendectin: Review of the Medical Literature of a Comprehensively Studied Human Nonteratogen and the Most Prevalent Tortogen-Litigen*, 9 REPRODUCTIVE TOXICOLOGY 337, 340 (1995). It should also be kept in mind that obstetricians were especially likely to report a temporal relationship between Bendectin ingestion and birth defects because of the still-fresh cautionary example of Thalidomide.

[11] *Id*. at 340.

[12] Jeffrey S. Kutcher, et al., *Bendectin and Birth Defects II: Ecological Analyses*, 67 BIRTH DEFECTS RESEARCH PART A: CLINICAL AND MOLECULAR TERATOLOGY 88 (2003).

[13] *See id*. at 89.

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association with a different, unrelated birth defect, a pattern consistent with random chance or imperfections in the studies, but not with causation by Bendectin.[14] Meanwhile, other studies reported a *negative* association between Bendectin and specific birth defects.[15] Moreover, the results of specific studies showing an association between Bendectin and various unrelated birth defects were invariably not replicable.[16] By the early 1980s, there was a solid consensus in the medical community that Bendectin was not a teratogen. Nevertheless, the litigation continued.

Berger and Twerski state that the manufacturer withdrew Bendectin from the market "due to widespread fears that it caused severe birth defects in the children whose mothers ingested the drug while pregnant."[17] As with other phantom risks,[18] however, the fears in question were the unreasonable fears of the lay public, stirred by irresponsible interest groups,[19] hired gun and delusional experts, credulous media coverage,[20] and plaintiffs' lawyers,[21] not the fears of the manufacturer, the FDA, or the scientific community.[22]

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[14] Brent, *supra* note 10, at 339 (emphasizing the importance of consistency of results in determining a "real" association).

[15] *See* Kutcher, et al., *supra* note 12, at 89.

[16] Brent, *supra* note 10, at 338-39.

[17] Manuscript at __.

[18] *See* KENNETH R. FOSTER, ET AL., PHANTOM RISK, SCIENTIFIC INFERENCE AND THE LAW 32 (1993); David E. Bernstein, *The Breast Implant Fiasco*, 87 CAL. L. REV. 457, 461 (1999).

[19] The Public Citizen Health Research Group consistently claimed, against the weight of the evidence, that Bendectin was dangerous. Louis Lasagna & Sheila R. Shulman, *Bendectin and the Language of Causation*, in PHANTOM RISK, *supra* note 18, at 101, 107-09.

[20] *See*, *e.g.*, Mark Dowie & Carolyn Marshall, *The Bendectin Cover-Up*, MOTHER JONES, Nov. 1980, at 43; *Experts Reveal . . . Common Drug Causing Deformed Babies*, NAT'L

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Over time Bendectin became the most-studied drug used during pregnancy, and "the massive amount of data does not support a consistent statistical association between Bendectin usage in pregnancy and a particular syndrome or group of malformation."[23] Two meta-analyses of the data from all the epidemiologic studies showed no association between Bendectin and birth defects.[24] The negative epidemiologic data are supported by "ecological analyses" showing that the withdrawal of Bendectin from the U.S. market did not lead to a reduction in *any* category of birth defects.[25] A 2003 study concluded that the "constant rate of birth defects after withdrawal of Bendectin from the market is not consistent with the hypothesis that Bendectin is a teratogen."[26]

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ENQUIRER, Oct. 9, 1979, at 20; John de St. Jorre, *The Morning Sickness Drug Controversy*, N.Y. TIMES, Oct. 12, 1980 (Magazine), at 11.

[21] Melvin Belli, in particular, was responsible for turning Mekdeci's lone case against Bendectin into a flood of litigation, not least by feeding a dramatic story comparing Bendectin to Thalidomide to the *National Enquirer*. *See* GREEN, *supra* note 7, at 134, 183.

[22] *See* C. I. Barash & Louis Lasagna, *The Bendectin Saga: "Voluntary" Discontinuation*, 1 J. CLINICAL RES. DRUG DEVELOPMENT 277 (1987). The FDA, reviewing a petition for approval of a generic version of Bendectin in 1999, confirmed that Bendectin was not withdrawn from sale "for reasons of safety or effectiveness." 64 FED. REG. 43190; *see also* SANDERS, *supra* note 5, at 31; Gideon Koren, et al., *Drugs in Pregnancy*, 338 NEW ENGLAND J. MED. 1128, 1129 (1998) (stating that Bendectin was withdrawn despite a substantial body of evidence that it was safe).

[23] Brent, *supra* note 10, at 338. *See*, *e.g.*, P. H. Shiono & M. A. Klebanoff, *Bendectin and Human Congenital Malformations*, 40 TERATOLOGY 151 (1989) (concluding that there is no increase in the overall rate of major malformations after exposure to Bendectin).

[24] Kutcher, et al., *supra* note 12, at 89.

[25] *Id*. at 96; C. Ineke Neutel & Helen L. Johansen, *Measuring Drug Effectiveness By Default: The Case of Bendectin*, 68 CANADIAN J. PUB. HEALTH 66, 69-70 (1995).

[26] Kutcher, et al., *supra* note 12, at 96.

