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Performance of the United States Vaccine Injury Compensation Program (VICP): 1988–2019

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Abstract

The United States (US) highly values the individual and societal benefits of vaccination and invests significantly in vaccine development and use as part of its national vaccine enterprise. In 1986, recognizing the small, but non-zero risks associated with vaccines, the US created a mechanism to collect excise taxes on each dose of vaccine to fund a national Vaccine Injury Compensation Program (VICP). The VICP includes a system for those claiming serious injuries from vaccines to seek compensation, and a process to pay individuals with legitimate claims and their legal counsel. Given the maturity of the VICP, we review experience with the vaccines and injuries covered, claims, and economics of the fund. Our review shows the excellent safety track record of vaccines, provides some evidence of injuries related specifically to vaccine delivery, and discusses the financial health of the fund.

Introduction

In the United States (US) vaccines prevent a significant burden of disease[1] and save substantial amounts of financial resources [2]. The US highly values the individual and societal benefits of vaccination, and invests significantly in vaccine research and development [3] as part of its national vaccine enterprise. Different partners in the enterprise contribute varying amounts of funds at various stages, including basic research (e.g., to answer questions about what is a protective immune response and how to induce it), clinical testing, manufacture, distribution, administration, and post-market monitoring and surveillance [3].

Concerns about the decline in vaccine manufacturers in the US following increased litigation in the 1970s and 1980s that made vaccine production less attractive, the US government sought a strategy that would ensure an adequate vaccine supply at an affordable cost and a vaccine enterprise that would provide sufficient incentives for the pharmaceutical industry to continue to develop new vaccines [4]. In 1986, the National Childhood Vaccine Injury Act (Public Law 99–660) recognized the health benefits of vaccination as well as the small, but

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non-zero individual risks associated with vaccines and the societal obligation to compensate individuals who suffer serious injuries associated with vaccine administration (independent of whether administered in the private or public sector) [5]. This act created the Vaccine Injury Compensation Program (VICP) as a mechanism to collect excise taxes on each dose of vaccine to pay for compensation. The enabling legislation for the VICP (Public Law 99–660, Section 312(b)) created a Vaccine Injury Table (42USC§100.3) that lists the illness, disability, injury, or condition covered, and the time period for first symptom or manifestation of onset of significant aggravation after vaccine administration. Since its creation, the VICP continued to grow and evolve. This review explores the changes in the VICP and associated legislation, the evolution of vaccine injuries covered, and the experience with claims and economics.

VICP legislation

Considering the initial Vaccine Injury Table, in 1987 Congress established an initial time-limited federal excise tax "based on the number of anticipated doses and current scientific views about the relative risk from each vaccine" [6]. It set the nominal amounts per dose of $4.56 for diphtheria-pertussis-tetanus (DPT), $4.44 for measles-mumps-rubella (MMR), $0.29 for oral poliovirus vaccine (OPV), and $0.06 for diphtheria-tetanus (DT) for the period of January 1, 1988 to December 31, 1992 for injuries incurred after September 30, 1988 and before October 1, 1992 [7]. Congress also appropriated funds for claims for injuries that occurred prior to October 1, 1988 (pre-Act cases) to support the initial phases of the program [6, 7]. After a brief lapse (with no tax applied in early 1993), on August 10, 1993 the federal excise tax became permanent and resumed at the prior nominal cost levels, and the creation of the Vaccines for Children (VFC) Program established a mechanism for ensuring universal pediatric immunization coverage in the US [8]. The Taxpayer Relief Act of 1997 [9] subsequently lowered the federal excise tax to a nominal amount of $0.75 per dose for each vaccine-preventable disease (i.e., $2.25 per MMR dose since MMR prevents 3 diseases), and the tax continues at that nominal amount to date (e.g., the real value of the tax decreases over time due to the use of a fixed nominal fee despite inflation). Manufacturers pay these excise taxes into the Vaccine Injury Compensation Trust Fund. In addition to paying for injury compensation and legal fees, the trust fund also provides financial support for VICP-related administrative expenses incurred by the Department of Health and Human Services (DHHS), Department of Justice, and the Claims Court (estimated total of approximately $10 million per year in the mid-1990s [6]).

The VICP covers all vaccines recommended by the US Advisory Committee on Immunization Practices (ACIP) for routine administration to children and subject to the excise tax by federal law. The ACIP recommendations also determine which vaccines are covered by the Vaccines for Children (VFC) program. Thus, as the ACIP increasingly recommends new pediatric vaccines, the list of covered vaccines increased. The VICP covers claims by individuals of all ages if the vaccine category is recommended for routine use in children (e.g., influenza vaccine), but it does not cover claims for vaccines that exclusively target adults (e.g., herpes zoster vaccines for shingles). Thus, no compensation mechanism similar to VICP exists in the US for vaccines recommended exclusively for adults. However, in 2016, the 21st Century Cures Act (Public Law 114–255) expanded VICP coverage to

include vaccines recommended for use in pregnant women, and clarified use of VICP funds to cover injuries alleged to have been sustained by both the pregnant women and their children who were *in utero* during the pregnancies.

The VICP set up a no-fault alternative to the traditional tort system [10]. This reduced the liability for vaccine manufacturers in a highly-litigious society and facilitated more rapid compensation for injured individuals. Although we cannot explore the counterfactual, the strategy of creating the VICP appears successful based on historically high immunization rates and low rates of most vaccine-preventable diseases [4]. Further, the law requires all petitioners alleging vaccine injuries by VICP-covered vaccines to go through the VICP process before they could access the traditional tort system, regardless of whether or not the claims are for Vaccine Injury Table-related injuries. This strategy continues to help with keeping vaccine manufacturers in the market, ensuring a stable vaccine supply, and providing some incentives for vaccine innovation by providing some protection from litigation [10].

