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United States Senate

COMMITTEE ON THE JUDICIARY  
WASHINGTON, DC 20510-6275

February 10, 2014

**VIA ELECTRONIC TRANSMISSION**

David E. Wright, Ph. D.  
Director  
Office of Research Integrity  
U.S. Department of Health and Human Services  
1101 Wootton Parkway, Suite 750  
Rockville, MD 20852

Dear Director Wright:

I am writing to inquire about the Office of Research Integrity's (ORI) recent handling of a serious case of research misconduct at Iowa State University (ISU) involving Dr. Dong-Pyou Han. According to ORI, Dr. Han used human antibodies to contaminate rabbit blood used in a research project to develop an HIV vaccine in order to create the false impression that the experimental vaccine caused the animal to build defenses against certain strains of the HIV virus. Dr. Han's fraud helped his research team secure millions of dollars in NIH grant money. Specifically, it has been reported that Dr. Han's research team received two grants totaling about \$9 million over five years, and later was awarded a third grant of \$10 million over five years.<sup>1</sup>

According to a notice published in the *Federal Register* on December 23, 2013, your office entered into a Voluntary Exclusion Agreement with Dr. Han, prohibiting him from receiving federal contract funds or serving in any advisory capacity with the U.S. Public Health Service for the next three years. This seems like a very light penalty for a doctor who purposely tampered with a research trial and directly caused millions of taxpayer dollars to be wasted on fraudulent studies. Moreover, there appears to be no evidence that ORI tried to recoup any of the \$19 million in grant money used to fund Dr. Han's research.

Federal law gives ORI the authority to seek recovery of funds spent in support of activities that involved research misconduct.<sup>2</sup> It seems that in a case of fraud as serious as this, ORI would have utilized that authority. However, James Bradac, who oversees AIDS research at NIH, stated that he does not believe there will be any attempts to

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<sup>1</sup> Aronsen, Gavin, *Iowa State HIV researcher reacts to former colleague's fraudulent research*, AMES TRIB. (Dec. 24, 2013), available at <http://amestrib.com/news/ames-and-story-county/iowa-state-hiv-researcher-reacts-former-colleague-s-fraudulent-research>.

<sup>2</sup> 42 C.F.R. 93.407 (b)-(c).

recoup funding that supported Dr. Han's research.<sup>3</sup> Mr. Bradac also said that nearly \$4 million of grant funds remain unspent and there would be a "meeting [...] to discuss what we will do with that money that remains."<sup>4</sup>

ORI has a responsibility to ensure proper oversight of taxpayer money used to fund medical research. When researchers abuse the public trust by tampering with trials, ORI should use all the powers at its disposal to resolve the problem and recover federal grant money for that research. ORI's agreement to ban Dr. Han from receiving grants for three years is a step in the right direction, but it appears that more could have been done to prevent any future abuses and to recover the \$19 million in grants.

Accordingly, please provide answers to the following questions:

1. Has ORI ever used its authority to recover funds spent in support of activities that involved research misconduct? If no, why not? If yes, please provide the total amount recovered and describe each instance in which ORI attempted to use this authority, including the outcome of those efforts.
2. Will ORI attempt to recover funds in the case involving ISU and Dr. Han? If no, why not? If yes, what is the status of the recovery process?
3. What will be done with the \$4 million in unspent grant funds related to Dr. Han's research?
4. How does ORI make the decision on whether to seek recovery of funds spent in support of activities involved in research misconduct?
5. Who makes the final determination at ORI on whether to seek recovery of funds spent in support of activities involved in research misconduct?
6. How does ORI determine the administrative action or penalty to be imposed on a researcher found to have been involved in research misconduct?
7. How does ORI hold accountable senior faculty or laboratory supervisors for researchers who engage in research misconduct while under their supervision?
8. How many cases has ORI encountered where a researcher intentionally falsifies data or research results? Please describe any other such instances.
9. Has ORI referred the information about Dr. Han's fraud to any other government agency for further inquiry? If so, please provide the name of the agency or

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<sup>3</sup> Aronsen, Gavin, *Iowa State HIV researcher reacts to former colleague's fraudulent research*, AMES TRIB. (Dec. 24, 2013), available at <http://amestrib.com/news/ames-and-story-county/iowa-state-hiv-researcher-reacts-former-colleague-s-fraudulent-research>.

<sup>4</sup> *Id.*

agencies and the date of the referral(s)? If there were no referrals, please explain why not.

10. How does ORI determine whether the administrative actions or penalties it imposes are working, and does ORI have any evidence that its administrative actions are effective in deterring research misconduct?
11. How many “repeat offenders” does ORI encounter with respect to research misconduct?

I would appreciate an individual response to each of these questions by February 24, 2014. Should you have any questions regarding this letter, please contact Tegan Millspaw of my staff at (202) 224-5225. Thank you for your cooperation in this important matter.

Sincerely,



Charles E. Grassley  
Ranking Member