ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,

Various Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

AUTISM MASTER FILE
Special Master Hastings
Special Master Campbell-Smith
Special Master Vowell

RESPONDENT'S BRIEF REGARDING APPLICABILITY OF THE *DAUBERT* STANDARD TO AUTISM PROCEEDINGS

A party purporting to offer scientific evidence in federal courts is obliged to demonstrate that the proffered evidence is indeed "scientific" and "reliable" as those terms have been defined by the Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), and its progeny. The thrust of this developing body of law is clear – if proffered scientific evidence is not shown to be "scientific," it may not be relied upon. As discussed below, these requirements clearly apply to proceedings under the Vaccine Act.

Discussion

I. The "Daubert Standard"

A brief background of events leading to the Court's decision in Daubert and a thorough discussion of the resulting standard for evaluating scientific evidence are obviously germane. Before Daubert, the predominant test applied by federal courts to evaluate expert evidence was the "general acceptance" standard first articulated by the then Court of Appeals for the District of

Columbia in Frye v. United States, 293 F. 1013 (1923). In Frye, the court held that an expert opinion based on a scientific technique should not be admitted into evidence unless the technique was shown to be "generally accepted" in the relevant scientific community. Daubert, 509 U.S. at 584. The Frye court further held that expert opinion based on a methodology that diverges "significantly from the procedures accepted by recognized authorities in the field . . . cannot be shown to be 'generally accepted as a reliable technique.'" Id. For the next 70 years, most federal courts applied the Frye "general acceptance" standard whenever faced with a proffer of expert evidence.

At issue in Daubert was whether the adoption of Rule 702 of the Federal Rules of Evidence ("FRE") superseded Frye's "general acceptance" test. As initially adopted, Rule 702 provided:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, training, or education, may testify thereto in the form of an opinion or otherwise.

FRE 702.[1] In its Daubert decision, the Supreme Court noted that neither FRE 702 nor its drafting history made any mention of "general acceptance" or Frye, and that "a rigid 'general acceptance' requirement would be at odds with the 'liberal thrust' of the Federal Rules . . . ." 509 U.S. at 588. The Court therefore held that the "austere [general acceptance] test, absent from, and

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[1] Rule 702 was amended in 2000 to incorporate explicitly the Supreme Court's Daubert standard. See FRE 702 advisory committee's note (2000 Amendments). The Rule now states that an expert may testify ". . .in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

incompatible with, the Federal Rules of Evidence, should not be applied in federal trials." Id. at 589.

In holding that FRE 702 had in fact replaced the Frye "general acceptance" rule, the Supreme Court provided trial courts with guidance in the application of FRE 702. It did so by focusing on the language of FRE 702, which the Court reasoned "contemplates some degree of regulation of the subjects and theories about which an expert may testify." 509 U.S. at 589. The Court's reasoning hinged on the Rule's use of the term "scientific knowledge":

> The adjective "scientific" implies a grounding in the methods and procedures of science. Similarly, the word "knowledge" connotes more than subjective belief or unsupported speculation. The term "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds." . . . Of course, it would be unreasonable to conclude that the subject of scientific testimony must be "known" to a certainty; arguably, there are no certainties in science. . . . But, in order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. *Proposed testimony must be supported by appropriate validation – i.e., "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.*

Id. at 590 (internal citations omitted and emphasis added). And so the Daubert standard was born – scientific evidence must be shown to be scientific through "appropriate validation." Id.

Daubert identified a number of factors or criteria for trial courts to consider when determining "whether the reasoning or methodology underlying [expert] testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." 509 U.S. at 592. Those factors were: (1) whether the theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether

there is a high rate of known or potential error and whether there are standards for controlling the error; and, (4) whether the theory enjoys "general acceptance." Id. at 593-94. The Court stressed that the list of factors it proposed was not definitive, and that the inquiry envisioned by FRE 702 was a flexible one: "Its overarching subject is the *scientific validity* and thus the *evidentiary relevance and reliability* of the principles that underlie a proposed submission." Id. at 594 (emphasis added).

A few years later, the Court again commented on FRE 702 in General Elec. Co. v. Joiner, 522 U.S. 136 (1997). While the original Daubert decision had admonished trial courts to focus solely on an expert's methodology (as opposed to his or her conclusions) when evaluating the reliability of the expert's opinions, the Court in Joiner added that expert conclusions also matter. The Court stated that:

> [C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit*[2] of the expert. *A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.*

522 U.S. at 146 (emphasis added).[3] In other words, Joiner teaches a trial court that a proffered expert's conclusions are not necessarily so, simply because the expert says they are so.