Vaccines and injuries covered over time

Part of the DHHS, Health Resources and Services Administration (HRSA), the Division of Injury Compensation Programs (DICP) administers and reviews VICP claims and updates the Vaccine Injury Table. Table 1 provides a summary of the vaccines/diseases covered by the excise tax, the date that the tax started, the Public Law that mandated the tax, the date the vaccine was listed in the Vaccine Injury Table, and the reference for its listing. With additional vaccines included in the list of ACIP-recommended vaccines and new information about existing vaccines obtained over time, the Vaccine Injury Table expanded to include more covered injuries and dropped some others.

Table 2 provides details about the evolution of vaccines and injuries eligible for coverage by the VICP over time. The left column in Table 2 summarizes the vaccine injuries (i.e., illness, disability, injury, condition, or death) covered for the relevant time period for the “first symptom or manifestation of onset of significant aggravation” (42USC§300.aa-11(C)(i)) of any injury after vaccine administration and the date of its inclusion in the Vaccine Injury Table. The middle column in Table 2 summarizes the vaccines for which the injury is covered and the date of the addition of each type of injury for each specific vaccine. Notably, the inclusion of a vaccine in the Vaccine Injury Table can take some time due to delays in the establishment of the excise tax, delays observing the specific injuries, and/or administrative processes required to add items. However, once included, claims submitted for any conditions can be evaluated and compensated. The right column in Table 2 notes the date of removal of some injuries from the table.

VICP claims

Each month the DICP publishes a report on the status of the VICP [11]. According to the November 2019 report, over its 30-year history, the VICP has received more than 21,000 petitions (or claims), adjudicated more than 18,300, determined approximately 6,900 to be compensable (with the other approximately 11,400 adjudicated petitions dismissed), and

paid approximately $4.2 billion in total compensation, roughly 8% of this for attorney's fees [11]. Notably, most individuals awarded VICP funds (approximately 70%) receive them as a result of negotiated settlements between the parties for which review of the evidence did not lead to a conclusion that the vaccine(s) caused the alleged injury [11]. The US experience with the delivery of more than 3.4 billion vaccine doses during 2006–2017 (for which the DCIP has estimates of doses administered) suggests that compensation for vaccine injury occurs for approximately one out of every one million doses [11].

Table 3 summarizes the numbers of claims by specific vaccine and the outcomes of those claims for the entire program to date (10/1/1988–11/1/2019) [11]. We estimated the current percentage of current claims pending (as of November 2019) for each vaccine in the third column from the right. The vaccines with 0% pending claims represent vaccines no longer or rarely used due to changes in US vaccine policy that led to the end of some vaccine-associated injuries and claims (e.g., vaccine-associated paralytic polio with the cessation of oral poliovirus vaccine (OPV) use, claims for standalone antigens (e.g., measles, rubella) now used in combination vaccines (e.g., MMR), and claims for combination vaccines (e.g., MR) now replaced by other combination vaccines (e.g., MMR)). We also estimated the current percentage of all total pending VICP claims associated with each vaccine in the second column from the right, and left the zeroes for vaccines with no pending claims blank. These results demonstrate that over 67% of pending claims involve influenza vaccines.

We could not obtain comparable data for the number of doses of each vaccine delivered during the entire time period of the VICP. However, the DICP reports the claims and doses distributed data for 1/01/2006 through 12/31/2017. We included the doses distributed for that time period in the rightmost column of Table 3 for context, although we emphasize the non-comparable time period. With the rightmost column excluding the doses distributed prior to 2006, we see 0 doses distributed for vaccines the US stopped using prior to 2006 [11]. A striking result of inclusion of the rightmost column comes from the significant number of doses for influenza since 2006 (i.e., 1.5 billion of the 3.5 billion doses or over 40% of all doses of VICP covered vaccines for 2006–2017). We highlight the large number of influenza claims, because although initially VICP claims were on behalf of children, the addition of influenza vaccine as a covered vaccine in 2005 led the claims for adult injuries to dominate VICP claims. As the years with inclusion of influenza vaccine as eligible for a VICP claim increase, we expect claims related to influenza vaccines will become the majority of all VICP claims ever compensated.

Figure 1 shows the number of new claims filed each fiscal year (FY, October 1-September 30, year shown in figure corresponds to the end of the fiscal year) and the outcome of the adjudicated claims (compensated or dismissed), along with the implied pending claims in the queue. The DICP reports that "on average, it takes 2 to 3 years to adjudicate a petition after it is filed" [11]. Figure 1 demonstrates the consequences of time delays between the filing of the claim and adjudication in the yellow line of pending claims. Notably, number of pending claims (the yellow line in Figure 1) increased substantially starting in 2003 when the program received a large and increasing number of claims alleging autism that led to a special process for evaluation [12]. These claims accumulated as the special process played out in the courts with court rulings in 2009 and 2010 on the test cases for the 3 theories of

causation put forth by petitioners [13] followed by upholding of these decisions on appeal [4]. Following the court decisions related to these claims, the VICP cleared the large backlog and it adjudicated a disproportionately large number of submissions in 2011 and 2012 as it dismissed those claims.

