

TESTIMONY OF BRIAN WOLFMAN*

Testimony in Opposition to H.R. 5, the HEALTH Act of 2011
Before the Subcommittee on Health of the Committee on
Energy and Commerce of the U.S. House of Representatives

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Introduction

Chairman Pitts and members of the subcommittee: Thank you for the opportunity to appear today in opposition to H.R. 5, the HEALTH Act of 2011. I have practiced law for more than 25 years. I am not a member of the private plaintiff's bar and never have been. I do not represent defendants in product liability or medical malpractice suits and never have. I have worked exclusively for non-profit organizations. I worked for nearly five years as a staff lawyer in a rural civil legal services program in Arkansas and, then, for nearly 20 years, at Public Citizen Litigation Group, the last five as its Director. Now, I'm the co-director of a non-profit student-centered legal clinic at Georgetown Law School. I'm no partisan when it comes to the civil justice system. Indeed, for years, my colleagues and I have challenged unfair class action settlements proposed by plaintiffs and defendants, because we believe that the civil justice system must serve the litigants and American consumers more generally.

But I believe that I know a bad deal for consumers when I see one, and H.R. 5 is a

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very bad deal. The free market works reasonably well in individual law suits, where the client's interest in maximizing recovery and the lawyer's interest in a fair fee are well aligned and do not require the kind of micro management and anti-free market regulation that H.R. 5 would impose. As I explain below, H.R. 5's draconian limits on recoveries and on attorney fees will harm consumers and undermine their health and safety. For those reasons, I urge the committee to reject H.R. 5.

**H.R. 5's Treatment of Medical Product Claims Would
Undermine The Interests of American Consumers.**

H.R. 5 mainly concerns medical malpractice claims, but it also applies to claims involving injuries from what the Act terms a "medical product," which in turn is defined as a prescription drug, medical device, or biological product, as those terms are defined in the Federal Food, Drug, and Cosmetic Act.¹ My testimony focuses on these medical product claims — specifically, claims by injured patients against drug and device manufacturers alleging that their products were defectively designed or manufactured and/or were not accompanied by adequate warnings.

Although I believe that nearly all of H.R. 5 would, if enacted, harm the American public, my testimony will focus on three of its most troubling provisions: its limits on non-economic damages, attorney's fees, and punitive damages. Before discussing those provisions in more detail, I want to take a moment to explain why state-law suits against

¹H.R. 5, § 9(14) (2011).

drug and device manufacturers benefit the public, which depends on safe and effective drugs and medical devices.

First, state “common-law claims,” such as those involving medical devices and drugs, “necessarily perform an important remedial role in compensating accident victims.”² Thus, if H.R. 5 undercuts a patient’s ability to be fully redressed for her injuries or to attract competent counsel to challenge the massive resources of drug and device companies — and, as explained below, H.R. 5 would do both — people harmed by defective or mislabeled drugs and devices will go without needed compensation.

Second, the civil justice system deters the sale of unsafe and ineffective products and encourages the sale of products that are, in fact, safe and effective. This role is particularly important with respect to products regulated by the Food and Drug Administration (FDA), which, with limited funding, must oversee thousands of products and review tens of thousands of reports of product failures and other adverse events. As the Supreme Court put it just two years ago:

The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.³

The Supreme Court understands that these two roles — compensation and safety

²*Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002).

³*Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (footnote omitted).

— are interrelated. The state-law tort system “serve[s] a distinct compensatory function that may motivate injured persons to come forward with information,” which, in turn, informs the FDA and the public about unsafe products.⁴ Thus, “the FDA [has] long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.”⁵

As I now explain, H.R. 5 threatens to undermine these positive attributes of the civil justice system.