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[2] Latin for "he himself said it." The term refers to a bare assertion resting on the authority of an individual. BLACK'S LAW DICTIONARY 828 (6th ed. 1990).

[3] In Joiner, the expert offered animal studies and a handful of epidemiological studies to support his causation opinion. The district court concluded that the animal studies were not sufficiently analogous to the facts presented in the case to support the expert's causation opinion. The district court found that the epidemiological studies also did not support the expert's opinion. 522 U.S. at 144-45. The Supreme Court upheld the trial court's decision based on this "analytical gap." Id. at 147.

Finally, in Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), the Court was asked to determine whether the Daubert standard applies only to scientific expert testimony, or to all expert testimony generally. The Court answered that question by affirming that the reliability requirements of FRE 702 apply to all expert testimony of a technical, scientific, or specialized nature. The Court acknowledged that for non-scientific expert testimony, the factors that it set out in its Daubert decision may not be appropriate, but it reemphasized that trial judges have the discretion to determine what factors are most appropriate for assessing whether expert opinions in a given case are based on "good grounds." The Court noted that the guiding principle for trial courts to follow in their reliability determinations is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom *the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.*" 526 U.S. at 152 (emphasis added). In sum, evidence billed as "scientific" must be shown to meet the rigors appropriate to that field of science. Otherwise, it is not science.

II. The Daubert Standard Applies to Vaccine Act Proceedings

As an initial matter, the issue of whether Daubert applies to Vaccine Act proceedings was arguably settled in this Circuit by the Federal Circuit Court of Appeals' ruling in Terran v. HHS, 195 F.3d 1302 (Fed. Cir. 1999), reh'g and reh'g en banc denied, (Fed. Cir. Feb. 2, 2000), cert. denied, 531 U.S. 812 (2000). In Terran, the petitioner appealed the special master's decision denying her compensation. One argument asserted by the petitioner on appeal was that the special master improperly applied the Daubert standard to determine whether her expert's causation testimony was "reputable and reliable." The Court of Federal Claims noted in its decision in Terran the general inapplicability of FRE in Vaccine Act cases, but concluded that:

> . . . Daubert is useful in providing a framework for evaluating the reliability of scientific evidence. See Leary v. Secretary of HHS, No. 90-1456 V; 1994 WL 43395, at *9 (Fed. Cl. Sp. Mstr. Jan. 31, 1994). While the Supreme Court designed the test to determine whether evidence is relevant and reliable in the context of the Federal Rules of Evidence, *it is equally capable of being used to determine whether information is relevant and reliable in the context of the Vaccine Act.*

Terran v. HHS, 41 Fed. Cl. 330, 336 (1998) (emphasis added). The Federal Circuit agreed with this reasoning. 195 F.3d at 1316. The special masters are obliged to apply Terran.[4]

Though Terran requires no defense by respondent, as discussed below, that ruling is sound as a matter of law and policy. The Vaccine Act and governing Rules of the Court of Federal Claims provide all that is needed to confirm Congress's intent that special masters' decisions be based on legitimate science. See also Knudsen v. HHS, 35 F.3d 543, 548 (Fed. Cir. 1994) (citing Daubert to support the conclusion that a vaccine petitioner's proof regarding the "logical sequence of cause and effect" in an off-table case "must be supported by a sound and reliable medical or scientific explanation"); Perreira v. HHS, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (upholding the trial court's rejection of a vaccine petitioner's expert, and citing Daubert for the proposition that "[a]n expert opinion is no better than the soundness of the reasons supporting it").

In fact, given the scientific issues inherent in Vaccine Act proceedings, and public policy questions engendered by the subject of vaccine-causation, the perils of relying on "junk" science

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[4] Terran certainly settles the question of whether special masters may apply Daubert – they most certainly may. The only question arguably left open by Terran is whether a special master ever has discretion to *decline to apply* a Daubert analysis. To the extent that question is presented here, it must be answered in the negative. Search as one may, there is no support in case law after Daubert giving a federal trial judge discretion to disregard altogether the requirements of Daubert when presented with a proper and timely objection to that evidence.

enunciated in Daubert exist with even greater force in Vaccine Act proceedings.

A. The provisions governing admission of evidence in Vaccine Act proceedings are comparable to Federal Rule of Evidence 702 with respect to scientific evidence.

To the extent petitioners argue that Daubert does not apply to Vaccine Act proceedings because FRE 702 does not apply, that argument must be rejected. Rule 8(c) of the Vaccine Rules provides: "In receiving evidence, the special master will not be bound by common law or statutory rules of evidence." RCFC, Appendix B, Vaccine Rule 8(c). This provision, well-known to Vaccine Act practitioners, gives special masters flexibility with regard to admission of evidence by providing that statutory rules of evidence are not applicable. Standing alone, this might support an argument that, because FRE 702 has been made inapplicable to Vaccine Act proceedings, Daubert's analysis must also be inapplicable. But this language does not stand alone.

