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April 14, 2020

Honorable Alex M. Azar II
Secretary of Health and Human Services
Office of the Secretary
330 C Street, SW
Washington, DC 20416

Mr. Thomas J. Engels
Office of the Administrator
Health Resources and Services
5600 Fishers Lane
Rockville, MD 20852

By Email and First-Class Mail

OPEN LETTER TO THE SECRETARY OF HHS AND HRSA ADMINISTRATOR

Re: HRSA Proposed Vaccine Rulemaking Making Dramatic Changes in Scope of the National Vaccine Injury Compensation Program

Dear Secretary Azar and Administrator Engels,

The Health Resources and Services Administration (“HRSA”) has recently released a Notice of Proposed Rulemaking (“NPRM”) that will make detrimental changes to the Vaccine Injury Compensation Program and negatively impact our nation’s vaccine policy. The NRPM recommends, among other things, the removal of Shoulder Injury Related to Vaccine (“SIRVA”) and syncope from the Vaccine Injury Table.

I strongly urge Administrator Engels to reject the Proposed Rulemaking recommended by your subordinates. Their proposal is ill-conceived and will do severe damage to our national health policy.

Should Administrator Engels proceed in signing this severely flawed NPRM, I call on Secretary Azar to reject the Administrator’s recommendation and stop the adoption of the Final Rule.

By way of background, I spent 30 years as an attorney at the Department of Justice working on cases in the Vaccine Injury Compensation Program (“VICP”). I was actually the very first attorney hired by the government to defend VICP claims back in the 1980s. Over the years, I have worked closely with all the Directors of HRSA’s Division of Injury Compensation Programs at HHS (this letter will refer to HRSA and HHS interchangeably) including Drs. Geoffrey Evans, Vito Caserta, Melissa Houston, Rosemary Johann-Liang, and Narayan Nair.

All of these outstanding medical professionals will vouch for my integrity and dedication to the VICP. For three decades, I also worked daily with the highly talented attorneys in HHS' General Counsel's Office regarding vaccine-related matters.

After having worked on thousands of cases in which I represented HHS, I retired from DOJ after 30 years of work with the VICP. I spent my entire professional career advancing the goals of the Vaccine Program: to make vaccines readily available and as safe as possible. I am staunchly pro-vaccine. As a government attorney proudly representing HHS for thirty years on many vaccine issues, I believe vaccines save lives. I understand that Congress enacted the Vaccine Act and created the Vaccine Trust Fund to compensate those who experience rare reactions that we know occur, and to ensure that pharmaceutical companies continue to develop and manufacture vaccines, and to further ensure that vaccine administrators continue to administer them.

In the interest of full disclosure, I retired from my government job in 2017, and in 2018, I was lured out of retirement by my wife, Leah Durant, and I now work at a small firm that she owns that, among other things, brings vaccine petitions in the VICP. The firm she founded started taking VICP cases after she suffered a severe SIRVA injury herself. I now personally represent 10 VICP petitioners who allege certain vaccines caused their injuries including brachial neuritis, Guillain-Barre syndrome ("GBS"), and SIRVA.

HRSA's current proposal to remove SIRVA and syncope from the Vaccine Injury Table is a 180-degree reversal of sound health care policy that HRSA debated exhaustively just three short years ago. At the conclusion of that process, HRSA enacted the Final Rule adding these two injuries, and others. In the years prior to enacting the 2017 Final Rule that added SIRVA, syncope, and GBS to the Vaccine Injury Table, HRSA and its advisors, consisting of world-renowned medical experts and legal professionals, worked tirelessly to review the medical, legal, and policy considerations associated with adding these three injuries to the Vaccine Injury Table. The pros and cons of adding these injuries to the Vaccine Injury Table were then openly discussed at public meetings for the sole purpose of seeking input from health care policymakers and the general public. Given that very public effort to alert others of changes to the Vaccine Injury Table three years ago, it shocks the conscience that the current proposal to reverse those changes is not open for discussion in ANY public manner.

HRSA has steadfastly refused to discuss the matter in any way. Indeed, despite repeated calls for more information by members of the Advisory Commission for Childhood Vaccines ("ACCV"), an entity *required* by Federal law to vote on the merits of any proposed deletions to the Vaccine Injury Table, HRSA remains silent. On top of that, HRSA has refused to meet with or brief Commission members in any way.

