

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF IOWA

UNITED STATES OF AMERICA

v.

CRIMINAL COMPLAINT

DONG PYOU HAN,

CASE NUMBER: 4:14-MJ-00142

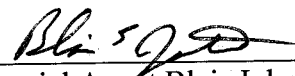
Defendant.

I, the undersigned complainant being duly sworn state the following is true and correct to the best of my knowledge and belief. On or about December of 2009, in the Southern District of Iowa, and elsewhere, the defendant violated 18 U.S.C. § 1001, and 18 U.S.C. § 2, an offense described as follows: False Statements.

I further state that I am a Special Agent with the Department of Health and Human Services-Office of Inspector General and that this Complaint is based on the following facts:

See Affidavit attached and incorporated.

Continued on the attached sheet and made a part hereof: ☒ Yes ☐ No


Special Agent Blair Johnston
HHS-OIG

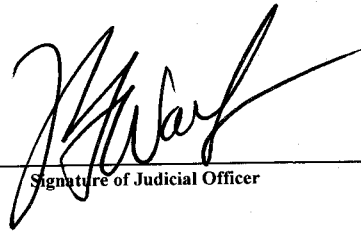
Sworn to before me and subscribed in my presence,

June 4, 2014
Date

at

Des Moines, Iowa
City and State

Hon. Ross A. Walters, U.S. Magistrate Judge
Name & Title of Judicial Officer


Signature of Judicial Officer

Affidavit

I, Blair E. Johnston, being duly sworn, state the following:

Purpose

1. The purpose of this affidavit is to establish probable cause to obtain a Complaint against Dong-Pyou Han, Ph.D. ("DR. HAN") and warrant for his arrest.

Background

2. I am a Special Agent of the U.S. Department of Health and Human Services, Office of Inspector General ("OIG"), Office of Investigations and have been so employed for approximately 17 years. I am assigned to the Des Moines, Iowa, Field Office. Prior to beginning this position, I worked as an Auditor for the OIG for approximately six years in the Des Moines Office of Audit Services. As a Special Agent, my primary focus is investigating fraud committed on the Medicare, Medicaid and grant programs funded by the U.S. Department of Health and Human Services. I have received specialized training in conducting investigations during my initial agent training at the Federal Law Enforcement Training Center in Glynco, Georgia, as well as through numerous periodic training seminars and conferences. I am a Certified Public Accountant.

3. This affidavit is based on my personal knowledge, as well as information obtained from other law enforcement personnel, witnesses, documents, and records. This affidavit does not contain all of the information known to law enforcement regarding this investigation, but rather contains only those facts believed necessary to establish probable cause.

4. Through a review of investigative reports, grant documents, and business records, as well as interviews of key officials at the National Institutes of Health, Iowa State University ("ISU"), Duke University, and Harvard University, your affiant obtained the facts set forth below.

Summary

5. DR. HAN was a research scientist at ISU and worked in the laboratory of Dr. Michael Cho ("Dr. Cho"). Dr. Cho led a team of scientists, including DR. HAN, in testing an experimental AIDS vaccine on rabbits. Dr. Cho has received funding for research relating to AIDS vaccines via three (3) grants from the U.S. Department of Health and Human Services, National Institutes of Health ("NIH") from 2008 to the present. During research conducted pursuant to the third NIH grant, it was discovered that DR. HAN faked experiment results by adding human antibodies to blood draws from rabbits, and made it appear that Dr. Cho's experimental AIDS vaccine was effective when, in fact, it was not. Further, DR. HAN provided false data from the lab experiments that made it appear Dr. Cho's experimental AIDS vaccine was producing an immune response in rabbits when, in fact, it was not. As a result, DR. HAN caused false information and statements to be included in grant applications and progress reports submitted to the NIH.

The National Institutes of Health ("NIH")

6. The NIH is a federal agency within the U.S. Department of Health and Human Services that administers the funding of research and grants around the United States and the world that are directed at health issues of concern. The NIH invests nearly \$30 billion annually in medical research. While the NIH performs research internally, more than 80 percent of NIH's

funding is awarded through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state and around the world. One particular health issue of concern to the NIH is the development of a vaccine to combat HIV/AIDS.

7. The HIV virus causing AIDS is variable and, to date, research has not been able to successfully develop a vaccine which combats all of the different viruses. The NIH initiative regarding HIV/AIDS is to develop a vaccine, or number of vaccines, that can work against all of the viruses associated with HIV/AIDS.

