Vaccines and Product Liability A Case of Contagious Litigation

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AWYERS THINK of the product liability revolution as completed in many of the larger states by 1970. This law, however, is taking years to work its implications through to the management decisions, engineering practices, and economic structure of the countless affected industries. It will have very different effects, depending on the risks, benefits, economic base, and the design, distribution, and manufacturing options available for each product. But, as to vaccines, it is becoming clear that liability law has had disastrous effects.

Product liability law evolved simply. First came the idea that a manufacturer who negligently makes and sells a harmful product should, like any other negligent actor, pay for harm caused. Then the rule was simplified in the interest of predictability and judicial economy: if the product was defective, why worry Edmund W. Kitch is professor of law and member of the Center for Advanced Study, University of Virginia. Beginning in mid-1983, Professor Kitch served on the Committee on Public-Private Sector Interaction in Vaccine Innovation, Institute of Medicine, National Academy of Sciences. He learned of the Johnson case from a New York Times editorial in late 1984, and subsequently discovered that American Cyanamid was represented in that case by Fleeson, Gooing, Coulson and Kitch of Wichita, Kansas, a firm in which his father and a brother are partners. That firm has provided him with parts of the transcript in that case.

whether the defect originated in "negligence"? The producer controls the manufacturing process and should be encouraged by the tort system to exercise a degree of care concomitant with all the costs of potential defects—including costs incurred by injured purchasers. Finally, judges decided that the concept of "defect" should not be limited to a product that deviates from the product design—the brakes that are unconnected, the defective metal casting but can include a product badly designed, so that every one of the products produced as intended is legally "defective." And so the courts plunged into a new and daunting enterprisethe design of products and their delivery systems, with all the subtle and difficult trade-offs of risk and benefit the design process involves.

Judges have proved to be bad designers. Confronted with isolated risks in the form of an injured or deceased plaintiff, and operating within the narrow focus of litigation, judges understandably have trouble giving appropriate weight to the risks and benefits not before the court—to the benefits lost or costs incurred by others if the product or its delivery system is changed to reduce the particular risk that befell the plaintiff. (See Peter Huber's recent article in the *Columbia Law Review* for an eloquent and wide-ranging exposition of this thesis.) Because of this institutional bias, the courts in product design liability cases often *increase* the product risks faced by society.

The liability treatment of vaccination is a striking case in point. Vaccination produces both great good, in the form of mass immunization against disease, and measurable harm, in the form of rare but serious side effects. Virtually all medical authorities agree that the public health balance tilts overwhelmingly in favor of vaccination. Yet the development of liability law now threatens to make both existing and promising new vaccines sporadically or entirely unavailable to a public and medical community that wants and needs them.

Two 1984 trial court verdicts demonstrate just how easily the product liability rules lead to trouble. In both cases, the verdicts were premised on the theory that American vaccine policy should be different from what it in fact is. A verdict for \$1.3 million was based on the argument that the United States should use a vaccine once manufactured by Eli Lilly & Co. but abandoned when the Food and Drug Administration (FDA) review committee raised questions about its efficacy. A \$10 million verdict depended on the argument that Salk killedvirus vaccine should be used instead of Sabin live-virus vaccine in polio immunization. Historical experience suggests that this policy shift would increase total U.S. cases of polio from some thirty to several thousand a year.

These decisions, and numerous others like them, illustrate how a few strong- and simpleminded judges can, in the face of near-universal repudiation by their peers and academic critics, unwittingly threaten the public health in order to confer a needed windfall on a few grievously suffering plaintiffs.

An Ambiguous Threat

Although the scope and nature of a manufacturer's liability is a state law question, all of the important decisions dealing with liability for vaccines have come from federal courts interpreting state laws. The first notably troublesome decision was *Reyes* v. *Wyeth Laboratories* (1974). Judge John Minor Wisdom of the Fifth Circuit Court of Appeals upheld a jury verdict finding Wyeth Laboratories liable for polio suffered by a young girl who had received Sabin oral polio vaccine, even though the vaccine was properly produced and administered and the scientific evidence showed that the polio was caused by an unrelated wild virus. Wyeth's

fault, Judge Wisdom held, was that it had not taken steps to make sure that the child's parents were advised of the very minute possibility that the vaccine might cause polio. If it had, the child's parents might have decided they did not want the vaccine administered.

