

## Expert Commentary Series

### “A Dose of Reality” Does Not Support Abolishing VICP

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In a recent article published in the Pennsylvania Law Review, Prof. Nora Freeman Engstrom suggested that the arguments for moving medical malpractice from the regular tort system to health courts are flawed, because we have reason to doubt whether health courts will fulfill the expectations of their proponents. She drew on the experience of the National Vaccine Injury Compensation Program (VICP) to demonstrate the point, suggesting the program has “stumbled” and did not meet expectations.

The article is thorough, thoughtful, and informative. It’s a valuable, important read for those considering whether to support health courts as an alternative to liability via the tort system. That said, I would like to point out some limitations and problems in Engstrom’s discussion of VICP, and suggest that the claim that the program “stumbled” is problematic.

I would like to emphasize three points.

First, note that this post is *not* a comprehensive response to Engstrom, nor is it on the subject of whether or not the US should adopt health courts. Engstrom raises many important points pertinent to health courts which I do not address in this post.

Second, I want to emphasize that for those interested in VICP, Engstrom provides a thorough, well supported, and accessible introduction to the structure and functioning of VICP. There is much to learn from it.

Third, I disagree with the implied interpretation suggested by anti-vaccine activists that flaws make the program a failure. For that reason, I would avoid saying that the VICP “stumbled”. Though Engstrom says the VICP has stumbled, Engstrom never says that the VICP is a flat-out failure. In fact, the last pages of her article point out several of the VICP’s strengths and pointing out the program’s many advantages is critically important. While it’s possible the VICP is imperfect, there’s little evidence it’s failed altogether. Imperfect is not failing. But the term “stumbled” is – and will be – used by anti-vaccine activists to claim otherwise. Likewise, the Press Release by Stanford is unhelpful since it uses language that supports that view.

Those who object to vaccination are already making inappropriate use of Engstrom’s analysis. The anti-vaccine movement has been deeply opposed to the VICP for some time. They have called for the abolishment of the program and for returning adjudication of vaccine injuries to state courts. That, in my view, would be a real error because sending vaccine injuries to the courts would be

more difficult for those with valid claims as well as for our overall health by endangering the vaccine supply.

The National Vaccine Injury Compensation Program is an administrative program created by Congress in the 1980s to solve two problems. One was the supply problem. Pharmaceutical companies were being crippled by liability litigation and were abandoning the vaccine manufacturing industry entirely. The program was an attempt to retain vaccine manufacturers and reduce the number of companies that were opting out of the industry by offering them limited liability protection. The second was to assist citizens who may have been harmed by vaccines in getting fair and timely compensation. (I addressed the technical details of how the VICP is substantially easier on plaintiffs, also known as petitioners, in another post [here](#).)

In her article, Engstrom raises three central problems with VICP, and then highlights four issues that lead, in her view, to the problems. This post proceeds in three parts: examining the problems Engstrom raises, examining her explanations for them, and then in closing, explaining why VICP is still a better option for those claiming vaccine injuries than the courts of justice.

### **The Critique and its Problems:**

Congress intended VICP to be an “expeditious and fair” way for victims who may have suffered a vaccine injury to be compensated. Engstrom sees three problems with the program that are in conflict with Congress’s intent: lack of consistency; delays in decision making; and the difficulty and duration of setting individualized compensation. Let’s address each in turn.

#### **Lack of Consistency:**

One goal of VICP was to make vaccine injury decisions more predictable, and lack of consistency undermines this goal. Drawing on a study by Ridgway and quotes from others, Engstrom emphasizes that different Special Masters arrive at different, inconsistent decisions.

However, lack of consistency is inevitable the moment an issue is subject to decision by human decision makers (and Engstrom herself acknowledges this). Further, the no-fault programs she addresses are not the only place where consistency is lacking. Regular courts – especially with a jury trial – can and do arrive at inconsistent results, as do federal circuits. Internally, VICP can strive for more consistency among Special Masters, but it is an inherent feature of adjudicative forums and other discretionary decision makers in the United States – including courts of law. There is no good reason to think returning the issue of vaccine injury to the various state courts – the natural venue for tort cases – would increase consistency, especially given the differences among states in tort law. If anything, given the large number of judges and the inconsistency of one-time jury panels, NVICP, with a small number of special masters acting on similar cases over time, is likely to have higher levels of consistency. (On a side note, other countries may do better on this. See, for example, David Johnson’s book *The Japanese Way of Justice: Prosecuting Crime in Japan*, on how Japanese prosecutors achieve more consistent results than their United States counterparts).

As valid as the critique may be, it does not support the view that VICP should be abolished in favor of tort liability.

