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Legal Liability for Medical Innovation

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Many of the major issues of health care today revolve around two familiar questions to students of tort and regulation. What are the proper institutional arrangements to minimize the level of risk associated with the delivery of products and services, and what level of compensation, if any, should be provided to those persons who are injured when the remaining risks materialize in losses? These questions are especially difficult in cases of medical innovation, where both risks and rewards frequently are great. The enormous complexity of issues is revealed by the range of institutional responses. Deterrence and compensation can be accomplished through tort law, specifically through suits for medical malpractice and products liability. Additionally, they can be handled by various forms of direct legislative and administrative overview—from Food and Drug Administration ("FDA") control over drugs to institutional review boards in local hospitals and medical centers. They also can be handled by private contracts among the various parties.

Each system of controls works in a different way. Tort remedies tend to operate by indirection: There is no direct supervision over the behavior of the various parties who, it is hoped, are induced to perform properly by the threat of actions for damages. The administrative controls, adopted in part out of the fear that some defendants may prove insolvent or some harms—for example, death or serious disabilities—will prove irreparable, represent direct public controls that deploy a mixture of fines, inspections, licensing, and approvals to prevent most losses from occurring. The private contractual element is designed to preserve for patients and consumers some measure of autonomy and choice, at least within the constraints of tort law and direct regulation.

The hardest problems arise over the mix of remedies. I will start with the tort approach to these questions, specifically medical mal-

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practice and products liability, and then consider how regulation complements or substitutes for it. Although I refer to the issue from time to time, I do not stress an argument that I have made elsewhere, which is that contractual solutions for all the flaws are better than the regulatory and tort alternatives that are so much in vogue today.¹ Instead, I want to address the various methods for the public control of medical innovation, and indeed, medical practice generally. That inquiry begins with a discussion of the connections between medical malpractice and products-liability law. Thereafter, it addresses the integration of tort remedies with direct public control.

One central theme is that more need not be merrier. Throughout this essay, I want to stress the importance of the coordination between the tort and regulatory sides of the issue, and to emphasize the great benefits that follow from the adoption of clear rules to handle complex problems. Much of what I have to say is a plea for a return to safe harbors, whether by custom or by statute, for new therapies or products introduced into the marketplace. The sheer number of cases that is influenced by possible private actions makes it imperative that there be some known and observable standard to guide parties who must act under the applicable legal rules. The present system tends to offer injured persons repeated bites at the apple: It is commonplace to examine medical or manufacturing practices under different standards, first in administrative and then in judicial settings. In my view, the duplication of supervision is the source of conflict, cost, and contradiction, all of which should be controlled to help medical innovation, indeed medical treatment, proceed along rational lines.

This essay is organized as follows. Section one argues that the rules of products liability and medical malpractice should be understood as an integrated whole; that is, they are best understood if their interactions with each other are taken into account. Section two examines the way in which these rules should be applied in three distinct contexts: routine cases and known risks, experimental treatment, and routine treatment that reveals an unknowable risk. In each case, the key element on which liability should turn is the proper transmission of information. Where the information to be transmitted is standardized in form, an official, uniform determination of its adequacy should be made before it is disseminated, not afterwards. As in so many areas of law, the greatest mistake in the current liability rules is their excessive ambition. Certain major risks can be controlled at a low price; but, in the effort to endow the system with a certainty that

it cannot possess, the limited, but vital, gains that are possible are systematically undone. The best again becomes the enemy of the good.

I. THE COMMON LAW OF MEDICAL MALPRACTICE AND PRODUCTS LIABILITY

The two bodies of tort law most relevant to questions of medical innovation are medical malpractice and products liability. The conventional understanding places them in separate domains. For physicians, liability is said to depend upon negligence, with its usual elements of duty, breach, causation, and damage. Liability for products is said to be strict, i.e., proof of negligence is irrelevant once the causal connection between the product defect, however defined, and the plaintiff's injury is established. The difference in liability rules is then reflected in two critical but subsidiary points. Where negligence is the test of liability, custom becomes at least probative, and in medical contexts is often regarded as dispositive in determining the standard of care. Where negligence is irrelevant, then customary practice tends to become irrelevant as well. Where negligence is the test of liability, res ipsa loquitur, "the thing speaks for itself," may assist in drawing the inference of negligence from proven facts. Where it is not, then the principle is said to be as irrelevant as the negligence that res ipsa could help to establish.

These traditional views of the subject tend to mislead. The similarities between medical malpractice and products liability are far more pronounced than the usual accounts might otherwise allow. The critical point often depends not upon the status of the defendant,

2 See, e.g., McCoid, The Care Required of Medical Practitioners, 12 Vand. L. Rev. 549 (1959); Morris, Custom and Negligence, 42 Colum. L. Rev. 1147, 1164-65 (1942). Some doubt has been raised on the issue by Helling v. Carey, 83 Wash. 2d 514, 519 P.2d 981 (1974) (ophthalmologist's failure to administer simple, inexpensive, and risk-free test to 32-year-old plaintiff for glaucoma constituted negligence, even though custom in profession was to give test only to persons over 40-years-old). While the decline of custom in medical cases has probably enjoyed a subterranean existence, the rule has not spread much beyond the glaucoma-testing cases that gave it its birth. See, e.g., Gates v. Jensen, 92 Wash. 2d 246, 595 P.2d 919 (1979) (glaucoma is unique in its symptoms and deserves unique treatment).

