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# A One Term Tort Reform Tale: Victimizing the Vulnerable

Andrew F. Popper

# ARTICLE

# A ONE-TERM TORT REFORM TALE: VICTIMIZING THE VULNERABLE

ANDREW F. POPPER*

*During its spring 1997 term, Congress passed the Volunteer Protection Act and considered but did not pass the Biomaterials Access Assurance Act of 1997. The Volunteer Protection Act provides a wide range of tort immunities to volunteers working for charitable organizations. The Biomaterials Access Assurance Act would have provided tort immunity to biomaterials producers. In this Article, the author examines the origins and possible implications of both these tort reform proposals from a class-based perspective and within the broader context of the ongoing tort reform debate. The author concludes that both of these proposals ultimately would harm individuals in vulnerable positions: those in need of volunteer services and those dependent on certain medical devices.*

During the spring 1997 term of Congress, tort reformers once again pursued those elusive, sweeping legislative rewards available only at the federal level.[1] As has been the case each year since 1983,[2] comprehensive legislation regarding product liabil-

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* Professor of Law, American University, Washington College of Law. During the spring 1997 term of Congress, the author testified before the House Committee on the Judiciary regarding tort immunity for volunteers, and before the Subcommittee on Telecommunications, Trade, and Consumer Protection of the House Committee on Commerce regarding immunity for suppliers of raw materials to the biomaterials industry. This Article is based on the author's testimony, observations, and reactions to those hearings. The views expressed are the author's, not those of American University or any other individual or organization.

[1] Proponents of tort reform attempted this without abandoning similar efforts in state legislatures. At least 25 states have, by legislation or judicial action, limited the capacity of injured plaintiffs to use the courts to secure redress. *See* BMW of N. Am., Inc. v. Gore, 116 S. Ct. 1589, 1618–19 (1996). For examples of recent state tort reform, see H.B. 637, 1995 N.C. Sess. Laws 522; H.B. 18, 1996 La. Sess. Law Serv. 1 (West); and H.E.A. 1741, 1995 Ind. Legis. Serv. 278 (West); *see also* Beth Rodgers, *Legal Reform—At the Expense of Federalism?: House Bill 956, Common Sense Civil Justice Reform Act and Senate Bill 565, Product Liability Reform Act*, 21 U. DAYTON L. REV. 513, 522 (1996) ("All fifty states have enacted changes to the basic structure of tort law."). Further, the American Law Institute has finished a draft of the Restatement (Third) of Torts, that embodies numerous aspects of the tort reform agenda, such as the elimination of strict liability for design defects. *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (Proposed First Draft 1997); *see also* Marshall S. Shapo, *In Search of the Law of Products Liability: The ALI Restatement Project*, 48 VAND. L. REV. 631 (1995).

[2] The first generic tort reform bill of consequence was S. 44, 98th Cong. (1983). This legislation would have rewritten the field in all areas, but most particularly with respect to punitive damages. Subsequent, comparable legislation includes S. 966, 105th Cong. (1997); S. 886, 105th Cong. (1997); S. 648, 105th Cong. (1997); S. 543, 105th Cong. (1997) (enacted); H.R. 872, 105th Cong. (1997); S. 364, 105th Cong. (1997); H.R. 956,

ity and tort law failed.[3] Of several narrow legislative initiatives, only one,[4] granting tort immunity to volunteers, was enacted. The passage of this one bill is significant, however, as it severely restricts the ability of injured consumers to pursue claims in various courts. Comment on the passage of this law, as well as on the near adoption of a second narrowly focused bill regarding biomaterials,[5] is thus timely.

This Article criticizes proposed changes in the system of civil liability. Part I examines the political and economic alignments behind tort reform, specifically with reference to the aforementioned legislative proposals. Part II analyzes the volunteer immunity legislation both in terms of the broad tort reform debate and from the vantage of the particular interests affected. Part III focuses on the legislative strategy employed in the failed attempt to immunize biomaterials producers, and evaluates their argument that the present tort system jeopardizes their industry's viability. The Article concludes that the reform proposals would significantly reduce legal protections for at-risk citizens whom the proposals purport to assist: the poor, the aged, the young, and the sick, who rely on the services and products offered by these sectors.

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104th Cong. (1995); H.R. 911, 104th Cong. (1995); H.R. 10, 104th Cong. (1995); S. 687, 103d Cong. (1993).

[3] The Product Liability Reform Act of 1997, S. 648, 105th Cong., was a broad tort reform bill similar to prior proposals. Its provisions would have limited access to the courts, capped damages, weakened joint and several liability, and mandated other changes in state law to the detriment of injured plaintiffs. Section 108(b)(1), with some exceptions, would have limited the amount of punitive damages to the greater of two times the sum of the amount awarded to the claimant for economic loss and non-economic loss, or $250,000. Section 110(a) states that the liability of each defendant for non-economic loss shall be several but not joint. This bill did not pass during the spring 1997 term. The text of the bill has been debated and considered before and was referred to as The Common Sense Legal Standards Reform Act of 1995 (considered first as H.R. 956, 104th Cong. (1995)). The Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737 (codified as amended at 15 U.S.C.A. § 77(a) *et seq.* (West Supp. 1996)), was Part I of the legislation and became law on December 22, 1995. *See generally* James Cahoy, *Tort Reform Legislation Since 1994*, W. LEGAL NEWS, Dec. 6, 1996, at 13,055, *available in* 1996 WL 699299.

[4] Volunteer Protection Act of 1997, 105 Pub. L. No. 19, 111 Stat. 218 (signed June 18, 1997).

[5] *See* Biomaterials Access Assurance Act of 1997, H.R. 872, 105th Cong. The Biomaterials Access Assurance Act was also a rider implanted in S. 648, the Product Liability Act of 1997, 105th Cong., Title II. *See infra* note 26. This bill has been referred to various committees for review as H.R. 872 (referred to the House Comm. on the Judiciary and Comm. on Commerce Feb. 27, 1997), S. 364 (referred to the Senate Comm. on Commerce, Science, and Transportation Feb. 26, 1997), S. 886, Subtitle B (referred to the Senate Comm. on Labor and Human Resources June 11, 1997), and S. 966 (referred to the Senate Comm. on Commerce, Science, and Transportation June 26, 1997).

## I. Tort Reform in the Context of the American Business Agenda

### A. *Generalizing the Class-Based Critique*

The term "reform" suggests affirmative change that benefits society, such as strengthened consumer protection laws and heightened civil liability to improve the quality of goods and services. Consumer advocates, however, have long contended that tort reformers have little intention of pursuing these goals.[6] They argue that the tort reform agenda instead promotes the aims of insurers and manufacturers.[7] Indeed, tort reformers have tried to limit civil litigation options,[8] reduce exposure to civil liability,[9] and enact legislation that allows industry to calculate its exposure in advance and pass the cost on to the consumer in the prices of goods and services.[10] Proponents frame tort reform as

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[6] *See* Michael L. Rustad, *Nationalizing Tort Law: The Republican Attack on Women, Blue Collar Workers and Consumers*, 48 Rutgers L. Rev. 673 (1996); *see also* David Baldus et al., *Improving Judicial Oversight of Jury Damages Assessments: A Proposal for Comparative Additur/Remittitur Review of Awards for Nonpecuniary Harms and Punitive Damages*, 80 Iowa L. Rev. 1109 (1995) (remarks of Advisory Panel Member Larry S. Stewart, Esq., Stewart, Tilgham, Fox & Bianchi, P.A., Miami, Fla.: "The reformers were not, however, interested in true reform to improve consumer rights. Rather, the tort reform advocates have spent untold millions of dollars to promote ways to eliminate or control jury decisions and thereby to reduce their individual and collective responsibility."); Andrew F. Popper, *A Federal Tort Law Is Still a Bad Idea: A Comment on Senate Bill 687*, 16 J. Prod. & Toxics Liab. 105 (1994).

[7] *See* Jerry J. Phillips, *Comments on the Report of the Governor's Commission on Tort and Liability Insurance Reform*, 53 Tenn. L. Rev. 679, 680 (1986) (criticizing state tort reform proposals as "more of an evisceration than a reform of the system"); Philip Shuchman, *It Isn't that the Tort Lawyers Are So Right, It's Just that the Tort Reformers Are So Wrong*, 49 Rutgers L. Rev. 485, 501 (1997) ("It is difficult to estimate the value of any provision in the tort reform bills to favored industries. Surely, in total they could be worth billions of dollars a year.").

[8] *See, e.g.*, H.B. 18, 1996 La. Sess. Law Serv. 1 (West) (repealing the judicially created strict liability doctrine exposing property owners to liability without proof of fault); H.B. 637, 1995 N.C. Sess. Laws 522 (expressly providing that there shall be no strict liability in tort for product liability actions); H.E.A. 1741, 1995 Ind. Legis. Serv. 278 (West) (restricting strict liability actions to the manufacturer of the product).

[9] *See, e.g.*, H.R. 956, 104th Cong., § 201(F)(1)(A) (1995) (versions 4 and 5) (precluding the awarding of punitive damages against a manufacturer or product seller of a drug that was subject to premarket approval by the FDA); Ohio Rev. Code Ann. § 2307.80(C) (Anderson 1995) (barring punitive damages against manufacturer of a drug manufactured and labeled in compliance with FDA requirements); Or. Rev. Stat. § 30.927 (1995) (barring punitive damages in a pharmaceutical case in which drug and labeling was approved by the FDA); Utah Code Ann. § 78-18-2 (1989) (prohibiting the award of punitive damages if the drug that caused the claimant's harm received premarketing approval or licensure by the FDA).

