

# In the United States Court of Federal Claims

February 8, 2007

To be Published

Lovett, No. 98-749V	Adler, No. 99-608V	Lippa, No. 99-202V
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Morrill, No. 99-309V	Rubin, No. 99-645V	Musarra, No. 99-667
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Phippen, No. 99-435V	Youngblood, No. 99-601V	

Petitioners,

v.

Shall the Omnibus findings  
be reopened on all issues

SECRETARY OF THE DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,

Respondent.

## Order in Omnibus Cases

In cases consolidated in the Omnibus hepatitis B vaccine-demyelinating diseases proceeding, petitioners' counsel in numerous cases, Mr. Clifford J. Shoemaker, has asserted in responses to the undersigned's Orders to Show Cause why the cases in which he represents petitioners should not be dismissed when the onset interval between hepatitis B vaccine and the

demyelinating disease exceeds 30 days that certain articles and the testimony of an immunologist Dr. Y. Schoenfeld will prove his clients' allegations. (The undersigned has also issued Orders to Show Cause to petitioners when the onset interval between vaccination and disease is less than three days.)

Unless petitioners show that this evidence was unavailable to petitioners at the hearing October 13-15, 2004 or before the undersigned issued decisions in the paradigm cases in 2006, petitioners may not resubmit evidence already submitted at the Omnibus hearing or proffer a different immunologist than the immunologist petitioners used at the Omnibus hearing in the hope that this immunologist's testimony will prove cases of demyelinating disease whose onsets were longer than the 30 days both parties' immunologists testified was the appropriate temporal relationship at the Omnibus hearing.

Mr. Ronald Homer, petitioners' counsel in many other Omnibus cases, in responding to similar Orders to Show Cause for onset beyond the 30 days, asked for judgment on the record.

In contrast, Mr. Shoemaker filed responses to the undersigned's Orders to Show Cause, asserting that the Hernán article filed and discussed in the Omnibus cases and testimony from an immunologist, Dr. Y. Schoenfeld, proves causal relationship after 30 days post-vaccination in MS cases, or that the Schonberger article that petitioners also filed and discussed in the Omnibus cases proves causal relationship after 30 days post-vaccination in GBS or CIDP cases.

Petitioners submitted the Hernán article<sup>1</sup> and the Schonberger article<sup>2</sup> at the Omnibus

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<sup>1</sup> "Recombinant hepatitis B vaccine and the risk of multiple sclerosis. A prospective study" was published in *Neurology* 63:838-42 in September 2004.

<sup>2</sup> "Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977," was published in *Amer J of Epidemiology*

hearing October 13-15, 2004, and petitioner's expert immunologist Dr. Vera Byers testified about the Hernán article. Mr. Shoemaker cross-examined respondent's expert Dr. Roland Martin about the Schonberger article in an attempt to persuade Dr. Martin to extend the temporal period from four weeks to 10 to 12 weeks post-vaccination for a causal relationship. Tr. at 256. Dr. Martin rejected that time period as excessive and did not go beyond 30 days. Tr. at 257.

Moreover, the immunologist Dr. Schoenfeld's articles were published before 2004 and 2006<sup>3</sup> and petitioners had the opportunity of putting Dr. Schoenfeld on the witness stand instead of Dr. Byers if his testimony would have been more helpful to petitioners than hers was.

Dr. Byers discussed the Hernán article in her direct testimony at the Omnibus hearing. Tr. at 92-95, 97. She stated that even though Dr. Hernán would go way beyond the 30 days post-vaccination (even years beyond), Dr. Beyers' opinion on the medically-appropriate temporal framework was that most authors have agreed on 30 days after vaccination. Tr. at 97, 102. She also would not ascribe causation before four days after vaccination unless petitioner were experiencing rechallenge from a prior vaccination. Tr. at 102.

The undersigned adopted respondent's expert Dr. Roland Martin's testimony of three days as the shortest appropriate onset interval after vaccination up until 30 days post-vaccination as consistent with a causal relationship, which tracks Dr. Martin's testimony as well as Dr. Byers' testimony that most authors agreed on 30 days as the medically-appropriate onset interval, and held in the paradigm cases that the medically-appropriate temporal interval for causation was

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110(2):105–23 in 1979.