Review of claims by the DICP can lead to publications of case series; for example for shoulder injuries related to vaccine administration (SIRVA) [14, 15]. SIRVA may occur following the unintentional injection of vaccine into tissues under the deltoid muscle of the shoulder [14]. We highlight SIRVA because it represents a common injury that applies across injected vaccines (independent of the biological components of vaccines). The DICP recognized SIRVA after noticing an increasing number of claims related to shoulder injuries for 2006–2010 [14]. Review of the scientific and medical evidence by the National Academy of Medicine found convincing support for a causal relationship between vaccine administration and deltoid bursitis [16]. SIRVA appeared in the Vaccine Injury Table in 2017 for all injectable vaccines, and the DICP continues to engage in efforts across the vaccine enterprise to raise awareness about and reduce these injuries. Table 4 shows the number of adjudicated claims compensated and the compensation paid by fiscal year (FY) since FY2011 for SIRVA. For FY2019, approximately 82% of the 510 compensated claims involved influenza vaccine. A recent review of SIRVA claims similarly showed an increasing number of claims per calendar year, discussed the variable nature of the claims, and reported that most SIRVA claims involved women (83%) and influenza vaccine (84%) [15].

Vaccine Injury Compensation Trust Fund performance

Figure 2a shows the total inflows (from excise taxes and interest paid on investments of funds held in trust by the US Treasury) by fiscal year since FY1992, since we could not find any report available before FY1992 (note that the report for FY2019 is also not yet available) [17]. Figure 2a shows the significant increase in inflows that resulted from both the increasing number of vaccines and doses included, with a notable jump after the inclusion of influenza vaccine.

Figure 2b shows the outflows over time by fiscal year, including payments to attorneys and administrative cost payouts for the US Claims Court and US Department of Justice [11, 17]. As shown in Figure 2b, the payments going toward the compensation of claims (i.e., compensation of petitioners) represent the bulk of the payments and administrative costs remain relatively low.

Overall, the dynamics of VICP (inflows and outflows) appear relatively stable and predictable, with the amounts of collected taxes exceeding the amounts of paid compensation, and interest payments on the fund (invested by the Department of the Treasury) also leading to significant revenue. Figure 2c shows the accumulation of equity in the Trust Fund over time [17], with a current balance exceeding $3.8 billion. Based on data for 2012–2018, the fund receives currently receives an average of approximately $324 million per year, and the VICP pays average compensation and administrative expenses of approximately $252 million per year [17]. Given delays in the adjudication of claims of

approximately 2–3 years, the fund should hold conservatively around $1 billion in reserve for expected payouts of existing claims.

Discussion

Recognizing the success of the VICP model, the National Vaccine Advisory Committee (NVAC) made two recommendations in the mid-1990s to the Secretary of HHS to extend the model to other vaccine safety initiatives. In September 1996, NVAC recommended establishing an additional $0.05 flat tax per antigen earmarked “to improve the understanding of vaccine safety” [18]. A year later, NVAC further recommended that the Secretary of HHS “propose legislation amending the Public Health Service Act to allow limited and judicious use of resources from the Vaccine Injury Compensation Trust Fund for purposes of expanding national vaccine safety activities, which are key to both fair compensation and prevention of vaccine-associated adverse events” [19]. Despite these recommendations, no changes have occurred and the excise tax remains a nominal $0.75 per disease for covered vaccines.

Although vaccine injury compensation programs exist in many high-income countries (with some dating back to the 1960s), other countries do not use the same approach as the US, despite success of the VICP model in the US [20]. Global vaccine injury compensation programs vary considerably in structure, and most do not include a dedicated trust fund generated by a specific excise tax, because countries with national health care systems cover vaccine injury-related costs in their annual health budgets [20]. The differences in litigiousness and compensation lead to different needs and incentives for the multiple stakeholders in the US vaccine enterprise than in other countries.

The size and nature of the VICP program allow the US to identify some injuries that might otherwise go unrecognized, and to consider strategies to incentivize efforts to reduce or eliminate them. Specifically, to the extent that innovations that improve existing vaccines and/or vaccine delivery technologies address an identified vaccine safety issue, these innovations offer the potential to reduce future VICP claims. For example, vaccine delivery technologies that avoid injections offer the potential to eliminate SIRVA (and provide multiple additional benefits that fall outside of the VICP (i.e., externalities), such as eliminating occupational needle-stick injuries and sharps disposal requirements that affect the health system).

With the continued high-performance of the VICP, we suggest that some opportunities may exist to use insights from reviews of VICP claims and some VICP resources to reduce future VICP claims. Any changes to the VICP must preserve its critical role in providing payment to individuals entitled to compensation for vaccine-related adverse events, and any “use of the resources must not interfere with the Program’s capacity to adequately provide such payments” [19].

The VICP represents a successful model for managing the risks of medical interventions in the US, and could serve as a potentially effective strategy for other necessary medications for which manufacturers face sufficiently high liability that the market is fragile or

threatened. With more than 30 years of experience with the VICP, we should recognize that the VICP continues to support the health and growth of the US vaccine enterprise, and consider further opportunities to learn from it to further improve the health and welfare of Americans.

