

**Knowledge of the Law  
Is No Excuse**

*by Peter Huber*

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## Knowledge of the Law Is No Excuse

In his whimsical poem, "The Objection to Being Stepped On," Robert Frost recounts how he accidentally "stepped on the toe of an unemployed hoe." The implement instantly "rose in offense" and struck Frost a blow "in the seat of [his] sense." Yes, the Bible had foretold the day when weapons would be turned into tools. "But what do we see? The first tool I step on, Turns into a weap-on."

There is a great insight here. The line between tools and weapons is exceedingly fine. Knives cut, irons scorch, dynamite explodes, poison kills. In the wrong hands, or under the wrong foot, the tamest and most domestic object quickly becomes an instrument of assault and battery.

Until the 1950s, the law on these matters was fairly simple. Wherever possible, the old tort law left it up to the individual to distinguish between weapons and tools in his own private universe. If someone wanted to buy a fast horse, lightweight canoe, sharp knife, or strong medicine, that was his business and his risk, or more precisely, it was a risk that he and his seller could allocate between themselves as they chose.

The new tort jurisprudence that developed in the 1960s was quite different. Tort law advanced; contract principles receded. A new tort system gradually stepped in to preempt and rewrite a million allocations of risk and responsibility that had once been decided by

contract. The new tort system was much busier than the old. And having made product "defects" the center of its attention, it had a very much more technocratic function.

Just how does one go about locating a "defect" in a complex product? "Manufacturing defects" are often easy enough to find. The jury compares the product as it reached the plaintiff with hundreds of others, intended to be identical, that came off the same assembly line. In effect, the mass manufacturer establishes his own standard, by which any one of his own products can be gauged. Manufacturing defect cases are easy. They are also comparatively rare.

Far more common today, and also far more difficult, are cases in which the product is said to be defective in design. The search for design defects often requires a jury to compare real with hypothetical products. What is a jury to do, for example, when a lawyer for a sick child claims that a whooping cough vaccine was defective in that it was based on a whole virus rather than a virus extract? The vaccine in question, that of Wyeth Laboratories, is the only whooping cough vaccine sold in this country. An alternative formulation has indeed been tested in Japan, but our own Food and Drug Administration does not approve its use here.

And how is a jury to decide whether a whole class of products—say, the intrauterine device (IUD) contraceptive—is inherently "defective"? The new tort system has apparently reached that conclusion, having driven from the market not only the notorious Dalkon Shield, but also its far safer substitutes, the Copper-7 and the Lippe's Loop IUDs. The FDA, Planned Parenthood, and the vast majority of doctors do not endorse the verdict, but the verdict stands, nonetheless.

It is not enough to identify a safety failing; the jury must also weigh the cost of remedying it. In the early 1970s, the Ford Pinto was to car "crashworthiness" cases what the Dalkon Shield later became to contraceptives. The Pinto weighed under 2,000 pounds and cost less than \$2,000. Ford's own tests revealed that its gas tank was vulnerable to rear-end collisions, but the company decided not to spend an extra \$10 per car to reinforce the structure—a calculation on which plaintiffs' lawyers subsequently grew very rich. Ten dollars is not much, but full-force, rear-end collisions aren't common either, and there are innumerable equally rare hazards that could also be averted for \$10 or less. Protecting against all of them would cost thousands. And people with thousands to spare don't buy a Pinto in the

first place; they buy a Mercedes. What about other cars in Pinto's class? Some certainly had safer gas tanks—which is not to say they were safer cars. A jury later fined Honda \$5 million for its “reckless” act of using lighter gauge materials than some other manufacturers in a 1971-model vehicle.<sup>1</sup> (The driver of that car admitted he had bought it for its economy.) Toyota lost a \$3 million judgment on similar grounds.<sup>2</sup> The subtle message here may be that all economy cars are inherently “defective” for tort purposes. But the National Highway Traffic Safety Administration, millions of consumers, and all major car companies view the matter quite differently.

With lawnmowers, kitchen appliances, airplanes, and safety valves the conclusion is almost always the same: Safety is no exception to the golden rule that buyers can pay more and get more. Design is an infinitely variable and subtle process. It is always possible to strengthen a airplane wing, or a column in a building; it is always possible to reduce the dosage of a drug, or change the method or timing of its administration. But the follow-up questions are the difficult ones. There are questions of function: Will the plane still fly? Will it fly as fast? There are questions of cost: At what point is an incremental benefit in safety no longer worth the price increase it would entail? There are questions of safety itself: Has the product really been improved, or has one risk just been traded off for another, possibly a more serious one?