3 The standard formulation of the res ipsa doctrine reads as follows: (1) the event must be of a kind which ordinarily does not occur in the absence of someone's negligence, (2) it must be caused by an agency or instrumentality within the exclusive control of the defendant, and (3) it must not have been due to any voluntary action or contribution on the part of the plaintiff. 9 J. Wigmore, Evidence § 2509 (J. Chadbourn ed. 1981). Note that the standard can be adapted to strict liability cases simply by eliminating the first requirement, so that it calls for proof of causation by elimination of both third-party conduct (by the second requirement) and plaintiff's conduct (by the third requirement). R. Epstein, Modern Products Liability Law 162-65 (1980).
that is, not upon whether the defendant provides medical products or medical services, but upon the nature of the enterprise in which that defendant is engaged and the types of risks that must be confronted. That the same pattern of liability rules should emerge in both areas should not be surprising. Most medical treatments involve coordinated interaction between the providers of both goods and services. As the goods and services work in combination, so too should the liability rules that govern them.\(^4\) The ideal system is one which makes the choice between different inputs to health care turn on the benefits they provide. Where products are subject to more stringent standards than medical services, there is a risk that treatment (services) will be substituted for products (goods), even when the latter is more suited to the task.\(^5\)

Consider the traditional distinction between liability for bad services and liability for bad products. By hornbook law, liability for products is strict and that for services is not. Yet, in particular instances, the alleged disparity could only be a source of difficulty. Thus, in some of the early hepatitis cases, the issue was the appropriate standard for holding a blood bank liable when a transfusion caused hepatitis in the recipient.\(^6\) Those cases which took the line that blood was a product were willing to apply strict liability principles.\(^7\) Yet, if the provision of blood had been found to be a service, negligence rules would apply.\(^8\) The obvious point is that the sale of blood contains both types of inputs, so that the proper question is:

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\(^4\) This approach works in other contexts as well. Thus, in order to understand the legal regime for industrial accidents, it is necessary to examine the way in which the principles of products liability interact with the principles of employer's liability both before and after the advent of workers' compensation. See Epstein, The Historical Origins and Economic Structure of the Workers' Compensation Law, 16 Ga. L. Rev. 775 (1982), which seeks to explain the restricted rights of action against manufacturers as an effort to focus liability for workplace accidents upon the employer in order to reduce litigation costs and general uncertainty.

\(^5\) See Miller & Schaffner, Ethical and Legal Issues Related to the Use of Computer Programs in Clinical Medicine, 102 Annals Internal Med. 529 (1985). Miller and Schaffner pose the question of whether computer programs should be strictly liability for wrongful results when physicians are liable only for negligence. One argument against that configuration is that it tends to retard the use of computer assists when they are more efficient than their rivals because of the differential burdens their use imposes.


\(^8\) E.g., Balkowitsch v. Minneapolis War Memorial Blood Bank, Inc., 270 Minn. 151, 132 N.W.2d 805 (1965) (negligence standard appropriate).
What regime of liability will tend to increase the net benefits from using blood, which is known to carry a certain risk? For reasons that shall be developed later, the strict liability system tends to work awkwardly in this context, and the negligence standard (at least as properly defined) is preferable. But the structural point is that there is little reason to have one standard of liability for the blood bank selling the product and another for the hospital or physician—as provider of services—using it. The distinction between products and services can be viable in some contexts, but the determinants of liability should be functional, not formal. As a general matter, close substitutes should be subject to identical regimes of liability in order to avoid skewing the choices between them. Indeed, in this area, where contracting is possible, the question should not be decided collectively at all, for private markets will work to create the desired parallelism in liability rules.

II. FROM ROUTINE TO INNOVATIVE RISKS

The need for a systematic approach to liability across separate systems is pervasive and applies whenever products and services are used in mixed proportions. With medical malpractice it is important to contrast, at the poles, the liabilities of physicians for routine practice with the liabilities of physicians who are engaged in developing experimental or innovative techniques for diagnosis and treatment. The intermediate case, of great importance and difficulty, is where a standard practice turns out to have a systemic defect that was unknown—and perhaps unknowable—at the time of its general adoption. The same classification is at work in the law of products liability. At the extremes, the rules governing the production of standard drugs are quite different from those governing the testing and development of new drugs. Similarly, the intermediate case is one where a standard drug turns out to have a uniform, undisclosed risk that is revealed only years later.

The simple distinction between medical malpractice and products liability, therefore, must give way to a more complex inquiry; one which asks how both products liability and medical malpractice law respond to three dominant kinds of cases. It is useful to examine both dimensions of the problem simultaneously in order to show how the doctrinal differences between products liability and medical malpractice can be harmonized once the institutional profiles of these three different situations are understood. In particular, the pitfalls for innovative treatments and therapies are by definition greater than those for routine treatments and therapies. The rates of return for innova-
tive treatment may be very high, but so are the risks. Long-term latent risks of routine practices and products are, if anything, more difficult to control, precisely because of the apparent success of standard practice. Once treatment has passed from the innovative to the routine without identification of its major adverse effects, the probability of any loss occurring may be very low. Yet, should anything be amiss, the danger of widespread disaster becomes far greater, for even the prompt removal of the dangerous drug or treatment still leaves large numbers of people at risk. Finally, routine treatments with known risks are investments that have known returns whether we speak of medical malpractice or products liability.

The question of the proper way to deal with a medical innovation reduces itself to the treatment of these three cases. I shall begin with the treatment of routine risks in routine cases and then move on to the experimental and latent-defect settings.