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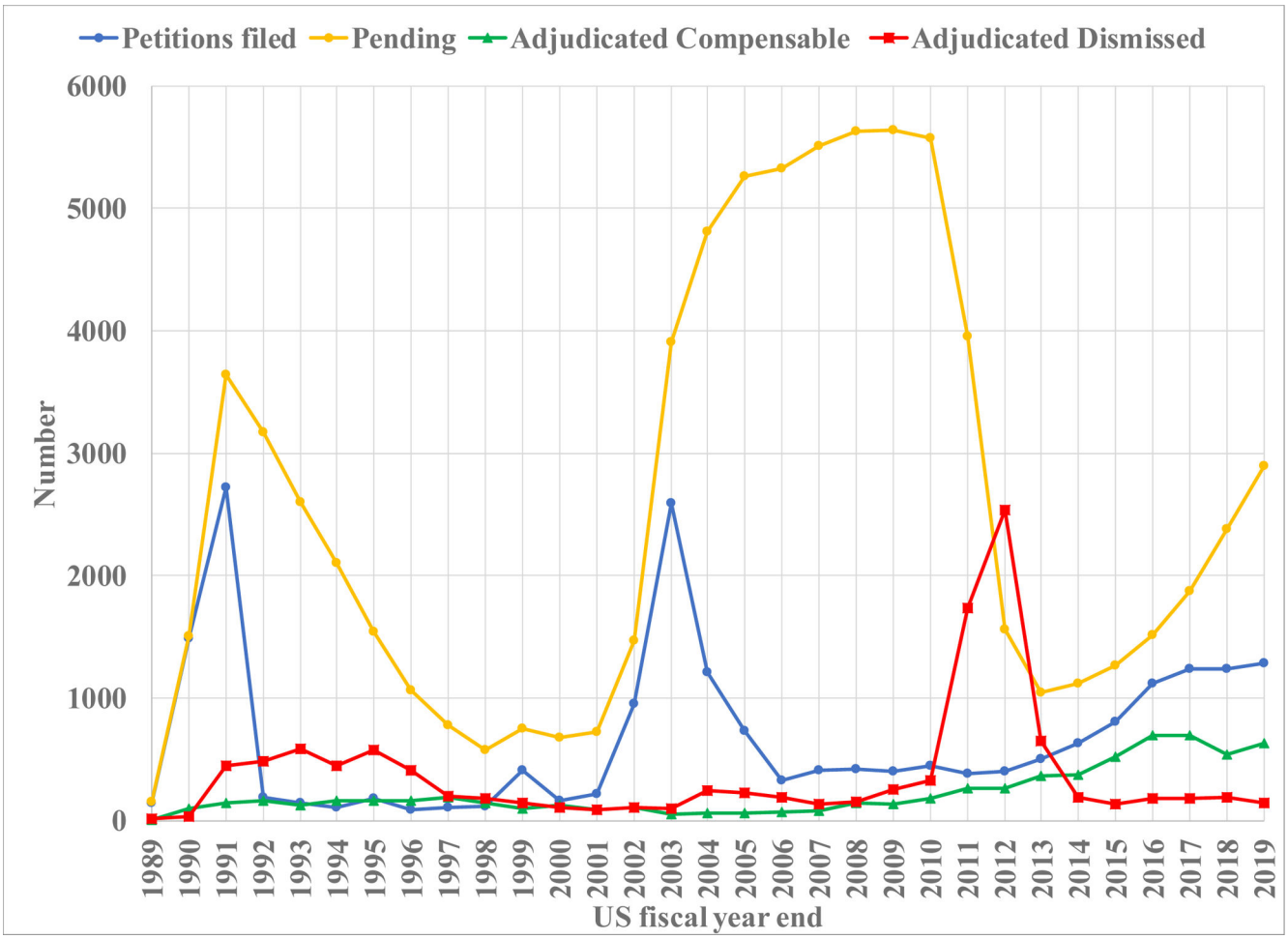

Figure 1:
Number of new petitions (claims) filed, adjudicated and compensated, adjudicated and dismissed and implied pending claims (in the queue) by US fiscal year [11]

