

**In the United States Court of Federal Claims**

**OFFICE OF SPECIAL MASTERS**

(E-Filed: April 10, 2008)

No. 02-1466 V

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HANNAH POLING, a minor,	)	
by her Parents and Natural Guardians,	)	TO BE PUBLISHED <sup>1</sup>
TERRY POLING AND JON POLING,	)	
	)	Disclosure of “information” to
Petitioners,	)	a non-party to a vaccine
	)	proceeding requires consent;
	)	42 U.S.C. § 300aa-12(d)(4)(A);
v.	)	When consent withheld, request
	)	for disclosure presented to a
SECRETARY OF HEALTH AND HUMAN	)	special master
SERVICES,	)	
	)	
Respondent.	)	

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**ORDER DEFERRING RULING ON PETITIONERS’ MOTION  
FOR COMPLETE TRANSPARENCY OF PROCEEDINGS**

Pending before the court are: (1) Petitioners’ Motion for Complete Transparency of Proceedings (Petitioners’ Motion); (2) Respondent’s Response to Motion for Complete Transparency of Proceedings (Respondent’s Response); (3) Petitioners’ Reply to Respondent’s Response to Motion for Complete Transparency of Proceedings (Petitioners’ Reply); (4) Respondent’s Sur-Reply to Petitioners’ Motion for Complete Transparency of Proceedings (R’s Sur-Reply); and (5) Petitioners’ Surreply to Respondent’s Surreply to Motion for Complete Transparency of Proceedings (Petitioners’ Sur-Reply). For the reasons discussed more fully below, the undersigned **DEFERS** ruling on petitioners’ motion for a period of 60 days.

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<sup>1</sup> In accordance with Vaccine Rule 18(b), when a special master files a decision or substantive order with the Clerk of the Court, each party has 14 days within which to identify and move for the redaction of privileged or confidential information before the document’s public disclosure. Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rule 18(b)

## I. Background

On October 25, 2002, petitioners Terry and Jon Poling, the parents and natural guardians of Hannah Poling, filed a short-form autism petition pursuant to the National Vaccine Injury Compensation Program<sup>2</sup> (the Act or the Program), 42 U.S.C. § 300aa-10 et seq. As permitted by Order dated July 8, 2002, petitioners electing to participate in the Omnibus Autism Proceeding (OAP) were permitted to file a short form “opt-in” petition.<sup>3</sup> See OAP Order of 7/8/02 at 4. Each short form petition consisted of the name of the injured child, the names of the injured child’s parents or legal representatives, and an election to opt into the OAP proceeding. *Id.* at 1. The petition did “not contain a detailed account of the relevant vaccinations and the vaccinee’s disorder.” *Id.* Nor were the vaccinee’s medical records required to accompany the petition. *Id.* By filing a short form petition, petitioners in this case elected to opt-in to the OAP.<sup>4</sup>

In September 2007, the court received for filing a compact disc containing petitioners’ medical records. On September 17, 2007, a committee of petitioners’ counsel in the OAP, known as the Petitioners’ Steering Committee, designated this case (with petitioners’ permission) as a potential test case to be heard on the second theory of general causation in the OAP. The second theory advanced by the Petitioners’ Steering

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<sup>2</sup> Hereinafter, for ease of reference, all “section” references to the Vaccine Injury Compensation Act will be to the pertinent subsection of 42 U.S.C. § 300aa (2006 ed.).

<sup>3</sup> The Omnibus Autism Proceeding (OAP) is a coordinated proceeding before the Office of Special Masters structured to facilitate the handling of nearly 5000 vaccine petitions involving claims that children who have received certain vaccinations have developed autism.

<sup>4</sup> The adopted procedure for addressing the claims in the OAP involves the conduct of a two phase proceeding. The first phase of the proceeding inquires into the general causation question of whether certain vaccinations can cause autism and, if so, under what circumstances. Three general causation theories advanced by petitioners are being evaluated in nine test cases. The conclusions reached in these test cases will inform the second phase of the OAP proceeding. The second phase of the proceeding involves applying the information acquired during the first phase of the proceeding to decide the specific causation question of whether the received vaccinations caused the autistic condition alleged in an individual case. At the request of petitioners’ counsel, through a designated Petitioners’ Steering Committee (PSC), petitioners were afforded a generous period of time to conduct discovery that would inform their theories concerning causation. After an extended discovery period, hearings were conducted in three test cases on the first general causation theory in the OAP. The hearings were held in May 2007, October 2007, and November 2007, respectively.

Committee in the OAP is whether thimerosal-containing vaccinations can cause autism. Coordinated trials to hear testimony in the designated three test cases on the second theory of general causation are scheduled for the last three weeks in May 2008.<sup>5</sup>

On November 9, 2007, respondent filed a Rule 4 Report conceding that petitioner should be awarded compensation in accordance with 42 U.S.C. § 300aa-11(c)(1)(C)(ii). Respondent stated that, based on a review of the petition, medical records and affidavits, the “facts of this case meet the statutory criteria for demonstrating that the vaccination Hannah received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism and manifested as a regressive encephalopathy with features of autism spectrum disorder.” Rule 4 Report at 7. Respondent further stated in the Rule 4 Report that the onset of Hannah’s complex partial seizure disorder, nearly six years after her July 19, 2000 vaccinations, was not related to her vaccinations. Rule 4 Report at 7.

The filing of respondent’s Rule 4 Report prompted the Petitioners’ Steering Committee to search for another potential test case for the second theory of general causation to be heard in May 2008. See Petitioners’ Motion, Attachment 1 (Order of November 19, 2007 modifying the schedule for the designation by the Petitioners’ Steering Committee of the third test case for the second theory of causation in the OAP). As explained in the e-mail attached to the issued November 19, 2007 Order modifying the schedule for the designation of an additional test case for the second general causation theory in the OAP, the Petitioners’ Steering Committee stated that respondent’s “concession places the case in [a] procedural posture that makes it inappropriate as a test case for hearing in May 2008.” Id.