Rule 8(c) goes on to require that: "The special master will consider all *relevant and reliable evidence*, governed by principles of fundamental fairness to both parties. . . ." Id. (emphasis added). Thus, the Rule retains explicitly the requirement that evidence considered in Vaccine Act proceedings be "reliable," and the Vaccine Act provides explicitly for consideration of "*scientific evidence* contained in the record." 42 U.S.C. § 300aa-13(b) (emphasis added). Thus, although FRE 702 does not apply to Vaccine Act proceedings *per se*, its key language on which the Supreme Court's decision in Daubert is based is found in the Vaccine Act and implementing Vaccine Rules of the Court of Federal Claims.[5]

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[5] In fact, given that the basic thrust of Daubert was to define what is "reliable" and to define what is "good science," there is no plausible argument, and certainly no statutory basis for (continued...)

Likewise, by inclusion of the terms "relevant and reliable," Rule 8(c) obviously "contemplates some degree of regulation" of the evidence to be considered by special masters, just as the Supreme Court found with respect to FRE 702.[6] See Daubert, 509 U.S. at 589. That "degree of regulation" suggested by FRE 702 was all the Supreme Court needed to fashion basic rules for evaluating scientific evidence in federal courts.

Indeed, the Federal Circuit Court of Appeals has held that those same rules are to be

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[5](...continued)
any argument, that Congress intended special masters in Vaccine Act proceedings to rely on anything less than that.

[6] Petitioners assert that application of Daubert's substantive standards for reviewing scientific evidence would be something new and contrary to "recent decisions of the Court of Federal Claims and Federal Circuit." They cite no support for that proposition, and cursory review of the case law shows just the opposite. A number of recent decisions cite Daubert approvingly. See, e.g., De Bazan v. HHS, 70 Fed. Cl. 687, 699 n.12 (2006) (Lettow, J.); Campbell v. HHS, 69 Fed. Cl. 775, 781 (2006) (Allegra, J.); Piscopo v. HHS, 66 Fed. Cl. 49, 53-54 (2005) (Firestone, J.); Ryman v. HHS, 65 Fed. Cl. 35, 40 (2005) (Wolski, J.) Manville v. HHS, 63 Fed. Cl. 482, 490 (2004) (Miller, J.); Guillory v. U.S., 59 Fed. Cl. 121, 125 (2003) (Hewitt, J.); Thomas v. HHS, No. 01-645V, 2007 WL 470410, at *26 (Fed. Cl. Spec. Mstr. Jan. 23, 2007) (Abell, SM); Carter v. HHS, No. 04-1500V, 2007 WL 415185, at *3 n.8 (Fed. Cl. Spec. Mstr. Jan. 19, 2007) (Golkiewicz, CSM); Colon v. HHS, No. 04-44V, 2007 WL 268781, at *19 (Fed. Cl. Spec. Mstr. Jan. 10, 2007) (Abell, SM); Szekeres v. HHS, No. 99-649V, 2006 WL 3725133, at *16 (Fed. Cl. Spec. Mstr. Nov. 29, 2006) (Vowell, SM); Capizzano v. HHS, No. 00-759V, 2006 WL 3419789, at *13 n.18 (Fed. Cl. Spec. Mstr. Nov. 8, 2006) (Golkiewicz, CSM); Williams v. HHS, No. 04-1725V, 2006 WL 2849817, at *6 (Fed. Cl. Spec. Mstr. Aug. 1, 2006) (Abell, SM); Jones v. HHS, No. 04-1147V, 2006 WL 2052379, at *21 (Fed. Cl. Spec. Mstr. Jul. 5, 2006) (Abell, SM); Sawyer v. HHS, No. 03-2524V, 2006 WL 1910971, at *3 n.5 (Fed. Cl. Spec. Mstr. Jun. 22, 2006) (Golkiewicz, CSM); Meyers v. HHS, No. 04-1771V, 2006 WL 1593947, at *2 n.6 (Fed. Cl. Spec. Mstr. May 22, 2006) (Campbell-Smith, SM); Lee v. HHS, No. 03-2479V, 2005 WL 1125671, at *4 n.9 (Fed. Cl. Spec. Mstr. Apr. 8, 2005) (Golkiewicz, CSM); English v. HHS, No. 01-61V, 2005 WL 3485963, at *3 n.6 (Fed. Cl. Spec. Mstr. Dec. 1, 2005) (Golkiewicz, CSM); Mahaffey v. HHS, No. 01-392V, 2003 WL 22424989, at *3 n.9 (Fed. Cl. Spec. Mstr. May 30, 2003) (Golkiewicz, CSM); White v. HHS, No. 98-426V, 2002 WL 1488764, at *5 n.11 (Fed. Cl. Spec. Mstr. May 10, 2002) (Golkiewicz, CSM); Smith v. HHS, No. 99-271V, 2002 WL 985432, at *9 n.31 (Fed. Cl. Spec. Mstr. Apr. 19, 2002) (Golkiewicz, CSM).

