Who is Responsible When A Vaccine Causes Injury?

By Chuck Dinerstein, MD, MBA — February 24, 2020

A lot of time in MBA school is spent on defining and discussing corporate social responsibility (CSR), giving back to the community, local or global. The recent concerns about the Wuhan Coronavirus, now re-labeled Covid-19, like the concern about Zika, Ebola, and SARS has lead to frantic calls to Big Pharma to provide a vaccine. Sanofi Pasteur has now partnered with our US Biomedical Advanced Research and Development Authority, BARDA, a part of Health and Human Services, to develop a vaccine. But that decision was also accompanied by other members of Big Pharma saying that they were not pursuing a vaccine. Do these large corporations have a broader social responsibility to create these vaccines?

La vaccine painted by Louis-Léopold Boilly, 1807 Courtesy of the Wellcome Library [1]

As Stat reports [2],

“GSK has made a corporate decision that while it wants to help in public health emergencies, it cannot continue to do so in the way it has in the past. …Merck has said while it is committed to
getting its Ebola vaccine across the finish line it will not try to develop a vaccine that protects against other strains of Ebola and the related Marburg virus."

Do these large corporations have a broader social responsibility to create these vaccines? In truth, who is better equipped, than Big Pharma to develop and bring vaccines to the scale required for a pandemic? But vaccines have a tumultuous history, not the rise of anti-vaxxers, but with the liability that comes from developing drugs that are mandated. It is time to take a moment to review our vaccine past. Cynics characterized gestures of corporate social responsibility as more about branding than service. Still, in the context of understanding how we have legislatively and judicially removed corporate liability in vaccine production, you might wonder just what CSR really means. The unstated quid pro quo of all the legislation passed to protect corporations from financial responsibility for the adverse effects of vaccines was based on the premise that they would provide this service to the community. If corporations are not willing to help when necessary, should they be afforded special protection?

Vaccines are beneficial and safe; they do not cause autism. They are one of our greatest public health triumphs, right up there with clean water and toilets. But vaccines like any medication can have idiosyncratic impacts on individuals when treatment goes from clinical trials to a more messy, real-world. Who is liable when mandated public health procedures go awry?

There is no 100% safe medication, none. When people are injured by prescribed medication, they can seek compensation through the legal system. But what can a person do, when an idiosyncratic reaction to a mandated vaccine leaves them injured?

US vaccine policy is based on state statutes governing children's vaccination before entering public school, pre-school, or daycare. Before 1986, over $3 billion in tort claims [1] were filed against vaccine manufacturers. As lawsuits mounted, manufacturers could no longer obtain liability insurance, and simply stopped research and production. The sentinel event involved the P in Diptheria, Tetanus, and Pertussis vaccine.

**Pertussis or "whooping cough" effects infants**

It is highly contagious, with an R0 of 5.5, making it three to four times as infectious as seasonal flu. The original problematic vaccine was made from inactivated *Bordetella pertussis* cells; its outer coating caused a plethora of mild side effects in about a third to half of children; severe side effects were less common, but increasingly attracted parental concern. [2] In what was one of the first patient-driven efforts, Dissatisfied Parents Together (DPT) lobbied for both safer vaccines and a compensation program that could replace the "costly, time-consuming, and usually under-compensated" tort system. They were joined by vaccine manufacturers, the American Association of Pediatricians, the American Medical Association, and Congress in seeking a solution. Their efforts resulted in the Vaccine Act of 1986.

**The Vaccine Act is a compromise**

The parents wanted compensation and safer vaccines, the manufacturers wanted no liability. The government wanted to maintain a wildly successful public health initiative. Continuing to compensate injuries through tort litigation was a crap-shoot for plaintiffs and defendants. Some
stakeholders favored mediation, but others like Dr. Jonas Salk felt that removing the threat of tort's financial penalties might let manufacturers become complacent and not work on newer, safer vaccines.

"Congress viewed child victims of vaccine injury as veterans in the war on disease; they deserved compensation just like soldiers injured on the battlefield."

Under the Vaccine Act, families have three years after the discovery of a vaccine injury, to file a claim with the National Vaccine Injury Compensation Program (NVICP). A mediator or special master, typically an attorney, has 240 days to review the case, determining "causality," and adequate compensation. If the family disagrees with the Special Master, they may file a civil suit.

The NVICP is a no-fault system; plaintiffs must demonstrate an injury within specified time frames, manufacturers are not involved, the government is represented by the Department of Justice, and provides compensation to claimants' attorneys [3]. Payment comes from monies generated from consumers, who pay a $0.75 tax on each vaccine. Causality is determined from a Vaccine Injury Table [3], that lists all vaccines and the specific injuries and time-frames that are considered by statute causal. The table is formulated and revised by the Secretary of Health and Human Services based on the opinions of expert panels within the Institute of Medicine of what injuries have a plausible scientific basis. If the claimant meets the criteria in the table, the vaccine "caused" the injury, and the patient will be compensated.