The rule of thumb for American engineers is that the perfect device will be too late, too heavy, or too expensive. “We make do with the third best,” the British said in World War II, “because the second best is always too late, and the first best never gets built.” The perfectly safe vaccine, or birth control pill, or airplane is also perfectly ineffectual, or impossible to use. Whether the objective is to cure disease, or alter the body's chemistry, or travel at 600 miles per hour, some trade-off between safety and functionality is always in order. Disquieting though these judgments may be, they are what real-world design is all about. In fact, they constitute the full-time business of countless design experts in both industry and government.

The more honest keepers of the new-tort faith recognized the problem and struggled to develop rational guidelines. A verbal blueprint evolved, which has since been widely quoted in jury instructions and appellate decisions.<sup>3</sup>

A jury is to consider, first, the utility of the product, including “the needs, wants and desires served by the

product," "the technological and economic feasibility of serving the same needs with alternative designs," and "the technological and economic feasibility of making the product safer." Next, it must weigh "the usefulness and desirability of the product—its utility to the user and to the public as a whole, the safety aspects of the product." It should then assess "the likelihood that [the product] will cause injury and the probable seriousness of the injury," considering of course "the user's ability to avoid danger by the exercise of care in the use of the product." Here, of course, the jury should take into account "the user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions." Also relevant are "the availability of a substitute product which would meet the same need and not be as unsafe, [and] the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility." Finally, the tireless jury must determine "the feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance."

Only a lawyer could love a mind-numbing profusion of words like this. Perhaps it conveys a sound message. But could any jury really follow its wonderfully subtle and complicated directive? If even a passing attempt were to be made, wouldn't trials have to become advanced seminars in industrial design?

In fact, they have. Experts line up on both sides of the courtroom to educate juries on the finer points of designing a morning sickness drug, a crashworthy car, or a safe playground swing. The old tort law refused to hear this kind of testimony in all but the most exceptional cases. But new, relaxed Federal rules of evidence were put on the books in 1975, just in time for the new tort system's purposes, given the monumental new task at hand. Today, one referral service in Pennsylvania maintains a nationwide list of about 10,000 experts grouped in 4,000 categories, and reports an annual growth rate of about 15 percent. Classified ads in the back pages of legal journals offer counsel on bicycle mishaps, lawnmowers, toys, grain dust explosions, beer barrels, playground accidents, battery or bottle explosions, hot-air balloon accidents, radiation incidents. Car "crashworthiness" cases now routinely inquire into the relative frequency and severity of the different sorts of accidents that can and do occur with a

given model, the probable extent of the injuries, the type of precautions that might have been taken, how those precautions might have impaired overall design and performance of the car, and how they might have affected the vehicle's price and the protection it affords against other types of accident hazards.

By the late 1970s, the technical and economic questions being raised in design defect cases were triggering titanic courtroom struggles. But these struggles remained, all the while, mere parodies of the actual process of real-world design. The original design of a car, drug, or appliance takes years, as does review, when required, by a government agency like the FDA. With or without help from two camps of experts, a jury typically has a few days, seldom more than a few weeks. As George Bernard Shaw caustically observed, "the theory of the adversary system is that if you set two liars to exposing each other, eventually the truth will come out." The paid experts and other hired hands have multiplied the numbers far beyond two, but there are few signs that any new truth has emerged.

### **The matrix of existing standards**

Since the beginning of the industrial revolution, professional associations and government agencies have been setting safety standards that embody their expert judgments. In the early days of steam technology, boilers exploded with appalling regularity, killing and maiming thousands of stokers and firemen and many bystanders. Engineering societies eventually settled on standards of proper design and operation for boiler manufacturers and users. Today these standards are well established and universally recognized. Boiler explosions are extremely rare.

Devising or endorsing such standards of good design practice was the mission of many of the regulatory agencies that proliferated in the 1960s and early 1970s. The Environmental Protection Agency and National Highway Traffic Safety Administration have joined the FDA and other similar bodies in setting thousands of safety standards for foods, drugs, cars, heart pacemakers, aircraft, pesticides, and much else. Where no government agency issues licenses or sets standards, the gap is usually filled by private non-profit trade associations or professional societies like the National Underwriters Laboratories.