## **Delays in Decision Making:**

Engstrom emphasizes that when Congress designed VICP it aimed for speedy resolution of claims, and included several features designed to help resolve claims quickly – including Congressional deadlines for the resolution of claims. Unfortunately, the mandated duration has not worked well in practice. Engstrom stresses that very few petitioners meet the 240 day congressional deadline, and most take much longer. In the passages on speed, Engstrom draws on two sources: the 1999 GAO report, “Vaccine Injury Compensation Program Challenged to Settle Claims Quickly and Easily” and a 2014 Associated Press (AP) report examining the program.

In my view, Engstrom’s analysis of this issue does not go far enough. First, the 2014 GAO report, “Vaccine Injury Compensation: Most Claims Took Multiple Years and Many Were Settled through Negotiation” noted an issue with delays, but emphasized that claims filed since 2009 have been resolved more quickly (id, pp. 10-11, Figure 2), which suggests that improvements have been made. Engstrom highlights the backlog caused by the number of claims were related to DTP and autism as a cause of delays (pp. 1688-1689). Indeed, part of the improvement seems to be the resolution of the over 5,000 autism claims after the Autism Omnibus Proceedings (OAP), which began in 2002 and concluded in 2010. The duration of the OAP certainly contributed to the overall length of time claims remained unresolved. Engstrom correctly points out that it’s impossible to plan the caseload of specialized courts in ways that prevent this problem, but the change since 2009 suggests that the program worked to improve this. In other words, when there’s a large influx of claims, delays may be created, but with efforts, they may be overcome, and resolution times improved (Engstrom addresses this – in a more qualified way than I have – in her footnote 253).

Second, the AP report Engstrom referenced (in footnote 253) suggested an additional reason for the delays, which explained that petitioners’ lawyers were filing cases without complete medical records or with insufficient evidence. Not having the proper documentation on hand at the time the case when the case is filed means that getting the case ready to adjudicate takes additional time. In the case (*Toomey v. Sec’y of Health and Human Services*, No. 98-643V) described in an AP news article (*Toomey v. Sec’y of Health and Human Services*, No. 98-643V), the Special Master states:

“In many cases, the primary delay in resolving the damages issue is petitioner’s failure to file its Life Care Plan in a timely manner. Aggravating the delay is the discovery that petitioner failed to file the information required by this Order, *infra*, in support of the compensation requested, such as medical and school records, medical insurance information, and provider information.”

If petitioners do not provide the information in a timely manner, the VICP must then choose to either dismiss the incomplete cases, or allowing cases to go on beyond the mandated timeframe. Dismissing cases means petitioners will not be heard, and in a program designed to help petitioners, there is good reason for decision makers to hesitate to dismiss cases. It seems the special masters have chosen, instead, to wait. That causes its own problems, including delays. But it’s not a flaw or mistake for the program to be generous in giving petitioners time to complete cases. It’s a choice.

## **Difficulty and Duration of Setting Individualized Compensation:**

Engstrom points out that although the program includes several provisions for reducing the need to determine individualized compensation – by setting a cap for death damages, pain and suffering, and standardizing lost wages – future medical costs still require individualized determination. Estimating the cost of long-term care for people with complex disabilities is not an easy process, nor can it be determined rapidly. She also documents the fact that the government, in some cases, has bickered with petitioners over the need to pay for very low-cost items.

The examples Engstrom provides of penny pinching by the government are very troubling. If the government has haggled to that degree, in a program designed to be generous, then the issue deserves investigation and improvement. But the problem of determining future medical costs is probably, as Engstrom suggests, inevitable, and will remain. In fact, it's an important part of a functioning program in order to fit compensation to the claimant's needs. The need to address that would apply in regular courts, too and other items of damages may need discussion. Again, this is a problem that's important to highlight and improve. It does not, however, support a call to dismantle the program. Nor is it a fatal flaw in its functioning, though it is something to consider when choosing between a no-fault program and regular courts.

### **Engstrom's Analysis of the Reasons for the Various Problems with VICP:**

Part V of Engstrom's article addressed why, in her view, the problems happened. The section's title includes the question "Why did the VICP stumble?"

That language troubles me, because it's not clear that the VICP *has* stumbled. Imperfections in the program are not fatal flaws or errors, and when those problems are inherent features of adjudicative programs, they don't constitute "stumbles." For the purpose of Engstrom's caution about the use of health courts, that point isn't important: her cautions may be all the stronger because of inherent features that would prevent such courts from having advantage over the regular courts. From the perspective of criticizing VICP, however – and especially since anti-vaccine activists are expected to use the article to support dismantling the program – the language is more problematic. Let's address those in turn.