applied by *all* federal trial judges, regardless of the whether the Federal Rules of Evidence are applicable. In Libas, Ltd. v. United States, 193 F.3d 1361 (Fed. Cir. 1999), an importer opposed the Customs Service's classification of the importer's fabric for duty rate, entry, and quota purposes. The importer challenged the reliability of the test used by Customs to classify the fabric under the Daubert standard.[7] The Court of International Trade, however, did not conduct a Daubert analysis because the Federal Rules of Evidence were not applicable to the proceedings. On appeal, the Federal Circuit determined that this was error, noting that the Supreme Court held in Daubert that "reliability is the touchstone for expert testimony." Id. at 1365-66. The Federal Circuit held that:

> [I]f a trial court relies upon expert testimony, it should determine that the expert testimony is reliable. It would make little sense to say that a trial court in its fact-finding role should accord much if any weight to expert testimony, the reliability of which is not established.

Id. at 1366 (citing Perreira v. HHS, supra, which was decided under the Vaccine Act).[8] The court therefore concluded that the Court of International Trade was required to apply the Daubert factors in cases involving "a technical process where the reliability of a scientific or technical

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[7] Under the rules applicable to the court's proceedings, Customs was required to file evidence regarding the test as part of the record. Therefore, because it was already in the record, the importer could not challenge the admissibility of that evidence. The Federal Circuit concluded, however, that the importer's right to challenge the reliability of the evidence was not waived. Libas, 193 F.3d at 1366 n.2.

[8] The Armed Services Board of Contract Appeals has adopted this approach as well. In Appeal of Universal Yacht, Inc., 04-2 BCA P 32648, ASBCA NO. 53951, 2004 WL 1330136 (A.S.B.C.A. May 24, 2004), the ALJ acknowledged that the rules governing those proceedings were "more flexible than the Federal Rules when it comes to the admissibility of evidence." However, the ALJ held that "to be credible, expert opinion must be reliable. In order for expert opinion to be reliable, it must meet the same standards set forth for the admissibility of expert testimony." Id. (citing the Federal Circuit's decision in Libas).

methodology has been raised as an issue." Id. at 1367.

Given that the Federal Circuit Court of Appeals has already determined that Daubert must be applied to scientific and technical expert evidence in other kinds of proceedings where the Federal Rules of Evidence are not at issue, it would almost certainly hold that Vaccine Rule 8(c), which includes an express requirement of evidentiary reliability, mandates the application of Daubert in Vaccine Act proceedings.

B. The special masters must fulfill the same "gatekeeping" role as all other federal trial court judges.

As a final matter, to the extent petitioners argue that Daubert does not apply to these proceedings because there is no jury and, therefore, it is unnecessary for the special masters to play the role of "gatekeeper" as contemplated by the Supreme Court, that argument must also be rejected. The original "gatekeeping" role described in Daubert was indeed calculated to screen unreliable expert evidence from juries. See Daubert, 509 U.S. at 597; see also Joiner, 522 U.S. at 147 (Breyer, J., concurring). However, federal courts, including the Court of Appeals for the Federal Circuit and the Court of Federal Claims, have held that Daubert is applicable in bench trials. See Seaboard Lumber Co. v. U.S., 308 F.3d 1283, 1302 (Fed. Cir. 2002) (rejecting the argument that Daubert was inapposite in bench trials, holding that "[w]hile these [concerns of unduly influencing juries] are of lesser import in a bench trial, where no screening of the factfinder can take place, *the Daubert standards of relevance and reliability for scientific evidence must nevertheless be met*" (emphasis added)). See also Benchmark Resources Corp. v. United States, 74 Fed. Cl. 458, 467 (2006) (relying on Seaboard Lumber to support the application of Daubert to expert evidence submitted by plaintiffs in a bench trial); Indiana

Michigan Power Co. v. United States, 60 Fed. Cl. 639, 646-47 (2004) (same).

