19-6339

Docket No. 19-_____ ORIGINAL

IN THE SUPREME COURT OF THE UNITED STATES

Jackson Miles - Petitioner

v.

Secretary of Health and Human Services - Respondent

Regarding Case No. 2019-1480 Miles v. HHS

of the United States Court of Appeals for the Federal Circuit

Denying Final Petition for Panel Rehearing (August 5, 2019)

ON PETITION FOR A WRIT OF CERTIORARI TO

United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

Jackson Miles, Representing Self, pro-se

1010 Hackberry Court

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Redact address and phone number per Rule 34.6

I. QUESTIONS PRESENTED

Where the special master of the Vaccine Injury Compensation Program (VICP) (hereafter noted as "the Program") violates the 2017 Secretary of Health and Human Services' (hereafter referred to as "the Secretary" or "respondent") posted Rule that revised the National Childhood Vaccine Injury Act of 1986 (NCVIA) (hereafter noted as "the Act"), under what circumstance can the special master arbitrarily overlook the Secretary's policy changes to shape a capricious decision?

Where the name implies a childhood law, does the Act fairly represent the rights of children in a "person" law and the constitutional right to a fair jury trial?

Where the Constitution mandates justice for all, does the Program adequately offer resources and legal representation to petitioners with disabilities?

Where the Act was written to protect commercial interests for public health concerns, where is a line drawn to protect an individual's constitutional rights to make informed decisions, to discuss ideas and science, and to freely make choices regarding drug and safety issues?

Where the Secretary manages multiple healthcare regulatory agencies, under what circumstances can the Program offer nonconforming science and facts which violate administrative and regulatory rules if held independently as facts?

Where the Secretary promises citizens to operate with utmost care and efficiency, under what discretion may the Secretary or any agent violate this promise by adding regulation and rules with no certified cost savings and dire added risks?

LIST OF PARTIES

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B: Opinion of the United States Court of Appeals for the Federal Circuit, Miles v. Secretary of Health and Human Services, No. 2019-1480, entered May 8, 2019.

C: Opinion of the United States Court of Federal Claims, Miles v. Secretary of Health and Human Services, No. 12-254V, Ordered and Affirmed Judgement on Motion for Review, Filed 12/20/2018

D: Order of the United States Court of Federal Claims, Office of Special Masters, Miles v. Secretary of Health and Human Services, No. 12-254V, Decision Ordered and Filed: June 28, 2018

Other material essential to understanding: Listed as:

E: Case report relating to influenza vaccine as a trigger of nephrotic relapses as related to timing and sequence.

F: Case study pointing to influenza vaccines as a trigger of nephrotic relapses.

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K: FDA approved Prograf professional package insert information relating to timing, sequence and linkage of treatment protocol, and true cause of cerebrovascular accidents and Posterior Reversible Encephalopathy Syndrome (PRES) misunderstood by lower courts.

L: NephCure Foundation and SickKids medical poster relating to influenza vaccine as a trigger of nephrotic relapses.

M: Expert study and report by PodoNet experts in 2015, as relating to understanding of term podocytopathy and Special Master Millman decision accepting it as a causational mechanism, while rejecting petitioner's causational claim of immune-mediated causation.

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O: Expert study further explaining podocytopathy and Angiopoietin-like 4 factors as presented to the Appellate Panel suggesting causation is multifactorial.

P: Trial discussion of respondent's expert demonstrating a lack of discussion and misunderstanding of the causation factors that the special master adopts for her decision.

Q. FDA and the Department of Health and Human Services provided reports and pharmacovigilance relating to influenza vaccine as a

trigger of nephrotic relapses, as reported in public record and confidential records acquired by petitioner.

R. Example of an FDA approved product insert, one of many with many FDA approved references in clinical and pharmacovigilance literature where it shows the FDA and pharmaceutical manufacturers accept immune-mediated causation as explained by petitioner as the causational mechanism of minimal change nephrotic syndrome as it relates to drug induced cases, but argued as podocytopathy by Secretary's respondent's experts which Special Master Millman, Senior Judge Smith, and Appellate Judges Dye, Moore and Taranto strongly affirmed, rejecting the immune-mediated argument. A nonsensical argument as the petitioner only must present a logical reasonable causational mechanism for a trigger of a relapse to occur. If FDA is incorrect, the FDA must fix this error in approved statements as the Secretary cannot have multiple agencies making conflicting statements.

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The Judgement and Order of the United States Court of Appeals for the Federal Circuit Panel (Petition Case No. 19-1480) is reported. The Decision of Special Master Laura Millman (Petition in the United States Court of Federal Claims Case No. 12-254V) is reported. The Opinion of Senior Judge Loren Smith (Motion for Review in the United States Court of Federal Claims in Case No.12-254-LAS) is reported.

JURISDICTION

The Court of Appeals issued its Order denying a rehearing on July 29, 2019 denying the petition for panel rehearing. This Court's jurisdiction is prayed under 28 U.S. Code § 1254 and 28 U.S. Code § 2403 (a), as served to the respondent and the Solicitor General.

STATEMENT

I, Jackson Miles, respectfully ask for a writ of certiorari to be granted to review the Judgment of the United Stated Court of Appeals for the Federal Circuit and the Decision of the Special Master in the United States Court of Federal Claims.

REPRESENTATION AND DISABILITY

As a fully disabled adult, covered under the Americans with Disabilities Act, with medically established physical and cognitive disabilities caused by cerebrovascular accidents (CVAs) which limit my ability to move and effectually communicate. My father provides supportive guidance and assistance in preparing this writ of certiorari.

The Secretary and lower Courts omit my disability by offering no assistance or accommodations with respect to my disability. Inexpertly implying I have no disability. My disability is well-known and material to my requests. Legal representation in the Program is unfairly balanced as competent attorneys serving disabled petitioners is disturbingly limited. I have no funds and no legal training and request now to proceed in forma pauperis.

The Act is unique as it does not define a child but defines all injured parties under "person" definitions. The Act generally implies constitutional rights to me as a person, with rights-in-trust as a child, and full rights to enjoy as an adult, as I am now an adult. Federal limits restrict access to my State rights to proceed with civil action regarding vaccines. I ask this Court to grant me full access to proper legal representation and accommodations to be heard and to enjoy my rights as an adult.