### **Causation Questions:**

Engstrom suggests that some of the problems described above can be attributed to the difficulty in proving causation in relation to vaccine injuries, which are not "traumatic, visible, or otherwise uncontested," unlike motor vehicle accidents or work injuries. First, I'm not sure the criteria capture what makes proving causation problematic. Whether there is clear causation evidence does not always depend on whether the injury is traumatic and visible or not. Traumatic injuries can create tricky causation problems, while non-traumatic injuries can involve clear cut signature ones.

Second, the problem with many vaccine injury cases isn't whether general causation is unclear. In these cases, general causation refers to the claim that a vaccine is capable of causing a specific condition. This needs to be shown, in a regular tort case, with evidence that is scientifically credible, which would meet the *Daubert* standard. For example, there is strong scientific evidence that smoking causes lung cancer, so showing general causation will be easy there.

There is a lot of data on the connection between vaccines and a variety of injuries. Therefore, the standard of general causation used in the Courts of Law to determine whether a vaccine is likely to have caused a specific injury should be relatively easy to illustrate. However, in the majority of cases, vaccines do not cause the harm claimed.

Engstrom suggests that there is substantial uncertainty by referring to a 1994 report from the Institute of Medicine (IOM) which states: “there was insufficient evidence to prove or disprove a relationship between vaccines and *two-thirds* of the seventy-five medical conditions studied.” (Engstrom, FN 333). But it’s important to put that language in context. There is a more recent IOM report which uses very similar language – but adds a line that makes the point easier to understand. The 2011 report, “Adverse Effects of Vaccines: Evidence and Causality” said: “for the majority of cases (135 vaccine-adverse event pairs), the evidence was inadequate to accept or reject a causal relationship. Overall, the committee concludes that few health problems are caused by or clearly associated with vaccines.”

In other words, the lack of good evidence led the writers of the 2011 IOM report to conclude against causation. The language is more equivocal. However, this is not a situation where the IOM says “maybe vaccines cause these, maybe not.” In a regular court such a finding would probably lead to a rejection of a case based on general causation: the plaintiff would not be able to prove that more likely than not, the condition in question is caused by the instrumentality – substance, drug or vaccine – it claims caused it.

To use one example from the 2011 IOM report, (pp. 111-118) there is discussion as to whether the measles, mumps and rubella (MMR) vaccine causes encephalitis. The report examined epidemiological studies and concluded that two of the relevant three found no causal connection, and the third suffered from methodological problems proving it to be unreliable. It also addressed 18 case reports of encephalitis after MMR – 14 of which had no evidence besides a temporal connection (the encephalitis happened after the vaccine), and others had specific problems.

In other words, what the IOM observed was evidence that *fails to* support a connection. The IOM does not say that in those terms; instead it leaves the possibility open. Dr. Paul Offit explains this in his book *Autism’s False Prophets*.<sup>1</sup> The way the scientific method works, scientists can never prove a negative. They can examine the connection and find none, but they will rarely clearly say there is none.

But in a court of law, plaintiff claiming that MMR caused encephalitis would not have good evidence of general causation and would be unable to meet the “more likely than not” criteria. It’s not a case of uncertainty, but rather a case where the available evidence does not support the suggested link, (and that’s before the more recent studies (Lack of association between childhood immunizations and encephalitis in California, 1998-2008 and Safety of Measles-Containing Vaccines in 1-Year-Old Children that suggest there is no connection).

So, the problem is not that causation is uncertain. The problem lies elsewhere.

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<sup>1</sup> Paul A. Offit, *Autism’s False Prophets: Bad Science, Risky Medicine, and The Search For A Cure* 206-210 (Columbia University Press. 2010).

VICP is subject to a standard of causation that does away with general causation, as decided in Althen v. Secretary of Health and Human Services, 418 F.3d 1274, 1278 (2005) (citing Shyface v. Secretary of Health and Human Services, 165 F.3d 1344, 1352 (1999)), under which, a plausible theory presented by an expert, and coupled with temporal proximity, is enough to prove causation. Doing away with general causation means that even when there is no good scientific evidence of causation injuries will still be regularly compensated. In fact, with VICP, quite a few of the cases for which there is uncertainty are cases that would fail in regular courts on general causation. In other words, the question of whether the vaccine caused this specific injury proceeds although science does not show a connection between the type of injury and vaccines.

