

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF IOWA

|                           |   |                            |
|---------------------------|---|----------------------------|
| UNITED STATES OF AMERICA, | ) |                            |
|                           | ) | CRIMINAL NO. 4:14-cr-00078 |
|                           | ) |                            |
| v.                        | ) |                            |
|                           | ) | <u>INDICTMENT</u>          |
|                           | ) |                            |
| DONG PYOU HAN,            | ) | 18 U.S.C. § 2              |
|                           | ) | 18 U.S.C. § 1001           |
|                           | ) |                            |
| Defendant.                | ) |                            |

**THE GRAND JURY CHARGES:**

**Introductory Allegations**

**The National Institutes of Health**

1. The National Institutes of Health ("NIH") is a federal agency within the United States 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.

2. 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.

3. The Preclinical Research and Development Branch within the Vaccine Research Program, within the NIH's National Institute of Allergy and Infectious Diseases, is responsible for all basic research grants related to potential HIV/AIDS vaccines.

4. 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.

5. 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.

6. 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.

**Research at Case Western Reserve and Iowa State Universities**

7. For many years, Dr. Michael Cho and his research team, which included Dr. DONG PYOU HAN, have been involved in the research and development of an HIV/AIDS vaccine.

8. Prior to 2001, Dr. Cho and Dr. DONG PYOU HAN worked for the NIH. In 2001, Dr. Cho was employed at Case Western Reserve University in Cleveland, Ohio, until 2009, when he was recruited to Iowa State University, where he is a professor in the College of Veterinary Medicine, Department of Biomedical Sciences, and the Director of the Center for Advanced Host Defenses, Immunobiotics, and Translational Comparative Medicine.

9 Dr. DONG PYOU HAN was the laboratory manager at Dr. Cho's laboratories at both Case Western Reserve University and Iowa State University. Dr. HAN held a non-teaching position at Iowa State University, and a portion of his salary was dependent on the receipt of grant monies.

10. In 2008, at Case Western Reserve University, Dr. Cho worked on the development of a potential HIV/AIDS vaccine known as gp41. Dr. Cho submitted two grant applications, P01AI074286 and R21AI076083, both solicited by the NIH, and received funding for this research.

11. At one year to 18 months into the grant periods, Dr. Cho's research included injecting infected rabbits with the gp41 vaccine and blood was subsequently taken and spun to separate the serum (a clear, yellowish substance containing antibodies) to test for antibodies. The appearance of antibodies would indicate that the vaccine was neutralizing, or controlling the virus.

12. Dr. DONG PYOU HAN was tasked with injecting the rabbits with the gp41 vaccine, drawing the blood from the vaccinated rabbits, and testing the sera for antibodies. Dr. HAN had access to the sera samples, and Dr. Cho requested that Dr. HAN provide him with the data from the vaccine experiments for NIH grant applications and progress reports.

13. Dr. David Montefiori, of Duke University, also received samples of sera from the rabbits vaccinated at Iowa State University. His laboratory tested the sera samples to see if Iowa State University's experiment results could be duplicated. This type of collaboration between universities is a common practice in the scientific community to ensure the validity of the data.

14. In 2009, Dr. Cho applied for an additional NIH grant, U19AI091031, relating to HIV/AIDS vaccine research, based, in part, on his belief that the gp41 vaccine appeared to neutralize, or control the HIV/AIDS virus in rabbits. The grant application was approved and funded by the NIH.

#### **Defendant's Manipulation of Data**

15. Beginning as early as 2008, Dr. DONG PYOU HAN, manipulated the gp41 experiment data, performed under NIH grants, to make it appear the gp41 vaccine neutralized, or controlled the HIV/AIDS virus in rabbits, when in fact it did not. The false data was then reported by Dr. Cho, as the Principal Investigator on HIV/AIDS research grants, to the NIH.

16. Dr. DONG PYOU HAN manipulated the gp41 experiment data in two ways. First, Dr. HAN falsified data in files of neutralization experiments performed at Iowa State University to make it appear that rabbits immunized with gp41 produced broadly neutralizing antibodies, when in fact, there was very little, or no broadly neutralizing activity. Dr. HAN then reported the fake results to Dr. Cho.

17. Then, to “verify” the false results he reported to Dr. Cho, Dr. HAN spiked the sera samples from immunized rabbits with human sera containing HIV antibodies. Dr. HAN then mailed, or knew the sera samples would be mailed, to Dr. Montefiori’s laboratory at Duke University, for testing to verify the Iowa State experiment results. The spiking of the rabbit samples made it appear that gp41 produced broadly neutralizing antibodies against the HIV/AIDS virus.

18. Prior to the discovery of Dr. HAN’s fraud, the experiment results yielded from gp41 were thought to be “groundbreaking” in the search for an HIV/AIDS vaccine.