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believe risks existed. Producers have since attempted to do so by writing an ever more elaborate package insert, by requiring doctors to advise patients of the risk, and by withdrawing from any active role in promoting use of vaccines. But under the surface, Reves was far more threatening to the producers. Judge Wisdom's logic depended on an assumption that the warning could make a difference, that families who were properly warned might decline the vaccine. That seems particularly unlikely in the circumstances confronted by the Reves family, for there was a polio epidemic in the area at the time of the vaccination, whereas the risks from the vaccine itself are minute. The opinion in fact appeared to reflect a deeper and more threatening principle: one way or the other, manufacturers will have to pay for any condition a jury finds to have been caused by a vaccine, regardless of the warning given. Since the range of available expert testimony from credentialed experts is quite large and the reach of the jury's fact-finding powers great, that raised the specter of producers' liability for many conditions not otherwise known to medical scientists as causally related to a vaccine.

Congress Ducks the Swine Flu Issue

The threatening implications of *Reyes* were not lost on the vaccine producers, who soon had an occasion to voice their concern. In January 1976 swine flu virus was discovered in a human

population with resulting illness (and one death) at Fort Dix, New Jersey. In response, the U.S. Public Health Service's Centers for Disease Control recommended immunization against swine flu for the entire U.S. population, citing the disastrous pandemic of 1918, which was caused by a nearly identical strain of influenza virus. As proposed to Congress, the program assumed that the drug industry would be willing to sell the vaccine at a price close to cost as a dramatic contribution to protecting the public health. But producers were not about to provide vaccine for administration to the entire population in a crash program without protection from *Reyes*.

Some in the industry must have hoped that the occasion would force Congress to repudiate Reves. Surely Congress would see the foolishness of imposing open-ended liability on vaccine producers as a condition of their selling the vaccine that could ward off a pending national epidemic. But Congress refused to confront the problem, and industry was caught in a bind. To argue that Reves stood for absolute liability, regardless of the warning given, would be to concede that reading of the opinion as the correct one in future litigation. Yet, if there was no liability when an adequate warning was given, then what was the problem? Surely the industry had to agree that a warning should be given.

In the end, Congress passed a statute providing a short-run, most unsatisfactory solution. The U.S. government assumed the liability of any "program participant," though it reserved the right to recover from participants any damages attributable to conventional negligence by the manufacturers. The substantive law from the plaintiff's perspective was left unchanged.

The Swine Flu Aftermath

The producers' concern about liability for the swine flu vaccine proved well-founded. Not only did swine flu fail to reappear after nearly 45 million people had been vaccinated, but amid the intense publicity that surrounded the program there were reports that vaccination was followed in a small number of cases by Guillain-Barré syndrome, a disabling impairment of the central nervous system. The Centers for Disease Control conducted a study and found

that, in the ten weeks following administration of the vaccine, the syndrome occurred at a rate greater than normal. The conclusion has been that the vaccine was statistically related to less than a 250-case increase of Guillain-Barré syndrome in the United States.

This correlation was medically important, for it pointed to a possible causal link. But the statistical correlation did not explain the phenomenon. Did the vaccine cause the syndrome? Did it reveal a preexisting condition? Did it accelerate an event that would have occurred anyway? Or was the correlation simply an "observation effect"—was the publicity about the possible connection inclining medical personnel to diagnose the syndrome in patients who had been vaccinated? There is still no answer to these questions, and the relationship has not appeared again with subsequent flu vaccines.

The publicity and the study, however, did prompt the filing of over 4,000 damage claims. The Department of Justice, representing the United States, adopted a liberal policy toward the settlement of the cases, and eventually paid over \$72 million on over 750 claims. It stipulated to liability for Guillain-Barré syndrome in cases where the claimant could show that the syndrome had been caused by the vaccine. This stipulation was hardly required unless one accepted a broad reading of Reves, but it reflected, in part, the fact that the Department of Justice did not have the resources to litigate all of the cases. Because of the statistical correlation demonstrated in the Centers for Disease Control study, the Department of Justice also adopted the policy of paying claims where the claimant could show the onset of Guillain-Barré syndrome within ten weeks after vaccination.

That settlement policy, however, hardly brought an end to the litigation. About 1,600 lawsuits were filed, resulting in over 100 opinions in the federal courts. The Department of Justice was very successful in defending its basic position—only six plaintiffs who apparently would not have recovered under the settlement policy recovered in court. But two of those six cases, coming near the end of six years of litigation, were decided by federal courts of appeals, and resoundingly and strikingly reaffirmed the threat of *Reves*.