INTRODUCTION

The U.S. Court of Appeals for the Federal Circuit affirmed and issued a mandate confirming the decision of Special Master Millman and opinion of Judge Smith in the Federal Court of Claims giving wide discretion affirming her finding of facts hold an authoritative standard under the Act. A Motion for Review opinion denied petitioner relief. The Court of Appeals considered but also denied a hearing and request for a rehearing on request for relief. All parties accept science and facts that are misunderstood and misinterpreted, including perjury. It is appropriate for this Court to review facts and legal process, and more significantly constitutionality of the Act.

The Program is defined in the Act as a "modified no fault" alternative to a tort liability legal process has progressively raised the bar and altered its standards for findings of facts. A special master is the "finder-of-facts" and decisionmaker for damage compensation and must act as a neutral party. The Program has participation by all branches of the government. I intend to show that constitutional rights are violated in the Program relating to fact-based science, limited oversight, and openly biased policy leanings.

The Act has evolved into a complex and discretionary law with limited avenues for redress should the special master be unequal with discretion that is arbitrary or

capricious, or biased in influencing the Program's legal process. Rare orphan conditions are left unsettled as government appointed experts fail to understand pharmacology.

A free-style form of discretion breaks away from science, and permits an Old-World authoritarian discretion granted to designated authorities in science given recognition as Patriarchs. The science is not the science of many, but the science of the few selected individual authorities. The "more likely than not" standard does not favor the petitioner as it should, as stated in the Act. Imbalanced and adversarial fact-finding discussions are harmed by limitations of court time, limits placed on experts permitted to testify and expert knowledge shared.

Special masters miscomprehend science to fit dicta and suggested holdings which are slanted to fit an often-biased decision . This Court should prescribe expressed dictum so that future litigants, the Secretary and the courts understand the Program, the legal process, fact finding transparency, and what are the limits to compensation, as restricted by resources and government interests as related to suggested fairness in the Act.

Equal justice under law applies to all legislation. The Act is unique but is not outside our prescribed rule of law. Laws must be sufficiently strong and flexible to meet the needs of the republic, and sufficiently limited and just to protect the promised rights of its citizens. This Court can balance society's need for order and the individual's right to freedom, and review facts not just as an error in weighed evidence by a special master, but

as an overriding legal issue where the Act's legal process has failed to provide accountability, transparency, accessibility and an impartial dispute resolution legal process.

CONSITUTIONAL AMENDMENTS AND STATUTORY PROVISIONS INVOLVED

1. Constitution of the United States, Amendment I.
2. Constitution of the United States, Amendment VII.
3. 1986 National Childhood Vaccine Injury Act (Public Law 99-660)
4. 42 U.S. Code Subchapter XIX - Vaccines
5. United States Federal Food, Drug, and Cosmetic Act of 1938
6. Americans with Disabilities Act of 1990 (42 U.S.C. § 12101)

A. STATUTORY AND REGULATORY BACKGROUND

In 1986, The National Childhood Vaccine Injury Act (42 U.S.C. 300 aa-10 et seq), ("The Act") established the VICP ("the Program") to provide compensation to persons thought to be injured by a listed covered scheduled vaccine. Where a petition for injury is filed in the United States Court of Federal Claims with a copy served on the Secretary who is designated as the respondent. The Act suggests claims are matrix-simple.

Where an approved "Table" injury evidencing a vaccine caused or significantly aggravated an injury (causation-in-fact) or as enumerated in regulation as a matrix "Vaccine Injury Table", the claim is recognized for timing and causation and paid as related to injury to assist the individual in returning to a normal life.

The "off-Table" injuries are more complex as the Secretary has not fully accepted the mechanisms of causality and timing and sends the claim to a special master for establishing facts for acceptance and damages determination. The Secretary consistently in public forums calls this legal process appropriate with a lower burden of proof.[1] Yet special masters are generally not scientists in practice but legal authorities applying legal logic to science. The Program has its own set of rules, an odd methodology for interpreting science, and policies are generally driven by commentary and doctrinal motivations.

Briefly defined, vaccines are regulated drugs approved by the Food and Drug Administration ("the FDA"). Vaccines stimulate production of antibodies in the body through cellular immune responses via exposure to antigen agents leading hopefully to protective immunity. The vaccine definition has grown in medical and research scope along with pharmacologic terminology usage in recent years. The Secretary implies

Footnote 1: As noted in Adverse Effects of Vaccines: Evidence and Causality, page 29, the Secretary states "off-Table" or "causation-in-fact" injuries "must pursue their claim before Special Masters" where "Claimants bear the burden of proving that the vaccine caused their injury, although the burden of proof is lower than that in the tort system."

an active vaccine pharmacovigilance program through multiple agencies in the National Vaccine Program Office. The Secretary's agencies are not appropriately fully accessible or user-friendly to the public (or government parties as well).

In February 2017, the Secretary adopted revised rules for Table injuries. Giving acceptance of a 2012 report Adverse Effects of Vaccines: Evidence and Causality created by the Institute of Medicine and nine Secretary agency workgroups. Conclusions and methodology suggesting better determination of causation and linkage for over 158 vaccine adverse events. My injury, nephrotic syndrome relapse triggered by influenza vaccine, was not covered in this publication.

The key revision to the Rule is clearer guidance as to what evidence is strong verse what evidence and mechanisms are weak or inconclusive as defined for acceptance relating to all covered vaccines, but the Secretary limits guidance as going forward and designated Table injuries only. This guidance is accepted but applied unevenly, as off-Table petitions are held to a different standard, where adopted guidance is not weighed but given administrative discretion. Such that in off-Table petitions, weak evidence and mechanisms may be misinterpreted as stated by a single expert given authoritative force.

My injury was a vaccine injury triggered by a vaccine listed in subparagraph (A) and suffered residual complications of the medical condition for more than 6 months after the inoculation, and resulted in inpatient hospitalization, a change in medical protocol, further complications, disability, or death. My injury fits the framework of the Act.

