

Bijwerkingen van vaccinaties vereisen speciale wetgeving

In de voorgaande twee delen van dit vierluik zagen we al hoe de pokken werden veroorzaakt door besmette bedwantsen en hoe uiteindelijk ook bleek dat Pasteur het aanvankelijk niet bij het juiste eind had. Die twee misvattingen hebben echter wel geleid tot de grootste misleiding in de medische praktijk, namelijk dat vaccins noodzakelijk, effectief en veilig zouden zijn en daarom een ‘must’ voor het welzijn van ieder kind en volwassene.

Echter: vele kinderen werden hierdoor het slachtoffer van – meestal ontkende en/of onbegrepen - bijwerkingen van die bejubelde vaccins. Dat leidde tot vele schadeclaims bij de vaccinfabrikanten, zoveel zelfs dat dit noopte tot wetgeving om de inkomsten van die fabrikanten veilig te stellen. Let wel: de onveiligheid van vaccins leidde tot speciale wetgeving om de aanklachten tegen de fabrikanten in goede banen te leiden en zoveel mogelijk te reduceren.

Hierover gaat dit derde deel van deze inleidende vierluik ter ontmaskering van de vaccinatiemythe. Hoe en waarom bij een percentage van de gevaccineerden deze bijwerkingen kunnen ontstaan probeer ik te beschrijven in de hierna volgende eigen studie. Nu eerst nog het artikel dat ik aantrof in de *New England Journal of Medicine* van 20-4-2011, dat ik originele versie hieronder weergeef:

Perspective

Safety, Supply, and Suits — Litigation and the Vaccine Industry

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On February 22, 2011, the U.S. Supreme Court ruled in *Bruesewitz v. Wyeth* that vaccine makers are immune from lawsuits charging that the design of a vaccine is defective. Many physicians and public health organizations applauded this outcome, believing that it will help to ensure the availability and promote the appropriate use of childhood vaccines. Others worry about what it may mean for patients’ rights.

The safety of vaccines is a thorny public health issue because vaccines occupy a unique position in the market. When other consumer goods are defective, including defects in their design, their manufacturers are generally strictly liable for resulting harms. Strict liability is strongly favorable for plaintiffs, because the manufacturer is responsible for any damages caused by its products, irrespective of the level of care it exercised. This standard is meant to provide manufacturers with an incentive to develop consumer goods that are appropriately safe. But medical products — including vaccines, drugs, and some medical devices — are unusual in that the same components that make them effective may also cause serious adverse effects. Thus, it may not be possible to design safer versions of them without losing their essential function. Influential legal experts have agreed that manufacturers of these “unavoidably unsafe products” should be exempted from strict liability for these products, as long as consumers are adequately warned about their risks.¹ This principle helps to assure that such products remain on the market, since they make a vital contribution to public health.

In the early 1980s, however, the supply of some essential childhood vaccines was threatened by manufacturers who argued that the cost of persistent lawsuits exceeded the income they could earn from these products. In particular, companies were held responsible for alleged vaccine-related injuries even when scientific evidence did not establish causation. Manufacturers claimed that the threat of such liability made it impossible to obtain liability insurance coverage and therefore to maintain operations.

In response, in 1986, Congress enacted the National Childhood Vaccine Injury Act (NCVIA), establishing a no-fault compensation system (“vaccine court”) for children who were harmed by adverse events following vaccine administration, as long as there was evidence that the vaccine actually caused the problem. The system is expert-driven, and there are no jury trials. Compensation covers the costs of medical expenses, projected lost earnings, and up to \$250,000 for pain and suffering but does not include punitive damages. It is paid out of taxes levied on each dose of vaccine. Although the NCVIA permits plaintiffs to reject an outcome and file a claim in court, its key preemption provision says that “no vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.”²

Controversy over the proper interpretation of this section of the legislation led to *Bruesewitz v. Wyeth*. In 1992, 6-month-old Hannah Bruesewitz received a third dose of her diphtheria–tetanus–pertussis (DTP) vaccine with whole-cell pertussis (Tri-Immunol) and had seizures shortly afterward, followed by a residual seizure disorder and developmental delay. In the vaccine court, the case was denied because the Department of Health and Human Services, concluding that there was no medical evidence of a connection, had recently removed residual seizure disorder from the list of adverse events eligible for administrative compensation.³