The line between the dangerous weapon and the useful tool is one that experts in pharmacology, engineer-

ing, medicine, and chemistry must draw all the time. But only on the basis of years of careful work. Good design is subtle and difficult. Tort lawyers know too well that an error in one direction can lead to carnage. What they often forget is that error in the other can be equally harmful, if it deprives people of valuable medicines or major technological advances that make life safer.

William Prosser, Robert Keeton, Guido Calabresi, John Wade, Roger Traynor, and the other founding fathers of the modern tort system might well have used the existing matrix of public or quasi-public standards to give structure to their new jurisprudence. The crux of their philosophy of accident law, after all, was that the protection of health and safety is part of a larger social contract that must supersede bilateral private agreement. Individual judgments about safety matters were to give way to publicly prescribed standards. The most obvious standards on hand were those prescribed by professional agencies and associations.

As it happened, the courts had long accepted that view, at least in a negative context. By the 1870s if not earlier, the violation of a regulatory standard was treated as conclusive evidence of "negligence." One of the clearest statements of the rule was supplied in 1920. Elizabeth and William Martin, driving their buggy near Tarrytown, New York, were hit by a car coming from the opposite direction, driven by Samuel Herzog. Who was at fault? A jury found Herzog to blame, even though the Martins had been traveling that evening without buggy lights, in violation of a local statute. But the court of appeals overturned the jury's decision and ruled against the Martins. "We think the unexcused omission of the statutory signals is more than some evidence of negligence," wrote Benjamin Cardozo for the court. "It is negligence in itself. . . . [T]o omit, willfully or heedlessly, the safeguards prescribed by law . . . is to fall short of the standard of diligence to which those who live in organized society are under a duty to conform."<sup>4</sup>

The idea was and is sensible enough: Safety standards are made to be obeyed. Modern courts, like their predecessors, simply will not permit a jury to reexamine, after a poisoning, whether it really was negligent for the Mammoth Drug Company to sell a drug the FDA had not approved. It is always possible, of course, that the FDA made a mistake—perhaps its rule was overly strict, and so a menace to would-be consumers who needed the drug. But there is little likelihood that an inexpert jury can provide important insight on the

safety question that the FDA has missed, and an ever-present risk that a jury might say yes to something that really should not be on the market. Nor will Mammoth Drug be heard to argue that it was simply unaware of the FDA regulation. Ignorance of the law is no excuse.

Knowledge of the law, surprisingly enough, is no excuse either. The longstanding rule, still applied in every jurisdiction in this country, is that even the most complete conformity with applicable regulation will not shield a defendant from tort liability.

This rule, too, has a venerable ancestry. On the night of October 21, 1928, the Hotel Berry in Athens, Ohio caught fire.<sup>5</sup> Ray Mitchell, a guest, injured herself jumping from her window, and she sued the hotel, claiming that it had not provided convenient fire exits. The trial court ruled for the hotel, on the ground that the hotel had complied fully with applicable fire exit laws. A court of appeals immediately overruled. “[A]lthough it be shown that the defendant had all the exits required,” the court declared, “it is not acquitted of a charge of common-law negligence by proof of its compliance with the statutes.”

The logic was uncomplicated, at least in the context of its times. Most products and activities were so sparsely regulated that full compliance with applicable rules meant little. That a driver was not intoxicated and had obeyed the speed limit hardly constituted proof that he drove prudently. Perhaps ice on the road dictated a speed lower than the posted one; perhaps the driver had rashly stayed at the wheel all night and drowsed off; perhaps he did all sorts of technically legal things that prudent drivers nevertheless do not do. In a thinly regulated world, full compliance with the regulations meant only that a defendant had done the minimum necessary, not that he had necessarily behaved prudently.

As regulation intensified in the 1960s and 1970s, however, the array of health- and safety-related rules began to fill up much more of the canvas. The FDA began spelling out every detail of how drugs could be composed, packaged, labeled, and prescribed. Significantly, since 1962 the FDA has had to pass not only on safety, but also on “efficacy,” which requires the agency to reach an *affirmative* conclusion that a drug approved is actually beneficial, not merely harmless. The Federal Aviation Administration and the Nuclear Regulatory Commission developed equally exhaustive standards for the operation of aircraft and nuclear power plants, again under a mandate to ensure not merely safety but advancement of the public good.

