In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS

(Filed: August 11, 2005)

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER OR A SIMILAR NEURODEVELOPMENTAL DISORDER	*	**AUTISM MASTER FILE**
VARIOUS PETITIONERS,	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

RULING CONCERNING ISSUE OF TIME FOR FILING EXPERT REPORTS

HASTINGS, ***Special Master.***

The above-captioned proceeding is a special proceeding conducted pursuant to the National Vaccine Injury Compensation Program (hereinafter "the Program").[1] As will be detailed below, this proceeding involves claims by numerous families, filed under the Program, alleging that their children's neurodevelopmental disorders were caused by certain childhood vaccines. This document constitutes my ruling concerning a motion by the petitioners seeking more time in which to file the expert reports on petitioners' behalf.

As set forth below, I hereby grant certain relief in this regard to the petitioners.

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[1]The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2000 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2000 ed.). I will also at times refer to the statute that governs the Program as the "Vaccine Act."

I

BACKGROUND

A. The "Omnibus Autism Proceeding"

The dispute that is the subject of this opinion arises in the context of an unusual situation involving multiple cases filed under the Program that share a common issue of medical causation. Each of these cases involves an individual who suffers from a neurodevelopmental disorder known as an "autism spectrum disorder"--"autism" for short--or a similar neurodevelopmental disorder. In each case, it is alleged that such disorder was causally related to one or more vaccinations received by that individual--*i.e.*, it is alleged that the disorder was caused by measles-mumps-rubella ("MMR") vaccinations; by the "thimerosal" ingredient contained in certain diphtheria-tetanus-pertussis ("DTP"), diphtheria-tetanus-acellar pertussis ("DTaP"), hepatitis type B, and hemophilus influenza type B ("HIB") vaccinations; or by some combination of the two. To date, almost 5,000 such cases have been filed with this court, and additional cases continue to be filed each week.

To deal with this large group of cases involving a common factual issue--*i.e.*, whether these types of vaccinations can cause autism--in 2002 the Office of Special Masters (OSM) conducted a number of informal meetings with attorneys who represent many of the autism petitioners and with counsel for the Secretary of Health and Human Services, who is the respondent in each of these cases. At these meetings the petitioners' representatives proposed a special procedure by which the OSM could process the autism claims as a group. They proposed that the OSM utilize a two-step procedure: first, conduct an inquiry into the *general causation issue* involved in these cases-- *i.e.*, whether the vaccinations in question can cause autism and/or similar disorders, and if so in what circumstances-- and then, second, apply the outcome of that general inquiry to the individual cases. They proposed that a team of petitioners' lawyers be selected to represent the interests of the autism petitioners during the course of the general causation inquiry. They proposed that the proceeding begin with a period of discovery concerning the general causation issue, followed by the submission of expert reports by each side, an evidentiary hearing, and finally a ruling on the general causation issue by a special master. Then, the general causation conclusions, reached as a result of the general proceeding, would be applied to the individual cases.

As a result of the meetings discussed above, the OSM adopted a procedure generally following the format proposed by the petitioners' counsel. On July 3, 2002, the Chief Special Master, acting on behalf of the OSM, issued a document entitled the *Autism General Order #1*.[2] That Order set up a proceeding known as the Omnibus Autism Proceeding (hereinafter sometimes

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[2]The *Autism General Order #1* is published at 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed. Cl. Spec. Mstr. July 3, 2002). I also note that the documents filed in the Omnibus Autism Proceeding are contained in a special file kept by the Clerk of this court, known as the "Autism Master File." Most of that file may be viewed on this court's Internet website at www.uscfc.uscourts.gov/osm/osmautism.htm.

