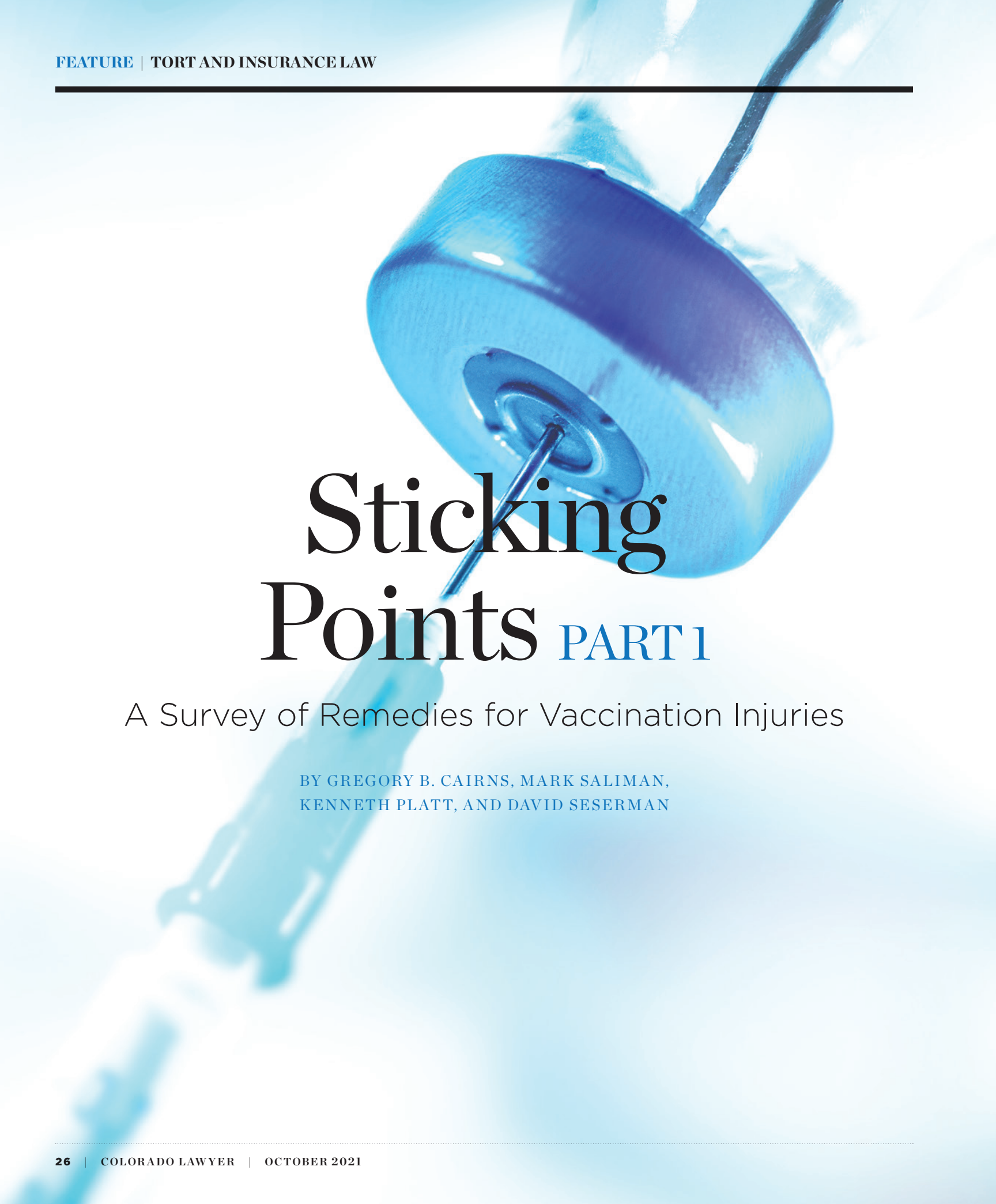

Sticking Points PART 1

A Survey of Remedies for Vaccination Injuries

BY GREGORY B. CAIRNS, MARK SALIMAN,
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This two-part article provides an overview of federal and state remedies available for vaccine injuries, including COVID-19 vaccinations. It offers practical guidance to triage injury claims. This part 1 focuses on two federal programs currently providing remedies for injuries caused by certain vaccinations.

Vaccines are subject to well-designed clinical trials and, ultimately, US Food and Drug Administration (FDA) approval. Despite this rigor, some vaccinations bring injury and even death to their recipients.[1] While injuries are rare, some people experience idiosyncratic reactions to serum, some encounter "bad batches" of the injected drug, and a few endure negative medication interactions, including with other recently obtained vaccinations. Significant numbers of Americans also suffer shoulder injuries from the intramuscular injection of vaccines, often because the wrong-sized needle was used or the needle was inserted incorrectly (SIRVA[2] injuries). Whether due to the serum or to its administration, the discomfort some recipients experience from the vaccination is temporary (e.g., anaphylaxis, fever, or soreness at the injection site), but for others the pain and functional deficit are long-lasting and devastating (e.g., chronic inflammation of affected tissue, paralysis, autoimmune disorder, or neurological condition).[3]

This two-part article acquaints practitioners with the panoply of remedies available for recipients of a vaccination that went awry. This part 1 addresses two significant federal programs: (1) the National Vaccination Injury Compensation Program (VICP) mandated under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act),[4] for those injured in the course of receiving specified childhood vaccinations, or routinely administered vaccinations such as seasonal flu; and (2) the Countermeasures Injury Compensation Program (CICP), for those who may be injured from the administration of designated public health emergency vaccinations, including a COVID-19 vaccination.[5]

Part 2 will outline residual state tort law remedies for injuries from vaccinations not covered by the VICP or CICP, or available following an authorized opt-out of the VICP. It also surveys other available remedies, including workers' compensation, non-workers' compensation funds, and general employment remedies.

> "The VICP does not provide an exclusive personal injury remedy in most cases where it applies. Instead, it provides a compensation program that a claimant must exhaust before pursuing a state law tort remedy."

The sidebar offers a decision tree for evaluating whether a potential claim is covered by the VICP or CICP.

History of Federal Vaccination Injury Programs

Since the mid-20th century, the approval and use of vaccines has been federally regulated by the same Food, Drug and Cosmetic Act (FDCA) and Public Health Service Act (PHSA) process that is applicable to other prescription medications.[6] Historically, personal injury claims arising from adverse health reactions from a vaccine, or injuries from the vaccination administration, were creatures of state law (absent some rare preemption issues under the Swine Flu Act of 1976[7] or the FDCA). By the 1970s and 1980s, vaccine use had become so commonplace and successful in preventing outbreaks of infectious disease that the public began to be more concerned about the risks and injuries from the vaccines than from the infectious diseases they mitigated.[8] According to medical-legal commentators, that concern led to a vast increase in the incidence of state law product liability claims against vaccine manufacturers by the mid-1980s, with a corresponding threat that such lawsuits would cause manufacturers to abandon the market and thus destabilize vaccine supplies.[9] At the same time, claimants were faced with enormous hurdles in successfully pursuing even the most legitimate personal injury actions due in large part to the difficulty and expense of proving the vaccine manufacturer's identity, the manufacturer's fault, and causation between the vaccine and the injuries.[10]

The VICP

In response to the problems inherent in pursuing traditional tort remedies, Congress passed the Vaccine Act, which created both the National Vaccine Program to study vaccines and prevention of adverse reactions and the VICP, a no-fault federal judicial "scheme of recovery designed to work faster and with greater ease than the civil tort system."[11] The VICP does not provide an exclusive personal injury remedy in most cases where it applies.