The undersigned conducted a status conference with the parties to address the filed Rule 4 Report. During the status conference, petitioners stated that they intended to file an expert report from Andrew Zimmerman, M.D., Hannah’s treating neurologist, in support of their claim that Hannah’s complex partial seizure disorder was a sequela of her vaccine-related injury. The undersigned directed respondent to file a status report after reviewing Dr. Zimmerman’s expert report that addressed respondent’s position regarding petitioners’ claim that Hannah’s seizure disorder was vaccine-related. Petitioners filed the expert report from Dr. Zimmerman after the status conference.

On February 21, 2008, respondent filed a Supplemental Rule 4 Report addressing

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<sup>5</sup> The coordinated trials permit the witnesses, who will be testifying for the parties in each of the three test cases, to avoid lengthy, duplicative proceedings for the taking of the same general causation theory testimony.

respondent's review of Dr. Zimmerman's expert report. See Supplemental Rule 4 Report at 1-2. Respondent stated that "[h]aving reviewed this additional evidence, [medical personnel at the Division of Vaccine Injury Compensation, Department of Health and Human Services (DVIC)] now recommend[] compensation for Hannah's seizure disorder as sequela of her vaccine-injury in accordance with 42 U.S.C. § 300aa-11(c)(1)(C)(ii)." Id. at 2. Based on respondent's concession, a damages determination is now underway in this case. See Order of March 6, 2008 (addressing plan to schedule "the filing of the parties' respective life care plans, or if possible, a joint life care plan"); see also Order of March 12, 2008 (establishing filing deadline for status report regarding damages determination).

After the filing of the Supplemental Rule 4 Report, petitioners' counsel informally contacted the chambers of the undersigned requesting "permission [for all parties] to discuss the details involved in the case of Hannah Poling v. Dept. of Sec'y of Health and Human Svcs., 02-1466V." See Order of February 28, 2008 at 1. As expressed in the court's Order, the undersigned subsequently learned that respondent's Rule 4 Report had become publicly available in an electronic format other than the format of the Public Access to Court Electronic Records (PACER) System, the court's official electronic medium. Id. Quoting section 12(d)(4)(A) of the Vaccine Act,<sup>6</sup> the undersigned stated that disclosure of the Rule 4 Report was proscribed by statute unless express written consent was obtained first. Id. at 2.

Subsequently, on March 4, 2008, petitioners filed a motion styled as "Petitioner's Motion for Complete Transparency of Proceedings."<sup>7</sup> See Petitioners' Motion at 1. As stated in the motion, petitioners "request[] an Order permitting the parties, or their

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<sup>6</sup> Section 12(d)(4)(A) of the Vaccine Act provides, in pertinent part, that:

[i]nformation submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

42 U.S.C. § 300aa-12(d)(4)(A).

<sup>7</sup> Although the motion refers to Hannah Poling as the petitioner, this vaccine claim is prosecuted by Hannah's parents because Hannah is a minor and is deemed legally incapable of prosecuting an action on her own. See Petitioners' Motion at 1; but see 42 U.S.C. 300aa-11(b)(1)(A) (requiring the legal representative of a minor, who is alleged to have sustained a vaccine-related injury, to file the petition for compensation under the Vaccine Program). Accordingly, as is correctly reflected in the case caption, the undersigned refers to the Polings as the petitioners.

representatives, to freely discuss with any person each and every aspect of this case, including the details of the Respondent’s concession that Hannah is entitled to compensation for her vaccine-related injuries, including her autism.” Id. at 4-5. Petitioners “believe[] the public has a right to know the details of her case and the extent of the Respondent’s concession.” Id. at 3.

As an attachment to their motion, petitioners have submitted a written “Authorization” that “express[ly] waive[s] [their] § 12(d)(4)(A) rights to confidentiality of the materials submitted in [Hannah’s] case (with the exception that the medical records can be discussed but not be made public).” Petitioners’ Motion, Authorization at 1. The authorization, however, “is contingent upon the respondent waiving its rights as well or upon the granting of [petitioners’] motion for complete transparency.” Id.

In their motion, petitioners assert that section 12(d)(4)(A) of the Vaccine Act “clear[ly] . . . prohibits Special Masters from disclosing evidence submitted in a case without the written permission of a party who submitted the evidence.” Petitioners’ Motion at 3 (citing 42 U.S.C. § 300aa-12(d)(4)(A)). But, petitioners argue, “[a] ‘Respondent’s report’ that concedes entitlement to compensation is clearly not ‘information submitted to a special master as evidence in a proceeding and is not protected by § 12(d)(4)(A).” Id. at 3-4.

After failed efforts by the parties to moot petitioners’ motion by reaching an agreement,<sup>8</sup> respondent filed his Response to Motion for Complete Transparency of

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<sup>8</sup> Respondent points out in the filed Sur-Reply to Petitioners’ Motion for Complete Transparency of Proceedings (R’s Sur-Reply) that while petitioners “did undertake initial steps necessary to permit discussion of their case before the Special Masters presiding in the Omnibus Autism Proceeding and before representatives of the Petitioners’ Steering Committee[,] [i]n fact, it is respondent who first approached and asked for petitioners’ consent to permit the Secretary of Health and Human Services to disclose medical information regarding this case in order for the Secretary to address inaccurate statements that were being made publicly concerning respondent’s position in this case.” R’s Sur-Reply at 2. At petitioners’ request, respondent drafted a consent document for petitioners to sign. Id. Having received no response from petitioners, respondent contacted petitioners’ counsel to inquire about the proposed consent form and to “inquire whether press reports were true that petitioners were planning press conference for the following day.” Id. Petitioners’ counsel replied to respondent, and represented during a status conference in this case, that the reports of a planned press conference were not true. See id. Petitioners’ counsel “stated, for the first time, that petitioners would only provide their consent to the disclosure of medical information if respondent consented to the public disclosure of the Rule 4(c) reports filed in this case.” Id. Thereafter, “[p]etitioners filed the current Motion, (continued...)

