

**From:** Jones, Sarah (CDC/OID/NCEZID)

**Sent:** Wednesday, December 06, 2017 1:23 PM

**To:** Nguyen, Lyn (CDC/OID/NCEZID) <ivx1@cdc.gov>; Limeres, Alexa (CDC/OID/NCEZID) <vst6@cdc.gov>; Clasp, Samuel (CDC/OID/NCEZID) (CTR) <nss4@cdc.gov>; Goodman, Jeremy A. (CDC/OID/NCEZID) <vhj2@cdc.gov>

**Cc:** DHQP\_Policy (CDC) <DHQP\_Policy@cdc.gov>; Holmes, Carissa B. (CDC/OID/NCEZID) <ipz3@cdc.gov>; McMillen, Amy (CDC/OID/NCEZID) <auh1@cdc.gov>; Knights, Paulette (CDC/OID/NCEZID) <pbf7@cdc.gov>

**Subject:** FW: OASH clearance -- HHS Vaccine Safety Responsibilities and Notice Pursuant to 42 U.S.C. § 300aa-31

Hi DHQP team,

Attached is a letter response to the Informed Consent Action Network on HHS vaccine safety and responsibilities.

Comments are due **by 10 a.m. Monday, Dec. 13.**

Thanks,

Sarah

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**From:** Toye, Sally (CDC/OD/OCS)

**Sent:** Wednesday, December 6, 2017 1:13 PM

**To:** Swartwood, Candice (CDC/OID/NCIRD) <[chj8@cdc.gov](mailto:chj8@cdc.gov)>; Beauvais, Denise (CDC/OID/NCIRD) <[cry2@cdc.gov](mailto:cry2@cdc.gov)>; Jones, Sarah (CDC/OID/NCEZID) <[nhd4@cdc.gov](mailto:nhd4@cdc.gov)>; NCHHSTP Policy (CDC) <[nchhstppolicy@cdc.gov](mailto:nchhstppolicy@cdc.gov)>

**Cc:** CDC Review Clear Coordinator <[rcc@cdc.gov](mailto:rcc@cdc.gov)>; Hoffmann, Lauren (CDC/OD/OCS) <[cpf5@cdc.gov](mailto:cpf5@cdc.gov)>; Clark, Cynthia K. (CDC/OD/OCS) <[cfc8@cdc.gov](mailto:cfc8@cdc.gov)>

**Subject:** OASH clearance -- HHS Vaccine Safety Responsibilities and Notice Pursuant to 42 U.S. C.Â§ 300aa-31

OS/ES assigned the attached letter to OASH for direct reply. The National Vaccine Program Office staff has pulled together a draft response and is requesting that it be cleared with CDC, OGC, FDA, HRSA, NIH, and AHRQ for review prior to signature.

Please send any comment by 10:00am on Monday Dec. 13<sup>th</sup>. Thanks!

NOV 07 2017



VIA FEDEX

November 6, 2017

U.S. Department of Health & Human Services  
HHS Office of the Secretary  
Eric D. Hargan  
Acting Secretary of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Re: *Correspondence Email Address*

Dear Secretary Hargan:

As a follow-up to our letter, dated October 12, 2017 (copy enclosed), any response to same should be sent via electronic mail to [del@icandecide.com](mailto:del@icandecide.com) and [cat@icandecide.com](mailto:cat@icandecide.com)

Very truly yours,

A handwritten signature in black ink, appearing to read "Del Bigtree". The signature is stylized and cursive.

Del Bigtree

Enclosure: *Copy of letter from  
Del Bigtree to Eric D. Hargan  
dated October 12, 2017*



**VIA FEDEX**

October 12, 2017

U.S. Department of Health & Human Services  
HHS Office of the Secretary  
Don Wright, M.D., M.P.H.  
Acting Secretary of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Re: *HHS Vaccine Safety Responsibilities and Notice Pursuant to 42 U.S.C. § 300aa-31*

Dear Secretary Wright:

Informed Consent Action Network hereby provides notice per 42 U.S.C. § 300aa-31(b).

Americans, including the over 55 organizations listed below, whose members exceed 5 million Americans, are concerned about vaccine safety. The National Childhood Vaccine Injury Act of 1986 (the **1986 Act**) made nearly every aspect of vaccine safety the exclusive responsibility of the Department of Health & Human Services (HHS). As the Secretary of HHS (the **Secretary**), this means you shoulder virtually all responsibility for assuring the safety of vaccines administered to America's 78 million children.

This notice respectfully requests confirmation that certain obligations regarding vaccine safety required under the 1986 Act have been fulfilled or will forthwith be fulfilled. These specific requests are numbered sequentially in this notice. We would welcome the opportunity to meet and discuss reasonable means for complying with these requests. If that is not possible, the 1986 Act authorizes "a civil action ... against the Secretary where there is alleged a failure of the Secretary to perform any act or duty" under the 1986 Act.

**I. Background**

The 1986 Act granted economic immunity to pharmaceutical companies for injuries caused by their vaccines. (42 U.S.C. § 300aa-11.) The 1986 Act thereby eliminated the market force which drives safety for all other products – actual and potential product liability. Recognizing the unprecedented elimination of this market force, the 1986 Act makes HHS directly responsible for virtually every aspect of vaccine safety. (42 U.S.C. §§ 300aa-2, 300aa-27.)

**From:** Shimabukuro, Tom (CDC/OID/NCEZID)  
**Sent:** 12 Dec 2017 13:34:55 -0500  
**To:** Destefano, Frank (CDC/OID/NCEZID)  
**Cc:** Nguyen, Lyn (CDC/OID/NCEZID)  
**Subject:** RE: Consolidated Response to ICAN\_Del Bigtree V3\_LN\_FD-tts- version 2

I had a few very minor editorial changes that I sent back to Lyn earlier today. FDA and NVPO were okay with our language.

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**From:** Destefano, Frank (CDC/OID/NCEZID)  
**Sent:** Tuesday, December 12, 2017 1:33 PM  
**To:** Nguyen, Lyn (CDC/OID/NCEZID) <[ivx1@cdc.gov](mailto:ivx1@cdc.gov)>; Shimabukuro, Tom (CDC/OID/NCEZID) <[ayv6@cdc.gov](mailto:ayv6@cdc.gov)>  
**Subject:** RE: Consolidated Response to ICAN\_Del Bigtree V3\_LN\_FD-tts- version 2

I think it looks good. Thanks.

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**From:** Nguyen, Lyn (CDC/OID/NCEZID)  
**Sent:** Monday, December 11, 2017 5:37 PM  
**To:** Shimabukuro, Tom (CDC/OID/NCEZID) <[ayv6@cdc.gov](mailto:ayv6@cdc.gov)>; Destefano, Frank (CDC/OID/NCEZID) <[fxd1@cdc.gov](mailto:fxd1@cdc.gov)>  
**Subject:** Consolidated Response to ICAN\_Del Bigtree V3\_LN\_FD-tts- version 2

Thank you again for walking me through the issues. Attached is the updated response to the areas we discussed. Let me know if you are OK with what we have and when you hear back from FDA.

-Lyn

Lyn Thi Nguyen, MPH  
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*Telework Mondays and Fridays - please contact by BB and e-mail*