

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: June 23, 2004)

FILED
JUN 23 2004
U.S. COURT OF FEDERAL CLAIMS

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

AUTISM UPDATE--JUNE 23, 2004

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated April 23, 2004. I note that counsel for both parties and I have continued to work diligently on the Proceeding during that time period. Unrecorded telephonic status conferences were held on May 6, May 17, and June 8, 2004.

A. Number of cases

At this time, more than 4200 petitions in autism cases have been filed, and more than 4100 remain pending, stayed (at the petitioners' own request) until the conclusion of the Omnibus Autism Proceeding. Additional petitions continue to be filed regularly.

1Counsel participating in those conferences included Thomas Powers and Ghada Anis for petitioners, along with Vincent Matanoski, Mark Raby, and Linda Renzi for respondent.

2Almost all of the cases that are no longer pending were voluntarily dismissed or withdrawn by the petitioners; in most of those cases, the dismissal was due to the fact that, inadvertently, a second petition had been filed pertaining to the same autistic child. In addition, thirteen autism cases have been dismissed because those cases were not timely filed.

B. Discovery

As indicated in my previous Autism Updates, a tremendous amount of work has been done by counsel for both parties concerning the petitioners' extensive discovery requests. I will not reiterate developments covered in my previous updates, but I will summarize below our progress and certain new developments in the discovery area.

1. General progress concerning initial Requests for Production

Certain material responsive to the petitioners' extensive initial set of Requests for Production was made available to petitioners during the fall of 2002 via various government web sites, and since then many thousands of pages of additional material have been copied from government files and supplied to petitioners. At this point, the respondent has now substantially complied with all of the petitioners' initial set of Requests for Production, except for the ongoing production discussed at point 2 below and the item concerning "ongoing studies" mentioned at point 4 below. (By my informal count, the total number of pages of documents provided by respondent to the petitioners (not counting the material available via website) approximates 126,000 pages.)

2. The vaccine license application files

One category of documents requested, pursuant to petitioners' Requests for Production Nos. 10 and 12, involves vaccine license applications. In this area, efforts to produce material have proceeded slowly, as detailed in my previous Autism Updates, but the process of production of that material continues to move forward. Since my last Update, the first portion of the Food and Drug Administration (FDA) file that pertains to the Wyeth/Lederle DTaP vaccine was submitted to the Petitioners' Steering Committee (hereinafter "the Committee"), along with the second portion of the file pertaining to the Aventis DTaP vaccine. Prior to that, large portions of the files for the Merck MMR combined vaccine, the Merck mumps vaccine, the Merck measles vaccine, the Merck rubella vaccine, the Merck hepatitis B vaccine, the GlaxoSmithKline hepatitis B vaccine, and the North American Healthcare DTaP vaccine were submitted to the Committee. And the files with respect to several additional vaccines are continuing to move at various stages through the arduous process toward disclosure.³

3. Organizational depositions

As previously reported, the Committee has filed a request to depose certain government officials. Two representatives of the Centers for Disease Control and Prevention ("CDC") were

³I note that while the Committee's discovery *requests* have been filed into the Autism Master File, the respondent's discovery *responses* have been filed into the file of an individual autism case, *Taylor v. HHS*, No. 02-699V. The latter file is available to autism petitioners and their counsel, via special procedures set up by the Committee, but not to the general public, as mandated by the Vaccine Act. (See discussion at part C, pp. 4-6, below.)

deposed on December 9, 2003; a representative of the Agency For Toxic Substances and Disease Registry was also deposed on December 9, 2003; and a FDA official was deposed on May 27, 2004. The respondent has declined, however, to provide an official of the National Institutes of Health (“NIH”) for deposition, however, and the Committee has recently requested that I order the respondent to provide such an official for deposition as part of the “motion to compel” discussed immediately below.