The 1984 decision by the Tenth Circuit Court of Appeals, *Unthank* v. *United States*, is

one of the least coherent circuit court opinions I have ever read. It seems to stand only for the proposition: someone must pay. The other case, Petty v. United States (Eighth Circuit Court of Appeals, 1984), returned to the warning game. The government had developed the warning actually provided with the vaccine in accordance with special requirements set out in the statute. It stated: "As with any vaccine or drug, the possibility of severe or potentially fatal reactions exists." This warning was given even though, at the time of administration, there was no established relationship between the vaccine and any serious, long-lasting side effect. But in *Petty* the judge found the warning inadequate because it did not specifically warn of the risk of the "serum sickness" that beset the plaintiff. (There is no epidemiological evidence that flu vaccine can cause that malady.) The decision provoked a striking dissent from Judge Myron Bright: "I think the practical consequence of the court's decision is to impose so stringent a warning requirement as likely to render any future mass inoculation program infeasible, no matter how desirable."

Polio and Whooping Cough

Two vaccines still on the market do appear to lead to adverse consequences in a few persons. Some recipients of Sabin live polio vaccine and some contacts of recipients appear to contract polio from the vaccine—a connection verified by the similarity between the vaccine virus and the infecting virus cultured from the afflicted person. There are now thought to be as many as thirty such cases a year. In Johnson v. American Cyanamid Co. (Eighteenth Judicial District for the District of Sedgwick County, Kansas, June 1984), a jury awarded a verdict of \$2 million in compensatory damages and \$8 million in punitive damages to a parent whose son was administered properly manufactured and marketed Sabin oral polio vaccine. The parent persuaded the jury that his son had been infected by polio virus derived from the vaccine.

A large-scale English epidemiological study has statistically associated pertussis vaccine—administered to children as the "P" component in the DTP vaccine to provide immunity against whooping cough—with adverse neurological symptoms. Although the statistical interpretation of such an uncontrolled study is tricky,

the study suggests that as many as one out of 100,000 of the recipients of the three doses of DTP may suffer severe adverse reactions—about thirty cases a year in the United States. In *Toner v. Lederle Laboratories* (U.S. District Court, April 1984), an Idaho jury awarded a verdict of \$1,131,200 to a child who suffered severe neurological impairment after receiving DTP.

In neither the Sabin oral polio nor the pertussis vaccine is the mechanism by which the vaccine leads to the effect understood. It is entirely possible that persons are afflicted only because of an idiosyncratic susceptibility to the disease or that the vaccine in some way triggers the onset of a latent but preexisting condition.

The Sabin Vaccine. The litigation concerning the Sabin oral polio vaccine engages one of the most long-standing and bitter controversies in modern medical science. The original polio vaccine in the United States (and elsewhere) was the Salk killed-virus vaccine. A decade after this vaccine had been widely administered, there were still several thousand cases of polio in the United States each year. At that juncture, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (the body that *de facto* governs medical standards for the administration of vaccines in the United States) switched its recommendation from Salk to Sabin. Its reasons were, first, that the more easily administered Sabin vaccine (taken orally rather than by injection) would, as a practical matter, be more widely administered and, second, that the live vaccine would pass to others in contact with the recipient, conferring immunity on those who had not been directly vaccinated. The Sabin vaccine was also thought to confer a stronger and more long-lasting immunity. The switch worked in the sense that polio (except for those cases that appear related to the vaccine) disappeared from the resident U.S. population.

But the choice between Salk and Sabin has continued to divide the medical and scientific communities. Some countries, most notably in Scandinavia, have relied almost entirely on the Salk vaccine. This vaccine does not seem to have the risk of causing polio in some recipients and contacts. It has not been associated with adverse side effects, although that may be

because its use, almost entirely outside the United States since 1962, has been studied less intensively than that of the Sabin vaccine. A National Academy of Sciences panel recommended in 1977 that the use of Salk should precede the use of Sabin so that the immunity conferred by the Salk would protect against the Sabin while retaining the enhanced immunization of the Sabin. Whether this strategy would actually work has not been confirmed: it is. however, clear that unimmunized contacts of the recipient would also have to take Salk first if they were to be provided with additional protection. ACIP did not change its recommendation in response to the academy's decision, although the package insert for the Sabin vaccine now advises that contacts should be informed of the opportunity to take Salk vaccine first. Sales of Salk vaccine in the United States remain small.