8. There are two ways in which grantees can receive monies from the NIH. One is through unsolicited applications, where a researcher comes up with an idea for research and puts together a grant application and sends it to the NIH. The NIH reviews the grant and assigns an internal NIH grant manager to determine whether the application is worthy of a grant award. The second way in which a grantee receives monies from the NIH is through solicited applications. When NIH identifies an area of research it believes needs work, it publicizes a request for grant applications from external researchers. The applications are reviewed by peers who are not conflicted and scored. The NIH reviews the scored applications and decides who will receive the grant(s). Grants funded by the NIH are usually five years in duration and are funded one year at a time.

9. After the NIH awards a grant, it ensures that the lead researcher who applied for the grant, or "Principal Investigator" ("PI"), is carrying out the work that was described in the grant application. One of the grant oversight requirements is that the grantee must file an annual progress report with the NIH. The annual report describes the accomplishments, any

publications made as a result of the grant, and the plans for the upcoming year. It is reviewed by an assigned grant program officer at NIH.

10. The program officer reviews the progress statements by the grantee and if the program officer believes progress has been made, the funding is continued. If there was no progress, the program officer can recommend the funding be discontinued. The decision to continue funding is based on work progress, rather than the actual success of the work.

NIH Grants Awarded to Dr. Michael Cho

11. Both Dr. Cho and DR. HAN worked for NIH until 1999, when Dr. Cho took a position at Case Western Reserve University ("CWRU") in Cleveland, Ohio. Shortly thereafter, Dr. HAN followed Dr. Cho to CWRU to work in his lab.

12. In 2008, at CWRU, Dr. Cho worked on the development of a potential HIV/AIDS vaccine known as GP41, and he believed his research showed promise. Dr. Cho submitted two grant applications, solicited by the NIH, and received initial funding for this research.

13. Research conducted in Dr. Cho's lab included injecting rabbits with the GP41 vaccine and drawing blood for analysis. The blood was spun to separate the serum (a clear, yellowish substance containing antibodies) to test for the presence of antibodies. Approximately one year to eighteen months into his NIH funded research, Dr. Cho's review of the experiments in his lab revealed the GP41 vaccine could neutralize, or control, viruses causing AIDS because the research data revealed the rabbits developed antibodies to HIV viruses.

14. Dr. Cho presented his findings to NIH officials who were "flabbergasted" with the impressive results. The NIH advised Dr. Cho of the need to validate the promising results with a collaborator researcher/institution. This is a common practice in the scientific community. As a result, rabbit sera from Dr. Cho's lab were sent to Dr. David Montefiori ("Dr. Montefiori") at

Duke University in Durham, North Carolina. Dr. Montefiori verified Dr. Cho's experiment findings that the rabbit sera from GP41 vaccinated rabbits showed neutralizing activity. The results of Dr. Cho's research were viewed by many in the scientific community to be a major breakthrough in HIV/AIDS vaccine research.

15. Dr. Cho's apparent success led him to focus his work on a particular region of the virus which responded to GP41 vaccine. Dr. Cho mapped the virus, and developed his vaccine further based on the results that he believed were showing success.

16. In September 2009, Dr. Cho was recruited by ISU from CWRU. Based on the promising results he was achieving with his research, Dr. Cho applied for, and received, a third NIH grant (Grant U19AI091031) in December 2009 while at ISU. The third grant was for five years with an initial award in July 2010. Information/data from Dr. Cho's laboratory work was included in this application from Iowa State University to NIH, including the breakthrough results Dr. Cho's laboratory believed it achieved on prior GP41 experiments. This information/data included:

- a. Information, provided by DR. HAN to Dr. Cho, which reported the existence of neutralizing activity in the rabbit sera, and
- b. Information that Dr. Montefiori confirmed the presence of neutralizing activity in the rabbit sera provided to his laboratory at Duke University for testing.

17. NIH grant U19AI091031 is scheduled to begin its final year of NIH funding in August 2014.

Discovery of Spiked Rabbit Sera

18. Dr. Cho's research continued to yield impressive results under NIH grant U19AI091031 through approximately December 2012. Dr. Montefiori's laboratory continued to

confirm apparent neutralizing activity of rabbit sera from Dr. Cho's laboratory during this time period.

19. In November 2012, the NIH grant program manager suggested that Dr. Cho provide samples of rabbit sera to another researcher, Dr. Ellis Reinherz ("Dr. Reinherz") at Harvard University. This type of collaboration is common in the research community, to assist researchers in learning and improving their work.

20. In December 2012, Dr. Cho's laboratory shipped samples of rabbit sera to Dr. Reinherz's laboratory.

21. In January/February 2013, Dr. Reinherz reported unusual results to NIH and Dr. Cho. Dr. Reinherz's lab had identified the existence of human antibodies in the rabbit sera provided by Dr. Cho's laboratory. The neutralizing activity, as reported by Dr. Cho's lab, was not accurate. Dr. Reinherz's findings revealed that the neutralizing activity Dr. Cho's lab reportedly achieved was due to rabbit sera spiked with human antibodies, and not from neutralizing activity via the rabbits generating their own immune response.