New agencies such as the NHTSA and EPA took as their mission not just the ad hoc rectifying of one or another case of flagrant defect in cars or pesticides, but the rethinking of overall composition and design.

Much of this was good news for plaintiffs. When regulations proliferate, so do opportunities to violate them. And when rules were violated, the courts continued to apply the old rule of incontestable negligence quite strictly. Whether a regulatory standard had been transgressed in a manner that was wanton and momentous, or merely inadvertent and technical, a violation remained a violation, and virtually conclusive evidence of negligence.

Significantly, the corollary implications about defendants' compliance were not changed in the least. Time and again defendants attempted to raise prior regulatory approval as a shield; time and again they failed.

So the Piper Aircraft Company discovered in a fairly typical case involving one of its Cherokee aircraft which crashed with Douglas Wilson and Arbie MacDonald on board.<sup>6</sup> Their surviving spouses sued Piper, claiming that the plane's engine had failed because the carburetor had iced. A better designed engine, they argued, would have used a fuel injector. Piper pointed out that its plane's design had been fully approved by the Federal Aviation Administration; over 80 percent of planes of similar size, in fact, also used carburetors rather than fuel injectors. A jury nevertheless returned large verdicts for the plaintiffs.

In a lengthy opinion, the Oregon Supreme Court conceded at the outset "special problems in the nature, and necessary proof, of a 'defect' in a product which reaches the consumer in precisely the condition intended by the designer/manufacturer." The court also noted sympathetically Piper's objection that "a lay jury is not qualified to determine technical questions of aeronautical design." The court went further: It reexamined all the evidence presented at trial and concluded that it was not "sufficient to permit the jury to find that the airplane was dangerously defective." But "[w]e have found no cases," the court finally ruled, "holding that compliance [with FAA regulations] is a complete defense. We hold that it is not." So it sent the carburetor-injector debate back for a second jury to weigh anew.

The law today can be simply stated: Advance regulatory approval, no matter how thorough, careful, and complete, counts for little in the subsequent lawsuit. In January the FDA may conclude that the Sabin polio vaccine is as safe as is technically feasible, vital for the

public health, and to be used in preference to the Salk vaccine, which is less effective in conferring mass immunity. In February a jury of 12 stout citizens may conclude that the Sabin vaccine is dangerously "defective," that the Salk vaccine is to be preferred, and the jury may carry that conclusion through to a multi-million dollar verdict, perhaps including punitive damages. Standards written by regulatory agencies, industry associations, insurance laboratories, or even Congress itself are given polite but only nominal attention. Juries, and juries alone, are the final arbiters of "defective design." It is simple as that.

If there was ever any doubt about this as the age of ubiquitous government regulation took hold, it was quickly laid to rest by the courts. Ophthalmologists almost uniformly agree that routine glaucoma tests are inappropriate, but an under-40 plaintiff who lost his sight to glaucoma prevailed on the theory that a doctor should have administered the test anyway.<sup>7</sup> The Dayton-Hudson Corporation paid \$1 million in punitive damages to a young girl burned after her cotton flannelette pajamas caught fire; the pajamas complied fully with the Federal Flammable Fabrics Act, but the victim's lawyer persuaded the jury that the government test was not reliable, and that Dayton-Hudson knew it.<sup>8</sup> A lawsuit brought by Karen Silkwood's family against the Kerr-McGee Corporation established that a reprocessor of nuclear materials could be held liable to its employees despite essentially complete compliance with all Federal safety regulation.<sup>9</sup> The manufacturer of a birth control pill paid \$2.75 million in punitive damages for an allegedly defective chemical formulation, despite complete compliance with FDA regulations.<sup>10</sup>

Similar logic has meant that the defendant's care and good faith are also irrelevant when the plaintiff alleges a defect in the warning rather than in the product itself. If compliance with the substantive rules of behavior addressing hotel fire exits or aircraft carburetors made no difference in liability cases, compliance with government-prescribed labels was not going to be an insurmountable problem either. So the Chevron Corporation discovered, in connection with a herbicide called paraquat.

Richard Ferebee was an agricultural worker at a U.S. Department of Agriculture research center in Beltsville, Maryland.<sup>11</sup> He claimed he had contracted pulmonary fibrosis, a serious lung disease, as a result of long-term exposure to dilute solutions of paraquat, and that Chevron had not adequately warned of the risk.