H.R. 5, § 4(b) — The \$250,000 Limit on Non-Economic Damages

H.R. 5, § 4(b) limits to \$250,000 non-economic damages in cases, among others, involving injuries from FDA-approved products. The most common forms of economic damages are lost income and the costs of medical care. But a person grievously injured by a drug or medical device is harmed in many ways that are non-economic and not fully captured by the non-descriptive term “pain and suffering.” A person who has gone blind or contracted cancer or lost a limb or developed a severe neurological disease from a defective or mislabeled device or drug may have lost the ability to work. But the damages go much farther. The victims of these kinds of injuries may never get to see or hold their grandchildren; they may never again have sex with their husband or wife; they not only may never draw another paycheck, but they may never experience the joy of hard work or

⁴*Id.* at 1202.

⁵*Id.* (footnote omitted).

professional challenge or satisfaction; they may experience excruciating phantom pain for the rest of their lives; they may live in constant fear of forgetting to take their anti-cancer or heart disease medication necessitated by their injuries; they may worry constantly about their inability to provide for their children; and they may fear abandonment by their friends and loved ones as their injuries become more debilitating. The idea that \$250,000 can fully compensate for these types of injuries — injuries that may last a lifetime — is, to be blunt, absurd. And the fact that H.R. 5 fixes non-economic damages at \$250,000 *forever*, regardless of the impact of inflation, underscores the conclusion that the \$250,000 cap is not a genuine attempt at gauging the impact on real people's lives of non-economic injuries.

Moreover, whether injured people are able to file meaningful suits against drug and device manufacturers depends entirely on their ability to attract competent counsel with the financial incentive to take on the litigation. Drug and device manufacturers almost always have large war chests for litigation. But ordinary people who are harmed by defective products do not. They cannot front the out-of-pocket expenses of product liability litigation, and they cannot pay their lawyers on an hourly basis. They depend on properly incentivized contingent-fee lawyers, who know that, if their clients succeed, the expenses of the litigation and their fees will come out of the clients' awards. (And, of course, those lawyers take the grave risk that if they are unsuccessful, they will be out all of the costs of litigation and receive no compensation for their time.)

Because of the disparity of power between the drug and device companies and the typical injured patient, the companies cannot be taken on without an investment *by the plaintiff's lawyer* of a large (sometimes massive) outlay of out-of-pocket expenses — for expert witnesses (and non-testifying experts), deposition transcripts, document search and reproduction, medical examinations, forensics, and the like — not to mention the huge expenditure of time and overhead for discovery, extensive motion practice, trial, and, not infrequently, one or more appeals (both before and after trial). Section 4(b)'s severe limit on non-economic damages will make it impossible for some injured patients to find lawyers, particularly in cases that are complex and difficult or involve the most deep-pocketed opponents — the very cases in which you want the most skilled, tenacious plaintiff's counsel. And even in cases where the \$250,000 limit does not make it impossible to find a lawyer, the limit — just like any limit on the return on one's investment — will mean that the lawyer will not be able to invest the time and resources (for instance, for hiring qualified experts or appellate counsel) needed to counter the defendant's effort. Put another way, even for cases that are filed, the \$250,000 limit will make it more likely that the plaintiff will lose, and that will become more and more likely as the limit loses value to the ever-present effect of inflation.

Moreover, the \$250,000 limit on non-economic damages would have a disproportionate impact on the victims of unsafe drugs and medical devices who are women, elderly, and/or members of economically disadvantaged minority groups.

Because these individuals are less likely than others to have significant (or any) wage income, their economic damages may be non-existent, small, or difficult to measure (as in the case of individuals who do not work outside the home). Put another way, legislation that limits the amount of non-economic damages an injured person may recover, disadvantages lower income people, who tend not to have significant wage income (the loss of which is a component of economic damages in many tort suits) and must rely more heavily on non-economic damages to be made whole. Thus, under H.R. 5, an older person who is retired and has been permanently and gravely injured by a mislabeled prescription drug could be limited to \$250,000 in damages, which would be grossly insufficient to compensate that person for her losses and, in any event, would likely make it impossible for that person to attract competent counsel.⁶ That makes no sense because society should want to compensate harm and discourage negligent conduct or intentional misbehavior just as much when it is visited upon a relatively poor person, as when it is visited upon someone who is economically advantaged.

