Institute for Nerve Medicine

Medical Associates Inc

Aaron G. Filler, MD, PhD, JD, FRCS

- Board Certified: ABNS American Board of Neurological Surgery
- FRCSN Fellow of the Intercollegiate Board in Surgical Neurology of England, Ireland, Edinburgh & Glasgow
- Fellow of the Royal College of Surgeons of England
- Member of the Bar of the Court of Appeals for the Federal Circuit
- Member of the Bar of the United States Supreme Court

900 Wilshire Blvd. Suite 310 Santa Monica, CA 90401

Phone: (310) 314-6410 Fax: (310) 496-0185

INSTITUTE FOR NERVE MEDICINE RESPONSE TO JUDICIAL COUNCIL EXPERT REPLIES MR# 200 100 300

DATE OF EXAMINATION: August 24, 2024 DATE OF RESPONSE REPORT: March 23, 2025 PATIENT NAME: Hon. Pauline Newman DATE OF BIRTH: 06/20/1927

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REPLY REPORT AS TO COGNITIVE ASSESSMENT OF HON. PAULINE NEWMAN

In response to the expert report which I provided on August 24, 2024, three experts have provided reports. This report responds to issues and concerns raised by the opposing experts, Colonel Jason Johnson, MD, MBA – a radiologist, Dr. James M. Noble, MD – a neurologist, and Dr. Jonathan DeRight, PhD – a neuropsychologist.

I. <u>QUALIFICATIONS</u>

1. I, Aaron G. Filler, MD, PhD, FRCS, JD, am a board-certified neurosurgeon with an MD from the University of Chicago, a PhD from Harvard University and am a Fellow of the Royal College of Surgeons of England. My board certifications are with the American Board of Neurological Surgery and as a Fellow in Surgical Neurology of the Intercollegiate Specialty Assessment Board of Edinburgh, Glasgow, Ireland and England and a Fellow of the American Association of Neurological Surgeons. I also hold a JD degree.

2. I completed an eight-year neurosurgical residency at the University of Washington and additionally completed a one-year fellowship in complex spinal surgery at UCLA and a one-year fellowship in advanced neuroimaging at the University of London and a sixmonth fellowship in peripheral nerve surgery at Louisiana State University. Subsequently I served as Co-Director of the Comprehensive Spine Program at UCLA and as a Medical Director at Cedars Sinai Medical Center in Los Angeles. I am a past President of the Society for Brain Mapping and Therapeutics – an international society involving thousands of neuroscientists, neurologists, neuroradiologists and neurosurgeons from around the world. I am a former Lieutenant Colonel US Army Reserve, former Commander of the 1466th Med Team Neurosurgery focused on brain injury in combat, and did my medical Newman, Pauline DOB: 6/20/1927 March 23, 2025 Page **3** of **25**

basic training at Ft. Sam Houston, San Antonio, Texas and Brooke Army Medical Center, Ft. Sam Houston, Texas. I have personally operated on over a thousand brain injured patients needing open emergency surgery and also have seen and examined more than three thousand patients suffering from mild traumatic brain injury/concussion and have relied on advanced neuroimaging together with clinical examination in the evaluation and treatment of more than twenty thousand patients over forty years. I have performed detailed assessments of intellectual function on a very wide array of individuals. I have more that 35 years of experience with DTI imaging – having invented the technology and performed the first DTI tractogram in 1992 which appears as figure 17 in US Patent 5,560,360.

3. Currently, I am completing data analysis on a three-year study of 1,200 brain injury patients who completed a detailed, neuroanatomically based, extensive questionnaire which I developed and on whom I personally performed a detailed neurological exam. These patients were then imaged by DTI (Diffusion Tensor Imaging) and various treatments including medications for specific treatable dysfunctions (such as memory impairment) and Transcranial Magnetic Stimulation (TMS) brain repair were carried out along with extended follow-up as to response to treatment.