[10] *See, e.g.*, Common Sense Product Liability Legal Reform Act of 1996, H.R. 956, 104th Cong. § 108(b) (limiting punitive damages to the greater of two times the sum of economic and non-economic loss or $250,000); H.B. 2210, 180th Gen. Assem., 1996

a matter of accountability; critics warn of its potential to marginalize yet further the most vulnerable members of society.[11]

Against the charge that tort reform would weaken consumer protection regimes,[12] insurance and industry interests counter that "reforms" will liberate research,[13] facilitate new entrants into markets of "excess liability,"[14] and restore sense to an "irrational" litigation system.[15] Such justifications are the polite stuff

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Pa. Legis. Serv. 135 (West) (enacted Nov. 26, 1996) (limiting punitive damages in medical malpractice suits to two times the compensatory damages); H.B. 20, P.A. 89-7, 89th Gen. Assem., 1995 Ill. Legis Serv. 224 (West) (limiting punitive damages in cases other than healing art or legal malpractice to three times economic damages, and creating a $500,000 cap on non-economic damages in all negligence and product liability actions); *see also* Popper, *supra* note 6; Rustad, *supra* note 6. *See generally* Mark McLaughlin Hager, *Don't Say I Didn't Warn You (Even Though I Didn't): Why the Pro-Defendant Consensus On Warning Law Is Wrong*, 61 TENN. L. REV. 1125 (1994); Shapo, *supra* note 1.

[11] *See* Helen R. Burstin et al., *Do the Poor Sue More? A Case-Control Study of Malpractice Claims and Socioeconomic Status*, 270 JAMA 1697, 1701 (1993); *see also* Richard L. Abel, *The Real Tort Crisis—Too* Few *Claims*, 48 OHIO ST. L.J. 443, 443 (1987) (stating that tort law "discriminates on the basis of class, race, and gender").

[12] See Rustad, *supra* note 6, at 758–59 ("The Common Sense Legal Reform Act blatantly attempts to reallocate power from consumers to corporations who market products with excessive preventable dangers.").

[13] *See* Browning-Ferris Indus. v. Kelco Disposal, Inc., 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part) ("The threat of such enormous awards has a detrimental effect on the research and development of new products."); Kimberly A. Pace, *The Tax Deductibility of Punitive Damage Payments: Who Should Ultimately Bear the Burden for Corporate Misconduct?*, 47 ALA. L. REV. 825, 869 n.215 (1996) ("Research and development in American industry are being halted or discouraged because of the threat of excessive punitive damage awards, thereby making American business less competitive in the international market. Consequently, the punitive damages problem is a direct threat to the economic stability of corporate America.").

[14] *See generally* George L. Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521 (1987) (contending that there is a genuine crisis). To support their conclusions, tort reformers often employ anecdotal evidence to prove the existence of the "excess liability" crisis. For example, recent proponents of the crisis argument consistently refer to *Liebeck v. McDonald's Restaurants, P.T.S., Inc.*, No. CV-93-02419, 1995 WL 360309 (D. N.M. Aug. 18, 1994), the infamous coffee spill case, without relying on hard data. Although sensationalized, the judge reduced the punitive damages award from $2.7 million to $480,000; *see also* Milo Geyelin, *Suits by Firms Exceed Those by Individuals*, WALL ST. J., Dec. 3, 1993, at B1 (reporting on a study conducted by the Rand institute for Civil Justice charting trends of 908 Fortune 1000 companies from 1971 to 1991, showing that product liability suits have actually dropped from a high of 3500 in 1985 to 1500 in 1991).

[15] *See* Carl T. Bogus, *War on the Common Law: The Struggle at the Center of Products Liability*, 60 MO. L. REV. 1, 87 (1995) (debunking the "mythology of a deranged judicial system"). The common allegation that the punitive damages regime operates irrationally rests on thin empirical evidence. *See, e.g.*, Saundra Torry, *Juries in the 1990's Reluctant to Make Punitive Damage Awards*, WASH. POST, June 17, 1997, at A3 (citing a Rand Institute study finding that "[p]unitive damages are awarded in less than four percent of civil lawsuits that reach juries and are given most frequently in business cases in which the claimant has been harmed financially rather than physically").

of lobbying.[16] The bills proposed and the laws passed provide no protection for consumers, furnish no incentive for greater safety, and significantly constrict the rights of the powerless, arguments about promoting "market opportunity" notwithstanding.[17]

The class-based nature of the tort-reform battle[18] is evident in the breakdown of the groups supporting and opposing reform. The insurance and manufacturing sectors have pushed for these changes,[19] while groups acting on behalf of under-represented populations have opposed such measures. For example, health care and women's groups have protested changes that would leave victims of defective birth control devices without meaningful recourse.[20] Accident victims (and hastily formed victims' organizations) have routinely opposed attempts to limit access to the courts or cap damages.[21] Broad-based consumer groups

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[16] Undoubtedly, politicians score points with members of the business community by supporting tort reform bills. When vulnerable segments of the populace with limited political power are the supposed beneficiaries of the legislation, the temptation to support these measures is nearly irresistible.

[17] *See* Rustad, *supra* note 6; *see generally supra* notes 3, 6, 10 and accompanying text.

[18] New laws that restrict the ability of injured consumers to secure redress in the courts will most impact low- to moderate-income claimants. Underinsured or uninsured, these individuals are at risk. Accordingly, "courts traditionally have had to look out for parties who lack the resources or the capacity to protect their own interests in the face of a better-funded or more-informed adversary." Jack B. Weinstein, *Some Benefits and Risks of Privatization of Justice Through ADR*, OHIO ST. J. ON DISP. RESOL. 241, 259 (1996) (footnote omitted). *See generally* Abel, *supra* note 11; Burton D. Fretz & Ethel Zelenske, *Judicial Conference Weighs Cutbacks in Federal-Court Jurisdiction*, 28 CLEARINGHOUSE REV. 1261, 1265 (1995) ("Perfect justice inside the courtroom becomes meaningless if the courthouse doors are closed to the poor."); Rodgers, *supra* note 1, at 525 ("Proponents of tort reform, primarily Citizens Against Law Abuse (CALA), exploit the facts of numerous lawsuits in order to promote lawsuit abuse hysteria to rally support for their position.") (footnotes omitted); Rustad, *supra* note 6.

[19] *See supra* note 7 and accompanying text.

[20] *See* Robert V. Costello, *Poll Shows Majority Opposed to 'Contract With America,'* 23 MASS. LAW. WKLY. 1380 (1995) (describing a poll commissioned and paid for by Citizens Action, the NOW Legal Defense Fund, the Women's Health Coalition, the National Breast Implant Coalition, DES Action, and the Association of Trial Lawyers of America). Many of these bills would immunize manufacturers of federally approved products from punitive damages, regardless of the knowledge of risk the producer or seller may have acquired after regulatory approval.

[21] *See generally* Dana Coleman, *Coalition of Consumers Is Newest Entry In Fray*, N.J. LAW., May 21, 1994, at 1 ("Consumers for Civil Justice . . . was formed about three weeks ago to mount a concerted fight against proposed tort reform legislation . . . ."); Stephen Schafer, *Federal-Style Tort Reform Does Matter To You*, 23 MASS. L. WKLY. 1587 (1995) ("Representatives of consumer groups and victims' groups may still be the better spokespersons in the debate over tort reform . . . ."). These groups respond because of the overt negative effect that legislation like the Product Liability

resist most tort reform plans, as they lack consumer protection provisions,[22] yet shield manufacturers of dangerous and defective products.[23] During the spring 1997 term of Congress, clashes between consumer and victims' groups, on the one hand, and business interests, on the other, occurred once again.[24]

### B. *Immunity for Volunteers and Biomaterials: Exemplars of the Class-Based Critique*

The two narrowly focused bills of interest are the Volunteer Protection Act[25] and the Biomaterials Access Assurance Act of 1997.[26] The first eliminates conventional tort liability[27] for volunteers acting on behalf of charities. Supporters of this proposal matched executives from tax-exempt organizations[28] with former

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Reform Act of 1997 would have had on their members. That bill would have limited punitive damage awards to situations of proven and flagrant indifference to the rights or safety of others and would have capped the potential amount that plaintiffs could recover. *See supra* note 3.

[22] *See generally* Heidi Li Feldman, *Harm and Money: Against the Insurance Theory of Tort Compensation*, 75 TEX. L. REV. 1567 (1997) (contending that the direct-loss/compensation model that restricts tort recovery, particularly for pain and suffering, lacks coherence and balance); Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1 (1995) (arguing that tort reform legislative proposals, if adopted, would restrict the ability of women to secure redress for product failure).

[23] *See* Rustad, *supra* note 6, at 758; Gregory B. Westfall, *The Nature of This Debate: A Look at the Texas Foreign Corporation Venue Rule and a Method for Analyzing the Premises and Promises of Tort Reform*, 26 TEX. TECH L. REV. 903, 925 (1995) ("The tort reform debate really boils down to a simple policy question: Do we favor the interests of business over the interests of those harmed thereby, or vice versa.").