The Act further has also evolved as limits to actions have narrowed. Manufacturers warnings of risk as noted "under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262" are not openly available. The Act's "three stage" legal process for determining causation, then determining damages, and pain and suffering damages are exceedingly mixed, mashed and melded into a single process decided by one judge.

The Act states the "more likely than not" standard goes to the petitioner, if facts support the claim. Facts support my petition as understood in three stages pretrial. The Secretary misuses the Program's funds and resources, encouraging special masters to arbitrarily draw lines to achieve lowered settlements, where a large sum is spent for lawyers and experts, rather than settling actual damages. The spirit and authenticity of the Program is questionable as it is does not serve the public interest and does not make truthful statements in public notice.

As my injury fits guidance standards, more emphasis must be given to facts, rather than discretion. The Secretary's Rule commentary notes:

> "individuals should not be disqualified from potentially receiving VICP compensation due to biodiversity and individual susceptibilities. Certain individuals may not meet the [Qualifications and Aids to Interpretation] definition, as it is impossible to develop a scientifically sound definition that allows for inclusion of every circumstance, particularly those that may arise when unique and sometimes complex pre-vaccination medical conditions exist. However, individuals who do not meet the Table criteria are not precluded from filing a petition and may be found entitled to receive compensation if they demonstrate that their condition was caused or significantly aggravated by a covered vaccine."

All of the Secretary's representatives under the Act express differing discretion of laws, rules and regulations. The balance of justice is lost in adjudicated facts, aggressive defense of the Act and the Program, and an adversarial viewpoint. The Secretary provides the public a positive but inadequate view of vaccine safety and efficacy, with emphasis given to efficacy. The Secretary is unhurried to create benchmark Rules, but these standards should be understood among all stakeholders under the Act beyond ambiguous public statements. Bad business practices among government agencies, which resonates as poor guidance to medical professionals who follow guidance as standards of care. This Court can correct these untrustworthy activities that notably harms individuals.

B. FACTS

Facts, evidence of causality, and timing were all presented at trial on record and in lower court briefs (see Appendix E – R) and are dispersed here above and below. Special Master Millman did not follow the holdings of decisions related to the Program and violated discretion, as the petitioner addressed guidance adopted by the Secretary as reasonable prior to trial. If Adverse Effects of Vaccines: Evidence and Causality offers a reasonable accepted standard, it should apply to my claim in a fair and balanced manner.

Not only does her decision not fit the guidance of weak evidence, but her medical facts and understanding changed from 2012 to 2018, as she changed evidence to fit her decision. Judicial bias is the only explanation.

The petitioner is responsible for fulfilling the Althen and Loving standards for clarity of injury. As *Althen v. Sec'y of Health & Human Servs* provides the evidentiary burden for petitioners attempting to succeed in a vaccine petition based on causation. To succeed, petitioners must provide a "reputable medical or scientific explanation" for their claim. *W.C. v. Sec'y of Health and Human Servs.* (citing *Loving v. Sec'y of Health and Human Servs)* provides the "correct framework for evaluating off-table significant aggravation claims." The Loving test is comprised of six parts. The petitioner met all six parts, but Special Master Millman misunderstood and misinterpreted three parts.

This Court notes review of evidence is not a matter of right, but of judicial discretion. The primary concern of the Court is not to correct errors in lower court decisions, as the errors are plentiful and the lower courts made no effort to be factually correct; but is interested in constitutional issues as authorized to address cases and controversies of importance to all Americans, that affects multiple agencies and parties, and impacts our place in our nation and in our world.

To summarize, Special Master Millman misses the mark on the *Munn* standard for abuse of discretion, as her decision's points are arbitrary and capricious, and she does not

make comments that are "the most deferential possible". Notably, she failed to properly cite and review a 2012 case report, filed in the post-trial petitioner's brief, excluding the proper scientific evidence, as was also omitted at trial (Appendix E & F). She failed the *Capizzano* standard, not giving the treating physician fair recognition as an expert, suggesting the Secretary's expert was an all-knowing patriarch.

She decides my injury had no logical cause and effect, yet suggested she understood the cause and effect for years prior to the trial hearing. She failed the *Broekelschen* standard stating "understanding the injury is a prerequisite to the analysis", which she understood in 2012, but does not explain her misunderstanding in her 2018 decision. The holdings and standards of the Program are growing, but do not follow legal holdings, rules and standards of judicial civil courts. The lower courts grant " findings and conclusions by the special master" the highest level of deference, and have rarely concede overreach. Holdings show generous interpretations of discretion, where dicta and understanding of scientific facts are deficient, but legal facts are determined to be enough.

The critical question is not just causation, timing and sequence, or lies and falsehoods that were speculative and not based on medical records but are serious flaws in facts based on science. The lower courts permit special masters to change causational mechanisms from case-to-case, as she changed the causation of nephrotic syndrome to podocytopathy, which in *Rus v. Sec'y of Health and Human Servs (2016)* was determined to be an insufficient causational assessment. It is in science, causation is studied and

learned. The special master choses her facts from a single expert, Dr. Bernard Kaplan, a paid expert with research and financial ties to vaccine manufacturers. Dr. Kaplan's testimony at trail could be described as strange, peculiar and certainly biased. Petitioner's experts simply referred to textbooks and journals as fair reference for understood science.

The question of timing was a key issue in the special master's decision. She questioned the science as she understood T-cell mechanisms but was confused by immune factors and cell function. She adopted calendar facts to be contemporaneous. No one stated they were prepared in such manner (Appendix G and H). I kept my weight before I had CVAs. My parents kept proteinuria strip readings. Such records are not medical records by any standard of practice. The special master violates this standard by shifting the burden of proof to my father in a random and unexpected line of questioning at trial. Her designation of facts is incorrect. She accepted the first-hand facts as understood in 2012-2017.

C. CONSTITUTIONAL VIOLATIONS OF MY INDIVIDUAL RIGHTS

Rather than arguing facts which are relevant, the constitutional argument is more compelling. Under U.S. Constitution Amendment I:

> "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances."