The EPA had long regulated the sale and labeling of paraquat under the Federal Insecticide, Fungicide, and Rodenticide Act, and had spelled out the exact terms of the warning label to be used. Chevron had followed the EPA requirements to the letter. The warning stated, in large, bold type, "DANGER. CAN KILL IF SWALLOWED. HARMFUL TO THE EYES AND SKIN." It went on to direct that any skin exposed to the chemical should be washed immediately and contaminated clothing removed. "Prolonged contact," the warning label concluded, would cause "severe irritation."

Not enough warning, a jury—and then a Federal court of appeals—concluded. The label inexcusably failed to mention "the specter of long-term lung disease culminating, perhaps, in death." Concededly, Chevron had no legal right to add to or depart from the EPA-prescribed warning in even the slightest detail. But "[e]ven if Chevron could not alter the label, . . . the manufacturer ought to bear the cost of compensating for those injuries that could have been prevented with a more detailed label than that approved by the EPA." Chevron could comply with both EPA rules under Federal herbicide laws and state tort judgments, the appellate court happily concluded, by simply "continuing to use the EPA-approved label and by simultaneously paying damages to successful tort plaintiffs."

Why doesn't a showing of good-faith compliance count for more? The usual explanation is that safety regulation is intended to set only a floor—a minimum standard, necessary but often not sufficient. Regulation may address only particular aspects of conduct, manufacture, or design. The regulators may never have contemplated the specific type of hazard involved in the accident at hand. What if they clearly did contemplate that hazard, and nevertheless judged it to be regrettable but unavoidable? No matter. Agencies and legislators are themselves not to be trusted: They may have tailored their regulations or statutes to suit producers rather than consumers. Industry standards deserve even less deference, having been written by the very sort of people whose conduct must be scrutinized at trial. To favor relaxing standards of tort liability, according to defenders of the legal status quo, is to be anti-safety and anti-consumer.

Is it really? Neither tenet of the new-tort order—that safety is an unconditional good, and that more liability leads to more safety—will hold up on examination. "*Gouverner c'est choisir*," Pierre Mendes-France used to say. Difficult safety choices have always been with us, and in an imperfect world of finite resources always

will be. What is new, under modern tort law, is not the need for choice, but who is doing the choosing. The courts have assumed the overwhelmingly dominant role as final arbiters on matters of safety.

What is wrong with that? Somebody has to help steer the world in progressive, safer directions. Why not the courts? Judges, for the most part, are well educated and well intentioned. And juries inject a commendable dose of populism into the process, serving as a sort of mini-legislature drawn straight from the people. The courts are there to watch out for things that the individual might not understand, or that a regulatory agency might ignore, or that a legislature might decline to consider under the corrupting effects of that most wicked of influences, representative politics. Somebody has to do the choosing between the acceptably safe and the unacceptably dangerous: Why not the courts?

There is a simple reason. Having the courts make safety choices is a certain path to a more dangerous world. The tort system, in the end, can only say no, equivocally and late in the day. But prudent promotion of safety ultimately depends on knowing when and how to say yes, firmly, convincingly, and in time to make a difference.

### **Safety in the affirmative**

Perfect safety and cleanliness, like perpetual motion, will always elude us. The challenge, then, is not so much to deter risky activities as to choose intelligently among them. The idea is to distinguish risks that are part of a problem from risks that are part of the solution. Getting to yes is vital, whether the issue is essentially private, or entirely public.

Most accidents, at least off the highway, arise in a fairly narrow, largely private context. It is not the nuclear meltdown that is likely to injure us, but the matter of diet, smoking, or sexual habit, the accident involving a consumer product, a doctor's services, or a hazard on the job. In all of these areas, of course, prudent choice involves a good many negatives. The consumer spurns the compact car, rejects the discount lawnmower, avoids the rural hospital, takes his specialty medical problems out the hands of the general practitioner. The just-say-no philosophy of safety regulation has much to commend it.

But knowing when to say yes is equally vital to safety. This means buying the appliance from the reputable manufacturer, accepting the specialized services of the

large urban hospital, favoring the safer car, cosmetic, or child's toy. Without a means for getting to yes, the consumer lives in a very spare world, devoid of countless goods and services that make life not only more convenient, but safer and healthier too. There is no doubt that the austere life of the hermit is infinitely more dangerous than life in the metropolis, in the cocoon of convenience and comfort that is possible in an age of affluence.