Instead, it provides a compensation program that a claimant must exhaust before pursuing a state law tort remedy. The compensation funds paid to claimants under the VICP are collected from an excise tax on doses sold by covered vaccine manufacturers.[12] While not applicable to all vaccine injury claims, the Vaccine Act and VICP evidence another foray (after the immunity of the Swine Flu Act) into re-routing vaccine injury claims from state tort law systems into a federal adjudication and compensation program.[13]

VICP-Covered Vaccines and the Vaccine Injury Table

As a general rule, vaccines covered by the VICP are listed on a VICP vaccine injury table (VICP Table) promulgated and amended by the Department of Health and Human Services (HHS). The VICP Table currently in effect lists the following vaccines:[14]

- vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT);
- vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib);
- vaccines containing measles, mumps, and rubella virus or any of its components (e.g., MMR, MM, MMRV);
- vaccines containing rubella virus (e.g., MMR, MMRV);
- vaccines containing measles virus (e.g., MMR, MM, MMRV);
- vaccines containing polio live virus (OPV);
- vaccines containing polio inactivated virus (e.g., IPV);
- hepatitis B vaccines;
- haemophilus influenzae type b (Hib) vaccines;
- varicella vaccines;
- rotavirus vaccines;
- pneumococcal conjugate vaccines;
- hepatitis A vaccines;
- seasonal influenza vaccines;
- meningococcal vaccines;
- human papillomavirus (HPV) vaccines; and
- any new vaccine recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children, after publication by the CDC Secretary of a notice of coverage.

The VICP Table identifies the vaccines covered by the program[15] and lists specific injuries ("On Table injuries") for each vaccine. While causation of On-Table injuries is rebuttably presumed, claimants suffering other types of injuries following the administration of a vaccine specified on the VICP Table may still recover compensation by proving that the administration of the vaccine caused their injury or aggravated a prior condition.[16]

Practitioners must keep current with any proposed and actual VICP Table changes that can significantly expand, or contract, the scope of VICP relief. For example, in July 2020 the HHS secretary issued a notice of a proposed rulemaking to revise the VICP Table to delete not only the final category of vaccines but also SIRVA injuries and vasovagal syncope (fainting) injuries, in an effort to reduce VICP liability to individuals injured from vaccine administration rather than reactions to vaccine serum components.[17] In one of his final official acts, the HHS secretary adopted the revised VICP Table as a final rule with an effective date of February 22, 2021.[18] The new administration, through its acting HHS secretary, postponed the rule's effective date until April 23, 2021, to review the revised VICP Table.[19] HHS has now rescinded entirely the revised VICP Table based on both procedural concerns over its last-minute adoption and policy concerns that deleting SIRVA and syncope would have a negative impact on vaccine administrators. The revised VICP Table would be at odds with the federal government's efforts to increase confidence in vaccinations, "particularly in light of efforts to respond to the [COVID–19] pandemic."[20] This recent episode illustrates the need to stay abreast of ongoing political and administrative changes and to review the most current VICP (and CICP) related regulations when advising a vaccine-injured client.

The VICP Process and Compensation

A detailed "how to" procedural guide for litigating a VICP case is beyond the scope of this article and is available elsewhere.[21] In a nutshell, a VICP claim is commenced by filing a petition and submitting medical and damages proof in the US Court of Federal Claims (vaccine court) alleging that the injured party received a covered vaccine and developed either an On-Table injury within the VICP Table's specified time period, or another injury caused by the vaccine, and suffered damages.[22] The claim is filed against HHS, which is represented in vaccine court by the US Department of Justice (DOJ). The claim is initially handled by a special master with broad procedural discretion to review the claim and response, resolve motions in opposition to the claim, permit discovery, and either resolve on the filings or through hearings the critical issues in the VICP case: whether the claimant established eligibility and, if so, the compensable damages.[23]

The Vaccine Act specifies the compensation that can be awarded to an eligible claimant as actual and future non-reimbursable costs for medical and custodial care, rehabilitation, and related expenses; actual and future lost earnings; up to $250,000 for actual and future pain and suffering; and, if applicable, death benefits up to $250,000.[24] The VICP also allows reasonable attorney fees and costs for compensated claims, and even for non-compensable claims pursued in good faith.[25]

At the conclusion of the claim review, the special master must issue a decision on eligibility and compensation that includes findings of fact and conclusions of law.[26] As a practical matter, many VICP claims are resolved through settlement between the claimant and DOJ and then entered as the special master's decision.[27] The special master decision must be entered within 240 days of the filing of a petition but that period may be, and frequently is, extended on a party's request or on the special master's own motion for up to another 150 days.[28] The claimant and DOJ may request review of the special master's decision by a court of federal claims judge.[29] If no request for review is submitted, the clerk enters a judgment on the special master's decision, but if either party moves for a review, the court must issue a ruling either affirming the findings, conclusions, and decision; setting them aside and issuing its own decision; or remanding the matter to the special master.[30] Once the vaccine

court issues its final judgment, either party may appeal the case to the US Court of Appeals for the Federal Circuit for review.[31]

Limitations Period Issues

The VICP petition must be filed in the vaccine court within three years from the date of the first symptom.[32] In contrast, the CICP's filing deadline is one year from the date of the use of the countermeasure, as discussed below, and most Colorado tort claims have a two-year statute of limitations.[33] While a claim filed under the VICP will stay state law limitations periods,[34] and may be accepted by HHS as a constructive CICP claim filing,[35] the filing of the VICP claim will not revive an otherwise stale claim.[36] Thus, the shorter limitations periods for CICP claims and state law claims make the VICP's stay or constructive filing potentially illusory. A VICP claim filed on the eve of the three-year deadline that is ultimately denied will not likely succeed as a Colorado tort claim because of the failure to timely file the VICP claim within two years of its accrual. And a VICP claim filed in the second or third year following vaccination that is denied on grounds that the vaccine is a CICP countermeasure (discussed below) will most likely be barred from a CICP remedy as untimely.

Even though the VICP provides a significantly longer limitations period than the CICP and many Colorado tort claims, practitioners should file VICP claims within the shortest possible time period to protect state law claims in case the VICP claim is dismissed, the injured party opts out of the VICP or rejects the VICP remedy, or the VICP claim is dismissed on grounds that the vaccine at issue is a countermeasure injury subject to the CICP.

Exhaustion of the VICP Remedy and Preempted Claims

For most vaccination injury claims, the VICP is not an exclusive remedy but is instead one that must first be exhausted before bringing a state law claim. There is a substantial exception to this rule: The Vaccine Act "pre-empts all design-defect claims against vaccine manufacturers" for any personal injury or death "caused by vaccine side effects," limiting those claims to only a VICP remedy.[37]

> "While a claim filed under the VICP will stay state law limitations periods, and may be accepted by HHS as a constructive CICP claim filing, the filing of the VICP claim will not revive an otherwise stale claim. Thus, the shorter limitations periods for CICP claims and state law claims make the VICP's stay or constructive filing potentially illusory."

An additional exception to the non-exclusivity of the VICP that is not dictated by the Vaccine Act itself was created by recent CICP countermeasures declarations concerning the COVID-19 public health emergency. This exception is addressed following the CICP discussion below.