I am currently a member of the Vaccine Section of the Advisory Council of the United States Court of Federal Claims. The Court of Federal Claims houses the Office of Special Masters, also known as the nation's "Vaccine Court." At the last meeting of the Advisory Council on April 6, 2020, the issue of the Proposed Rulemaking was placed on the agenda set by the Court. Numerous members of the Vaccine Advisory Council, including myself, asked the representatives of HHS (a lawyer from HRSA) and DOJ numerous questions about the Proposed Rulemaking. HHS and DOJ repeatedly refused to answer *any* questions whatsoever, as they

reported that they were under strict instructions not to discuss the issue. Over and over the HRSA lawyer said she was only permitted to bring questions back to her leadership rather than make any comments about the proposed changes to the Vaccine Injury Table. This lack of transparency and refusal to engage in any form of dialog about removing Vaccine Table Injuries which comprise well more than 50% of all vaccine cases filed in the Vaccine Program, stands in very sharp contrast to HHS' approach over the past 30 years when I represented the Vaccine Program, including as recently as 2017.

HRSA's efforts to reverse vaccine policy has been kept secret from our nation's most important vaccine policy makers. I have confirmed that HRSA made no effort to discuss, or even inform, the CDC's prestigious Advisory Committee on Immunization Practices ("ACIP") or HHS' own advisors at the National Vaccine Advisory Committee ("NVAC") that changes to the Vaccine Injury Table were being proposed.

What HRSA is now proposing is a huge health policy mistake. It puts liability back on vaccine manufacturers (companies that develop and produce vaccines like Sanofi, Merck, and others) and vaccine administrators (doctors, physician's assistants, nurses, medical techs, pharmacists, and pharmacy techs) for SIRVA and syncope injuries, and the results of this misguided reversal will have our nation revert back to where we were in the 1980s when so many manufacturers and administrators were leaving the vaccine industry due to high litigation costs. Please do not allow this to happen.

The policy reasons being put forth by HRSA in the Proposed Rulemaking are not sound. Having worked as a lawyer for the VICP for over 30 years, as recently as two and a half years ago, and now seeing it from the "other side" for almost two years, **I can positively assure you that the sole reason HHS is pursuing this reversal of their own policy is due to the increased workload at HHS and DOJ.** Recent information released by HHS at the ACCV meeting on March 6, 2020, indicated that 54% of all claims filed in the VICP over the last three fiscal years are SIRVA cases. That means approximately 677 SIRVA cases per year have been added to the work required by the medical personnel at HHS and the lawyers at DOJ. While both offices have added staff to deal with this increased caseload, they are overwhelmed with the workload. I completely understand their stress, and frankly I lived in that frenzied work environment myself until my retirement in 2017. Nonetheless, a heavy workload is NO reason to deny citizens compensation for legitimate vaccine injuries as Congress intended.

HRSA's NPRM is flawed medically and legally, and it reverses decades of good vaccine policy.

Medical Considerations

The science underlying SIRVA is sound. HRSA itself, with its original Atanasoff article in 2010, did the initial study identifying SIRVA as a vaccine-related injury. Atanasoff et al. identified a reliable medical theory that antigenic material from the vaccine which is injected into synovial tissues results in an immune mediated inflammatory reaction causing severe and chronic pain. This peer-reviewed article, published in the prestigious medical journal "Vaccine," as well as several other peer reviewed articles, were carefully examined by the highly respected

National Academy of Medicine (“NAM”) and the NAM concluded that certain shoulder injuries were caused by the administration of a vaccine. From 2010 through 2017, HHS and the ACCV proudly proclaimed that the science was more than sufficient to add the SIRVA injury to the Vaccine Injury Table. Hesse (from CDC’s Immunization Safety Office) and Atanasoff did a second peer-reviewed article in 2019 affirming the original findings.

HRSA’s NPRM incorrectly states that “There is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than by the vaccine itself.” This assertion is belied by published vaccine studies performed by HRSA and the CDC. In 2019, Hesse (from CDC’s Epidemic Intelligence Service) and Atanasoff conducted a scientific review of the clinical characteristics of SIRVA in 476 VICP claims filed between 2010 and 2017. In all of these cases, the VICP issued a “concession” that the administration of the vaccine actually caused the claimant’s SIRVA. Of those 476 cases, only 36.1 percent revealed evidence that the vaccine site was responsible for SIRVA (that the vaccine was administered “too high” on the arm). This article was also published in the journal *Vaccine*.