Proceedings (R's Response). Construing petitioners' motion to pertain primarily to a discussion of the Rule 4 Report and the Supplemental Rule 4 Report, filed by respondent with the court on November 9, 2007, and February 21, 2008, respectively, respondent contends that petitioners lack a legal basis for their request. R's Response at 2. Respondent argues that, contrary to petitioners' representations, the term information is not limited narrowly to "evidence," but is a broader term. Id. at 3. Respondent points to other sections of the Vaccine Act and to the Vaccine Rules that include certain limitations on the disclosure to non-parties of filings with the court and on the disclosure to non-parties of particular information contained in a decision to be issued by the court. Id. at 3-5 (citing sections 300aa-12(d)(3)(B) and 300aa-12(d)(4)(B) of the Vaccine Act and Vaccine Rule 18).

Petitioners filed a Reply to Respondent's Response to Motion for Complete Transparency of Proceedings (Petitioners' Reply). Petitioners assert that under the Vaccine Act, an example of a circumstance in which "respondent submits information to the court that requires protection from public disclosure by petitioners" is when the government, as it has done during discovery process in the OAP, provides data under government control to which privacy protections are attached or provides information that contains data that is proprietary to vaccine manufacturers. See Petitioners' Reply at 3. Petitioners further assert that protecting the expert reports filed by respondent in the OAP test cases from "fil[ing] on the internet for all to see"<sup>9</sup> (as petitioners' experts have done

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<sup>8</sup>(...continued)

and two days later they held a press conference and appeared in nationally televised and print interviews discussing the case." Id. Respondent explains in the filed Sur-Reply:

Respondent agreed to petitioner's request for mutual consent to public disclosure in this case with the understanding that such consent on the part of respondent was effective only as to disclosures occurring after respondent's representative signed the consent. Respondent's consent would not cover the disclosure of any information that occurred prior to the execution of the mutual consent form. Petitioners, however, refused to accept those terms . . . .

Id. at 4.

<sup>9</sup> Petitioners misstate in their argument that petitioners' expert reports from the OAP are "filed on the internet." Petitioners' Reply at 3. In general, filings with the Office of Special Masters (or the court) are not filed on the internet. Rather, access to filings with the Office of Special Masters is available only to parties, who have proper accounts, through the internet-based Public Access to Court Electronic Records (PACER) System. In the exceptional circumstances (continued...)

with obtained waivers of privacy from petitioners) is an improper exercise of protection from disclosure because the expert reports are “based on exhibits filed by petitioners.” See id. Petitioners reason that because “[a] rule 4 report summarizing records and indicating whether or not the respondent concedes or contests causation in a case can only be protected by the petitioners whose records are being described[,] . . . the disclosure of the rule 4 reports in this case are solely dependent on the will of the petitioners and that permission from respondent is not required.” Id. at 4. Petitioners contend that “[t]here is nothing in these reports that is ‘information’ supplied by the respondent and . . . [i]f there were such ‘information[,]’ presumably the respondent would point that out.” Petitioners’ Sur-Reply at 1. Petitioners submit that respondent’s failure to “offer[] a redacted Rule 4 Report demonstrat[es] . . . [that] there is no such ‘information’” that requires protecting. Id.

Petitioners’ motion is now ripe for a ruling.

## II. Discussion

Styled as a motion for complete transparency of proceedings, petitioners’ motion specifically requests that the undersigned grant permission for the parties to discuss the details of this case now that petitioners have provided an express, written waiver of the protection against disclosure afforded to information submitted to a special master in section 12(d)(4)(A) of the Vaccine Act. See Petitioners’ Motion at 4-5. While petitioners’ executed waiver permits a discussion of the medical records filed in this case, the waiver does not extend to the actual release of petitioners’ medical records. Petitioners’ Motion, Authorization at 1.

At first glance, petitioners’ motion appears to request relief that the undersigned is without authority to grant. As respondent has correctly observed in his response, see R’s Response at 1-2, the undersigned lacks any authority to direct parties in a case to conduct discussions with non-parties about the details of a case “without limitation.”

The purpose of petitioners’ motion, however, as clarified during status conferences held with the parties after the filing of the motion, is to obtain a ruling that respondent’s two Rule 4 Reports filed in this case are not the type of “information” contemplated by

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<sup>9</sup>(...continued)  
presented by the OAP, most of the documents filed into the OAP have been posted on the court’s website for informational purposes, after obtaining the consent of the party who submitted the information. Therefore, any posting of petitioners’ expert reports in the OAP on the internet, with the obtained consent of petitioners, is a matter of personal election by the petitioners.

section 12(d)(4)(A) of the Vaccine Act and thus, permission from respondent is not required for petitioners to discuss those Rule 4 Reports publicly. Based on this understanding, the undersigned construes petitioners' motion as a request for the public release of the filed Rule 4 Reports, or alternatively, for permission to discuss the two Rule 4 Reports publicly.