* * *

So far, I've described what I will call the logic of the problem: Tort cases against large drug and device companies are expensive, both in terms of out-of-pocket costs and

⁶The disproportionate impact of limits on non-economic tort compensation on women, older people, and members of minority groups has been demonstrated empirically in studies of similar limits imposed by state legislatures. *See, e.g.*, "The Hidden Victims of Tort Reform: Women, Children, and the Elderly," 53 Emory L.J. 1263 (2004); *see also* Finley, "Female Trouble: the Implications of Tort Reform for Women," 64 Tenn. L. Rev. 847 (1997).

time, and they will not be brought if the amounts recoverable are so low that they render the investment risks too great.

But it is also useful to review real cases. In each of the examples that follow, the costs of litigation were high, the defense of the litigation was tenacious, and the plaintiff claimed severe non-economic losses. In some cases, the plaintiff won; in others, the defendant won. But one should not measure whether the tort system properly incentivized the plaintiff (and his and her lawyer) to come forward to sue based on the results of the litigation. The question is whether before suit was filed a plaintiff, armed with a competent, risk-taking contingent-fee lawyer, would have been willing to take on a well-heeled drug or device company, with its team of well-paid lawyers. In each case, I believe that, if non-economic damages had been limited to \$250,000, it is quite unlikely that such a plaintiff would have come forward.

*Wyeth v. Levine*⁷

In this well-known case, the Supreme Court held that the FDA's approval of prescription drug labeling does not preempt a state-law tort suit premised on the drug manufacturer's failure to warn of the hazards associated with the drug. The plaintiff, Diana Levine, a professional musician, went to the hospital for treatment of a headache. After being injected with a drug manufactured by the drug company Wyeth, Ms. Levine suffered injuries that led quickly and irreversibly to the loss of her right arm. More

⁷129 S. Ct. 1187 (2009), *aff'g*, 944 A.2d 179 (Vt. 2006).

specifically, Ms. Levine's arm had to be amputated because Wyeth's drug Phenergan, prescribed to alleviate nausea associated with a migraine headache, reached Ms. Levine's arteries. Here's a short recap of the facts:

On April 7, 2000, Diana Levine received injections of Wyeth's prescription drug Phenergan to treat nausea associated with a migraine headache. The drug was first administered by intramuscular injection. Later that day, the drug was administered intravenously through a technique known as direct IV, or "IV push." In this method, a syringe pushes medication directly into the patient's vein. The method is called "direct" to distinguish it from a more common means of intravenous administration in which the medication is placed into a stream of saline flowing from a hanging IV bag. Wyeth has known for decades that when Phenergan is administered by the IV push method, even by experienced clinicians, inadvertent arterial contact can result. In fact, there were at least 20 reported cases where Phenergan has caused an amputation, all resulting from IV push. Based on undisputed expert testimony, the trial court found as fact that [o]ne way to reduce the risk of inadvertent intra-arterial injection is to set up a free-flowing IV bag and introduce the drug into the IV solution. This is an alternative to injection through the [IV push] infusion set into a patient's vein. Administration through a free flowing IV bag reduces the risk of inadvertent arterial injection because the nurse or physician can be more certain that the needle has been placed in a vein. A solution dripping from an IV bag will not flow freely into an artery due to back pressure from the patient. An expert testified that using a hanging IV bag involves virtually no risk of arterial exposure and is "far safer" than IV push.

The testimony indicated that Wyeth knew that when Phenergan comes in contact with an artery, the artery dies, and necrosis, gangrene, and amputation result. Four experts testified that if Phenergan is used intravenously, it should be done only through a hanging IV bag and that the label should have precluded use of IV push, but it did not do so. Indeed, even one of Wyeth's experts acknowledged that he would hesitate to use direct IV injection for use in non-life-threatening situations and stated that he would have written the label to instruct that Phenergan be administered into a running, established IV. Another Wyeth expert agreed with Ms. Levine's expert that it was safer to administer Phenergan through a free-flowing IV than through the direct method.