"the Proceeding"). In that Proceeding, a group of counsel, selected from attorneys representing petitioners in the autism cases, was designated as the Petitioners' Steering Committee, and began the process of obtaining and presenting evidence concerning the *general issue* of whether these vaccines can cause autism, and, if so, in what circumstances. Expert reports for the petitioners and the respondent will be filed, and an evidentiary hearing will be held. A special master will issue an analysis of that general issue, and the results of that analysis will then be applied to the individual cases. (2002 WL 31696785 at *3; 2002 U.S. Claims LEXIS 365 at *8.)

The *Autism General Order #1* assigned the responsibility for presiding over the Omnibus Autism Proceeding to the undersigned special master. In addition, I have also been assigned responsibility for all of the individual Program petitions in which it is alleged that an individual suffered autism or an autistic-like disorder as a result of MMR vaccines and/or thimerosal-containing vaccines. The individual petitioners in each of those cases have requested that, in general, no proceedings with respect to the *individual petitions* be conducted until after the conclusion of the Omnibus Autism Proceeding concerning the *general* causation issue.[3] The OSM will then deal specifically with the individual cases.

B. The schedule for the Omnibus Autism Proceeding, and the petitioners' request here at issue

The *Autism General Order #1* contained an initial schedule for the anticipated activities in the Omnibus Autism Proceeding. (See Part D of that *Order*, and Exhibit E attached thereto.) The schedule anticipated a discovery period of fourteen months; petitioners' expert reports to be filed in November 2003; an evidentiary hearing to commence in March 2004; and the special master's ruling on the general causation issues to be issued by July 2004.

The actual course of the Omnibus Autism Proceeding, quite obviously, has deviated from that initial schedule. As detailed in my Autism Updates filed into the Autism Master File (and posted on this court's website) regularly over the past three years, the discovery process has taken much longer than initially anticipated. The Petitioners' Steering Committee (hereinafter "the Committee") made a very extensive initial request for production of materials from government files, and later an extensive second request. At a couple of points, disputes between that Committee and respondent's representatives delayed production. However, respondent's representatives have cooperatively worked with the Committee, and those disputes have eventually been resolved between the parties on each occasion. As a result, a massive amount of material from government files--approximately 200,000 pages--has been provided to the Committee. Moreover, much of this material has been from the Food and Drug Administration's (FDA) vaccine license application files, which means that production of each set of documents (with respect to each vaccine of each manufacturer) can occur

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[3] I note that it is up to each individual petitioner to determine whether to defer proceedings concerning his or her own case pending the completion of the Omnibus Autism Proceeding. If an individual petitioner has proof of causation in his own case that he wishes to put before a special master at any time, that petitioner will be allowed to do so.

only after a very lengthy and cumbersome procedure involving review of the material (1) by FDA personnel, (2) by Department of Justice personnel, and (3) by personnel of the vaccine manufacturer that originally submitted the material for the license application. Production of this huge amount of material, via such a complicated process, has simply taken a long time, despite conscientious efforts by all involved.

Further, the discovery process was additionally delayed due to efforts by the Committee to obtain records directly from the files of a vaccine manufacturer, an effort that proved unsuccessful. See *In Re Autism Claims*, 2004 WL 1660351 (Fed. Cl. Spec. Mstr. July 16, 2004).

Unsurprisingly, the Committee has desired to delay the filing of expert reports until after the completion of the discovery process. I have, accordingly, deferred, until after the end of discovery, the time for the Committee to submit the expert reports on behalf of petitioners. Now, however, the completion of that discovery process is close at hand, with the final documents from government files due to be submitted to the Committee within the next several weeks. Therefore, I instructed the Committee to propose a new date for the submission of the petitioners' expert reports. The Committee submitted a filing in that regard on June 14, 2005, and the respondent filed a response thereto on July 12, 2005.

In its filing, the Committee requested that it not be required to submit the petitioners' expert reports prior to "late 2006." The Committee pointed to the existence a number of ongoing medical studies, relevant to the general causation issue, that are scheduled to be published in late 2005, or late 2006. The Committee argues that it makes sense that its experts be able to evaluate these studies before filing their expert reports.