The special master impeded free speech in the courtroom. In *Gertz v. Robert Welch, Inc. (1974),* this Court decided, "[T]here is no constitutional value in false statements of fact. Neither the intentional lie nor the careless error materially advances society's interest in "uninhibited, robust and wide-open" debate on public issues." As vigorous debate permits judges to assess sincerity and logic of false statements, but this value vanishes as discussions move away from honest errors to deliberate lies. Special Master Millman was inequitable and prejudiced in accepting Dr. Kaplan's false statements and lies as knowledge-based scientific facts. This unbalanced weight given to one-side's statements does not support justice.

This Court has suggested "speech that matters" can be put at risk by false statements that are not protected as a right. Parties must have a right to discuss facts during all stages of legal process, to understand questions and answers to relevant issues. The Program violates these rules of evidence, as not required, suggesting each party is open to fair discussion in a process meant to address the injured party, but instead devolves into an adversarial game in trial of one-upmanship, of little value to anyone. False statements of fact that are said with a "sufficiently culpable mental state" can be subject to civil or criminal liability. Dr. Kaplan made numerous false statements under such mental state as it was clear to everyone present at the trial. The special master was sympathetic and reassuring, rather than concerned of the facts.

A person knowingly making a false statement under oath can be punished. Dr. Kaplan knowingly made false statements under oath to protect his expertise, not to support his facts. Negligently false statement of facts tips the scale of justice and should not be given judicial discretion, as it is a civil liability. Implicit statements of fact with a false factual connotation are not protected, but the lower courts do not seem moved or concerned.

This Court held in *New York Times v. Sullivan (1964)* that lies about or by the government may be protected. However, this protection is not absolute, as the question of whether false historical or medical claims are protected is still a point in dispute. The respondent and their experts made numerous false historical claims and reference to medical records and scientific facts. If the government uses experts to express the government's message of facts and understanding it is constitutional. But this analysis changes if the government is using experts to encourage a "diversity of private views indiscriminately". If it is indiscriminate, as under *Legal Services Corp. v. Velazquez (2001)*, the government must act in a viewpoint-neutral position. The government must base judgment of the "quality" of the views, such that "invidious viewpoint discrimination" statements are barred. Such views in my case were not barred and were harmful to me.

Special Master Millman and the lower courts throw a veil of protection over Dr. Kaplan relating to his "so what" statement (Appendix I), as stated that vaccines cause

relapses but "so what". Dr. Kaplan did not answer the question posed to him. Why did he flip-flop his opinion between 2010 and 2013? Or more specifically why the contradiction with his earlier trial statement that vaccines do not cause or trigger relapses. At trial, the courtroom sunk into silence after the short video for many minutes, as Dr. Kaplan was dumbfounded and lied and perjured his way out of questions (Appendix J). A tort jury would have easily understood the mistakes. Dr. Kaplan should be punished for perjured statements. Rather than ask for clarity, the special master and lower courts anointed him a patriarch, expressing the "government's message", which was unbalanced and not neutral. No expert should be anointed the independent overseer of scientific facts and standards by a government official where supporting literature is not given or supportive of such claims.

This Court has clarified "reckless disregard," as a speaker who subjectively believed statements were false and insincere, which are protected in the context of an open discussion but should be considered unprotected if known facts are manipulated. Dr. Kaplan made numerous false and insincere statements under oath as an expert and did not truthfully address my case and my medical record as it related to the vaccine injury and complications. Special Master Millman not only "chilled" our experts' statements, she literally froze most discussion limiting statements to her chosen viewpoint.

Dr. Kaplan's biased private views are not the collective laws of science and medicine.[2] Protection of his privileges to use false statements with insincerity should not

be protected free speech. It has however become a common practice in the Program to create an adversarial environment, where the petitioner is censured for bringing a claim against the government's Program. Falsity and insincerity have no place in the Program's courtroom or proceedings as temperament leads to arbitrary and capricious beliefs.

Under U.S. Constitution Amendment VII:

> "In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law."

The Act and the Program violate the individual's right to seek a fair trial by jury, as the government and its agents are the sole executioners of the vaccine program and act to restrict the message released to the public. The individual's rights under the Act are seized and supported by all branches of government as a claim of concern for public health and safety. The Act however was established for a commercial need to preserve a public health concern (of the moment) in 1986. The validation of the Act is questioned here, as a failed experiment in permissions legislated which violate an individual's constitutional rights. Is this legislated discretion permitted? And with what limits?

Footnote 2: 2017 Rules adopts Adverse Effects of Vaccines: Evidence and Causality statements: "A conclusion of "favors acceptance of a causal relationship" must be supported by either epidemiologic evidence of "moderate" certainty of an increased risk or by mechanistic evidence of intermediate weight." Pages 52-53.

Special Master Millman violates not only the statutory standard ("preponderance of the evidence") which the Program must determine "that a vaccine has caused harm" but also the reality that these are administrative civil actions in lieu of judicial civil trials. These actions violate the Seventh Amendment, governing civil lawsuits, as any such change would implicitly deviate from the "... according to the rules of common law" requirement as the Program's administrative proceedings are provided in lieu of civil lawsuits, noted as "Suits at common law, where the value in controversy shall exceed twenty dollars...".

Transparency of actions by our government is required for justice. The Program is the sole dominant healthcare court of thought in violation of this constitutional amendment. A person's right to a fair trial by jury is a right all people should enjoy, and not based on selectivity of harm to any one individual over another person's implied protection.

It is proper to send a message that individual cases have shown that the Act does not work as suggested or implied. Vaccine safety and efficacy are popular statements in a public debate. Protection of commercial interests however are not what the Constitution and public ask for as a fair trade for loss of a person's constitutional right. My request for judicial discretion by this Court is not an overriding legal issue, but a constitutional rights issue.

Our nation was founded on principles of individual responsibility and decision-making dedicated to shared knowledge and concern for fellow Americans through information, facts, and shared interest. Democracies should not default to a select few authorities that believe they know better than the masses what is best for the masses. The U.S. Constitution provides for an individual's protection and rights. Under the First Amendment, an individual is given rights to Free Speech, and protections from harmful speech, such as lies and perjury. The Constitution also preserves a right, under the Seventh Amendment, to a trial by jury, with understood and well-defined court rules and procedures for evidence. These rights form a foundation for our democratic state. It should not be permissible for representatives to enact any law that violates these rights.