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A review of the relevant medical literature finds a consensus that Bendectin is not a teratogen.[27] Prominent teratologist Robert Brent concluded in 1995 that "[t]here has never been a drug that has been studied so completely. . . . these data do not even suggest that Bendectin administration during pregnancy represents reproductive or teratogenic risk.[28] The Food and Drug Administration, the World Health Organization, and the March of Dimes have all found that Bendectin is not a teratogen,[29] as did (well before the Bendectin litigation concluded) the governments of Canada,[30] the United Kingdon, Switzerland, West Germany, and Austria.[31] Meanwhile, none of the experts who testified for the plaintiffs in the Bendectin litigation has

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[27] Raafat Bishai, et al., C*ritical Appraisal of Drug Therapy for Nausea and Vomiting of Pregnancy*, 7 CANADIAN J. CLINICAL PHARMACOLOGY 138, 139 (2000) (stating that views that Bendectin is unsafe are "unsubstantiated fears created by misinformation and misperceptions"); D. Jewell & G. Young, *Interventions for Nausea and Vomiting in Early Pregnancy*, THE COCHRANE DATABASE OF SYSTEMATIC REVIEWS, 2003, No. 4 (remarking that observational studies show "no evidence of teratogenicity" from Bendectin); Laura A. Magee, et al., *Evidence-Based View of Safety and Effectiveness of Pharmacologic Therapy for Nausea and Vomiting of Pregnancy (NVP)*, 186 AM. J. OBSTETRICS & GYNECOLOGY S256 (May 2002) (concluding that Bendectin is "safe and effective" for treating morning sickness); Paolo Mazzotta, et al., *Attitudes, Management and Consequences of Nausea and Vomiting of Pregnancy in the United States and Canada*, 70 INT'L J. GYNECOLOGY & OBSTETRICS 359, 360 (2000) (stating that claims that Bendectin has teratogenic effects "were subsequently proven to be unsubstantiated"); Jennifer R. Niebyl, *Overview of Nausea and Vomiting of Pregnancy with an Emphasis on Vitamins and Ginger*, 186 AM. J. OBSTETRICS & GYNECOLOGY S-253, 254 (May 2002) ("no other agent given in pregnancy has more conclusive safety data with regard to teratogenicity").

[28] Brent, *supra* note 10, at 343.

[29] Thomas H. Strong, Jr., *Alternative Therapies of Morning Sickness*, 44 CLINICAL OBSTETRICS & GYNECOLOGY 653, ___ (2001).

[30] *See* Melanie Ornstein, et al., *Bendectin/Diclectin for Morning Sickness: A Canadian Follow-up of an American Tragedy*, 9 REPRODUCTIVE TOXICOLOGY 1, 2-3 (1995).

[31] *See* SANDERS, *supra* note 5, at 87.

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ever published "an analysis, review, or research paper that indicated that Bendectin was a human teratogen."[32]

If Berger and Twerski believe that the causal relationship between Bendectin and the birth defects of the Bendectin plaintiffs was "unresolved" during the litigation (which continued through at least 2000![33]) and (as I read their article) remains "unresolved" now, one struggles to conceive of any purported causal relationship that they would acknowledge has been resolved.

**Criterion 2:** *The drug is not therapeutic but rather its purpose is to avoid discomfort or to improve lifestyle*

According to Berger and Twerski, the "assault on autonomy" through lack of informed consent "is especially egregious in the case of lifestyle drugs where the drug has little therapeutic value." They admit that "there is no bright line that can be drawn between lifestyle and therapeutic drugs," but consider Bendectin to be a lifestyle drug.[34] This suggests that the category of "lifestyle" drug is extremely broad.

Bendectin was used to treat nausea and vomiting during pregnancy, commonly known as morning sickness, and known in the medical literature as NVP. For some women, NVP is a very serious complication of pregnancy. Approximately 1% of pregnant women require hospitalization due to severe vomiting.[35] More generally, women who experience severe vomiting "are at increased risk for preeclampsia, intrauterine growth retardation, and

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[32] Brent, *supra* note 10, at 346.

[33] *See* Blum *ex rel.* Blum v. Merrell Dow Pharmaceuticals, Inc., 764 A.2d 1 (Pa. 2000).

[34] Manuscript at __.

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hospitalization."[36] A significant fraction of women who suffer from severe NVP consider terminating their pregnancies,[37] and one study found that approximately three percent do so.[38]

For a much greater number of women, NVP is "merely" extremely unpleasant and somewhat debilitating. Researchers estimate that 35% of pregnant women have impairment of their daily routine from NVP.[39]

Bendectin was the only FDA-approved drug to treat NVP.[40] Withdrawal of Bendectin may have actually slightly increased birth defect rates, as mothers with severe NVP have difficulty getting proper nutrition,[41] and some pregnant women used "off-label" prescription remedies or "alternative" therapies that had "little, if any, safety information" to relieve their suffering.[42]

Several studies have compared the effects of NVP in the U.S. and Canada. One study found that in both countries, hospitalization rates for NVP doubled when Bendectin was removed

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[35] Niebyl, *supra* note 27, at ___.

[36] Ornstein, et al., *supra* note 30, at 1.

[37] Mazzotta, et al., *supra* note 27, at 364; Paolo Mazzotta, et al., *Factors Associated with Elective Termination of Pregnancy among Canadian and American Women with Nausea and Vomiting of Pregnancy*, 22 J PSYCHOSOM OBSTET GYNAECOL. 7 (2001).

[38] Mazzotta, et al., *supra* note 27.

[39] Niebyl, *supra* note 27.

[40] Mazzotta, et al., *supra* note 27, at 360.

[41] Neutel & Johansen, *supra* note , at 70.

[42] Strong, *supra* note 29.

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from the market following the litigation scare of the early 1980s.[43] Once Bendectin (in a generic version) returned to the Canadian market 1989,[44] hospitalization rates declined in Canada in parallel with increased prescriptions for the drug, while American hospitalization rates remained constant.[45] Another study concluded that "American patients tended to lose, on average, more weight during their NVP, were hospitalized more often than their Canadian counterparts despite similar distribution of the severity of symptoms, and lost more time from paid work."[46] This study concluded that the absence of Bendectin had caused "American women unwarranted and preventable suffering."[47] The withdrawal of Bendectin from the market, was, as one article puts it, "an American tragedy."[48]

**Criterion 3:** *It is almost certain that a patient made aware of the risk that is alleged to be associated with consumption of the drug would have refused to take it.*

Berger and Twerski argue that "[t]here is little doubt that the vast majority of expectant mothers suffering from the discomfort of morning sickness would have refused to take Bendectin to alleviate their discomfort if told that the drug carried with it an uncertain risk of birth defects to their fetuses."[49] In fact, this depends on how the "risk" would have been portrayed. If the risk

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[43] Ornstein, et al., *supra* note 30.