It has also long been understood that some safety choices cannot be left to purely private control. Electric power plants, chemical factories, mass immunization programs, waste disposal, and countless other activities of modern industrial society create both risks and benefits that are broadly shared by the public at large. And public risks necessarily require public choice. The individual may lack the information or incentive to deal prudently with risks of this kind. Even if he starts with a legal right not to be exposed to the factory's smoke, the individual may lack the motivation to sue the polluter. He hopes that someone else will attend to the problem; he is inclined to understate his own concern in the hope of free-riding on someone else's lawsuit. A second reason is a mirror image of the first. When it is in the communal interest to agree to a publicly risky activity—the construction, say, of a needed power plant, waste dump, or factory—the selfish individual may be tempted to overstate his aversion to it, in the hope of being bought off by the community at a price reflecting the large collective benefit at stake. Finally, it is sometimes useful to make safety choices collectively for reasons of pure convenience. We delegate all sorts of important decisions to experts like lawyers, bankers, and doctors, and sometimes it makes sense to delegate safety choices too, as we routinely do with drugs and aircraft, for example.

Whoever is in charge, for whatever reason, safety regulation inescapably involves two halves, a negative and a positive. The negative side is familiar enough: The government regulator refuses to license the unduly hazardous pesticide or power plant, and shuts down the excessively dirty smokestack. But the other side is no less important. Of the available ways to generate electricity, or control a crop pest, or fight an infection, some will be best under given circumstances. No matter who is in charge—the individual or the government—safety lies in positive choice, intelligently exercised. The simple assumption that life is made safer by a relentless hostility to all risk is wrong. Safety lies as

much in beatifying good risks as in exorcising bad ones.

Until the new-tort revolution of the 1960s, the two-sided nature of safety regulation was universally understood, and it was reflected in the most important elements of the law. Safety choices in the individual's private domain and control were made largely by private contract. The consumer who wanted to say no refused to buy the good or service. Getting to yes was equally straightforward. Every private contract is an affirmation. The core of contract is consent—a meeting of the minds, as it was called in the days when consent still mattered. Contract law is what two parties depend on to give an effective yes to a service, yes to a sale, yes to a mutual venture or adventure, risky or otherwise.

Safety choices in the public domain had a similar, two-sided character. If a business was of a type the government had chosen to regulate comprehensively, it was conducted under license or it was not conducted at all. The negative side of things was obvious enough. So was the positive. A "license" is a formal "yes," the government agency's equivalent of a contract, the official assent by which the acceptably safe is distinguished from the unacceptably dangerous. For licensing agencies, the core of the regulatory function is to say yes—selectively, of course—on the basis of a critical comparison of the full range of options available.

The courts can never make effective positive choices about safety. They are decentralized, uncoordinated, dispersed, and operate at the grass roots. Judges, as a group, do not constitute a coordinated management team. There are thousands of lower state courts, 50 state supreme courts, and several hundred Federal district courts. Each is an individual fiefdom, and each jury is a new authority.

This makes systematic affirmative choice impossible in court. No positive safety judgment is ever really final under tort law; there is no such thing as a definitive clean bill of health. Today's plaintiff will win or lose, but tomorrow's files a new lawsuit and is entitled to a new decision. Even in class actions, individual litigants can and do opt out and fight their own, private crusades. The results, especially with products marketed nationwide, compare with the progress of a bus steered by a fractious committee of its passengers.

Is Bendectin a safe and valuable morning sickness therapy, as the FDA has concluded, or a teratogenic poison responsible for countless birth defects as sev-

eral juries have declared, with a conviction measured in the hundreds of millions of dollars? The mainstream scientific community has agreed with the FDA. So too have most juries, but not all, and the courthouse door is always open for the issue to be relitigated anew. Bendectin is off the market as a result.

Are any and all contraceptives "defective"? There have been several multi-million dollar judgments against birth control pills (which very occasionally cause kidney failure or strokes), and against the spermicides used with condoms and diaphragms (blamed for birth defects).<sup>12</sup> In all of these cases the products reached the end user precisely as the manufacturer and the FDA intended.

The same story has been repeated time and again with other products, in a process of heads-you-lose, tails-we-flip-again that guarantees full employment for lawyers on all sides. There is no way a company can win an effective go-ahead on a new product before committing to actual production and marketing. This means it must stake huge sums on what might be called liability futures—which even in the best of circumstances are a highly speculative venture. Worst of all, it is quite possible to win most tort battles and still lose the war. The litigation process itself becomes the punishment.