#### A. Statutory Analysis

Questions regarding statutory interpretation of the Vaccine Act are questions of law. Avera v. Sec'y of Health and Human Servs., 515 F.3d 1343, 1347 (Fed. Cir. 2008) (An "issue[] [that] turns on the statutory interpretation of the Vaccine Act [is] a question of law."); Zatuchni v. Sec'y of Health and Human Servs., 516 F.3d 1312, 1315 (Fed. Cir. 2008) (stating that a "question of statutory interpretation . . . requires an analysis of the text and structure of the applicable statute"). The statutory provision in question here is section 12(d)(4)(A) of the Vaccine Act. It states:

Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

42 U.S.C. § 12(d)(4)(A).

What this statutory provision means "must, in the first instance, be sought in the language in which the act is framed, and if that [language] is plain, . . . the sole function of the courts is to enforce it according to its terms." Caminetti v. United States, 242 U.S. 470, 485 (1917); 2A Sutherland Statutory Construction § 46:1 (7th ed. 2007) (quoting same); see also Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997) ("Statutory construction begins with the plain language of the statute."); White v. Department of Justice, 328 F.3d 1361, 1374 (Fed. Cir. 2003) (same). "In the absence of a specific indication to the contrary, words used in the statute will be given their common, ordinary and accepted meaning, and the plain language of the statute should be afforded its plain meaning." 2A Sutherland Statutory Construction § 46:1 (7th ed. 2007); see also Medrad, Inc. v. Tyco Healthcare Group, LP, 466 F.3d 1047, 1051 (Fed. Cir. 2006) (when interpreting a statute, "give words their ordinary, contemporary, common meaning unless Congress has indicated otherwise . . . with a view to their place in the overall statutory scheme")(internal quotations omitted); cf. 1A Sutherland Statutory Construction § 20:8 (6th ed. 2002) ("When a legislature defines the language it uses, its definition is binding upon the court even though the definition does not coincide with the ordinary meaning of the words.").



The term in section 12(d)(4)(A) of the Vaccine Act of particular interest to petitioners is “information.” That term is not defined in the definition section of the Vaccine Act. See 42 U.S.C. § 300aa-33. Nor is a definition of that term found in the legislative history. Accordingly, consistent with the guiding principles of statutory construction, the term must be afforded its plain meaning, which may be supplied by its dictionary definition. See, e.g., Desper Products, Inc. v. QSound Labs, Inc., 157 F.3d 1325, 1333 (Fed. Cir.1998) (consulting the dictionary definition of a term to determine its “plain meaning”). As defined in Merriam-Webster’s online dictionary, information is variously defined as “the communication or reception of knowledge or intelligence,” “knowledge obtained from investigation, study, or instruction,” and “intelligence, news, facts, data.” See <http://www.merriam-webster.com/dictionary/information>; see also The American Heritage College Dictionary 712 (4th ed. 2002) defining “information” as “[k]nowledge derived from study, experience, or instruction,” “[k]nowledge of a specific event or situation; intelligence or news,” and “[a] collection of facts or data”).

The United States Supreme Court has instructed that “[w]here the language [in a statutory provision] is plain and admits of no more than one meaning, the duty of interpretation does not arise and the rules which are to aid doubtful meanings need no discussion.” Caminetti, 242 U.S. at 485 (citation omitted); 2A Sutherland Statutory Construction § 46:1 (7th ed. 2007) (same proposition). It is the view of the undersigned that the breadth of the definition of the term “information” does admit of more than one meaning and thus, requires some interpretation of what it means in section 12(d)(4)(A) of the Vaccine Act.

The Federal Circuit has counseled that judicial interpretation of words in statutory language must consider the “place [of the words] in the overall statutory scheme.” See Medrad, Inc. v. Tyco Healthcare Group, LP, 466 F.3d at 1051 (Fed. Cir. 2006) (when interpreting a statute, “give words their ordinary, contemporary, common meaning unless Congress has indicated otherwise . . . with a view to their place in the overall statutory scheme”). The Supreme Court offered the following instruction in 1899 in Hamilton v. Rathbone:

The general rule is perfectly well settled that, where a statute is of doubtful meaning and susceptible upon its face of two constructions, the court may look into prior and contemporaneous acts, the reasons which induced the act in question, the mischiefs intended to be remedied, the extraneous circumstances, and the purpose intended to be accomplished by it, to determine its proper construction.

Hamilton v. Rathbone, 175 U.S. 414, 419 (1899). Moreover, “[t]he rules of statutory

construction require a reading that avoids rendering superfluous any provision of the statute.” Ishida v. United States, 59 F.3d 1224, 1230 (Fed. Cir. 1995).

Applying these interpretive principles to glean the meaning of the word “information” in section 300aa-12(d)(4)(a), the undersigned examines first the whole of section 300aa-12(d)(4) of the Vaccine Act. It provides:

(4)(A) Except as provided in subparagraph (B), **information** submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the **information**.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include **information**–

(I) which is trade secret or commercial or financial **information** which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such **information** objects to the inclusion of such **information** in the decision, the decision shall be disclosed without such **information**.

42 U.S.C. § 300aa-12(d)(4) (emphasis added).<sup>10</sup>

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<sup>10</sup> The term information does appear in other sections of the Vaccine Act. The term appears in the title, “Additional Information,” of the statutory subsection 300aa-11(d), which provides that “[a] petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.” 42 U.S.C. § 300aa-11(d) (emphasis added). The use of the term here applies to “available, relevant medical records” of the vaccinee that exceed the scope of the documents required under section 11(c) of the Act, as an apparent effort to create as complete a record as possible for review. See Remarks by Sen Kennedy on introduction of S. 1922, 135 Cong. Rec. H29876, H29878 (daily ed. Nov. 17, 1989) (“We intend for the parties and the court to construe this provision broadly so as to require the submission of a meaningful file of information but not so as to hold up proceedings unreasonably if petitioner makes a good-faith effort to supply records and name unavailable ones.”).