Sabin oral polio vaccine was administered to Emil Johnson's child in 1975, just after the Reves decision. Emil became ill shortly thereafter. Diagnosis of his condition proved difficult and Lederle offered evidence at trial that he had not had polio at all. The plaintiff mounted a direct attack on the use of Sabin vaccine. Daryl Salk, son of Jonas, the Salk of Salk vaccine, testified as an uncompensated expert for the plaintiff that Sabin was dangerous and should not be used at all. A videotaped deposition was offered to the jury, in which a Dr. Batenger, said to be the head of immunization in Sweden, testified that Sabin vaccine is too dangerous, is inferior to Salk, and is not used in Sweden. The tenor of the argument is captured by the opening statement of the plaintiff's lawyer:

Now, another thing we contend that American Cyanamid did wrong in this case was . . . they knew, they and the government . . . really pulled the wool over everybody's eyes together. . . .[T]hey knew that this vaccine had the following characteristics. . . . [T]hat it had a live virus in it that would be shed by the person it was given to, and that by that shedding process of the fecal material, and also by oral shedding, slobbering, drools, kissing the baby, whatever, that by that process other people would be immunized. That is to say, if Joe Smith, a member of the public who had not been immunized, went to visit his

brother, Jim Smith, and they had a baby that had received . . . [the vaccine], the government and Lederle . . . knew that anyone handling that person who had received the [vaccine] ... would also get vaccinated. And in the process, that the vaccine that was given to the baby might get stronger or more virulent and give the person polio.

Now, admittedly, it was not something that happened very often. But it happened often enough that you're going to find that five to ten people in this country every year have been paralyzed or died as a result of it. Unknowingly and without their consent. ... And the government and Lederle knew it and sacrificed those people without telling them. . . . [W]e contend that you assess punitive damages to set an example to that company, to say, "Hey, this is not fair. We're going to set an example, and you don't do this anymore, going to punish you."

Compare that statement with the one in the 1974 package insert, in effect at the time of the Johnson vaccination:

Paralytic disease following the ingestion of live poliovirus vaccines has been reported in individuals receiving the vaccine, and in some instances, in persons who were in close contact with subjects who had been given live oral poliovirus vaccine. Fortunately, such occurrences are rare, but considering the epidemiological evidence developed with respect to the total group of "vaccine related cases" it is believed by some that at least some of the cases were caused by the vaccine. The estimated risk of vaccine-induced paralytic disease occurring in vaccinees or those in close contact with vaccinees is extremely low. A total of approximately 30 of such cases were reported for the 8 year period covering 1963 to 1970, during which time about 147,000,000 doses of the vaccine were distributed nationally. Even though this risk is low, it should always be a source of consideration.

Against this background, it is clear that the jury in Johnson was invited to, and did, impose punitive damages for the purpose of forcing the United States to change its polio vaccination policy. That jury of twelve men and women decided that the risk to some recipients and contacts outweighed the risk that the use of the Salk vaccine would lead to a higher incidence of polio from which many more would suffer.

The unstable and idiosyncratic nature of this type of litigation is illustrated by the fact that, only ten months earlier, the Sixth Circuit Court of Appeals affirmed a verdict in favor of American Cyanamid (doing business as Lederle Laboratories) in an action brought by an immune-deficient child who developed polio after

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being given the Sabin vaccine. The court found that the package insert adequately warned of that risk (*Schindler* v. *Lederle Laboratories*, 1983).

The Pertussis Vaccine. In Toner, the plaintiff argued that the pertussis vaccine was negligently designed because a safer vaccine, Trisolgen, was once marketed by Eli Lilly. Trisolgen was made from portions of the pertussis virus rather than from the whole killed virus. It caused fewer short-term side effects such as localized swelling and irritation. The plaintiff argued that Trisolgen was therefore probably also safer with respect to long-term side effects than the whole virus vaccine, that it was effective because none of the persons who had received it had been reported as having contracted whooping cough during the years it was sold, and that therefore sale of the whole virus vaccine was negligent. The jury was persuaded and thus repudiated existing U.S. vaccination policy by means of a damage verdict.

