The Judges' Book

Volume 4 Article 11

2020

Health Law: The Unstoppable Growth of Prescription Drug Prices

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The Unstoppable Growth of Prescription Drug Prices

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Everyone has a limit. Every budget has an end point. Although sellers would love to raise prices continually, it doesn't take fancy economics to know that, at some point, the money runs out. Why isn't that basic principle working as expected in the pharmaceutical industry? Instead, drug prices are rising continually and reaching astronomical levels, with no end in sight. In May 2018, analysts reported that a company is contemplating a $1.5 million price tag for its new hemophilia cure.[2] Along the same lines, Spark Therapeutics's cure for a rare form of blindness will cost $850,000,[3] rivaling Novartis's planned $475,000 price tag for its Car-T drug Kymriah.[4] Similarly, an analyst report concluded that, in 2016, the average price for a set of specialty drugs known as "orphan drugs" was $140,000 a year and the average price of ordinary drugs was almost $28,000 a year.[5]

Beyond the eye-popping headlines, prescription drug prices across the board have risen to an alarming and puzzling level. A Health and Human Services Inspector General's report found that the high cost of brand medications for common conditions (diabetes, high cholesterol, and asthma) were the true problem for patients on Medicare.[6] In fact, pharmaceutical companies have raised the prices most sharply for commonly used medications such as these.

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1. Summarized and excerpted from ROBIN C. FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES (Cambridge 2019).

2. Meg Tirrell, *First U.S. Drug Priced at More Than $1 Million May be on the Horizon*, CNBC (May 7, 2018).

3. Meg Tirrell, *A U.S. Drugmaker Offers to Cure Rare Blindness for $850,000*, CNBC (Jan. 3, 2018).

4. Paul Kleutghen et al., *Drugs Don't Work If People Can't Afford Them: The High Price of Tisagenlecleucel*, HEALTH AFF. (Feb. 8, 2018).

5. EvaluatePharma, *Orphan Drug Report 2017* (2017).

6. Ricardo Alonso-Zaldiviar, *Feds: Skimping Can't Save Seniors from RisingMed Cost*, AP NEWS (June 4, 2018); *see also* Ned Pagliarulo, *To Shame Drugmakers, CMS Publicizes Price Hikes*, BIOPHARMA DIVE (May 16, 2018); Ctr. for Medicare & Medicaid Serv., Fact sheet, *Drug Spending Information Products* (2018).

The list price of drugs tells only part of the story, given the many rebate and discount processes that exist within the industry. Nevertheless, real spending for drugs is rising as well. According to the Inspector General's report, even after accounting for rebates, Medicare spending for branded drugs still rose 62 percent between 2011 and 2015.[7] Worse yet, the department responsible for Medicare and Medicaid projects that the increase in national prescription drug spending will more than double in 2018 from the prior year's significant rise.[8] In 2017, this increase in spending outpaced increased healthcare spending as a whole and the 2017-18 consumer price index (CPI).[9] All of this has happened despite the fact that roughly 80 percent of the prescriptions in this country are filled using generic drugs.[10]

No one would ever suggest that spending within the healthcare system follows an ordinary, rational model. The patient as consumer does not absorb the full costs of healthcare, given the effects of private insurance and government programs.[11] Nor does the consumer possess full information about the products purchased or the cost of choices, and even physicians may experience information gaps. Most importantly, the value consumers place on their own lives creates distortions that differ from buying choices in ordinary markets. Nevertheless, dollars are finite, and some limits must exist.

One can see the mounting pressure on government budgets, which are struggling to cover the cost of new, expensive medicines. If the Defense Department had treated all Veterans Administration (VA) patients infected with hepatitis C in 2015 using the breakthrough cure Sovaldi, the $12 billion cost would have accounted for 20 percent of the Department's

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7. Alonso-Zaldiviar, *supra* note 6.

8. Norman R. Augustine et al., *Making Medicines Affordable: A National Imperative*, NAT'L ACAD. SCI., ENG'G, & MED. 76 (2017) [hereinafter NAS REPORT]; Ed Silverman, *Spending Growth on Prescription Drugs Will Double This Year*, STAT (Feb. 14, 2018).