Because the IV push method was used to administer Phenergan to Ms. Levine, the drug penetrated her artery. For seven weeks after the injection, Ms. Levine suffered unimaginable physical and emotional pain as she watched her right hand turn black and die. As one witness put it: “Pain scales usually are run from one to ten. This is a ten. ... there’s not much worse than this type of scenario.” Ms. Levine herself testified about her excruciating pain, terror, and fear of dying and losing her arm. In short, as a result of being subjected to an unsafe and unnecessary method of administration of a drug to curb nausea, Ms. Levine endured two amputations. She first lost her right hand and then her right arm up to the elbow, which forever destroyed her ability to play music — her profession and lifelong passion.⁸

Ms. Levine was represented by a very skillful, small-town Vermont lawyer. He was up against one of the largest drug companies in the world. Wyeth had as many lawyers as it needed, including, when the case was on appeal, teams of lawyers from two of the largest Washington, D.C. law firms; they filed multiple pre-trial motions and fought the case at every turn (as they had every right to do). To do a competent job, Ms. Levine’s lawyer had to hire four experts, pay for reams of depositions, and endure the rigors of a contested trial. Out-of-pocket expenses ran into the tens of thousands of dollars, all spent years before either he or Ms. Levine knew whether they would ever see a dime. The jury returned an award of \$7.4 million, \$5 million of which was for non-economic damages, but that was five years before the appellate process would run its course. During that process, the financial impact of Ms. Levine’s injuries became so severe that Ms. Levine accumulated massive debt and had to take out a large loan against

⁸The facts are taken from the record in the *Levine* case. I read the trial transcript when I was representing Ms. Levine in the Supreme Court.

the judgment.

I want to be clear about what Ms. Levine's \$5 million in non-economic damages entailed. It's not what you might think, and it's not what the Chamber of Commerce wants you to think. The sterile terms "non-economic damages" or even "pain and suffering" do not adequately describe those injuries. Ms. Levine experiences phantom pain in her missing arm every day. Sometimes it is excruciating. And she has pain and tendinitis in her other arm because, having lost one arm, the other arm has to do a disproportionate amount of the physical work that most people accomplish with two arms. Ms. Levine had been a well-known Vermont musician who loved to play and create music. You can hear that clearly if you listen to one of her CDs, as I have. All that has been fundamentally altered — forever. Imagine the difficulty of completing ordinary tasks — driving, cooking, dressing, fixing one's hair, to name a few — that able-bodied people do easily every day. There's the disfigurement that will always be with her. And then there's the depression, the mental anguish that frays relationships, undermines desire, and just plain hurts — all stemming from the experience of losing one's arm, the constant physical pain, and the realization that she is living a life that will never be fully restored.

Someone might think the potential award of \$2.4 million in economic damages ought to have been sufficient to have induced a competent lawyer to have taken on Ms. Levine's case. But, again, that's not how a system of economic incentives works. No one

knows the result of the case before it is litigated. In preparing for this testimony, I called Ms. Levine's lawyer and asked him whether, given the possibility of an award of economic damages, he would have taken the case if there had been a \$250,000 limit on non-economic damages. There was a long pause, and I think I know why. Not because \$250,000 in non-economic damages is an adequate incentive to take on a case like Ms. Levine's. It isn't. Her lawyer paused, I believe, because knowing what Ms. Levine had gone through and how much she had needed him, he didn't want to say "no." But, in fact, after that long pause, he did, quietly, say "no."