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<sup>10</sup>(...continued)

Subsequently, the term appears in section 12(b)(2) of the Act. That provision prescribes a period of “30 days after the Secretary [of Health and Human Services] receives service of any petition filed under [the Vaccine Act,] . . . [for] the Secretary [to] publish notice of such petition in the Federal Register” and the designated special master “to . . . afford all interested persons an opportunity to submit relevant, written information . . . relating to any allegation in a petition” that a received vaccine caused or significantly aggravated an illness, disability, injury, or condition. 42 U.S.C. § 300aa-12(b)(2)(B). The information contemplated in this statutory subsection seems to refer to any information that would provide guidance with respect to petitioner’s claim of a vaccine-related injury.

Later in section 12(d)(3)(B) of the Act, the term appears in the enumerated list of what a special master may require “[i]n conducting a proceeding on a [vaccine] petition.” 42 U.S.C. 12(d)(3)(B). That list includes, but is not limited to, “such evidence[,], . . . the submission of such information[,], . . . the testimony of any person and the production of any documents[, and] . . . such hearings as may be reasonable and necessary.” *Id.* The use of the term in this context suggests that “information” is a broader category of matter for a special master to consider than evidence, testimony, and produced documents. It seems to the undersigned that the use of the term “information” in this statutory provision reflects an effort to permit a special master to become reasonably well-informed during the course of a vaccine proceeding.

Additionally, the term appears in subsection 25(c) of the Vaccine Act which pertains to the release of certain information in the governmental process of recording and reporting claims of vaccine-related injuries. The subsection prohibits the release, either through a request pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, or otherwise, of “[i]nformation . . . in the possession of the Federal Government . . . which may identify an individual” who has received a vaccine. 42 U.S.C. § 300aa-25(c)(1). Subsection 25(c)(2) defines “[f]or purposes of paragraph (1), the term ‘information which may identify an individual’ . . . [to include only] the name, street address, and telephone number of the person who received the vaccine and of that person’s legal representative and the medical records of such person relating to the administration of the vaccine.” 42 U.S.C. § 300aa-25(c)(2). Subsection 25(c)(2) states explicitly that the proscription against the release of “information which may identify an individual” does “not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.” *Id.* Subsection 25(c)(3) further provides that, with the exception of the “information which may identify an individual,” “all information reported under this section [concerning an alleged vaccine-related condition] shall be available to the public.” 42 U.S.C. § 300aa-25(c)(3). The information referenced in the subsection is clearly defined, and the statutory provision evinces an interest in public disclosure of reports involving

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Section 12(d)(4) of the Vaccine Act places certain limitations on the disclosure to non-parties of “information” submitted to a special master in a vaccine proceeding and on the disclosure of submitted information to a special master that is included in a decision issued by the special master.<sup>11</sup> In subsection 12(d)(4)(A), the disclosure of submitted information in a vaccine proceeding is prohibited in the absence of express written consent from the person who submitted the information. In subsection 12(d)(4)(B), the person who submitted certain information (information of the type described in that statutory subsection) may object to the disclosure of “such” information in a decision issued by the special master. Effectively, section 12(d)(4)(B) of the Vaccine Act affords an opportunity for the redaction of certain information from a decision prior to the decision becoming publicly available, as is required by the E-Government Act of 2002.<sup>12</sup> Although what constitutes information for purposes of section 12(d)(4) of the Vaccine

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<sup>10</sup>(...continued)

conditions alleged to have resulted from received vaccines as balanced against the privacy concerns of an individual.

<sup>11</sup> Under the Vaccine Act, a decision issues either when a claim for Program compensation is denied or when a claim for Program compensation receives a damages award. See 42 U.S.C. § 300aa-12(d)(3)(A) (“A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation.”) see also Widdoss v. Sec’y of Health and Human Servs., 989 F.2d 1170, 1175 (Fed. Cir. 1993) (stating that “proceedings on a petition conclude with the special master’s final act of ‘issu[ing] a decision on the petition”). No decision has issued yet in this case. The merits of petitioners’ claim were not litigated. Rather, respondent conceded the claim. Based on that concession, a damages determination is pending. Consistent with the Vaccine Act, a decision will issue after a determination of damages has been made.

<sup>12</sup> The E-Government Act of 2002 requires federal courts, including the United States Court of Federal Claims, to provide on their respective websites “[a]ccess to the substance of all written opinions issued by the court, regardless of whether such opinions are to be published in the official court reporter, in a text searchable format.” 44 U.S.C. § 205(a)(5). The E-Government Act further requires “each court [to] make any document that is filed electronically publicly available online. . . . [with the exception of those] [d]ocuments that are filed that are not otherwise available to the public.” 44 U.S.C. § 205(c)(1), § 205(c)(2). Moreover, the E-Government Act authorizes the United States Supreme Court to “prescribe rules . . . to protect privacy and security concerns relating to electronic filing of document and the public availability . . . of documents filed electronically[, and] . . . such rules provide for the redaction of certain categories of information in order to protect privacy and security concerns . . . [from the] copy [of the document] in the public file.” 44 U.S.C. § 205(c)(3)(iv).

Act requires further analysis, the language of that statutory provision does make clear that before submitted information may be disclosed to a non-party or disclosed in a decision of the special master, either consent to the disclosure or an ascertainment that there is no objection to the disclosure must first be obtained.

Subsection 12(d)(4)(A) is silent on what type of “information” requires express written consent prior to disclosure to a non-party. Subsection 12(d)(4)(B), however, does provide some guidance regarding what type of information submitted by a person may not be disclosed if the submitting person objects to the disclosure. Subsection 12(d)(4)(B) defines two categories of information that are not to be disclosed over the objection of the submitting party: (1) information “which is trade secret, or commercial or financial which is privileged and confidential;” and (2) information “which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” 42 U.S.C. § 300aa-12(d)(4)(B). Although the Vaccine Act does not address what constitutes “similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,” experience with vaccine cases teaches that “files” submitted in connection with Program claims may include employment records, police records, social services records, and educational records that often contain factual information and personal identification information that, if disclosed outside of the vaccine proceeding, might be found to “constitute a clearly unwarranted invasion of privacy.” Additionally, in connection with a damages determination in a vaccine case, information may be submitted to a special master from one or more life care planners that adverts to information contained in tax records, the disclosure of which also might be found to “constitute a clearly unwarranted invasion of privacy.” It appears to the undersigned that the type of information that is to be afforded protection against disclosure, absent consent to the disclosure, is information that is commercially sensitive or that is unjustifiably intrusive into an area of privacy.