[24] *See supra* note 3 and accompanying text; *see generally* Pace, *supra* note 13, at 826–27 (taking the position that punitive damages, a target of the tort reformers, serve a vital function in deterring severe misconduct and should not be deductible as a business expense); William Powers, Jr., *Some Pitfalls of Federal Tort Reform Legislation*, 38 ARIZ. L. REV. 909 (1996) (discussing the difficulties of implementing tort reform through federal legislation); Gary T. Schwartz, *Considering the Proper Federal Role in American Tort Law*, 38 ARIZ. L. REV. 917, 919 (1996) (discussing the problem of federalizing tort law: "It seems clear enough that in this recent tort reform debate, federalism arguments were deployed (and withheld) strategically. If for substantive reasons one favored the tort reforms Congress was considering, one simply ignored the federalism issue. Yet if for substantive reasons one opposed those tort reforms, one invoked the theme of states' rights.").

[25] Pub. L. No. 105-19, 111 Stat. 218 (1997).

[26] This Act was integrated into the Product Liability Reform Act of 1997, S. 648, 105th Cong., Title II.

[27] "Conventional" liability refers to misconduct short of intentional torts.

[28] *See The Volunteer Protection Act of 1997: Hearings on H.R. 911 and H.R. 1167 Before the House Comm. on the Judiciary*, 105th Cong. (1997) (testimony of Rep. Newt Gingrich (R-Ga.); Sen. Paul Coverdell (R-Ga.); Sen. Mitch McConnell (R-Ky.); Sen. John Ashcroft (R-Mo.); Sen. Rick Santorum (R-Pa.); Rep. John Edward Porter (R-Ill.); Mr. Conrad Teitell, on behalf of the Am. Council on Gift Annuities; Mr. Robert

National Football League players[29] to lobby for new law.[30] At the signing ceremony,[31] President Clinton seemed implicitly to note the eclectic nature of the lobby: "Americans recognize that we are responsible for one another and that we are members of a *true community*."[32] Yet the celebrities and charity representatives fronting the lobbying effort distract attention from the deleterious ramifications for "true community." Individuals who need charitable or public services will have no recourse against negligent doctors, careless attorneys, and coaches who intimidate or negligently harm children.[33] A uniform expectation of due care now belongs exclusively to those with the resources to pay for such services.

The second tort reform proposal, the Biomaterials Access Assurance Act, would dramatically lower due care liability standards for producers of the raw materials used to manufacture certain medical devices and implants.[34] Proponents argued that such reform would encourage innovation and lower prices as new players competed in the market. The Act did not pass. As a result, several industry representatives informed the appropriate committee in the House that their companies might cease production.[35]

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Goodwin, CEO of the Points of Lights Found.; Mr. John Graham, IV, CEO of the Am. Diabetes Ass'n; Dr. Thomas Jones, managing director of the Washington office of Habitat for Humanity; Mr. Fred Hanzalek, Prof'l Eng'r, Am. Soc'y of Mechanical Engineers; Mr. Charles Tremper, senior vice president of Am. Ass'n of Homes and Services for the Aging; and, in opposition, Prof. Andrew Popper, Washington College of Law at American University) [hereinafter *Volunteer Protection Act Hearings*].

[29] *See id.* (testimony of Mr. Lynn Swann, national spokesman for Big Brothers/Big Sisters of Am.; Mr. Terry Orr, the Orr Co.).

[30] Curiously, not one witness could identify a single "unjustified" lawsuit brought against his or her respective organization. *See id.* Instead, the needs of individual volunteers became the focus. For example, Mr. Lynn Swann testified, "It is [the] volunteers . . . who . . . should remain the focus." *Id.* This demonstrates the failure of the legislation to consider the issue from the perspective of those who receive volunteer services.

[31] The ceremony took place on June 18, 1997. *See* Jeffrey P. Altman & Joanne M. Kelly, *V-Day for Volunteers: A New Law Shields Volunteers from Liability Concerns, but It Doesn't Protect Their Organizations*, LEGAL TIMES, July 28, 1997, at S. 39.

[32] President's Statement on Signing the Volunteer Protection Act of 1997, 33 WKLY. COMP. PRES. DOC. 911 (June 19, 1997) (emphasis added); *see also Volunteers Get Immunity From Some Lawsuits*, ST. LOUIS POST-DISPATCH, June 22, 1997, at 14A.

[33] *See* Volunteer Protection Act § 4(a)(3) (stating that personal liability obtains only if the volunteer's misconduct constitutes willful, gross, or reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer).

[34] *See* S. 648, 105th Cong., Title II § 205 (1997) (articulating the specific liability limitations of raw material producers).

[35] *See The Biomaterials Access Assurance Act of 1997: Hearings on Product Liability Reform and Consumer Access To Life-Saving Products Before the Subcomm. on Telecommunications, Trade, and Consumer Protection of the House Comm. on Com-*

## II. THE VOLUNTEER PROTECTION ACT OF 1997: PROTECTING PROVIDERS AT THE EXPENSE OF THOSE SERVED

The Volunteer Protection Act immunizes those who voluntarily provide services under the auspices of any tax-exempt organization.[36] Without the risk of tort liability, so its premise goes, more people will volunteer, and the quality and volume of charitable work will increase. Backers of the proposal did not offer even a single study to support the claim that tort immunity would raise the number or quality of volunteers. More disturbing, this law erodes the right to expect others to exercise due care.[37] Further, while this law most affects recipients of charitable services, no representatives of these recipients testified in the hearings that culminated in the bill's adoption.[38]

### A. *Immunizing Volunteers: Standard Tort Reform*

Like most tort reform proposals, the Volunteer Protection Act came packaged as a response to the "potential for [excess] li-

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*merce*, 105th Cong. (1997) [hereinafter *Biomaterials Access Assurance Act Hearings*]. During his testimony, Jorge E. Ramirez, Ph.D. (Hoechst Group) suggested that the "continued availability of biomaterials and the continued participation of companies, such as Hoechst" depended on the adoption of the Biomaterials Access Assurance Act. Ronald W. Dollens (Guidant Corp.) delivered a similar message when he asserted that this legislation was necessary to "help ensure the continued availability of the biomaterials they need to make the products American patents require." *Id.* at 59.

[36] *See* Volunteer Protection Act § 4(a). The protection does not extend to groups that fall within the federal definition of "racist" or that engage in "hate crimes." *See id.* at § 4(f)(1)(B).

[37] From this point forward, conformity with due care, that "standard of conduct imposed by the law . . . based upon what society demands generally of its members," is more than can be expected of volunteers. W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 31, at 169 & nn.6–8 (5th ed. 1984); *see also* H.R. 911, 105th Cong., § 4(a)(2) (1997) ("[A]ny volunteer of a nonprofit organization or governmental entity shall incur no personal financial liability for any tort claim alleging damage or injury from any act or omission of the volunteer on behalf of the organization entity . . . if such damage or injury was not caused by willful and wanton misconduct.").

[38] *See Volunteer Protection Act Hearings*, *supra* note 28. No tenants' organization, representative of those receiving public assistance, or other individual acting on behalf of those served by charities testified before any committee that studied this bill prior to recommending it to the Congress. In fact, only one or two opposition witnesses testified during the hearings discussing the bill. *See* H.R. REP. No. 105-101, pt. I (1997) (including the sole statement of congressional opposition signed by Rep. John Conyers, Jr. (D-Mich.), Rep. Jerrold Nadler (D-N.Y.), Rep. Robert C. Scott (D-Va.), and Rep. Zoe Lofgren (D-Cal.)); *see also* 143 CONG. REC. S3861 (1997); 143 CONG. REC. S4915 (1997). These reports on the Volunteer Protection Act discuss the legislation; yet, they

ability . . . and unwarranted litigation costs."[39] In the past, when the insurance and manufacturing sectors have claimed crises from excess exposure, independent research has proved such claims to be baseless.[40] Often, the research arms of Congress performed these studies.[41] This time, no study or statistical analysis was even proffered to support the claim that the volunteers immunized under the new law needed protection against rampant, unwarranted liability.[42]

### B. *Core Components of the Volunteer Protection Act of 1997*

The preemption language of the Volunteer Protection Act differs significantly from that of the more comprehensive reform

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contain no oppositional testimony by any group acting on behalf of persons foreseeably served by volunteers covered under the act.

[39] Volunteer Protection Act §§ 2(a)(1), (a)(5) ("The willingness of volunteers to offer their services is deterred by the potential for liability . . . . [and] . . . high liability costs and unwarranted litigation costs . . . .").

[40] *See supra* notes 6, 9, 11, and accompanying text. As to volunteer liability, "[n]o statistics were given during the debate over the bill on how widespread lawsuits against volunteers are, or how great a factor the fear of lawsuits is in discouraging charitable work. But proponents offered anecdotes." Marianne Lavelle, *Volunteers Now Have Tort Shield*, NAT'L L.J., July 14, 1997, at A10. *See* 143 CONG. REC. S3744-47 (1997) (statement of Sen. Coverdell (R-Ga.) in support of the Volunteer Protection Act); 143 CONG. REC. H3096-97 (1997) (statement of Rep. Bob Inglis (R-S.C.) in support of the Volunteer Protection Act); *see also Volunteer Liability: Hearing Before the House Comm. on the Judiciary*, FDCH CONG. TEST. (Apr. 23, 1997) (testimony of Rep. John Edward Porter) (citing a 1988 Gallup survey that concluded there is a great deal of concern for the risk of liability, though only "one in twenty organizations reported being sued on a directors and officers liability question" in the past five years).