If the judicial process is one of fragmentation, it is also one of polarization. Decision-making in the courts is inescapably bilateral; what one side wins the other necessarily loses, and the bystanders whose interests may also be affected, though only indirectly, do not appear at all. But bilateral decision-making is exactly what cannot work for managing matters that touch public (as opposed to purely private) safety and welfare. Such matters require public management, and are lifted out of the world of private contract, precisely because a bilateral approach will not yield a desirable outcome. The courts' dominance of the most far-reaching issues of public safety undoes all that was originally accomplished in transferring such matters out of the control of the individual into an administrative government forum in the first place.

These problems are sharpest when the stakes are the highest. What will our modern tort system do when we are finally ready to undertake a mass-immunization program against AIDS? How will it deal with genetic engineering of crops and animals, with its far-ranging risks and benefits? What coherent signal can tort liability provide for the still novel and unfamiliar technologies of gas-cooled nuclear reactors, fetal surgery,

hepatitis vaccines, bullet trains, and countless other innovations that promise enormous benefits, including safety benefits, but may also entail some unfamiliar new risks? Other branches of government can weigh these technologies and select among them, saying no to one and yes to another. The courts can only sit brooding on the sidelines, always holding out the threat of hostile intervention, never able to provide a reliable go-ahead, unable to offer any certain or definite promise of acceptance or approval.

Whether they decide private safety matters through a multiplicity of identical lawsuits, or public matters through the polarized framework of bilateral litigation, the courts are ill-equipped to make positive safety choices. Piecemeal adjudications, orchestrated by self-interested lawyers on both sides, crafted according to each individual jury's limited preconceptions of what is acceptably safe, do not magically coalesce into a coherent program for advancing either individual or public safety. It amounts merely to a safety management system whose legs are suited to kicking but not to purposeful locomotion. A blackball system is not the ideal way for a club to recruit promising new members.

### Getting to yes

The largest irony in all this concerns the simple question of jury competence. The new-tort edifice of product liability was founded on the assumption that members of the general public are not qualified to make intelligent and therefore binding choices about the safety of complex products and services. That is why we abandoned *caveat emptor*, that is why disclaimers of liability are no longer binding, that is why even the most explicit and detailed product warnings are often dismissed out of hand in the post-accident litigation. Now, however, the inexpert member of the public is called upon to make choices in the jury box that he has already been judged incompetent to make in the marketplace.

If guerrilla warfare in the courts is not the way to make life safer, what are the alternatives? It is unrealistic to suppose that the product of a 30-year legal crusade that is the law today can be replaced overnight with sweeping reforms proposed by a new generation of academics. But change at the margins is possible and urgently needed. The key is to promote positive, consensual safety choices made outside the courts, and so downplay the importance of the negative, adversarial

decision-making inside.

One may start with warnings. A strong link between tort liability and warning makes a great deal of sense. It also sits quite comfortably with venerable legal tradition and core principles of contract and individual control. The doctor or drug manufacturer often knows of risks that the consumer does not. Full disclosure should be an ordinary and essential part of fair dealing in the modern commercial world. And detailed warnings have indeed long been the commercial and regulatory norm for such things as therapeutic drugs, vaccines, medical care, consumer appliances, pesticides, and cigarettes, in part because of commendably persistent pressure from the tort system. Warning and disclosure enhance individual autonomy. Accurate information, sensibly conveyed and intelligently used, is an unconditional good. A tort jurisprudence built around warning can serve society far better than one built around erratic judicial attempts to ferret out "defective designs" in products or "negligence" in services. Not because the choices will always be wise—they surely won't—but because such a system at least permits positive choice, which, when it is wisely exercised, offers the only real road to greater safety.

The most urgently needed correction here concerns warnings crafted by Federal agencies like the FDA and EPA. Such agencies write, rewrite, and refine the warnings that must accompany drugs, vaccines, medical devices, food additives, pesticides, and toxic chemicals. The agency-prescribed warning is mandatory, and no substitutions or elaborations are allowed. The objective, of course, is to provide just the right amount of warning, not too little certainly, but not too much either, for the risk on that side is of deterring the use of safety-enhancing—perhaps even life-saving—products. This, at the very least, should be one inviolable safe harbor from liability. If the agency has weighed the question of warning in detail, and spelled out the language to be used, that should be an end to the warning debate for tort purposes.