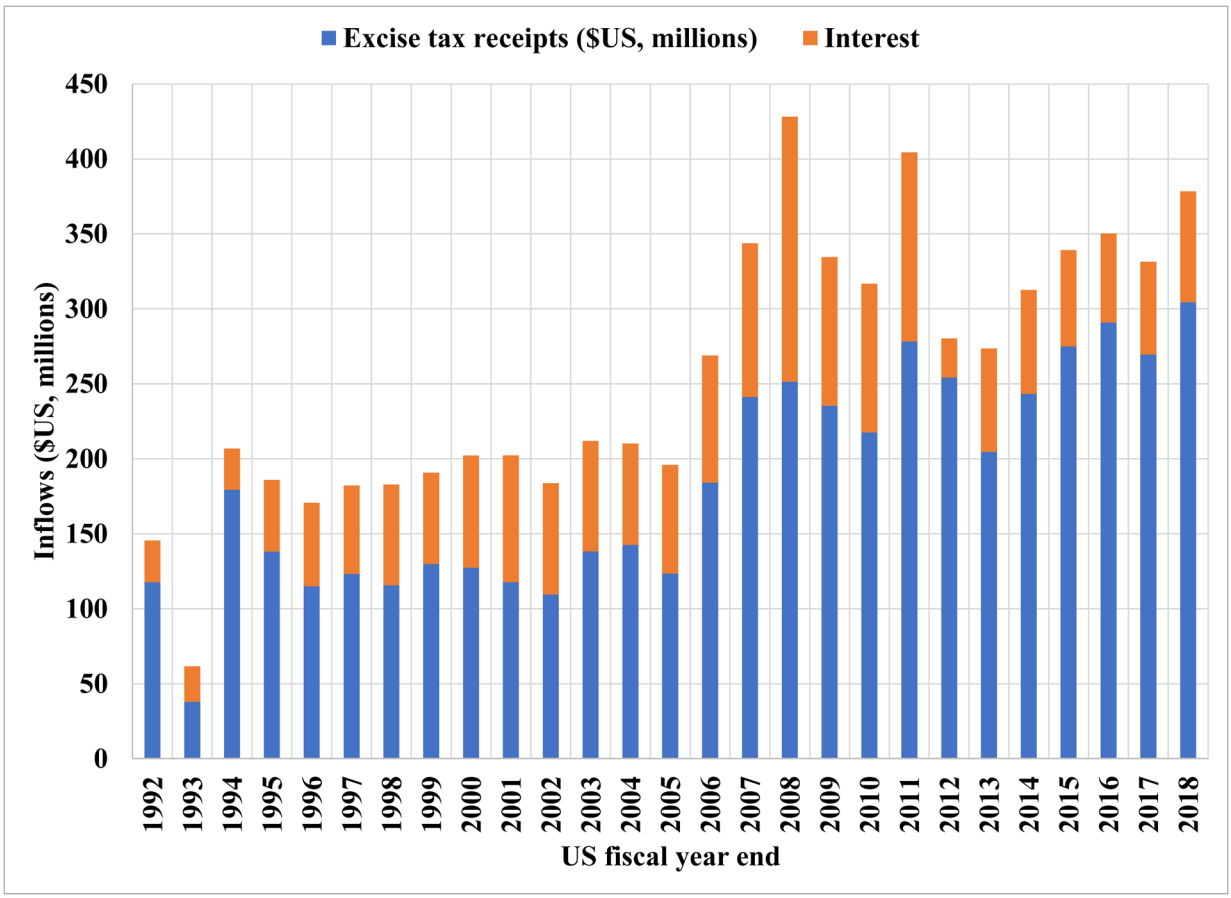

Figure 2a:

Annual excise tax and interest payments to the Vaccine Injury Compensation Trust Fund by fiscal year (top of stacked bar shows total inflows) [17]

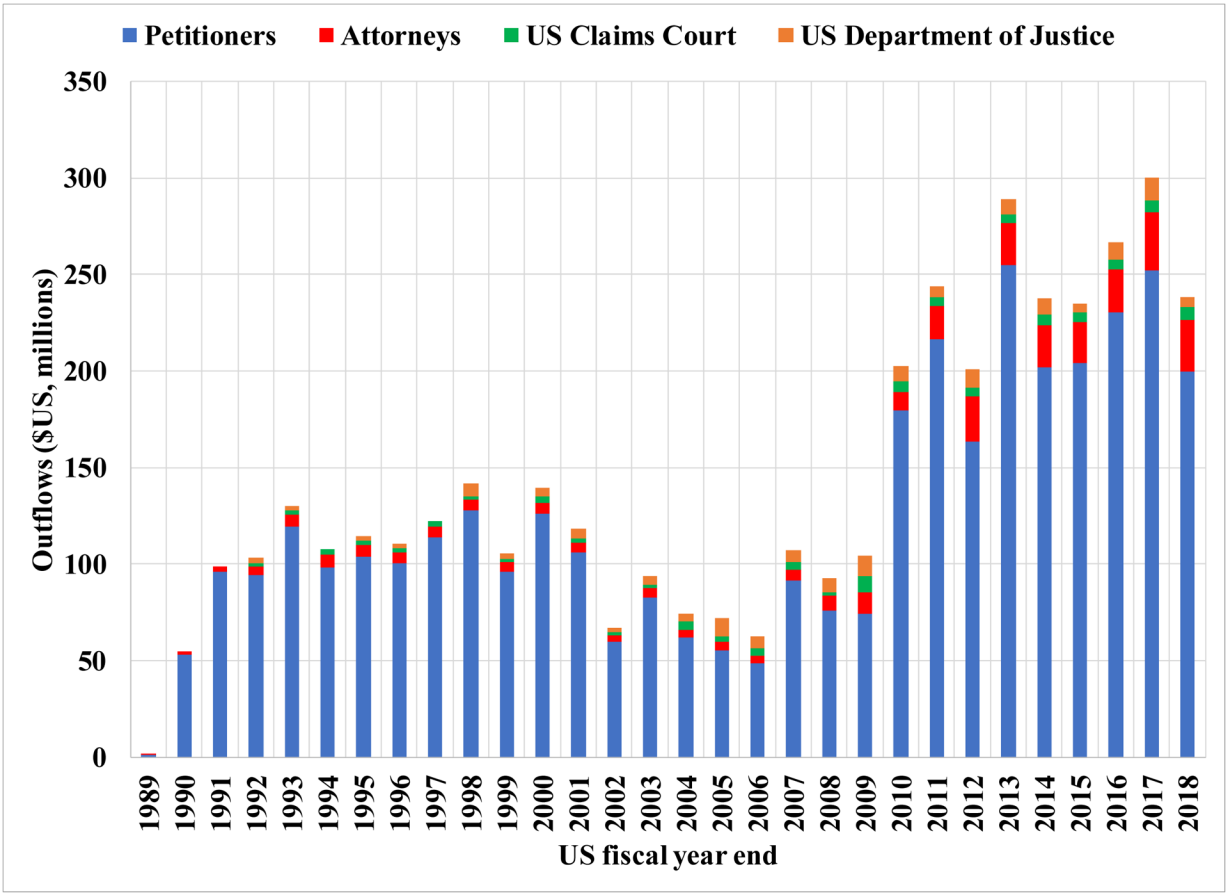

Figure 2b:

Outflows from the Vaccine Injury Compensation Trust Fund by type and fiscal year (top of stacked bar shows total outflows) [11, 17]

