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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

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January 4, 2018

VIA ELECTRONIC TRANSMISSION

Dr. Randy J. Dunn
President
Southern Illinois University System
Carbondale, IL 62901

Dear President Dunn:

As you know, testing involving the use of human subjects in the U.S. is regulated by Title 45 CFR Part 46, which encapsulates the Common Rule. The responsibilities of researchers applying for an investigational new drug application (NDA) at the U.S. Food and Drug Administration (FDA) are regulated at Title 21 CFR 312. The National Institutes of Health (NIH) website has posted the public policy requirements, objections and other appropriation mandates to which NIH grants are subject.¹ Both FDA and NIH are operating divisions within the U.S. Department of Health and Human Services (HHS).

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.² The vaccine was allegedly administered in a Holiday Inn Express and a Crowne Plaza Hotel near the SIU lab.³ 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.⁴ His research was later moved out of the continental United States. SIU claims that it was unaware of the research practices.⁵

¹ https://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch4.htm

² 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/>

³ 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>.

⁴ 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/>

⁵ *Id.*

The Department of Health and Human Services “demanded the university account for the research.”⁶ In response, the university found “serious noncompliance with regulatory requirements and institutional policies and procedures.”⁷ Furthermore, the U.S. Food and Drug Administration (FDA) reportedly did not monitor this research.⁸

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. Since Southern Illinois University found “serious noncompliance with regulatory requirements...”⁹ what corrective action did you take to ensure that noncompliance does not occur again?
2. Please explain, in detail, the process SIU follows once a complaint about potentially unapproved research is received.
3. How many reports of unapproved research have been reported at SIU in the past 5 years?
4. Of the reported cases, how many resulted in an internal review? What were the results of each internal review?
5. Of those cases reviewed, 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

⁶ 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/>

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*