But the relationship between short- and long-term side effects has never been seriously studied and, since the source of the adverse effects is not known, it is impossible to know if they are correlated. During the extended review of pre-1962 drugs that the FDA conducted in the late 1960s and early 1970s, the review committee for vaccines raised questions about the efficacy of Trisolgen. That efficacy had never been established in clinical trials, and if the portions of the virus that were taken out were important for effective immunization, it would

have reduced effectiveness. Confronted with the challenge from the review panel and the expense of establishing effectiveness in clinical trials satisfactory to the FDA, and no doubt aware of the threat of *Reyes*, Eli Lilly stopped marketing the vaccine in 1975.

Warning and Causation

The most astonishing aspect of these two recent cases is the verdict for punitive damages in Johnson. Punitive damages are awarded for "outrageous" behavior. The idea that disagreements about what should and should not be included in the package insert are an appropriate basis for punitive damages is odd, though one that the Kansas Supreme Court had embraced the year before (Wooderson v. Ortho Pharmaceutical Corp., 1984). But the package insert in *Johnson* did warn of the possibility of contact polio. So the jury's theory must have been that the insert either "outrageously" failed to go further and tell the treating doctor what to do about the risk (the plaintiff argued that Salk should have been administered first) or "outrageously" understated the risks of the vaccine. An internal Lederle memo had indeed urged the company to respond to Reves with a more draconian warning, and the plaintiff in Johnson used this memo to bolster his argument that Lederle was engaged in intentional deception. Thus does the failure to embrace all the implications of an extreme legal decision based on medical misinformation become an "outrage."

If the issue is the appropriate wording of a warning, the courts should recognize that a warning can both overstate and understate a risk. A warning that overstates the risk is a health hazard to those who are deterred from using the vaccine. It seems plain that the sober, balanced warning in fact provided in *Johnson* was, to say the least, *not* "outrageously" deficient.

If the cases really stand for the unannounced and undefended rule that the manufacturers should pay for all adverse side effects of the vaccines, then the courts have a lot of explaining left to do. Why should vaccines, one of the most successful health technologies of the century, be singled out for such a harsh rule? Why should the rule be imposed on vaccines but not, for instance, on automobiles,

which, in exactly the same sense as "cause" is used in the vaccine cases, "cause" death and injury on the highways? Is it socially more important to have inexpensive cars than to have inexpensive vaccines?

Another unexplained and undefended aspect of the vaccine law is the use made by the courts of the concept of cause. The courts treat evidence that a vaccine (or any drug) increases the incidence of a condition as proof that the vaccine causes the condition. Cause is usually proved only by an increase in the rate of the condition above the background rate in the period after administration of the vaccine. If the courts accept this as proof of cause (as the Department of Justice did with swine flu, for instance), then the compensated conditions will include those in the background rate, conditions that would have occurred anyway.

Even more troubling, cause is presumed when harm cannot otherwise be explained. The plaintiff proves he was fine until the vaccine was administered, and then he was not. Doctors testify that the vaccine must be to blame because they cannot detect any other cause. Liability in this situation will impose on the vaccine large costs for conditions that are, in fact, unrelated to the vaccine, particularly in the case of the pediatric vaccines, which are administered early in life to infants whose development may thereafter reveal previously latent and undiagnosed abnormalities.

Both Johnson and Toner are now on appeal (Johnson to the Kansas Supreme Court and Toner to the Ninth Circuit Court of Appeals). and their outcomes will be significant. But even if both verdicts are reversed, the first decade of this case law makes it reasonable to fear that some judges, acting out of sympathy for afflicted plaintiffs, will impose substantial liabilities on the manufacturers.

How Industry Is Responding

Reves, the swine flu statute, and subsequent developments sent the industry a message. Perhaps Reves really could be avoided by better warnings, but it might take decades of litigation to find out. A number of firms quietly stopped producing vaccines.

It is easy to minimize the importance of this exit. But under a hostile and unpredictable legal regime the principal competitive weapon

for rival firms becomes not the quality of their product, research and development, or marketing, but how they price the risk of liability. Liability costs for vaccines now dwarf even the historic gross revenues of the industry. For instance, the DTP vaccine is administered three times to about 3 million children a year, at a wholesale price that was until recently about a dime a dose. One tort verdict can exceed that \$900,000 in annual revenue. (The price is now \$2.80.) The firms that remain in the industry are not necessarily those with superior technological competence or more efficient production techniques, but those willing to gamble against the trend of the case law.