Likewise, on January 29, 2020, *Vaccine* published a study by Hibbs et al. (from CDC’s Immunization Safety Office) that searched the Vaccine Adverse Event Reporting System (“VAERS”) database from July 2010 to June 2017 for reports of atypical shoulder pain and dysfunction within 48 hours of administration of an inactivated influenza vaccine. 1221 reports fit their criteria. Hibbs et al. concluded, “While specific etiology of cases is unknown, improperly administered vaccine, which is preventable, *might be a factor*” (emphasis added).

The 2019 study by Hesse and Atanasoff, and the most recent study published by CDC’s Hibbs et al. in January 2020 simply do not support the NPRM’s central thesis that uniform agreement exists in the scientific community that SIRVA is caused by improper vaccine administration rather than by the vaccine itself. Nor is the NPRM’s thesis supported by HRSA’s original study in 2010.

Finally, a highly respected orthopedic shoulder surgeon from Johns Hopkins, Dr. Uma Srikumaran, has written a scholarly open letter to the Secretary disagreeing with the NPRM’s central thesis. Dr. Srikumaran reviews the medical literature and evidence on SIRVA. See <https://www.sciencemag.org/sites/default/files/Srikumaran%20Open%20Letter%20to%20Health%20and%20Human%20Services%203.26.20%20FNL.SIRVA%20Insider.pdf> As quoted in *Science Magazine*, Dr. Srikumaran believes HRSA’s proposal “represents the scientific literature in a misleading way.” <https://www.sciencemag.org/news/2020/04/us-wants-end-most-payouts-leading-vaccination-related-injury>. Dr. Srikumaran’s letter argues against one of HRSA’s central assertions that the antigen from the vaccine has nothing to do with SIRVA. It indeed has everything to do with it, and Dr. Srikumaran’s conclusions are buttressed by the peer reviewed scientific studies discussed above as well as those cited in his letter. Please note that the *Science Magazine* article provides a quote from my spouse, Leah Durant, and describes her as an attorney and a SIRVA survivor.

Legal Considerations

There are many legal problems with HRSA's NPRM. I will discuss only two here.

HRSA cannot adopt an administrative rule that is contrary to Federal law. The Vaccine Act is an Act of Congress that was signed into law by President Ronald Reagan in 1986. The NPRM contravenes the express provisions of the Federal law. The NPRM wants to shift the liability for SIRVA and syncope injuries back to vaccine administrators and vaccine manufacturers in clear contradiction of the Act. The NPRM proposes to have Americans who suffer SIRVA bring a civil action against the administrators for negligence, so that "those who failed to properly administer the vaccine" would face liability. The Federal statute, however, was specifically designed to shield administrators from any liability.

HRSA's attempt to separate out the "administration of a vaccine" provisions from the protections of the Vaccine Act is legally incorrect. HRSA completely ignores several provisions of the Vaccine Act. 42 U.S.C. § 300aa-11, specifically provides protection for "administration" of a vaccine. Section 11(a)(2) of the Act explicitly states, "No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death **associated with the administration of a vaccine** after the effective date of this part..." Likewise, Section 11(3) clearly states, "No vaccine administrator or manufacturer may be made a party to a civil action . . . for damages for a vaccine-related injury or death **associated with the administration of a vaccine** after the effective date of this part." Further, Section 11(b)(2) plainly states "Only one petition may be filed **with respect to each administration of a vaccine**."

In all, Congress used the term "administration of the vaccine" in 17 separate instances in the Vaccine Act. If HRSA wants "administration of a vaccine" to be excluded from the Act's coverage, HRSA's sole remedy is to lobby Congress to change the law, not to pass an administrative rule that disregards the express language of the Federal law passed by Congress. HRSA has no authority to override the actions of Congress and the President of the United States.

The NPRM also ignores 42 U.S.C. § 300aa-17. HRSA advocates for the position that monetary payment for negligence in the administration of a vaccine should be borne by the vaccine administrator, not the Vaccine Fund. That is contrary to law. Congress specifically envisioned instances where there might be negligence on the part of vaccine administrators and vaccine manufacturers, and they expressly provided a provision in the Act to deal with such circumstances. In Section 17 of the Act, the Vaccine Act's Subrogation provision, Congress places on the Secretary of HHS the responsibility to recoup Vaccine Trust Funds that were paid to a claimant for the negligence of a vaccine administrator or manufacturer. Rightfully so, Congress instructed HRSA, not John Q. Public who received a vaccine at his local doctor's office or pharmacy, to seek reimbursement from the administrator. Interestingly, in the thirty-two years since the effective date of the Vaccine Act, HRSA has never once availed itself of the Act's Subrogation provision. If the Secretary is sincerely interested in preserving Vaccine Trust

Funds, as the NPRM claims, Section 17 of the Vaccine Act provides the best mechanism for doing so.