4. I have written or participated in peer reviewed publications in a variety of surgical topic areas as well as the subject of advanced neurological imaging. While at Harvard University, I founded, organized, and taught a course in biomechanics. I am a section editor for Youmans & Winn Neurological Surgery – the leading textbook in Neurosurgery and am the author of multiple chapters in the recent 2022 8th edition including Chapter 14 about Brain DTI (Diffusion Tensor Imaging) and other advanced neurological imaging techniques (see Exh W). I have served for many years as a member of the Joint Guidelines Committee of the American Association of Neurological Surgeons and the Congress of

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Neurological Surgeons and currently serve on the Continuing Medical Education Committee of Cedars Sinai Medical Center and have done so for many years as well. I have presented DTI evidence in numerous courts, including three cases before the Court of Appeals for the Federal Circuit in Washington, DC and in the Seventh Judicial District of the State of Montana before Hon. Katherine M. Bidegaray winning admissibility of DTI and exclusion of defense expert reports which had no actual basis in science and disqualifying said supposed experts; in the District Court of Harris County, Texas proving the reliability and admissibility of DTI data (motion to exclude denied by Hon. Robert K. Schaffer – in *Hernandez v. Cemex Construction*); and similar successes establishing admissibility of DTI in numerous courts in the State of California; in United States District Court in the State of Oregon; in Federal District Court in Virginia, in a capital case on behalf of the State of Florida, and including proving admissibility of Magnetic Resonance Neurography and of Diffusion Tensor Imaging in the District Court of Clark County, Nevada.

5. I maintain an active clinical surgical practice and frequently obtain and interpret Diffusion Tensor Imaging MRI and frequently see, examine, and treat patients suffering from cognitive impairments from a variety of causes including toxic exposures, closed head injury and general degenerative issues. I have evaluated thousands of such clinical cases.

6. I am the original inventor of the DTI technique and lead inventor on US 5,560,360 – MRI Neurography and Diffusion Anisotropy Imaging, filed in March of 1993 and granted in October of 1996. I have been engaged in the performance of diffusion tensor imaging from the time of obtaining the first tractographic image in November of 1991 – a period of more than 34 years of experience and am therefore the world's most experienced specialist in this field. I have a background in the use of multi-variate mathematics and tensor analytics to analyze cranial structures dating back to 1976 and so have 49 years of

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experience in this general field and have taught these methods as well as teaching in neurological biophysical/biomechanical analysis at Harvard University. I am currently engaged in actively advancing the field and have ongoing new clinical advances – reported as recently as February of 2025 at the annual meeting of the Society for Brain Mapping & Therapeutics.

7. In 1992, I was the co-author of the first peer reviewed paper in the field of DTI imaging – *Howe FA, Filler AG, et al, Magnetic Resonance Neurography*, 28 Magnetic Resonance in Medicine 328 (1992) wherein we disclosed the fundamental discovery in physics that makes DTI possible. This is a means of suppressing destructive cross terms that arise when magnetic field diffusion gradients are applied in directions diagonal to the main x, y and z location gradients of an MRI scanner. We used the term "neurography" in the sense that DTI "tractography" is now used. This technique is the basis of our granted patent – *Filler et al, Image Neurography and Diffusion Anisotropy Imaging* – US 5,560,360 which was filed in March of 1993 following a provisional filing in March of 1992 which includes the very first brain tractogram image as figure 17. This patent has withstood numerous challenges and has been licensed to Siemens and GE, and contracted to Philips, Hitachi, Toshiba, Medtronic and Brainlab. Most recently, Brainlab voluntarily dismissed its challenge to validity of the patent in November of 2020 after eight years of litigation.

8. I hold a medical license in the State of California, in several other states including Massachusetts, Nebraska, Ohio, Texas, Florida, Indiana, Virginia, the District of Columbia and New York. I maintain a clinical office in Santa Monica, California and Houston and Dallas, Texas. Since the commencement of my residency training, I have seen, examined, imaged, and performed surgical treatment for several thousand patients suffering from various degrees of brain injury.

