DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Witness appearing before the

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Subcommittee on Water and Wildlife

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Good afternoon, Mr. Chairman, Ranking Member Sessions and Members of the Subcommittee. I am James Anderson, the Director of the Division of Program Coordination, Planning, and Strategic Initiatives ("the Division") in the Office of the Director at the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services. I am pleased to appear before you today to testify about NIH's efforts to implement recent recommendations offered in a December 2011 report[1] by the Institute of Medicine (IOM) and accepted by NIH regarding the use of chimpanzees in NIH-supported research. As the Subcommittee begins consideration of S. 810, the Great Ape Protection and Cost Savings Act, I look forward to discussing the recommendations of the IOM and NIH's efforts to implement them as we continue to focus on our mission of improving human health and saving lives.

About the Division

First, I would like to tell you about the Division and its role in NIH-supported chimpanzee research and in implementing the IOM report recommendations. Among its activities, the Division plans and implements trans-NIH, transformative initiatives and coordinates research across NIH related to AIDS, behavioral and social sciences, women's health, disease prevention, and – more recently and relevant to this hearing – research infrastructure. Included in the mission of the research infrastructure office is NIH's Chimpanzee Management Program, a program that supports long-term, cost-effective housing and maintenance at facilities for chimpanzees. The Chimpanzee Management Program provides programmatic oversight of the facilities and ensures they comply with the Animal Welfare Act, and policies concerning laboratory animal care and use. These activities were previously supported by the National Center for Research Resources (NCRR). As a result of a recent organizational change within the NIH, independent of the IOM report, the Division gained this and other research infrastructure activities from NCRR..

[1] http://www.ncbi.nlm.nih.gov/books/NBK82797/pdf/nap13257.pdf

The Division is advised by the NIH's Council of Councils, a Federal Advisory body composed of approximately 27 members selected from the NIH Institutes and Centers' Advisory Councils and broad lay representation, including a member of the NIH Council of Public Representatives. The Council advises the NIH Director and me on matters related to the policies and activities of the Division. A working group of this Council is currently developing recommendations on how NIH should implement the IOM recommendations.

Background

The use of animals in research has enabled scientists to identify new ways to treat illness, extend life, and improve health and well-being. Chimpanzees are our closest relatives in the animal kingdom, providing exceptional insights into human biology and the need for special consideration and respect. NIH is deeply committed to the care and welfare of chimpanzees.

While used very selectively and in limited numbers for medical research, research involving chimpanzees has served an important role in advancing human health in the past. For example:

- Contributing significantly to the development of vaccines against hepatitis A and B infection that are in use today. These vaccines most often are given as pediatric immunizations. Since 1991, there has been a 98 percent decline in hepatitis B in children under the age of 15 years. The rate of new hepatitis A infections in the United States declined by more than 92 percent between 1995 and 2008.
- Determining that dietary salt is a major causative factor of elevated blood pressure (Denton et al., 1995).
- Developing FDA-approved monoclonal antibodies for use in treating lymphomas and other cancers, and establishing that certain in vitro differentiated immune cells can serve as vehicles for cancer immunotherapy (Larsson et al., 2004).

However, new methods and technologies developed by the biomedical community have provided alternatives to the use of chimpanzees in several areas of research..

About the IOM Report

In December 2010, with the support from Senator Udall on this subcommittee and other members of Congress, NIH commissioned a study by the IOM to assess whether chimpanzees are or will be necessary for biomedical and behavioral research in today's advanced technological environment. Specifically, the IOM committee reviewed the current use of chimpanzees for biomedical and behavioral research and explored contemporary and anticipated future alternatives to the use of chimpanzees in biomedical and behavioral research that will be needed for the advancement of the public's health.

A year later on December 15, 2011, the IOM issued its findings. The IOM concluded that:

- The use of chimpanzees in current and future research should be guided by the following principles and criteria (pp. 4-5):
    - The knowledge gained must be necessary to advance the public's health.
    - There must be no other research model by which the knowledge could be obtained, and the research cannot be ethically performed on human subjects.
    - The animals used in the proposed research must be maintained either in ethologically appropriate physical and social environments (i.e., as would occur in their natural environment) or in natural habitats.
- Based on these principles, the IOM concluded that most current use of chimpanzees for biomedical research is unnecessary, with the exception of some areas of research that may still require their use, including (pp: 4-5):
    - some ongoing research on monoclonal antibody therapies;
    - research on comparative genomics; and

    - non-invasive studies of social and behavioral factors that affect the development, prevention, or treatment of disease.
- The committee was evenly divided on the necessity of the chimpanzee for the development of prophylactic hepatitis C virus vaccine.
- New, emerging, or re-emerging infectious diseases may present challenges that defy non-chimpanzee models and therefore, may require that chimpanzees be used in future research.
- NIH should continue development of non-chimpanzee models and technologies.