*Boles v. Merck*⁹

Plaintiff Shirley Boles, a woman in her 50s, was suffering from osteopenia — a weakened condition of the bones. The condition often precedes osteoporosis. She was prescribed Fosamax, which is supposed to inhibit bone resorption. Several years later, Ms. Boles had a tooth extracted and developed complications that suggested the presence of an infection. She underwent curettage and debridement of the affected area, but they were not effective. Her condition worsened. In 2005, her jaw began to exhibit areas of exposed necrosis — that is, the death of a bone. The damage extended to her inferior alveolar nerve, which innervates the cheek, gums, and lower lip. The first trial against Merck ended in a mistrial. During a second trial in which Ms. Boles argued that Fosamax led to the death of her jaw, she put on six expert witnesses (some or all for a second time)

⁹2010 WL 5086699 (S.D.N.Y. June 25, 2010).

in clinical trials, oral surgery, gynecology, infectious diseases, oral surgery, and new drug review/approval procedures. She was eventually awarded \$8 million for “past and future pain and suffering.” A case requiring six experts would not have been brought if non-economic damages had been capped at \$250,000.

*Eichmiller v. Wyeth*¹⁰

Linda Eichmiller, a 54-year-old nurse, took the diet drug Pondimin, manufactured by Wyeth. In 1997, the drug was pulled from the market because studies showed it increased the risk of heart disease. Ms. Eichmiller contracted valvular heart disease and claimed, consistent with the drug’s removal from the market, that Pondimin was responsible. Ms. Eichmiller employed five experts, one each in cardiology, medical care, general medicine, epidemiology, and pharmacology. The jury came back with a verdict for Wyeth, and Ms. Eichmiller received nothing. Given that risk, why would someone take on the pharmaceutical giant Wyeth, and hire six experts, if she were limited to \$250,000 in non-economic damages?

*Bartlett v. Mutual Pharm. Co.*¹¹

Karen Bartlett was prescribed a non-steroidal anti-inflammatory drug (NSAID) called Clinoril for pain in her right shoulder. Within weeks, Ms. Bartlett went to the emergency room complaining of skin blisters, eye irritation, and other symptoms. She was

¹⁰2008 WL 22998351 (Ga. Super. Nov. 26, 2003).

¹¹2011 WL 32520 (D.N.H. Jan. 5, 2011).

soon diagnosed with Stevens-Johnson syndrome (SJS), which progressed to toxic epidermal necrolysis (TEN), a serious and potentially fatal condition characterized by necrosis of the skin and mucous membranes. Her doctors concluded that the SJS/TEN was caused by Clinoril. She spent about three months in the hospital recovering — two of them in a medically induced coma — and ended up with permanent injuries, including blindness. Ms. Bartlett litigated under three theories, two of which were rejected by the court, after a series of motions filed by the defendant. After several more rounds of briefing regarding the sufficiency of Ms. Bartlett's claim, almost 50 additional challenges to expert witnesses and testimony in advance of trial, and nearly 50 motions in limine, the court held a three-week trial in August 2010. The plaintiff used four expert witnesses — a pharmacologist, burn surgeon, an economist, and a life-care planner. The jury returned a verdict for about \$21 million, \$16.5 million of which was for pain, suffering, and loss of enjoyment of life. Ms. Bartlett's lawyers then successfully fought a series of post-trial motions challenging her expert witnesses among a slew of other legal challenges.

Even if we assume that Ms. Bartlett had determined before she filed suit that she had a 50-50 chance of obtaining *some* economic damages, the massive costs of the case — hiring four of her own experts, pre-trial motions that threw out two of her three claims, 50 motions challenging her experts, 50 motions in limine, presumably a large number of expert and other depositions, not to mention the post-trial motions — almost certainly would have dissuaded a rational lawyer from pursuing the case if it had been subject to a

\$250,000 limit on non-economic damages.

*Rush v. Wyeth*¹²

At age 65, Helen Rush, a newsletter writer began to undergo hormone therapy as a result of a gynecological condition. The hormone was manufactured by Wyeth. She was diagnosed with breast cancer and sued Wyeth, alleging that the breast cancer warning on the drug was inadequate and that the risks, including breast cancer, of hormone therapy outweighed its benefits. The jury found for Wyeth. Ms. Rush's case involved six experts — in family medicine, epidemiology, cancer, new drug review and approval procedures, and breast surgery. The jury's verdict left Ms. Rush with nothing, which is the risk she and her lawyer took. But Ms. Rush almost surely would not have taken that risk had her non-economic damages been limited to \$250,000, particularly because, at age 65, Ms. Rush's future earnings potential may not have been very great.