Respondent, in reply, offered solely a legal argument, contending that under the statute I do not have the *legal authority* to delay the Omnibus Autism Proceeding any further.

II

ANALYSIS OF RESPONDENT'S ARGUMENT

Respondent's argument, as I understand it, can be summarized as follows. Respondent begins with the statutory direction that the special master's "decision" in each Vaccine Act case is to be filed within 240 days of the date on which the petition was filed. § 300aa-12(d)(3)(A)(ii). Respondent notes that this 240-day period may be in effect extended for up to 180 days, by the granting of a "suspension of proceedings" of up to 180 days pursuant to § 300aa-12(d)(3)(C). Respondent contends that if I delayed the due date for the filing of the Committee's expert reports in the Omnibus Autism Proceeding, I would be, in effect, granting an improper "suspension of proceedings" in each autism case *exceeding* in each case the 180-day limitation of § 300aa-12(d)(3)(C).

Respondent's argument is without merit. Respondent simply is incorrect that the relief sought by the Committee here amounts to a "suspension of proceedings" in excess of the maximum allowed under § 300aa-12(d)(3)(C). And respondent's argument *totally ignores* the most relevant sections of the statute--§§ 300aa-12(g) and 300aa-21(b).

Respondent is correct, of course, that the basic direction of the statute is that a special master is to render a decision on a petition within 240 days from the petition filing date. § 300aa-12(d)(3)(A)(ii). Further, as respondent points out, while that 240-day time period may be, in effect, extended by the "suspension of proceedings" provision of § 300aa-12(d)(3)(C), such an extension is undoubtedly limited to 180 days. Respondent, however, errs in the apparent conclusion that, therefore, in every Vaccine Act case a special master *must* file a final decision within the extended "240-day plus 180-day" period. Respondent seems to argue that at the end of the extended period, the special master *must* decide the case, and has no jurisdiction or authority to keep the case pending on his or her docket for any further time period. Respondent is clearly wrong in this part of respondent's argument, as is clear from an examination of §§ 300aa-12(g) and 300aa-21(b).

Section 300aa-12(g) and § 300aa-21(b) are the statutory sections which specify what is to happen when the special master's decision is *not* filed within the prescribed "240-day plus 180-day" period. Section 300aa-12(g) provides, in pertinent part, as follows:

> **(g) Notice**
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> If-
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> > (1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) of this section (excluding (A) any period of suspension under subsection (d)(3)(C) * * *) * * *,
>
> the special master * * * shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa-21(b) of this title or the petitioner may choose under section 300aa-21(b) of this title to have the petition remain before the special master * * *.

Section 300aa-21(b) then provides, in pertinent part, as follows:

> **(b) Continuance or withdrawal of petition**
>
> A petitioner under a petition filed under section 300aa-11 of this title may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if--

> (1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa-12(d)(e)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) * * *) * * *.

In other words, pursuant to § 300aa-12(g), if the special master for any reason cannot meet the "240-day plus 180-day" deadline, then a "notice" (hereinafter the "§ 12(g) notice") must be sent to the petitioner informing the petitioner of that failure. And, the issuance of that "§ 12(g) notice" then triggers an *option* for the petitioner under § 300aa-21(b). That is, when a special master issues a "§ 12(g) notice," the petitioner may, within 30 days, leave the Program by filing a notice of withdrawal of his petition, or may, instead, "choose * * * to have the petition remain before the special master."

It seems to me that the very existence of §§ 300aa-12(g) and 300aa-21(b) make it quite clear that respondent is *wrong* when respondent asserts that at the end of the "240-day plus 180-day period," the special master has no further jurisdiction or authority to keep the case pending on the special master's docket. To the contrary, those sections obviously are designed *specifically* to give the petitioner the option of *staying in the Program* beyond the time deadlines. Sections 300aa-12(g) and 300aa-21(b) each plainly state that the petitioner may "choose to have the petition remain before the special master" for an unspecified further period of time. The petitioner may leave the Program if the petitioner wants to do so, but the petitioner also clearly has an *option* to remain in the Program.