A. Routine and Known Risks

1. Correction or Warning

As might be expected, the liability rules for routine cases are not without controversy, although they are, in principle, the easiest to articulate. The sources of risk are generally understood, and while they may be great, efforts can be made to counter them. Sometimes the appropriate defense is to eliminate the peril in its entirety. Therefore, compensation after the fact need not be examined in the vast majority of cases where the precautions are successful. Where correction is possible before the fact, and where its benefits exceed its costs, someone will normally try to do it, no matter how the law sets the original liability.9 The innovator need not be a party who has to bear the loss in the absence of innovation. Thus, if the medical loss were left with the patients, they would pay handsomely for any test that would reduce the risk. Similarly, if liability were imposed upon either a blood bank or a hospital, independent firms would still have an incentive to develop cost-effective tests. The new liability only means that blood banks and hospitals, as well as patients (who rarely receive perfect compensation for injury) would all be willing to pay the innovator a price greater than the costs of production, but less than the loss averted. It is for just this reason that drug companies introduce new products whether or not they are at risk for liability. The hepatitis B

9 This is an example of the Coase theorem, which predicts that, when transaction costs are low, voluntary exchanges that work to the benefit of both parties will take place, no matter how the original liability is set. See Coase, The Problem of Social Cost, 3 J.L. & Econ. 1 (1960).
vaccine, for example, was introduced after the vast majority of states made it clear that liability for the supply of bad blood depended upon proof of negligence and could not be maintained on a strict liability theory. The same principles apply to new advances in medicine, most of which are developed by persons who have no personal risk of liability.

In other cases, however, correction of the peril is simply impossible, or at least too costly. In the extreme, the effort to remove the risks of certain treatment can rob that treatment of its promised benefits. Many lifesaving drugs have very serious known side effects. For example, it is worth bearing the debilitating side effects of steroids in order to control some life-threatening condition. Yet here, too, it should be possible to avoid the question of damages by warning of the side effects that follow from the use of this treatment or product. In principle, there is a question of whether the warning should be directed to the physician or patient. Where the information is technical, there is good reason to warn the physician, who can in turn—as is now required under the doctrine of informed consent—make the information intelligible to the patient and relate it to the concrete particulars of individual cases. In other circumstances, package inserts for patients may be appropriate, if only as supplements to warnings directed to physicians. Once informed about side effects, the patient, who best knows his own preferences, can compare the risks and benefits of treatment, allowing for the uncertainties of the case.

More controversially, I believe that one can go further. So long as there is notice to the patient that information is needed, it becomes possible for him to make independent inquiries, through a second opinion, for example, on how to treat the known risks and hazards. The key point, therefore, is to assure that relevant information is transferred, not necessarily that the defendant will do the transferring. In some cases, that burden will be assumed by the patient in order to avoid the need to refer to third parties; but in other cases, the independent judgment may well prove essential to the job. Indeed, it may well be that this system is far better than one which demands that generic warnings—especially in products cases—be complete, for second opinions allow the individuation of risk in a way that any collective determination of standardized warnings does not.

No matter how one phrases the duty-to-warn question, the transfer of information to the proper party should be the limit of the relevant duty for both the drug company and the physician. Once all the benefits and costs of any action rest upon the same individual, there is no danger that one person, say, the physician, will externalize costs
while preserving benefits. The normal conflict of interest between private contracting parties is therefore eliminated, either by transferring a safe product, or by providing accurate information as to why and how the product is dangerous, or even by providing information about the need to inquire further about certain material risks. Information transfer is the key. Accordingly, the patient’s decision should not be reviewable anew in the public arena by some social cost-benefit calculation. Legal intervention has placed it in the hands of parties with every incentive to get it right.

In doctrinal terms, this argument leads to the adoption of a position which says that the patient assumes the risk once the relevant information about the risks is received.\(^\text{10}\) It contrasts with the view that liability should turn in any way on the reasonableness of the private evaluation, corresponding to the principle of contributory negligence, which accordingly should be kept out of the discussion. No one should claim that every person always does his sums correctly under conditions of uncertainty and stress. But it is proper to claim that the inevitable errors of calculation made by individual patients should not be the source of extensive liabilities for either physicians or manufacturers who have properly supplied the relevant information.

2. The Choice of Liability Rule

a. Fitness of Goods and Services

The next question is what rules of liability should be used to ensure that a safe course of action is taken or proper information supplied? With correctable risks, I think that the appropriate standard of liability is strict in both medical malpractice and products liability.

\(^{10}\) Alan Weisbard objects to my reliance on the assumption-of-risk defense, which he notes has been widely rejected by both courts and scholars in the industrial accident cases that gave it birth. Weisbard, On Not Compensating for Bad Outcomes to Biomedical Innovation: A Response and Modest Proposal, 8 Cardozo L. Rev. 1161 (1987). He is clearly correct about the unkind reception that the defense has received in the 20th century, but I think he is wrong on the merits. The theory of assumption of risk is that the parties themselves are the best judges of the risks they want to take. So stated, the defense is required by the principle of individual autonomy that Weisbard himself prizes. The weakness of the defense has always been the risk of imperfect information, be it by patient or employee. Yet the system of warning is designed to obviate just that problem and to allow individual patients to make whatever level of additional search they think appropriate, given their own taste for risk and their desire for information. There is no reason to assume that parties, once informed, would not act in their own best interest in regard to industrial accidents. Many large firms developed explicit, voluntary compensation programs for their workers before the advent of the compulsory workers' compensation system. The emergence of such programs is wholly inconsistent with the dominant legal view that the employment relationship systematically exploited workers. Yet, it is wholly consistent with the view that contracts are struck for the mutual benefit of the parties. See Epstein, supra note 4, at 819.
Indeed, I believe further that this solution would be adopted consensually even if not required by law. But strict liability for what?—for the requisite standard of treatment or for the wholesomeness of the drug, not for the cure or recovery of the patient. In essence, therefore, the defendant becomes an insurer, but only of his own product or conduct, not the health of the patient.