This is exacerbated by the presence on the Table of Injuries. The Table of Injuries was created to simplify the process of demonstrating causation. Currently, this list includes injuries that science has shown to be caused by vaccines, as well as some injuries that were once believed to be caused by vaccines, but for which the scientific evidence has now proved otherwise such as encephalopathy for DTP or encephalitis for MMR. This outdated list of injuries supports the need to revise and update the table in order to remove injuries that science has since shown are unrelated to vaccines. In addition, the program's mandate – being generous towards petitioners – seems to lead to compensation in weak cases. So, it's not that the science is uncertain for many types of claims. More often than not the issue is that the program compensates for some injuries that, under the scientific evidence, are not caused by vaccines. Among other things, the result can be that in being generous to the first petitioner, the program encourages others with equally unfounded claims to file suit. When the subsequent petitioners' claims are refused, these subsequent petitioners are bound to be frustrated, and to perceive the program as hostile and insensitive.

This is a value choice: a choice to allow compensation in cases where the evidence goes the other way.

### **Problems with Decision Aids:**

Engstrom highlights the fact that in 1988, the authors of the NVIC legislation envisioned that most petitioners' injuries would fit into the Table of Injuries. Now, most claims are decided off-table. She points out that aids like the Table are inherently problematic: if they include clear cases, they are of little value; if they include controversial claims, they become, themselves, controversial. Engstrom's points make sense, but the Table can still be a valuable aid to petitioners and to the program if it were to be updated. So the question is how to make the Table work to support the program. It may be a case where either changes to the program's design – like giving the power to update the table to a non-political body, rather than the secretary, for example – or standard setting – creating criteria for inclusion – are necessary. But I'm not convinced that the connection between the table's imperfection and Engstrom's complaints of delays and lack of consistency or delays is a strong one.

### **Boundary Issues:**

Engstrom points out that the existence of a special tribunal leads to questions of which claim should be decided where: should a claim go to the special tribunal, or to the regular courts? The author is completely right because whenever there are multiple systems there are questions of boundaries between them. For example, European civil law countries constantly face the question of

jurisdictional boundaries between administrative and regular courts. That's also true for no-fault programs that substitute for the courts, and is inherent in creating such programs.

But this issue is not directly connected to the problems of consistency and delays that the author highlights. While it is certainly something to consider when deciding whether an administrative substitute to the court system is appropriate, but it is one factor to consider, not the definitive answer.

### **Adversarial Issues Are Inescapable:**

Engstrom makes a powerful case that in the United States, no-fault programs are bound to become adversarial. That said, it might be more a question of culture – of the United States leaning towards adversarial legalism, as defined by Robert Kagan<sup>2</sup> - than of the no fault programs themselves. And adversarial as the program may have become the courts of justice, which have been proposed as an alternative by anti-vaccine activists, – are just as adversarial.

And while, again, it's a factor to consider when choosing whether to move to a no-fault system, it does not negate the value of VICP.

### **Why VICP is Still A Better Choice for Most Deserving Petitioners than Moving Vaccine Injuries Back to the Regular Courts:**

Engstrom discusses two main reasons for the creation of the VICP program: the need to protect the vaccine supply, and the difficulties petitioners had in winning cases. She points out that in terms of securing the vaccine supply, the program was a success. However, I believe she fails to give enough credit to the importance of the program in terms of the benefits to petitioners. I've addressed the issue in more detail [elsewhere](#), but I would like to conclude by highlighting two points. In the regular courts, plaintiffs would have to show a product defect, which Engstrom mentions would be difficult, especially given the extensive process for licensing vaccines. Additionally, in the regular courts, plaintiffs would have to show general causation, while bound by rules of evidence. With its relaxed caution standard, the VICP reduces the burden on petitioners in regard to admitting evidence. In other words, people believed to be injured by a vaccine will likely find it much harder and often impossible to win a case in the regular courts, even if the dismissal in the regular courts comes quicker.

I believe no-fault programs are appropriate to vaccine injuries because it would be troubling to require those injured by vaccines to prove fault. Vaccines provide two benefits: one to the person being vaccinated who is protected against disease, and the other to the general public. Those vaccinated contribute to herd immunity, and help prevent the disease from catching hold in the population. Because this is a general benefit, it is unfair to burden a specific individual with the cost of an injury. Rather it's more appropriate for the state to bear the cost, even if no one was at fault in causing the injury. And it's inappropriate to leave the victim with no remedy.

The United States is not the only country using a no-fault system to handle vaccine injuries. In fact,

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<sup>2</sup> Robert Kagan, *Adversarial Legalism: The American Way of Law* (Harvard University Press, 2001).

19 countries also use similar programs, and the difficulty of obtaining compensation in countries that don't – like Canada and Australia – help demonstrate the benefits of VICP.

In conclusion, while the current program may be imperfect, it's still much better than the alternative of sending vaccine injuries to the regular courts.