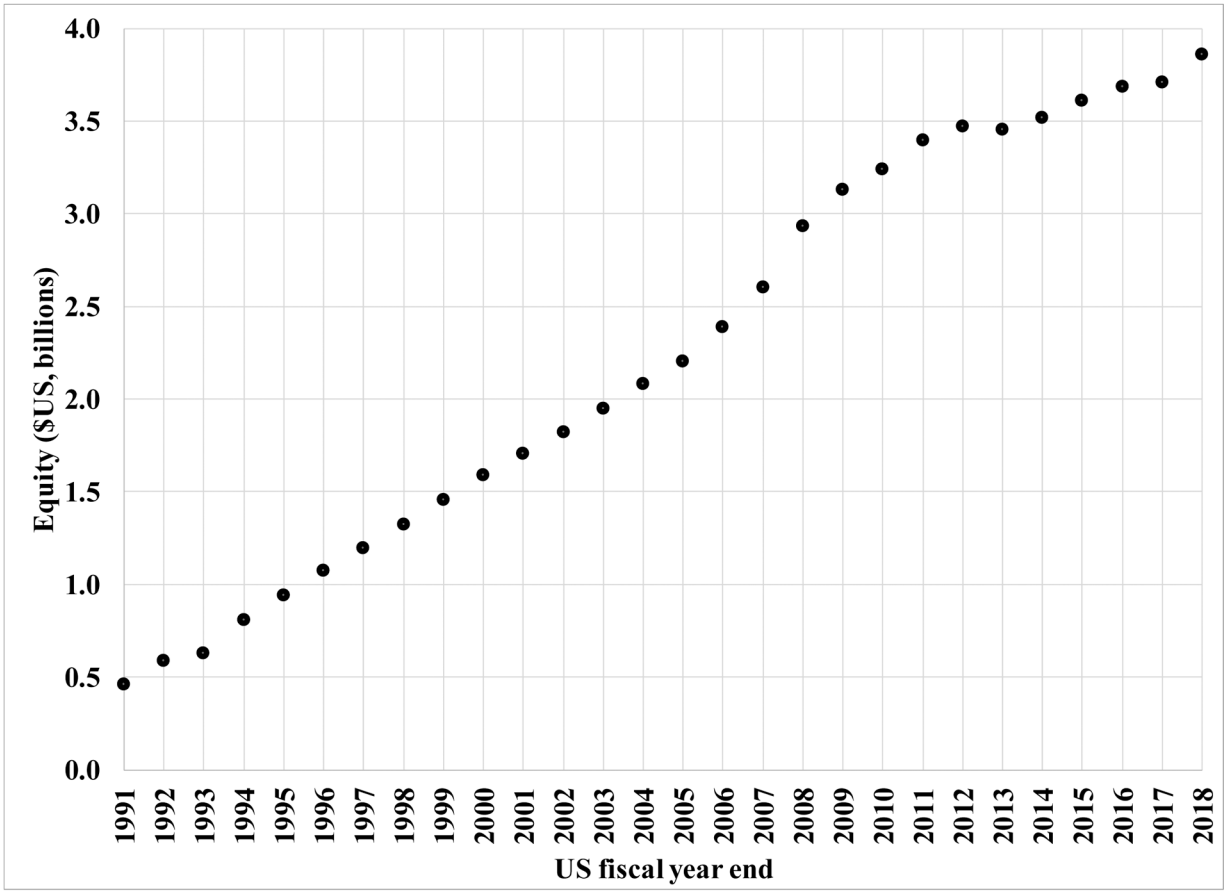

Figure 2c:
Equity in the Vaccine Injury Compensation Trust Fund [17]

Table 1:

List of vaccines/diseases covered by the VICP

Vaccine covered by excise tax	Excise tax (Snoniinal)	Effective date of excise tax	Public Law	Vaccine Injury Table Add Date	Source
DPT	4.56	1/1/1988–12/31/1992, 8/10/1993–8/6/1997	100–203	1/1/1988	Original table
MMR	4.44	1/1/1988–12/31/1992, 8/10/1993–8/6/1997	100–203	1/1/1988	Original table
OPV	0.29	1/1/1988–12/31/1992, 8/10/1993–8/6/1997	100–203	1/1/1988	Original table
DT	0.06	1/1/1988–12/31/1992, 8/10/1993–8/6/1997	100–203	1/1/1988	Original table
Any vaccine containing diphtheria toxoid	0.75	8/6/1997-present	105–34	2/20/1997 *	62 FR 7688
Any vaccine containing tetanus toxoid	0.75	8/6/1997-present	105–34	2/20/1997 *	62 FR 7688
Any vaccine containing pertussis bacteria, extracted or partial cell bacteria, or specific pertussis antigens	0.75	8/6/1997-present	105–34	2/20/1997 *	62 FR 7688
Any vaccine against measles	0.75	8/6/1997-present	105–34	2/20/1997 *	62 FR 7688
Any vaccine against mumps	0.75	8/6/1997-present	105–34	2/20/1997 *	62 FR 7688
Any vaccine against rubella	0.75	8/6/1997-present	105–34	2/20/1997 *	62 FR 7688
Any vaccine containing polio virus	0.75	8/6/1997-present	105–34	2/20/1997 *	62 FR 7688
Hemophilus influenzae type b (Hib) polysaccharide vaccines (unconjugated, PRP vaccines) ***	0.75	8/6/1997-present ***	105–34	2/20/1997	62 FR 7688
Any Hib vaccine	0.75	8/6/1997-present	105–34	2/20/1997 **	62 FR 7688
Any vaccines against Hepatitis B	0.75	8/6/1997-present	105–34	2/20/1997	62 FR 7688
Any vaccine against chicken pox (varicella vaccines)	0.75	8/6/1997-present	105–34	2/20/1997	62 FR 7688
Live, oral, rhesus-based rotavirus vaccine against rotavirus gastroenteritis	0.75	10/22/1998–8/26/2002	105–277	7/25/2002	67 FR 48560
Any conjugate vaccine against streptococcus pneumoniae	0.75	12/18/1999-present	106–170	7/25/2002	67 FR 48560
Any vaccine against Hepatitis A	0.75	10/22/2004-present	108–357	12/1/2004	69 FR 69945
Any trivalent vaccine against seasonal influenza	0.75	10/22/2004-present	108–357	7/1/2005	70 FR 19092
Any meningococcal vaccine	0.75	2/1/2007-present	109–432	2/1/2007	72 FR 19937
Any vaccine against the human papillomavirus (HPV)	0.75	2/1/2007-present	109–432	2/1/2007	72 FR 19937