As a practical matter, the information submitted to a special master in a vaccine proceeding that is privileged and confidential based on its trade secret, commercial or financial content is most likely to pertain to a vaccine manufacturer. The information submitted to a special master in a vaccine proceeding that is protected from disclosure to avoid “a clearly unwarranted invasion of privacy” most likely pertains to petitioner and is submitted by petitioner. Such “information,” however, is not necessarily limited to information that pertains to petitioner, and such information may be submitted to the special master by respondent. Moreover, information submitted by respondent during the course of a vaccine proceeding generally incorporates information that was submitted originally by petitioner.

A Rule 4 Report, in particular, is a document that is filed by respondent in a

vaccine proceeding and that incorporates medical information that pertains to petitioner. Moreover, the referenced medical information may have been submitted originally to the special master by the petitioner. Respondent files a Rule 4 Report in accordance with Vaccine Rule 4(c). That rule provides:

Within 90 days after the filing of the petition, or in accordance with the schedule set by the special master after petitioner has satisfied all required documentary submissions, respondent shall file a report that shall set forth a full and complete statement of respondent's position as to why an award should or should not be granted. The report shall contain respondent's medical analysis of petitioner's claims. It shall also present any legal arguments that respondent may have in opposition to the petition. General denials are not sufficient.

Vaccine Rule 4(c), Appendix B, Rules of the Court of Federal Claims. This report is known as a Rule 4 Report. The report generally includes a detailed discussion of petitioner's medical history as well as a discussion of petitioner's claimed vaccine-related injury. The report may also contain an evaluation of petitioner's medical claim by one or more of respondent's experts. Additionally, the report may include the concession of a claim by respondent, together with an explanation for the position respondent has taken. The report is signed by counsel for the Department of Justice and includes contact information for counsel, which may include a direct dial telephone number.

In the routine practice of the Office of Special Masters, what constitutes information under section 300aa-12(d)(4) of the Vaccine Act has not required close scrutiny. Admittedly, information pertaining to a petitioner is routinely shared in vaccine cases with non-parties to the litigation such as experts, litigation consultants (retained by petitioner), life care planners, and annuity brokers, among others, who work closely with counsel for the parties to resolve the pending claims. This information sharing is presumed to occur with the consent of petitioner, and the shared information should be handled with the care generally afforded to private, sensitive, and confidential material and with the care generally exercised by retained experts and consultants who are involved in the litigation process.<sup>13</sup>

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<sup>13</sup> This sharing of information in furtherance of the litigation process requires protection against unauthorized disclosures. Parties are urged to advise their retained experts and consultants to safeguard the shared information. Additionally, requiring the execution of a non-disclosure form by that party's retained experts and consultants is a strongly recommended practice.

Requests for disclosures, such as the one at issue in this case, to non-parties to the proceeding that permit unrestricted public access to information submitted in a vaccine proceeding, are unusual and necessarily compel close scrutiny. The presumption that information submitted to a special master in a vaccine proceeding is handled confidentially and is not made available to the public typically until a decision issues is implicit in Vaccine Rule 18 which addresses the availability of filings. That rule states, in pertinent part:

(a) General. All filings with the clerk pursuant to the Vaccine Rules are to be made available only to the special master, judge, and parties, with the exception of certain court produced documents as set forth in subdivision (b) of this rule. A transcript prepared pursuant to Vaccine Rule 8(b) shall be considered a filing for purposes of this rule.

(b) Decisions of Special Masters and Judges. When a decision of a special master or of the court is filed with the clerk, each party will be afforded 14 days in which to object to the public disclosure of any information furnished by that party

(1) that is trade secret or commercial or financial in substance and is privileged or confidential; or

(2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.

If the party furnishing information objects to disclosure, that information shall be redacted prior to public disclosure of the decision. In the absence of an objection, the entire decision will be made public.

Vaccine Rule 18, Appendix B, Rules of the Court of Federal Claims (emphasis added). The rule, which pertains to all filings in vaccine proceedings, limits the availability of filed documents to non-parties to the proceeding and specifically affords both parties the right to redact certain information from a decision issued by the court prior to public disclosure of the decision.

Here, petitioners assert that the information sought to be disclosed in this case, specifically, respondent's Rule 4 Reports, could be obtained through a "simple" request

under the Freedom of Information Act (FOIA), 5 U.S.C. §552.<sup>14</sup> See Petitioners’ Motion at 4. Petitioners’ proposed FOIA request, however, is not necessarily a “simple” one. As defendant points out in the filed responsive brief, FOIA does not apply when a statutory framework is in place that proscribes certain disclosures. See R’s Response at 5 n.4 (quoting 5 U.S.C. § 552(b)(3) (stating that FOIA “does not apply to ‘matters . . . specifically exempted from disclosure by statute . . . provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld”). Other exceptions to the statutorily authorized public disclosure of information held by governmental agencies under FOIA are set forth in section 552(b) of Title 5. Among the delineated exceptions to public disclosure are: (1) “trade secrets and commercial or financial information obtained from a person and privileged or confidential,” 5 U.S.C. § 552(b)(4), and (2) “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy,” 5 U.S.C. § 552(b)(6).