[41] *See* OFFICE TECH. ASSESSMENT, DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE, OTA-H-602 (1994); OFFICE TECH. ASSESSMENT, IMPACT OF LEGAL REFORMS ON MEDICAL MALPRACTICE COSTS, OTA-BP-H-119 (1993); Rustad, *supra* note 6, at 702–03 ("All the empirical studies point to one conclusion: punitive damages are not out of control. Tort reformers continually inform journalists that the numbers are in dispute . . . [but] [t]he key finding of every empirical study of punitive damages is that the number and size of awards do not indicate a nationwide litigation crisis."); Shuchman, *supra* note 7; *see also* Andrew M. Moskowitz, *Meaning is in the Eye of the Beholder:* BMW v. Gore *and Its Potential Impact on Toxic Tort Actions Brought under State Common Law*, 8 FORDHAM ENVTL. L.J. 221, 229–30 (1996) ("[O]ne recent study that examined verdicts in forty-five of the . . . most populous counties . . . found that plaintiffs received punitive damage awards in only six percent of cases.").

[42] Rep. John Conyers, Jr. (D-Mich.), a member of the House committee responsible for reviewing the legislation, expressed doubt about the "reality" of a liability crisis with volunteers: "It looks like we are dealing more with myth than fact." *See* Ken Foskett, *GOP Pushes Law to Exempt Volunteers From Liability*, ATLANTA CONST., Apr. 24, 1997, at A10; *see generally Volunteer Protection Hearings*, *supra* note 28. The concerns of Rep. Conyers were set forth in the sole dissenting report accompanying the Volunteer Protection Act legislation. *See* H.R. REP. No. 105-101, pt. 1 (1997) (accompanying H.R. 911, 105th Cong. (1997)).

bills of the past.[43] Instead of overt preemption of state law, this legislation "preempts the laws of any State . . . except that this Act shall not preempt any State law that provides additional protection from liability relating to volunteers."[44] In addition, the statute permits a state to opt out.[45] The drafters thus neutralized states' rights opposition to tort reform. While it is hard to conceive that a state legislature would make the political blunder of re-imposing tort liability on volunteers, the presence of opting-out language presumably made it possible for states' rights legislators to back the new law.

The heart of the legislation involves a bar to liability for individual volunteers. The law provides, "no volunteer of a nonprofit organization or governmental entity shall be liable for harm caused by an act or omission of the volunteer on behalf of the organization."[46] Immunity is not absolute; in the event that the harm is caused by "willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer," the plaintiff may pursue a claim.[47] Further, immunity does not apply to injuries caused by the volunteer in the course of "operating a motor vehicle, vessel, aircraft, or other vehicle for which the State requires . . . [a] license."[48]

The new law does preserve the right of one injured by the negligence of a volunteer to pursue a claim against the organization that sponsors or supervises the volunteer.[49] Undoubtedly, retaining institutional liability enhanced the appeal of this legislation. Organizational liability minimizes the risk posed by the unaccountable volunteer. Such a notion, however, implies that a volunteer worker will proceed with the same level of caution and care as if personally responsible simply because a sponsoring organization ultimately could be civilly liable for misconduct. Again, no testimony or information was submitted to support an

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[43] Preemption in prior tort reform bills is explicit. *See, e.g.*, H.R. 1167, 105th Cong. § 3 (1997) ("This Act preempts the laws of any State . . . ."); S. 648, 105th Cong. § 102(a) (1997) ("This Act governs any product liability action brought in any State or Federal court on any theory for harm caused by a product.").

[44] Volunteer Protection Act § 3(a).

[45] *See id.* at §§ 3(a), 3(b)(2) (permitting a state to "enact[ ] a statute . . . declaring the election of such State that this Act shall not apply").

[46] *Id.* at § 4(a).

[47] *Id.* at § 4(a)(3).

[48] *Id.* at § 4(a)(4)(A).

[49] *See id.* at § 4(c) ("Nothing in this section shall be construed to affect the liability of any nonprofit organization or governmental entity . . . .").

assumption that volunteers will exercise the same level of care regardless of personal accountability.[50]

The Act also retains liability for the volunteer if his or her action constitutes a federal crime, a hate crime, a sexual offense, a violation of a civil rights law, or a harm caused while the volunteer was under the influence of alcohol or drugs.[51] Despite this retention of liability, the Act restricts the amount of damages a plaintiff may receive. The law prohibits punitive damages "unless the claimant establishes by clear and convincing evidence that the harm" was caused by action "which constitutes willful or criminal misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed."[52] The law also limits the amount of damages by putting a restriction on non-economic loss, which effectively abolishes joint and several liability for pain and suffering.[53]

### C. *Potential Consequences of the Volunteer Protection Act of 1997*

Assuming for a moment that tort immunity for volunteers will increase the population of those willing to serve,[54] it is important

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[50] *See* Daniel L. Kurtz, *Protecting Your Volunteer: The Efficacy of Volunteer Protection Statutes and Other Liability Limiting Devices in Not-For-Profit Organizations: The Challenge of Governance in an Era of Retrenchment*, 726 A.L.I.-A.B.A. 263 (1992) (reporting of insurance coverage for volunteers). Any analogy to granting immunity to prosecutors is inapposite. Personal immunity is a risky proposition, provided only when massive public policy goals are at stake, for example, providing immunity for prosecutors to ensure vigorous enforcement of the law without fear of personal liability. Unlike volunteers, however, a prosecutor can be disciplined, dismissed, or disbarred. Sanctions sufficient to relieve concerns about the lack of personal accountability are unavailable for activity involving the vast majority of volunteers.

[51] *See* Volunteer Protection Act § 4(f)(1).

[52] *Id.* at § 4(e). This provision is virtually identical to provisions found in earlier tort reform bills, *see supra* note 2, which propose the use of the "conscious flagrant disregard" standard (the functional equivalent of criminal intent) as a threshold for punitive damages, and a quantum of evidence standard of "clear and convincing evidence," which places a significantly higher burden on plaintiffs than does the "preponderance" test used in various states. State tort reform limits punitive damages in various ways. *See, e.g.*, H.B. 20, 1st Ex. Sess., 1996 La. Sess. Law Serv. 2 (West) (repealing the statute that authorized punitive damages to be awarded for wrongful handling of hazardous substances); H.E.A. 1741, 109th Gen. Assem., 1st Reg. Sess., 1995 Ind. Legis. Serv. 278-1995 (West) (limiting punitive damages to the greater of three times compensatory damages or $50,000); H.B. 20, P.A. 89-7, 89th Gen. Assem., 1995 Ill. Legis. Serv. 224 (West) (limiting punitive damages in certain cases to three times economic damages).

[53] *See* S. 543, 105th Cong. § 5(b)(1) (1997) (limiting recovery for non-economic loss and determining damages "in direct proportion to the percentage of responsibility of that defendant"). Thus, there is no joint and several liability for non-economic damages.

[54] Whether the legislation would accomplish its purported goal may not have been

to consider the individuals most affected by this law: those served by volunteers. They are victims of disasters, students assisted in public and private schools, children receiving day care or engaged in organized athletics, patients in hospice care, clients requiring counsel through charitably funded legal services programs, and countless others in need of the help, compassion, and diverse skills that volunteers can provide.[55] This is a highly vulnerable group, legally unsophisticated, often powerless to select the person who will assist them, and sometimes unable to discern inappropriate behavior. Unfortunately, the process by which the law was enacted took no account of the risks associated with volunteer service when the recipient is powerless.[56] It is worth asking why in this situation, involving those least able to bargain in the marketplace for assistance, Congress would eliminate the incentives of volunteers to act with due care. Not even the most extreme of the broader tort reform proposals attempted this. The debate over most of those bills concerned the virtues of strict liability or damages.

An underlying principle of tort law is that the threat of personal liability creates individual accountability and thereby enhances the quality of goods and services.[57] Accordingly, the com-

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an overriding concern in passing this law. Rather, it seems likely that the bill's supporters may have been motivated by the positive publicity generated by the idea. The congressional process, including hearings and a variety of press conferences, for the Volunteer Protection Act took place during the week of the "Presidential Summit." President Clinton, past presidents, war heroes, and other dignitaries were invited to Philadelphia to share ideas on the topic of how to increase volunteerism. If media coverage is any indication of public reaction, public sentiment for volunteerism seemed to have been at an all-time high: "The media gushed all over it. Volunteerism got two thumbs up on the covers of all the major news weeklies." *The Volunteer State*, PROGRESSIVE, June 1997, at 8; *see also* BULLETIN'S FRONTRUNNER, Apr. 28, 1997 ("Most papers led with the volunteer summit."). In this setting, a vote against this legislation would have been perceived as a vote against hard-working volunteers, rather than a vote in favor of assuring that those who receive volunteer services have a right to expect delivery of those services in a reasonable manner.

[55] The hearings focused on volunteer virtuosity, not the needs of service recipients.

[56] In the hearings for this law, there was passing reference to a child abuse case involving a scout leader. Otherwise, there was no mention of the types of injuries inflicted on recipients. (Although there is no published transcript of this hearing as of the time of printing, the author was present at the hearing.)

