The National Childhood Vaccine Act

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Exam QueBtion I

Prior to passage of the National Childhood Vaccine Act in November 1986,1 manufacturers could be held strictly liable in tort for vaccine-related injuries, a lamentable situation which allegedly caused increasing prices, discontinuation of childhood vaccine production, and a reduction in vaccine innovation.[2] To solve this liability crisis–which industry officials, legal commentators, and policymakers contended had plagued the vaccine industry since the late 1960s– Congress enacted a law which eschews state tort law as a compensatory mechanism, and instead shifts the product liability burden from manufacturers to a public National Vaccine Injury Compensation Fund. While this innovation fairly compensates the innocent victims of our compulsory vaccination laws, it assumed that the opponents of strict liability had correctly explained why vaccines were being removed from the market; if this assumption was erroneous, the preexisting manufacturer tort liability regime should have been left intact, thereby preserving market incentives for investment in product innovation and additional safety.

Before deploying tlaw˜and˜economics arguments (with which I am admittedly only slightly familiar) to attack the premises of the liability-crisis theorists, some historical and scientific background is appropriate. Eradicating or controlling infectious

1 42 U.s.c.A **x300aa—lO to 33**

2 ˜ Peter Huber, Safety and the second Best: The Hazards of Public Risk Management in the courts. 85 columbia Law Review 277 (1985); George L. Priest, The current Insurance crisis and Modern Tort Law. 96 X˜˜L˜i ˜n˜1 1521 (1987); Note, The National childhood Vaccine Injury Act of 1986: A Solution to the vaccine Liability crisis?' 63 Washington Law Review 149 (1988). This note will hereinafter be referred to as note'.

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diseases through childhood vaccination has been an enormously successful public health strategy: [t]he disappearance of mortality from one disease (smallpox) and the rarity of deaths from two others (tetanus and poliomyelitis) can be attributed almost entirely to active immunization.[3] Indeed, smallpox is no longer one of the diseases against which children are routinely immunized: children generally receive inoculations for polio, measles, mumps, rubella, diptheria, tetanus, and pertussis.[4] Statistical evidence demonstrates the dramatic reductions in disease-incidence caused by vaccination: people reported 200,000 cases of diptheria in 1921 (five to ten percent of which were fatal), but an average of only three cases per year between 1980 and 1984; pertussis (whooping cough) killed 7,518 people in 1934, but only 12 people in 1984; 12.5 million people contracted rubella (German measles) during an epidemic in 1964-1965, while just 11 cases were reported per year between 1980 and 1982; and the incidence of polio was reduced from 57,000 cases in 1952 to an average of 12 cases per year from l974-l983.˜

Nevertheless, vaccination is not an unmitigated success because no vaccine is completely safe.[6] While minor side-effects

˜ Edward Mortimer, Immunization Against Infectious Disease. 200 ˜ 902 (1978), in cases and Materials on Food and Drua Law, 2d Edition. Peter Barton Hutt and Richard A. Merrill, eds. The Foundation Press, Inc. (Westbury, New York: 1991). The notes will hereinafter refer to the casebook as casebook.

˜ Subcommittee on Health and the Environment of the House committee on Energy and commerce, 99th cong., 2d Session, childhood Immunizations, at 1. (committee Print 1986) . The notes will hereinafter refer to this report as report.

˜ Id. at 5—15.

6 Indeed, regulators and public health officials discovered this as far back as 1813, when smallpox vaccine furnished by the federally chartered vaccine Agent caused an outbreak of smallpox in North carolina. In response, congress repealed the Smallpox Act (1813) in 1822, aborting the federal government's first foray into vaccination regulation. casebook at 660-661.