9. I am also the author of: *Filler AG; MR Neurography and Diffusion Tensor Imaging: Origins, History, & Clinical Impact of the First 50,000 Cases with an Assessment of Efficacy and Utility in a Prospective 5,000 Patient Study Group.* 65 Neurosurgery (4 Suppl), pA29-A43 (2009). (DOI: 10.1227/01.NEU.0000351279.78110.00) (PMID: 19927075) and: *Filler AG: "The History, Development and Impact of Computed Imaging in Neurological Diagnosis and Neurosurgery: CT, MRI, DTI*; 7 Internet Journal of Neurosurgery, (1) (2010) (http://ispub.com/IJNS/7/1/12184) which set forth the history, mathematics, physics, and neuroscience that underlies this methodology. I am the author of *Filler AG: Diffusion Tensor Imaging, Chapter 14 in H.R. Winn ed., Youmans & Winn Neurological Surgery 8th edition*, Elsevier, New York (2022). Therefore, I am fully qualified to opine on the clinical and technical issues in this matter.

10. I have been qualified as an expert to testify on surgical image guidance (*Sarif v. BrainLAB*, 1:13-cv-00846-LPS, D-Delaware, Dkt#82) and in relation to the NeuroGrafix cases before a Multi-District Litigation in D-Mass, (MDL- *NGFX v. Philips, et al* 1:13-md-02432-RGS, D-Mass, Dkt# 202-2 & 459-2) in ND-IL (*NGFX v. Brainlab* 2:12-cv-06075), and in *NGFX v. Siemens* (2:10-cv-01990-MRP, CD-Cal, Dkt #103-4) and in State District Court in Clark County, Nevada (A-12-664451-C). In addition, I have been admitted as an expert witness in numerous California courts, including the Los Angeles County, San Diego County, Orange County, Contra Costa County, Santa Clara County and Alameda County as well as in other states including Florida, Oregon, Pennsylvania, New York, Virginia, Kentucky, Nevada, Texas and Montana (I am an expert in MRI physics, multi-dimensional mathematics, Magnetic Resonance Imaging, Diffusion Tensor Imaging, neurosurgery, neuroimaging, brain pathomechanics, cognitive impairment and neuroscience). I have personal knowledge of the facts herein, and, if called as a witness in a court of law, could testify competently thereto.

II. Overview of Responses

A. Preliminary Comments on the Radiology Report of Colonel Jason Johnson

11. Col. Jason Johnson, MD, MBA, a radiologist affiliated with Yale University, indicates that the FDA has not approved the sale of Perfusion CT scanners or Perfusion software with an advertising claim asserting they can be used to assess dementia. Of course, there is also no FDA approval of the use of neuropsychology or neuroradiology or neurology to assess dementia. The FDA is not involved in regulating clinical activity of physicians or psychologists. CT scanners have many uses. There is not a separate FDA approval for each type of clinical use and each diagnosis CT scans are used to investigate, nor are all uses of CT scanners listed anywhere on any FDA document. The FDA issue identified by Col. Johnson is wholly irrelevant to the issue at hand.

12. As noted in my article on the history of computed imaging, the first CT scan was performed by its inventor Godfrey Hounsefield working with Jamie Ambrose at Atkinson Morley's Hospital in Wimbledon, where I did several years of training and carried out the invention of MR Neurography and Diffusion Tensor Imaging with the hospital's research funding. We had a saying at Atkinson Morley's from the time of that first week of CT scanning: One CT scan is worth a roomful of neurologists. It was used to diagnose and treat tumors and haemorrhages immediately and without waiting for the FDA or the UK Medicines and Healthcare Products Regulatory Agency to render approval for device sales.
13. Col. Johnson also questions the accuracy of the label on one image provided with

the report, but his interpretation is incorrect. This is not a vascular anatomy image – Perfusion CT is used to create Cerebral Blood Flow (CBF) assessments that calculate differences regional differences between the Arterial Input Function (AIF) and the Venous Outflow Function (VOF). It is therefore necessary to include flows outside of the Newman, Pauline DOB: 6/20/1927 March 23, 2025 Page **8** of **25**

hippocampus itself in order to calculate a CBF for the area of interest. The arrow designates a CBF region that includes some of the of hippocampal venous outflow. There is no means to separate—for instance choroidal flow from hippocampal flow in a CT scan obtained even with the very high initial acquisition resolution used. Therefore, the literature in this field considers the perfusion of the hippocampal region and is not intended to be a highresolution anatomical image of the hippocampus or individually identified vessels. Although Dr. Johnson provides a list of 87 published articles and 29 book chapters, none include "perfusion" in the title, so his expertise and understanding in this area may be limited.