[57] *See* Joseph A. Page, *Deforming Tort Reform*, 78 GEO. L.J. 649, 688 (1990) (reviewing PETER HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES (1988)) ("The business community provides some support for the argument that tort law has deterrent effects that encourage safe products . . . . Managers say products have become safer, managing procedures have been improved, and labels and use instructions have become more explicit."); *see also* Bogus, *supra* note 15, at 4 ("Even some scholars who view the product liability system with less than unqualified enthusiasm acknowledge it to be the principal mechanism protecting the public from dangerous products."). Bogus refers to George L. Priest's comment that, rather than

mon law imposes a minimum level of due care on people who choose to volunteer.[58] The Volunteer Protection Act changes that standard,[59] and in so doing, reduces the incentive to provide quality services. The potential liability of the sponsoring organization is simply an inadequate substitute for personal accountability. Thus, while increasing the number of volunteers is a legitimate government objective,[60] eliminating standards of due care to accomplish this end may adversely affect the quality of services provided.

In addition to threatening the quality of volunteer services, the Volunteer Protection Act immunizes too many people from personal liability. The law applies to anyone acting under the auspices of a 501(c)(3) entity, with the exception of those that fall within the Hate Crimes Statistics Act.[61] Due to this broad definition, the number of persons liberated from personal accountability is estimated to be 90 million.[62] While it might make sense to immunize trained Red Cross volunteers from liability, this law would have the same effect on numerous medical centers (where volunteers occasionally administer care and keep records), legal aid offices, day care providers, college sororities and fraternities, and countless social organizations.

Another option available to Congress, considered at the same time as the Volunteer Protection Act, was similarly flawed. That plan, H.R. 911, was a fiscal incentive measure designed to en-

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regulatory agencies, "our society relies on liability actions to police the manufacturing process." *See* Bogus, *supra* note 15, at 5 n.13 (citing George L. Priest, *Product Liability Law and the Accident Rate*, *in* LIABLILITY: PERSPECTIVES AND POLICY 184, 190–91 (Robert E. Litan & Clifford Winston eds., 1988)).

[58] *See* Schulker v. Roberson, 676 So.2d 684 (La. App. 1996); Marsallis v. LaSalle, 94 So.2d 120, 124 (La. App. 1957) (involving the power to impose liability on one who volunteers to undertake a duty, in this instance, the oddly difficult task of watching a potentially rabid cat for two weeks).

[59] H.R. 1167, 105th Cong. § 4(a)(3) (1997) ("Except as provided in subsections (b) and (d), no volunteer of a nonprofit organization or governmental entity shall be liable for harm caused by an act or omission of the volunteer on behalf of the organization or entity if . . . the harm was not caused by willful or criminal misconduct . . . or a conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer.").

[60] While this is a legitimate objective, it is curious to note that no documentation of a "crisis" in volunteerism was offered during the political process leading to the enactment of this legislation. Perhaps no such documentation exists. "During the past five years alone, the average amount of time given by volunteer workers has more than doubled." Edward J. Rice, Jr., *Presidents Page: Community Service: It's Good for the Public, the Profession, Your Firm and You*, 62 DEF. COUNS. J. 489 (1995).

[61] S. 543, 105th Cong. §§ 5(4), 6(4)(A) (1997).

[62] *See National Service or Government Service?*, J. AM. CIT. POL'Y REV., Sept.-Oct. 1996, at 33.

courage the states to do what many of them (for better or worse) already did: modify internal state tort law.[63] Like the opt-out provision of the Volunteer Protection Act, such legislation would have provided an opportunity for states to consider the complex ramifications of granting immunity to volunteers. The bill responded to a perceived reduction in the number of volunteers by offering hard cash to any state willing to remove due care obligations from potential volunteers.[64] Although the bill failed, it is worth noting that, in this era of balanced budgets, no one offered an estimate of the program's cost.[65] Rather than immunize potentially negligent volunteers, there might have been greater value in providing the Red Cross and similar organizations a direct annual grant of millions of dollars.[66]

One can only speculate about the future impact of the Volunteer Protection Act.[67] The law could increase costs to organizations in at least two ways. First, liability for the negligence of the volunteers may impose direct costs on the organizations. Second, fear of this liability[68] may lead to indirect costs. For example, the increased prospect of organizational liability in lieu

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[63] *See, e.g.*, Mark Thompson, *Letting The Air Out Of Tort Reform*, 83 A.B.A. J. 64, 65 (1997) ("Legislatures in 31 states had capped punitive damages or made them harder to win, and five states . . . have prohibited them outright in tort actions.").

[64] The incentive to the states would have been a one percent additur for social service funding. *See* H.R. 911, 105th Cong. § 5(a) (1997).

[65] The Act does not explain what is included in "social services." Assuming, however, that it refers, inter alia, to food stamps, a program that cost $24.4 billion in 1995, a one percent "benefit" for relieving volunteers of the duty to use due care could have cost up to $240 million. *See* Todd G. Cozenza, Note, *Preserving Procedural Due Process for Legal Immigrants Receiving Food Stamps in Light of the Personal Responsibility Act of 1996*, 65 FORDHAM L. REV. 2065, 2079 (1997).

[66] *But see* Miriam Galston, *Lobbying and the Public Interest: Rethinking the Internal Revenue Code's Treatment of Legislative Activities*, 71 TEX. L. REV. 1269, 1298 n.80 (1993) (citing INST. OF THE NAT'L COUNCIL OF NONPROFIT ASS'NS, NONPROFITS' RISK MANAGEMENT AND INSURANCE, STATE LIABILITY LAWS FOR CHARITABLE ORGANIZATIONS AND VOLUNTEERS 1 (1990)).

[67] There is no question about the immediate legal effect: volunteers are no longer personally responsible for harms caused through negligence, short of gross, wanton, or willful misconduct. Given this effect, one has to wonder if the services delivered today are sufficiently safe to *immunize 90 million people* who come into contact with those in need of assistance. "Service has a long and venerable history in the U.S., and it remains strong today . . . . About 90 million adults volunteer . . . ." *National Service or Government Service?*, J. AM. CIT. POL'Y REV., *supra* note 62, at 33.

[68] A fear of liability has motivated the actions of charitable organizations under the previous tort regime. Consider that, even before this legislation passed, there were "attempts by nonprofit organizations to shield themselves from suit by claiming to be a government agency." Francis Leazes, *Pay Now or Pay Later: Training and Torts in the Public Sector*, 24 PUB. PERS. MGMT. 167 (1995). This effort has failed because of the increasingly limited application of sovereign immunity. *Id.*

of individual accountability[69] might compel charitable organizations to train, control, and manage volunteers more carefully.[70] The burden imposed by these increased costs may force organizations *to limit the number of volunteers*,[71] and select only those who appear to pose the least risk.[72]

It is likely that the Volunteer Protection Act will adversely affect low- to moderate-income individuals, who are the primary recipients of volunteer services.[73] The message sent is clear: the underclass is not entitled to the same due care as those with resources.[74] Legislation of this type forgives malpractice by doctors[75] and lawyers when the victim receives charitable medical or legal services. It excuses harmful behavior (short of gross, wanton, or willful acts) toward children, so long as they are poor.

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[69] In the world of public sector and non-profit organizations, concern about misconduct and harm by volunteers existed before this legislation passed. Commentators in the field often urge increased training to "minimize negligent, harmful actions." *Id.*

[70] "(F)ailing to train staff has emerged as an increasing area of legal concern for public and private organizations." *Id.* With the advent of the personally unaccountable volunteer, this concern may be heightened due to the retention of organizational liability, resulting in increased costs to charities.

[71] While there is no data available as yet to support this, it is only logical to assume that if charitable organizations become exclusively responsible for the tortious conduct of immunized volunteers, they will have to exercise greater care in selecting those who work on their behalf. The decrease in the number of volunteers as a result of screening would defeat the purported purpose of the act. Furthermore, no data was presented to support the proponents' view that the removal of the potential of liability would increase the number of volunteers.

[72] The costs imposed on these organizations may not seem quite so threatening when one considers the impressive financial support for the 90 million newly immunized volunteers. An Associated Press release published in 1996 indicates that "Americans donated 23.5 billion dollars to charities last year, which is a 5% increase in charitable giving." Amelia David, *The Benefits of Giving: Sharing the Gift of Yourself This Holiday*, BACK STAGE, Dec. 6, 1996, at 20. "Health charities number in the thousands, [and] receive billions of dollars annually in contributions." James T. Bennet & Thomas J. DiLorenzo, *What's Happening to Your Health Charity Donations*, CONSUMER RES., Dec. 1996, at 10.

[73] Although there are others who fall victim to natural disaster or catastrophe, they number far fewer than those who, due to economic circumstances, must rely on others.

[74] *See* Fretz & Zelenske, *supra* note 18, at 1265.

[75] Even before this legislation, doctors were often unaccountable for their treatment of the poor. *See* Burstin, *supra* note 11, at 1700 (discussing a recent study illustrating that not only do indigent victims lack adequate medical care and malpractice claim representation, but are also less likely to sue when injured).