Producing vaccines at a profit thus means, increasingly, staffing and operating a large, ongoing product liability defense and predicting accurately the outcome of highly unpredictable litigation. These incentives will often move production away from technologically superior and well-financed firms, which have the most to lose. It is not unimaginable that the vaccine firm of the future will consist solely of vaccine production facilities spun off into an underfunded corporation owned by highly entrepreneurial and litigation-hardened lawyers. Vaccines will become unavailable at any price if even such entrepreneurs conclude that charging prices high enough to justify the liability risk will simply stimulate the courts to impose increased liabilities. This remains a possible though still unlikely—result.

Moreover, when only a single producer remains—as is now the case in the United States for such vaccines as measles, mumps and rubella, Sabin polio, Salk polio, and rabies—there will usually be only a single production facility. Vaccine production is an art, and vaccine production facilities can be disrupted by unexpected difficulties. For instance, in the fall of 1984, Lederle found that a batch of DTP did not meet standards and could not be marketedan event that required the Advisory Committee on Immunization Practices to recommend reduced use of the vaccine.

Perhaps even more important, the threat of liability further attenuates the incentives and resources to innovate in an industry where incentives to innovate are already low because the product is only taken (at most) a few times. Only many years of mass marketing can determine whether a vaccine will have low-incidence side effects. If the courts are going to impose strict liability for side effects, it would wipe out any possible profit from even a fabulously successful (in a medical sense) vaccine. Thus, no producers have shown any serious interest in paying the costs of testing possibly safer pertussis vaccines. And though the popular press has carried frequent stories in the last two years about possible vaccines for AIDS and herpes, testing and obtaining regulatory clearance for such vaccines is not currently of interest to any potential producer. Those invisible non-litigants who would benefit from new vaccines are probably the most dramatic victims of the threat of product liability law.

From the consumer's perspective, the erratic liability law not only reduces the availability of existing and improved vaccines, but also reduces the incentives to take them. Openended liability raises the price of vaccines, which makes it difficult to maintain high rates of immunization. The increasingly dire risk warnings included with vaccines, and the melodramatic publicity that litigation creates, have similar negative effects. Unimmunized people, who benefit second-hand when their neighbors are immunized, are also badly served by the current state of the law.

Because the law is evolving on a case-bycase basis and because much of it remains the subject of vigorous professional dispute, the litigation costs are and will remain very high for the foreseeable future. With the outcomes so uncertain, it is very difficult for the parties to agree on a settlement figure. This is fine for lawyers, but not for their clients.

An Injection of Reform

Efforts to obtain reform legislation from the Congress have begun. In 1983 the National Academy of Sciences convened a Committee on Public-Private Sector Relations in Vaccine Innovation to study the organization and support of vaccine research, the adequacy of incentives for the commercial development of new vaccines, the delivery of both new and established vaccines to the relevant populations, and the problem of liability for and compensation of vaccine-related injuries. Its intensive study of the matter is due for release in July. A commission convened by the American Medical Association recommended in 1984 that a specialized

and exclusive federal compensation system be created.

The American Academy of Pediatrics and a group of concerned parents jointly drafted a bill creating a compensation system, which was submitted in the last session of the Congress by Senator Paula Hawkins (Republican, Florida). After hearings on the bill, it has been improved by requiring an applicant for compensation to forgo a tort suit and by adding provisions limiting failure-to-warn liability and providing for the possibility of government liability insurance for the manufacturers. It has been introduced in this Congress as S. 827, again by Senator Hawkins, with Senators Orrin Hatch (Republican, Utah), Dale Bumpers (Democrat, Arkansas), and Spark Matsunaga (Democrat, Hawaii) as cosponsors.

On April 6 the Interagency Working Group on Vaccine Supply and Liability, chaired by the secretary of health and human services, called for major changes in vaccine liability law designed to ensure continued supply of all child-hood vaccines. Specifically, it recommended eliminating punitive damages and limiting pain and emotional distress awards to \$100,000.

Parents of children injured by vaccines vigorously oppose any limits of liability, but what they and their advocates overlook is that enormous public health benefits are at stake here, too. These benefits have been slighted by too many judges and juries with alarming consequences. Vaccine policies present difficult choices among less than perfect alternatives. Faced with an injured plaintiff, the courts are too prone to believe that the "other" choice, whatever it might have been, should have been preferred. In the case of vaccines, too many judges have proved to be poor scientists and incompetent regulators. Legislative correction is urgently needed.

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