The Bruesewitz family rejected the judgment and sued the manufacturer for failing to develop a safer vaccine. Company documents, identified through discovery in the subsequent civil action, did refer to increased adverse reactions with Tri-Immunol — although not residual seizure disorder specifically — as compared with a vaccine with an acellular pertussis component (DTaP). In other documents, company representatives appeared to conclude that pursuing this “better pertussis component” was “not worth it for the total market.”⁴ The DTaP vaccine is now standard in the United States, and Wyeth removed Tri-Immunol from the market in 1998.

The case reached the Supreme Court, which held that the NCVIA preempted the Bruesewitzes’ lawsuit.⁵ Writing for the majority in a six-to-two decision, Justice Antonin Scalia concluded that the NCVIA provided no options for plaintiffs who set aside the vaccine court’s determination, unless they could argue that the vaccine was poorly manufactured or accompanied by improper warnings. In her dissent, Justice Sonia Sotomayor rejected this view, writing that the NCVIA’s preemption of further litigation was intended to apply only to cases in which the manufacturer can demonstrate that “the side effect stemming from the particular vaccine’s design is ‘unavoidable.’”

Their disagreement centers on the question of what Congress intended to do in the NCVIA and highlights the uneasy relationship between preemption and product safety. Federal preemption of product liability lawsuits that rely on state law is a powerful prerogative that places heavy emphasis on the quality of regulation by the Food and Drug Administration (FDA). Litigation such as the Bruesewitzes’ can help the FDA in its oversight function by

revealing important and previously unknown information about product-related risks, especially during the postapproval period, and by deterring manufacturers from acting irresponsibly and engaging in business tactics aimed at increasing product sales at the expense of patient safety. These considerations were prominent in *Wyeth v. Levine*, a 2009 Supreme Court decision that held that federal law did not preempt state-court lawsuits over drug safety.

However, childhood vaccines differ from drugs in many ways. They are given widely to healthy children to prevent potentially deadly infectious diseases. The childhood vaccine market is also apparently less stable than the drug market, since there are fewer vaccine suppliers and there's therefore a real risk of shortages if companies leave the field. In this environment, an administrative forum in which considerable expertise informs determinations about causation can play an essential role by resolving fairly most cases of alleged vaccine-related adverse events. For example, in the autism cases, the vaccine court rightly found no link between vaccination and that condition. But should the existence of the vaccine court necessarily preempt all lawsuits alleging that a vaccine could have been made safer? Civil litigation could be useful in the rare cases in which a plaintiff was contending that a plausible alternative vaccine design would have prevented the adverse event at issue. This argument is particularly relevant because the FDA doesn't usually consider whether a safer product design exists when deciding whether to approve a vaccine or keep a vaccine on the market.

The Court's reasoning in *Bruesewitz* was based in part on concern about the exploitation of such an exception by plaintiffs' lawyers, who could bring cases based on testimony about a "universe of alternative designs" that is "limited only by an expert's imagination." Might opening this possibility defeat the purpose of the vaccine court and again potentially jeopardize market stability and vaccine availability? The Supreme Court noted that in place of litigation, the NCVIA "provides many means of improving vaccine design."⁵ Among those listed were oversight by the FDA, voluntary reporting and monitoring of adverse events (both of which are known to be imperfect means of detecting risk and ensuring safety), and the National Vaccine Program. Amendments to the NCVIA may be required to provide additional regulatory support, because these systems are now operating without one important safety net.

[Disclosure forms](#) provided by the author are available with the full text of this article at NEJM.org.

Source Information

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References

1. Restatement (Second) of Torts § 402A cmt. k (1965).
2. 42 U.S.C. § 300aa-22(b)(1) (2010).
3. National Vaccine Injury Compensation Program revision of the vaccine injury table: final rule. Fed Regist 1995;60:7678-7696
4. Joint appendix, *Bruesewitz v. Wyeth*, No. 09-152 (May 24, 2010).
5. *Bruesewitz v. Wyeth*, 562 U.S. ____ (2011).