Within the framework of medical malpractice, this result is reached in essence under the negligence rubric, where the custom of the profession becomes the standard of care. The traditional formulation understates the strictness of the rule by treating custom as one deposit of a uniform standard of reasonable care. But while the scope of the strictness may be narrow, within that domain it is remorseless. There is, of course, more than one permissible approach to a given problem, and it is possible to depart consciously from a known but fallible procedure in an effort to find a superior alternative. Yet putting these complications to one side, the physician who deviates from the permissible procedures by inadvertence does so at his own peril.11 He can surely defend himself on the ground that the deviation in question was not causally connected with the losses in question, an issue of great difficulty when the inferior treatment only works to increase the probability of loss.12

There is a precise parallel with respect to the production of drugs. Under the law of products liability, there has emerged a threefold classification of defects: production or formula defects, warning defects, and design defects. Where a drug is manufactured that does not meet its own formula specifications, then the construction defect is established. It is no defense to say that all reasonable care was taken in order to produce the safe product. As before, the finding of liability does not follow from the finding of defect because of the lurking causal difficulties that remain. But with liability clear, cases of this sort are rarely tried today once the factual matters are resolved.


12 One possible rule is to make all-or-nothing determinations on a case-by-case basis, and then to award full compensation in some cases and none in others. Another method is to seek to determine the extent of the increased risk and to award compensation on a probabilistic basis. The error rate of both procedures is, of course, very high. See, e.g., Herskovits v. Group Health Coop., 99 Wash. 2d 609, 664 P.2d 474 (1983) (even though decedent's original chances of surviving lung cancer were less than 50%, evidence that defendant's failure to properly diagnose the illness reduced decedent's chances of survival by 14% was sufficient to allow the proximate cause issue to go to the jury). See Robinson, Probabilistic Causation and Compensation for Tortious Risk of Harm, 14 J. Legal Stud. 779-98 (1985).
Strict liability makes good sense in both the medical and products contexts. The control of risk lies exclusively within the hands of the defendant, as it is unlikely that any unusual conduct by an individual plaintiff or by any third party can change the magnitude of the risk.\textsuperscript{13} The questions of product misuse or patient behavior are of very minor importance and are best handled by affirmative defenses, which should apply when a consumer knows, say, because of discoloration or smell, that the drug is indeed defective.\textsuperscript{14} These rare cases aside, a simple rule which says to the defendant, “bear the losses that you have caused,” will serve to induce the appropriate level of care, with a minimum of administrative costs, and without creating any unwarranted distortions in the patient’s behavior.\textsuperscript{15} Creating the liability also works to the benefit of both the physician or manufacturer, as the case may be, and the patient, because it induces individuals to accept the services or goods in question even when they cannot fully understand what the services are or how the drug is manufactured. The rules of liability state with sufficient clarity what outcomes should follow if an accident occurs. They give a neutral road map that allows disputes to be resolved in accordance with known and reliable standards when and if they occur. Thus, investigation into standards does not have to be undertaken upon receipt of the drugs or treatment, when the probability of any failure or defect is too low to warrant it.\textsuperscript{16}

The pattern of mutual benefit suggests that such rules would be adopted by contract where these are permitted by law (as they now are not) and that they should be kept, at least as “off the rack” provisions to minimize the cost of contracting when they are allowed in these areas. One persuasive piece of evidence of the desirability of the powerful, but limited, domain of strict liability comes from the various proposals for reform in both medical malpractice and products

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\textsuperscript{13} There are many cases in which the plaintiff’s conduct is critical, as with operators of machine tools and drivers of automobiles. For a discussion of the mistakes that arise when this conduct is downgraded or overlooked, see Epstein, Products Liability as an Insurance Market, 14 J. Legal Stud. 645-69 (1985).

\textsuperscript{14} See Restatement (Second) of Torts § 402A comment n (1965).

\textsuperscript{15} There is an extensive literature devoted to the proposition that the optimal negligence standard, defined as taking all cost-justified precautions, will yield the same outcome on care, even if a different result on compensation. The classic formulation is still that put forth by John P. Brown. Brown, Toward an Economic Theory of Liability, 2 J. Legal Stud. 323 (1973). But the administrative-error costs of the rule have led—rightly, in my view—to its rejection in these bad-batch cases. On the question of error costs, see, e.g., Grady, A New Positive Economic Theory of Negligence, 92 Yale L.J. 799 (1983).

\textsuperscript{16} I have elaborated on the use of custom as an antidote to imperfect information in Epstein, Medical Malpractice, Imperfect Information, and the Contractual Foundation for Medical Services, 49 J.L. & Contemp. Probs. 201 (1986).
liability. During the ebbs and flows of the past ten years, both physicians and manufacturers have worked to restrict the scope of liability rules, but none of their proposed reforms has been directed toward the stringent liability rules at issue here.