[44] *Id*. at 1.

[45] *Id.*

[46] Mazzotta, et al., *supra* note 27, at 360.

[47] Mazzotta, et al., *supra* note 27, at 365.

[48] Ornstein, et al., *supra* note 30.

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was portrayed as "there is an uncertain risk of birth defects" from Bendectin, Berger and Twerski are likely correct. If it was 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, and there is no reputable evidence to the contrary" the vast majority of women would have reasonably decided to take Bendectin to relieve NVP.[50]

More generally, this raises the issue of what Berger and Twerski consider a "risk" worth informing patients about. Berger and Twerski are inspired in part from the *Davis*[51] and *Reyes*[52] cases, in which plaintiffs, whose children contracted polio from the oral polio vaccine, sued the manufacturer of the vaccine for not disclosing to patients the (well-established) one in a million risk that the vaccine could itself cause polio. Yet a one in a million risk is so small a risk that, prospectively, no reasonable person would worry about. Consider that over a two-year period, the average American has a greater than a one in a million chance of being killed by a lightning strike.[53] The one in a million risk is put in even greater perspective when one recognizes that

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[49] Manuscript at __.

[50] This is how the risk should have been reasonably portrayed to women, and women with mild symptoms of NVP may have chosen to avoid even this "risk." The evidence suggests, however, that some women were inaccurately told by their physicians that Bendectin was "proven safe." For further discussion, see supra note 9.

[51] Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968).

[52] Reyes v. Wyeth Labs., 498 F.2d 1264, 1274 (5th Cir. 1974).

[53] http://www.stats.org/record.jsp?type=news&ID=402.

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being vaccinated for polio actually significantly *reduced* the overall risk of polio to the vaccinee.[54]

More generally, one in a million risk is so low that a drug manufacturer could almost certainly *never* guarantee that an individual drug (or for that matter, many food products!) poses less than this risk of birth defects. Does that mean that every product ingested by women of childbearing age need carry a warning, even if it has been studied extensively and shown not to be teratogenic?

Or, returning to the Bendectin example, does the fact that a few outliers and hired guns are willing to speculate that a drug causes birth defects mean that there is a meaningful "risk" of birth defects? If so, every relevant pharmaceutical product sold in the United States should carry a warning about any conceivable harm that any credentialed doctor or scientist could imagine may arise from using it.

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[54] The *Davis* court argued that while the risk of contracting polio from the vaccine was approximately one in a million, the risk of contracting polio from other sources was also approximately one in a million, so that a rational person might have chosen not to take the risk from the vaccine. The court, however, failed elementary statistics, which points to the hazards of trusting the judicial system with public risk management. The polio vaccine need be given only once, with the one in a million risk providing lifelong immunity. The one in a million risk of contracting polio otherwise was, by the court's own reckoning, *annual*, and thus, over a period of years, far greater than the risk of contracting polio from the vaccine.

It's especially odd that Berger and Twerski use these cases as positive models because it was undisputed in both cases that the risk of the polio vaccine *was* disclosed to the medical community. Berger and Twerski suggest (manuscript at 24) that drug manufacturers would escape liability under their "failure to warn" tort if they "alert physicians so that they in turn can provide information to patients that will enable them to make a meaningful choice." So by their own lights, the polio vaccine cases should be examples of litigation run amok.

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**Criterion 4:** *Defendant drug company was aware of the potential risk or should have undertaken reasonable testing to discover the risk and failed to provide the requisite information to the physician or patient*.

Berger and Twerski conclude that the risk of birth defects from Bendectin was a "material risk" that should have been disclosed to physicians or patients because "it is impossible to rule out" the possibility that Bendectin created a small risk.[55] The primary allegation against Bendectin was that it caused "limb reduction" birth defects, as in the Mekdeci case, but plaintiffs in other cases alleged that Bendectin caused many other, unrelated, fetal problems, ranging from mental retardation to cleft lip to deafness to club feet,[56] and including even genetic defects.[57] As with limb reduction defects, it is "impossible to rule out" the possibility that Bendectin causes any of these defects, because "proving that Bendectin does not cause birth defects is logically impossible."[58] Under the informed choice proposal, these plaintiffs, like Ms. Mekdeci, would

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[55] Manuscript at 26.

[56] Brent, *supra* note 10, at 342.

[57] Robert Brent, *Bendectin and Birth Defects: Hopefully the Final Chapter*, 67 BIRTH DEFECTS RESEARCH 79, 82 (2003).

[58] Lasagna & Shulman, *supra* note 19, at 109. One cannot, as a general matter, prove a negative, and certainly not with epidemiological studies or other tools currently at scientists' disposal. *See* Margaret A. Berger, *Converting Unknown Risk Into Phantom Risk*, http://jurist.law.pitt.edu/lawbooks/revsep99.htm#Berger ("Epidemiological studies are incapable of proving that something has no effects. . . .") (reviewing PHANTOM RISK, *supra* note __).

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deserve compensation for lack of informed consent for the nonexistent "risk" to which they were exposed.[59]

Thus, considering the four "informed choice" criteria discussed above in the context of Bendectin, one concludes that a pharmaceutical manufacturer could be held liable for failure to provide informed choice: (a) even when there was never any sound scientific evidence suggesting that the product caused the harm at issue, and there was an unbroken consensus among leading experts in the field that the product did not cause such harm; (b) when the product prevented serious harm to a significant number of patients, and prevented substantial discomfort to a much greater number, even when there were no available alternative products; (c) when a plaintiff claims that she would not have taken the product had she been informed of an incredibly remote and completely unproven risk; and (d) when the defendant is unable to do what will generally be impossible, that is, prove that there is no possibility that the product in question causes the harm alleged.