In those cases where the table covered the vaccine-related injury, the legislation was very effective; 99% of families accepted the compensation they received, less than 0.5% went on to pursue litigation. For every million doses of vaccine, one patient is compensated. The program has mediated roughly 18,500 cases, 38% in favor of the claimants, with an average compensation of $600,000.

When a claimant specifies an injury not listed or disagrees with the decision of the Special Master, they may pursue civil litigation. But the bar of proof is quite high, requiring them to show the scientific basis for why the vaccine caused the injury – a more expensive and arduous endeavor. The table has changed little since 1986 despite the addition of 9 new vaccines. While the first cases were usually resolved based upon the table, today 98% are resolved off-table, through litigation.

"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."

In addition to awarding damages because of medical malpractice, e.g., giving the wrong vaccine, incorrect dosage, and so on, the law allowed manufacturer liability for defects in vaccine design and manufacture. The inclusion of thimerosal in vaccines was found to be a "design defect" by the Supreme Court of Georgia. But other state courts rule differently. A case was brought before the US Supreme court to create a uniform interpretation of the Vaccine Act.

The specific case involved vaccination with the third of the DPT series in a healthy six-month-old girl who experienced seizures within a few hours of administration of the vaccine and was subsequently "developmentally delayed." Residual seizure disorder had been an on-Table side
effect until one month prior to the parents filing a claim with NVICP. It was removed by the then Secretary of HHS, Donna Shalala. Without the presumption of causality, the parents were unable to demonstrate scientific causation between her vaccination and subsequent seizures. After 15 years of litigation in the NVICP system the parents took the case to civil court. The parents, echoing those concerns of Dr. Salk filed suit against Lederle, subsequently purchased by Wyeth for maintaining this specific whole-cell vaccine on the market, when there were acellular vaccines, with fewer side effects, available.

Justice Scalia writing for the 5-member majority found that manufacturers bear no liability for the design of the vaccine, once the FDA approves it. Justice Sotomayor, writing for the minority, argued that the decision "leaves a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and technological advancement when designing or distributing their products."

FDA approval of drugs is inadequate in determining their actual safety. Their decision based on clinical testing often differs significantly from real-world use; that is why the FDA conducts "post-market" surveillance of medications. Some legal scholars agreeing with Justice Sotomayor feel manufacturers have no financial incentive to develop a better product, only an unenforceable civic responsibility - corporate social responsibility. "If consumers cannot sue firms for product liability, the only barrier to sales is regulatory approval."

**The European Union follows a different path**

The European Court of Justice, the EU version of our Supreme Court, provides interpretations for EU member Courts. They felt that requiring scientific proof of causality was too high a burden "for a fair apportionment of the risks." Causality required simply biologic and temporal plausibility. Courts could consider "serious, specific, and consistent presumptions capable of proving the defect in the vaccine and the existence of a causal relationship," even if the science was undecided, even a consensus was unnecessary.

There was a lot of pushback from the scientific community over that ruling, including that of our occasional contributor, Dr. Paul Offit. The thrust of their decision tilted the playing field towards the patient, and scientific proof was not required as it is in US Courts.

But our world is increasingly interconnected. Several vaccines in use across the globe could now face design defect litigation in the EU. Modification of these vaccines to meet EU requirements might well be echoed globally, just as their more stringent privacy laws ripple into the new terms of service agreements in the US.

**The PREP Act**

When the Secretary of Health and Human Services authorizes a public health emergency, as was done with the Ebola virus and the 2009 H1N1 virus, and as some public voices might desire in the face of the Covid-19, it activates the Public Readiness and Emergency Preparedness Act. It provides a tort "shield" for medical personnel, manufacturers of vaccines, and other public health countermeasures not covered by the Vaccine Act. Like the vaccine act it involves mediation, a shortened statute of limitations and is own, [Countermeasures Table](#). The only exceptions are
cases where the plaintiff can demonstrate "willful misconduct" on the part of the manufacturer – a higher bar perhaps than demonstrating science-based causality. For some legal scholars, PREP provides less consumer protection and more manufacturer protection than does the Vaccine Act.

I return to my original question if corporations are not willing to help when necessary, should they be afforded special protection?

[1] A tort is a wrongful act, through negligence, or intention, that injures another party. Most medical malpractice involves torts.

[2] Today's current pertussis vaccine is made from acellular elements with far fewer side effects, although it also appears to be slightly less effective.

[3] The low levels of compensation make it difficult for claimants to find representation, much as patients utilizing Medicaid find it challenging to see physicians.