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AMERICAN BAR ASSOCIATION

STANDING COMMITTEE ON MEDICAL PROFESSIONAL LIABILITY

REPORT TO THE HOUSE OF DELEGATES

RESOLUTION

1 RESOLVED, That the American Bar Association urges the federal government to adopt laws that
2 protect patients and promote patient safety from defective medical products.

3 FURTHER RESOLVED, That the American Bar Association opposes legislation that limits
4 and/or bans punitive damages for claims of patient harm allegedly caused by manufacturers of
5 FDA-approved medical products or devices.

REPORT

For decades the ABA has participated in national discussions on the interrelationship between the healthcare professions and the legal system. The ABA has resolved to assure that patients continue to have access to the civil jury system in the nation's courts and that they will also be awarded damages, as supported by evidence, without being subject to an arbitrary cap on actual or punitive damages.¹ This Resolution is consistent with and furthers these policies by opposing efforts to ban punitive damages for claims of patient harm allegedly caused by manufacturers of FDA-approved medical products or devices, as proposed by past, and likely to be reintroduced by future Congresses.²

The ABA House of Delegates first opposed caps on damages in 1978.³ Later, in 2006, there was discussion about proposed federal legislation to deny full compensation to individuals by imposition of arbitrary caps and to create a system of involuntary "health courts." In response, the House passed a resolution that "[r]eaffirms opposition to legislation that places a dollar limit on recoverable damages that operates to deny full compensation to a plaintiff in a medical malpractice action, recognizes that the nature and extent of damages in a medical malpractice case are triable issues of fact (that may be decided by a jury) and should not be subject to formulas or standardized schedules, and opposes the creation of healthcare tribunals that would deny patients injured by medical negligence the right to request a trial by jury or the right to receive full compensation for their injuries."⁴

On December 29, 2008, the ABA continued to advocate for patient rights and safety by sending letters to the House and Senate urging support for legislation to allow injured patients to hold negligent medical device manufacturers liable for damages for product related deaths and injuries in state courts under state laws.⁵

The Help Efficient, Accessible, Low-cost, Timely Healthcare ("HEALTH") Act of 2011,⁶ was introduced in the 112th Congress, and had been introduced in previous Congresses in similar if not identical form, and given the ongoing controversy about health care reform can expected to be reintroduced in future Congresses. The HEALTH Act's scope applies to the large realm of all healthcare related tort actions, not just medical negligence. It applies to any "health care lawsuit" which is broadly defined to include many claims against a number of institutions - not just providers - including hospitals and nursing homes, defective product claims against pharmaceutical companies and medical device corporations, and even bad faith claims against health insurers and HMOs. Additionally, "health care lawsuit" applies to any claim regarding the

¹ ABA Resolution 114 (Feb. 1986).

² Help Efficient, Accessible, Low-cost, Timely Healthcare ("HEALTH") Act of 2011, H.R. 5, 112th Congress (2011).

³ ABA Resolution 117 (Feb. 1978).

⁴ ABA Resolution 103 (Feb. 2006).

⁵ Letter from H. Thomas Wells, Jr., President, American Bar Association, to Hon. Representative Frank Pallone, Jr., Chairman Subcommittee on Health Committee on Energy and Commerce, U.S. House of Representatives (Dec. 29, 2008) (on file with the American Bar Association's Governmental Affairs Office) and Letter from H. Thomas Wells, Jr., President, American Bar Association, to Hon. Senator Edward M. Kennedy, Chairman Committee on Health, Education, Labor, and Pensions, U.S. Senate (Dec. 29, 2008) (on file with the American Bar Association's Governmental Affairs Office).

⁶ H.R. 5, 112th Congress (2011).

provision of health care goods or services “regardless of the theory of liability,” and thus, would apply to negligence and intentional tort causes of action.