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are commonly associated with vaccination, unpreventable adverse reactions such as encephalomyelitis following pertussis vaccination, and paralytic poliomyelitic after administration of live polio vaccine will infrequently impose tragic financial and personal costs on the families of vaccinated children. Notwithstanding a manufacturer's adherence to rigorous government safety standards,[7] severe reactions may occur due to some biological property of the vaccine or from an undefinable characteristic of the person vaccinated. For example, polio contracted from oral polio vaccine occurs approximately once in 3.2 million doses, causing some five cases per year. Encephalitis resulting from administration of the diptheria, tetanus, and pertussis (DPT) vaccine occurs about 3.2 times per million doses, causing an estimated 43.2 cases each year. Lastly, deaths due to anaphylactic shock from all vaccines occurs approximately once in every 10 million doses, or five times per year **8**

While these risks are not trivial, and certainly translate into profound pain for the unfortunate few who suffer adverse reactions, public health officials have concluded that the risk/benefit calculus counsels that childhood immunization remain a centerpiece of America's preventative health care arsenal. All 50 states and the District of Columbia now have laws requiring proof of immunization as a condition of school entry. By the

Report at p. 22. The Food and Drug Administration's center for Drugs and Biologics sets biological standards for new products, licenses both the manufacturers of biological products and the products themselves, requires and evaluates the results and scientific rigor of pre-market product safety and efficacy tests, inspects manufacturing facilities, and ensures that products are properly labeled with information regarding safety and intended uses. **B** Note at n.3.

Report at 47. **10** ˜ at 4.

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beginning of the 1981-82 school year, 97 percent of all students initially entering school in the United States had been immunized against measles, 96 percent against polio, diptheria, tetanus, and pertussis, and 95 percent against mumps.[9]

Mandatory immunization exposes individual vaccinees to minute private risks so that society may benefit from the reduced risk of infectious-disease epidemics by avoiding the health care and opportunity costs associated with such diseases. Even those individuals whose bodies are immunologically incapable of sufficient response to vaccination, or who have not been vaccinated (because they are not within the ambit of mandatory vaccination laws) benefit from vaccinees' assumption of risk because the high levels of immunization in the population will provide protection:

This concept is known to epidemiologists as herd immunity.' It means that when a large proportion of the members of a group or community is immune to a disease, there is a reduced likelihood that the disease can be introduced into the group and spread to the few susceptible individuals. Herd immunity accounts for the absence of epidemics in communities with a high proportion of immune individuals, because the chance of contact between infected and susceptible persons is greatly reduced. **10**

But without a compensatory mechanism in place for those injured by this private risk/public benefit regime, mandatory immunization compels a few individuals to shoulder the cost of society's improved public health. Offensive to traditional principles of fairness and progressivity–which posit that societal costs be distributed evenly or according to ability to pay–this cost

allocation inefficiently leaves vaccine-injury costs where they lie, rather than imposing them on entities or institutions most able to obtain insurance or spread risk. Most courts and commentators have deemed this outcome unacceptable; they have debated, however, whether the cost of vaccine injuries should be absorbed by manufacturers or the federal government.

In the late 1960s and 1970s, when confronted with the nettlesome vaccine-injury compensation question, courts imposed liability on manufacturers by extending the strict liability doctrine that had been revolutionizing state products liability law since the 1940s1[1] In Reves v. Wyeth Laboratories,[12] the seminal opinion in this line of cases, a plaintiff sued the manufacturer of Sabin oral polio vaccine because her daughter had contracted polio two weeks after receiving the vaccine in a state-sponsored mass immunization program. The court held that section 402A of the Restatement (Second) of Torts (1965) rendered liable to the ultimate consumer the manufacturer of a product in a defective condition unreasonably dangerous. Although the polio vaccine was not itself defective, it was (for the reasons discussed above) an unavoidably unsafe product, **13** the benefits of

˜ Justice Traynor's concurring opinion in Escola v. coca-cola Bottlino co.,

24 cal.2d 453 (1944) is widely viewed as the inauguration of the movement toward strict liability of product manufacturers.