Most efforts by physicians to revise the rules of liability in medical malpractice cases have centered on returning custom to its dominant position, and not to inventing a position in which no liability attaches to well-understood forms of malpractice. Nor should we expect otherwise, for within limits it is in physicians' interests to maintain the warrantability of their services in order to induce individual consumers to sign on with them. There are enormous imperfections in information in medical markets, none of which is necessarily eliminated by direct regulation.

The same point is true for drugs. It would be nothing short of calamitous for drug companies, which are often not in privity of contract with their users, to be forced to try to duplicate by contract the express warranties that the tort law now commands. In the swine flu fiasco, the entire dispute among the drug companies, their insurers, and the government was the question of the adequacy of warnings. But throughout the dispute, the companies were willing to take full responsibility for production errors, that is, for vials of vaccine that did not meet governmental standards. Again, the warranty, on balance, costs the company less than it benefits consumers. The question of liability standards, then, is pretty much solved in this easy case. To be sure, many difficult matters of fact will arise in individual cases, but these fact-dense issues (Who took what drug when?) have little precedential value and do not raise any institutional concerns.

b. **Warnings**

The question of warnings is, however, more vexatious. Here, in principle, the argument takes the form that whether we deal with products or services, the physician or manufacturer meets his full obligation when all relevant disclosures are made, even if the outcome is adverse. Within the law of medical malpractice, that proposition is captured by the black letter law of informed consent, which emphasizes disclosure of the relevant risks of alternative forms of treatment. Within products liability, that proposition is embodied in the rules on the duty to warn of known defects, which adopt parallel standards of relevance and materiality. There are important differences between the two areas. The physician, who has greater knowledge of

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the patient's condition, must tailor the warnings to take into account the personal idiosyncrasies of users in order to discharge his duty, while the drug company’s warnings are generally directed to generic features of its products. Yet, in both cases, the central dispute in the common-law cases is over what kind of disclosures are sufficient to exonerate the defendant from liability.

In contrast to the flaws in the medical malpractice/drug production defects determinations, the problem with warnings is the irreducible question of degree, for there is no single litmus test to determine the adequacy of warnings. The intense disputes tend to belie the original black letter proposition on adequacy, for it is easy to find cases where extensive disclosures have been held (or so a jury could find) to be insufficient. In practice, it becomes possible, under the dominant standards of reasonableness, to argue that whatever warnings were given were inadequate as a matter of course.\(^\text{19}\) Once the outcome is known to be bad, some further warnings of adverse side effects must be good, given that it would discourage the unfortunate course of action. Yet the extreme position only reveals the false confidence of hindsight. When the treatment was undertaken, or the drug administered, there was some probability of a successful outcome as well as some probability of an unsuccessful outcome. The ideal warning is that which conveys the proper probabilities and their associated gains and losses. Warnings that are too severe are as bad as those that are too soft. Both tend to distort, if in opposite directions, the relevant patient or consumer choices. The full costs of overwarning would only be known if legal actions were available to people deterred from taking needed therapy by excessive warnings. But these losses are now obscured because of their intolerable administrative demands.

In the end, therefore, modern common law creates a bias, intensified by the discretion left to juries, toward finding all warnings inadequate when judged by the standards of hindsight. On a selective basis, the theory of improper warnings becomes an elaborate, expensive, and erratic pretext for compensation for bad outcomes alone. As every skillful trial lawyer knows, the question of the adequacy of warnings is a form of reverse engineering. First find out what warnings were given, and then tailor the claim to characterize them as insufficient on grounds of inadequacy.

\(^\text{19}\) For those who doubt the proposition, see, e.g., Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977), discussed critically in R. Epstein, supra note 3, at 108-12. See also Kitch, Vaccines and Product Liability: A Case of Contagious Litigation, Regulation, May-June 1985, at 11 (discussing Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096 (1974), and the issues of adequate warning labels and strict liability).
What, if anything, can be done in order to prevent the risks of overcompensation for bad outcomes when proper information is transmitted? At this juncture, an important structural difference between the informed-consent cases and the drug cases, alluded to above, influences the correct institutional response. The informed-consent cases arise out of one-on-one interactions and are fact-dense. Until the particular situation of each patient is known, it is impossible to have a sense of what disclosures should be made. It seems impossible, therefore, to dictate any single form of words to govern all cases. Thus, the best that can be expected of courts, if the doctrine is to be retained at all, is to be aware of the twin perils of overwarning and underwarning. Some comfort may be taken from the casual empiricism of the trade; that it is very hard for a plaintiff to win a malpractice action on a straight informed consent theory. There does not seem to be any institutionalized response that can be used to replace tort-law doctrine, even with the notorious difficulties of deciding informed-consent cases.

The drug cases, however, do present systematic features that make possible a coordinated institutional response to the problem of imperfect information. Drugs and vaccines are distributed on a mass basis, as was the case with the swine flu and Sabin live polio virus vaccines that were so controversial in the 1970's and the ominous pertussis vaccine problems of the 1980's. It should be possible to standardize the warnings in advance in ways that resist legal liability after the fact. What is needed, I believe, is a rule that provides that certain warnings approved by, say, the FDA shall be conclusively regarded as adequate in any subsequent lawsuit. The only triable issue on the question will be the simple one of whether the warning as issued complies with the standard form. At this point, it becomes necessary to

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20 For an elaboration, see Epstein, supra note 1, at 119-28.