VICP claimants can exhaust the VICP remedy and pursue available state law remedies in two ways. First, they can opt out of the VICP by withdrawing their petition if the special master does not timely resolve the claim or the federal claims court does not timely enter judgment on the special master's decision.[38] Upon a proper and timely withdrawal of the petition, the injured party may pursue state law remedies.[39] Second, if the vaccine court issues a VICP final judgment either awarding insufficient compensation or no compensation, the claimant may elect to reject the judgment and pursue state law remedies.[40] The election to reject the judgment must be timely made, even to a judgment awarding no compensation, or the claimant will be deemed to have accepted the VICP judgment.[41]

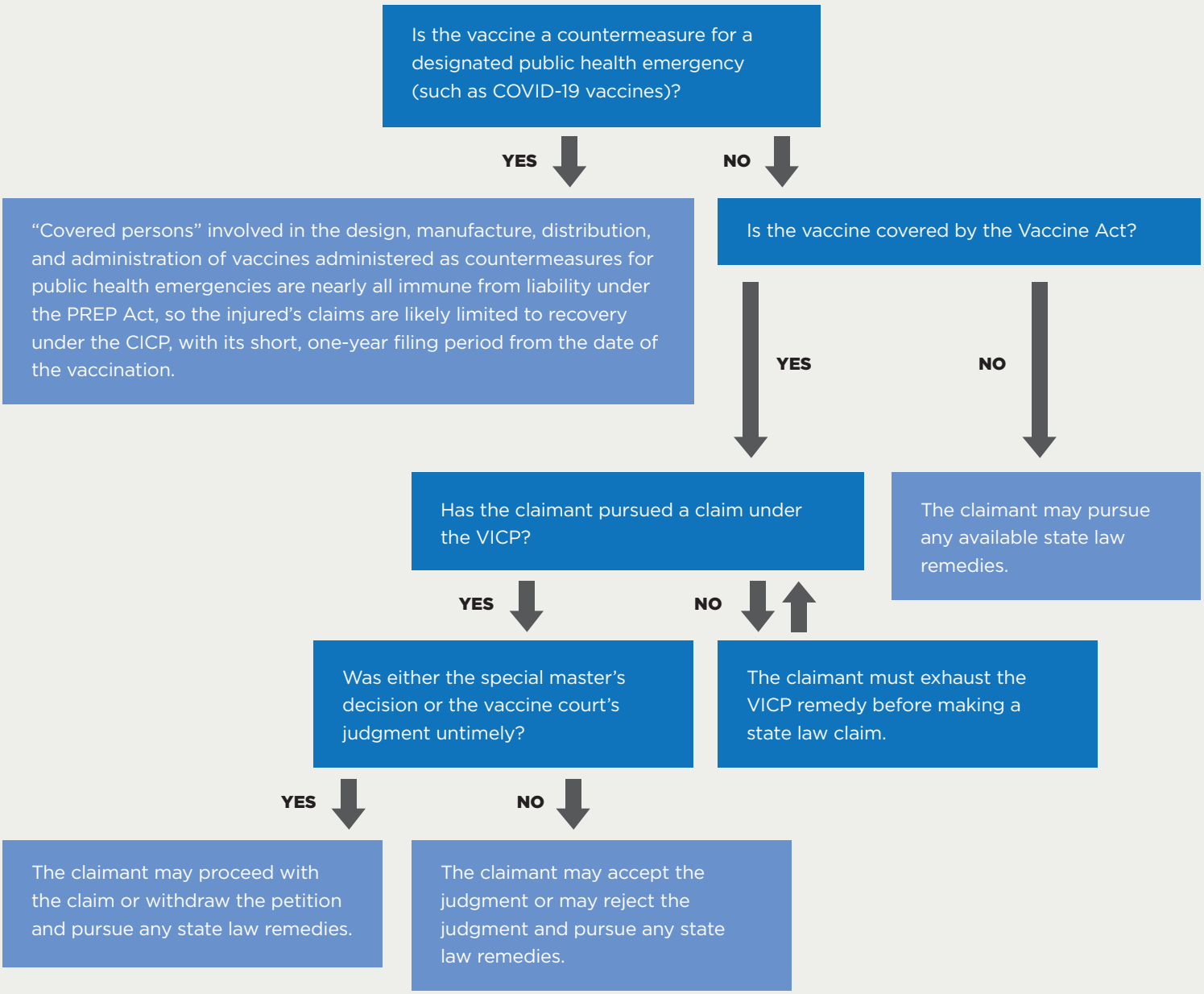
While the no-fault standard, oftentimes presumptive causation, and panoply of available relief including attorney fees make the pursuit of eligible vaccine injury claims under the VICP appealing in most cases, pursuing a fault-based state law claim may still be necessary if the vaccine court finds the claim to be outside the VICP's scope or finds lack of causation for the injury.

The CICP

The CICP has primary importance now because it currently provides the exclusive remedy for COVID-19 vaccine injuries. In 2005, in response to concerns over an avian flu pandemic and the risk of public health crises caused by human threats or microbial evolution, Congress enacted the Public Readiness and Emergency Preparedness Act (PREP Act),[42] which authorizes the HHS Secretary to determine that "a disease or other health condition or other threat to health constitutes a public health emergency, or . . . may in the future constitute such an emergency" and declare "the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures" necessary to combat the emergency.[43] For each declaration, HHS must define the health threat for which use of a countermeasure is recommended; the time periods and geographic area of the health emergency and need for countermeasures; the population for which countermeasures are

DECISION TREE FOR EVALUATING VACCINE INJURY CLAIMS

The VICP and CICP differ substantially with regard to availability, compensable injuries and benefits, exclusion of other remedies, and transparency. The decision tree below shows the remedies available for various vaccine injury claims.



recommended; and the persons whose conduct in manufacturing, developing, distributing, or administering the countermeasure is covered by the PREP Act's protections.[44]

The PREP Act provides broad immunity against federal or state law claims to any "covered person" for any loss "caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure" that falls within the scope of the declaration.[45] The PREP Act's broad definition of countermeasures includes vaccines (whether fully approved or authorized for emergency use under the FDCA) as drugs, biological products, or products developed, manufactured, and used to mitigate, prevent, cure, or limit a pandemic's harm.[46] In consideration of this overwhelming immunity, the PREP Act established a fund to compensate individuals for "injuries directly caused by the administration or use of a covered countermeasure"[47] and directed HHS to promulgate a regulatory process to determine eligibility and award permitted compensation.[48]

That process, codified as the CICP, "provide[s] medical and lost employment income benefits [and death benefits to] individuals who sustained a covered injury as the direct result of the administration or use of a covered countermeasure consistent with a declaration . . . or in the good faith belief that administration or use of the covered countermeasure was consistent with a declaration."[49] If an individual received a vaccine provided as a countermeasure to a declared public health emergency and suffered physical injury or death from the use of a countermeasure, pursuing a claim through the CICP will likely be the only available personal injury claim.

CICP-Covered Vaccines

Currently, HHS has declared health emergencies and provided liability immunity for countermeasures, including vaccines, for the following:[50]

- COVID-19[51]
- Marburg[52]
- Ebola[53]
- Zika[54]
- pandemic influenza[55]
- anthrax[56]
- botulinum toxin[57]
- smallpox.[58]

The CICP Remedy

For any vaccine injury claim, the practitioner must review the countermeasures declarations and amendments to determine if the vaccine is a covered countermeasure and if the scope of the declaration's liability immunity and CICP remedy applies to the client's specific injury claims.[59] Of critical current importance, HHS's declarations for the COVID-19 emergency provide that countermeasures include vaccines; covered persons include almost anyone who has been involved in the development, manufacture, testing, approval, transportation, or administration of the vaccine; and the effective time period for the emergency, and the countermeasure immunity, runs until at least October 1, 2024. It is no exaggeration to state that the COVID-19 countermeasures declaration creates one of the largest liability immunization programs in US history as part of the most massive disease immunization program in US history.[60]

The CICP Claim Process

The precise process, requirements, and benefits awardable are contained in the CICP regulations.[61] In essence, any individual suffering a "serious physical injury,"[62] or serious aggravation of a preexisting condition, as a result of the use of a countermeasure vaccine used pursuant to a PREP Act declaration, or in a good faith belief it was used under a declaration, may submit a request form to HHS seeking medical benefits and lost income benefits as compensation for the injury.[63] While a biochemical alteration leading to physical changes and functional abnormalities may constitute a serious injury, in general "only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries."[64] If the countermeasure recipient dies as a result of use of the countermeasure, his or her survivors may request a death benefit.[65]