9. NAS REPORT, *supra* note 8, at 25. *See also* U.S. Dep't of Labor, Bureau of Labor Statistics, *Prescription Drugs in the U.S. City Average, All Urban Consumers, Seasonally Adjusted* (2018); Silverman, *supra* note 8.

10. How Critics Say Drug Companies Play "Games" to Stave off Generic Competitors, CBS NEWS (Feb. 2, 2018); Rachel Schmidt & Shinobu Suzuki, *The Medicare Prescription Drug Program (Part D): Status Report*, MEDICARE PAYMENT ADVISORY COMM'N 11 (Jan. 11, 2018).

11. ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 16, 86, 97 (2017).

annual medical budget—just for treating a single disease.[12] With budgets in the home, patients report rationing or forgoing medications for lack of funding.[13] This is precisely the type of boundary point that should create pressure to reduce prices. And yet the rise persists.

This phenomenon has puzzled modern commentators and policymakers alike. Why do drug prices stubbornly continue to rise, despite the promise of competition from generic drugs? Quite simply, the phenomenon occurs because internal incentives push every market participant toward behaviors that increase prices, knocking out the normal checks that should operate as breakpoints on the market.

At the center of the system lies the highly secretive and highly concentrated industry known as "pharmacy benefit managers" (PBMs). These middle players negotiate prices between branded drug companies and those who pay the bills, arranging for rebates from various drug companies. PBMs also establish formularies, which are the schedules that determine whether patients can access particular drugs and the reimbursement rates patients will get. The PBM middle players are supposed to act to ensure good bargains for patients and health insurers, but the reality is far from that ideal. Moreover, the system is deeply hidden. The contracts between drug companies and the PBMs are a closely guarded secret, with the details known only to the drug companies and the PBMs themselves. Government entities and the private insurers who pay the bills are not permitted to see the full terms of the contracts. Even their auditors generally are not permitted full access to the contract terms.[14] Those who pay are given periodic rebates without full information regarding the actual net pricing for any particular drugs. The system is reinforced by lockstep contracting in the highly concentrated PBM market and claims of trade secrecy, which have yet to be fully vetted in the courts. Markets thrive on information, and, from the standpoint of competition, such an industry design is problematic.

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12. Patricia Kime, *VA, DoD Spend More than $450M on Costly Hepatitis Drug*, USA TODAY (Jan. 8, 2015).

13. NAS REPORT, *supra* note 8, at 110; Robyn Tamblyn, *The Incidence and Determinants of Primary Nonadherence with Prescribed Medication in Primary Care: A Cohort Study*, 160 ANN. INTERN. MED. 441 (2014).

14. Linda Cahn, *Don't Get Trapped By PBMs' Rebate Labeling Games*, MANAGED CARE (Jan. 1, 2009); Michael Hiltzik, *How "Price-Cutting" Middlemen Are Making Crucial Drugs Vastly More Expensive*, L.A. TIMES (2017); Neil Weinberg & Robert Langreth, *Inside the "Scorpion Room" Where Drug Price Secrets Are Guarded*, BLOOMBERG (May 4, 2017).

Despite the extreme secrecy, details have begun to seep out—through case documents (including recent contract disputes among parties), government reports, reports to shareholders, state Medicaid actions, and industry insider reports. Piecing together information from these original sources reveals—for the first time—a full picture of the perverse profit-taking incentive structures in the industry. Encouraging consumers to use drugs with higher prices operates in the interests of so many players—including doctors, clinics, hospitals, PBMs, brand-drug companies, health plans, patient-assistance programs, and patient-advocacy groups. Payment flows are structured so that higher prices benefit the very intermediaries who should be the watchdogs for the patients. Given these incentive structures, higher-priced drugs receive more favorable reimbursement treatment, and patients are channeled toward more expensive drugs.

