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GREAT APE PROTECTION AND COST SAVINGS ACT OF 2011

NOVEMBER 30, 2012.—Ordered to be printed

Mrs. BOXER, from the Committee on Environment and Public Works, submitted the following

R E P O R T

[To accompany S. 810]

[Including cost estimate of the Congressional Budget Office]

The Committee on Environment and Public Works, to which was referred a bill (S. 810) to prohibit the conducting of invasive research on great apes, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill, as amended, do pass.

GENERAL STATEMENT AND BACKGROUND

While chimpanzee research has helped in the past to address certain diseases, current research is rapidly moving away from the use of Chimpanzees. At Congress' request, the National Institutes of Health (NIH) commissioned the Institute of Medicine (IOM) to assess the current and anticipated need for chimpanzee biomedical research. After nine months of evaluation, discussion and review, which included hearing from the nation's leading experts in chimpanzee research and many science and animal advocacy groups, the IOM issued its report in December 2011, concluding—

> "While the chimpanzee has been a valuable animal model in past research, most current use of chimpanzees for biomedical research is unnecessary, based on the criteria established by the committee, except potentially for two current research uses."
>
> "The present trajectory indicates a decreasing scientific need for chimpanzee studies due to the emergence of non-chimpanzee models and technologies."

The Great Ape Protection and Cost Savings Act of 2011 includes prohibitions on invasive research on great apes. The legislation also requires the Secretary of Health and Human Services (HHS), within three years of enactment, to permanently retire all great apes that are owned by the federal government and that are being maintained in any facility for the purpose of conducting invasive research.

However, the bill as reported also recognizes that new or emerging diseases could present unique challenges in the future and establishes a process for future consideration of invasive research necessary to address a new, emerging, or reemerging threat.

OBJECTIVES OF THE LEGISLATION

The Great Ape Protection and Cost Savings Act of 2011 seeks to prohibit the conducting of invasive research on great apes, except in instances where a determination is made that a new, emerging or reemerging disease requires the use of great apes for invasive research.

SECTION-BY-SECTION ANALYSIS

Section 1. Short title

Section 1 provides that this Act may be cited as the "Great Ape Protection and Cost Savings Act of 2012".

Section 2. Findings and purpose

Section 2 provides Congressional findings regarding invasive research on great apes and describes the purposes of the Act.

Section 3. Definitions

Section 3 defines terms used in the Act.

Section 4. Prohibitions

Section 4 prohibits the following—

- invasive research on a great ape;
- possession or housing a great ape for the purpose of conducting invasive research;
- use of federal funds for invasive research on a great ape;
- breeding of a great ape for the purpose of conducting or facilitating invasive research;
- transport, move, deliver, receive, lease, rent, donate, purchase, sell, or borrow a great ape in interstate or foreign commerce for the purpose of conducting or facilitating invasive research on a great ape;
- transfer of ownership of a great ape by a Federal agency to any non-Federal entity other than a suitable sanctuary

Section 4 includes an exemption provision clarifying that nothing in the Act limits or prevents individualized medical care performed on a great ape by a licensed veterinarian or physician for the well-being of the great ape.

Section 5. Invasive research to address human health threats

Section 5 establishes a process for approval of invasive research when a new, emerging or reemerging disease or disorder presents a challenge to treatment, prevention or control that defies non-

great ape models and technologies. If research is approved under this section, the prohibitions of section 4 do not apply.

Three years after the date of enactment, the Secretary of Health and Human Services (Secretary) may issue a preliminary finding that great apes may be required because a new, emerging or re-emerging disease or disorder presents a challenge to treatment, prevention or control that defies non-great ape models and technologies.

If the Secretary makes such a finding, the Secretary must convene the Great Ape Research Task Force, which consists of—

- the Secretary,
- the Director of the National Institutes of Health,
- the Secretary of Defense,
- the Secretary of the Interior,
- the President of the Institute of Medicine,
- the Chair of the Association of Zoos and Aquariums Ape Taxon Advisory Group,
- an individual appointed by the Secretary with scientific expertise in the use of great apes in areas of research relating to the disease or disorder for which the Task Force is considering authorizing invasive research,
- an individual appointed by the Secretary with scientific expertise in the use of research models that do not use great apes in areas of research relating to the disease or disorder for which the Task Force is considering authorizing invasive research, and
- an individual appointed by the Secretary who is a representative of an animal protection organization.

The Task Force must review proposed research protocols and determine whether to authorize invasive research on great apes. In reviewing protocols, the Task Force must consult with the Animal Welfare Information Center. The Secretary must also allow public comment on any proposed research protocol prior to final authorization. The Task Force may issue written authorization for a person to carry out an approved research protocol if it determines based on the best scientific evidence available that the following criteria are met—

- for invasive research for biomedical purposes—there is no suitable model available other than great apes; the research in question cannot be performed ethically on human subjects; foregoing the use of great apes will significantly slow or prevent important advancements to prevent, control, or treat life-threatening or debilitating conditions; and the research has not already been found to be unnecessary by a committee of the Institute of Medicine
- for invasive research for comparative genomics and behavioral studies—a study using great apes would provide otherwise unattainable insight; each experiment is performed on acquiescent animals, using techniques that are minimally invasive, and in a manner that minimizes pain and distress; and the research has not already been found to be unnecessary by a committee of the Institute of Medicine.

The Task Force must require any person carrying out authorized research to identify each individual great ape on which research will be performed, minimize pain and physical and mental harm or

distress to the great ape, and maintain the great ape in ethologically appropriate physical and social environments throughout the course of the authorized research protocol.

Section 5 states that the Federal Advisory Committee Act does not apply to the Task Force.