Time Period for Filing a Claim

To commence a claim, the injured person or his or her survivor or representative must submit a request form "within one year of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury."[66] The request form can be obtained from the Heath Resources and Services Administration (HRSA), which is the HHS division responsible for the CICP.[67] If HHS promulgates a new or revised CICP countermeasures injury table (CICP Table) for a specific countermeasure, an injured person may establish that his or her injury is an On-Table injury that could not previously have been established and submit a request form within one year of the effective date of the new or revised CICP Table.[68] Additionally, if an injured person files a claim with the federal government, such as a VICP or Federal Tort Claims Act (FTCA) claim, within one year of an injury from use of a countermeasure, HHS may, but is not required to, accept that legal filing as constructive receipt of a CICP request.[69]

The injured person, representative, or survivor must provide medical records, including all records for services on or after the date of the use of the countermeasure and all records for a year before that date, that are necessary for HHS to determine if a covered injury was suffered and eligibility is established.[70] The records may be submitted after the request form is filed.

Eligibility

The CICP is a no-fault program, so for HHS to determine eligibility the claimant need only submit a request form and documentation establishing receipt of a vaccine countermeasure pursuant to a declaration, or in the good faith belief it was pursuant to a declaration, and that a serious physical injury occurred as a direct result of the countermeasure.[71] The claimant must establish causation in one of two ways. First, if HHS has promulgated a CICP Table for the countermeasure, the injured person can provide records substantiating an On-Table injury that occurred within the specified time period and at the required severity establishing a "rebuttable presumption that the covered countermeasure was the cause of the injury."[72] Second, if there is not a CICP Table for the specified countermeasure or if the claimant's injury does not satisfy a table injury, direct causation must be established by documentation. The standard of proof on the latter course is onerous: "Such proof must be

based on compelling, reliable, valid, medical and scientific evidence. Temporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove that the countermeasure caused the injury."[73]

As of the date of this writing, HHS has promulgated a CICP Table for only one of its 10 declared PREP Act emergencies: pandemic influenza. That table, adopted in September 2015 (more than eight years after the initial declaration of a pandemic influenza emergency) lists 10 countermeasures and their presumptive injuries and occurrence times, including three vaccines: "vaccines administered by needle" (causing anaphylaxis, deltoid bursitis, and vasovagal syncope); "intranasal vaccine" (causing anaphylaxis); and "2009 H1N1 vaccine" (causing Guillain-Barré syndrome).[74]

For the other PREP Act emergencies designating vaccine countermeasures, including COVID-19, there are no tables. Therefore, claimants are required to prove through compelling medical and scientific evidence that serious injury was directly caused by the vaccine. While the regulations provide that information other than medical records is "generally not required if a Table injury was sustained, a requester may introduce additional medical documentation or scientific evidence in order to establish that an injury was caused by a covered countermeasure."[75] Because so few CICP Table injuries from vaccines are identified, as a practical matter a practitioner in a CICP case must submit as part of the request package (either at the time of the initial submission or as soon as possible thereafter) scientific and medical data supporting a direct causal link between the injury and the vaccination. For syncope, anaphylaxis, SIRVA, and deltoid bursitis injuries from injected vaccines, it is advisable to submit, in addition to other materials establishing causation, the injury tables and administrative history for both the pandemic influenza countermeasure vaccine and analogous VICP injuries.

Coverage Determination

Following submission of the documentation, HHS will either request additional materials to prove eligibility (and may deny eligibility if not supplied within 60 days),[76] or issue a determination on whether the claimant is eligible for an award.[77] If HHS determines that the claimant is not eligible for any award, the claimant has limited rights to seek reconsideration, as discussed below. If the claimant is eligible, HHS will also determine the types and amounts of benefits to be awarded or request additional information to determine benefits, if needed.

The CICP permits only a narrow and limited range of compensation. An eligible injured person is entitled only to (1) past and future medical services or items "reasonable and necessary to diagnose or treat a covered injury, or to diagnose, treat, or prevent the health complications of a covered injury;"[78] and (2) "loss of employment income incurred as a result of a covered injury . . . paid as a percentage of the amount of employment income earned at the time of injury and lost as the result of the covered injury [if] supported by the severity of the covered injury."[79] Additionally, eligible survivors may recover a death benefit if HHS "determines that an otherwise eligible countermeasure recipient sustained a covered injury and died as a direct result of the injury or its health complications."[80] The CICP does not permit any recovery for noneconomic injuries or attorney fees.

All three categories of benefits are "secondary to any obligation of any third-party payer to pay for" the same medical benefits; lost employment income; disability or retirement benefits, and used and not refunded paid leave or sick days; and death benefits, Public Safety Officers' Benefits (PSOB) program benefits, or life insurance benefits to the injured person or to the injured person's dependents.[81] The claimant is required to provide information on primary sources of benefits payments, and all benefits actually received, in the request package. In addition to reducing benefits by the amounts owed by primary third-party obligors, HHS has a right to pursue recovery from those obligors of any benefits it pays to a claimant.[82]

Appeal Rights

Upon a final determination of benefits eligibility, a claimant may seek reconsideration by HHS. The request must be made within 60 days of the determination and may not rely on additional documentation.[83] The reconsideration is initially performed by a "qualified panel, independent of the Program"[84] based only on the documentation available to HHS at the time of the original determination. The panel submits its findings back to HHS for a final determination.[85] The panel's findings are not binding, and the agency's decision on reconsideration becomes the "final determination on the request for Program benefits with regard to the injury."[86] No further review of a reconsidered determination is permitted, and judicial review is not allowed.[87]

Willful Misconduct Exception

The PREP Act's only exception to liability immunity and the CICP remedy is for an exclusive federal action against a covered person whose "willful misconduct" proximately caused a claimant's death or serious physical injury.[88] "Willful misconduct" is defined as an act or omission taken "intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit,"[89] a standard to be established by a burden "more stringent than a standard of negligence in any form or recklessness."[90] Procedures for filing and litigating the willful misconduct case before a three-judge panel of the US District Court for the District of Columbia are set out in the PREP Act.[91] Notably, the substantive law for the state where the misconduct occurred applies; and the complaint must be verified, include an affidavit by an independent physician certifying that the plaintiff suffered serious physical injury or death proximately caused by use or administration of the countermeasure; and include certified medical records documenting the injury and causation.[92] A successful claimant may recover both economic and noneconomic damages in an amount proportional to the defendant's percentage of responsibility for the injury, but any damages are reduced by the amount of collateral benefits such as health insurance, workers' compensation, or disability coverage.[93]

CICP Cautions

Because the CICP is currently the only remedy available for nearly any injury caused by the use

of a COVID-19 vaccine, practitioners must be fully aware of the program's severe limitations. Given the broad immunity for covered persons, the short one-year time period to file a claim, the limited categories of recoverable benefits, the fact that all benefits are secondary, and the lack of any right to recover the costs and fees of pursuing a claim, the CICP provides only minimal protection to individuals injured by a countermeasure vaccine. Indeed, for any potential client suffering a countermeasure vaccine injury who has the benefit of quality health insurance coverage (i.e., without substantial out of pocket costs) and lost income protection coverage, a practitioner will have to evaluate prudently whether there is any benefit to the client or lawyer in pursuing a CICP claim. This conundrum has led many commentators and vaccine injury advocates to call for COVID-19 vaccines to be covered by the VICP rather than the CICP.[94] While the policy question of whether the most massive vaccine program in history should be regulated under the VICP instead of the CICP, or under a new program entirely, is beyond the scope of this article, given the differences between the programs, practitioners must remain vigilant in reviewing any change to PREP Act declarations or the VICP.[95]