12 498 F.2d 1264 (5th cir. 1974)

13 In comment K to section 402A of the Restatement, the reporter explains what is meant by unavoidably unsafe products: There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such

which outweighed the risks.[14] A manufacturer could therefore avoid liability if an adequate warning accompanied its product. The most troubling aspect of the holding, from the vaccine manufacturers' perspective, was the court's conclusion that Wyeth could not discharge its duty to warn merely by advising the public health nurse of the foreseeable risks associated with the polio vaccine. The court instead held that in mass innoculation contexts where the manufacturer can reasonably foresee that no individualized medical judgment intervenes between... [it] and the ultimate consumer, the manufacturer has a duty to assure that the warning reaches the vaccinee.[15] Essentially, the consuming vaccinee must be furnished with sufficient information so that he may weigh the risks and benefits before rendering a true-choice judgment. After concluding that the vaccine had proximately and factually

a product, properly prepared, and unaccompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

14 In holding that the polio vaccine was not unreasonably dangerous per se, the court found that the qualitative and quantitative benefits outweighed the costs. the evil to be prevented–poliomyelitiS and its accompanying paralysis–is great. Although the danger that vaccinees may contract polio is qualitatively devastating, it is statistically minuscule. On balance then, marketing the vaccine is justified despite the danger

15 The court therefore rejected the prescription drug exception to the duty to warn, which says that a prescription drug manufacturer may satisfy its duty to warn by apprising physicians of the risks associated with its drug product. The rationale is that the prescribing physician, if adequately informed of drug risks, will undertake an individualized balancing of the attendant risks in light of the patient's needs and susceptibilities. See Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th cir. 1968). courts have applied the prescription drug exception in the vaccine context when a private physician, after adequate warning, administered the vaccination. See. e.a., Johnson v. American cvanamid, 239 Kan. 279 (1986); Schendler v. Lederle Laboratories, 725 F.2d 1036 (6th cir. 1983); Kearl v. Lederle Laboratories, 172 cal.App.3d 812 (1985). cf. Givens v. Lederle, 556 F.2d 1341 (5th cir. 1977) (manufacturer liable for injury caused by Sabin oral polio vaccine administered by private physician because physician not adequately warned of risk that polio could be contracted through bystander contact with recently inoculated infant) . For a discussion of these cases, see Note at 154 and n.46.

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caused the victim's polio, the court upheld the plaintiff's verdict.

The ˜ex˜ line of cases placed paramount importance on allocative equity and the dignitary interests of plaintiffs, which entitled vaccinees to undertake an informed cost/benefit calculation of vaccination risks. Manufacturers bitterly complained about this legal development, asserting that they were being forced to finance costs that were more properly the province of the public treasury. Furthermore, they suggested that expansive manufacturer liability would imperil public health by increasing the cost of vaccines, reducing manufacturer participation in mass immunization programs, reducing incentives to develop innovative vaccine technologies, and, ultimately, curtailing the vaccine supply as manufacturers pulled products from the market due to the lack of affordable liability insurance.[16] The American Academy of Pediatrics and the Conference

16 Most critics of manufacturer liability cite the Swine Flu experience to exemplify how strict manufacturer liability could imperil public health. confronting an outbreak of virulent swine flu in 1976, congress appropriated money to finance quickly the development of a vaccine against the disease. When the vaccine was in production, however, the manufacturers' insurance companies refused to underwrite liability insurance due to fear of excessive vaccine-injury liability stemming from the ˜ warning requirement. Because the manufacturers would not continue production without insurance, the Federal Government agreed to create an exclusive remedy against itself for injuries arising from the vaccination. The government indemnified manufacturers and other program participants for injuries that resulted from neither negligence nor failure to carry out a contractual obligation under the Swine Flu Program. By December 18, 1978, when the statutory limitations period expired, some 3,700 individuals had filed claims praying for more than $3.3 billion in damages. See Thomas Baynes, Liability for Vaccine Related

Injuries: Public Health considerations and some Reflections of the Swine Flu Experience. 21 St. Louis University Law Journal 44 (1977) in casebook at 716-717; casebook at 718; Note, Apportioning Liability in Mass Inoculations: A comparison of Two Views and a Look at the Future. 6 N.Y.U. Rev. R. & Soc. chance 239 (1977).

Nevertheless, the skittishness of insurers during this affair may have been unusually acute since the vaccine was developed and tested quickly to respond

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of State and Territorial Epidemiologists, in amicus briefs filed in ˜ echoed the manufacturers' public health arguments: these organizations maintained that a manufacturer duty to warn in the mass innoculation context would inhibit participation since complicated warnings would frighten or confuse potential vaccinees.