Quite properly, Berger and Twerski might protest that their proposal shouldn't stand or fall on the poorly chosen example of Bendectin.[60] There may very well be another product—

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[59] Indeed, Berger and Twerski might allow these plaintiffs to be compensated if they were not apprised of the risk of limb reduction defects, even though their children did not suffer this particular problem. They praise *Canesi v. Wilson*, 730 A.2d 805 (N.J. 1997), a case in which the plaintiffs were unable to produce *any* expert evidence of a relationship between the mother's ingestion of Provera and their baby's limb reduction defect. The court nevertheless allowed recovery for "wrongful birth" because the plaintiff's physician failed to warn that at the time of her pregnancy, there was concern that Provera caused congenital defects, including limb reductions. Had the mother been warned she may have aborted the child. The dissent eviscerates the majority's logic, which eliminates proximate cause from the tort of wrongful birth.

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say, Parlodel, which Berger and Twerski also discuss—whose history would support an informed choice cause of action under a far narrower interpretation of the proposed criteria. However, the informed choice proposal would still have weaknesses that make it a very bad idea, as discussed below.

A. *The Proposal Invites Reliance on Unreliable Testimony*

Berger and Twerski note that a great deal of marginal testimony on causation in toxic torts cases has been excluded under the *Daubert* trilogy. However, they argue that much of this testimony would be admissible in an informed choice action. Defendants would be hard-pressed, they argue, to successfully challenge plaintiffs' expert on their ability to assess risk, given that they generally have the appropriate academic credentials.[61]

Risk assessment experts with appropriate credentials will certainly be *qualified* to appear as experts. Federal Rule of Evidence 702 (incorporating the *Daubert* trilogy), however, requires that testimony by a qualified expert (1) be "based upon sufficient facts or data", (2) be "the product of reliable principles and methods," and (3) "appl[y] the principles and methods reliably to the facts of the case." These criteria apply to risk assessment as much as to causation testimony. As Berger and Twerski argue, in specific cases, expert testimony based on a mosaic

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[60] But see notes __ to __ and accompanying text (noting that Berger and Twerski praise highly questionable court decisions on other issues).

[61] Berger and Twerski earlier sound a more cautionary note, stating that "courts will have to remain sensitive to allowing junk science to enter the courtroom" and that courts should ferret out "unworthy and frivolous claims." Manuscript at 25-26. But their later focus on the credentials of expert risk assessors suggests an unduly narrow interpretation of "junk science" and "unworthy and frivolous claims."

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of evidence[62] from sources that are frequently excluded when used to prove causation—such as anecdotal evidence,[63] animal studies,[64] chemical structure analysis,[65] in vitro studies,[66] and preliminary epidemiological studies[67]—could, taken together, be sufficient to objectively warrant a warning about a product.[68] But the mere fact that a "qualified" adversarial expert is willing to testify that a product was sufficiently risky to require a warning does not make his testimony sufficiently reliable to be admitted under Rule 702.

In addition the stringent requirements of Rule 702, there are sound reasons why courts are skeptical of "mosaic" testimony. The essential problem is that extrapolating from various types of evidence that are individually of dubious value to determine the riskiness of a product or

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[62] See Ferebee v. Chevron Chemical Co., 736 F.2d __, 1535 (D.C. Cir. 1984) (popularizing the "mosaic" concept in toxic tort litigation).

[63] David H. Kaye & David A. Freedman, *Reference Guide on Statistics*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 91–92 (Federal Judicial Center ed., 2d ed. 2000) (discussing the general unreliability of anecdotal evidence of causation).

[64] For articles noting the difficulty of extrapolating teratogenicity to humans from animal studies, see, e.g., Koren, et al., *supra* note **Error! Bookmark not defined.**, at __; Louis Lasagna, *Predicting Human Drug Safety from Animal Studies: Current Issues*, 12 J. TOXICOLOGICAL SCI. 439, 442-43 (1987). Similar problems arise with regard to animal studies and cancer.

[65] *See* DeLuca v. Merrell Dow Pharmaceuticals, Inc., 791 F. Supp. 1042, 1054 (D.N.J. 1992), *aff 'd* , 6 F.3d 778 (3d Cir. 1993) (concluding that there is no evidence that Bendectin is associated with birth defects simply because other drugs with similar chemical structures are associated with birth defects).

[66] *See* Brent, *supra* note 10, at 342 (stating that in vitro studies "can never establish human teratogenicity by themselves").

[67] *See* Gary Taubes, *Epidemiology Faces its Limits*, 269 SCIENCE 164 (1995) (noting that epidemiology is subject to systematic errors, biases and confounders).

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substance inevitably requires a certain amount of educated guesswork and even speculation. In a typical courtroom setting, however, the experts engaging in this guesswork and speculation will not be neutral scientists chosen because of their expertise and objectivity, but instead will be adversarial experts chosen by the plaintiffs because the plaintiffs' attorney knows that they are willing to testify that agree with his theory of the case.

The problem with such adversarial experts is two-fold. First, the experts in question may be hired guns "who view their role less as helping the trier of fact and more as aiding the cause of the attorneys who hired them."[69] Second, given liberal expert qualification standards,[70] especially for medical testimony, many "qualified" experts who are chosen to testify in toxic torts cases are outliers who hold views far outside the mainstream of their professions, with little if any valid evidence supporting their views. Over the years, the courts have been flooded with qualified experts who seem to sincerely believe in various forms of quackery.[71]

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[68] *See*, *e.g.*, NATIONAL ACADEMY OF SCIENCES, DIETARY SUPPLEMENTS: A FRAMEWORK FOR EVALUATING SAFETY 255-60 (2004).

[69] *See* DAVID H. KAYE, ET AL., THE NEW WIGMORE: EXPERT EVIDENCE 5 (2004).

[70] *Id.* at ch. 2.