The system also operates to support competition-free zones for pharmaceutical companies. The perverse incentive structures allow pharmaceutical companies to share monopoly profits with parties at each level of the market, maintaining their position at the top and ensuring that lower-priced competitors cannot knock them off their perch. In exchange for financial payoffs, structured in different ways to appeal to different groups, drug companies can ensure that, as lower-priced substitutes enter the market, those firms cannot gain a foothold.

Although Hatch-Waxman encourages the rapid entry of generic drugs as soon as patents expire, drug companies have proven extraordinarily adept at holding onto their protections. Companies can move through a progression by, first, extending patents and exclusivities to block generic approval; then (for some companies), paying generics to stay off the market when approval looms; and, finally, moving on to formulary games to keep generics from gaining traction in the market.

Thus, the rebates that drive prices higher do more than feed the spread for intermediaries such as PBMs; they also enhance a drug company's ability to continue extending protections of its drugs. That broader behavior has become pervasive.

In the past, anecdotal evidence has identified examples of "evergreening," which can be defined as artificially extending the life of a patent or other exclusivity by obtaining additional protections to extend the monopoly period.[15] Scholarly work, including my own, has

15. ROBIN FELDMAN, RETHINKING PATENT LAW 170–78 (2012).

documented these behaviors as examples have emerged in individual cases and in press reports.[16]

One cannot overstate the value to companies of engaging in evergreening strategies. Consider the simple approach of combining existing drugs into a single medication. Although patents on the individual components may have expired, companies can reclaim their market positions by patenting a pill that combines the components. For example, a recent study in the highly respected *Journal of the American Medical Association* looked at Medicare spending on branded combination drugs, the individual components of which are available in generic form. The study concluded that Medicare could have spent close to $1 billion less if patients had simply bought the generic medications and taken them together.

Thus, despite the quaint theory that competitors will enter after a pharmaceutical patent expires, the reality appears quite different. Numerous strategies and opportunities exist that allow companies to extend their protection and prolong the period of market monopoly for their drugs. Such strategic behavior involving patents and exclusivities has been explored primarily from a theoretical standpoint and by means of case studies. But just how pervasive are such behaviors? Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry? Only by answering these questions can we contemplate the extent to which strategic behaviors aimed at blocking competition may be contributing to rising drug prices.

I conducted such a robust empirical analysis. It was no easy task. Transparency is not in the industry's interests, and companies have been known to go to great lengths to camouflage strategic behavior.[17] After all, a pharmaceutical company would be loath to let regulators and legislators know what it is up to, let alone competitors, which might mimic the clever strategies. To accomplish the study, I turned to government sources,

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16. FELDMAN & FRONDORF, *supra* note 11; Robin Feldman et al., *Empirical Evidence of Drug Pricing Games: A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39 (2017); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009). One admirable empirical analysis exists, of the period 1988-2005, which looks at secondary patents rather than all forms of exclusivities. *See* Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE 1, 1 (2012).

17. FELDMAN & FRONDORF, *supra* note 11, at 49–65.

analyzing more than a decade of data published by the Food and Drug Administration (FDA). This involved extracting and analyzing detailed information on as many as 11 different aspects of roughly 1,800 drugs.

The task would have been sufficiently challenging if the information were readily available. It was not. The project required teasing information painstakingly out of each monthly and annual publication, many of which are no longer available from the government in any form. Moreover, the complexities of pharmaceutical regulation and approval require intricate analysis of the information disclosed by the government, when that information is disclosed at all. In all, the work required assembling and analyzing more than 160,000 individual cells of data, all entered by hand. Consistent with a commitment to transparency and ethical standards in data-driven academics, the data set has been made publicly available.

The results, however, are striking, and they show a startling departure from the classic conceptualization of intellectual property rights protection for pharmaceuticals. The data demonstrate that, throughout the industry, companies create serial barriers to hold off the type of competitive entry that is fundamental to our innovative system.

Key results include the following:

- Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, 78 percent of the drugs associated with new patents were not new drugs coming on the market; they were existing ones.
- Adding new patents and exclusivities to extend the "protection cliff" is particularly pronounced among blockbuster drugs. Of the roughly 100 bestselling drugs, more than 70 percent had their protection extended at least once, with more than 50 percent having the protection cliff extended more than once.
- Looking at the full group, almost 40 percent of all drugs available on the market created additional market barriers by having patents or exclusivities added on to them.
- Once a company starts down this road, there is a tendency to keep returning to the well. Of those that added protections, 80 percent added more than one.
- Among those adding more than one barrier, some were serial offenders, with almost half adding four or more protections and some adding more than 20.