**THE GRAND JURY CHARGES:**

**COUNT 1**  
**(False Statements)**

19. The grand jury re-alleges paragraphs 1-18 of the Introductory Allegations as if fully set forth herein.

20. On or about December 10, 2009, in the Southern District of Iowa, and elsewhere, Defendant, DONG PYOU HAN, in a matter within the jurisdiction of the NIH, knowingly and willfully caused Iowa State University professor Dr. Michael Cho, to make materially false, fictitious, and fraudulent statements and representations in NIH Grant Application U19AI091031, “Enhancing B cell immunity against HIV-1 using novel vaccine delivery platforms.” Specifically, material false, fictitious, and fraudulent statements and representations in the application included:

- a. **Page 21 – Figure 4:** The grant application stated that “HIV-1-specific neutralizing activity was observed with significant breadth in immunized rabbits (Fig. 4).” This statement and figure were derived from the false data that DONG PYOU HAN provided to Dr. Cho, during the preparation of the grant application.

- b. **Page 54 – Figure C6:** The grant application contained a table of graphs, numbered Fig. C6, entitled, “HIV-1 Pseudovirus neutralization assay using TZM-bl cells.” This table contained false data that DONG PYOU HAN provided to Dr. Cho, for the preparation of the NIH grant application.
- c. **Page 55 – Table C1 and Figure C7:** The grant application contained Table C1, “Neutralization assay (Conducted at Dr. David Montefiori’s laboratory),” and Fig. C7, “Neutralization assay for Q23.17.” The table and figure were derived from false data as a result of DONG PYOU HAN having spiked rabbit sera samples with human antibodies that were mailed to Dr. Montefiori’s lab for testing. Dr. Montefiori’s lab unwittingly reported the false data to Dr. Cho, and Dr. Cho included the false information in the NIH grant application.
- d. **Page 109 – Figure C5:** The grant application contained a table of graphs, numbered Fig. C5, entitled, “HIV-1 Pseudovirus neutralization assay using TZM-bl cells.” This table contained false data that was provided from DONG PYOU HAN to Dr. Cho, for the preparation of the grant application.
- e. **Page 110 – Table C1 and Figure C6:** The grant application contained Table C1, “Neutralization assay (Conducted at Dr. David Montefiori’s laboratory),” and Fig. C7, “Neutralization assay for Q23.17.” The table and figure were derived from false data as a result of DONG PYOU HAN having spiked rabbit sera with human antibodies that were sent to Dr. Montefiori’s lab for testing. Dr. Montefiori’s lab unwittingly reported the false data to Dr. Cho, and Dr. Cho included the false information in the NIH grant application.

This is a violation of Title 18, United States Code, Sections 1001(a)(2) and 2.

**THE GRAND JURY FURTHER CHARGES:**

**COUNT 2**  
**(False Statements)**

21. The grand jury re-alleges paragraphs 1-18 of the Introductory Allegations as if fully set forth herein.

22. On or about March 1, 2011, in the Southern District of Iowa, and elsewhere, Defendant, DONG PYOU HAN, in a matter within the jurisdiction of the NIH, knowingly and willfully caused Iowa State University professor Dr. Michael Cho, to make materially false, fictitious, and fraudulent statements and representations in NIH Progress Report P01AI074286, "Characterization of immunogenic and structural properties of HIV-1 envelope." Specifically, material false, fictitious, and fraudulent statements and representations in the progress report included:

- a. **Page 8** – The progress report stated, "Neutralization assays conducted in Dr. Cho's laboratory showed that immunized rabbits mounted broadly reactive neutralizing antibodies against HIV-1 isolates AD8, DH12, Bal, 89.6 and LAI. Assays conducted in Dr. David Montefiori's laboratory, which are summarized below in Table 1, also demonstrated that immune sera exhibited potency and breadth." These statements were derived from false data that DONG PYOU HAN provided to Dr. Cho, during the preparation of the progress report, and from DONG PYOU HAN having spiked rabbit sera with human antibodies that were sent to Dr. Montefiori's lab for testing. Dr. Montefiori's lab unwittingly reported the false data to Dr. Cho, and Dr. Cho included the false information in the NIH progress report.

- b. **Page 9 – Table 1:** The progress report contained Table 1, “HIV-1 pseudovirus neutralization assay (conducted by Dr. Montefiori).” The table contains false data as a result of DONG PYOU HAN having spiked rabbit sera with human antibodies that were sent to Dr. Montefiori’s lab for testing. Dr. Montefiori’s lab unwittingly reported the false data to Dr. Cho, and Dr. Cho included the false information in the NIH progress report.

This is a violation of Title 18, United States Code, Sections 1001(a)(2) and 2.