14. Generally, even if radiologists do not offer a particular class of medical services, that fact does not apply any limit on neurosurgeons as to clinical action. As explained below, neurosurgeons are permitted to consider the opinion of neuroradiologists but are strictly disallowed from relying directly or solely on their opinions. For example, if a neuroradiologist incorrectly reports that a herniated disk is at C5/C6 when it is actually at C6/C7 and the neurosurgeon then proceeds to operate at C5/C6, *i.e.*, the wrong level, it is no excuse for the neurosurgeon to say that the neuroradiologist told him to do the incorrect surgery. The neurosurgeon is 100% responsible for interpreting the images and planning the treatment components that rely on image interpretation. In contrast, neurologists generally do not themselves interpret images and therefore are expected to rely directly on neuroradiologists. This separates the diagnostic process between neurology and neuroradiology, and indeed the two specialties often have little direct personal contact with each other in relation to the care and management of any given patient.

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B. Preliminary Comments on the Neurology Report of James M. Noble, MD

15. Dr. Noble's comments are appreciated, but he is wrong on a number of important points, and he misunderstands important context. Firstly, there is no error on the labelling of the CT Perfusion study – as pointed out above and explained further below in this report.
16. There is no use in avoiding—as he has done—the unique nature of Judge Pauline Newman's work-related dispute. She has been able to produce a series of excellent opinions—including dissenting from her colleagues and being affirmed over them by the U.S. Supreme Court—all since her suspension commenced. I understand that clerks could have aided her, but that is one issue I sought to investigate by conducting the exam and interview after her clerk had departed so she could not rely on a subordinate's assistance.

17. My principal concern with the routine tests is that context. Arguably, the judges of the Court of Appeal of the Federal Circuit represent the absolute pinnacle of human cognitive capability. Not only must they handle a staggering number of appeals, like any other appeals court judge in the U.S. or elsewhere in the world, but they also must encounter the oncoming vast array of all the most advanced technologies in every imaginable technical field of knowledge being developed in the United States and around the world. I believe, as a primary matter, that that capability had to be tested first of all. Dr. Noble completely skipped over that portion of the exam and I suspect he did not try to read the patents (in physics and molecular biology) which I asked Judge Newman to explain back to me as to technology and to comment on patent law issues they posed as part of my examination. The obverse of this purpose in examining Judge Newman is that even if she could pass all the standard tests of cognitive impairment that would not prove she was capable of hearing patent appeals and judging them fairly.

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18. I understand that Dr. Noble has made a tremendous effort to standardize and advance routine testing as it has been done for decades. In the area of mild Traumatic Brain Injury, however, it is my experience that neuropsychology and MOCA tests are being abandoned in favor of DTI on an increasingly widespread basis. The problem, which I see every day in my practice, is that there is always a defense and plaintiff neuropsychology report and they almost always differ on every single point including their principal conclusions. I see no evidence that these tests are objective. It is not the case that the current issue is a personal matter of Judge Newman wanting to have her competence assessed. It is in the context of a dispute as to whether or not she can be removed without being impeached by the Senate as the U.S. Constitution warrants. Allowing one party – the Judicial Council of the Court of Appeals for the Federal Circuit to rely on a test by an examiner they chose – seems to have the pitfalls of what occurs in legal disputes as to mental impairments generally.

19. Perfusion CT has been shown to be effective for assessing the presence of dementias. There is no threshold of 1,000 publications for many medical issues. For example, once the COVID vaccine was clearly shown to work, it was immediately put into regular use around the world. I know it may be threatening to professionals who carry out cognitive assessments, such as Dr. Noble, whose careers are based on the older testing methods, but having an objective method of assessment is extremely helpful. The potential value of Perfusion CT has been known about for more than a decade, so I would expect Dr. Noble to begin to perform these tests on every patient he evaluated, at least on an investigative basis, in order to learn if his own assessments and decades of standardized methodology were still needed. CT Perfusion is a threat to Dr. Noble's practice and legacy so he can hardly be expected to comment impartially about it.