D. THE SECRETARY VIOLATES DUTIES TO INFORM PUBLIC

All Americans should understand, all vaccines can cause an adverse event. The public should also be aware of what those adverse events are, in an up-to-date fashion. The Secretary inadequately manages and fails to oversee agencies which harm citizens as public proclamations of rules and regulations that are not enforced, not understood and not properly regulated.

The Act suggests my injury would be covered. I had steroid-sensitive nephrotic syndrome which was well managed prior to my 2009 vaccine injury. My nephrotic condition relapsed within 24 hours after receiving an influenza vaccine. Diagnosis and

treatment began in a normal fashion eight days later. The condition worsened, and shifted to steroid-dependent nephrotic syndrome, which is more serious. I was treated for nephrotic syndrome for the next four years. The Act suggests it would be accepted my medical condition, which followed the sequence of a relapse, exacerbation, complications, and disability are accepted as to be related.

Special Master Millman and lower courts misunderstood the acute and extended complications of my vaccine injury can lead to CVAs through medical and treatment complications. Suggesting vaccines do not cause CVAs was Dr. Kaplan's argument. All legal professionals misunderstood the sequence. The vaccine triggered the relapse. The relapse worsened the nephrotic state. The worsened state led to more medical complications. Medical complications led a change in pharmaceutical protocol. And the change in medication led to the strokes through currently understood mechanisms of causation related to Prograf (Appendix K) . Absent and flawed legal arguments led to a critical misunderstanding of facts.

Prograf was my treatment protocol, in 2010. Its use necessitated by the failure of the standard protocol, prednisone; which failed related to the commonly understood influenza vaccine triggering a relapse (Appendix L) causing less pharmaceutical function and tolerance, leading to a physiological dependency, causing a more severe rebound response of nephrotic syndrome and lack of steroid responsiveness. The lower courts suggest this as a random and chaotic event, and a function of the medical condition, which

is untrue. This is a function of pharmaceutical and medical actions, which no one could effectively explain in simple terms to the special master. The lone pharmacist was prohibited from discussing science and medicine, as he was my parent.

It should be clear the Prograf warnings of adverse risks of CVAs and Posterior Reversible Encephalopathy Syndrome (PRES) were not listed in FDA approved product statements until 2013. It was listed in product statements in other countries prior to 2010 and today (and in 2017 at time of trial) is understood to have an almost thousand-fold increase in risk of CVAs in patients taking Prograf, which are usually transplant patients, but must include nephrotic patients with complicated medical protocols.

Dr. Quan was the prescriber of Prograf and was not present on Day Two of the trial. Our attorney excluded Prograf as a cause, as the Petitioner's claim was against the vaccine, as the initiating factor in the sequence. It was advised, Dr. Quan could not testify suggesting the Prograf as the cause of CVAs, as this would imply a liability. Doctors are protected by liability protection laws in Texas, such that he cannot be held liable, but the manufacturer can be, as I must address my complications should this Court decide the vaccine trigger was not a serious contributory factor.

American doctors follow FDA standard of care guidelines. The Secretary's FDA could have facilitated avoidance of this risk with stricter guidance and oversight, as the CVA risk was known before 2010-2011. The Secretary could have informed multiple

parties including the respondent's counsel, as the FDA was slow to address this serious adverse risk

The Act revision further address the relevance of the "entire medical record". Special Master Millman, and the lower court, do not give relevance to my entire medical record, giving added importance to my childhood logged weight measurements which was not in any "medical record". There is also failure to understand definitions for relapse verse remission, and rapid onset of nephrotic syndrome, which are medical terms used loosely and incorrectly in trial. The "entire record" was never presented to the court, as Dr. Seikaly and Children's Medical Center both failed to produce all their records, even on a subpoena. The decision to move forward without these vital records was the special master's choice. She chose a nurse's notes as enough.

My medical record demonstrated I was in good health. Complications began after inoculation, not before inoculation as speculated. My pre-vaccination medical condition was not chaotic or difficult to manage as respondent's experts suggested, as it was controlled and well managed with standard protocols of prednisone. The influenza vaccine was the exclusive, and most likely trigger of the relapse injury, as no other triggers were present in any record.

The question for the special master was related to timing and sequence. Both she and the lower courts fail to understand either. This Court should decide if there was no

temporal relationship and that vaccines do not trigger nephrotic relapses, which was speculative and idiopathic arguments that holdings suggest are not appropriate arguments. Current medical literature points to influenza vaccine as a trigger of nephrotic relapses. Deference to the special master would remove this argument from science and certainly the Secretary's agencies medical literature.

Special Master Millman was arbitrary and capricious, suggesting she did not understand the underlying condition, which affected her decision suggesting "identifying the injury is a prerequisite to the analysis." She violates the *Grant* standard of "proof of a logical sequence of cause of and effect showing that the vaccination was the reason for the injury, the logical sequence being supported by a "reputable medical or scientific explanation"." Her decision points to "evidence in the form of scientific studies or expert medical testimony", choosing Dr. Kaplan as her isolated expert, dismissing a case report and studies from Japan's regulatory agency and other reputable medical sources (Appendix E, M, N, O, P, Q and R), which would have met the reputable medical explanation standard.

Nephrotic syndrome is not wholly idiopathic but falls into several groupings. Dr. Kaplan suggested genetic and speculative forms of nephrotic syndrome. The petitioner suggested drug-induced reactions temporarily affecting the immune cellular function. Medical records show I have no genetic markers which rules out every speculative form Dr. Kaplan suggested I might have. My nephrotic syndrome has been resolved, but my

significant disability from the CVAs will persist for a lifetime. The special master and lower courts failed to understand my condition and my injury.

