



March 12, 2020

U.S. Department of Health & Human Services
HHS Office of the Secretary
Alex M. Azar II, Secretary of Health & Human Services
Tammy R. Beckham, Acting Director, National Vaccine Program Office
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 Azar:

In our letter of October 12, 2017, we notified the Department of Health & Human Services (HHS) about a number of serious concerns regarding how HHS fulfills its obligations to ensure vaccine safety under the National Childhood Vaccine Injury Act of 1986 (the **1986 Act**).¹ We voiced these concerns along with 55 other organizations who were copied on our letter and who represent over 5 million Americans.²

HHS responded to our letter in a reply dated January 18, 2018. That letter was reviewed and cleared by the following agencies within HHS: the Centers for Disease Control and Prevention (CDC), the Food & Drug Administration (FDA), the National Institutes of Health (NIH), the Office of the General Counsel (OGC), the Human Resources & Services Administration (HRSA), and the Agency for Healthcare Research and Quality (AHRQ).³

After carefully reviewing the extensive information provided in HHS's reply, ICAN responded by letter dated December 31, 2018.⁴ ICAN provided detailed information, mostly from HHS's own primary sources, as to why HHS's reply of January 18, 2018 either did not address or heightened the serious concerns raised in ICAN's prior letter. In that regard, we submitted a number of follow-up questions in Appendix A to that letter.

¹ <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

² <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

³ <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

⁴ <https://icandecide.org/hhs/vaccines-safety-12-31-18.pdf>

It has now been over 13 months since ICAN submitted these follow-up questions and concerns regarding vaccine safety. Nonetheless, HHS has failed to respond to the questions posed in our letter of December 31, 2018, nor to any of the substance in that letter.

HHS's failure and/or apparent inability to respond to ICAN's simple vaccine safety questions and concerns provides further support that the Secretary of HHS has failed to fulfill his vaccine safety obligations pursuant to the 1986 Act.

Absent a substantive response to the questions and substance of our December 31, 2018 letter within sixty days of this notice, an action against the Secretary of HHS shall be filed pursuant to 42 U.S.C. § 300aa-31.

For your convenience, copies of the three prior letters are enclosed herein.

ICAN reserves all rights. Govern yourself accordingly.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Del Bigtree', with a stylized flourish at the end.

Del Bigtree
President

Enclosures