PREP Act Immunity Creating an Exclusive Remedy for Certain VICP Claims

Recent amendments to the PREP Act Declaration of the COVID-19 health emergency illustrate again the need for practitioners to remain abreast of developments in the VICP and CICP whenever evaluating a vaccine injury claim. In the Third Amendment and Eighth Amendment to the COVID-19 Prep Act Declarations, HHS defined PREP Act "covered persons" to include state-licensed pharmacists (and state registered pharmacy interns and technicians supervised by a licensed pharmacist) when they provide standard childhood vaccinations to recipients aged 3 to 18, and when they provide seasonal flu vaccines to persons 19 and older.[96] In the Eighth Amendment, HHS expressly reiterated that with certain exceptions "a covered person is immune from suit and liability under Federal and State law" for claims resulting from their use of a covered countermeasure.[97] Yet as it had in the Third Amendment, HHS sought to clarify that the PREP Act was not seeking to place seasonal influenza vaccinations or routine childhood vaccinations, when administered by pharmacists and their interns and technicians, within the CICP scheme:

> Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 et seq. are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.[98]

While injuries caused by childhood vaccinations and seasonal flu vaccinations that are administered by licensed pharmacists and their interns and technicians still appear to be covered by the VICP's procedures and remedies, the COVID-19 PREP Act Declarations substantially change those categories of cases by making the VICP the exclusive remedy against the pharmacist or the pharmacist's techician or intern. If the vaccine court special master or judge does not timely decide the case or decides it adversely to the claimant, the injured party does not have the right to withdraw from the VICP or reject the VICP judgment and pursue remedies under state law.

Currently, the exclusive remedy applies only to pharmacists and their interns and technicians who comply with a number of express oversight requirements, and only for vaccinations given during the appropriate time period: childhood vaccinations between August 24, 2020, and the end of the COVID-19 emergency (or October 1, 2024, whichever comes first); and seasonal flu vaccination beginning on August 4, 2021.[99]

Conclusion

Colorado practitioners presented with a victim of a vaccination injury must understand the VICP and CICP. Armed with knowledge of the relevant substantive and procedural requirements, practitioners can properly triage cases to pursue all available federal and state remedies.

Part 2 of this article will explore additional remedies, including workers' compensation, non-workers' compensation funds, employment remedies, and tort remedies. CL

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NOTES

1. Adverse effects of vaccination injury are reported to the Vaccine Adverse Event Reporting System (VAERS), which is a US vaccine safety program co-managed by the CDC and the FDA. VAERS is a post-marketing surveillance program that collects information about adverse events occurring after vaccine administration to ascertain whether the risk/benefit ratio is high enough to justify continued use of any particular vaccine. For details and reported adverse effects organized by vaccination type and year, *see* https://vaers.hhs.gov.

Pharmaceutical companies are required by federal law to report injuries and death, but physicians are not similarly required to do so, although they may be ethically bound to report such adverse events. The VAERS website cautions that a report to the system does not prove a vaccine caused

the adverse event. No proof that the event was caused by the vaccine is required for VAERS to accept the report.

2. Shoulder pain, restricted motion, frozen shoulder, and impingement following intramuscular injection are categorically referred to as shoulder injury related to vaccine administration, or "SIRVA." SIRVA "is an adverse event following vaccination thought to be related to the technique of intramuscular percutaneous injection . . . into an arm resulting in trauma from the needle and/or the unintentional injection of a vaccine into tissues and structures lying underneath the deltoid muscle of the shoulder." National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45136 (July 29, 2015) (proposed rule to add SIRVA to the VICP Table). From 2017 to 2019, more than half of the claims filed under the VICP program were for SIRVA injuries. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 85 Fed. Reg. 43794, 43798 (July 20, 2020) (proposed rule to remove SIRVA from the VICP Table).

3. For a more detailed listing of reported adverse effects from common vaccines, *see* https://vaers.hhs.gov; Vaccine Injury Compensation Program Data and Statistics at hrsa.gov; and Institute of Medicine, Adverse Effects of Vaccines: Evidence and Causality at Appendices B and D (Nat'l Academies Press 2012), https://pubmed.ncbi.nlm.nih.gov/24624471.

4. 42 USC §§ 300aa-1 et seq.

5. The CICP is codified at 42 CFR §§ 110.1 to 110.100 and is authorized by the PREP Act, 42 USC §§ 247d-6d and 247d-6e.

6. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 226 (2011).

7. In 1976, in response to the swine flu epidemic threat, the nation sought to immunize every adult and immunized over 45 million people in what was then the largest vaccination program in US history. Noting a collapse in the insurance market for vaccine manufacturers and providers, Congress enacted the Swine Flu Act of 1976, which provided immunity from any tort claim against a swine flu vaccine manufacturer and replaced it with an exclusive claim against the United States that had to be pursued under the FTCA. While no swine flu epidemic actually occurred in 1976–77, individuals who suffered injuries from the vaccine brought tort claims under the Swine Flu Act. Each claimant was required to prove proximate causation by evidence more compelling than a temporal relationship between the vaccination and the onset of harm. The swine flu vaccination program lasted only from October 1, 1976, to its suspension on December 16 of that year. *See In re Swine Flu Immunization Products Liab. Litig.*, 533 F.Supp. 567, 571–72 (D.Colo. 1980).

8. *Bruesewitz*, 562 U.S. at 226.

9. *Id.* at 227 n.6 (citing Pauly et al., eds., *Supplying Vaccines: An Overview of the Market and Regulatory Context, in Supplying Vaccines: An Economic Analysis of Critical Issues*, 45, 51–52 (Univ. of Mich. 1996)).

10. *Bruesewitz*, 562 U.S. at 227; *Andreu v. Sec'y of Health and Human Servs.*, 569 F.3d 1367, 1373–74 (Fed.Cir. 2009).

11. *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995).

12. 26 USC §§ 4131, 4132(1). The tax assessed per dose is $.75. 26 USC § 4131(b)(1). The revenue from that tax is placed in the Vaccine Injury Compensation Trust Fund. 26 USC § 9510.

13. The VICP's basic operation was described in Pearsall, "Your First Vaccine Injury Case," 49 *Colo. Law*. 64 (Nov. 2020), https://cl.cobar.org/features/your-first-vaccine-injury-case. This article supplements the Pearsall article by addressing the CICP, the differences between the VICP and CICP, and the availability of state law remedies for vaccines not covered by either federal program or as a result of opting out of the VICP.

14. 42 CFR § 100.3. The current version of the VICP Table has been effective since March 21, 2017.

15. While the VICP Table's list of covered vaccines provides the starting place for analyzing whether a client's non-countermeasure vaccine injury is a VICP claim, practitioners may need to take additional steps to assure that their client's vaccine is actually covered by the VICP. For example, in *Scanlon v. Sec'y of Health and Human Servs.*, 114 Fed.Cl. 135 (2013), claimants injured by administration of the varicella zoster (shingles) vaccine brought timely claims under the VICP process for compensation, asserting that the vaccine contained live attenuated varicella virus and, therefore, is on the VICP Table. The special master disagreed and denied eligibility and compensation, concluding that while both the chicken pox vaccine and shingles vaccine contain the same attenuated varicella virus, the shingles vaccine was not on the VICP Table because the diseases sought to be prevented were different and HHS had not imposed an excise tax on the shingles vaccine from which to fund the VICP. On review, the court of claims agreed that while the VICP Table's identification of covered vaccines was ambiguous, the special master was correct and affirmed denial of the claim. In a subsequent ruling the court reversed the special master's denial of attorney fees to the claimant, concluding that the VICP Table's ambiguity provided a good faith and reasonable basis for the claim. *Scanlon v. Sec'y of Health and Human Servs.*, 116 Fed.Cl. 629 (2014). Of additional local interest, the vaccine court special master who decided *Scanlon* was the Hon. Lisa D. Hamilton-Fieldman, a long-standing member of the Colorado Bar.