<sup>3</sup> One of the articles petitioners have cited from Dr. Schoenfeld ("Vaccination and autoimmunity - 'Vaccinosis:' a Dangerous Liaison?" in *J. Autoimmunity* 14: 1-10) was published in 2000.

three to 30 days..

Respondent's expert Dr. Lawrence Moulton discussed the Hernán article and rejected its conclusions at the Omnibus hearing. Tr. at 395-405, 489. Mr. Shoemaker cross-examined Dr. Moulton about the Hernán article extensively. Tr. at 442-52. Mr. Shoemaker cross-examined respondent's expert Dr. Thomas Leist on the Hernán article as well. Tr. at 656-60. Dr. Leist mentioned that the journal publishing the Hernán article simultaneously published an editorial criticizing the article. Tr. at 658.

The whole purpose of the Omnibus hearing was to resolve common issues in the more than 60 cases<sup>4</sup> involving hepatitis B vaccine and demyelinating diseases. To relitigate one of the three issues (the third Althen<sup>5</sup> prong) because petitioners in some cases would not prevail because their onsets were after 30 days post-vaccination would defeat the whole purpose of the Omnibus proceeding to settle issues in common.

Mr. Shoemaker cannot claim ignorance of the Omnibus petitioners' immunological expert Dr. Byers' testimony. He was one of the petitioners' attorneys at the Omnibus hearing and actively participated in it. In preparation for this lengthy hearing, Mr. Shoemaker must have consulted with Mr. Homer about what Dr. Byers' opinion was. Since she would not go beyond 30 days for the onset interval, the time for Mr. Shoemaker to switch to another immunologic expert was before the Omnibus hearing, not afterward.

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<sup>4</sup> Two cases (Stevens, No. 99-594V; Eklund, No. 99-618V) have proceeded to damages and judgment has been entered. Five cases have been dismissed (Schwankl, No. 99-592V; Gonzales, No. 99-656V; Monaco, No. 00782V; Zlotnick, No. 01-187V; and Simmons, No. 99-546V).

<sup>5</sup> Althen v. Secretary of HHS, 418 F.3d 1274 (Fed. Cir. 2005).

Mr. Shoemaker now implies in his responses to the undersigned's Orders to Show Cause that he is going to relitigate the Omnibus issue of temporality (the third Althen prong) with the same Hernán article or the same Schonberger article filed in the Omnibus hearing and use a different immunologist, Dr. Schoenfeld, that he assumes would be better for his clients' cases than Dr. Byers.

If Mr. Shoemaker wants to reopen the Omnibus proceedings to take further evidence, to have another bite of the apple, by refiling the Hernán article or the Schonberger article which petitioners already put in evidence at the Omnibus hearing and have another immunologist, Dr. Schoenfeld, testify, then the undersigned will consider reopening the entire Omnibus proceeding and allow respondent to submit any evidence on the first two Althen prongs (plausible medical theory and logical sequence of cause and effect).

The undersigned gives Mr. Shoemaker one month from the date of this Order to respond to this Order and explain what exactly Mr. Shoemaker wants to do: (1) accept the ruling of the undersigned based on petitioners' immunologist Dr. Byers' testimony in the Omnibus hearing that a medically-appropriate temporal framework for causation is not longer than 30 days post-vaccination; (2) submit only evidence that was not available by October 13-15, 2004 or before the 2006 decisions on the paradigm cases (i.e., newly-discovered evidence, not evidence petitioners already submitted and not testimony by someone who was always available to petitioners and whose articles were published years before the Omnibus hearing); or (3) reopen the Omnibus proceedings to take evidence, whether old or new, on all three Althen prongs.

Respondent shall have 30 days to reply to Mr. Shoemaker's response after the date of his responses in the cases in which this situation has arisen.

**IT IS SO ORDERED.**

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Dated

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Laura D. Millman  
Special Master