Some safety matters will always remain too complex or far-reaching to be collapsed into the world of private agreement, with or without full warning. Informed consent by the individual is never going to take care of such things as chemical waste disposal, mass vaccination, or central power generation. These are and obviously must remain matters to be delegated to agents acting for the collective good.

An agent, in legal terms, is someone who acts on behalf of his principal. The agent negotiates, buys, and

sells, and if he has been properly vested with authority, his decisions are fully binding on the principal, as if the latter were there in person. In safety matters, the government agency fits comfortably into the standard mold. Its responsibility is to make good choices for the public, just as individuals would do for themselves if they were in a position to do so. To represent his principal effectively, a broker must be able to buy as well as sell. That means not just rejecting bad safety choices, but also embracing good ones.

The key, again, is to restore some balance to the tort law. We would certainly be appalled if tort law invited judges to order a nuclear power plant into operation after the NRC had refused a license on safety grounds. In the reverse case, however, the modern law does not hesitate to intervene, blithely inviting a lay jury to second-guess the agency and say no where the regulators had said yes. This asymmetry makes no sense, except on the premise that nuclear power is so awful that any way of stopping it is all right. The licensing of a nuclear plant, after all, reflects a conscious decision that the risks are worth bearing compared with those of alternative energy sources, in accidents, pollution, and security of supply.

It may be politically unrealistic to propose that, in cases where activities are conducted with the express approval of qualified regulatory agencies, liability should be utterly cut off. But at the very least it should be rigidly curtailed. At a minimum, complete compliance with a comprehensive licensing order should provide protection against punitive damages. The courts should be required, or at least strongly encouraged, to respect the risk and safety choices made by expert agencies. The formal, Federal licensing of a new drug, medical device, vaccine, aircraft, or nuclear power plant should be far more than a routine and irrelevant pleasantries, to be forgotten as soon as the first tort plaintiff enters the courthouse. This simple prescription sounds radical only in the context of a tort law that has itself reached radical excess. It has always been true that ignorance of the law is no excuse. At present, knowledge of the law is no excuse either. It should be. □

## Footnotes

1. *Dorsey v. Honda Motor Co.*, 655 F. 2d 650 (5th Cir. 1981) (\$5 million punitive verdict).
2. *Toyota Motor Co. v. Moll*, 438 So. 2d 192 (Fla. Dist. Ct. App. 1983); see also *American Motors Corporation v. Ellis*, 403 So.2d 459, 6 Fla.Law Weekly, 1808 (Fla.Ct. of App., 5th District, 8/14/81); *Leichtamer v. American Motors Corp.*, No. 5223 (Ohio Ct.App. July 30, 1980), 424 N.E.2d 568, No. 80-1354 (Ohio Aug. 5, 1981).
3. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L. J. 825 (1973); Owen, *Rethinking the Policies of Strict Products Liability*, 33 Vand. L. Rev. 681 (1980); Keeton, *The Meaning of Defect in Products Liability Law—A Review of Basic Principles*, 45 Mo. L. Rev. 579 (1980).
4. *Martin v. Herzog*, 126 N.E. 814 (1920); Restatement (Second) of Torts 288B(1), Comment a.
5. *Mitchell v. Hotel Berry Co.*, 34 Ohio App. 259, 171 N.E. 39 (Ohio 1929).
6. *Wilson v. Piper Aircraft*, 282 Ore. 61; 577 P.2d 1322 (Ore. 1978).
7. *Helling v. Carey* (83 Wash. 2d 514, 419 P.2d 981 (1974).
8. *Gryc v. Dayton-Hudson Corp.*, 297 N.W. 2d 727, 741 (Minn.); cert. denied, 449 U.S. 921 (1981).
9. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984).
10. *Ortho Pharmaceutical Corp. v. Wooderson*, 235 Kan. 387, 681 P.2d 1038, cert. denied, 105 S. Ct. 365 (1984).
11. *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (1984).
12. *Ortho v. Wooderson*, No. 84-290 Prod. Lia. Rptr. Para 10,100; *MacDonald, et al. v. Ortho Pharmaceutical Corp.*, 475 N.E. 2d 65 (Mass. 1983); *Brochu v. Ortho Pharmaceutical Corp.* 642 F. 2d 652, 656 (1981); *Wells v. Ortho Pharmaceutical Co.*, Nat'l. L.J., Feb. 11, 1985, at 11, col. 1.