[71] For example, for decades, many qualified experts testified that physical trauma to a body part can cause cancer. More recently, qualified experts have testified that minor exposure to radiation causes a huge increase in cancer risk, and that exposure to chemical fumes can cause the body's immune system to shut down, leaving the victim "allergic to everything." *See* PHANTOM RISK, *supra* note 18, at 349-53, chs. 13, 15-16, 425-28. Qualified experts have also provided extremely tendentious testimony in asbestos litigation, finding that almost every person referred to them by plaintiffs' attorneys has been harmed by asbestos exposure, however minimal. *See* David E. Berntsein, *Keeping Junk Science Out of Asbestos Litigation*, 31 PEPP. L. REV. 11 (2003); *cf. In re* Silica Prods. Liab. Litig., 2005 WL 1593936, slip op. (S.D. Tex. June 30, 2005) (describing in excrutiating detail the inadequacies and unreaonableness of plaintiffs' experts' testimony).

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Between the outlier problem and the hired gun problem, qualified experts have been all too willing to testify to causal relationships lacking sound scientific support,[72] even when, as was the case with Bendectin, a solid line of epidemiological studies contradicted their views. It would likely be even easier to find an expert willing to testify to his purchased or idiosyncratic views regarding a mere risk. Given the fact that "[s]cience can never demonstrate the absence of hazard, still less the absence of 'reasonable' grounds for anxiety," but "can only place an upper limit on risk,"[73] fear of professional embarrassment is less likely to deter experts from speculating regarding risk than regarding causation. While excluding mosaic evidence may lead to some "false negatives," it is likely to exclude far more "false positives," and courts would be well-served to demand a guarantee of reliability beyond the say-so of the adversarial expert.

An additional and related problem with the Berger and Twerski proposal is that it would present an irresistible lure to interest groups to promote junk-science based lawsuits that would further their goals. One can already point to many examples of interest groups helping to spawn and sustain litigation based on extremely weak evidence where the plaintiffs were, at least in theory, required to meet traditional causation requirements.[74] It would be even easier for interest groups to stir up or engage in litigation when all that is required for victory is some marginal evidence of "risk."

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[72] *See generally* PHANTOM RISK, *supra* note 18 (discussing expert testimony on various causation issues that was at variance with the consensus of scientific research and opinion on the issues).

[73] *Id.* at 435.

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For example, several preliminary epidemiological studies—more evidence than the Bendectin plaintiffs ever had—have suggested that abortion increases the risk of breast cancer.[75] Even though those studies have since been debunked,[76] anti-abortion groups have nevertheless seized on them to argue that women should be warned about the risk of breast cancer before they can have an abortion. Under the informed choice proposal, it would seem that abortion providers should be subject to lawsuits by women who had abortions and later contracted breast cancer.[77]

B. Jury Are Not Competent to Determine Subtle Risk Assessment Issues:

Berger and Twerski write that their proposal requires juries to decide "whether the signs of risk and their potential gravity were sufficiently strong to require a drug manufacturer to alert

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[74] *Id*. at 32-33 (mentioning oral contraceptives, Bendectin, dioxin, and PCBs); Bernstein, *supra* note 18, at 465-66, 469-70 (discussing silicone breast implants).

[75] *E.g.*, Malcolm C. Pike, et al., *Oral Contraceptive Use and Early Abortion as Risk Factors for Breast Cancer in Young Women*, 43 BRIT. J. CANCER 726 (1981); H.L. Howe, et al., *Early Abortion and Breast Cancer Risk among Women under Age 40*, 18 INT. J. EPIDEMIOLOGY 300 (1989); Janet Daling, *Risk of Breast Cancer Among Young Women*, 86 J. NAT'L CANCER INST. 1584 (1994); P. Newcomb, et al., *Pregnancy Termination & Risk of Breast Cancer*, 275 JAMA 283 (1996)

[76] *See, e.g.*, Valerie Beral, et al., *Breast Cancer and Abortion: Collaborative Reanalysis of Data from 53 Epidemiological Studies, Including 83,000 Women with Breast Cancer from 16 Countries*, 363 LANCET 1016 (2004); Committee on Gynecologic Practice, American College of Obstetricians and Gynecologists, *ACOG Committee Opinion: Induced Abortion and Breast Cancer Risk*, 83 INT'L J GYNAECOLOGY & OBSTETRICS 235 (2003).

[77] Indeed, though they analogize their tort to informed consent in medical practice, Berger and Twerski's proposal could easily be expanded beyond the medical context, and permit individuals to sue based on lack of "informed consent" to the purported risks from flouride in the drinking water, pesticide residue on fruit, brief exposure to carbon monoxide in parking garages, and so on. Certainly, dentists would be on the hook for not warning patients of the "risk" from mercury in fillings. *See*, *e.g.*, http://www.holisticmed.com/dental/amalgam/. For the scientific evidence, see http://www.quackwatch.org/01QuackeryRelatedTopics/mercury.html; http://www.ada.org/prof/resources/positions/statements/amalgam.asp

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physicians so that they in turn can provide information to patients that will enable them to make a meaningful choice." Such risks need not be "significant enough to warrant forceful or drastic action by the FDA such as requiring black box warnings or removing the drug from the market." Yet there is little reason to believe that jurors (or judges) with no expertise in science in general or risk assessment in particular, privy only to paid adversarial expert testimony, and subject to hindsight bias[78] (if data supporting the existence of risk was discovered after the company made its decision not to warn), are competent to make such subtle determinations.[79]

Indeed, juries have often proven themselves incapable to making "easy" scientific determinations—often finding, for example, in favor of Bendectin and breast implant plaintiffs, despite a lack of reliable evidence on even general causation.[80] Juries are even less likely to accurately resolve far more difficult and subtle "failure to warn of a risk that the defendant knew or should have known but that doesn't rise to the level where the FDA should take action" claims.

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[78] *See generally* Jeffrey J. Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, 65 U. CHI. L. REV. 2 (1998).

[79] *See generally* I. M. Lipkus, et al., *General Performance on a Numeracy Scale among Highly Educated Samples*, 21 MED. DECISION MAKING 37 (2001) (concluding that "even highly educated participants have difficulty with relatively simple numeracy questions"). The problem of lack of jury competence to deal with complex scientific issues is recognized throughout the common-law world. *See* David E. Bernstein, J*unk Science in the United States and the Commonwealth*, 21 YALE J. INT'L L. 123 (1996)

[80] For Bendectin, see SANDERS, *supra* note 5, at 118; for breast implants, see Bernstein, *supra* note 18. A more recent example is "toxic mold" cases. *See* Daniel Fisher, *Dr. Mold*, April 11, 2005, at 100.