Notably, the language in section 12(d)(4)(B) of the Vaccine Act is substantially similar to language in the statutory subsection of FOIA delineating those matters to which the public disclosure requests do not apply. Compare 42 U.S.C. § 12(d)(4)(B) (stating that if the party to a vaccine proceeding submits information “that is trade secret or commercial or financial in substance and is privileged or confidential; or . . . that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy” and the submitting party objects to the public disclosure of the information in an issued decision, that information “shall be redacted prior to public disclosure of the decision”) with 5 U.S.C. § 552(b)(4), §552(b)(6) (information that a federal agency need not make available to the public pursuant to a FOIA request includes those matters that are “trade secrets and commercial or financial information obtained from a person and privileged or confidential” and those matters that are “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy”).

These exceptions are of particular interest to the undersigned in the current statutory analysis because incorporated into the determination of what may be disclosed is a balancing of interests between the public’s interest in disclosure and the privacy

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<sup>14</sup> The Freedom of Information Act (FOIA), 5 U.S.C. § 552, governs how government agencies (that do not have another statutory scheme in place establishing a procedure for the public disclosure of information) shall make information available to the public. See John Doe Agency v. John Doe Corp., 493 U.S. 146, 151 (1989) (stating that the “fundamental principle . . . that animates the FOIA” is “public access to Government documents”).



interests attached to the information sought.<sup>15</sup> This balancing of interests is instructive in the instant case.

The undersigned returns to an examination of the statutory provision at issue in this case, section 12(d)(4)(A) of the Vaccine Act. The broad term “information” is used in section 12(d)(4)(A) of the Vaccine Act (and not the term “document” or “record”) to describe that which is submitted to a special master during the course of a vaccine proceeding that requires the consent of the party who submitted the information prior to its disclosure to a non-party. By definition, information is the both the “communication of knowledge or intelligence” as well as “intelligence,” “facts” and “data.” See <http://www.merriam-webster.com/dictionary/information>; see also The American Heritage College Dictionary 712 (4th ed. 2002). The “communication of knowledge or intelligence” includes the process of conveying “intelligence,” “facts” and “data.” But, because the conveyance process is already contemplated by the word “submitted” in the statutory phrase “information submitted to a special master,” it is the view of the undersigned that the use of term “information” in section 12(d)(4)(A) applies to the “intelligence,” “facts” and “data” that are conveyed or “submitted” to the special master in a vaccine proceeding. The use of the term “submitted” and not the term “filed” suggests that the proper focus of the undersigned is on the one who presented the information for consideration. The use of the term “person” (rather than the more limited term “petitioner” or the term “party”) suggests that the statutory protection against the disclosure of submitted information to a non-party to the proceeding is available to persons providing information that is submitted in a vaccine proceeding. Such persons may include both parties to the proceeding, but the language of the subsection 12(d)(4)(A) does not limit “persons” to “parties.” Moreover, the language of section 12(d)(4)(B) of the Vaccine Act, does not restrict the information that can be withheld from disclosure in an issued decision, based on the expressed objection of the person who submitted the information, solely to information submitted by petitioner or information pertaining to petitioner.

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<sup>15</sup> Because the intent of FOIA is to facilitate the disclosure of and public access to information in the possession of governmental agencies, a purpose that is contrary to the conduct of private proceedings in the Vaccine Program, the undersigned is informed by the type of considerations that would prevent the disclosure, pursuant to a FOIA request, of personnel, medical, or similar file content because such disclosure would constitute a “clearly unwarranted invasion” of privacy. The undersigned reasons that if such privacy concerns militate against disclosure under a statute that is intended to facilitate public access to information, then such privacy concerns may militate similarly against disclosure under the Vaccine Act, a statutory scheme that disfavors disclosure based on those same privacy concerns.

Information, whether factual matters or opinions informed by factual matters, that is supplied in a vaccine proceeding for litigation purposes or as part of an effort to resolve a claim through alternative dispute resolution is likely to be more forthright and more complete when the person submitting the information is assured that the submitted information will not be disclosed before the granting of consent or, if consent is withheld, that no disclosure will occur prior to the issuance of a ruling by a special master on a presented request for disclosure. Accordingly, when consent to disclosure is not given, a request for disclosure should be presented to a special master prior to the disclosure. A request for disclosure requires: (1) an examination of the information sought to be disclosed and the purpose of the disclosure; (2) consideration of the stage of the vaccine proceedings at which the request for disclosure is made and whether the requested disclosure will affect adversely the course of the proceedings; and (3) a determination of whether the information sought to be disclosed merits protection against disclosure on either of the grounds set forth in section 12(d)(4)(B) of the Vaccine Act. If the information sought to be disclosed does merit the statutory protection against disclosure set forth in section 12(d)(4)(B) of the Vaccine Act, a further determination of whether the implicated statutory protection might be provided by a redaction that permits some limited disclosure, if appropriate, should be made.

In this particular circumstance, petitioners effectively seek the disclosure of respondent's two Rule 4 Reports. In each of the reports, respondent refers to information that was contained in medical records that were submitted in this vaccine proceeding by petitioners. Additionally, in the Supplemental Rule 4 Report, respondent refers to information that was contained in an expert report that was submitted in this proceeding by petitioners.

Respondent points out in the filed Sur-Reply that "legal argument supporting [petitioners'] contention that a Rule 4(c) report is not 'information' under section 12(d)(4)(A) of the Vaccine Act" is "[n]oticeably missing from petitioners' Motion and Reply," R's Sur-Reply at 1, and states that "a Rule 4 report may not be publicly disclosed absent express, written consent from respondent," *id.* at 3. Respondent, however, also fails to articulate the legal basis for its position that a Rule 4 Report is information, but the undersigned infers from "respondent's position in every case brought under the Vaccine Act, pursuant to section 12(d)(4)(A)," that, in respondent's view, the act of filing a Rule 4 Report qualifies as a submission of information under that statutory provision and the disclosure of the report is prohibited absent express written consent. See R's Sur-Reply at 3.