H.R. 5, § 5 – Restrictions on Contingent Fees

Section 5 of H.R. 5 imposes severe restrictions on contingent fees and is perhaps the Act's most anti-consumer provision, the one most likely to undermine the public's health and safety. Section 5 limits attorney fees to 40% of the plaintiff's recovery up to \$50,000; to 33 1/3% of the next \$50,000; to 25% of the next \$500,000; and to 15% of the recovery in excess of \$600,000. These numbers appear to have been plucked out of thin air, with no explanation of whether they somehow correct purported distortions in the

¹² 2007 WL 912211 (Feb. 15, 2007).

market for contingent-fee legal services. Moreover, in perhaps the Act's greatest affront to free-market contracting, § 5 gives a court the power in any case to "redirect" to the plaintiff a part of the previously agreed-on attorney fee whenever it wishes "based upon the interests of justice and the principles of equity."¹³

At first blush, for someone who does not understand the economic reality of contingent-fee legal practice, or, indeed, the economic reality of risk taking in a free-enterprise economy, § 5 may appear rational and pro-consumer. After all, once the plaintiff's recovery hits \$600,000, why not limit the lawyer's recovery to 15% of the excess? To be sure, once a case has been won or a settlement finalized, § 5 "benefits" the client, who may receive a much larger portion of the pie than she would if she were required to live up to the 1/3 contingent fee to which she had earlier agreed. So, why should we care, if the client — whose interests we want to protect — takes home more money?

But that looks at the attorney-client transaction after-the-fact, which makes no sense. This may be easier to explain outside of the attorney-client context. Say, for instance, a person decides to open a coffee shop. She invests a quarter million dollars, her entire life savings (much like a contingent-fee lawyer might invest in expert witnesses, deposition costs, various office overhead, and the like). The prices she charges for coffee and other items are set by the market (just like the market sets lawyer's contingent fee

¹³H.R. 5, § 5(a).

rates). The coffee shop may fail entirely (like a contingent-fee lawyer may lose all or most of his cases); it may struggle, providing some jobs for its workers and just enough for the owner to scrape by (like a contingent-fee lawyer who wins a few cases here and there), or the coffee shop may hit it big, with lines out the door and large profits for the owner (akin to a multi-million dollar verdict for the contingent-fee lawyer). The latter situation is rare. Some businesses fail and others struggle. But when the business succeeds, in a free-enterprise system, we do not say that the coffee shop owner has achieved a windfall, and the law certainly does not require the successful owner to rebate some of the coffee shop profits to her customers on the ground that she has victimized them. Why not? Because we know that, if we treat *all* entrepreneurs as if they failed or have barely scraped by, we won't have any entrepreneurs; they will not be willing to take the risks that the market imposes if they cannot reap the rewards that the market promises to people who have worked hard, invested sensibly, and understood what it takes to win.

So, let's return to the market for contingent fee lawyers. A plaintiff harmed by a drug or medical device shops for a lawyer. Depending on the locality, the difficulty of recovery, the complexity of the case, and the expected tenacity of the defendant, the contingent fee may be 25%, 33%, or 40%, or even higher on occasion, if the case has to be tried or appealed. Sometimes the contingent fee contract itself builds in differing percentages based on the amount of recovery. Not all contingent fee contracts are alike, and the client is of course free to shop around for a lawyer based on the contract terms

(with the understanding, of course, that, as in most situations, you get what you pay for).