The Secretary's website (https://www.hrsa.gov/vaccine-compensation) suggests, "under the Act, persons with petitions of vaccine-related injuries or deaths resulting from covered vaccines must first exhaust their remedies under the VICP before they can pursue legal action" against the administrators or manufacturers. This statement is false, as this Court is the final remedy for resolution of my vaccine claim. A reversion to the Act's original statement would permit me to pursue fair and proper civil action against the vaccine and treating protocol manufacturers as product liabilities for complications leading to CVAs. Federal and state holdings prevent me from pursuing any action against the vaccine manufacturer without action by this Court. The special master's decision and lower courts judgements and opinions advance legal privilege to manufacturers that vaccines do not trigger nephrotic relapses, which may stand as the standard without being overturned.

The Secretary's website also suggests "the VICP is not absolute", where individuals may file a civil suit for damages of $1000 or less in a civil action, suggesting a push to lower settlement costs for damage claims. This suggested action is a complex legal action that is not thoughtful, nor a useful settlement process for small claims. If it were simple, there would be many claims. This statement further supports my claim the Act is controversial and contradicts the Seventh Amendment principles.

The Secretary is the overseer of multiple health agencies at every level of government responsible for issuing rules, regulations and guidance. Issuing public false statements suggesting guidance where no guidance exists is harmful and not informative. The Secretary violates his duty to serve, inform and protect all Americans.

The Secretary's website also states, "conclusions regarding vaccine safety should not be drawn from the fact that cases were settled. Settlements are one way of quickly resolving a petition." It is noted in Government Accountability Office reports that difficult and complex cases are rarely settled quickly or efficiently as Congress suggested in its original intent. The Secretary submits, "settlements are not an admission" that a "vaccine caused the injury", as "Petitions may be resolved by settlement for many reasons" including prior court decisions, settlement certainty, and time and expense considerations "to resolve a case quickly and efficiently."

The Secretary's advised beliefs are unrelated to real world actions, as most vaccine claims are rejected upfront for lacking: evidence, health professional inaccuracy and mendacity, and mechanisms of causality, which may be attributed to a poorly informed medical community and citizenry. The government, acting as overseers and protectors of the Program, aggressively defends all claims unsympathetically if the injury is not in the Table.

Empirical evidence is not shared between special masters who are granted a wide discretionary standard. Expenses are not a concern, except for the individual filing the petition, or the VICP Petitioner Bar attorneys and experts wanting to get paid for years of "expert" service. These are obvious areas where the government has failed in administering the Act in a fair and just manner. A plea for help, even requests for disability accommodations, go unheard, as the Act is the law open to interpretation by parties granted authority through the Secretary.

The Secretary's website adds:

> "if a licensed new vaccine product is in a category of vaccines that is not covered by the VICP, then the new vaccine will not be covered under the VICP until the general category of vaccines is covered. For a category of vaccines to be covered, the category of vaccines must be recommended for routine administration to children or pregnant women by the Centers for Disease Control and Prevention (e.g. vaccines that protect against seasonal influenza), subject to an excise tax by federal law, and added to the VICP by the Secretary of Health and Human Services."

It is here, the Secretary claims full authority through proctorship to address claims and governance of the Program, which have been assumed by the Secretary, but are not fully granted. Americans expect the Secretary and its agencies to inform, to provide consent, and have recourse from injury and liability from commercially developed drugs where negligence is clear or reasonably understood. The Secretary suggests authority exceeding what was authorized in the Act.

The Secretary's website further states, "there are no requirements that the petitioner show that the vaccine was used pursuant to Food and Drug Administration labeling or specific Advisory Committee on Immunization Practices or Centers for Disease Control and Prevention administration recommendations, or otherwise was administered pursuant to any standard of care." This guidance suggests claims are not bound to any standard of care policy. Standards of care form the basis of all medical and product liability. Yet the Secretary grants discretion based on a wider government advocacy message. Forsaking standards held by medical professionals and regulatory agencies places the Secretary in a conflicted position setting standards no one can truly understand.

E. Proceedings Below

In April 2012, my father filed a proper petition eighteen months after the vaccine injury, as my medical condition worsened, complications exacerbated and did not improve. The vaccine injury did not require an immediate petition filing, but later evidence pointed to treatment of the injury further complicating and leading to my CVAs, as causation was highly suggestive. All parties met in August 2012 and were favorable to settlement of my claim.

The suggested settlement in 2012 was $250,000 in pain and suffering, reimbursement for out-of-pocket medical expenses, and a nominal sum for long-term care. My parents did not agree with a nominal long-term care settlement, which they felt

needed to be determined by a long-term care professional. In 2013, the respondent promptly withdrew their interest in settlement and the claim moved forward with expert reports.

In 2016, after modest expert reports, the special master mandated settlement through an arbitrator to decide on a fair settlement. My father dutifully arranged an independent (special master approved) arbitrator, found a highly respected life care planner, a neuropsychologist and arranged for all parties to meet and discuss settlement options. The offer on the table was understood by all parties to be that of Laura Fox, a government contracted nurse life care planner. Mrs. Fox's settlement was correct as to the level of long-term care needed but was seriously flawed in financial analysis violating Federal Justice Center, Health and Human Services, and tax rules and holdings. The special master suggested social welfare programs fill the gaps, which is not permitted by law. The offer was a mess and very substandard in financial terms. My parents have advanced degrees in finance, healthcare, insurance and accounting, and the special master's offered plan was evaluated by several independent financial and healthcare long-term care professionals. Everyone agreed, the offer was a dud, but at least the special master and her life care planner seemed to be on the right path. The Secretary disinclined to settle, as the Secretary never gave a financial term, suggesting this was the special master's offer, so we proceeded to a hearing.

Moments before the trial was to begin, the special master unexpectedly issued a threat to my parents to accept her life care planner's "offer" or she would be inclined to decide in the respondent's favor. Again, the respondent failed to provide any details for financial terms, and we believed the facts would speak for themselves in our arguments. Little did we know, our attorney had not filed all the evidence and case reports, and the special master would not allow discussion of evidence and facts on an equal basis by both parties. Trial discussions were false, distorted, shifted, adversarial, insensitive, the list could go on. The trial was not fair, and the facts were not true. My petition was clear. The Program's intentions were unclear and false and led to an incorrect decision, pushed by an aggressive Secretary and a biased special master. The lower courts accede to discretion and acceptance of the Act, which is flawed.