The ABA continues to strongly advocate for patient’s safety and rights and allowing the jury system to promote and protect those rights.⁷ If adopted, the HEALTH’s Act provisions regarding its ban on punitive damages in defective product claims relating to FDA-approved products will run contrary to the American Bar Association’s longstanding policy to oppose caps on damages, including punitive damages which encourage responsible behavior by manufacturers of consumer products. This is because the HEALTH Act contains a complete ban on punitive damages for claims alleging a medical product caused the claimant's harm. The manufacturers or distributors of a medical product would receive that benefit of this ban on punitive damages if:

- (1) that medical product “was subject to premarket approval, clearance, or licensure by the Food and Drug Administration with respect to the safety of the formulation or performance of the aspect of such medical product which caused the claimant's harm or the adequacy of the packaging or labeling of such medical product” and was “so approved, cleared, or licensed;” or
- (2) where “such medical product is generally recognized among qualified experts as safe and effective with respect to the safety of the formulation or performance of the aspect of such medical product which caused the claimant's harm or the adequacy of the packaging or labeling of such medical product”⁸

The HEALTH Act caps punitive damages at \$250,000 or twice the amount of compensatory damages – of which non-economic damages are also capped - whichever is greater.⁹ Therefore, while all defendants in “health care lawsuits” would get the benefit of the \$250,000 cap on punitive damages, manufacturers and distributors of medical products would get the additional benefit of an almost complete ban on punitive damages in product liability cases involving their medical products in the event that their medical product received FDA-approval or was “generally recognized among qualified experts as safe and effective.”¹⁰

Banning all punitive damages is poor legal policy and is also contrary to ABA’s existing policies. There is no justification to cap or limit punitive damages in any tort cases. Empirical studies have concluded that punitive damages are rarely awarded, are correlated to the plaintiff’s injuries and are reserved for the most egregious behavior.¹¹ Additionally, there is no evidence

⁷ Patient Safety Resolution adopted by the House of Delegates of the American Bar Association 113 (Feb. 2011); Near Misses Resolution adopted by the House of Delegates of the American Bar Association 115 (Aug. 2008).

⁸ H.R. 5, Section 106 (a)(i).

⁹ H.R. 5, Section 106 (b)(2). As early as 1995 the ABA opposed federal legislation that would have limited punitive damages to “sellers” of products absent conduct manifesting actual malice and with a punitive damages cap of \$250,000. As here with the case of manufacturers, the ABA found that punitive damages in these cases promoted consumer safety. ABA Resolution 303 (Feb. 1995).

¹⁰ H.R. 5 allows for limited exception to ban on punitive damage awards primarily related to fraud in the FDA approval process. Sec. 106(c)(4).

¹¹ See, e.g., Michael L. Rustad, *The Closing of Punitive Damages Iron Cage*, 38 LOYOLA OF LOS ANGELES L. REV. 1297, 1298-99, n. 8 (2005). See also, Michael L. Rustad, *Unraveling Punitive Damages: Current Data and Further Inquiry*, 1998 WIS. L. REV. 15, 69; Michael Rustad, *In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data*, 78 IOWA L. REV. 1, 50 (1992); Michael Rustad & Thomas Koenig, *Reconceptualizing Punitive Damages in Medical Malpractice: Targeting Amoral Corporations, Not “Moral*

that punitive damage awards are increasing, or that judges and juries are not fairly and properly awarding punitive damages.¹²

Further, the deterrent effect and purpose of punitive damages is eliminated by capping or eliminating punitive damages.¹³ “Unless one wishes to ignore the literature, it is apparent that caps reduce the deterrent effect of the civil justice system, protect wrongdoers who cause harm, and transgress the most basic rights associated with civil justice, including the right to a jury trial.”¹⁴

There is no justification to cap or limit punitive damages in tort cases, particularly in cases alleging defective consumer products. As a practical matter, not only are punitive damages only awarded in one percent of product liability actions in state courts,¹⁵ but furthermore, in the rare cases where punitive damages are awarded in product liability actions, their award serves an important deterrent role in ensuring that dangerous products are taken off the market. Research of punitive damages in product liability actions has shown that:

Punitive damages played a vital social policy role in discouraging firms from marketing dangerous products or failing to recall them. The vast majority of dangerous products have been recalled, modified, and redesigned by their manufacturers. Of the cases studied, as many as eighty-two percent of the defendants took some safety step to remedy the dangerous situation. Forty-three percent of the defendants took remedial steps prior to litigation. This is heartening but does not negate the need for punishment in situations in which firms had prior notice but did not correct the danger before injury ensued . . . In general, companies think twice about cutting corners on safety when faced with the prospect of indeterminate punitive damages.¹⁶

The HEALTH Act’s ban on punitive damages for defective product claims caused by FDA-approved products evidences a misunderstanding of the role of punitive damages and product liability law. As an example, in claims alleging a manufacturing defect of an adulterated drug, the fact that the product design received FDA approval or is “generally recognized as safe” is entirely unrelated to the cause of action or whether corporate misconduct in the manufacturing defect would warrant a punitive damage award.