16. For Off-Table injuries the claimant must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health and Human Servs.*, 165 F.3d 1344, 1352 (Fed.Cir. 1999). A claimant may also seek compensation for aggravation of a previous condition. *Loving v. Sec'y of Health and Human Servs.*, 86 Fed.Cl. (2009) (listing the six elements of proof for significant aggravation of Off-Table injuries).

17. Nat'l Vaccine Injury Compensation Program, Notice of Proposed Rulemaking, 85 Fed. Reg. 43794, 43796 (July 20, 2020) ("SIRVA [and syncope] is, of course, not a vaccine, and it is not an injury caused by a vaccine antigen, but by administration of the vaccine by the health care provider. The Department does not think the term 'associated with' . . . was meant to sweep in injuries caused by negligent administration of the vaccine.").

18. Nat'l Vaccine Injury Comp. Program, Final Rule Revisions to the Vaccine Injury Table, 86 Fed. Reg. 6249 (Jan. 21, 2021).

19. Nat'l Vaccine Injury Comp. Program, Delay of Effective Date, 86 Fed. Reg. 9308 (Feb. 12, 2021); Nat'l Vaccine Injury Comp. Program, Delay of Effective Date, 86 Fed. Reg. 10835 (Feb. 23, 2021).

20. Nat'l Vaccine Injury Comp. Program, Recission of Revisions to Vaccine Injury Table, 86 Fed. Reg. 21209, 21211 (Apr. 22, 2010) (while acknowledging that "the COVID–19 vaccine is not covered under the VICP, HHS recognizes that any action taken that concerns administration of other vaccines could impact . . . efforts to combat COVID–19.").

21. An excellent procedure and practice guide for VICP claims is Abramson et al., *Vaccine, Vaccination, and Immunization Law*, ch. 9 (BNA Books 2018). *See also* Kirkland, *Vaccine Court: The Law and Politics of Injury* (NYU Press 2016). The federal government's explanation of the process is located at https://www.hrsa.gov/vaccine-compensation/index.html. The Pearsall article, *supra* note 13, also provides a useful primer on the logistics of pursuing a VICP claim.

22. *See* 42 USC § 300aa-11–13; Abramson, *supra* note 21 at 9-14 to 9-18.

23. *See* 42 USC § 300aa-12(d) and 13; Abramson, *supra* note 21 at 9-18 to 9-23.

24. 42 USC § 300aa-15; Abramson, *supra* note 21 at 9-24 to 9-26. The Vaccine Act excludes from compensation otherwise compensable losses, so expenses covered by other government benefits programs or private health insurance cannot be compensated under the VICP, and the obligated provider of those benefits may not withhold them based on potential VICP recovery. *Id.* (also noting that Medicaid is an exception to this rule).

25. 42 USC § 300aa-15(e); Abramson, *supra* note 21 at 9-26 to 9-29. If fees are awarded, the attorney cannot charge additional fees. 42 USC § 300aa-15(e)(3). Interim costs and fees can be awarded under certain circumstances. *Avera v. Sec'y of Health and Human Servs.*, 515 F.3d 1343, 1352 (Fed.Cir. 2008); Abramson, *supra* note 21 at 9-27.

26. 42 USC § 300aa-12(d)(3).

27. Abramson, *supra* note 21 at 9-29 to 9-30.

28. *Id.* at 9-29.

29. 42 USC § 300aa-12(e).

30. *Id.*; Abramson, *supra* note 21 at 9-31 to 9-32.

31. 42 USC § 300aa-12(f); Abramson, *supra* note 21 at 9-30 to 9-31. The parties may also seek certiorari review of a court of appeals decision in the US Supreme Court. 42 USC § 300aa-12(e).

32. 42 USC § 300aa-16(a)(2). A claim alleging death from vaccine administration must be filed within two years of the death but not more than

four years from the onset of the first symptom. 42 USC § 300aa-16(a)(3). Where the VICP Table is revised to either permit a claim not previously allowed or increase the likelihood of proving eligibility, a claimant has two years from the effective date of the revision, but not more than eight years from the date of the injury or death, to file a petition in the vaccine court. 42 USC § 300aa-16(b).

33. *See* CRS § 13-80-102(1)(a) and (b) (general two-year statute of limitations for tort claims), -102.5(1) (two-year statute of limitations for claims against health care providers), and -106(1) (two-year statute of limitations for claims against manufacturers and sellers of products).

34. 42 USC § 300aa-16(c). The state law limitation period is stayed from the date of the VICP filing until the date the claimant elects to decline the vaccine court's judgment and pursue a state court remedy or elects to withdraw the petition on timeliness grounds and pursue a state court remedy. *Id.* If a VICP action is errantly pursued in a state or federal court and dismissed, the filing date of that case will be deemed the filing date for the VICP action so long as the VICP claim is properly filed within a year of the dismissal. 42 USC § 300aa-11(a)(2)(B).

35. 42 CFR § 110.42(e).

36. Practitioners should also note that a state law vaccine injury claim may be subject to the Colorado Governmental Immunity Act (e.g., a claim against a vaccinator working for a state or county owned health care facility), which requires a 180-day notice to preserve a claim, even if the claim must first be resolved through the VICP. *See* CRS § 24-10-109.

37. *Bruesewitz*, 562 U.S. at 243. Other exceptions also exist: A claim seeking less than $1,000 or a claim alleging an injury resulting from an adulterant or contaminant intentionally added to a vaccine may be pursued without resort to the VICP. 42 USC §§ 300aa-11(a)(2)(A), 300aa-33(5).

38. 42 USC § 300aa-21(b) and (c) provides that if a special master has not reached a decision on the case within 240 days (plus permitted extensions), or if a special master decision was reached but the court has not entered judgment within 420 days (plus permitted extensions), the claimant can withdraw the petition and pursue state law remedies. The special master or the court are required to notify the claimant of the right to withdraw the petition. 42 USC § 300aa-12(g).

39. Abramson, *supra* note 21 at 9-29. If the claimant does not file the notice to withdraw within 30 days of the notice of right to withdraw, then he or she will be presumed to intend to stay in the VICP. A claimant who elects not to withdraw based on the special master's delay in issuing a decision will not be precluded from withdrawing once that decision is entered if the court does not timely enter a judgment. *Id.*; 42 USC § 300aa(21)(b).

40. 42 USC § 300aa-21(a). The decision not to withdraw a petition on timeliness grounds does not prevent the claimant from later rejecting an adverse or insufficient vaccine court judgment.

41. Abramson, *supra* note 21 at 9-32 to 9-33. The election to reject the judgment must be filed within 90 days of the judgment, or 90 days from the issuance of a court of appeals mandate if an appeal was timely taken, or the claimant will be deemed to have accepted the judgment. 42 USC §300aa-21(a).

42. 42 USC §§ 247d-6d and 247d-6e.

43. 42 USC § 247d-6d(b)(1).

44. 42 USC § 247d-6d(b)(2) and (3).

45. 42 USC § 247d-6d(a)(1). In addition to providing liability immunity, the PREP Act expressly preempts state law claims relating to design, manufacture, distribution, and administration of any covered countermeasure during the effective period of the emergency declaration. 42 USC § 247d-6d(b)(8). It also expressly precludes judicial review of the declaration. 42 USC § 247d-6d(b)(7).