In other words, it seems clear to me, from the very face of this part of the statute, that this "remain in the Program" option was *specifically designed* by Congress to provide for those situations in which, for any reason, a petitioner's claim could not be satisfactorily adjudicated within the "240-day plus 180-day" time period, but the petitioner wanted to stay in the Program and receive a decision on his claim. But if those statutory provisions are not plain enough on their face, *legislative history* confirms this interpretation. The current relevant language of § 300aa-12(g) and § 300aa-21(b) was enacted in 1991. Prior to that statutory amendment, the statutory language appeared to mean that if the special master's decision was not filed within the "240-day plus 180-day" time period, then the special master lost jurisdiction over the case. The legislative history of that 1991 amendment to §§ 300aa-12(g) and 300aa-21(b) includes the following statement:

> Under the program as currently in force, if a special master or the court does not enter a decision on a petition for compensation within specified time limits, the master or the court no longer has jurisdiction to continue consideration of the petition. Subsection (c) eliminates the provisions automatically withdrawing jurisdiction and, instead, allows the petitioner to elect to continue or withdraw the petition.

137 Cong. Rec. H9358-60 (daily ed. Nov. 15, 1991) (Statement of Rep. Waxman).

Thus, the legislative history *confirms* the legislative intent that seems obvious from the statutory wording itself--*i.e.*, that a petitioner *may*, at his option, remain in the Program past the end of the "240-day plus 180-day" period.[4]

In short, relying upon § 300aa-12(g) and § 300aa-21(b), I reject respondent's apparent legal argument that I have no authority under the statute to keep a Vaccine Act petition pending beyond the conclusion of the "240-day plus 180-day period" described above. I conclude, to the contrary, that I *do* have legal authority to do so. I conclude that in each case I have *discretion* to allow the petitioner to keep the petition pending as long as it seems appropriate under all the circumstances of the case.

III

EXERCISE OF DISCRETION IN THIS PROCEEDING

Of the nearly 5,000 autism cases pending before me, most have already, in fact, progressed beyond the "240-day plus 180-day period." In each such case, I have issued a "§ 12(g) notice" as described above. In a very few such cases, the petitioners have elected to withdraw from the Program. In the vast majority, however, the petitioners have not utilized the withdrawal option, instead electing to remain within the Program. Clearly, those petitioners hope that the Omnibus Autism Proceeding may reach an outcome favorable to the proposition that autism may be caused or aggravated by MMR vaccinations and/or thimerosal--containing vaccinations. As set forth above, I conclude as a matter of law, pursuant to §§ 300aa-12(g) and 300aa-21(b), that I have *discretion* to allow such petitioners to keep their petitions pending, after they have received their "§ 12(g) notices," as long as is appropriate under all the circumstances of each case. The questions before me, for my exercise of discretion, then, are (1) whether it is appropriate for me to permit those autism petitioners to keep their petitions pending until the conclusion of the Omnibus Autism Proceeding, and (2) whether I should grant the Petitioners' Steering Committee the additional time now requested, in which to file the petitioners' expert reports in that Proceeding.

As to the first question, the answer seems obvious. I see no reason not to let these petitioners keep their petitions pending. The Omnibus Autism Proceeding may turn up evidence that may assist these petitioners in making successful Program claims. The desire of these petitioners is to wait and see if that happens. And there is no harm to respondent by allowing these petitioners to wait and see. Accordingly, I will allow them to do so.

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[4]It is noteworthy that the relevant language of §§ 300aa-12(g) and 300aa-21(b) has existed in its current form since 1991. Since that time, certainly hundreds (perhaps thousands) of Vaccine Act cases have remained pending before a special master long after the expiration of the "240-day plus 180-day period," in situations in which the petitioners needed extra time to locate and present their evidence. Yet respondent has never before, to my knowledge, offered the argument raised in this case.