Monsters”, 47 RUTGERS L. REV. 975, 1009 (1995).

¹² Theodore Eisenberg et al., *Judges, Juries and Punitive Damages*, 3 JOURNAL OF EMPIRICAL LEGAL STUDIES 263, 293 (2006) (“We report evidence across 10 years and three major data sets that: (1) juries and judges award punitive damages in approximately the same ratio to compensatory damages, (2) little evidence of increasing levels of punitive awards exists, and (3) juries’ and judges’ tendencies to award punitive damages differs in bodily injury and no-bodily-injury cases.”)

¹³ Andrew Popper, *Capping Incentives, Capping Innovation, Courting Disaster*, 60 DEPAUL L. REV. 975, 997 (2011) (“It forces actors to consider the possibility of harm and injury associated with product or service failure. It pushes companies to optimize safety, within reasonable limits. This pressure is absent with a cap on liability.”)

¹⁴ *Id.*

¹⁵ Only one percent of plaintiffs in product liability trials were awarded punitive damages in 2005. Thomas H. Cohen, *Punitive Damage Awards in State Courts, 2005*, BUREAU OF JUSTICE STATISTICS, (March 2011).

¹⁶ Michael Rustad, *In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data*, 78 IOWA L. REV. 1, 79 (1992).

Moreover, adherence to government regulations is already relevant and considered in product liability cases. Under current tort law, any manufacturer in any industry, including a pharmaceutical or medical corporation, can defend an allegedly defective product by introducing evidence of its compliance with industry or government standards. However, mere compliance with an industry standard does not excuse what is otherwise culpable misconduct. The Restatement of Torts provides that:

a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.¹⁷

Similarly, there is no justification to assume that adherence to a government standard, such as FDA approval or clearance for a medical product, should completely eliminate the availability of punitive damages where there may otherwise be a finding of intentional or wrongful conduct that warrants an award of punitive damages. Indeed, in *many* product liability claims alleging a design defect or failure to warn defect in a medical product, the product was *nearly always* FDA-approved.

Certainly, defendants may continue to introduce evidence of their compliance with FDA rules and regulations as part of their defense, and judges and juries may consider such information in evaluating any award or amount of damages, but adherence to a government standard will not, nor should it, forgive a company of an award of punitive damages if that company is otherwise guilty of gross misconduct. This is especially true where the government's approval process, itself, has been subject to widespread criticism.¹⁸

The consequences for specifically exempting FDA-approved products from punitive damages are particularly grave since these products inherently present the most serious risks of all consumer products and to the safety of patients. "While admittedly these products are socially useful, they also pose some of the greatest risks to human beings. Consider, for example, the widespread injuries that thousands of women suffered as a consequence of using the Dalkon Shield or DES, to name but two prescription products. Indeed, the level of potential risk from such products is one of the reasons they are so closely regulated."¹⁹

There exist other examples of FDA-approved products where FDA's regulatory review process proved inadequate in protecting the public from serious risks posed by a medical product.²⁰ As summarized in a recent report from the Congressional Research Service:

Problems related to medical devices can have serious consequences for consumers. Defects in medical devices, such as artificial hips and pacemakers, have caused severe patient injuries and deaths. In 2006, FDA reported 116,086 device-related

¹⁷ RESTATEMENT OF TORTS (THIRD): PRODUCT LIABILITY, § 4, *Noncompliance and Compliance With Product Safety Statutes Or Regulations* (2012).

¹⁸ In 2009 and 2011 the GAO identified FDA's oversight of medical products on its list of high-risk areas. GAO Report to Congressional Committees, "High-Risk Series: An Update," February 2011.

¹⁹ Teresa Moran Schwartz, *Punitive Damages and Regulated Products*, 42 AM. U. L. REV. 1335, 1347-48 (1993).

²⁰ *Id.* at 1348-49. The listed examples include Oraflex, Orcolon, Breast Implants, Aspirin warning labels, and Copper 7 IUD, among other medical products approved by the FDA.

injuries, 96,485 malfunctions, and 2,830 deaths; an analysis by the National Research Center for Women & Families claims there were 4,556 device-related deaths in 2009.²¹

Where there is corporate wrongdoing rising to the level of gross misconduct, an award of punitive damages should appropriately be considered and current ABA policy would support that submission to a jury. Yet, the HEALTH Act would forbid such an award in these cases.