46. 42 USC § 247d-6d(i)(1) and (7).

47. 42 USC § 247d-6e. *See also* 42 USC § 239e (calculation of death benefits payable under smallpox countermeasures emergency declaration incorporated into PREP Act).

48. 42 USC § 247d-6e(b)(4).

49. 42 CFR § 110.1. The CICP is codified at 42 CFR § 110.1 to 110.100.

50. HHS also has two current PREP Act declarations for health emergencies that do not, at this time, include vaccines as countermeasures: Nerve Agents and Certain Insecticides, 82 FR 21819 (May 10, 2017); and Acute Radiation Syndrome, 80 FR 76522, 76525 (Dec. 9, 2019) (expressly omitting "vaccines . . . as such countermeasures are not relevant to acute radiation syndrome").

51. The initial HHS Declaration for COVID-19 was effective February 4, 2020. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020). To date HHS has issued eight amendments to the COVID-19 Declaration: 85 Fed. Reg. 21012 (Apr. 15, 2020), clarifying certain countermeasures and effective dates; 85 Fed. Reg. 35100 (June 8, 2020), expanding defined countermeasures to expressly address any vaccine; 85 Fed. Reg. 52136 (Aug. 24, 2020), expanding the definition of covered persons to include pharmacists administering routine childhood vaccinations; 85 Fed. Reg. 79190 (Dec. 9, 2020), making substantial clarifications to the countermeasures, and defining administration to include, in certain cases, a covered person not administering a limited availability countermeasure to an injured person to be within liability immunity; 86 Fed. Reg. 7872 (Feb. 2, 2021), expanding covered persons to include certain health care providers whose state license or certification has lapsed or become inactive to administer countermeasures upon a showing of specified training (the effective dates of this amendment were corrected at 86 FR 10588 to be February 2, 2021, through October 1, 2024); 86 Fed. Reg. 9516 (Feb. 16, 2021), expanding covered persons to include federal employers, contractors, and volunteers involved in the transportation, distribution, and administration of countermeasures (this amendment was corrected to also include as covered persons members of a uniformed service, including specified members of the National Guard, and to correct the effective dates to February 16, 2021, through October 1, 2024); 86 Fed. Reg. 14462 (Mar. 16, 2021), expanding covered persons to include additional healthcare professionals and students, including midwives, paramedics, emergency medical technicians, physician assistants, respiratory therapists, dentists, podiatrists, optometrists, and veterinarians as vaccine administrators; and 86 Fed. Reg. 41977 (Aug, 4, 2021), expanding covered persons to include pharmacists, pharmacy interns, and pharmacy technicians providing COVID-19 vaccines, childhood vaccines, and seasonal flu vaccines. Any practitioner involved in a COVID-19 countermeasure injury claim should carefully read the declaration and each amendment to understand the scope of immunity applicable to the specific case.

52. Notice of Declaration Under the Public Readiness and Emergency Preparedness Act for Countermeasures Against Marburgvirus and/or Marburg Disease, 85 Fed. Reg. 79198 (Dec. 9, 2020) (currently in effect until August 1, 2025).

53. Ebola Virus Disease Vaccines—Amendment, 84 Fed. Reg. 764 (Jan. 31, 2019) (currently in effect until December 31, 2023).

54. Declaration Under the Public Readiness and Emergency Preparedness Act for Zika Virus Vaccines, 83 Fed. Reg. 38701 (Aug. 7, 2018) (currently in effect until December 31, 2022).

55. Pandemic Influenza Medical Countermeasures—Amendment, 80 Fed. Reg. 76506 (Dec. 9, 2015) (currently in effect until December 31, 2022).

56. Anthrax Medical Countermeasures—Amendment, 80 Fed. Reg. 76514 (Dec. 9, 2015) (currently in effect until December 31, 2022).

57. Botulinum Toxin Medical Countermeasures—Amendment, 80 Fed. Reg. 76529 (Dec. 9, 2015) (currently in effect until December 31, 2022).

58. Smallpox Medical Countermeasures—Amendment, 80 Fed. Reg. 76546 (Dec. 9, 2015) (currently in effect until December 31, 2022).

59. With regard to the pandemic influenza declaration, for example, HHS originally declared an emergency in February 2007 with regard to Avian Flu A (H5N1) addressing vaccines as a countermeasure with an effective time period of the declaration from December 2006 to February 2010. Pandemic Countermeasures; Declaration Under the Public Readiness and Emergency Preparedness Act, 72 Fed. Reg. 4710 (Feb. 1, 2007). Since 2007 HHS has amended, revised, and restated the pandemic influenza declaration on numerous occasions, and expanded "pandemic countermeasures [to include] influenza A H5N1, H2, H6, H7, H9, and 2009 H1N1 vaccines and any associated adjuvants," Pandemic Influenza Vaccines—Amendment, 74 Fed. Reg. 51153 (Oct. 5, 2009), and later more broadly as any "vaccines against pandemic influenza A viruses with pandemic potential, all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines [except to the extent the vaccine is listed in the VICP program]." Pandemic Influenza Vaccines—

Amendment, 77 Fed. Reg. 13329 (Mar. 6, 2021). HHS has also repeatedly extended the effective time period of the countermeasure declaration, which now runs through December 31, 2022. Pandemic Influenza Medical Countermeasures—Amendment, 80 Fed. Reg. 76506 (Dec. 9, 2015). Thus, a practitioner counseling a client injured by a "flu vaccine" must engage in sufficient diligence to determine whether that vaccine is a pandemic influenza countermeasure subjecting the client to a claim under CICP or a seasonal flu vaccine covered by the VICP.

60. Given the scope of this declaration and the amendments it is unlikely that anyone involved in the COVID-19 vaccination process, from the vaccine designers to the manufacturers, the shippers, the vaccinators, and even those managing and operating the facilities where the vaccinations occur, is not immune from liability from their acts with regard to the vaccine. Therefore, in any case with a nexus to a COVID-19 vaccine, from products liability to negligence in administering the vaccination, and even a slip and fall at an arena or drug store while waiting in line to get the vaccine, the practitioner must be aware of the scope of immunity and preserve the client's CICP claim.

61. 42 CFR Part 110. HHS provides an overview of the CICP process at https://www.hrsa.gov/cicp.

62. 42 CFR § 110.3(z).

63. 42 CFR § 110.20(a). If the injured person dies, his or her survivors or estate can seek recovery of medical and lost income benefits caused by the covered injury up until the time of the injured person's death, regardless of the cause of death. If the injured person dies as a result of the use of the countermeasure, only survivors are entitled to a death benefit.

64. 42 CFR § 110.3(z). The PREP Act's definition is slightly different: an injury "is life threatening; . . . results in permanent impairment of a body function or permanent damage to a body structure; or . . . necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." 42 USC § 247d-6d(i)(10).

65. 42 CFR § 110.2(a)(3), 110.11.

66. 42 CFR § 110.42(a). The filing date is the date of the postmark or shipping receipt, or electronic submission. The administrative history notes that if the countermeasure vaccine was taken in multiple doses on different dates, "the filing deadline is one year from the date of the vaccine administration associated with the injury." Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule, 75 Fed. Reg. 63666 (Oct. 15, 2010).

67. Forms and instructions are posted on the HHS web page at https://www.hrsa.gov/cicp/filing-benefits.

68. 42 CFR § 110.42(f). Claimants may also submit a new request form within a year of a new or revised CICP Table if their previous request was denied for lack of eligibility.

69. 42 CFR § 110.42(e). Significantly, no provision allows HHS to deem the filing of a state law tort claim within a year of administration of a countermeasure vaccine as a permissible constructive filing of a CICP claim. *See* Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule, 75 Fed. Reg. 63666 (Oct. 15, 2010).

