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ing Policy: Law, Politics, and Culture (with S. Sugarman), Oxford University Press (1993).

THE VACCINE NO-FAULT ACT: AN OVERVIEW

Robert L. Rabin*

My brief overview of the Vaccine Act¹ is meant to set the stage for the other presentations on this panel. In doing so, I will outline the vaccine no-fault program, comment on its distinctive character, and discuss briefly the high profile autism/thimerosal controversy, which has tested the program's limits.

Unlike workers' compensation and auto no-fault plans, the Vaccine Act had its origins in a proactive industry effort in the 1980s to avoid the perception of unpredictability that had generated considerable criticism of vaccine-related tort claims. When the Act was adopted in 1986, there was only one manufacturer of the polio vaccine, one of measles, mumps, and rubella ("MMR"), and two of the diphtheria, tetanus, and pertussis ("DTP") vaccine—and these manufacturers were all at various stages of threatening to withdraw from production. In fact, according to a congressional study² that was a lead-up to the adoption of the Vaccine Act, just prior to the enactment of the program the annual number of claims was fairly predictable and relatively small in every category with the exception of pertussis. It seems fair to say that open-ended tort damages played a dominant role in animating the industry concern; more so than the unpredictability of the volume of cases. So the Act was passed in 1986, and the program came into effect in 1988.

Although the Act is a no-fault scheme, it does not, in fact, eliminate recourse to tort. But it does diminish its appeal.³ Initial recourse to the no-fault scheme is required, and either dismissal there or rejection by the petitioner of the administrative award before a tort claim can be filed—but more about the administrative process in a moment. The tort remedies have been scaled back: no punitive damages, no liability for "unavoidable injuries," (the magic statutory term in the preemption case just cited and discussed by other panelists) when the vaccine has been properly prepared and

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1. National Childhood Vaccine Injury Act ("NCVIA") of 1986, Pub. L. No. 99-660, § 2110, 100 Stat. 3755, 3758-3771 (1986) (codified at § 300aa-1 to 300aa-34); *see also* National Vaccine Injury Compensation Program ("VICP"), *About the VICP*, HRSA.GOV, <http://www.hrsa.gov/vaccinecompensation/> (last visited Mar. 29, 2011).

2. H.R. Rep. No. 99-908, reprinted in 1986 U.S.C.C.A.N. at 6361.

3. Undoubtedly, even more so after *Bruesewitz v. Wyeth, Inc.*, 131 S.Ct. 1068 (2011), decided after this talk was given, holding that design defect claims are preempted by the Act.

a proper warning has been provided.

The framework of the administrative compensation scheme itself, which is preliminary to the tort option, is that no-fault benefits are provided for enumerated covered vaccines—coverage that has been greatly expanded in recent years. Under the statutory scheme, the covered vaccines were accompanied by a vaccine table.⁴ A statutory index was established linking each covered vaccine to designated side effect injuries and time frames for the occurrence of injury. So, for example, with regard to the MMR vaccine, if one suffered anaphylactic shock within four hours of the vaccination, the victim fell within the index. As a consequence, by establishing a “table claim,”—that is, an injury satisfying the table criteria—there is a statutory presumption of eligibility for compensation.

In addition, there is provision for the possibility of a so-called “off-table” injury from a covered vaccine, one that isn’t listed in the scheme; these are also eligible for compensation. But in these latter off-table cases, no presumption operates: the claimant has to satisfy a preponderance of the evidence standard in order to recover.

As one might surmise, causation becomes a critical issue in these latter cases. Expert testimony is needed and extensive documentation of past health records is required. Currently, most claims are in fact actually for off-table injuries, because a more refined scientific approach to table listings has replaced the more loosely-based, evidence-shy original table listings. Indeed, some of the initially-covered table injuries have actually been eliminated so that the claims are now off-table, and vaccines that have come under the Act more recently have come without the specification of associated injuries. Thus, a special master with many years of experience tells me that in the early years of the program when he first started, ninety percent of the cases were covered cases, and now roughly ninety percent are off-table cases: it is that dramatic a change.

Procedurally, the Act adopts an adversary process: Department of Justice attorneys represent the Department of Health and Human Services, which serves as the administrator for the Vaccine Injury Compensation Trust Fund (the “Fund”),⁵ in the Vaccine Court. The Vaccine Court consists of special masters, who hear the cases, a possibility of appeal to the U.S. Court of Federal Claims, and from there to the Circuit Court of Appeals for Federal Claims. The claimant has a number of options: If the claimant gets an award, it can either be accepted or rejected with the option to file a tort claim in federal or state court; or, if there is an adverse decision

4. See NCVIA § 2114; see also National Vaccine Injury Compensation Program, *Vaccine Injury Table*, HRSA.GOV, <http://www.hrsa.gov/vaccinecompensation/table.htm> (last visited Mar. 29, 2011).

5. National Vaccine Injury Compensation Program, *Vaccine Injury Compensation Trust Fund*, HRSA.GOV, http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm (last visited Mar. 29, 2011).

in the Vaccine Court, a tort claim can similarly be filed in state or federal court.

In terms of the structure of awards, recovery is provided for medical expenses, without limit, for injury claims; wage loss for a child, based on lifetime national average wages as a ceiling; and pain and suffering with a cap of \$250,000. Death claims have an absolute cap on overall recovery of \$250,000. There is no contingency fee for attorneys; fee awards are for reasonable hours and are determined by the special masters. Interestingly, if the claim appears to have been brought in good faith, attorney's fees are available even in cases where benefits are denied. The Fund is financed by a per-dose tax on manufacturers.