22. In February 2013, Dr. Cho informed the ISU Research Integrity Officer, and Associate Vice President for Research, Dr. Charlotte Bronson ("Dr. Bronson"), of the apparent research misconduct in his laboratory as identified by Dr. Reinherz. Dr. Bronson notified the U.S. Department of Health and Human Services, Office of Research Integrity of the apparent misconduct and advised that ISU would conduct an inquiry.

Research Misconduct by Dr. Dong-Pyou Han

23. In the months following February 2013, Dr. Cho worked with Dr. Bronson to identify who had spiked the rabbit sera in Dr. Cho's laboratory. As an initial step, Dr. Cho asked Dr. Montefiori to test rabbit sera maintained at Duke University that had been sent to him in 2008

from Dr. Cho's laboratory at CWRU. Dr. Montefiori tested the 2008 rabbit sera for human antibodies, something he did not do prior to this request, and found human antibodies present in the rabbit sera. With this information, Dr. Cho knew the person, or persons, in his laboratory who spiked the rabbit sera had to be someone who came to him when he took the job at ISU from CWRU.

24. When Dr. Cho moved his laboratory to ISU, effective April 2010, two research associates and two post-doctoral researchers agreed to move to ISU to continue working in his laboratory. During the inquiry by Dr. Cho and Dr. Bronson, it was determined one of the research associates left Dr. Cho's laboratory in the summer of 2011, and spiked rabbit sera continued to be produced after this employee's departure. Thus, this employee was eliminated from suspicion. Additionally, another employee had drawn rabbit sera for a different vaccine in Dr. Cho's laboratory over the years and the samples in Dr. Montefiori's laboratory were tested for human antibodies. These samples were determined to be negative for human antibodies.

25. With two remaining laboratory employees under suspicion, DR. HAN (a research associate) and a post-doctoral researcher, Dr. Cho set-up a controlled environment whereby both employees were asked to draw blood from the rabbits under the idea it was part of the routine research being conducted in the laboratory. The post-doctoral researcher was the first employee to draw blood from the rabbits and the sera was sent to Dr. Montefiori's laboratory. This blood tested negative for human antibodies.

26. DR. HAN was asked to draw rabbit blood and the serum was sent to Dr. Montefiori. The serum tested positive for human antibodies. To further solidify that DR. HAN was the person responsible for the research misconduct, Dr. Cho had another of his laboratory personnel draw blood from the rabbits and test the serum for neutralizing activity. That test determined

there was no neutralizing activity. Dr. Cho then gave the samples to DR. HAN and asked him to test for neutralizing activity and provide Dr. Cho with the results. DR. HAN tested the samples and reported to Dr. Cho the presence of neutralizing activity via data reports. Dr. Cho knew at this point that DR. HAN was the person who had been spiking the rabbit sera over the years with human antibodies.

27. DR. HAN had a non-teaching position at Iowa State and, according to Dr. Cho, his employment was dependent on Dr. Cho's lab continuing to receive grant funds to support research. DR. HAN served as Dr. Cho's laboratory manager and had great access to rabbit sera samples throughout the course of the vaccine experiments, and he trained the other lab personnel on how to handle the rabbit sera. DR. HAN worked closely with Dr. Cho on NIH grant research and Dr. Cho would often ask DR. HAN to provide him with his research results to include in NIH grant applications and reports. In response, DR. HAN emailed Dr. Cho the results, and Dr. Cho would put Dr. HAN'S data into readable format before including it in any NIH document.

28. In August 2013, DR. HAN was placed on administrative leave based on the results of the research misconduct inquiry by ISU.

29. In a letter signed and dated October 3, 2013, DR. HAN provided a written statement (see attachment) to ISU officials stating he engaged in the research misconduct as alleged. DR. HAN admitted he spiked rabbit sera with human antibodies and submitted the samples to Duke University. DR. HAN stated the first spiked sample he submitted to Duke University was on August 11, 2009. DR. HAN admitted he manipulated data to give the appearance that rabbit sera sample contained neutralizing activity. DR. HAN advised ISU he acted alone in this misconduct. DR. HAN resigned from ISU effective October 4, 2013.

30. In addition to a written confession, ISU provided your affiant with a list detailing the NIH reports in which his false data was used. Specifically, in **NIH grant U19AI091031**, submitted December 10, 2009, from ISU to the NIH for funding consideration, DR. HAN admitted the following false information was provided in the grant application.