Seaboard Lumber recognized that Daubert was intended to set standards for scientific evidence for *all* federal court rooms – whether tried by jury or bench. While the mechanics of that application might differ in a bench trial – a judge alone must obviously "admit" the evidence to review whether it meets basic standards of scientific reliability – the end is the same. Evidence that is not "scientific" may not be relied upon. In fact, this is precisely the approach endorsed by the Court of Federal Claims in Ryman, supra. In that case, the chief special master ("CSM") rightly discounted petitioner's expert evidence based in part on his analysis of that evidence under the Daubert standard. In sustaining the CSM's decision, the Court of Federal Claims noted:

> In Daubert, the Supreme Court assigned the trial judge a "gate-keeping" function to ensure the reliability of evidence presented to the trier-of-fact. *The CSM, of course, performs this same function when he determines whether a particular petitioner's expert medical testimony supporting biologic probability may be admitted or credited or otherwise relied upon.*

Ryman, 65 Fed. Cl. at 40 (citing Vaccine Rule 8(c)) (emphasis added). This reasoning has also been applied by the special masters. See, e.g., Wolfe v. HHS, No. 05-878V, 2006 WL 3419835, at **6-7 (Fed. Cl. Spec. Mstr. Nov. 9, 2006) (including a detailed Daubert analysis assessing the reliability of the petitioner's expert evidence in determining the probative value it should be given); Corder v. HHS, No. 97-125V, 1999 WL 476256, at **6 n.15, 8-9 (Fed. Cl. Spec. Mstr. May 28, 1999) (same); Trojanowicz v. HHS, No. 95-215V, 1998 WL 774338, at **3-6 (Fed. Cl . Spec. Mstr. Jul. 1, 1998) (same).

Likewise, federal courts handling civil bench trials have adopted the same approach. See,

e.g., SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp.2d 1101, 1042 (N.D. Ill. 2003) (concluding that, while Seaboard Lumber held that Daubert must be applied even in bench trials, "it did not say it must be followed *rigidly*," and, therefore, "[i]n a bench trial, it is an acceptable alternative to admit evidence of borderline admissibility and give it the (slight) weight to which it is entitled"), aff'd, 365 F.3d 1306 (7th Cir. 2004); United States v. Brown, 279 F. Supp. 2d 1238, 1243 (S.D. Ala. 2003) (noting that "district courts conducting bench trials have substantial flexibility in admitting proffered expert testimony at the front end, and then deciding for themselves during the course of the trial whether the evidence meets the requirements" of FRE 702).

Regardless of the mode selected by the special masters to fulfill the gatekeeping function (i.e., excluding unreliable expert evidence preliminarily, or admitting it but giving it no weight), Daubert must be applied. Scientific evidence must be evaluated. It must be shown to be "reliable" by some independent means, and expert opinions must be based on something more than speculation. Evidence that fails to meet reasonable standards of scientific reliability must be called what it is – unscientific – and either excluded or given no weight.[9]

III. Notice of Intent to Request Specific Findings Regarding Daubert in Autism Proceedings

As discussed above, it is manifestly clear that Daubert applies fully to these proceedings. Therefore, to the extent petitioners offer "scientific" evidence to meet their burden of proving vaccine-causation, respondent will object to evidence that is not shown to be "scientific" and

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[9] The requirement for evaluating the scientific reliability of evidence is even more important "where there is a large body of contrary epidemiological evidence, [and] it is necessary to at least address it with evidence that is based on medically reliable and scientifically valid methodology." Norris v. Baxter Healthcare Corp., 397 F.3d 878, 882 (10th Cir. 2005).

"reliable" as those terms are defined under Daubert and its progeny. To ensure this issue is properly preserved for review, respondent will also ask the special masters to make specific findings regarding the scientific reliability of that evidence.

Conclusion

The Daubert standard applies to Vaccine Act proceedings. While special masters are granted flexibility in how to apply the Daubert standard, they are not free to disregard it by relying on evidence that has not been shown to be "reliable." With respect to scientific evidence, special masters have a "gatekeeping" responsibility under Daubert and its progeny to fashion appropriate tests of scientific reliability to use in evaluating such evidence. Evidence that fails to meet these tests cannot be regarded as "scientific," and is entitled to little or no weight in these proceedings.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this 22nd day of May, 2007, a copy of the foregoing **RESPONDENT'S BRIEF REGARDING APPLICABILITY OF THE *DAUBERT* STANDARD TO AUTISM PROCEEDINGS** was served, by prepaid Federal Express, upon:

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In addition, respondent hereby provides his written consent, pursuant to Section 12(d)(4) of the Vaccine Act, to disclose this pleading on the Court of Federal Claims's website/"Docket of Omnibus Autism Proceeding."