After careful consideration, the NIH Director decided to accept the IOM recommendations, and announced that NIH was in the process of developing a plan for implementing the IOM's guiding principles and criteria. Upon accepting the IOM recommendations, NIH immediately halted issuance of any new awards for research involving chimpanzees until processes for implementing the recommendations are in place. In addition, the NIH has assembled a Working Group within the Council of Councils to provide advice on the implementation of the IOM recommendations, and to consider the size and placement of the active and inactive populations of NIH-owned or -supported chimpanzees.

Status of the Working Group

The Working Group was officially charged on February 1, 2012 and held their first meeting a day later, on February 2. They have been charged with:

- Developing a plan for implementation of the IOM's guiding principles and criteria;
- Analyzing currently active NIH-supported research using chimpanzees to advise on which studies currently meet the principles and criteria defined by the IOM report and advising on the process for closing studies if any do not comply with the IOM recommendations;
- Advising on the size and placement of active and inactive populations of NIH-owned or NIH-supported chimpanzees that may need to be considered as a result of implementing the IOM recommendations; and

- Developing a review process for considering whether potential future use of the chimpanzee in NIH-supported research is scientifically necessary and consistent with the IOM principles.

Ongoing research involving NIH-owned or -supported chimpanzees is currently being reviewed on a project-by-project basis by the NIH Working Group to assess whether it meets the IOM principles and criteria. Projects that are found not to meet those standards will be phased out, but in a fashion that preserves the value of research already conducted, and minimizes the impact on the animals involved. Therefore, until the NIH Working Group has made their recommendations, currently funded projects will continue.

NIH welcomes public input into the Working Group's deliberations. In fact, the NIH has already begun seeking public input to further inform the Working Group's deliberations through a Federal Register Notice that was published in February. Our public website[2] provides information about the members of the Working Group, their charge, and upcoming Council of Councils meetings. With regard to timing, the Working Group will update the Council of Councils during the open session of the June 5, 2012 meeting, and again in September 2012. The NIH anticipates that the Working Group will present its final report during an open session of the Council of Councils in early 2013. After the Council considers the Working Group's report and recommendations, the NIH will open a 60-day public comment period on the implementation of the report and recommendations.

NIH's Commitment to Care and Welfare

Throughout this process, NIH remains committed to conducting and supporting high-quality science in the interest of advancing public health, and to the humane care and use of animals used in NIH research. It cannot be emphasized enough that **all** animals used in Federally-funded research are protected by laws,

[2] http://dpcpsi.nih.gov/council/working_group.aspx

regulations, and policies to ensure the greatest commitment to their physical and emotional comfort and welfare.

Since 2001, the animals housed in our four chimpanzee facilities constitute a closed colony; no new animals are introduced into this population from non-NIH facilities and none are transferred to other chimpanzee populations, such as zoos, other entertainment, or wild populations. This policy helps to ensure these chimpanzees are maintained as a unique and distinct population based on highly regulated and monitored welfare and guaranteed lifetime care and housing. NIH-supported chimpanzee facilities are uniquely designed for these large animals, including indoor housing with air conditioning/heating, special wall furniture, and outdoor housing tailored to chimpanzee size and behavior. In 2002-2004, NIH constructed a Federal sanctuary facility operated by Chimp Haven to provide lifetime housing for approximately 130 Federally-owned chimpanzees that have been retired from research.

Based on an analysis of the most recent awards and payments, NIH spends an average of $35 per day per chimpanzee (n=421) in research facilities; $47 per day per chimpanzee (n=119) in the Federal sanctuary facility operated by Chimp Haven; and $67 per day per chimpanzee (n=173) in the research reserve facility at Alamogordo Primate Facility.

Closing

I would like to close by thanking the subcommittee for inviting NIH to provide an update on its activities to implement the IOM recommendations. NIH shares the concern over animal welfare, and I want to assure you Mr. Chairman and Members of the Subcommittee, that we place the appropriate care and use of animals as a fundamental principle at the core of all of our research activities. The agency also is driven by its mission to improve human health and save lives: for example, deaths of children from leukemia and other loved ones from heart disease, and illnesses from liver disease have been prevented through the use of animal models to develop treatments and vaccines.

While we pursue this mission, NIH seeks to minimize the use of animals wherever possible to find appropriate alternatives. As we continue to manage an important population of animals -- our Federally supported chimpanzees -- we look forward to hearing the Working Group's recommendations on how the agency should implement the IOM recommendations.

Thank you for the opportunity to present this update to you. I will be happy to try to answer any questions.