**THE GRAND JURY FURTHER CHARGES:**

**COUNT 3**  
**(False Statements)**

23. The grand jury re-alleges paragraphs 1-18 of the Introductory Allegations as if fully set forth herein.

24. On or about March 29, 2012, in the Southern District of Iowa, and elsewhere, Defendant, DONG PYOU HAN, in a matter within the jurisdiction of the NIH, knowingly and willfully caused Iowa State University professor Dr. Michael Cho, to make materially false, fictitious, and fraudulent statements and representations in NIH P01AI074286 Progress Report, “Characterization of immunogenic and structural properties of HIV-1 envelope.” Specifically, material false, fictitious, and fraudulent statements and representations in the progress report included:

- a. **Page 8 –** The progress report stated,

“The results of neutralization assays conducted by Dr. David Montefiori’s laboratory is shown on Table 1 and they are summarized below:

1. All of the Tier 1 viruses tested were neutralized, including those from clades A, B, C and AE.
2. All Tier 2 viruses tested, except two, were also neutralized, albeit at a lower titer.

3. Neutralized viruses included recombinant forms, including clades AE and CRF01-AG.
  4. Very high neutralizing titers were detected even against Tier 2 viruses in assays using A3R5.7 cells (see Table 1B), validating results seen in TZM-bl assays (Table 1A).
  5. Slower immunization protocol induced higher Nab titers than what was observed from a more rapid schedule.
  6. Three immunizations were needed to detect significant levels of neutralizing activity.
  7. Fourth immunization significantly enhanced neutralizing activity.
- These results confirm that our gp41-54-Q antigen can elicit Nabs with significant potency and breadth. In comparison to other immune sera evaluated in A3R5 cells against tier 2 viruses. Dr. David Montefiori indicated, 'it is quite evident that your gp41 immunogen stands out above the rest. Neutralization was stronger against B viruses than C viruses but higher in both cases compared to other immunogens.' He also indicated 'Your responses are stronger than anything we've seen in humans, NHP and rabbits.' Thus, we believe these results represent a significant breakthrough in the HIV-1 vaccine field."

These statements were derived from false data that DONG PYOU HAN provided to Dr. Cho, during the preparation of the progress report, and from DONG PYOU HAN having spiked rabbit sera with human antibodies that were sent to Dr. Montefiori's lab for testing. Dr. Montefiori's lab unwittingly reported the false data to Dr. Cho, and Dr. Cho included the false information in the NIH progress report.

- b. **Page 9 – Table 1:** The progress report contained Table 1, "HIV-1 pseudovirus neutralization assay (conducted by Dr. Montefiori)." The table contains false data as a result of DONG PYOU HAN having spiked rabbit sera with human antibodies that were sent to Dr. Montefiori's lab for testing. Dr. Montefiori's lab unwittingly reported the false data to Dr. Cho, and Dr. Cho included the false information in the NIH progress report.

This is a violation of Title 18, United States Code, Sections 1001(a)(2) and 2.

**THE GRAND JURY FURTHER CHARGES:**

**COUNT 4**  
**(False Statements)**

25. The grand jury re-alleges paragraphs 1-18 of the Introductory Allegations as if fully set forth herein.

26. On or about July 2, 2012, in the Southern District of Iowa, and elsewhere, Defendant, DONG PYOU HAN, in a matter within the jurisdiction of the NIH, knowingly and willfully caused Iowa State University professor Dr. Michael Cho, to make materially false, fictitious, and fraudulent statements and representations in NIH U19AI091031 Progress Report, "Enhancing B cell immunity against HIV-1 using novel vaccine delivery platforms." Specifically, material false, fictitious, and fraudulent statements and representations in the progress report included:

a. **Page 11:** The progress report stated "We finished immunizing rabbits with gp41-54Q-GHC immunogen loaded onto GNP. From this first immunization study, we saw potent, broadly neutralizing antibodies (bnAbs) in two of three animals after four immunizations. All viruses tested were neutralized in both TZM-bl and A3R5.7 assays as shown in a Table below (conducted in Dr. David Montefiori's laboratory). The statement and table were derived from false data that DONG PYOU HAN provided to Dr. Cho, during the preparation of the progress report, and from DONG PYOU HAN having spiked rabbit sera with human antibodies that were sent to Dr. Montefiori's lab for testing. Dr. Montefiori's lab unwittingly reported the false data to Dr. Cho, and Dr. Cho

included the false information in the NIH progress report.

This is a violation of Title 18, United States Code, Sections 1001(a)(2) and 2.

**A TRUE BILL.**

/s/  
FOREPERSON

Nicholas A. Klinefeldt  
United States Attorney

By: /s/ Rachel J. Scherle  
Rachel J. Scherle  
Assistant United States Attorney