In essence, a complete ban on punitive damages from government-approved products represents poor public policy and highlights a misunderstanding of the purpose of punitive damages and product liability laws. The consequences of banning punitive damages in medical product liability actions is particularly troubling given the risks of these particular consumer products and the history at the FDA to inadequately protect public health in its review process of particular medical products.²² In such case, punitive damages serve as an important deterrent against gross corporate misconduct and a safeguard to better ensure the safety of medical products on the market.

Furthermore, the HEALTH Act's ban on punitive damages violates existing ABA policies regarding the availability of punitive damages in medical liability cases. The ABA has previously concluded that there is no justification to limit or ban punitive damages for specific sets of defendants. In the 1986 ABA Resolution, the ABA concluded that, "[n]o justification exists for exempting medical malpractice actions from the rules of punitive damages applied in tort litigation to deter gross misconduct."

While the 1986 Resolution was focused on punitive damages award in medical malpractice actions against healthcare providers -- which as explained above are not the type of cases implicated by the HEALTH Act's ban on punitive damages for FDA-approved products -- it is clear that the ABA's policy implied application to apply to all tort and personal injury causes of action.

The 1986 Resolution relied upon the report of the Special Committee on Medical Professional Liability. This Special Committee Report recognized that the recommended policy against limits on punitive damages applies broadly, not just medical malpractice causes of action. The Special Committee found that:

The purpose of punitive damages is to deter gross wrongful conduct. There has been no justification shown for eliminating those damages when the gross misconduct occurs in the delivery of health care services, and there, this committee opposes treating medical malpractice defendant differently than any other wrongdoer accused of acts of gross misconduct. . . .

In passing the 1986 Resolution, the ABA has affirmed the purpose and intent of punitive damages and has shown its unwillingness to cap or eliminate the award of punitive damages. The

²¹ Johnson, Judith, "FDA Regulation of Medical Devices," June 25, 2012, at 6.

²² See, e.g., a 2011 study by the Institute of Medicine which found the FDA approval process for medical devices is seriously flawed. <http://www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx>

Special Committee Report stated, “This committee emphasizes that punitive or exemplary damages are reserved for the rare situation in which a physician – or any other defendant in a tort action – has committed willful wrongs of such a heinous nature that the punishment is appropriate.”

Additionally, the ABA has previously recognized that punitive damages are particularly important in the cases alleging corporate wrongdoing, since traditional criminal punishments for reprehensible conduct is not available in product liability claims. In the ABA’s 1987 Report of the Action Commission to Improve the Tort Liability System,²³ the Commission found the following in making its recommendations:

From the standpoint of tort theory, punitive damages express the full measure of societal outrage and assure the appropriate deterrent effect in cases where a defendant’s conduct is outside the bounds of civilized behavior. . . .Typically, there is no effective criminal remedy to complement civil redress Hence, punitive damages traditionally have served the important function of ensuring a measure of punishment for essentially private unlawful conduct that is commensurate with the antisocial nature of the action.²⁴

The ABA’s prior position is well founded, but particularly for product liability claims. It is impossible for a corporation to face criminal prosecution, and there is not criminal remedy for most patients injured by a defective medical product. Indeed, for many of these cases an award of punitive damages may be the only means to punish a corporation for any willful misconduct. If anything, the availability of punitive damages in allegations of corporate wrongdoing deserves special protection, the exact opposite of the limits offered by the HEALTH Act.

While the ABA has previously recommended some types of reforms to punitive damage awards, none of those reforms are remotely correlated to the HEALTH Act’s ban on punitive damages. In the 1987 Report, the ABA recommended other reforms to punitive damage awards, such as altering the standard of proof in awarding punitive damages and implementing pre-trial procedures to weed out frivolous claims for punitive damages.²⁵ However, the ABA has never endorsed – as discussed above previously, the ABA has in fact opposed - any proposal that limits or bans punitive damages

Such statements readily acknowledge that questions of availability and amount of punitive damages properly rest with a jury under the normal judicial oversight of the judge. Bans on punitive damages, as proposed in the HEALTH Act, would take these decisions away from juries and judges, fundamentally altering the inherent purpose and effect of punitive damages in the American judicial system.

Conclusion

The ABA recognizes that availability of punitive damages serves the purpose of deterring gross wrongful conduct, regardless of the type of defendant or regulatory approval of their

²³ In 1985 then-ABA President William W. Falsgraf appointed this Commission, chaired by Robert B. McKay. It was charged with examining all aspects of the tort liability system.