## III. THE BIOMATERIALS ACCESS ASSURANCE ACT OF 1997: THE STRATEGY OF CAPITALIZING ON FEAR[76]

As narrow in scope as the Volunteer Protection Act is, it nonetheless applies to multiple disciplines and interests, and is therefore broader in scope than other tort reform proposals that target specific industries. Over the past fifteen years, groups such as airline manufacturers and pharmaceutical producers have asked Congress for immunity or other forms of special treatment, claiming that their industries cannot survive if state tort law applies to the products they produce or the services they provide.[77] These requests often come accompanied with an even graver message: protection is needed to avert health and safety disasters. During the 1997 term, as well, tort reformers asserted that a failure to give immunity to biomaterials producers, which would force major manufacturers and researchers into bankruptcy, would leave biomaterials production to the unsuited, the foreign,[78] and the back alley.[79]

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[76] Although most health and safety legislation is, in part, generated by fear of a discernible harm, the biomaterials debate was unusual in that it involved private citizens showcasing their illnesses and disbilities before Congress. *See infra* note 83 (involving the use of a three-year-old child in a formal congressional hearing by Rep. George Gekas (R-Pa.)).

[77] *See Statements of Introduced Bills and Joint Resolutions, Remarks of Senator McConnell in Support of S. 1979, the 'Lawsuit Reform Act,'* 137 CONG. REC. S16852-53 (Nov. 15, 1991) (contending that pharmaceutical companies have "stopped making vaccines" and exited the contraceptive market, and that the "general aviation industry" is "decimated": problems that federal tort reform would allegedly solve); *Hearings on the Civil Justice Fairness Act*, S. 672, 104th Cong. (1995) (opening statement of Sen. Orrin Hatch (R-Utah)) (reciting the plea of the pharmaceutical manufacturers for immunity from punitive damages, noting how "reform" has benefited the aviation industry); *see also* Richard J. Mahoney & Stephen E. Littlejohn, *Innovation on Trial: Punitive Damages vs. New Products*, 246 SCI. 1395, 1397 (1989) (correlating strict liability, huge jury awards, and punitive damages with declining production or development of contraceptives, vaccines, suit-case-size kidney dialysis units, and anesthesia machines).

[78] *See Biomaterials Access Assurance Act Hearings*, *supra* note 35 (prepared testimony of Mark A. Behrens, Esq.) ("Federal biomaterials legislation would help stop the needless exportation of jobs to foreign countries by allowing market needs to be met by sound U.S. companies.").

[79] *See, e.g.*, *supra* note 35 and accompanying text. The opening remarks in the Biomaterials hearing by Rep. George Gekas, a vocal supporter of immunity for biomaterials producers, were devoted to the fear that essential life-saving devices would be taken from those in need if the grant of immunity were not given to the raw materials suppliers. To underscore his point, he read a letter from a mother who feared the loss of such products: "'[w]ithout a shunt Nathan would suffer brain damage and die . . . . [It] would be a matter of hours or days and would be extremely painful.' A crisis exists and there are 7.5 million Americans who are depending on us to do something about it." *Biomaterials Access Assurance Act Hearings*, *supra* note 35.

### A. *Pursuing Legislative Advantage by Threatening Market Abandonment*

The biomaterials legislative proposal came before the Subcommittee on Telecommunications, Trade, and Consumer Protection of the House Committee on Commerce in April 1997.[80] Virtually all who testified in favor of the bill suggested that, absent immunity, many life-saving resources and devices would become unavailable.[81] Producers insisted that tort immunity was simply indispensable.[82] Such fear-mongering has become standard in the tort reform debate.

This time, however, families terrified by the prospect of losing essential life-saving products echoed industry admonitions in their own testimony before Congress.[83] Undoubtedly, the families believed such legislation necessary.[84] Those who orchestrated their testimony, however, exploited their raw emotions. Lobbyists have the responsibility to inform—not to scare—Congress and the American public, even if this means waiving an easy means to bolster popularity for tort reform.[85] As with lob-

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[80] *See Biomaterials Access Assurance Act Hearings*, *supra* note 35.

[81] *See supra* notes 35 and 79. On February 10, 1997, ten members of Congress sent a "Dear Colleagues" letter seeking to secure co-sponsors for the Biomaterials Assurance Act of 1997. The letter warned that a "looming crisis exists" in which providers of raw materials will "limit, or cease altogether, shipments of raw materials." *Activity of the Comm. on Governmental Affairs During the 103rd Congress*, S.R. 104-27 (1995). *See also* Victor Schwartz & Mark Behrens, *Liability 'Overkill' Threatens Lives and Wallets*, LAS VEGAS REV.-J., Mar. 30, 1997, at 1E ("Unfortunately for Tara, life saving medical devices like the shunt may not be available when they are needed because manufacturers can no longer obtain supplies of basic raw materials. This is due to product liability overkill.").

[82] *See Biomaterials Access Assurance Act Hearings*, *supra* note 35 (testimony of Ronald Dollens, Bd. of Dir., Health Indus. Mfr. Ass'n) ("The destructive impact of current liability laws on the medical device industry and the patients it serves is especially profound . . . . As Senator Joe Lieberman has accurately stated, 'biomaterials access is a public health time bomb.'").

[83] *See id.* Ms. Belinda Simonini testified eloquently before the subcommittee, expressing her fear for the well-being of her beautiful three-year-old son, Titus, who benefits from a shunt made from a biomaterial and who was present in the hearing room. *See id.* His presence was not lost on Rep. George Gekas. At the outset of the hearing, Titus was brought center stage. Rep. Gekas, who chaired the hearing, introduced Titus. The transcript of the hearing did not fully capture the emotional impact Titus had on those assembled. It reads, in part, as follows: "Mr. Gekas . . . . Titus, can you come up here for a minute? Put him on top of this chair here. Stand him on top. This is Titus. He has presented to me . . . a documented gift . . . [a note saying, *inter alia*] please support the Biomaterials Access Assurance Act, love Titus." *Id.* at 21.

[84] The author wishes to express that this commentary is not in any way directed at these families, who showed great courage and compassion, but rather at those who would capitalize on their suffering.

[85] In calling the April 10, 1997 hearings to order, Rep. Henry Hyde, Chairman of the

bying efforts for volunteer immunity, the responsibility to inform was taken lightly: no credible evidence corroborated claims of a biomaterials availability crisis.[86]

### B. *If There Is a Problem with Biomaterials, It Has Little to Do with Tort Liability*

Admittedly, precedent exists for the type of relief sought by the biomaterials industry. For example, in a few cases involving vaccines, in which researchers could document the likelihood of severe crisis in the industry, narrow, carefully conceived legislation has been used.[87] The biomaterials industry, however, shows no signs of crisis. Rather, this is an industry that has prospered,[88] has sustained no substantive negative judicial decisions, has dozens of stable companies and many new market entrants,[89] and has enjoyed relative regulatory inaction by the FDA.

Tort liability remains essential because the FDA alone cannot ensure public health and safety. Three years ago, an oversight committee analyzing the FDA's effectiveness in regulating biomaterials and their downstream products gave the FDA low marks. It found, *inter alia*, that the FDA had allowed a product on the market "that actually killed patients . . . [and] may have been

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House Comm. on the Judiciary, stated "[a]s poll after poll shows, the American public wants reform of our current, out-of-control legal system and they deserve it." *Biomaterials Access Assurance Act Hearings*, *supra* note 35.

[86] In fact, there was no testimony of a single case in which a supplier of biomaterials was held liable in tort. The absence of a demonstrable crisis has not prevented tort reformers from using the crisis theme. *See generally* STEPHEN DANIELS & JOANNE MARTIN, CIVIL JURIES AND THE POLITICS OF REFORM 4, 163–94 (1995) (stating that product liability cases accounted for only 4.2% of all of the jury verdicts in the 82 sites studied and that "a limited number of business entities were named as defendants in a substantial number of cases"). Moreover, it is difficult for reform advocates to base their generalized claims of a litigation explosion on increased federal filings when over one-half of the growth of filings from 1974 to 1985 involved only three products: asbestos, the Dalkon Shield, and Benedectin. *See id.*

[87] *See* The Vaccine Act, 42 U.S.C. § 300aa *et seq.* (1988).

[88] The *Wall Street Journal* and the *Journal of Medical Economics* both praised the economic and investment virtues of biomaterials and related companies in the months preceding the hearings on the legislation. *See* Elyse Tanouye, *Three Drug Companies Post Hefty Earnings Increases*, WALL ST. J., Jan. 29, 1997, at B4; Doreen Mangan, *Why Medical Device Stocks Belong in Your Portfolio*, J. MED. ECON., Jan. 13, 1997, at 55.

[89] For example, Baxter Int'l, Pfizer, Inc., Medtronic, DuPont, Dow, Sigma Aldrich, 3M, Abbott Labs, Hoechst Celanese, Cordis, Inc., Bio-Pace Tech., Cardiac Control Systems, Inc., Ela Med., Intermedics, Inc., Novocain, Siemens Pacesetter, Alcon, Inc., DGR, Inc., Hymedix Int'l, Inc., and others, are all relatively new to the industry.

ineffective in treating life-threatening diseases."[90] Other FDA-approved products later turned out to be similarly flawed, such as the Bjork-Shiley heart valve, certain types of implant materials, and the Copper-7 IUD.[91] The tort system, then, is a necessary complement to the FDA.[92]

The campaign for tort immunity in this area is particularly troubling given the barriers to civil liability that already exist.[93] Outside of clear and overt negligence, liability of a component-part producer is rare.[94] In 1986, a Massachusetts appellate court surveyed a number of states and rejected an implied duty to warn, finding, "the prevailing view is that a supplier of a component part . . . has no duty to warn . . . of any danger that may arise after the components are assembled."[95] Federal courts also follow the restrictive liability rules regarding component-part providers.[96] Even New Jersey, the state that birthed absolute

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[90] SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 103RD CONG., LESS THAN THE SUM OF ITS PARTS: REFORMS NEEDED IN THE ORGANIZATION, MANAGEMENT, AND RESOURCES OF THE FDA'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, (1993).