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20. Dr. Noble additionally points out his concern that one of the labelled areas of blood flow in one of the image slices is inches away from the hippocampus. However, his concern is misplaced - this is a test of perfusion which calculates differences between rates of arterial inflow and venous outflow. The distance is not the issue so much as the inclusiveness – the hippocampus is a long thin structure that passes through several different vascular zones – so inclusiveness is more the challenge. It is, for instance not the case that renal blood flow in the renal vein must be measured right next to the kidney to be accurate as opposed to measuring it three inches away just before its outflow enters the vena cava. The measurement will be the same in the two locations.

Fornix and Proximal Limbic System – injuries to the fornix impair new memory formation: PF – pillar of fornix, CF –Crus of fornix, FF-ST – Fimbria fornix and stria terminalis;
 HC – Hippocampal Cingulum (injury: impaired attention)
 SC – supracallosal cingulum (injury: depression & anxiety)



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A DTI MRI image of the white matter axonal fibers of the hippocampus and fornix and related anatomical elements which I obtained from a volunteer imaging subject - (not Judge Newman).

C. Preliminary Comments on the Neuropsychology Report of Johnathan DeRight, PhD

21. Several of the issues raised above with regard to Dr. Noble apply to Dr. DeRight's report as well. In more than a thousand patients I have seen in the past three years I have found the difference in opinion and findings between the defense and the plaintiff side to be so complete that I have come to the opinion that neuropsychology is not capable of helping to resolve the question of competency in a legal dispute. Lawyers still retain neuropsychologists substantially because it leaves an opening for them to argue to a jury or a mediator that the findings that don't help their side can be disregarded.

22. The fact that the component tests have been in use for many years (and decades and centuries) is not actually a positive. In many other fields knowledge advances and new technology is embraced. As I pointed out for Dr. Noble - has Dr. DeRight used objective imaging tests as part of an investigation parallel with his traditional tests in order to learn if the new methods are equally good or better, thereby advancing his field? It is his business as to how he runs his practice, but what has he done to advance the use of objective imaging tests?

23. Dr. DeRight is not expected to understand the legal evidentiary basis of being able to testify about alleged changes in Judge Newman's demeanor, speed of thought, or intellectual content of speech because he lacks the personal experience of prior interactions with Judge Newman. Dr. DeRight's assertion that my prior interactions as a practicing

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attorney in the Court impairs my ability to assess her simply raises questions about Dr. DeRight's understanding of the legal context of this entire situation. It is not a matter of bias (as one the three Federal Circuit judges leading this process was also on one my judicial panels and wrote the opinion deciding in my favor). This is all about doing my part as a Member of the Bar of the Court of Appeals for the Federal Circuit to help this Court do what it does best, which is to be excellent in its decision making.

24. The issue with the fundamental program of using Perfusion CT is that the wide array of dementias and cognitive impairments that afflict humans fall into categories and appear to have certain typical patterns of image findings. It therefore becomes possible to do the test to learn if one of these set of findings appears. This may aid in accurate diagnosis and treatment. Contrary to Dr. DeRight's assertions, the field is not in "nascency" more than 12 years after strong evidence of utility were reported. The large number of papers in neuropsychology he points to —with virtually none dealing with new technology like Perfusion CT—does nothing to undermine this entirely different but parallel field, although it does reflect poorly on neuropsychology as a discipline.

25. A real-world clinical example can illustrate why the views of Dr. DeRight and Dr. Noble are mistaken. A 25-year-old young man suffered a head injury with two hours loss of consciousness. He had extensive post-concussive symptoms initially, but most resolved over three- to four- weeks and he returned to work in a high stress high demand job. He did well initially. Thereafter, he developed progressively severe anxiety and then panic attacks which prevented him from continuing with his employment.

26. The part of the brain that typically is injured in trauma that causes depression and anxiety and poor toleration of stress is the supra-callosal cingulum (NOTE – this is an anonymized patient and NOT images of Judge Newman)
27.