21 Weisbard takes a different view on vaccines, claiming that it is socially unfair to have one person suffer from vaccine-related illness without compensation so that others may benefit. Weisbard, supra note 10, at 1165-69. His view is that, in the absence of some legislative system of no-fault compensation, the tort system should be invoked. He thus defends the current position, as set forth in Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096 (1974), and Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968). It is a disastrous social prescription. First, it assumes incorrectly that vaccine injury raises a "we-they" question, where there is some determinate group of persons that benefits and another that pays. This opposition is a false one because no one knows ex ante who will get what illness, with or without vaccines; but we do know that reducing the overall level of illness leaves everyone better off, even if no explicit compensation is provided ex post. Given the choice between a 10% chance of the natural disease and a 0.1% chance of vaccine injury, who would not assume the latter to be rid of the former?

Second, Weisbard writes as though imposition of tort liability had no adverse allocative consequences. His position is belied by the massive disruption in vaccine markets. Supplies
use the administrative process to determine the content of the warning, a task already required under the present rules. To be sure, the public input on the question will have to be stronger, precisely because there is no judicial check on the matter of adequacy. Nonetheless, there are huge gains from balanced warnings that do not conceal the net benefits of taking the product. Where there are special cases (for example, whether the vaccine should be given to pregnant women or to asthmatics) a sound set of warnings could indicate persons at special risk, and for whom consultation with a physician might be appropriate. Any system of warnings could be published in newspapers and distributed through physicians long before the drug or vaccine is used, in order to allow time for study and review. Any warning so prescribed should, of course, be quickly updated as new information is revealed. The system itself should be viable, because its costs can be spread over a large number of production units.

In making this proposal, I do not want to suggest that the administrative process is ideal. Indeed, the FDA has been highly criticized because of its conservative approach to the release of new drugs on the market. Nonetheless, if we are prepared to trust to the agency the basic decision of whether or not the drug will be marketed, then it seems odd to say that it cannot confront, with an assist from the medical profession, the warning issue as well. Warnings and package inserts are already required by the FDA, so the critical point is only to provide the firms safe harbor when they comply with the demands of the statute. Once lawyers have little to gain from the way the warnings are phrased, one divisive element is removed from the fray. On matters of this sort, it should be possible to find enough persons with independent judgment to minimize the risk that drug companies will

are now being interrupted and work on new vaccines has been cut back. In consequence, the present tort liability may push us back to a worse social state for all persons: There could be less tort liability because there are fewer vaccines. A vaccine-related injury compensation system may be desirable, or it may not; but there is no reason whatsoever for courts to impose perverse tort liabilities and punitive damages, against the clear weight of the evidence, because the legislature has not adopted some no-fault compensation program. It is wholly mistaken to act as if vaccines take lives while ignoring the great number of lives they save. There is no one who does not grieve at "the plight of a young girl afflicted with polio." Weisbard, supra note 10, at 1176. It is precisely to minimize the number of such cases that the vaccinemakers should not be made to fund a compensation program under the clumsy auspices of the tort system. See Huber, Safety and the Second Best: The Hazards of Public Risk Management in the Courts, 85 Colum. L. Rev. 277 (1985). Note too that the passage of the recent National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 311, 1987 U.S. Code Cong. & Admin. News (100 Stat.), does not yield the neat solution that Weisbard envisions. We now have a compensation system plus tort remedies plus punitive damages. The interconnections among the various systems are very intricate and difficult to understand. Yet, they are inferior to any ideal solution because they refuse to vest the written warnings with the type of finality that they deserve, especially in the mass-tort context.
softpedal their warnings in order to escape liability. Where compa-
nies do withhold or tamper with the evidence, then very severe penal-
ties, both civil and criminal, are warranted as is the case under
current law.

It may be objected that the need for fixed standards is alarmist
because the price of drugs is free to move to take into account the
added liabilities. Empirically, the swine-flu cases and the recent cases
of Bendectin and of pertussis vaccine have shown the point to be false.
Firms withdraw from the market, even if they are free to set whatever
price they choose. The easy way to explain the point is to treat the
present rules on products liability as a restraint upon voluntary con-
tractual transactions, at least in one dimension—product warranties.
When the price term is free to move while the liability term is not,
there need not be a market clearing price which will allow production
to continue. The key question is whether the costs generated by
the new liability rules exceed the joint gains to consumers and producers
under the previous voluntary contract. If in the aggregate the net
gains are wiped out by the liability costs, then the product will no
longer be made. If some net gains survive, then fewer units will be
produced to reflect the changes in rules and some marginal consumers
must do without.

The critical question, then, is how to estimate the size of the
losses imposed by the present legal regime. Several points suggest
that these are substantial. First, there are very heavy administrative
costs to work the transfers from which no consumer derives any di-
rect benefit even though producers must charge to cover them. Sec-
ond, there is the possibility—real today—that the damages awards
paid will exceed those demanded in private markets.\textsuperscript{22} Damages
levels for death cases may be too high, and excessive levels of coverage
may be provided when collateral benefits—for example, medical in-
surance—are not subtracted from recovery. Third, once the defend-
ant is not safe on the warning question, it may be forced to pay for
losses that its products did not cause, if there is false attribution of
disease to the vaccine. This problem arose in vivid fashion in the Sab-
bin vaccine cases.\textsuperscript{23} In such cases, the risk arises because the vaccine
tends to be called into use when the risk of polio is greater. It is,
therefore, very easy to charge against the vaccine an illness brought
on by natural causes. Similarly, with the pertussis vaccine, the risk is

\textsuperscript{22} See the evidence collected in Danzon, Tort Reform and the Role of Government in