[91] *See, e.g.*, Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517 (D. Minn. 1989); Corrigan v. Bjork Shiley Corp., 227 Cal. Rptr. 247 (Cal. Ct. App. 1986), *appeal dismissed for lack of jurisdiction*, 479 U.S. 1049 (1987), *and overruled by* Stangvik v. Shiley, Inc., 819 P.2d 14, 17 (Cal. 1991) (involving a wrongful death action against corporation for alleged defective heart valve); Waitek v. Dalkon Shield Claimants Trust, 908 F. Supp. 672 (N.D. Iowa 1995) (involving products liability action against manufacturer, asserting claims for negligence, strict liability, breach of warranties, fraud, and infliction of emotional distress in reference to the Dalkon Shield IUD).

[92] "Medical devices have not been subject to the same rigorous pre-market clearance procedures that govern the marketing of prescription drugs." Teresa Moran Schwartz, *Prescription Productions and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1391 (1994) (footnote omitted).

[93] *See generally* Robert L. Haig & Stephen P. Caley, *Successfully Defending Products Liability Cases*, 4 Mealey's Litig. Rep.: Toxic Torts No. 15, at 23 (1985) (explaining that there are many ways to defend a raw materials provider, although all the defenses originate with the "bulk suppliers" defense); Gregory L. Harper, Comment, *An Analysis of the Potential Liabilities and Defenses of Bulk Suppliers of Titanium Biomaterials*, 32 GONZ. L. REV. 195 (1996) (discussing litigation options, strategies, and defenses in cases brought against raw materials suppliers).

[94] *See* Kealoha v. E.I. DuPont de Nemours & Co., 844 F. Supp. 590, 594 (D. Haw. 1994) ("A manufacturer of a nondefective component part has no duty to analyze the design and assembly of the completed product of an unrelated manufacturer to determine if the component is made dangerous by the integration into the finished product."). There is no case regarding biomaterials in which the raw products producer was found liable or in which the component part provider defenses failed, outside of those situations where the bio-product itself was defective. The defenses include the conventional bulk supplier defense, the learned intermediary or sophisticated user defense, and the doctrine of intervening cause. *See* Harper, *supra* note 93, at 222.

[95] Mitchell v. Sky Climber, Inc., 487 N.E.2d 1374, 1376 (Mass. 1986).

[96] *See, e.g.*, Sperry v. Bauermeister, 4 F.3d 596, 599 (8th Cir. 1993) (holding that manufacturer of component part was not liable for failure to warn of danger that

liability,[97] rejects component-part liability outside of negligence. The New Jersey Supreme Court recently found that, outside of negligence, "no public policy can be served by imposing tort liability on a manufacturer of specialized parts . . . when . . . the parts were created in accordance with . . . specifications of the owner and assembler of the unit."[98] Although the biomaterials industry already benefits from significant rules that reduce its exposure to liability, it seeks to operate outside of the tort system entirely.[99]

In the U.S. marketplace, the uniform use of contractual indemnification protects manufacturers of component parts, whether biomaterials or wooden wheel spokes. Indemnification is incomplete only in those situations in which the assembler of the component parts is bankrupt or otherwise unavailable for suit. Embracing a regime of immunity and unaccountability for biomaterials providers is thus unwarranted.

Part of the biomaterials industry's plea is that tort litigation costs (as distinguished from the payment of judgments) will overwhelm them.[100] This argument suffers from at least two flaws. First, if fear of litigation costs justify immunity, then it is hard

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resulted from design defect of product that used the component part). *See also* Hager, *supra* note 10, at 1149, 1159, 1161.

[97] *See* Beshada v. Johns-Manville Prod. Corp., 447 A.2d 539, 546–49 (N.J. 1982) (holding that a duty to warn of an unknowable risk exists); *see also* Feldman v. Lederle Lab., 479 A.2d 374, 388 (N.J. 1984) (limiting absolute liability to asbestos cases).

[98] Zaza v. Marquess, 675 A.2d 620, 633 (N.J. 1996).

[99] The purpose of the biomaterials legislation has been clear for some time. This legislation is designed to "allow raw materials suppliers to be dismissed from lawsuits against medical device manufacturers, without incurring extensive legal costs, where the raw materials used in a medical device met contract specifications and the supplier . . . [is not] a manufacturer or a seller . . . ." S. REP. No. 104-83, at 3 (1995). In other words, raw materials suppliers would have no generic due care obligations and no possible liability in a strict liability case.

[100] DuPont, the materials suppliers for the Vitek jaw implant, is a leading proponent of the argument that "excessive costs" destroy raw materials producers. DuPont's General Counsel Ross Schmucki contends, "the cost of . . . these cases teaches raw materials suppliers . . . that excessive and unrecoverable costs are associated with the sale of raw materials." Gary Taylor, *A Discovery by DuPont: Hidden Costs of Winning*, NAT'L. L.J., Mar. 27, 1995, at B1. Several factors limit sympathy, however. First, DuPont has won every case brought against it in its capacity as raw materials supplier. Second, when Vitek, the assembler of the TMJ implant, went bankrupt, thousands of victims of the fragmenting jaw implant were left without recourse. A court could have permitted recovery against downstream suppliers, just as courts permit redress against an otherwise protected or indemnified retailer when a manufacturer of a defectively designed product goes bankrupt. The courts, however, spared DuPont that responsibility. Finally, DuPont has successfully sought recovery of costs against injured plaintiffs. In one case, the company recovered $26,000. *See id.*; *see also* Ross F. Schmucki, *How To Manage Mass Tort Litigation Inside the Law Department*, CORP. LEGAL TIMES, Oct. 1996, at 13 (discussing the costs of avoiding tort liability).

to imagine an industry or profession that would not qualify. Second, the costs imposed on manufacturers by the product liability system serve an important deterrent function. Professor Carl T. Bogus notes that while "the common law has receded in importance," product liability "has become an essential participant in promoting public safety."[101] Professor Bogus observes generally that if the "common law has become underappreciated by legislators," then the viability of the product liability system is at extreme risk.[102] Adopting federal legislation undercutting state product liability law, such as the biomaterials proposals, would eviscerate consumer protections.

Others who have studied the tort and product liability system for decades share these concerns. Professor Michael J. Saks argues that the tort system "may be doing a better job as a deterrent than it usually receives credit for."[103] After completing a thorough empirical study of the tort system, Professor Saks drew several limited[104] conclusions: only a "tiny fraction" of accidental deaths and injuries actually become claims; large loss claims and negotiated settlements actually appear to be "under compensated" at the end of the process; and jury awards are "remarkably predictable."[105] For biomaterials producers, then, the risks of financial ruin are minimal.

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[101] *Supra* note 15, at 87. Professor Bogus notes that, at present, the product liability system is functioning despite the general "war on the common law." *Id.* at 70 n.380. In conjunction with effective regulation, product liability law provides "an essential auxiliary." *Id.* at 87.

[102] *Id.* at 70.

[103] Michael J. Saks, *Do We Really Know Anything About the Behavior of the Tort Litigation System—And Why Not?*, 140 U. PA. L. REV. 1147, 1286 (1992).

[104] Professor Saks determined that existing studies are insufficient to permit global characterizations about the way the system functions: "We canot draw rigorous or even reasonable conclusions about . . . the litigation system . . . ." *Id.* at 1288.

[105] *Id.* at 1287–89. Saks also concluded that the system as a whole is more "efficient and effective as a deterrent" than as a method of compensation, and that there is an unfortunate likelihood that some "reforms will produce effects contrary to the intentions of their makers"; indeed, some already have. *Id. See, e.g.*, Bruce Glassner, *An Affidavit With No Merit*, N.J. L.J., Sept. 2, 1996, at 27 (discussing the use of affidavits of merit as a malpractice tort limitation mechanism and finding "as with so many other recent tort reform measures, the affidavit of merit will fail to achieve its desired purpose . . . ."); Steven R. Berger, *The Medical Malpractice Crises: How One State Reacted*, 11 FORUM 64, 78–79 (1975) (finding that tort reform measures failed to limit increases in Florida medical malpractice premiums).