4. Motion to compel discovery from respondent

As indicated in previous Autism Updates, the parties have been in disagreement concerning the issue of production of materials relating to certain studies, especially those related to one recently completed study known as the “Thimerosal Screening Analysis” (“TSA”). After extensive efforts to settle this issue were unsuccessful, the Committee on March 9, 2003, filed a “Motion to Compel,” requesting that I order respondent both to produce certain documents and to provide a witness from the NIH for deposition. The motion seeks, *inter alia*, documents relating to (1) the TSA; (2) other completed and published studies; and (3) studies in progress. It also seeks documents from the vaccine license application files in addition to those that have been disclosed as discussed above in paragraph (B)(2) of this update.

Respondent filed a written response to that motion (into the *Taylor* file) on May 14, 2004, and the Committee filed a reply brief on June 7, 2004. An evidentiary hearing concerning that motion was originally tentatively scheduled to be held sometime between June 21 and 29, 2004. However, during the discussion at the status conference on June 8, 2004, respondent’s counsel argued that a June hearing would be premature, since in respondent’s view a number of the petitioners’ production requests are ambiguous and lack specificity. Further, petitioners’ counsel stated that while the Committee may wish to present an expert witness concerning the issue of the “necessity” of the requested documents, the Committee was still unsure of the identity of such a witness. Accordingly, I concluded that, because the specificity of the document requests was not clear and the Committee is still unsure of what (if any) expert will be presented, it would not be possible to take complete oral argument and/or evidence, concerning the issue of whether I should compel the requested disclosure by the respondent, by the end of this month. Instead, I ordered that respondent file by June 15, 2004, a brief describing the alleged ambiguity of the petitioners’ document requests,⁴ and that the Committee file by June 25, 2004, a written response thereto. Further, by June 29, 2004, the Committee will determine whether it wants to provide an expert witness concerning the “necessity” issue, and, if possible, submit a report from that expert summarizing the expert’s testimony. We will then have a conference on June 29, 2004, to determine what additional procedures are needed for resolving this discovery dispute.⁵

⁴That brief has, in fact, been filed.

⁵See my Scheduling Order filed into the Autism Master File on June 10, 2004.

5. Non-party discovery

As previously noted, in February of this year the Committee announced that it intended to redirect its initial effort to obtain discovery from the vaccine manufacturer, Merck and Company. The Committee filed a request for documents from Merck concerning its MMR and measles vaccines on February 26, 2004, and then filed the Committee's initial documentation and argument supporting that request on March 23, 2004. The participants agreed to a briefing schedule concerning that discovery request, by which Merck filed its response on April 26, the Committee filed a reply on May 10, and oral argument was held on May 26. I have recently received the transcript of that oral argument, and I will soon be filing a written ruling concerning this issue.

C. Issues concerning the autism website and disclosure of information

Because the Omnibus Autism Proceeding affects numerous petitioners, and appears to be of considerable general interest, it has been my goal to make the proceeding as easily accessible as possible to both petitioners' families and the general public. The *Autism General Order #1* established the "Autism Master File," into which documents relevant to the Proceeding are filed. (See 2002 WL 31696785 at *3.) That Autism Master File originally was open to inspection by the public at the courthouse; moreover, all of the documents submitted into that File were placed on a page of this court's Internet website devoted to the Omnibus Autism Proceeding.

However, my goal of easy accessibility is complicated by a unique feature of the Vaccine Act. That is, while in most types of litigation, documents filed with the court clerk generally become publicly available, in setting up the National Vaccine Injury Compensation Program, Congress provided otherwise. Specifically, 42 U.S.C. § 300aa-12(d)(4)(A) explicitly provides that--

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.

The only exception is that the special master's "decision" in a case may be disclosed. 42 U.S.C. § 300aa-12(d)(4)(B). Therefore, in the typical Vaccine Act proceeding, the case file is closed to the public, and only the special master's decision is disclosed.

In deciding initially to make the Autism Master File open to the public and accessible via the Internet, it was my belief that the items to be filed by the parties, at least in the initial stages of the Proceeding, would not involve the submission of "information." Rather, the parties would be stating positions on issues and advising me concerning procedure, but would not likely be submitting "information," so making the file public would not be contrary to § 300aa-12(d)(4)(A). And, indeed, during the early stages of the proceeding, neither party expressed any reservations about making the Autism Master File available via the website.