These arguments, if empirically true, cast doubt on the private tort system's ability to balance against the public health the competing and compelling interests of injured vaccinees. Many of our peers had, in fact, moved to a public compensatory structure to deal with vaccine-related disabilities.[17] Nevertheless, although the liability-crisis theorists accurately described the complexion of the vaccine industry in the mid-1980s, they did not conclusively implicate tort law in this predicament.

The following discussion principally focuses on vaccine price as a proxy for the manufacturers' cost of production. The liability crisis proponents–which included manufacturing and insurance industry officials–argued that expanded tort liability rendered insurance unaf fordable or unavailable, thus raising the cost of doing business. Increasing costs, they argued, had a

to a feared epidemic. Thus, insurance companies may not have felt comfortable with the available data about potential claims, which would limit their capacity to assess and price risks and set liability insurance premiums at a profitable level. Moreover, the legal uncertainty insurers confronted in the immediate aftermath of such decisions as ˜ and D˜xia likely exacerbated the technical difficulties confronting the underwriters. With well-established vaccines, the epidemiological and litigation-incident data are more reliable and limit the uncertainty confronting insurance companies. Thus, lessons from the Swine Flu experience should be viewed cautiously. **17** By 1976, six countries had enacted laws or issued regulations to compensate patients suffering from vaccine-induced maladies: Denmark, Hungary, Japan, Monaco, Switzerland, and West Germany. See Irving Ladimer, Legal and Regulatory Perspectives in Mass Immunization Programs. 1976 Insurance Law Journal 469.

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corresponding impact on price and threatened to render vaccines unaf fordable to consumers. Demand dissipation, which they suggested was inextricably connected to the judicial embrace of strict liability, compelled manufacturers to discontinue socially useful products.

Indeed, prices for the major childhood vaccines had risen steadily between 1980 and 1986,18 making more expensive the cost of publicly-sponsored immunization programs[19] and the cost of vaccine stockpiles. According to manufacturers, the costs associated with researching and developing new and improved drugs,[20] and an increasing number of product liability suits explained the upward pressure on prices.[21] Even by the manufacturers' estimation, therefore, tort law's impact on production costs and price was not solely responsible for increasing prices. Moreover., examination of vaccine price trends from immediately after the ˜ decision in 1974 until 1980 reveals that vaccine prices declined in constant dollars, suggesting that other factors may have caused the price increases in the 1980s.[22] While it is possible that a

18 In constant dollars, the price of measles, mumps, rubella vaccine increased

from $2.14 in 1980 to $5.09 in 1986 and the price of polio vaccine increased from 28 cents to 94 cents. The prices for measles, rubella vaccine, and solitary measles and solitary rubella vaccines also more than doubled during this period. No data were available for diptheria, pertussis, tetanus price changes. Report at p.65.

19 Some 50 percent of certain vaccines are purchased and administered through

public sector programs. j˜. at 60.

20 The industry estimated that it costs $20 to $50 million to develop and test

a new vaccine, and bring it to market. The total annual sales in the vaccine
industry in 1982 were $172 million. ˜. at 66.

21 For example, Lederle Laboratories' potential liability for DTP injury lawsuits exceeded 200 times its annual sales of DTP vaccine. Moreover, plaintiffs filed 299 vaccine-injury lawsuits between 1980-1985 requesting damages in excess of $3.5 billion. ˜ **at 69, 86.**

22 In constant dollars, the price of measles, mumps, rubella vaccine decreased

from $2.93 in 1975 to $2.14 in 1980. The prices for measles, rubella vaccine, and solitary measles and solitary rubella vaccines declined or remained steady

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maturation period existed before the increased litigation costs were expressed in vaccine prices, the expansion of manufacturer liability had begun even earlier than ˜ with such decisions as Gottsdanker v. Cutter Laboratories Inc.,[23] and Davis v. Wyeth Laboratories. Inc 24