### C. *Fear of the U.S. Legal System Is Not a Basis for Legislating Unaccountability*

In response to the claim that the actual risk of liability is small,[106] supporters of biomaterials immunity trotted out the ill-fated Vitek jaw implant as their star witness.[107] When the implant failed, allegedly fragmenting in the mouths of numerous patients, the victims sued not only Vitek, the producer of the implant, but also DuPont, the raw materials supplier.[108] In 1990, the FDA, in one of its better moments, ordered Vitek to inform oral surgeons that the implant had a tendency to fragment.[109] The FDA subsequently recalled the product. In his opening remarks to the Congressional hearings held thereafter, subcommittee chairman Ted Weiss said, "[t]here is evidence that the overwhelming majority of grafts and implants will fail if they haven't already."[110]

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[106] Claims against raw materials providers often founder on the notion that raw materials are not inherently unreasonably dangerous, and that only after conversion for use in implants or similar products does risk appear. Given that raw materials producers know the uses to which their products are put (tolerances and specifications are spelled out in contracts) and also profit from the sale of the end product, some responsibility by them for product failure seems reasonable. Nevertheless, courts have been uniformly disinclined to impose such liability. "[T]here is little social utility in placing the burden on a manufacturer of component parts or supplier of raw materials of guarding against injuries caused by the final product when the component parts or raw materials themselves were not unreasonably dangerous." Bond v. E.I. DuPont de Nemours & Co., 868 P.2d 1114, 1120–21 (Colo. Ct. App. 1993). Based on this policy, raw materials suppliers do not have conventional duties, such as the duty to warn of a reasonably foreseeable risk. *See* Welsh v. Bowling Elec. Mach., Inc., 875 S.W.2d 569, 574 (Mo. Ct. App. 1994); Doll v. E.I. DuPont de Nemours & Co., No. 01-95-00375-CV, 1997 WL 69862 (Tex. App. Feb. 20, 1997); Zaza v. Marquess, 675 A.2d 620 (N.J. 1996). When the raw materials provider is also the manufacturer, standard negligence/due care obligations attach. *See* Putensen v. Clay Adams, Inc., 12 Cal. App. 3d 1062 (Cal. Ct. App. 1970).

[107] *Supra* note 100 and accompanying text. *See* In re TMJ Implants Prod. Liab. Litig., 872 F. Supp. 1019 (D. Minn. 1995); Frederick D. Baker, *Effects of Product Liability on Bulk Suppliers of Biomaterials*, 50 FOOD & DRUG L.J., 455, 457 (1995) ("Vitek, Inc. produced temporomandibular jaw (TMJ) implants made of Proplast, a material developed by Vitek. Proplast contained a number of raw ingredients, including DuPont's Teflon. It was alleged that Proplast deteriorated after implantation, causing serious and painful injury, and that the deterioration occurred because Teflon is unsuitable for use in implants.").

[108] *See* Baker, *supra* note 107, at 457 ("Many lawsuits were filed [against Vitek], and Vitek rapidly ran out of both its assets and its insurance coverage. After Vitek filed for bankruptcy protection, plaintiffs' attention shifted to . . . DuPont").

[109] *See* Berry v. United States, No. 94-7173, 1995 WL 434831, at **1 (10th Cir. July 25, 1995) (pointing out the FDA "Safety Alert" issued Dec. 1990 with respect to TMJ implants manufactured by Vitek).

[110] *Are FDA and NIH Ignoring the Dangers of TMJ (Jaw) Implants? Hearings Before the Subcomm. on Hum. Resources and Intergovernmental Rel. of the House Comm. On Gov't Operations*, 102d Cong. (1992).

Nevertheless, on February 20, 1997 the Court of Appeals of Texas affirmed summary judgments that had been granted in favor of DuPont.[111]

From a consumer perspective, it is hard to see a string of victories by DuPont as grounds for a grant of federal immunity.[112] Further, DuPont's success is not surprising, given the preferential position that materials suppliers enjoy in the legal system. As is the case in many areas of torts, the case law and literature have shifted in favor of producers and manufacturers. Plaintiffs now face nearly insurmountable difficulties when seeking relief against biomaterials suppliers.[113]

As the capacity of the substantive law to redress the harms of injured persons erodes,[114] so too do plaintiffs' evidentiary options.[115] In *Daubert v. Merrell Dow Pharmaceuticals*,[116] the Supreme Court limited the plaintiff's ability to introduce expert testimony based on statistical and empirical evidence unless the plaintiff met fairly demanding guidelines regarding scientific reliability and validity. The Court promulgated factors that trial judges should consider in deciding whether to allow expert testimony, including whether the expert evidence is based on clear scientific knowledge, has been subject to peer review, is capable

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[111] *See* Cason v. E.I. DuPont de Nemours & Co., No. 01-94-01191-CV, 1997 WL 69858, at *17 (Tex. App. Feb. 20, 1997); Doll v. E.I. DuPont de Nemours & Co., No. 01-95-00375 CV, 1997 WL 69862, at *18 (Tex. App. Feb. 20, 1997) (finding that DuPont "did not have a duty to warn").

[112] *See supra* notes 93–96, 108, and accompanying text.

[113] *See supra* notes 93, 94, and 112; *see also* Kealoha v. E.I. DuPont de Nemours & Co., 82 F.3d 894 (9th Cir. 1995), for a thorough treatment of the duty to warn in the Vitek situation. That case held that DuPont, as a raw products supplier, had no duty to warn TMJ recipients, and was entitled to assert raw materials supplier defenses to negligence and products liability claims. The court found that DuPont's awareness of the risk was easily documented, taking notice of a 1984 conference attended by DuPont staff in which the fragmentation potential of the Vitek implant was a central topic. The staff in attendance submitted a memorandum to the management of DuPont regarding the problems with the product. *See id.* at 895–98.

[114] For example, the Court of Appeals in Texas, a state with a history of forceful consumer-oriented product liability law, recently declared that a component part manufacturer producing a product that conforms with the purchaser's specifications cannot be held strictly liable, outside of a demonstrated defect in the component part. *See* Molina v. Kelco Tool & Die, Inc., 904 S.W.2d 857, 861 (Tex. App. 1995).

[115] *See* Michael H. Gottesman, *Should State Courts Impose a Reliability Threshold?*, TRIAL, Sept. 1997, at 20 (arguing that changes in the field of evidence at the federal level are harsh and that states should reject new rules that make it difficult, if not impossible, for plaintiffs to succeed in a product liability case involving scientific or technical data).

[116] 509 U.S. 579, 593–94 (1993) (holding that, under the Federal Rules of Evidence, a trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable).

of independent testing, and has an established error analysis pattern.[117]

Predictably, in a recent biomaterials case, *Cabrera v. Cordis*,[118] a federal court blocked the use of four expert witnesses proposed by the plaintiff, basing its decision on *Daubert*. As these measures mature at the state level, there is at least the hope that the states, the laboratories of tort law, will restore balance to the system.[119] If, however, federal legislators enact laws that preclude consumers from pursuing legitimate claims either in state or federal court, powerful and essential consumer protection options may be destroyed.

## IV. CONCLUSION

All too often, courts, legislators, and scholars assess tort reform in purely economic terms, i.e., whether tort law promotes safety most efficiently, or whether market forces optimize safety without the external costs of the litigation process. While this debate is reasonable, its terms, unfortunately, have expanded too far. The entitlement to due care has become negotiable, and industry interests have capitalized on the fear of those whose well-being is in their hands.

While it is too early to track statistically the impact of the Volunteer Protection Act, millions of individuals entitled to due care from those who provided volunteer service prior to June 19, 1997, are now without that personally enforceable entitlement. Children, the homeless, victims of natural disasters, clients or patients in legal and medical clinics, and many others, have lost an expectation of consequence.

Beyond the rhetoric and natural inclination to assist charities, virtually no facts were placed before Congress to justify the deprivation of the entitlement to due care. The record, in both the House and Senate, lacks any showing that volunteers face undue tort liability, that the number of volunteers has declined,

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[117] *See id.* at 593–94. *Daubert* expands the precautionary impact of Rule 702 of the Federal Rules of Evidence, compounding the challenges a plaintiff faces in biomaterials cases where there is a good chance that the totality of the plaintiff's case will rest on empirical data only available through expert opinion testimony.

[118] 945 F. Supp. 209 (D. Nev. 1996) (finding that four expert witnesses proposed by the plaintiff failed to satisfy the *Daubert* standard for reliability).

[119] If the Biomaterials Access Assurance Act of 1997, H.R. 872, 105th Cong., had become law, the ability of the states to evolve standards would have ended, since the bill was written to preempt state law in this field.

or that individual volunteers who seek protection from personal liability must cope with excessive insurance rates. Instead, the record contained the same slogans, tirades against trial lawyers, and anecdotes about egregious cases (that either never existed, were reversed on appeal, or settled) that have distorted the tort reform debate for two decades. This time around, the sleight-of-hand succeeded, perhaps because cynical lobbyists mustered the right combination of popular charities, media stars, and earnest families suffering personal loss.

It is now the task of the legal community to determine the reach of this law. Courts will have to decide whether volunteer physicians and pro bono attorneys who perform negligently will be liable for malpractice; they will have to decide whether coaches and teachers who are negligent and, as a result, harm children, will be held accountable. The plain language of the new law makes it unlikely that victims of this type of misconduct can hold miscreants personally accountable. This is not the type of legislative signal that inspires.

As to the matter of proposed immunity for the sellers of biomaterials, Congress resisted their plea, presumably unconvinced by their claims of a looming crisis. Just as it is too early to determine the consequences of volunteer immunity, it is also too early to discern the effect of denying immunity to biomaterials suppliers. Should providers of raw materials vanish, it would not be reasonable to ascribe causality to a tort system that consistently protects the interests of raw materials producers in every state and federal court.

If a future session of Congress sees fit to grant such immunity, consumers of biomaterials products will not find their position bettered. Persons injured when a company knowingly supplies materials unsuited for the contemplated medical use will not benefit from a deprivation of their right of redress against those who harmed them. Such a deprivation would constitute yet another "dark side of tort reform."[120]

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[120] *See* Frank M. McClellan, *The Dark Side of Tort Reform: Searching For Racial Justice*, 48 RUTGERS L. REV. 761, 791 (1996) (coining the phrase "dark side of tort reform").