- The problem is growing across time. The number of drugs that had a patent added on to them almost doubled during the period of study. The addition of certain other types of barrier, such as "orphan drug" exclusivity, increased at an even greater rate—some even tripling.

These results may easily understate the landscape. The methodology repeatedly adopted a conservative approach, following the path that would point away from suggesting a competitive barrier. In addition, the pharmaceutical industry has developed techniques for erecting competitive barriers that do not involve obtaining additional patents and exclusivities—techniques that would not be captured by the analysis.[18] Finally, the analysis examined only the patents listed at the FDA. A range of other patents exist that drug companies do not need to file.[19]

For the first time in the literature, these results definitively show that stifling competition is not limited to a few pharma bad apples; rather, it is a common and pervasive problem endemic to the pharmaceutical industry. Although the end of life for a patent or exclusivity may be a traumatic event in the life of a pharmaceutical enterprise, companies increasingly decline to "go gentle into that good night."[20]

In short, this is not an image of innovation and competitive entry; it is an image of a system that provides for repeated creation of competition-free zones, pushing a competitive market further and further out into the future. The problem is not only pervasive and persistent; it is also growing across time. Against this backdrop, it is no wonder that drug prices are skyrocketing.

The book also describes changes within the legal system that could better realign incentives. For example, approaches such as "one-and-done" for drug protection, properly interpreting the obviousness requirement in patent law, and ruthless simplification, coupled with transparency measures, could go a long way toward returning the system of pharmaceutical innovation to its proper competitive pathway.

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18. Feldman et al., *supra* note 16; HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 12.5 (2002); Mark S. Levy, *Big Pharma Monopoly: Why Consumers Keep Landing on "Park Place" and How the Game is Rigged*, 66 AM. U. L. REV. 247, 276–79, 291–93 (2017).

19. 21 C.F.R. § 314.53(b).

20. DYLAN THOMAS, THE COLLECTED POEMS OF DYLAN THOMAS: THE ORIGINAL EDITION 122 (Paul Muldoon ed. 2010).

There will, of course, be much wailing and gnashing of teeth. The drug industry has become comfortably accustomed to working with a system that provides space for creating noncompetitive environments. The industry will not relinquish this environment with ease and grace, and the nation is likely to hear impassioned pleading that pharmaceuticals cannot withstand any reform of the current system.[21] Foreshadowing such public relations battles, the chief executive officer of pharmaceutical company Allergan published a 2017 op-ed in the *Wall Street Journal* arguing that the 2011 patent reforms, which created a new post-grant review process for patents, left the company with no choice but to transfer its patents to Indian tribes to avoid having its patents reviewed. When companies plead with the government for beneficial treatment by arguing that they cannot withstand competition, one should be deeply skeptical. Our challenge as a society is to restore the balance provided by the patent system itself, in which the inventor of a truly innovative product receives a limited period of time in which to attempt to garner a return, following which open competition reigns supreme. The system has strayed far from that ideal.

As a final thought, imagine the landscape a decade from now. Where will we be if drug prices have continued to soar—if basic medications cost tens of thousands of dollars a year and more complex medications cost millions—and if drug development continues to focus on churning and repurposing existing drugs, with little true innovation? Is that the future we wish to usher in? Perhaps, instead, we will have stepped back from the precipice, bringing some measure of sanity and rationality to an industry that has defied efforts to introduce competition. Or perhaps we should all reach for anti-anxiety medication. At least today, it's a mere $1,285 for 30 tablets.[22]

21. Brent Saunders, *Reverse Patent Trolls are Harming Drug Innovation – and Patients*, WALL ST. J. (Oct. 8, 2017).

22. *Latuda Prices, Coupons and Patient Assistance Program*, DRUGS.COM, www.drugs.com/price-guide/latuda (last visited Oct. 30, 2018). For the inspiration for this sentence, see Jeff Mosenkis, *IPA's Weekly Links*, CHRIS BLATTMAN BLOG (Sept. 14, 2017).

