OFFICE OF SPECIAL MASTERS

No. 99-559V

Filed: February 14, 2003

MICHAEL LOIZZI by CARL LOIZZI,		
Petitioners,		
v.		PUBLISHED
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,		
Respondent.		

ORDER

On February 12, 2003, this court conducted a detailed status conference with representative counsel from petitioners' bar and the government on the discovery issues involving the Hepatitis B cases pending before this court. As an introduction to that telephonic conference, the court instructed the parties of its view of the guiding principles for resolving these discovery issues. To that end, the undersigned read the following:

> Agree or disagree, my view of the less adversarial nature of this Program and the special master's inquisitorial role is that we all, collectively, have an obligation to determine the vaccine's causative role. That is we will work together to collect records, pursue other relevant information and analyze that information to determine its medical significance. We will look to petitioners first for providing all information, expect the government to assist where necessary and rely on the court to play cleanup, plugging any remaining gaps in the record. We have different perspectives, different roles, and from our different viewpoints may reach different conclusions as to the meaning of the collected information. However, we will work together to gather the information and complete the record.
>
> As I told you before, and let me emphasize again, this is not civil litigation; this is an alternative. Unlike civil litigation, there is no right to discovery. The only discovery allowed is that approved by the special master. There will be no fishing expeditions. There will be no unlimited time frames. My standard, my guideposts, for allowable

discovery will be:

> is the information reasonably available and will it assist us in answering the medical causation questions presented.

If it is not reasonably available or cannot be shown to assist in answering the causation issues - it will not be allowed.

I intend to involve myself extensively, monitor this closely, and push this process. I expect cooperation and diligence. I welcome ideas and suggestions as long as they are constructive. I urge the parties to think creatively, consider different approaches, and to use the court to assist if roadblocks are encountered. But don't forget the common mission, because I won't.

The status conference held on February 12th was informative and fruitful. The court appreciated all of the participants' cooperative and helpful efforts. The insights provided and issues discussed will assist greatly in finalizing the discovery requests, ensuring the production of evidence, and in moving the bulk of the Hepatitis B cases towards resolution.

To that end, and as discussed fully with the participants during the status conference, the parties shall, within the next **thirty (30) days:**

1. Discuss jointly the possibility of submitting a protocol (based on one or more identifiable injuries/injury categories), or having the court submit a protocol, to the Vaccine Safety Datalink System for conducting a study, and devise a game plan for such submission;

2. Consider and discuss the possibility of the court appointing an outside and independent expert/panel to review any discovered materials; in the event of an agreement by the parties on this suggestion, counsel should be prepared to discuss with the court the names of one or more potential court-appointed experts, or a process for identifying such experts, at the next status conference; and

3. Schedule **by no later than March 21, 2003**, the next Hepatitis B Discovery status conference. The parties may contact Meredith A. Mills, at (202) 504-2329, to reserve a date for this call; the parties shall also inform the court at that time whether they agree to placing the conference call on the record, through a court reporter.

In addition, respondent's counsel shall, in the next **thirty (30) days**:

1. Determine from the Centers for Disease Control whether any Hepatitis B studies are underway involving the Vaccine Safety Datalink System and the studies' anticipated

completion dates; and

2. Determine the status of the FDA's efforts to provide, in the Omnibus Autism Proceedings, the Products License Application (PLA) information requested in regards to the two Hepatitis B vaccines at issue here, the Recombivax and the Engerix-B vaccines. Counsel shall particularly ascertain what information the FDA is producing, the timing of the release of that information to petitioners in the autism cases, and any costs involved.[1] The parties shall also discuss the possibility of obtaining from the manufacturers *directly* the information and materials contained in the Products License Application, should it prove too costly or difficult to procure the PLA information from the FDA.

The tasks assigned above will be discussed at the March 2003 status conference. Once again, the court appreciates the parties' diligence and creativity in tackling these difficult discovery issues. The undersigned remains committed to resolving the Hepatitis B discovery issues in a cooperative, flexible, and timely fashion. The court is willing to aid the parties in any manner in this endeavor, including through mediation. Thus, the parties may contact Meredith A. Mills, at (202) 504-2329, to request the court's assistance prior to the next status conference or to raise any questions regarding this Order or the discovery proceedings in the Hepatitis B cases.

IT IS SO ORDERED.

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Gary J. Golkiewicz
Chief Special Master

[1] For the reasons stated in the status conference, the court does not believe at this time that petitioners' other requested information is necessary to the prosecution of these cases. As the FDA representative stated, the PLA contains the potentially meaningful information; the other requests are duplicative of the PLA. In addition, the requested information related to the pediatric Comvax vaccine is apparently irrelevant. Unless petitioners present persuasive information to the contrary, these requests will be denied.