Vaccine covered by excise tax	Excise tax (Snoniinal)	Effective date of excise tax	Public Law	Vaccine Injury Table Add Date	Source
Any other vaccine against seasonal influenza	0.75	6/25/2013-present	113–15	11/12/2013	78 FR 67369
Any vaccine against rotavirus gastroenteritis	0.75	10/22/1998-present ****	105–277	7/24/2013	78 FR 44517

* Format of the description changed by Public Law 105–34 to reflect specific disease instead of specific vaccine products previously used (Public Law 100–203)

** Included in the Vaccine Injury Table as polysaccharide conjugated vaccines

*** Polysaccharide unconjugated vaccines listed despite use prior to December 1987 and no likely eligible claims, PRP stands for Polyribosylribitol Phosphate

**** In June 2006, CDC recommended pentavalent human-bovine reassortant rotavirus vaccine for use in children, which it updated in June 2008 to include monovalent rotavirus vaccine derived from the human rotavirus strain

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Table 2:

Injuries covered in the Vaccine Injury Table [16] and the dates of the addition to the table of each type of injury for specific vaccines

Injury (i.e., illness, disability, injury, condition, or death) and associated acute complications covered (time period for first symptom or manifestation of onset of significant aggravation after vaccine administration) (date added to the Vaccine Injury Table)	**Vaccine (date explicitly covered)**	**Date removed (if applicable)**
Anaphylaxis (≤4 hours) (November 14, 1986, original table)	Vaccines containing pertussis bacteria, tetanus toxoid, measles virus, mumps virus, rubella virus, inactivated poliovirus (January 1, 1988, original table), hepatitis B (February 20, 1997, 62 FR 7688), varicella virus, seasonal influenza virus, human papillomavirus virus (HPV), or meningococcal vaccine (March 21, 2017, 82 FR 6300)	
Encephalopathy or encephalitis (≤72 hours) (November 14, 1986, original table)	Vaccines containing pertussis bacteria or tetanus toxoid (January 1, 1988)	
Shock-collapse or hypotonic-hyporesponsive collapse (≤72 hours) (November 14, 1986, original table)	Vaccines containing pertussis bacteria (January 1, 1988)	February 8, 1995 (60 FR 7694)
Residual seizure disorder (first seizure within 72 hours, plus at least 2 additional seizures within 1 year, with fever over 102 F) (November 14, 1986, original table)	Vaccines containing pertussis bacteria or tetanus toxoid (January 1, 1988)	February 8, 1995 (60 FR 7694)
Encephalopathy or encephalitis (not less than 5 days and not more than 15 days) (November 14, 1986, original table)	Vaccines containing measles, mumps, or rubella (January 1, 1988)	
Residual seizure disorder (first seizure within 15 days, plus at least 2 additional seizures within 1 year, with fever over 102 F) (November 14, 1986, original table)	Vaccines containing measles, mumps, or rubella (January 1, 1988)	February 20, 1997 (62 FR 7688)
Paralytic polio (in a non-immunodeficient recipient (≤30 days), in an immunodeficient recipient (≤6 months), in a vaccine associated community case (not applicable) (November 14, 1986, original table)	Polio vaccines other than inactivated polio (January 1, 1988)	
Chronic arthritis (not less than 7 days and not more than 42 days) (February 8, 1995)	Vaccines containing rubella (February 8, 1995, 60 FR 7694)	
Early-onset Hemophilus influenzae type b (HIB) (≤7 days) (February 20, 1997)	Hemophilus influenzae type b polysaccharide vaccines (unconjugated, PRP vaccines) (February 20, 1997, 62 FR 7688, Listed despite use of vaccine prior to December 1987 and no likely eligible claims)	July 25, 2002 (67 FR 48560)
Thrombocytopenic purpura (not less than 7 days and not more than 30 days) (February 20, 1997)	Vaccines containing measles (February 20, 1997, 62 FR 7688)	
Vaccine-Strain Measles Viral Disease in an immunodeficient recipient (Vaccine-strain virus identified then not applicable, if strain determination is not done or if laboratory testing is inconclusive ≤ then 12 months) (February 20, 1997)	Vaccines containing measles (February 20, 1997, 62 FR 7688)	
Brachial Neuritis (not less than 2 days and not more than 28 days) (February 20, 1997)	Vaccines containing tetanus toxoid (February 20, 1997, 62 FR 7688)	
Vaccine strain polio infection (in a non-immunodeficient recipient (≤30 days), in an immunodeficient recipient (≤6 months), in a vaccine associated community case (not applicable) (February 20, 1997)	Polio vaccines other than inactivated polio (February 20, 1997, 62 FR 7688)	
Intussusception (<30 days) (July 25, 2002)	Live, oral, rhesus-based rotavirus vaccines administered between October 22, 1998 and August 26, 2002 (July 25, 2002, 67 FR 48560)	October 9, 2008 (73 FR 59528)
Intussusception (not less than 1 day and not more than 21 days) (July 24, 2013)	Rotavirus vaccines (July 24, 2013, 78 FR 44518)	