70. 42 CFR § 110.50. HHS prefers that claimants provide releases to permit the agency to obtain records directly from health care providers. 42 CFR §§ 110.50(e) and 110.51(a)(4).

71. A survivor seeking a death benefit must also submit documentation proving the countermeasure recipient's death, that the death was a direct result of the covered injury, that the survivor is an eligible survivor to receive benefits under the designation provided in the program, and a listing of other defined survivors and their priorities. 42 CFR § 110.52. *See also* 42 CFR § 110.53 (specifying the documentation required for an estate to seek benefits (other than death benefits) for a deceased injured person).

72. 42 CFR § 110.20(b).

73. 42 CFR § 110.20(c). Additionally, the regulations clarify that any injury suffered from the disease for which the vaccine was administered is not a covered injury. 42 CFR § 110.20(d).

74. 42 CFR § 100.100(a). This table, which included symptom occurrence times, became effective September 8, 2015, although the first declaration of PREP Act Pandemic Influenza emergency was in early 2007. Pandemic Countermeasures; Declaration Under the Public Readiness and Emergency Preparedness Act, 72 Fed. Reg. 4710 (Feb. 1, 2007). The interpretation aids in the table provide useful explanations and limitations for these injuries, including clarification that "bursitis is an inflammation of the bursa that lies beneath the deltoid muscle and between the acromion process and the rotator cuff [manifesting itself with, but distinct from] pain in the lateral aspect of the shoulder similar to rotator cuff tendonitis [and requiring the injury] in the same shoulder that received the pandemic influenza vaccine." 42 CFR § 100.100(b)(2). While HHS proposed a smallpox declaration injury table in October 2020 covering injuries for countermeasures including three vaccines (notably, the proposed rule rejected SIRVA injuries but included injuries from vasovagal syncope), that table was not adopted as a final rule before commencement of the new executive administration and its fate remains uncertain. *See* Countermeasures Injury Compensation Program: Smallpox Countermeasures Injury Table, 85 Fed. Reg. 65311 (Oct. 15, 2020).

75. 42 CFR § 110.50(b).

76. 42 CFR § 110.71.

77. 42 CFR § 110.72.

78. 42 CFR § 110.31. There are no caps or limits on reasonable and necessary medical benefits. The documentation necessary to establish the past and future medical expenses is outlined in 42 CFR § 110.60.

79. 42 CFR § 110.32. The documentation necessary to establish lost income benefits is outlined in 42 CFR § 110.61. The method for the calculation is set forth in 42 CFR § 110.81. While each case must be uniquely considered, in general the benefit is either 66.66% (if claimant

has no dependents) or 75% (if claimant has dependents) of claimant's gross employment income at the time of the injury, without consideration of projected future income (except for minors), but with an annual inflation adjustment. 42 CFR § 110.81(a)(1). This benefit is capped at $50,000 per year, with a lifetime cap equal to the full death benefit payable under the PSOB program, 34 USC § 10281, during the year the injury occurred. 42 CFR § 110.81(c)(2) and (3). The maximum death benefit under the PSOB program is $250,000 with inflation adjustment, which, for the year beginning October 1, 2020, is $370,360 42 CFR § 110.81(c)(3), https://psob.bja.ojp.gov/psob-data.

80. 42 CFR § 110.33. "Eligible survivors" are defined in 42 CFR § 110.11, generally using the same categories and priorities as the PSOB program. The documentation necessary to establish death benefits is outlined in 42 CFR § 110.62. The method for calculating death benefits is set forth in 42 CFR § 110.82. As with lost income benefits, each case must be uniquely considered, but the maximum death benefit is generally limited to the full death benefit payable under the PSOB program, unless there is a survivor under 18 years of age who may then request an alternative calculation based on the decedent's income.

81. *See* 42 CFR § 110.31(c) (medical benefits); 42 CFR § 110.32(b) and (c) (lost income benefit, secondary third party obligations to pay lost income, retirement, or disability, or employee's use of paid leave); and 42 CFR § 110.33 (b) and (c) (standard calculation death benefit secondary to PSOB benefits, and alternative calculation death benefits secondary to payment for loss of income, death or disability benefits, retirement benefits, and life insurance benefits).

82. 42 CFR § 110.84.

83. 42 CFR § 110.90.

84. 42 CFR § 110.90(c).

85. *Id.*

86. *Id.*

87. 42 CFR § 110.92. Nonetheless, the HHS secretary retains seemingly unlimited discretion to review and modify at any time any determination made for a claimant, either on the claimant's request or by the secretary's own motion. 42 CFR § 110.91.

88. 42 USC § 247d-6d (d) and (e). The PREP Act includes an exception to the exception for a willful misconduct action against a manufacturer or distributor for an act subject to FDCA regulation if the United States has not instituted an enforcement action for the alleged misconduct or such action has been resolved favorably to the manufacturer. 42 USC § 247d-6d(c)(5)(A).

89. 42 USC § 247d-6d(c)(1)(A).

90. 42 USC § 247d-6d(c)(1)(B).

91. 42 USC § 247d-6d(e).

92. 42 USC § 247d-6d (e)(2) and (4). Notably, the PREP Act does not specify the limitations period for filing a willful misconduct claim.

93. 42 USC § 247d-6d (e)(7) and (8). While damages are reduced by the amount of collateral benefits received, the benefits provider is not permitted to recover any subrogation lien amounts from the award to the plaintiff. *Id.*

94. *See, e.g.*, Van Tassel et al., "Covid-19 Vaccine Injuries—Preventing Inequities in Compensation," *New England J. of Medicine* (Jan. 20, 2021), https://www.nejm.org/doi/full/10.1056/NEJMp2034438?cookieSet=1; Engstrom and Meyers, Coronavirus Vaccines and the Law, Stanford Law School Blogs (Dec. 22, 2020), https://law.stanford.edu/2020/12/22/coronavirus-vaccines-and-the-law.

95. At the time of this article's publication, at least two pieces of legislation had been introduced in the US House of Representative to streamline the process for adding vaccines, such as the COVID-19 vaccine, to the VICP. *See* HR 3656, Vaccine Access Improvement Act of 2021 (June 1, 2021); and HR 3655, Vaccine Injury Compensation Modernization Act of 2021 (June 1, 2021).

96. The Third Amendment, effective August 24, 2020, added to "covered persons" pharmacists and pharmacy interns providing childhood vaccinations due to the fact that the COVID-19 crisis was decreasing the rate of routine childhood immunization, leading to an increased rate of other infectious diseases. 85 Fed. Reg. 52136 at 52140. In its most recent COVID-19 PREP Act amendment, effective August 4, 2021, HHS expanded the Third Amendment to include pharmacy technicians and to add to covered conduct the administration of seasonal influenza vaccines to adults due to the fact that "states have largely lifted the community mitigation measures previously in place at the height of the COVID–19 pandemic. Seasonal influenza has the potential to inflict significant burden and strain on the U.S. healthcare system in its own right; and in conjunction with the ongoing COVID–19 pandemic, a spike in influenza cases could overwhelm healthcare providers." 86 Fed. Reg. 41977 at 41979. Recognizing recent guidance allowing the co-administration of COVID-19 vaccine and seasonal influenza vaccine, HHS also determined that allowing the same vaccinators to provide those vaccines concurrently under the PREP Act would increase vaccination rates. *Id.*

97. 86 Fed. Reg. 41977 at 41978.

98. 86 Fed. Reg. 41977 at 41979; 85 Fed. Reg 52136 at 52140 (same).

99. 86 Fed. Reg. 41977 at 41982. As of the date of this writing, the authors are not aware of any case law or other guidance addressing this issue.