The first complication came when it came time for respondent to submit documents in response to the Committee's discovery requests. These documents clearly did appear to contain substantive "information," the disclosure of which to non-parties would seem to violate § 300aa-12(d)(4)(A). That problem was solved, however, when the parties agreed that the documents produced by respondent in response to the Committee's discovery requests would not be filed into the Autism Master File, but would be filed into the record of an individual autism case, *Taylor v. Secretary of HHS*, No. 02-699V. Those documents, thus, would not be disclosable to the public, but could be shared by the Taylors' counsel with the Committee and with any petitioner or counsel having a pending autism case.⁶ With that agreement in place, respondent's documents that have contained information have been filed, during the last 18 months, into the record of the *Taylor* case, while the documents filed into the Autism Master File, which did not contain "information," continued to be available via the website.

In recent months, however, more concerns have arisen about the "nondisclosure" provision of § 300aa-12(d)(4)(A). Both the Committee and Merck have submitted into the Autism Master File briefs concerning the discovery disputes discussed above, with *exhibits* attached thereto. Some of those exhibits clearly contained "information," including information that had been submitted by respondent to the Committee. Pursuant to § 300aa-12(d)(4)(A), I may not disclose this information to a non-party without the "express written consent of the person who submitted the information," and such consent has not been granted.

Therefore, I have had to alter the procedures for access to the Autism Master File. First, that File is no longer available for public inspection at the courthouse, though the vast majority of the File remains accessible via the website. Second, when I have placed the above-mentioned briefs concerning discovery issues onto the website, I have deleted those exhibits that contain nondisclosable "information."

I also note that in recent weeks the respondent's counsel, at our unrecorded telephonic status conferences, has expressed reservations concerning my continued policy of making most of the Autism Master File available via the website. Counsel has pointed out, correctly, that by enacting § 300aa-12(d)(4)(A), Congress clearly indicated the extent that, in general, the files in Vaccine Act cases *not* be available to the public.

These concerns of the respondent are reasonable, and I have carefully considered them. However, I am not persuaded that it would be appropriate to abandon the website at this time, for several reasons. First, I am being careful to evaluate documents, to see if they contain "information" submitted by a person, before placing them onto the website. I am consulting with the parties at the regular telephonic status conferences, and whenever either party indicates the view that a filed document contains nondisclosable "information," I have refrained from placing that document onto the website.

⁶That agreement was formalized in my Order filed on December 19, 2002, in the Autism Master File.

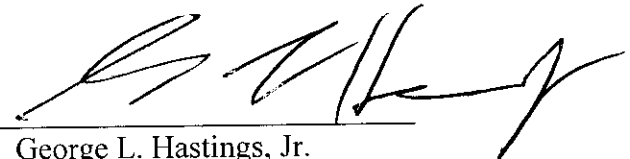
Second, I note that the main (though not the only) concern of Congress behind § 300aa-12(d)(4)(A) was obviously the *medical privacy of individual Vaccine Act petitioners*, who for obvious reasons might not wish their personal medical records to be publicly available. That is not a concern, however, with regard to the Autism Master File, which does not contain documents concerning individual petitioners.

Finally, I find that the original considerations which led me to create the website remain compelling. With more than 4,000 autism petitioners, the website is clearly a highly efficient way to disseminate up-to-date information concerning the Proceeding to the petitioners themselves, saving the court and/or the Committee from the need to mail out over 4,000 copies of every document related to the Proceeding. Moreover, there seems to be continued general public interest in how this court is dealing with this important public health issue, and it seems inherently desirable for this court to be as open as possible in dealing with this issue.

Accordingly, for the time being I intend to continue my recent policy of (1) maintaining a complete Autism Master File at the Clerk's office closed to the public, but (2) putting onto the website those items in the File that do not contain nondisclosable "information."

D. Future proceedings

The next status conference in the Omnibus Autism Proceeding is scheduled for June 29, 2004.



George L. Hastings, Jr.
Special Master