Policy Considerations

The only reason that HRSA is completely reversing course now and seeking a change in the Vaccine Injury Table is because there were many, many more claims than they anticipated. They are now feeling overworked and thus regret adding SIRVA and syncope to the Vaccine Injury Table. But making national health policy based on government workload considerations is unwise and short-sighted.

Because of my “inside perspective” I know that that the primary goal of this reversal in policy is to alleviate the workload of overworked Federal employees at HHS and DOJ who are responsible for reviewing, evaluating and litigating all vaccine claims filed in the VICP. However, that is not the reason cited by the Secretary for eliminating SIRVA and syncope from the Vaccine Injury Table. The NPRM cites three different policy reasons for eliminating the two injuries. First, HRSA cites the fact that they want to preserve Vaccine Trust Funds thereby ensuing funds will be available for other more-meritorious cases. HRSA states that from Fiscal Year 2016 through Fiscal Year 2019, the Act paid \$119,154,985 to successful SIRVA petitioners. The average yearly payment then is \$39,718,328.30. That is nothing compared to the \$4,013,972,370 in the Vaccine Fund as of January 31, 2020. In fact, the Fund earned a whopping \$26,167,862 in interest on its investments in just the first three months of Fiscal Year 2020. And, of course, as noted above, by availing themselves of the Act’s Subrogation provision, HRSA could actually recoup every penny they paid out in SIRVA claims if in fact all instances of SIRVA are actually caused by administrator negligence as HRSA suggests.

The second policy consideration put forth by HRSA is that medical providers are sloppy, and there is no incentive for them to be careful when administering vaccines because they know they are protected by the VICP. This is an outrageous and insulting statement by HRSA and all medical professionals should be highly offended. According to HRSA’s logic, medical professionals such as doctors, nurses, and pharmacists will *only* be incentivized to do their jobs correctly if they can be sued for improperly administering a vaccine that results in SIRVA or syncope. HRSA’s logic is absurd. It is akin to proposing that we outlaw car insurance to incentivize drivers to be more careful.

Finally, as a justification for their reversal of policy, HRSA cites the fact that payouts from the VICP may convince some people that vaccines are not safe and that the Vaccine Program statistics will be used as justification by such people for not getting vaccinated at all. This argument is without merit. We cannot adopt standards for vaccine policy that cater to those who do not receive vaccinations. Our national vaccine policy must be geared to protect the 150,000,000 or more individuals who actually receive vaccines each year.

The timing of HRSA’s proposal could not be worse and quite frankly, is very suspicious. While Americans are distracted by the pandemic, HRSA is quietly working behind the scenes to reverse course and may ultimately cripple our nation’s vaccine provider infrastructure by exposing doctors, nurses and pharmacists to billions of dollars in lawsuits. If the proposed changes are

approved, it is highly likely the cost of malpractice insurance will skyrocket for these providers as well. Hopefully, our country is months away from a coronavirus vaccine. Now is not the time for HHS to put American lives at risk by reducing the pool of vaccine administrators and burdening the heroic medical care providers who are on the frontline of battling COVID 19. Now more than ever, our nation's doctors, nurses, and pharmacists need the protections provided by the Vaccine Act.

One final word, the NPRM refers to SIRVA and syncope cases as "frivolous" and "dubious" claims. They are not. Please bear in mind that HHS has been conceding SIRVA cases as being vaccine-related injuries since 2010. In fact, HRSA compensated syncope cases since the inception of the Program over 30 years ago. Ask anyone who has ever experienced SIRVA or syncope from a vaccine if their injury is frivolous. They are very painful injuries, often requiring one or more surgeries, and in some cases results in permanent damage. No one who has suffered one of these injuries would say it is frivolous or dubious.

I have spent my whole professional life in the VICP, and I am vested in seeing it succeed. Frankly, I am very scared that the proposed changes will cause the Program to unravel, a thought that makes me very worried having devoted my entire career to advancing the very noble goals of the Vaccine Act.

Secretary Azar and Administrator Engels, please stop this harmful proposal from moving forward.

I am happy to discuss this matter with you.

Thank you very much.

Respectfully yours,



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