If the market does *not* cap contingent fees at 15% for recoveries above \$600,000, it is presumably because lawyers are not willing to offer that term to their clients. And that is understandable. This risk of product liability litigation is too great. In the *Bartlett* case discussed above, though the client ultimately obtained a multi-million dollar verdict, the lawyer did not know that result going in. But the lawyer might well have known that the opposing side was likely to put on a formidable, scorched-earth defense, requiring the hiring of four experts, the defense of dozens upon dozens of pre-trial motions (which resulted in the loss of two of the plaintiff's three claims), depositions, and an appeal. Sure, viewed in hindsight, Ms. Bartlett would have done better if a larger chunk of the lawyer's fee had been paid to her, but given (1) that the market values generally lawyer's contingency services at well above 15%, (2) the high-risk nature of the case, and (3) the immense investment that were needed to prevail, it seems highly unlikely that a 15% fee would have attracted competent counsel to take the case. And, don't forget, buying the services of a lawyer is not like buying coffee. If the market for trendy coffee shops dries up because of overzealous regulation, you can still make a pretty good cup of coffee at home. You cannot take on Wyeth or Pfizer or Merck on your own. If the market dries up there, or if the market is comprised of only the least capable lawyers, the drug and device companies may rejoice, but patients will suffer.

Moreover, complex product liability cases, such as those involving drugs and

devices, are the last kinds of case that a legislature would want to subject to a cap on attorney fees. Those cases require lawyers with the most talent and drive, willing to take the most risk. They involve complex issues of medical causation, a wide array of very difficult legal doctrines, an understanding of the drug approval process, and, as has been noted, investment of lots of time and expense. If you want to drive good, non-risk-averse lawyers out of the business of representing people injured by defective and mislabeled drugs and devices, § 5 is the best way to do it. For these reasons, I urge you to reject § 5.

H.R. 5, § 7(c) — Restrictions on Punitive Damages

H.R. 5, § 7 contains limits on punitive damages, none of which is sensible and all of which would harm consumers. I want to focus on a special limit on the award of punitive damages that would apply to drug and device cases. Under § 7(c), no punitive damages may be awarded if the product was approved, cleared, or licensed by the FDA or if the product “is generally recognized among qualified experts as safe and effective pursuant to conditions established by the Food and Drug Administration and applicable Food and Drug Administration regulations”

Rather than trust the state tort systems to determine whether and in what circumstances regulatory compliance should serve as a defense to punitive damages,¹⁴ § 7(c) would establish a nearly categorical rule prohibiting an award of punitive damages if the product was approved by the FDA. Given the reality of FDA regulation, that makes

¹⁴See Restatement (Third) of Torts: Prods. Liab. § 4(b) & cmt. e (1988); 63B Am. Jur. 2d Prods. Liab. § 2022 (2007).

no sense. With respect to medical devices, products are frequently updated. The updated product may replace an earlier version of the product that had safety problems, although the old version may stay on the market. Even where the manufacturer continues to sell a defective or ineffective version solely to maximize its profits and clear its inventories,¹⁵ under §7(c), no court would be able to impose an award of punitive damages.

Prescription drugs present a different problem. Drugs are approved by the FDA as safe and effective after relatively small clinical trials that necessarily do not always unearth all of the product's hazards, contraindications, and side effects. After approval, the product is used by the public at large — a sort of mammoth clinical experiment — and the manufacturer learns more about the product. Indeed, fully half of all drug labeling updates to warn of serious adverse drug reactions occur seven or more years after the drug is first approved.¹⁶ As a result, many, perhaps most, product liability suits regarding drug safety concern information that was not before the FDA at the time of the drug's approval, and, thus, it is irrational to immunize the manufacturer based on that approval. Under § 7(c), however, the manufacturer would be insulated from an award of punitive damages by FDA approval, even in cases where the manufacturer was grossly negligent (or worse) in monitoring the product's safety record after approval and in assuring that its

¹⁵See *Blunt v. Medtronic, Inc.*, 2007 WL 2176136, ¶¶ 2-3 (Wis. App. 2007); *id.* ¶ 22 (Fine, J., dissenting).

¹⁶See Lasser, et al., "Timing of New Black Box Warnings and Withdrawals for Prescription Medications," 287 JAMA 2215 (May 1, 2002).

product label remained up-to-date. For this reason as well, H.R. 5 would undermine consumer health and safety, and the committee should reject it.