The second question is a bit more difficult. The Omnibus Autism Proceeding has already lasted for three years, when the original proposed schedule called for completion in two years. Further, ideally, I certainly would like to see these autism causation issues move to a conclusion as soon as possible--not for the sake of the respondent, the vaccine manufacturers, or myself, but for the sake of the many *families* who have pending Vaccine Act claims, who need help for their developmentally-impaired children, and who have voluntarily elected to stay proceedings concerning their own individual Vaccine Act petitions pending the completion of the Omnibus Autism Proceeding. For the sake of these families, I would *very much* like to reach a resolution of the Omnibus Autism Proceeding as soon as possible.

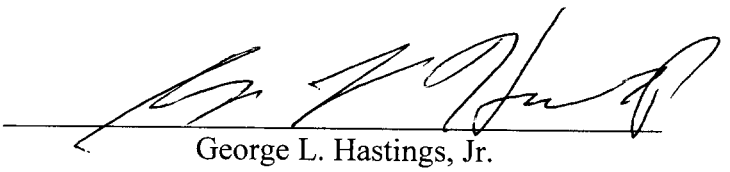
However, it must be kept in mind that one primary purpose of the Vaccine Act is to *benefit the petitioners*, and in these autism cases the petitioners are families with children suffering from devastating disorders. I believe that it is appropriate to give the petitioners' representatives the time that they need in order to develop their causation case to the greatest extent possible. All of us involved in the Omnibus Autism Proceeding would like to see it conclude soon, but it is also important to give these families the chance to present the best case that they can. It is true that this process is taking longer than Congress ideally envisioned for most Vaccine Act cases, but the length of the process is simply the result of the fact that these cases involve novel and difficult scientific issues of medical causation. And, as pointed out above, Congress clearly understood that *some* Vaccine Act cases *would* take longer than the ideal, as shown by the fact that Congress gave each petitioner the option under § 300aa-21(b) of staying in the Program even after the initial time period for decision had expired. Accordingly, it does not seem desirable to arbitrarily force the Committee to present its evidence in the Omnibus Autism Proceeding before that Committee deems itself ready to do so.

Moreover, the Committee has now pointed to specific relevant ongoing studies. (Filing filed June 14, 2005, p. 5.) For two of those studies there are anticipated publication dates later in 2005 (items 1, 5), and for three more studies, publication or completion is anticipated about September 2006 (items 2, 3, 9). Based on those circumstances, it seems that it may very well be reasonable to wait for the results of these particular, identified studies.

Accordingly, at this time I will defer indefinitely the due date for the petitioners' expert reports. However, by January 31, 2006, petitioners shall designate who their experts will be. (Respondent shall then designate respondent's experts two months later.) The parties' experts, of course, have much material *already available* concerning the general causation issues, so it seems to me that there is no reason not to soon designate experts and have them begin work. Then, once the ongoing studies mentioned above have been completed, such experts can incorporate the results of those studies into those experts' already-in-progress reports.

Further, along with the designation of experts, the Committee shall also file a statement from one or more of the Committee's *experts*, giving the *expert's* views as to whether it is necessary--and, if so, *why* it is necessary--to wait until late 2006 to file the expert reports. Such statement should include *updated information* as to when the identified ongoing studies are anticipated to be

published. If such a petitioners' *expert* states the opinion that it is necessary to wait until late 2006, and adequately explains such opinion,[5] then at that time I may elect to defer the due date until late 2006.



George L. Hastings, Jr.
Special Master

[5]In this regard, I note that it seems likely that for *years* into the future, there will be ongoing studies as to the possible cause of autism. Therefore, it seems doubtful that it will be appropriate to wait for every last conceivable study to conclude. Rather, the petitioners' expert or experts should explain specifically why any *particular* ongoing studies are important enough, in the context of the existing studies, to warrant further delay of the Omnibus Autism Proceeding.