²⁴ Report of the Action Commission to Improve the Tort Liability System (ABA Feb. 1987) at 16.

²⁵ See ABA Resolution 120D (Aug. 1987) implementing some of these recommendations.

product. Without question, eliminating punitive damages against pharmaceutical and medical device corporations in product liability claims would allow such corporations to avoid the deterrent purpose of punitive damages. Indeed, in cases such as medical devices, where patient safety is at stake, and when awards of punitive damages are rare for product liability cases, there is no justification for legislation to shield wrongful conduct or limit the jury's and court's ability to deter such conduct.

The Standing Committee on Medical Professional Liability requests the House of Delegates to adopt the resolution herein.

Respectfully submitted,

Howard Wall, Chair
Standing Committee on Medical Professional Liability
August 2015

GENERAL INFORMATION FORM

Submitting entity: Standing Committee on Medical Professional Liability

Submitted by: Howard Wall, Chair, Standing Committee on Medical Professional Liability

1. Summary of Recommendation.

The American Bar Association supports patient safety. The ABA further opposes any legislation limiting or banning punitive damages for claims of patient harm allegedly caused by manufacturers of FDA- approved medical devices.

2. Approval by Submitting Entity.

The proposed resolution has been approved by the Medical Professional Liability Standing Committee via electronic balloting on May 4, 2015.

3. Has this or a similar resolution been submitted to the House or Board previously?

Previous resolutions have dealt with different areas of broad policy against limiting punitive damages and on general support of legislation that protects patients. This resolution builds on existing ABA policy particularly 1978 and 2006 resolutions opposing limits on damages and fair compensation for persons in medical malpractice actions, as well as 1995 and 2003 policies regarding regulation of product liability law.

4. What existing Association policies are relevant to this resolution and how would they be affected by its adoption?

The proposed recommendation will supplement the following American Bar Association policies:

Resolution adopted by the House of Delegates of the American Bar Association February 1978 and 2006 cited in the Report.

5. What urgency exists which requires action at this meeting of the House?

There are numerous advocates seeking national changes to torts involving medical device manufacturers. We strongly believe a form of H.R. 5 will be introduced in Congress and the ABA should be ready to oppose bans on punitive damages as to wrongful conduct of medical device manufacturers.

6. Status of Legislation. (If applicable.)

See #5 above.

7. Brief explanation regarding plans for implementation of the policy, if adopted by the House of Delegates.

The Standing Committee and interested sections will work closely with our Government Affairs Office to oppose legislation that may be introduced in the next Congress.

8. Cost to the Association. (Both direct and indirect costs)

There are no direct or indirect costs to the Association anticipated as a result of its adoption of this Resolution as ABA policy.

9. Disclosure of Interest. (If applicable)

Members of the Standing Committee represent all stakeholders in healthcare claims, as counsel for plaintiffs and defendants, including insurance companies. We are not aware of any potential conflicts of interest related to this Resolution.

10. Referrals.

Referral is being made to all Sections, Divisions, and interested Committees, especially:

Health Law
Litigation
Tort Trial and Insurance Practice
Commission on Law and Aging

11. Contact Name and Address Information. (Prior to the meeting. Please include name, address, telephone number and e-mail address)

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12. Contact Name and Address Information. (Who will present the report to the House? Please include name, address, telephone number, cell phone number and e-mail address.)

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EXECUTIVE SUMMARY

1. Summary of the Resolution

The American Bar Association supports patient safety. In so doing, it opposes efforts, by way of federal legislation, that would limit or ban punitive damages for claims of patient harm allegedly caused by manufacturers of FDA- approved medical devices.

2. Summary of the Issue that the Resolution Addresses

In recent Congresses, as part of the ongoing debate over accessibility and cost of health care, bills have been proposed to place limits on what persons may recover in medical malpractice cases. Included have been provisions to limit punitive damages against manufacturers for medical products and devices that have received FDA approval. This is despite evidence that punitive damages promote patient safety as well as shortcomings in the FDA approval process. This resolution will allow the ABA to oppose such legislation, consistent with our other ABA approved policies on medical malpractice liability.

3. Please Explain How the Proposed Policy Position will address the issue

This Resolution will specifically oppose legislation that would limit or ban punitive damages for manufacturers of FDA approved medical devices

4. Summary of Minority Views

No minority views or opposition have been identified at this time.