Injury (i.e., illness, disability, injury, condition, or death) and associated acute complications covered (time period for first symptom or manifestation of onset of significant aggravation after vaccine administration) (date added to the Vaccine Injury Table)	**Vaccine (date explicitly covered)**	**Date removed (if applicable)**
Disseminated varicella vaccine-strain viral disease (Vaccine-strain virus identified, not applicable, If strain determination is not done or if laboratory testing is inconclusive (not less than 7 days and not more than 42 days) (March 21, 2017)	Any vaccines containing varicella (March 21, 2017, 82 FR 6300)	
Varicella vaccine-strain viral reactivation (not applicable) (March 21, 2017)	Any vaccines containing varicella (March 21, 2017, (82 FR 6300)	
Guillain-Barré Syndrome3–42 days (not less than 3 days and not more than 42 days) (March 21,2017)	Seasonal influenza vaccines (March 21, 2017, 82 FR 6300)	
Shoulder Injury Related to Vaccine Administration (≤48 hours) (March 21, 2017)	Vaccines containing tetanus toxoid, pertussis bacteria, measles, mumps, rubella, inactivated polio, hepatitis B, *Haemophilus influenzae* type b (Hib), varicella, hepatitis A, seasonal influenza, or human papillomavirus virus (HPV), or meningococcal or pneumococcal conjugate vaccine, and any new injectible vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage (March 21, 2017, retroactive to March 21, 2009 if filed by March 2019, 82 FR 6300)	
Vasovagal syncope (≤1 hour) (March 21, 2017)	Vaccines containing pertussis bacteria, tetanus toxoid, measles virus, mumps virus, rubella virus, inactivated poliovirus, hepatitis B virus, *Haemophilus influenzae* type b (Hib), varicella virus, hepatitis A virus, seasonal influenza virus, human papillomavirus virus (HPV), pneumococcal conjugate or meningococcal vaccine (March 21, 2017, 82 FR 6300)	

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Table 3:

Petitions filed by type, by adjudication status (compensated or dismissed), and estimated percentage of current claims (as of 11/1/2019) by vaccine and total pending claims by alleged vaccine injury for 10/1/1988 through 11/1/2019, and number of doses distributed 1/1/2006 through 12/31/2017 (after inclusion of influenza vaccine) [11]

Vaccines	Filed			Adjudicated		Current claims pending		Doses distributed 1/1/2006 – 12/31/2017
	Injury	Death	Total	Compensated	Dismissed	% by vaaccine	% of total	
DTaP-IPV	12	0	12	4	3	42%	0.2%	24,237,580
DT	69	9	78	26	52	0%		794,777
DTP	3,286	696	3,982	1,273	2,709	0%		0
DTP-HIB	20	8	28	7	21	0%		0
DTaP	461	84	545	231	253	11%	2.1%	101,073,594
DTaP-Hep B-IPV	89	38	127	42	55	24%	1.0%	68,764,777
DTaP-HIB	11	1	12	7	4	8%	0.03%	1,135,474
DTaP-IPV-HIB	44	21	65	14	32	29%	0.6%	62,397,611
Td	213	3	216	125	75	7%	0.5%	65,170,306
Tdap	749	6	755	398	79	37%	9.4%	248,258,803
Tetanus	141	2	143	76	47	14%	0.7%	3,836,052
Hepatitis A (Hep A)	104	7	111	58	33	18%	0.7%	176,194,118
Hepatitis B (Hep B)	707	61	768	279	423	9%	2.2%	185,428,393
Hep A-Hep B	36	0	36	18	7	31%	0.4%	15,826,685
Hep B-HIB	8	0	8	5	3	0%		4,787,457
HIB	44	3	47	19	20	17%	0.3%	119,947,400
HPV	418	15	433	133	172	30%	4.3%	111,677,552
Influenza	5,592	176	5,768	3,251	524	35%	67.7%	1,518,400,000
IPV	269	14	283	8	270	2%	0.2%	72,962,512
OPV	282	28	310	158	152	0%		0
Measles	143	19	162	55	107	0%		135,660
Meningococcal	90	2	92	45	9	41%	1.3%	94,113,218
MMR	984	61	1,045	406	585	5%	1.8%	101,501,714
MMR-Varicella	53	2	55	23	13	35%	0.6%	24,798,297
MR	15	0	15	6	9	0%		NR *
Mumps	10	0	10	1	9	0%		110,749
Pertussis	4	3	7	2	5	0%		NR *
Pneumococcal Conjugate	216	17	233	66	57	47%	3.7%	228,588,846
Rotavirus	98	5	103	62	25	16%	0.5%	107,678,219
Rubella	190	4	194	71	123	0%		422,548
Varicella	103	9	112	68	31	12%	0.4%	116,063,014

Vaccines	Filed			Adjudicated		Current claims pending		Doses distributed 1/1/2006 – 12/31/2017
	Injury	Death	Total	Compensated	Dismissed	% by vaaccine	% of total	
Nonqualified[1]	104	9	113	3	104	5%	0.2%	0
Unspecified[2]	5,426	9	5,435	9	5,401	0%	0.8%	0
Grand Total[3]	19,991	1,312	21,303	6,947	11,411	14%	100%	3,454,269,356

*NR, not reported in original source [11], presumed 0 due to non-use or rare use of the vaccines as of 2006

[1]Nonqualified petitions are those filed for vaccines not covered under the VICP.

[2]Unspecified petitions are those submitted with insufficient information to make a determination.

[3]Total reported from original source [11], numbers in rightmost column sum to 3,454,305,356 doses (36,000 more than shown in the table).

Table 4:

Cases and compensation for Shoulder Injury Related to Vaccine Administration (SIRVA) since 2011 (Division of Injury Compensation Programs, personal communication, January 2020)

Fiscal Year	Total Cases Compensated	Total Petitioner Compensation
2011	7	$1,738,785
2012	4	$315,674
2013	11	$1,867,457
2014	39	$5,325,246
2015	125	$17,497,672
2016	260	$29,869,178
2017	288	$32,231,058
2018	284	$26,699,487
2019	510	$43,941,301