\textsuperscript{23} See, e.g., Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S.
1096 (1974); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968).
that severe damage brought on by independent causes is chalked up erroneously as a side effect of the vaccine or that the vaccine only hastens harmful conditions that would have occurred anyway. In each case, the erroneous attributions after the fact lead one to overstate the risks of the vaccine and hence to overstate its true cost of production. These errors then work themselves back into the pricing and production decisions. At some point, if the number of false positives attributed to a vaccine rises sufficiently, then the private costs imposed upon the manufacturer diverge from the social costs of the vaccine. Systematic underproduction results. Drug companies are not in the risky end of the life insurance business. If their losses from the line of production exceed the profits that they can make from the sale of vaccines, then they will leave the market. The enormous consumer surplus from the purchase of vaccines can be, and has been, dissipated by unsound liability rules. The public health benefits are likewise lost. Markets work because the costs to the seller are justified by the benefits to buyer. They cannot survive when costs are falsely charged to the seller for whom there are, in fact, no parallel buyer benefits.

B. Experimental Situations

The proper role of medical malpractice and products-liability law in experimental situations is, if anything, more complicated because the level of information about risks is necessarily lower than in the routine cases just discussed. Nonetheless, the same analytical framework applies, because the central function of the legal rules still should be to provide consumers with the lower levels of information that are available. Imperfect information is better than no information at all. Within the experimental context, matters are often especially vexing, since controlled studies are designed to isolate the effects of a given drug or treatment. Typically, the size of the sample will be far smaller than the groups that are involved with mass-vaccination programs. Nonetheless, they will be large enough for the results that flow from them to be of statistical significance. Given these modest economies of scale, standardized warning procedures should be available to reduce the role of tort liability against either physicians or drug manufacturers.

The traditional rules of tort liability function fitfully at best in experimental situations. The standards of customary care, for example, lack specificity when dealing with treatments or techniques for which no customary practices have yet been established. To be sure, it is possible to develop a set of metacustoms which are designed to
deal with those particular gaps in knowledge, but these rules will have
far less bite than specific directives about the use of given products or
treatments. In addition, the doctrine of informed consent is under far
greater pressure, first, because the persistent conflicts of interest be-
tween the physician's experiment and the patient's well-being, and
second, greater uncertainty means that there is much more that
should be said about the problems.

Under these circumstances, it is not surprising that the tort ap-
proach has not proved adequate for the task. Instead, the dominant
institutional response works at two levels. The first is to insist upon
individual consent on the part of persons who work in the programs.
Such consent must bring home the fact that they will often be in-
volved in double-blind experiments in which they may not receive the
treatment a researcher believes, but is unsure, is preferred. The sec-
ond is to insist upon independent review boards, given that many of
the risks themselves are hard to convey to individual patients. The
function of the boards is to act as independent experts before the fact
and to pass upon the desirability of the programs in the abstract. The
hard question is always whether this extra layer of protection is worth
the costs that it imposes, as measured both by its direct costs and by
the soundness and the speed of its internal procedures. That question
is extremely difficult for someone outside the medical establishment to
evaluate. Much may turn upon the particular details of institutional
organization which vary widely from board to board and from case to
case. Indeed, even if one could show that the decisions across boards
are wildly inconsistent with each other, it does not necessarily fol-
low that the procedures should be condemned. It could well be that
the average level of experimentation is higher when there are boards
than when investigators are left to their own discretion. Nonetheless,
these boards cannot be dismissed simply as a governmental creation
by persons like myself who believe in the superiority of voluntary con-
tacts over governmental regulation. The participants in these experi-
ments might well want some form of external independent review to
offset their own ignorance. The risk of governmental regulation is
that it imposes a monopoly of practices that makes it difficult to ob-
tain the information that might lead to informed choices. The rele-
vant variables are many, and certain situations—for example, psy-
chological harm—may not call for as much supervision as others.

24 The point is stressed in C. Fried, Medical Experimentation: Personal Integrity and So-
25 Id. at 32-36.
26 See, e.g., Goldman & Katz, Inconsistency and Institutional Review Boards, 248 J.
Yet the insistence on uniform standards prevents the acquisition of additional information by institutional experimentation. The boards may well serve to introduce this needed variation.

These forms of direct control also bear upon the question of whether there is a place for individual compensation for bad outcomes within the experimental setting. Here my own answer comes in two parts. First, the central purpose of the elaborate mechanisms of disclosure and review up front are a good reason to displace the tort-liability system after the fact. I do not have any objection to tort damages actions for injuries sustained because of departures from the experimental design. These cases are too close to the routine cases of inadvertent deviation from custom. Yet, by the same token, I think that it is mischievous, or worse, to look behind the experimental design after the fact when the outcomes are bad, as they often will be. As with the warnings in vaccine programs, the gains from experimental work can easily be dissipated by lawsuits that depend upon second-guessing the myriad difficult choices necessary for any experimental design.

Second, should some other compensation system be set up for participants in the program who have bad outcomes, wholly without regard to improper conduct by the medical personnel? Again, my response is to resist the proposal. One initial point is that it is very difficult to determine the baseline against which compensation is awarded. In many experimental programs, such as those for cancer, the persons who participate are in very dire circumstances to begin with, so that bad outcomes will be the norm, even where the proposed innovation enjoys some modest success. Any system of compensation, therefore, must be able to measure the marginal contribution of the experimental input, which may well be small compared to the underlying disease. There are also many forms of implicit compensation that derive from the simple fact of participation in experimental programs, not the least of which is superior conventional medical care of the sort that helped throw off the original investigations into the efficacy of diethylstilbestrol ("DES"). The persons who elect to participate in these programs, moreover, can easily be made to understand that compensation is not forthcoming. Consent remains consent,

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27 Note that it is implicit in this argument that institutional uniformity accounts for far less here than it does in any mass distribution of drugs or vaccines, which I believe is the case. The variation between programs is greater, and there is no concern with inconsistent results, because the separate programs need not be subject to litigation under a common rule.