- a. **Page 21 – Figure 4:** The grant application, submitted by Iowa State University to the NIH, states that “HIV-1-specific neutralizing activity was observed with significant breadth in immunized rabbits (Fig. 4).” This statement and figure is false data that was provided to Dr. Cho from DR. HAN, when the grant application was prepared.
- b. **Page 54 – Figure C6:** The grant application contains a table of graphs, numbered Fig. C6, entitled, “HIV-1 Pseudovirus neutralization assay using TZM-bl cells.” This table contains false data that was provided to Dr. Cho from DR. HAN, during the preparation of the grant application.
- c. **Page 55 – Table C1 and Figure C7:** The grant application contains Table C1, “Neutralization assay (Conducted at Dr. David Montefiori’s laboratory),” and Fig. C7, “Neutralization assay for Q23.17.” The table and figure are derived from false data as a result of DR. HAN spiking rabbit sera that was sent to Dr. Montefiori’s lab for testing. Dr. Montefiori’s lab unknowingly reported the false data to Iowa State University, and it was included in the grant application.
- d. **Page 109 – Figure C5:** The grant application contains a table of graphs, numbered Fig. C5, entitled, “HIV-1 Pseudovirus neutralization assay using TZM-bl cells.” This table contains false data that was provided to Dr. Cho from DR. HAN, during the preparation of the grant application.

- e. **Page 110 – Table C1 and Figure C6:** The grant application contains Table C1, “Neutralization assay (Conducted at Dr. David Montefiori’s laboratory),” and Fig. C7, “Neutralization assay for Q23.17.” The table and figure are derived from false data as a result of DR. HAN spiking rabbit sera that was sent to Dr. Montefiori’s lab for testing. Dr. Montefiori’s lab unknowingly reported the false data to Iowa State University, and it was included in the grant application.

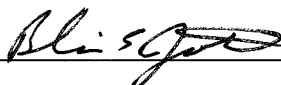
31. The U19AI091031 grant application was approved for initial award on July 28, 2010, and has been funded by the NIH, to date, for approximately \$5 million.

32. The falsified information in the U19AI091031 grant application was material to the NIH, in that the NIH relies on accurate information and data in the application when deciding whether or not to fund a grant, in determining how much money should be awarded, and the duration of the grant.

Conclusion

33. Your affiant believes the facts set forth above establish probable cause to believe that DR. HAN has violated Title 18, U.S.C. § 1001, 2, False Statements.

I swear to the facts stated herein are true and correct.



Blair E. Johnston
Special Agent
U.S. Department of Health and Human Services
Office of Inspector General, Office of Investigations

Subscribed and sworn to before me this 4th day of June, 2014



Ross A. Walters
U.S. Magistrate Judge

Research Misconduct Complaint (RMC) #002

To Dr. Charlotte Bronson

I (Dong Pyou Han) confess my misconducts on my research as indicated on the attached files. I am very ashamed myself about my misconduct. I did two kinds of my misconducts. First, in order to investigate a neutralizing activity of rabbit sera to Duke University, I sent the wrong samples that were added human or rabbit sera with a neutralizing activity as indicated in the attached file 1. Second, I have manipulated the data about a neutralizing activity. When I did the neutralizing assay with the non-spiking samples that are shown the neutralizing activity in the attached file 1, they have a weakly or no neutralizing activity. But, I manipulated their activity increased highly in order to look better as shown in the attached file 2. Now, I do not have the original files (data), which are stored in the computer files connected to an assay instrument (Bio-Tek).

The problem starts from the first samples that I sent to Duke on 8/11/09. I found the samples were something wrong later. I have thought those samples were contaminated with human sera with a neutralizing activity. Because I worked the rabbits sera and human sera (CWRU4) at the same time though I do not remember the date, may be some samples were contaminated (mixed). Though later I found some samples were wrong and the data were from the wrong samples, I could not tell to Michael Cho. At that time, I was afraid of because the data were presented to our collaborators and others, and I hoped/expected other derivatives will be elicited a neutralizing activity. So, in order to show the neutralizing activity continuously I added the human sera with a neutralizing activity to the second samples that I sent to Duke as indicated in the attached file 1. However, I falsified only

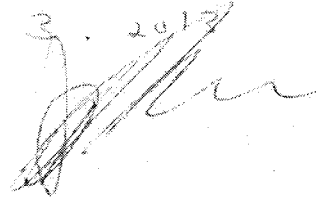
samples that showed some activity because I wanted them to look better. The abstract and presentation, which included the falsified or spiked samples' data, is included in the attached file 3.

I have regretted deeply the fact that I did and did not tell it. I was foolish, coward, and not frank. My misconduct is not done in order to hurt to someone. All cause by my foolishness and are my faulty and responsibility. I will resign with my responsibility about my misconduct.

September 30. 2013

Han, Dong Pyou

Oct. 3. 2013



Witnessed by?

Charlotte R. Bronson Charlotte R. Bronson 10-3-13

Dawn Bratsch-Prince  10-3-2013