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Ironically, Twerski himself has warned against open-ended failure to warn schemes precisely because juries have no sound way of making the determinations require, concluding that "the standards governing failure-to-warn negligence claims provide restraints on jury discretion that are so inadequate as to be virtually nonexistent. . . . [T]he problem resides in the fact that the standards governing failure to warn too frequently rely on unavailable data and unverifiable facts.[81] Twerski's critique applies precisely to his and Berger's informed choice proposal.

C. Even Assuming Juror Competence, the Proposal Asks Too Much of Juries

Berger and Twerski argue "informed choice" plaintiffs should also be permitted to present to the jury evidence of causation. The Court would rule on the Rule 702 issue with regard to causation only at the end of the trial. If the court excluded that evidence, "Plaintiffs would then be free to use the testimony of their experts to support their claim for informed choice."

The jury, then, would be in the position of knowing that qualified experts, relying on what they (but not the judge) believe to be reliable evidence, think that the product in question more likely than not caused the plaintiff's horrible injury; that plaintiff has, due to this injury, suffered grievous and costly physical and emotional harm; and, potentially, that the defendant has allegedly engaged in all sorts of misconduct warranting punitive damages. The jury is then supposed to ignore the causation and damages evidence they just heard and dispassionately decide whether the evidence of "risk" presented by the plaintiff's experts warrants granting the

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[81] James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products*

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plaintiff emotional distress damages based on lack of informed choice, knowing that if they rule for the defendants on this issue, the plaintiff will receive no compensation.

To expect such dispassion after juries hear evidence on both causation and damages requires an unwarranted belief in the ability of juries to both follow limiting instructions[82] and ignore their emotions.[83] The latter is especially problematic because good trial attorneys are masters at appealing to juries' emotions.[84] One likely outcome in many informed choice cases would be that jurors would implicitly shift the burden to defendants to prove that there was no risk worth warning about.[85] Because, as noted previously, science can't prove a negative, this would mean that the defendants would generally lose.

D. The Proposal Ignores the Problems Inherent to Multiple Trials

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*Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 289 (1990).

[82] Jeffrey J. Rachlinski, et al., *Can Judges Ignore Inadmissible Information? The Difficulty of Deliberately Disregarding*, 153 U. PA. L. REV. 1253 1260-74 (2005) (reviewing the evidence that individuals in general, and jurors in particular, are frequently unable to wilfully ignore relevant information, and that, in fact, jurors sometimes give *more* weight to evidence they are told to ignore).

[83] *See* Kari Edwards & Tamara S. Bryan, *Judgmental Biases Produced by Instructions to Disregard: The (Paradoxical) Case of Emotional Information*, 23 PERSONALITY & SOC. PSCYHOL. BULL. 849, 856 (1997) (concluding that information that elicits emotions is especially difficult to ignore).

[84] *See* WALTER K. OLSON, THE RULE OF LAWYERS ch. 12 (2003) ("the art of the runaway jury"); Bernstein, *supra* note 18, at 495 (providing examples from the breast implant litigation).

[85] Such implicit burden-shifting already occurs even with regard to causation issues. *See, e.g.*, Bernstein, *supra* note 18, at 496 (providing an example from the breast implant litigation). Such burden-shifting would not necessarily trouble Professor Berger, who has previously advocated burden-shifting in certain toxic torts cases. Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2144-45 (1997). I criticize Berger's proposal and like-minded proposals, while suggesting an

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Let's assume *arguendo* that despite the problems noted above, 90% of juries reach the objectively correct conclusion on informed choice claims. A manufacturer of a popular and perfectly safe product could still face thousands of successful claims.

For example, even with a ninety percent success rate, Merrell Dow Pharmaceuticals, manufacturer of Bendectin, could have faced liability for claims from over twenty thousand women that they should have been warned that Bendectin could cause heart defects in their offspring.[86] The efficient response for Merrell Dow once this success rate became clear would have been to settle all two hundred plus thousand claims for ten cents on the dollar. If each successful plaintiff was awarded an average of fifty thousand dollars in "dignitary" damages, Merrell Dow would have been forced to pay over one billion dollars, and would also have been on the hook for the expenses and distractions of litigation. No rational legal system would expose innocent manufacturers to such risk.

E. The Proposal Fails to Consider the Potential Costs of Informed Choice Litigation

One cost of informed choice litigation involves those who, out of fear generated by the publicity attending lawsuits (often stoked by plaintiffs' attorneys and public relations firms they hire), avoid using a safe product that could be useful to them. For example, as a result of the Bendectin litigation many women fail to get treatment for nausea during pregnancy because of

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alternative mechanism for encouraging corporations to engage in appropriate behavior with regard to risk, in Bernstein, *The Breast Implant Fiasco*, *supra*.

[86] Brent, *supra* note 10, at 340 (noting that statistically, one would expect that women who ingested Bendectin would give birth to two hundred and forty thousand children with congenital heart malformations, the same ratio as for women not exposed to Bendectin).

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unfounded fears of teratogenicity.[87] For that matter, doctors became very afraid to recommend any medication for NVP, including a version of Bendectin that could be created by combining two over-the-counter ingredients.[88]

Publicity warning of purported risks "may create stress whether the warnings are realistic or not."[89] Some individuals may even engage in truly risky or damaging actions to avoid a well-publicized phantom risk. Publicity over Bendectin's purported association of birth defects led at least seven women to abort their unborn children because they were afraid that their ingestion of Bendectin would lead to birth defects.[90] Many women unnecessarily had their breast implants explanted after claims that implants are associated with immune system disease or cancer were circulated in the media by litigants and activist groups.[91] Others underwent costly, unnecessary, and risky treatments to combat nonexistent implant-related ailments; many more delayed getting treatment for the true underlying causes of their medical problems.[92] Parents are increasingly

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[87] Paolo Mazzotta, et al., *The Perception of Teratogenic Risk by Women with Nausea and Vomiting of Pregnancy* 13 REPRODUCTIVE TOXICOLOGY 313 (1999); Koren, et al., *supra* note **Error! Bookmark not defined.**.