83 percent of brain injury vaccine compensation payouts were for autism caused by vaccines

Onder deze kop ontving ik op 17-5-2011 van *NatureNews* een beschrijving van een nieuwe 'peer-reviewed' studie die op 10-5-2011 werd gepubliceerd in *Pace Environmental Law Review*. Ik citeer uit deze beschrijving van dit artikel:

[...] The federal government has been publicly denying any link between autism and vaccines for over two decades, while it has quietly been paying out damages for vaccine injury to children with autism, a study released May 10th shows. The study underscores the need for Congressional hearings and independent scientific research into the connection between autism and vaccines (<http://www.news-medical.net/news/20...>).

The federal government's Vaccine Injury Compensation Program was created in 1989 to act as a "no fault" taxpayer-funded alternative for those seeking compensation for proven vaccine injury. The new peer-reviewed study, published May 10th in the Pace Environmental Law Review, looked at cases of vaccine injury that have been monetarily compensated by the VICP. The study looked at 1300 cases of children with brain injury resulting from vaccines where the court's records referenced autism, symptoms of autism or disorders commonly associated with autism – twenty-one cases outright stated "autism or autism-like symptoms" in the court records. The researchers then identified and contacted 150 of the families that were compensated to find out whether the children had autism. 62 of the families they contacted (greater than 40 percent of their sample) reported children with autism, for a total of 83 cases of autism. (<http://www.prnewswire.com/news-rele...>).

"What we did is we looked at the people who the government said are clearly vaccine injuries and awarded them compensation," said Lou Conte, the vaccine compensation recipient who helped coordinate the study.

"We asked the next question and that question was: Do some of these people also have autism?" said Conte. "We found that in 83 of the cases we were able to locate, the families report that their children have autism and symptoms of autism.

(<http://www.myfoxdc.com/dpp/health/n...>) [...]

Bulletin of the World Health Organization

Onder deze titel werd op 31-3-2011 een nieuwe compensatieregeling voor slachtoffers van vaccinatie gepubliceerd. Ik citeer het eerste deel hieruit:

[...] No-fault compensation following adverse events attributed to vaccination: a review of international programmes.

Introduction

The public health benefits of vaccination are clear. The World Health Organization estimates that, in 2008, more than 2.5 million deaths were prevented by vaccination. Immunization programmes have led to the eradication of smallpox, the elimination of measles and poliomyelitis in many regions, and substantial reductions in morbidity and mortality from Haemophilus influenzae type b, diphtheria, whooping cough and tetanus.

However vaccines are not without risks and it is commonly accepted that, regardless of proper design, manufacture and delivery, adverse events occur following vaccination although serious adverse events are rare.

At a population level, it is considered that these small risks are balanced by the benefits of widespread population immunization. However this means that an individual occasionally bears a significant burden for the benefit provided to the rest of the population. Although these vaccine-related adverse events occur occasionally due to negligence, more often there is no clearly attributable fault.

*Without evidence of clear negligence, it is difficult to obtain compensation through traditional legal mechanisms. Recognizing this, several countries have implemented vaccine-injury compensation programmes. **These programmes reflect a belief that it is fair and reasonable that a community that is protected by a vaccination programme accepts responsibility for and provides compensation to those who are injured by it.***

In 1999, Evans conducted a thorough review of 13 compensation programmes. We aimed to update this review examining similar programme elements to those described both by Evans and by Mariner in the 1985-6 study [...]

Lees vooral dit fragment:

... that it is fair and reasonable that a community that is protected by a vaccination programme accepts responsibility for and provides compensation to those who are injured by it.

Een vaccinatieprogramma dat een gemeenschap beschermt en tegelijkertijd leden van diezelfde gemeenschap beschadigt... Er moet dus een groep slachtoffers opgeofferd worden ten bate van de rest van die gemeenschap. En om die gemeenschap het idee te geven dat al dat menselijk leed kan worden afgekocht, heeft men een ‘schijn-compensatieregeling’ in het leven geroepen die zo goed als nooit een uitkering doet omdat men tegelijkertijd blijft roepen dat de meeste schade niets te maken heeft met de voorafgaande vaccinatie.