Health Law:
Why Anti-Vaccine Claims About NVICP Cases are Wrong

Dorit Reiss[1]

This Chapter provides an introduction to the National Vaccine Injury Compensation Program and its autism jurisprudence. The Chapter also examines claims by anti-vaccine activists that certain decisions by a special administrative program created to compensate vaccine harms, and settled cases in that same program, are evidence that vaccines cause autism. The claims are mistaken, not only because extensive scientific evidence shows no such link, but also because the program the cases came from—the National Vaccine Injury Compensation Program (NVICP)—has, when examining directly whether vaccines cause autism (and at this point, there have been several cases using several theories to make the claim), found no link between vaccines and autism, and the cases used as evidence are cases that did not directly address the question. In essence, trying to claim that using off-topic cases from a program that, when it squarely faced the topic, went the other way as evidence is highly problematic.

A recurrent concern of parents who do not vaccinate is the long-standing claim—over two decades old at this point—that vaccines cause autism-spectrum disorder. Extensive studies from all around the world, covering millions of children (and reaching back for decades), have found no such link. A strong scientific consensus exists, in the United States and abroad, that vaccines do not cause autism. Nonetheless, a small but dedicated group of opponents—the Vaccines Cause Autism Community—continues to argue that vaccines cause autism. One of the tools they have used repeatedly is to claim that cases compensated by the National Vaccine Injury Compensation Program demonstrate that vaccines cause autism.

Other scholars have highlighted the tension between science and the law and suggested that legal decisions cannot overcome a scientific

1. Summarized and excerpted from Dorit Rubinstein Reiss & Rachel Heap, *Using and Misusing Legal Decisions: Why Anti-Vaccine Claims about NVICP Cases Are Wrong*, 20 MINN. J.L. SCI. & TECH. 191 (2018).

consensus.[2] But courts have a role in examining causation and addressing scientific uncertainty.[3] While courts do not directly do science, they routinely have to rule on scientific questions and examine the limits of scientific knowledge. This Chapter addresses opponents' claims that these cases show that vaccines cause autism from a different direction. It explains that the specific cases in question, examined seriously, cannot be used to support the claim that vaccines cause autism because none of them compensated a child on the legal theory that vaccines cause autism, most of them were settlements, and many of them compensated children for specific issues that were not autism.

The National Vaccine Injury Compensation Program is a no-fault program, created in response to a crisis in the 1980s. In response to an increase of lawsuits against vaccine manufacturers, manufacturers were leaving the market, and Congress was concerned about the vaccine supply. Plaintiffs, too, were dissatisfied with the legal process, where most lawsuits were dismissed or otherwise failed. A coalition of unlikely allies—concerned health officials, doctors, anti-vaccine organizations, and manufacturers—led to the passage of the National Childhood Vaccine Injury Act, which, among other things, created the NVICP.[4] The final result, as explained by Anna Kirkland, was a set of compromises nobody was completely happy with, but everyone could live with.[5]

The program's goals were several and included making compensating claims easier and more certain and protecting the vaccine supply. Before litigating a claim of harm from a vaccine, claimants have to go through the program. The process for obtaining compensation includes substantially less of a showing than a civil lawsuit would. As a no-fault program, petitioners do not have to show a product defect (or negligence). Causation is also relaxed. For some injuries, listed in a special table of injuries, causation is presumed. Even for those not on the table, general causation does not have to be demonstrated by scientific literature but can be supported by a plausible expert opinion. The goal was to allow scientific

2. Joelle Anne Moreno, *"It's Just a Shot Away": MMR Vaccines and Autism and the End of the Daubertista Revolution*, 35 WM. MITCHELL L. REV. 1512, 1517 (2009).

3. Joelle Anne Moreno, *Toxic Torts, Autism, and Bad Science: Why the Courts May Be Our Best Defense Against Scientific Relativism*, 40 NEW ENG. L. REV. 409 (2006).