Another possible explanation for the price increases in the 1980s was the lack of intra-industry competition. Between 1966 and 1977, half of the commercial producers of vaccines in the United States ceased production. This trend continued in the 1980s so that by 1984, only eight manufacturers were licensed to produce the vaccines most commonly used in childhood immunization.[25] The concentration was even more pronounced within the specific vaccine markets: by 1986, Merck was the only producer of mumps, measles, rubella vaccine; Lederle was the only producer of oral polio vaccine; and Connaught was the only producer of inactivated polio vaccine.[26] With such thin competition, manufacturers arguably could raise prices with virtual impunity, assuming they could credibly justify the increases and avoid violation of the antitrust laws.[27] The specter of increasing and

during this period. The polio vaccine did, however, increase over this **period.** ˜. **at 65.**

23 182 cal.App.2d 602 (1960) (sustaining an implied warranty action by a party **not in privity with the drug manufacturer)**

24 ˜ F.2d 121 (9th cir. **1968) (manufacturer has duty to assure that individual recipients were warned of the known risks involved in taking polio vaccine)**

25 Of these eight, four are domestic commercial manufacturers: connaught **Laboratories, Inc., Lederle Laboratories, Merck Sharp & Dohme, and Wyeth Laboratories, Inc. Michigan and Massashusetts have their own licensed vaccine labs. The final two producers are foreign corporations. Report at 67.**

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27 The pitfalls of an excessively concentrated market extend beyond the lack **of incentives to compete through price and product adjustments. concentration also poses public health dangers if the sole or major supplier of a certain vaccine experiences a supply disruption, as occurred with DPT vaccine in 1984.**

ruinous litigation may have offered a nifty and persuasive justification.

While manufacturers and many commentators contended that the market concentration was the result of the very same vaccine liability explosion which had caused price increases,[28] this explanation is difficult to prove conclusively. All commercial vaccine manufacturers had umbrella liability insurance policies which also covered the liability of their parent corporations for the other products they manufactured and distributed. As the House Subcommittee on Energy and the Environment concluded after evaluating the results of its survey of vaccine producers: it is difficult to separate the cost and coverage of insurance for liability related to vaccine injuries from the cost and coverage of liability insurance for other products. Also, changes in a parent corporation's premium or coverage may be related to liability for products other than vaccines.[29] Low profit margins, high production risks, increasing research and development costs, and the costs associated with demonstrating safety and efficacy are other non-tort factors that may have caused the market attrition 30

Notwithstanding the preceding discussion, even if one assumes that the lion's share of vaccine price increases and market

The Federal centers for Disease control now stockpile vaccines to avoid future supply shortages. Id. at 68-70.

28 Upon abandoning the whooping cough vaccine market in 1984, both Wyeth and

connaught Laboratories cited their inability to procure affordable liability insurance. Wash. Post, June 19, 1984, at Al, col. 1 and N.Y. Times, December

12, 1984, at A21, col. 1. Both articles are cited in Huber, Public Risks.

29 Report at 87-88.

30 Note, Immunization Injuries: Proposed compensatory Mechanisms–An

Analysis. 11 connecticut Law Review 147, 160 (1978).

concentration derived from expanded manufacturer tort liability, this merely reflected the proper internalization of all risks associated with vaccination. The cost of the private risk assumed by vaccinees was shifted to the manufacturer, which then incorporated a risk premium into vaccine prices in order to preserve its profit margin. Accident costs were therefore distributed across the spectrum of vaccine consumers–public agencies, private hospitals, and clinics alike. Through this compensation system, the public paid in two ways for the health benefits that inured to it from the vaccinees' private risk assumption. First, the portion of the public that obtained vaccines from private sources (such as private physicians or hospitals) paid higher prices. Second, the taxpaying public (which likely consisted of many of the same people who received inoculations from private sources) absorbed the balance of the cost since the federal government also purchased vaccine at the higher, risk-adjusted price.[3']

One problem likely hindered the efficiency of this compensation arrangement. In the past, when confronted with vaccine prices that incorporated the cost of all product risks, some consumers may have decided that in a vaccinated society the benefits of vaccination–the reduced probability of acquiring an infectious disease–were insignificant and no longer outweighed the price. Such consumers would choose to free-ride and absorb the benefits a vaccinated society externalized via herd immunity.

31 While higher prices may not be desirable in an era of limited governmental resources, cost internalization allows policymakers to calculate the true cost of its public vaccination program.