[88] *See* Gina Kolata, *Controversial Drug Makes a Comeback*, N.Y. TIMES, Sept. 26, 2000, at F1.

[89] Paul R. Lees-Haley & Richard S. Brown, *Biases in Perception and Reporting Following a Perceived Toxic Exposure*, 75 PERCEPTUAL & MOTOR SKILLS 531, 531 (1992).

[90] Strong, *supra* note 29, at __.

[91] *See*, *e.g.*, Norris v. Baxter Healthcare Corp., ___ F.3d ___, 2005 WL 290025 (10th Cir. 2005) (noting that plaintiff had her implants removed because of fear that they were causing "silicone-induced lupus").

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reluctant to vaccinate their children because of unsubstantiated claims, currently pending in a major class action, that thimerosal in the vaccines causes autism.[93] And so on.

Another cost of contentious litigation over scientific issues is the burden it places on the scientific community. Litigation often leads to burdensome discovery requests to, or even harassment of, scientists whose work on the issue conflicts with one side's views. For example, one scientist who conducted a study on Bendectin reports that an attorney subpoenaed all of the original records involved in the study, including 4,500 interviews, computer tapes, and all printed computer output.[94] This material was never used by the attorney. Epidemiologists conducting research on breast implants were subpoenaed to provide "huge quantities of primary data in a reportedly intimidating manner."[95]

Finally, there is the cost to innovation. For example, unjustified litigation over products such as Bendectin, spermicides, and birth control pills spurred a decline in contraceptive research;[96] unjustified lawsuits against vaccines led to a decline in vaccine research;[97] and

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[92] *See* MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 147-151 (1996).

[93] For the latest media hysteria on this issue, see Robert F. Kennedy, Jr., *Deadly Immunity*, http://www.salon.com/news/feature/2005/06/16/thimerosal/index1.html. For a thorough debunking, see *Salon.com Flushes its Credibility Down the Toilet*, http://oracknows.blogspot.com/2005/06/saloncom-flushes-its-credibility-down.html.

[94] Michael B. Bracken, *Alarums False, Alarums Real: Challenges and Threats to the Future of Epidemiology*, 8 ANNALS OF EPIDEMIOLOGY 79, 80 (1998).

[95] *Id.*

[96] Peter W. Huber, *Litigation Thwarts Innovation in the U.S.*, SCI. AM., March 1989, at 120; *see also* Elizabeth Connell, *The Cost of Frivolous Lawsuits*, FAMILY PRACTICE NEWS, Jan. 15, 2004, at 14.

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unjustified lawsuits against breast implants threatened entire categories of medical products research.[98]

At least in federal court, Rule 702, incorporating the *Daubert* trilogy has removed much of the danger of liability for causation based on highly speculative evidence. But Berger and Twerski would have plaintiffs get around *Daubert* by suing for informed choice. While successful informed choice actions would individually be less costly than causation actions,[99] it would be much easier to persuade judges and juries to rule in favor for plaintiffs. One could therefore expect pharmaceutical companies to face far more lawsuits for lack of informed choice than they ever faced for causation. Under such circumstances, "who in their right mind would work on a product that would be used by pregnant women?"[100]

F. The Informed Choice Proposal Would Lead to a Vast Surfeit of Warnings

Berger and Twerski acknowledge that "there is little social utility in providing information that is so tentative and unreliable that it will serve no other purpose other than to frighten patients who need the drug away from its use."[101] But given the issues discussed above, if drug manufacturers wanted to immunize themselves from unpredictable and potentially

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[97] *See, e.g.,* Henry I. Miller, *How Lawsuits Can Kill*, Scripps Howard News Service, Dec. 9, 2004.

[98] *See* Bernstein, *supra* note 18.

[99] Disturbingly, however, Berger and Twerski praise the New Jersey Supreme Court's opinion in Canesi v. Wilson, 730 A.2d 805 (N.J. 1999), in which a victim of lack of "informed choice," resulting in "wrongful birth," was awarded damages not just for emotional injury, but for the cost of raising a baby with a birth defect, despite the absence of evidence from plaintiffs' experts of a connection between the defect and the product ingested.

[100] *See* Huber, *supra* note 96.

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unlimited liability, they would, if courts found that it shielded them, likely warn doctors and patients about every conceivable risk. Perhaps a standard disclaimer along the lines of "this drug has been proven safe and effective to the satisfaction of the FDA, but it may cause birth defects, cancer, stroke, hypertension, hives, convulsions, sexual dysfunction and [use your imagination]" would become standard. Such defensive warnings would be worse than useless—they would diminish the impact and credibility of warnings based on substantiated concerns, and make it more difficult for physicians and patients to properly weigh the risks and benefits of a product.[102]

G. The Informed Choice Proposal May Be Barred by the Preemption Doctrine

In a case involving an allegation that Pfizer failed to warn of the alleged risk of suicide from taking Zoloft, the FDA filed an amicus brief arguing that "to require a warning of a supposed danger that FDA concludes has no actual scientific basis, no matter, the warning's language, would be to require a statement that would be false and misleading, and thus contrary to federal law."[103] The FDA, for example, would not have approved a label warning that Bendectin may cause birth defects, and, according to the FDA (and at least one district court),

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[101] Manuscript at __.

[102] *See* Doe v. Miles Labs., Inc., 927 F.2d 187 (4th Cir. 1991) ("if pharmaceutical companies were required to warn of every suspected risk that could possibly attend the use of a drug, the consuming public would be so barraged with warnings that it would undermine the effectiveness of these warnings"); Henderson & Twerski, *supra* note 81, at 296 ("The most significant social cost generated by requiring [defendants] to warn against remote risks is the reduced effectiveness of potentially helpful warnings directed at risks which are not remote."). For a discussion of some of the difficulties consumers face in deciphering even rather basic pharmaceutical safety information, see P. Knapp, et al., *Comparison of Two Methods of Presenting Risk Information to Patients About the Side Effects of Medicines*, 13 QUALITY & SAFETY IN HEALTH CARE 176 (2004).

