United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

January 4, 2018

VIA ELECTRONIC TRANSMISSION

Eric D. Hargan
Acting Secretary
Department of Health and Human Services
Washington, DC

Dr. Scott Gottlieb
Commissioner
Food and Drug Administration
Silver Spring, MD

Dr. Jerry A. Menikoff
Director
Office for Human Research Protections
Rockville, MD

Dear Mr. Hargan, Dr. Gottlieb, and Dr. Menikoff:

As you know, testing involving the use of human subjects in the U.S. is regulated by Title 45 CFR Part 46. The regulation is codified in separate regulations by 15 Federal departments and agencies known as "The Common Rule" – three other departments and agencies comply with all subparts of 45 CFR Part 46. Pursuant to the Common Rule, research must be reviewed and approved by an Institutional Review Board (IRB) using the following criteria: 1) risks to subjects must be minimized; 2) the risks to subjects must be reasonable in relation to anticipated benefits; 3) the selection of subjects must be equitable, with attention to the special problems of research involving vulnerable populations; 4) informed consent must be sought and appropriately documented if the risk is greater than minimal; 5) researchers must continually monitor the data collected to ensure safety of subjects; and 6) the privacy of subjects must be maintained.[1] In effort to make sure results are widely available and can be subjected to public scrutiny, Title 21 CFR Part 50, Subpart B (Informed Consent of Human Subjects), requires a description and

[1] 45 C.F.R. 46. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.124. U.S. Department of Health & Human Services (HHS), Information on Protection of Human Subjects in Research Funded or Regulated by U.S. Government, http://www.hhs.gov/1946inoculationstudy/protection.html.

summary of the results for applicable clinical trials involving human subject testing be posted to ClinicalTrials.gov.[2]

Recently, investigative news reports have indicated that a Southern Illinois University (SIU) professor, William Halford, may have violated almost every requirement of the Common Rule. For example, Professor Halford reportedly administered an experimental vaccine to patients who were not enrolled in an approved study and therefore did not have the proper human subjects protections required by U.S. law.[3] The vaccine was allegedly administered in a Holiday Inn Express and a Crowne Plaza Hotel near the SIU lab.[4] He also reportedly did not acquire written consent from the test subjects. Emails from the professor reportedly stated that it would be "suicide" if the manner in which he conducted the research were to be made public.[5] His research was later moved out of the continental United States. SIU claims that is was unaware of the research practices.[6]

The Department of Health and Human Services "demanded the university account for the research."[7] In response, the university found "serious noncompliance with regulatory requirements and institutional policies and procedures."[8] Furthermore, the U.S. Food and Drug Administration (FDA) reportedly did not monitor this research.[9]

If the reporting is accurate, this entire episode illustrates a failure in necessary governmental oversight of vaccine research as well as a failure by SIU to properly oversee its research staff. The type of research conducted, apparently all under-the-radar to the Obama administration and the very university that employed him, has put individuals at extreme health risk.

In order to better understand the situation, please provide the following:

1. Has HHS, OHRP, or the FDA performed a formal investigation and review into the reported research? If so, what were the results? If not, why not?

2. Has HHS, OHRP, or the FDA found SIU to be culpable for Professor Halford's reported research? If so, what steps were taken to make sure SIU properly oversees its research professors? If not, why not?

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[2] U.S. Food and Drug Administration (FDA), 21 CFR Part 50, Subpart B, Informed Consent of Human Subjects, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25.

[3] Marisa Taylor, *Years Before Heading Offshore, Herpes Researcher Experimented on People in U.S.*, Kaiser Health News (Nov. 21, 2017). Available at https://khn.org/news/years-before-heading-offshore-herpes-researcher-experimented-on-people-in-u-s/

[4] Marisa Taylor, *Desperate Quest For Herpes Cure Launched 'Rogue' Trial,* Kaiser Health News (Oct. 19, 2017).. Available at https://khn.org/news/desperate-quest-for-herpes-cure-launched-rogue-trial.

[5] Marisa Taylor, *Years Before Heading Offshore, Herpes Researcher Experimented on People in U.S.*, Kaiser Health News (Nov. 21, 2017). Available at https://khn.org/news/years-before-heading-offshore-herpes-researcher-experimented-on-people-in-u-s/

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.*

3. Did HHS, OHRP, or the FDA find SIU's response to Professor Halford's work to be adequate? Please explain.

4. Since SIU found "serious noncompliance with regulatory requirements…"[10] what corrective action did HHS, OHRP, or the FDA take to ensure that noncompliance does not occur again?

5. Has HHS or the FDA ever reported research malpractice to federal or state law enforcement for potential prosecution?

6. Please explain, in detail, the process OHRP follows once a complaint about potentially unapproved research is received.

7. How many reports of unapproved clinical trials have been received by OHRP in the past 5 years?

8. Of the reported cases, how many resulted in an internal review by the institution in question?

9. Of the reported cases, how many resulted in referral to federal or state law enforcement?

A written response to these questions is requested by January 18, 2018.

Sincerely,

Charles E. Grassley
Chairman
Committee on the Judiciary

[10] Marisa Taylor, *Years Before Heading Offshore, Herpes Researcher Experimented on People in U.S.*, Kaiser Health News (Nov. 21, 2017). Available at https://khn.org/news/years-before-heading-offshore-herpes-researcher-experimented-on-people-in-u-s/