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The removal of vaccines from the market (due to reductions in demand as prices rose), therefore, may [have been] less attributable to the increasing costs from tort liability and more attributable to the fact that consumers [did] not internalize the full benefits of consuming vaccines.[32] The vaccination laws enacted by all 50 states and the District of Columbia would have solved, perhaps inadvertently, this free-rider problem[33] since mandatory vaccination creates demand inelasticity and enables manufacturers to spread among consumers the cost of unpreventable vaccine accidents.[34] Therefore, a credible argument can be advanced that despite all the criticism of the tort-based compensation mechanism, the system that existed in 1986 was neither dysfunctional nor dangerous.

Yet Congress, convinced that a liability crisis was causing vaccine market attrition and reduced innovation, intervened and fashioned a no-fault, nontort compensation mechanism for

32 See Steven P. croley and Jon D.Hanson, What Liability crisis? An **Alternative Explanation For Recent Events in Products Liability. 8 Yale J.** on Reg. 1, 87-88 (1991).

3˜ Mandatory vaccination should also relieve manufacturers of much tort **exposure since proximate cause will be difficult (or impossible) to prove; essentially no alternative to vaccination exists that a plaintiff could have chosen after being duly warned of a product's risks. ˜& Note at 161.**

˜ In an article advocating manufacturer liability for prescription-drug related injuries, Richard Merrill states: The relative inelasticity of demand for prescription drugs would presumably permit manufacturers to pass on to consumers the costs of preventing and compensating adverse reactions without significantly affecting the level of consumption. Richard A. Merrill, compensation for Prescription Drug Injuries, 59 Virginia Law Review 1, 115 (1973). **Since vaccine consumption is now mandatory, this argument should apply even more strongly in the vaccine context.**

Moreover, while legal uncertainty complicated insurance companies' risk valuation and premium pricing, the epidemiological data for common childhood vaccines should have been sufficiently reliable to allow insurance companies to underwrite manufacturer risk. And if insurers still balked, market forces would induce some new niche insurer to develop the necessary technical expertise to underwrite these insurance lines.

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individuals injured by mandatory childhood vaccines.[35] Although the petitioner may reject the statutory award and proceed against the vaccine manufacturer, his right of action is circumscribed:

the Act overrules ˜ and says a manufacturer is not liable if the injury resulted from the unavoidable side effects of a vaccine that was properly prepared and accompanied by FDA-approved warnings and directions for use. Thus, once a manufacturer provides an adequate warning to the learned intermediary, the manufacturers' potential liability to injured vaccinees is severed. 36

The statute has many virtues. Like a strict manufacturer liability regime, the statute creates a mechanism through which the public compensates injured parties for the harm society deliberately thrusts upon them in the name of public health)[7] It ensures that similarly situated parties receive uniform compensation, rather than be subjected to the vagaries of state tort law (which in some cases denied recovery altogether). The system also guarantees that petitioners will recover their claims more promptly than through litigation. Lastly, the statute offers manufacturers the certainty of a fixed liability standard.[32]

The statute raises a concern, however. Because a no-fault system operates more expeditiously and predictably than state tort law, some risk-averse plaintiffs will forego manufacturer

˜ **An excise tax on vaccine sales funds the program.**

36 Note at 162.

˜ **See ˜** pages 12 for a discussion of how strict liability spreads the **costs of product injuries to the public. concededly, the statute operates more visibly and directly than a tort-based compensation system.**

38 ˜ **at 159—164.**

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negligence claims about which they harbor some doubt. While this concededly eliminates some unmeritorious litigation, it chills legitimate negligence suits as well, thereby dampening incentives for manufacturers to adjust their care-levels. Reduced litigation will lower liability insurance premiums, allowing vaccine manufacturers to externalize the portion of their controllable risks that go unpoliced (or undetected) by FDA and state tort law.[39] Thus, the National Childhood Vaccine Act's virtues should neither obscure the inefficiency it creates nor convince us that it necessarily averted a vaccine market crisis.

˜ As Richard Merrill concluded in the prescription drug context: Government

liability, unless coupled with some form of direct levy against manufacturers...would reduce the economic incentives for... (them) to reduce accident costs. Merrill at 106.

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