REASONS FOR GRANTING THIS PETITION

The decision below conflicts with numerous interrelated issues that affect all Americans and their constitutional rights, and rights to pursue compensation for vaccine injuries. The Secretary has forever altered the Program that is underhanded for many claims and does not properly address the challenging evidence of vaccine injuries.

I urge this Court to consider my right to a fair jury trial under the Seventh Amendment. The Program's process does not support fact finding, leans on bias and

commercially linked experts acting in collaboration with the government, unkindly treating petitioners as adversaries, and limiting rules of evidence and due process.

All parties understood my medical condition worsened following the influenza vaccine. The respondent's experts did not know Prograf's risk profile. Legal experts and judges are not medical experts, but arbitrarily confer retired experts as superior experts in science. My claim was a sequential claim against two drugs, as permitted under the Act. The special master did not properly address these concerns or evidence.

The special master understood and accepted causation as Angiopoietin-like 4 podocytopathy, a mechanism acceptable to all parties. The Secretary's FDA Commissioner does not agree with this causational statement as the FDA must provide "accuracy of data and statements" in sponsored drug product information.[3] Medical experts have not accepted podocytopathy as the cause of nephrotic syndrome, and any such action would require reevaluation and misbranding actions to change product statements for hundreds

Footnote 3: FDA Rules in 21 U.S. Code § 201 states drug labeling: (1) "must contain a summary of essential scientific information", "must be updated when new information becomes available" and "changes requiring...appropriate human study...relating to safety". In such cases, drugs in violation shall be deemed to be misbranded under 21 U.S. Code § 352 as "its labeling is false or misleading in any particular" . All states and U.S. territories have substantially similar versions of drug laws, where false information makes a drug misbranded. Renaming causations such as podocytopathies is a simple process but special masters should not jump ahead of science and the FDA

of drugs that notably cause nephrotic syndrome. Immune-mediated and interrelated factors are understood as causational factors linked to minimal change and drug-induced nephrotic syndrome. Podocytopathies research preliminarily applies to genetic and steroid-resistant nephrotic cases which I do not have. This Court can reinforce the FDA as the proper regulatory agency for drug facts. The special master's statements hold legal weight but fail science arguments that would adversely affect numerous drugs and millions of Americans, which for legal clarity can be judged an affirmation, and relevant to future litigation. Suggesting the FDA must respond to this Court's action.

The key question is, should the government be permitted to continue to violate my constitutional rights? We live in 2019, not 1986. The world has changed. Actions by the Secretary points to gross negligence in practices and egregious actions harmful to individuals. Citizens have a right to facts and medical care that is informed and based on broad up-to-date science. Designated government authorities should not dictate choices but should proactively inform and research best options for medical choices by individuals.

THIS COURT SHOULD REVERSE THE MADATE BY THE FEDEAL COURT OF APPEALS FOR THE FEDERAL CIRCUIT AS THE PANEL DID NOT REVIEW ADJUDICATIVE FACTS SUBMITTED

The Panel did not address misstatements and misunderstood science. This Court sets on-point factual precedent valuable to all litigants. The Program is an interpretive

arena where this Court can fix upstream flows of information that are incorrect, so that downstream decisions are factual and true before they become enshrined in the U.S. Reports. Congress must fix what this Court decides is not constitutionally valid. The Executive branch must act upon this Court's actions where it is clear cabinet members, notably the Secretary, are not properly administering their oversight.

This Court offers factual authority, beyond persuasive and political rhetoric. It permits a panel of justices and their clerks an opportunity to carefully deliberate and examine reliable sources, processes overlooked, and tools misused or misunderstood. This Court is the highest authority on law and should look to science and medicine for evaluation of complex medical cases.

Vaccines, nephrology, neurology and cellular function are complex science subjects. The Program exploits discretionary actions as fully granted, but also must favor the petitioner case for any assessment of fairness. As the Secretary represents the framework of the government's policy, it is the Secretary's duty to act in the interest of Americans as a neutral and concerned party, unbiased by false and insincere actions, which has continually evolved as a concern among Americans since inception of the Act in 1986.

THIS COURT SHOULD REJECT THE FEDEAL COURT OF CLAIMS DECISION BY SPECIAL MASTER MILLMAN AS SHE MISUNDERSTOOD AND MISINTERPRETED FACTS.

The standards of review must be certain on whether the question at hand is a legal one or a factual one. The lower court reviewed the special master's decision as constructed on material discretion. However, her medical facts and understanding of causation, timing, and the condition are incorrect.

Holdings in prior cases does not prevent special masters and lower courts from making unjust discretionary choices. The Act establishes an unfair barrier for proper discretion. Suggestively letting the foxes run the hen house. This Court is designated as the final reviewer of VICP cases and must identify issues as factual matters and constitutional matters. The special master was arbitrary and capricious, ripe for reversal based on a biased process and misunderstood facts.

All factual claims in a case can be tested or retested with a degree of detached certainty. Medical claims and science follow this natural law, which require methods of replication to validate. The lower courts ignore these validations, which this Court can review and confirm as valid. Most notably, vaccines trigger relapses, and complications can be severe adverse events.

THIS COURT SHOULD REJECT THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 AS IT VIOLATES MY CONSITITUTIONAL RIGHTS. UNDER PROPER STANDARDS GRANTED UNDER THE CONSTITUTION, A FAIR AND

PROPER JURY TRIAL WOULD HAVE FOUND A JUST CONCLUSION BASED ON MERIT AND EVIDENCE.

The Secretary has crafted an injury compensation program that favors the government's political voice and not the facts of science and medicine. Lower courts give the Act exempt status to unbalanced arguments. The original argument that vaccines will become safer and more accountable to injuries has failed to materialize. FDA pharmacovigilance reports by manufacturers are obscured as confidential files with limited accessibility. The Secretary's agencies shift questions of vaccine safety to workgroups with limited oversight and limited public access. Concerns of science are delegated to authorities selected by the Secretary. Truly independent thought is not promoted or encouraged. This Court has competent jurisdiction to review the Secretary's rules and regulations which are not in compliance, nor in agreement with what most Americans understand as a health related trade-off.