4. 42 U.S.C. § 300aa, *et seq.*

5. ANNA KIRKLAND, VACCINE COURT: THE LAW AND POLITICS OF INJURY (2016).

uncertainty to be resolved in favor of claimants. Further, the special masters are not bound by the rules of evidence, reasonable lawyer fees and litigation costs are covered by the program, and contingency fees are disallowed. The program has some disadvantages for claimants compared to regular courts: there is a three-year statute of limitations that is not tolled for minors, discovery is limited and in the special master's discretion, and compensation for death and noneconomic damages is capped at $250,000, a sum not updated since the law was enacted.

The Vaccines Cause Autism Community's claim that the program's body of cases shows that vaccines cause autism misuses those cases. Many of the cases are settlements, where the government denied causation but settled the case anyway—and those cases cannot be used as evidence of causation. In other cases, the theory of compensation was not autism. In some cases, the compensation was given for a seizure disorder, which is not autism; in others, it was given for encephalopathy—a general brain disorder that is different than the criteria used to diagnose autism. Further, because in the 1980s, when the program was created, some data suggested that the DTP vaccine, then used to protect children against diphtheria, tetanus, and pertussis, was a rare cause of brain damage and seizure disorder, in the early stages seizure disorder and encephalopathy were included in the table of injuries, and causation was presumed for these cases unless the government proved another cause.

Large studies since have not found a link between the DTP vaccine and brain damage or seizure disorder, and additional evidence suggested a genetic cause for most seizure disorders, including those initially blamed on vaccines. But studies like this take time to do, and at the time many of the cases in question were decided, the data were not yet available. Several of the cases were compensated for seizure disorder based on the then-available data and may well have gone the other way if litigated today. They were also, again, not directly about autism. In fact, in some of the cases used to allege that vaccines cause autism, the claim that the child's problem was autism was raised by the government as an argument against compensating the family—and rejected. In others, the court expressly stated that the child's problem was not autism.

Using these cases as evidence of a link between vaccines and autism is highly problematic. Only one case even comes close. In a case involving a child named Hannah Poling, the government conceded that vaccines may have aggravated and made more severe the child's encephalopathy, which was the result of a pre-existing mitochondrial disorder—of genetic origin, and that the child's encephalopathy had "features of autistic spectrum

disorder." However, even that case cannot be convincingly used as evidence linking vaccines and autism. First, the child's main problem was a genetic one, an extremely rare and severe one, which likely predisposed her to regress regardless of whether she was or was not given vaccines. Second, the link between the vaccines and her condition was tenuous, and later cases rejected an alleged link between mitochondrial disorders and vaccines harms. Because the Poling case was conceded by the government, we will never know the result had it been fully litigated. But the trajectory of the later cases does not support using it as evidence.

Finally, in addition to the fact that the cases in question were either never fully adjudicated or not decided on a theory that vaccines caused a child's autism, NVICP did explicitly litigate claims that vaccines cause autism. First, in 2009-2010 it litigated a set of cases serving as test cases in the Omnibus Autism Proceedings. After extensive hearings and abundant evidence submitted, six detailed, thorough NVICP decisions rejected the alleged link based on two legal theories: that the measles, mumps, and rubella vaccine caused autism, or that thimerosal—a mercury-based preservative present in tiny amounts in vaccines until 2000—caused autism when present in vaccines. Later decisions rejected other theories trying to link vaccines and autism, such as claims of mitochondrial disorder making children vulnerable to autism if given vaccines, or the claim that fetal DNA in vaccines caused autism.

Using off-topic cases, or settled cases, from a program that looked at the issue directly and arrived at an opposite conclusion, is not a good way to support a claim. NVICP directly addressed several theories on the link between vaccines and autism, and in careful and detailed decisions explained why they are invalid. Several of these cases have been appealed up to the federal circuit courts, and the decisions were upheld. Under these circumstances, it is at best an error to try to use the other cases discussed here—where a family was not compensated based on a child's autism, but on a different claim—to try and counter the extensive scientific evidence showing that vaccines do not cause autism.