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28. The first scan (top left) was done four days post-injury and the supra-callosal cingulum is normal bilaterally. Progressively over months, that structure shrinks into the appearance usually seen in someone who has injured that structure – and this progressed bilaterally. The Professor of Neuroradiology who read the initial CT missed a sub-arachnoid hemorrhage in this area and the MRIs showed persistent blood. The problem

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was vasospasm from blood break-down products. The patient did not need counseling psychotherapy, benzodiazepines, transcranial magnetic stimulation, but instead nimodipine to reverse the vasospasm. This substantially resolved the anxiety syndrome. Yet, he was initially treated not for the vasospasm, but for psychological symptoms, precisely because the traditional neuropsychologic diagnostic tools could not pinpoint the actual problem. It was not previously known that one could observe the progression of this type of "psychological disorder" with a series of structural images.

29. What we see here is that by persisting with decades-old methodology, wrongly invoking the FDA to try to stop the use of new technology and pleading to use only "well-established" psychological tests performed by non-physicians, a vast disservice is done to the American public. Perfusion CT is newer, but it does work to effectively, objectively, and conclusively, rule out the known forms of dementia.

III. <u>Findings in the Perfusion CT Exam of Judge Newman</u>

30. Dr. Jason Johnson's assertion of mis-labelling of the area of blood flow is due to his failure to understand that Perfusion CT does not image blood vessels or anatomical structures per se. The relevant measure is a comparison of the AIF (Arterial Input Function) and the VOF (Venous Outflow Function). The spatial resolution is low – but is better than what can currently be accomplished with the similar method of MRI with Arterial Spin Labelling (ASL). The point made by Dr. Noble that several references dealt with ASL and not with Perfusion CT is true but beside the point. Both study the same phenomenon and clinical issue and both sets of studies are relevant to understanding the medical role of assessments of perfusion. Perfusion CT uses a bolus of iodine contrast to mark the movement of the front of the blood flow, whereas MRI with ASL uses a magnetic label to

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mark a bolus of blood so it can be tracked through tissue. However, the end results of all of these studies are comparable.



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31. In the areas of the temporal lobe demonstrated in the images of Judge Newman, the hippocampus is in close contact with the lateral ventricle. Further, detailed published neuroanatomical assessments show that parts of the hippocampus typically have their venous outflow through veins draining the choroid plexus. Choroid flow and hippocampal flow are not readily separable. However, comparison of this type of measurement of

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combined hippocampal and choroid flow has been shown to correlate significantly with the relevant mental status measures in assessing dementia and other cognitive impairments. Such perfusion measurements should therefore be obtained to supplement or replace the current near complete reliance on subjective psychological testing. Newman, Pauline DOB: 6/20/1927 March 23, 2025 Page **21** of **25**



Livingston et al, figure 3, row 2 of 4, image 3 of 4.

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Livingston et al – Figure 3 perfusion data.

32. The report from Livingston, Kiemes, et al Neuropsychopharmacology 49:1448-1458 (2024) – shows the scale of the areas of blood flow relevant to the hippocampus and para-hippocampal gyrus. This clearly includes all of the areas of outflow marked as relevant in the Perfusion CT obtained for Judge Newman on August 22, 2024.

33. For all of the reasons above, the Court should give no credence to and make no reliance upon the reply reports of Col. Jason Johnson, MD, Dr. James M. Noble, MD and/or Dr. Jonathan DeRight, PhD. Rather, the Court should proceed to rely upon the findings of the evaluation which I provided to the Court on September 24, 2024 based on the imaging evaluation of August 22, 2024 and the in person evaluation I carried out on August 24, 2024.

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I, the undersigned do hereby certify and declare that:

I am over the age of 18, am a resident of the County of Los Angeles and of the State of California. I am an attorney duly licensed to practice law before all Courts in the State of California. I am a member of the Bar of the Court of Appeals for the Federal Circuit. I am a physician licensed to practice medicine in California, Virginia and the District of Columbia.

I declare that the above statements of this 25-page document are true and correct under the pains and penalties of perjury under the laws of the State of California, the laws of the District of Columbia, and under the laws of the United States of America.

Executed on March 23, 2025, at Santa Monica, California.

AARON G. FILLER, MD, PhD, FRCS JD

By:

Aaron Filler, Esq.

Tensor Law PC and Institute for Nerve Medicine 900 Wilshire Blvd, Ste. 314 Santa Monica, CA 90401 310 450-9689 afiller@tensorlaw.com *Chief of Clinical Services* Institute for Nerve Medicine Center for Advanced Spinal Neurosurgery Neurological Injury Specialists