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any common law claim based on failure to warn that Bendectin may cause birth defects would be preempted.[104] While the FDA's position is thus far a minority view among federal courts that have addressed the issue,[105] the ultimate outcome of the preemption issue awaits Supreme Court decision.

## Conclusion

The problems Berger and Twerski purport to address---the inadequacy of premarket review for detecting small but material risks, and the failure of the current federal regulatory system to adequately address postmarket safety review---are serious ones.[106] But given the inability of the tort system as it is currently situated to address product safety in general, and drug safety in particular, in a rational, scientifically justifiable manner, the least attractive possible response to the postmarket review problem is to create a new, broad, openended, common law tort—especially one that, as conceived by Berger and Twerski, virtually invites attorneys to bring claims based on junk science, fails to take any account of the limitations of

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[103] Amicus Brief of the United States in Support of the Defendant-Appellee and Cross-Appellant, Motus v. Pfizer Inc, Sept. 10, 2002, 2002 WL 32303084, at *2 (9th Cir.).

[104] Ehlis v. Shire Richwood, Inc., 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002), *aff'd on other ground*, 367 F.3d 1013 (8th Cir. 2004).

[105] *See* Cartwright v. Pfizer, Inc., ___ F. Supp. 3d __, 2005 WL 1155201 (E.D.Tex.).

[106] *See* Funmilayo O. Ajayi, et al., *Adverse Drug Reactions: A Review of Relevant Factors*, 40 J. CLINICAL PHARMACOL. 1093, 1099 (2000) (concluding that the safety profile of a newly marketed drug cannot be fully understood until two to three years after it reaches the market); C. L. Bennett, et al.,*The Research on Adverse Drug Events and Reports (RADAR) Project*, 293 JAMA 2131 (2005); Timothy Brewer & Graham A. Colditz, *Postmarketing Surveillance and Adverse Drug Reactions: Current Perspective and Future Needs*, 281 J. AM. MED. ASS'N 824 (1999) (discussing the incompleteness of premarket trials); D. M. Roden, *An Underrecognized Challenge in Evaluating Postmarketing Drug Safety*, 111 CIRCULATION 246 (2004).

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juries, and that would almost certainly have counterproductive overall safety effects. In fact, their proposed informed choice tort seems more designed to allow plaintiffs an end run around *Daubert*/Rule 702 than to address the problems at hand. [107]

By contrast, Professor Catherine Struve has recently proposed[108] a hybrid *qui tam* system, subject to opt-in or opt-out by drug companies, that (1) is a clever rejoinder to the advocates of absolute FDA preemption; (2) 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; and (3) provides incentives for potential claimants to discover real hazards, instead of giving plaintiffs' attorneys incentives to pursue lucrative, albeit bogus, cases.[109] While this brief Response is not the appropriate forum for a full-fledged discussion of Struve's proposal, I commend it to readers as a starting point for thinking about how better postmarket review of pharmaceutical safety can be achieved.[110]

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[107] Otherwise, why require that the plaintiff show that she actually suffered the injury not warned against? Why not let all consumers deprived of their "dignity" through lack of informed choice to sue? Also, if Professor Twerski is not implicitly endorsing an end-run around *Daubert* I find it very difficult to reconcile his advocacy of an "informed choice" tort with his scathing critique of emotional distress damages for asymptomatic asbestos plaintiffs. *See* James A. Henderson, Jr. & Aaron D. Twerski, *Asbestos Litigation Gone Mad: Exposure-based Recovery for Increased Risk, Mental Distress, and Medical Monitoring*, 53 S.C. L. REV. 815 (2002). Not to mention that part of the Article's title is "Unmasking *Daubert*."

[108] Catherine T. Struve, The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation, (forthcoming, Yale J. Health Pol'y, L. & Ethics).

[109] I briefly sketched a system for incentivizing the reporting of safety hazards ignored by corporations consistent with Professor Struve's system in Bernstein, *supra* note 18.

[110] A more radical solution to the problem of asymmetries in (and the absence of) information regarding pharmaceutical safety would be to create information markets to predict the probability that the manufacturer or the FDA will, over some long time horizon, permanently

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Instead of addressing this issue head-on, Berger and Twerski's informed choice proposal seeks to provide either peace of mind from, or compensation for, irrational, unsubstantiated fears and regrets. Thus, Betty Mekdeci (and presumably thousands of others) should have been able to recover from Merrell Dow Pharmaceuticals for her irrational and unsubstantiated fear that Bendectin caused her son's birth defect, and for her concomitant regret that she ingested Bendectin.

The real victims of the Bendectin saga, however, were women who unnecessarily became frightened that they had harmed their babies by taking Bendectin (including those unfortunate few who aborted their unborn children); women who have gone without treatment for NVP, because of the withdrawal of Bendectin and the accompanying hysteria; women who continue to have a dearth of NVP treatments, contraceptives, and other medical choices because medical companies have learned from the Bendectin and other products liability litigation that such products are "litogens" and therefore avoid them; and (d) Merrell Dow Pharmaceuticals, its shareholders, and insurer, which faced protracted and expensive litigation based on junk science. Such victims are, of course, given no redress under Berger and Twerski's proposal, nor would the perpetrators of the Bendectin tragedy---Mekdeci herself, the plaintiffs' attorneys, Public Citizen, the media, and hired gun expert witnesses---have faced any punishment. Berger and Twerski have learned the wrong lessons from an American tragedy.

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recall or revoke permission to distribute a drug. *See* Michael Abramowicz, *Information Markets, Administrative Decisionmaking, and Predictive Cost-Benefit Analysis*, 71 U. CHI. L. REV. 933, 992-93 (2004).

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