In deze studie staat te lezen dat ziekten niet zijn uitgeroeid door vaccinatieprogramma's. Dat vaccinaties geen levens redden. En dat gevaccineerden enige tijd na vaccinatie besmettelijk blijven voor de rest van de populatie, hetgeen juist de infectiedruk vergroot. Ook beschrijf ik hoe vaccinaties verantwoordelijk zijn voor een epidemie van allergie, autoimmuunziekten, astma, neurologische aandoeningen enz. Door vaccinatieprogramma's wordt een gemeenschap niet beschermd tegen ziekten, maar juist blootgesteld aan het risico van allerlei ziekten en (chronische) aandoeningen, die vaak een ernstiger verloop hebben omdat vaccinatieprogramma's het afweersysteem verzwakken.

Er worden naar willekeur slachtoffers gemaakt omdat men – zoals ik in deze studie uitgebreid beschrijf – niet voorafgaand aan de eerste vaccinaties een test doet om te bekijken of het Cytochroom P450-ontgiftingssysteem wel gezond is, zodat de schadelijke en giftige stoffen in de vaccins wel naar behoren kunnen worden ontgift.

Omdat de vaccinindustrie ook heel goed weet dat zo'n 10 procent van de blanke bevolking niet goed kan ontgiften - en er dus altijd slachtoffers zullen blijven vallen - heeft men dus dat compensatieprogramma opgezet, als een soort van ‘doekje voor het onvermijdelijke bloeden’. Want als men wel zou testen op Cytochroom P450 (plus Glutathion S-Transferase) dan zou het publiek vooraf geconfronteerd worden met de risico's van vaccineren en dat zou de beoogde vaccinatiedekking – lees: winst op vaccins - dan niet ten goede komen. Dus wordt er gezwegen over de genoemde contra-indicaties voor vaccineren plus de ineffectiviteit ervan. Onwetend van deze reeds bij de vaccin-industrie bekende risico's worden zoveel mogelijk kinderen (blind voor de afwijkingen aan het ontgiftingssysteem) gevaccineerd. Bijwerkingen worden daarna afgedaan als niet gerelateerd aan die vaccinaties en – om het publiek koest te houden – wordt er sporadisch een schadeloosheidsuitkering gedaan, zonder dat de fabrikanten

van de vaccins aansprakelijk kunnen worden gesteld. (Bij andere rassen speelt het Cytochroom P450-probleem ook, maar in diverse andere percentages.)

Als vaccins echt voor iedereen veilig en effectief zouden zijn, zoals het RIVM en consorten roepen, dan waren er helemaal geen compensatieprogramma's nodig en hadden we niet ook nog steeds uitbraken van bof, mazelen en kinkhoest. Volgens het Lareb bestaat er zelfs niet eens medische vakliteratuur die twijfelt aan de veiligheid van vaccins. Verderop in deze studie komen honderden in de medische vakbladen gepubliceerde artikelen aan bod die wel ernstig twijfelen aan de veiligheid en effectiviteit van vaccins. Over het Cytochroom P450 bestaat ook inmiddels veel medische literatuur.

Ik durf te stellen dat vaccinatieschade ontstaat doordat de gezondheidsautoriteiten stelselmatig het belang van het Cytochroom P450-systeem blijven ontkennen en nalaten om daar vooraf op te testen. Het gaat hier dus inderdaad om grove nalatigheid van de gezondheidsautoriteiten.

Kennelijk is het voor de vaccin-industrie goedkoper om zo nu en dan een uitkering te doen, dan om rekening te houden met 'slechte ontgifters' die niet gevaccineerd mogen worden. Vaccins zijn ook relatief duur omdat er per vaccin een bepaald bedrag opzij wordt gelegd voor de uitkeringen aan de onvermijdelijke slachtoffers. En die hoge prijs wordt dan weer opgehoest door de gezondheidszorg van de overheden, zodat voor de vaccin-industrie de winst op zoveel mogelijk vaccins gegarandeerd blijft.

De burgers zijn de onwetende slachtoffers die dus in feite zelf de kosten moeten dragen van zowel die vaccinaties als de uitkeringen bij schade. Maar zelfs met een financiële schadeloosstelling krijg je nooit meer een onnodig overleden kind terug of een geïnvalideerd kind weer gezond.