Let me make a few brief comments on the framework before I turn to the autism controversy. First of all, from a compensation perspective, in death cases, as I just mentioned, there is a scheduled ceiling of \$250,000. But that cap should not necessarily be regarded as a pale shadow of tort—at least not in those states following the traditional statutory approach of limiting tort wrongful death recovery to pecuniary loss to survivors. By contrast, however, under modern wrongful death statutes that allow survivors to recover non-pecuniary loss in the torts system, tort would compare favorably to the compensation scheme, since there is no designated ceiling on non-pecuniary loss.

In injury cases, as I indicated, the Fund has a ceiling on wage loss, and scheduling of pain and suffering; this is consistent with the no-fault model generally and it does avoid open-ended speculation that would particularly characterize a child or infant claim for lifetime lost wages, as well as pain and suffering, in the tort system. There is no collateral source rule under the Fund; in other words, unlike the majority approach in torts, collateral sources are netted out. And the attorney fee awards—rejecting the contingency fee system—are yet another major departure from the tort system.

From a process perspective, like tort, the Fund is based on an adversary model; but it is an expertise model. The special masters hear only vaccines cases and the process anticipates liberal rules of admitting evidence and expert testimony—although, I am told by special masters, that as scientific evidence has come to be dominant, and as the off-table cases have come to characterize the caseload, the admission of evidence and admissibility of experts has become very similar to the tort system. In fact, the special masters purport to be following *Daubert*⁶ on admissibility.

From an efficiency perspective, the administrative costs of delivering benefits are considerably lower than in the tort system. While the figures I have seen vary, it appears that somewhere between ten and thirty percent in administrative costs are incurred in payouts under the system, which is far lower than tort. The processing time, however—and this comes as a sur-

6. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

prise—is quite substantial. Even in undisputed cases it can be up to three years between filing and an award, and in disputed cases it can be five to seven years, or even more, before the cases run the full administrative process (including the time in which the special master determines the attorney's fees).

In sum, as the special master proceedings have come increasingly to be demanding of science-based findings on causation, the hearings have increasingly come to resemble the tort process with attendant delays in delivering compensation. But having said that, the ceilings on awards, the credits for collateral source benefits, the routinization of attorney's fee awards, and the existence of no-fault recovery seem to lead to far greater predictability for manufacturers about payouts and to injury victims about eligibility. And, the program is considerably less expensive than torts to administer.

Let me close with a brief comment on the thimerosal/autism cases that test the limits of the program. In May 2010, the Circuit Court of Appeals for the Federal Circuit decided *Hazelhurst v. Secretary of Health and Human Services*,⁷ an appeal from the denial of a claim that an MMR vaccination caused autistic-like symptoms in a child who was just under one year old. The court affirmed a special master's denial of compensation. The case had been consolidated with two other test cases as part of the Omnibus Autism Proceeding,⁸ in which more than five thousand cases have been filed. At this point, there have been no successes; all of the cases that have been decided have been dismissed by special masters, although most of the claims have yet to be heard.

Two types of claims have been brought: One type is based on the thimerosal preservative and the MMR vaccine in combination; the second set of cases is based on the MMR vaccine itself causing autism. On appeal in *Hazelhurst*, it was the latter theory that was relied on; that is, that the MMR vaccine in and of itself caused the injury. The plaintiff's theory is that the measles component of MMR causes an immune system dysfunction leading to inflammation of the gastrointestinal tract and in turn inflammation of the brain, with the latter causing autism. That theory, which has been widely discredited, stems from scientific papers first published in *Lancet*,⁹ a British journal, in 1998. Subsequently, the lead author lost his license to practice medicine and there have been innumerable charges of fraud in those studies.

7. *Hazelhurst v. Sec'y of Health and Human Svc.*, 604 F.3d 1343 (Fed.Cir.2010).

8. See National Vaccine Injury Compensation Program, *About the Omnibus Autism Proceeding*, HRSA.GOV, <http://www.hrsa.gov/vaccinecompensation/omnibusproceeding.htm> (last visited Mar. 29, 2011).

9. A.J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637 (1998), available at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(97\)11096-0/fulltext#article_upsell](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)11096-0/fulltext#article_upsell).

Indeed, just before this panel presentation, the *New York Times* published an article discussing new findings adding yet another voice to the consensus of discrediting research.¹⁰

Nonetheless, the plaintiffs were able to find expert witnesses to provide testimonial support in the special master hearings, and in *Hazelhurst* itself, the full administrative record ran thousands of pages of medical literature, four thousand pages of hearing testimony, and fifty expert reports. As in all the other proceedings, the special master in *Hazelhurst*, found that the lab procedures were flawed and that there was no scientific basis for establishing causation. With a handful of inconclusive exceptions, the cases have yet to enter the tort system, so it is impossible to know how they will play out, if at all, before juries assuming tort is pursued—despite the total lack of success in the administrative system.

Examining the special master opinions in these cases, as I have, one cannot help but note the serious character of the assessment of the scientific data and the virtues, as I see it, of low visibility decision-making—by which I do not mean opaqueness. Indeed the administrative proceedings are characterized by very lengthy opinions assessing the scientific findings; the special master process is highly transparent, far more than jury verdicts. What I do mean by low visibility is the insulation from the political pressures and personal sympathies that can lead even the Food and Drug Administration, let alone judicial trials, to compromise the mandate to base compensation awards on scientific findings.

In the end, the autism/thimerosal controversy is a case study of the vaccine no-fault system under maximum and unusual stress. And by all accounts, the resolution, at least at present, provides a positive endorsement for the expertise model in this particular set of toxic exposure cases, with the qualification that the massive proceeding has unfolded over a decade and has not yet been concluded.

10. Editorial, Autism Fraud, N.Y. TIMES (Jan. 12, 2011), <http://www.nytimes.com/2011/01/13/opinion/13thu2.html>.