The undersigned has concluded, based on an interpretation of the statutory language, that "information submitted to a special master . . . in a proceeding on a

petition” contemplated by section 12(d)(4)(A) can pertain to information that is included in a filed Rule 4 Report for which respondent must provide consent prior to the sought disclosure. But, a recitation of petitioner’s medical history by respondent in a filed Rule 4 Report, without more, does not become information submitted by respondent that requires respondent’s consent prior to disclosure simply because respondent has filed a document summarizing the content of petitioner’s medical files.

To avoid running afoul of the statutory protection against disclosure to a non-party, a party is well-advised to make efforts to secure, prior to a disclosure to a non-party (or to the public), the consent of the person who submitted the information.<sup>16</sup> And if consent to disclosure is withheld, a party is urged to make application to the assigned special master for a ruling on the request for disclosure.

In this case, petitioners seek the disclosure of two Rule 4 Reports filed by respondent that contain information about the vaccinee’s medical condition and the basis for respondent’s concession of petitioners’ claim. The stated basis for respondent’s concession reflects respondent’s reasoning, based on medical facts pertaining to the vaccinee, for its position that petitioners’ claim should be compensated by the Vaccine Program. That reasoning set forth in the Rule 4 Report filed on November 9, 2007 arguably could be construed to be information as that term is used in section 12(d)(4)(A) of the Vaccine Act. Moreover, the disclosure of the direct dial number for respondent’s counsel could be construed to “constitute a clearly unwarranted invasion of privacy” in light of the strong public interest in and strong public opinions about autism cases in general and this case in particular. Respondent, however, has not advanced either of these arguments in the filed briefing.

Rather, respondent has expressed in the filed Sur-Reply a willingness to “agree[] to petitioners’ request for mutual consent to public disclosure in this case with the understanding that such consent on the part of respondent [i]s effective only as to disclosures occurring after respondent’s representatives signed the consent.” R’s Sur-Reply at 4. Additionally, petitioners have attached to their motion a waiver of the

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<sup>16</sup> Indeed, this practice has worked well for obtaining the necessary consent for the posting on the court’s website of information relevant to the test cases for the first and second general causation theories in the OAP. Moreover, as respondent observed in the filed Sur-Reply, “the lead attorney for the Petitioners’ Steering Committee, Thomas Powers, Esquire, who is also co-counsel to petitioners in this case, has sought consent from respondent to share respondent’s expert reports, and any other information filed by respondent, with other members of the Petitioners’ Steering Committee. At no time has respondent ever denied such a request.” R’s Sur-Reply at 3 n.2.

protection against disclosure afforded to information submitted to a special master permitting a discussion of the details of their claim. See Petitioners' Motion, Authorization at 1. Notwithstanding the mutually expressed willingness to provide consent, the parties have been unable to execute a signed consent form. In light of the parties' expressed willingness to execute a signed consent form, the parties are strongly encouraged to effect the execution of a signed consent form.

### III. Conclusion

For the foregoing reasons, the undersigned has determined that certain content in the two Rule 4 Reports filed by respondent, and sought by petitioners to be disclosed to the public, arguably is information as contemplated by the use of that term in section 12(d)(4)(A) of the Vaccine Act. Section 12(d)(4)(A) of the Vaccine Act requires that prior to the disclosure of such information to a non-party, consent from the person who submitted the information, determined in this case to be respondent, must be obtained. Although both parties have expressed a willingness to provide consent, the parties have been unable to execute a signed consent form. In light of the parties' expressed willingness to execute a signed consent form, the undersigned strongly encourages the parties to do so.

As a practical matter, petitioners' request for disclosure of the two Rule 4 Reports in this case (styled originally as a motion for complete transparency) is moot based on an earlier unauthorized disclosure. Nonetheless, had an unauthorized disclosure not already been effected in this case and were the parties still unable to execute a signed consent form, the undersigned would undertake a balancing of the interests for and against disclosure in deciding whether to permit the requested disclosure (or a modification of the requested disclosure), over the objection of the person who submitted the information.<sup>17</sup> Among the interests to be considered would be the petitioners' interest in sharing the details of this case with the public, the public's strong interest in the details of this particular case, the impact of the disclosure on the final resolution of this claim, and the impact of this disclosure on the pending litigation of the autism cases in the OAP. Although a balance of the interests in this case might militate in favor of the disclosure of the requested reports after the parties have been afforded an opportunity, consistent with Vaccine Rule 18(b), to propose redactions to the reports, the disclosure of the documents

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<sup>17</sup> The undertaking of a balancing of the interests for and against disclosure in deciding whether to permit the requested disclosure is informed by section 12(d)(4)(B) of the Vaccine Act. When, consistent with section 12(d)(4)(B) of the Act, a request for redaction is presented prior to the disclosure of an issued decision, a special master takes care to safeguard the protected information without rendering the issued decision unintelligible.

does not force a party to discuss the documents, and the undersigned is without authority to compel such discussion.

The undersigned again observes that petitioners' request to disclose to the public the two filed Rule 4 Reports, which are documents submitted in the course of vaccine litigation, is an extraordinary request. To afford the parties another opportunity to execute a signed consent, consistent with the mutually expressed willingness of the parties, the undersigned **DEFERS** ruling on petitioners' motion for a period of 60 days. If the parties are unable to execute a signed consent on or before **Monday, June 9, 2008**, the undersigned shall issue a ruling consistent with the reasoning set forth in this Order.

**IT IS SO ORDERED.**

s/ Patricia E. Campbell-Smith  
Patricia E. Campbell-Smith  
Special Master