28 These were corrected by the Dieckmann study. Dieckmann, Davis, Rynkiewicz & Pottinger, Does Administration of Diethylstilbestrol During Pregnancy Have Therapeutic Value?, 66 Am. J. Obstetrics and Gynecology 1062, 1062-81 (1953).
even if the options available to the participant are limited by the disease, for the defendant only expands the set of opportunities for the patient that the disease itself limits. There seems, therefore, little reason to bear the very heavy additional costs that a compensation system will impose. The funds saved could be turned to more productive uses.

C. The Unknowable Hazard

The last case that needs to be considered is that of the unknown and unknowable hazard of certain medical or product innovations. As before, the problem is one that can arise either in a medical malpractice or a products liability setting. Arguably, the routine use of radiation to treat tonsillitis falls into this category, as does the use of DES, with its untoward side effects. In all these cases, the traditional legal view was that liability did not attach where the treatments or drugs met the applicable standards. In the medical malpractice context, the general rule of customary care provided a limitation upon liability: It was no longer necessary to test a procedure forever before adopting it as a matter of general use. Under the law of products liability, the general position was that strict liability principles did not apply to drugs that fell into this category.

The question of liability for unknowable defects has been much mooted in recent cases. While there was some move to hold defendants liable for such risks in at least one state, there has generally been a quick retreat, at least in the drug cases. There is commendable caution in the limited situation. The critical arguments parallel those in cases of warning for adequate defects. It is simply that the accumulated costs and errors of the system, be it in determining causation or damages, threaten to exceed the enormous gains from marketing new products or using new medical technologies. With drugs, the institutional response is preferable. The obvious idea is to encourage only that level of investment in resources that is cost-justified. The system will keep too many beneficial products and treatments off the market if it insists that they be risk-free. Instead of allowing reasonableness standards after the fact to decide whether liability is appropriate, it becomes critical to answer the liability question in conclusive form before products are marketed.

I have no great confidence in the


30 The received wisdom is otherwise. See, e.g., Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973). My quarrel with that decision is not with the proposition that all administrative procedures are ideal, but that the costs of finding out which deter-
ability of the FDA to determine the optimal level of social research on drugs. The point is, given that the FDA undertakes that inquiry as part of its general licensing procedures, there is little to be gained by running every case through the second filter of common law reasonableness standards. Those tests are difficult enough to apply in routine accident cases, and the cost and error in their elaboration only increase when applied to firm and industry behavior that may well have taken place decades ago. Risks are surely higher when dangers are unknown, but it does not follow that the difference in risk levels dictates a greater common-law liability for unknowable hazards. Rather, so long as the information that is acquired has been transferred, and all appropriate administrative procedures have been followed, the providers of the product should be spared liability.

The same administrative route is not available in cases of medical practice, given the lack of any centralized system of approval. By default, therefore, customary standards are the appropriate ones for litigation. Here, as above, no one should defend the use of custom on the ground that it is perfect; clearly it is not. Most customary practices, for example, are not routinely verified by randomized control trials before they are placed into use. But the best should never be made the enemy of the good. Randomized experiments are costly to operate and difficult to maintain in the face of the ethical objections raised to them—for example, when it is suspected that one course of treatment is superior to another in a given case. The debate over whether they should be adopted routinely is one that can proceed elsewhere, but the important point is that, unless and until that day is reached, customary standards should afford the complete defense, leaving the control of unknown risks to the steady, if erratic, course of medical science.

**CONCLUSION**

The question of legal liability for medical innovation is part of a larger complex of issues that relate to the liability of medical services.

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31 See, e.g., McKinlay, From Promising Report to Standard Procedure: Seven Stages in the Career of a Medical Innovation, 59 Health & Soc'y: Milbank Memorial Fund Q. 374 (1981). Notwithstanding the strong criticisms of the current procedures used to assess new drugs and therapies, McKinlay does not raise the possibility that tort liability should be imposed upon physicians who follow customary practices. For a more guarded reception of randomized controlled trials, see C. Fried, supra note 24, at 50-60.
and products generally. In all of these cases risks are involved, knowable or not, quantifiable or not. There are obviously large social gains that can be obtained from the control or the elimination of these risks. The issue is not whether an investment should be made, but where it should be made. In my view, the place of tort liability within this scheme is limited. Lawsuits are a poor place in which to determine the wisdom of various courses of treatment on which the experts themselves are divided. They are a poor place to review the subjective judgments of individual patients and consumers who now are disappointed with choices that may have been rational in their inception, if unfortunate in their consequences. The best we can expect of the judicial system is to ensure that the standards that are developed elsewhere—be it by statute or administrative order, by institutional review board or ordinary custom—are applied faithfully in the cases that they govern. It is hard enough to perform accurately the translation function in order to ensure that standards developed elsewhere are applied sensibly within the legal context. It is quite beyond the power of courts to use the amorphous principles of cost-benefit analysis to forge independent standards for judging the provision of medical goods and services. There is great virtue in doing small tasks well.