All parties know vaccines cause adverse events and are unavoidable despite best efforts. The actions of the Secretary and the Act legislation transcends the dispute between me and the Secretary. My facts are formed from information that collectively forms our understanding of the Act and form the foundational building blocks we use to understand science, medicine and law. The facts can be misrepresented or misunderstood but at some point must be addressed to move forward. It is appropriate for this Court to address my facts and constitutional issues at his point in time.

THIS CASE PRESENTS A RECURRING QUESTION AND PROBLEM OF EXCEPTIONAL IMPORTANCE INVOLVING A CONTROVERSIAL MOVEMENT OF HIGH IMPORTANCE IN THE PUBLIC HEALTH ARENA WARRANTING THE COURT'S IMMEDIATE ACTION AND RESOLUTION.

A child's parents and the State are trustees in the care of the child charged with the duty of guiding a child's development and safety through actions that demonstrate fairness and capable understanding of logic in laws and science. Legislation and legal process must permit development of capable citizens that are permitted full enjoyment of their constitutional rights. The Act is not structured legislation that provides fairness and full guidance to all stakeholders. Fundamental rights of the "person" noted in the Act are lost and not respected in the legal process.

Empiricism and technology point to a current requirement that facts be supported by evidence from numerous sources. This Court with excellent clerks should provide the support needed to address a growing conflict in our country, as vaccine safety is an important issue. My injury is valid and should be addressed properly. All Americans deserve the facts of drugs they are prescribed to make sensible decisions that are impactful to all citizens of society. The Secretary and its agencies suggest if an individual has an adverse event related to a listed vaccine, and your facts are correct, your government will work with you to make things right. The Secretary fails to meet this

promise to the American people and to me. I am an injured and disabled party, and my case is the proper case to address these important questions.

THE STANDARDS OF THE VICP AND THE NCVIA CONSTITUTES A BREACH OF FAITH TO ME AND TO HUNDREDS OF MILLIONS OF AMERICANS WHO ARE VACCINATED EVERY YEAR WITHOUT KNOWING THE RISKS OF VACCINATION AND THE WAY INJURIES ARE COMPENSATED. INFORMED CONSENT SHOULD BE MANDATORY AND FULLY EXPLAINED TO ALL PATIENTS, AS OUR GOVERNMENT CANNOT BE TRUSTED UPON TO PROVIDE RELIEF.

The Constitution and its amendments should be interpreted strictly giving the right to govern oneself without being impeded by government authorities that misunderstand and misinterpret facts in a condensed legal setting, violating facts based on discretion of a single special master. The Secretary manages the Program as "window-dressing" to the nation's vaccine advocacy policy. The Program suggests foundational holdings, and interest in public welfare, but violates the public trust through actions that are unfair and unjust. The Secretary and judicial system have created a complex and biased maze for injury claimants to solve, one with many obstacles, including substandard representation and disregard for disabilities. This is harmful to all Americans.

THE QUESTION OF VACCINE SAFETY AND VALIDITY OF THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 ARE RIPE FOR THIS COURT'S

REVIEW AND MY CASE IS AN IDEAL VEHICLE FOR RESOLVING AMERICAN'S CONCERNS REGARDING VACCINE INJURIES AND PROPER COMPENSATION ISSUES.

The Act is written as a person law covering all ages, such that constitutional rights implied within the Act should apply to all people, regardless of age. Informed consent covering procedural requirements and substantive obligations must be understood by citizen through facts that are proven in science. A federal requirement providing facts and drug risk concerns is warranted, as state requirements vary in general. Free-will rights as a person cannot be enjoyed if the government does not fulfil its duties to protect my rights as a person.

I enjoy the right to seek civil action for the injury caused by Prograf, but the Act prohibits such civil action against vaccines, choosing to protect a commercial interest rather than the individual, and further harming the child through legal process and limits on actions. No government agency or party should restrict my rights to thoughts and inquiry, my liberty to develop a point of view that may be different from others, and to choose the action that is best for myself and for all. This Court can correct these issues by removing limits to pursuing legal recourse against the vaccine manufacturer laid out and restricted in the Program and in the courts.

UNINTENDED LEGISLATED DRIFT HAS CAUSED MAJOR FAULTS IN LEGAL INTERPRETATION WHICH GIVES THE PROGRAM UNINTENDED DISCRETION AND PROTECTIONS AND VACCINE MANUFACTURERS UNINTENDED COMMERCIAL ADVANTAGES AND PROTECTED STATUS

The government aims to aggressively debate and establish an edge in vaccine injury claims as the DOJ website states:

> "A significant, positive result of the Program is that costly litigation against drug manufacturers and health care professionals who administer vaccines has virtually ceased. Although an individual who is dissatisfied with the Court's final judgment has the option to file a lawsuit in State or Federal court, very few lawsuits have been filed since the Program began. The supply of vaccines in the U.S. has stabilized, and the development of new vaccines has markedly increased."

The DOJ, as the defendant for the Secretary, promotes its successful defense of the Act as related to shutting down vaccine litigation, acting as an advocate of vaccines generally, not necessarily regarding vaccine safety actions, and not as a neutral party or protector of citizens. The Act is less of a tool to protect Americans through vaccine safety measures, than it is a promotional tool for efficacy statements and a business arrangement to protect the vaccine manufacturers who now use it as a tool to generate revenue and profits through research of novel science, not entirely public safety measures. The Secretary offers vaccines preferential treatment as sponsored drugs in clinical research, which further protects the manufacturers, not individuals.

The tools and methods of the Act used by the Secretary to run the Program and its growing authority is harmful and is a violation of our constitution. I ask this Court to reject the Act, and to restore my rights granted under the Constitution.

CONCLUSION

For the foregoing reasons, I respectfully request that this Court issue a writ of certiorari which should be granted.

Date Submitted: October 22, 2019

Humbly submitted,

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Redact address and phone per Rule 34.6

MM/

With understood support and assistance in preparation by Mark Miles, acting as caring parent and supportive authorized agent.

Certificates of Service Attached