This section clarifies that nothing in this section authorizes research on a great ape retired pursuant to the Chimpanzee Health Improvement, Maintenance, and Protection Act (P.L. 106–551).

Section 5 requires the Secretary to submit a report to Congress detailing the findings and recommendations of the Working Group on the Use of Chimpanzees in NIH-supported Research of the Council of Councils of the National Institutes of Health (Working Group). The report must include any legislative recommendations relating to the Task Force and the requirements of this section that are necessary to ensure consistency with the recommendations of the Working Group.

Section 5 authorizes the Secretary to promulgate regulations to carry out the findings and recommendations of the Working Group and the requirements of this section.

Section 6. Retirement

Section 6 requires, within three years after the date of enactment, the Secretary to effectuate the permanent retirement of all great apes owned by the Federal Government for the purposes of breeding, holding for, or conducting invasive research.

This section requires a federally owned great ape selected for invasive research authorized under Section 5 to be returned to a suitable sanctuary immediately after the research is concluded.

Section 7. Civil penalties

Section 7 authorizes a civil penalty of not more than $10,000 for each violation of a provision of this Act. This section also clarifies that each day that a violation of this Act continues shall constitute a separate offense.

Section 8. Great Ape Sanctuary System Fund

Section 8 establishes a Great Ape Sanctuary System Fund to receive funds equivalent to amounts collected as penalties under Section 7. Funds may be used for construction, renovation, and operation of the sanctuary system established pursuant to section 404K of the Public Health Service Act (42 U.S.C. 283m).

Section 8 requires the Secretary to submit an annual report on the deposits into and expenditures from the Fund, recommendations for additional authorities to fulfill the purpose of the Fund, and a statement of the balance remaining in the Fund at the end of each fiscal year.

Section 9. Effective dates

Section 9 states that the prohibition on invasive research in Section 4(a) takes effect on the date that is three years after the date of enactment for great apes assigned to an active protocol on the date of enactment and immediately for great apes not assigned to an active protocol. The prohibitions in Section 4(b) and (c) on housing a great ape and providing Federal funding for great apes takes effect three years after the date of enactment.

Section 10. Severability

Section 10 states that if any provision of the Act is held invalid or unenforceable in any respect, it shall not affect any other provision of this Act.

LEGISLATIVE HISTORY

S. 810 was introduced by Senator Cantwell and 14 co-sponsors on April 13, 2011. The bill was received, read twice, and referred to the Committee on Environment and Public Works. On July 25, 2012, the full Committee on Environment and Public Works met to consider the bill. The bill was ordered reported favorably, as amended, by voice vote.

HEARINGS

On April 24th, 2012, the Water and Wildlife Subcommittee of the Senate Environment and Public Works Committee held a legislative hearing on multiple bills, including S. 810.

ROLLCALL VOTES

The Committee on Environment and Public Works met to consider S. 810 on July 25, 2012. The Committee adopted an amendment offered by Senators Boxer and Cardin by voice vote. The bill, as amended, was ordered reported favorably by voice vote with Senators Alexander and Johanns recorded as "no".

REGULATORY IMPACT STATEMENT

In compliance with section 11(b) of rule XXVI of the Standing Rules of the Senate, the committee notes that S. 810 would prohibit invasive research on great apes, unless authorized by the research task force established in the bill. The bill will not cause any adverse impact on the personal privacy of individuals.

MANDATES ASSESSMENT

In compliance with the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), the committee noted that the Congressional Budget Office has found, "S. 810 would impose intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) by prohibiting invasive research on great apes, unless authorized by the research task force established in the bill . . . CBO estimates that the cost of the mandate would be small and would not exceed the annual thresholds established in UMRA for intergovernmental or private-sector mandates."

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, November 12, 2012.

Hon. BARBARA BOXER,
Chairman, Committee on Environment and Public Works,
U.S. Senate, Washington, DC.

DEAR MADAM CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 810, the Great Ape Protection and Cost Savings Act of 2011.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Jamease Miles.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

S. 810—Great Ape Protection and Cost Savings Act of 2011

Summary: The Great Ape Protection and Cost Savings Act of 2011 would prohibit invasive research on a great ape, as well as the transport or breeding of great apes to be used in such research within and outside of the United States. For great apes that are owned by or are under the control of the federal government, the bill also would require their permanent retirement and lifetime care in a suitable sanctuary. In addition, the bill would establish the Great Ape Sanctuary System Fund to support the construction, renovation, and operation of the sanctuary system. Civil monetary penalties collected as a result of violations of the bill would be used to endow the Great Ape Sanctuary System Fund.

CBO estimates that implementing S. 810 would cost $56 million over the 2013–2017 period, assuming appropriation of the necessary amounts. Because fines may be collected as a result of violations of this legislation, there could be an increase in revenues and direct spending; therefore, pay-as-you-go procedures apply. However, CBO estimates that any effects on revenues and direct spending would be insignificant for each year.

S. 810 would impose intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) by prohibiting invasive research on great apes, unless authorized by the research task force established in the bill. Based on information from public and private entities, including research institutions, CBO estimates that the cost of the mandates would be small and would not exceed the intergovernmental or private-sector thresholds established in UMRA ($73 million and $146 million, respectively, in 2012, adjusted annually for inflation).

Estimated cost to the federal Government: The estimated budgetary impact of S. 810 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2013	2014	2015	2016	2017	2013–2017
CHANGES IN SPENDING SUBJECT TO APPROPRIATION[a]						
Estimated Authorization Level	30	4	8	7	7	56
Estimated Outlays	9	25	8	7	7	56

[a] Enacting S. 810 could affect revenues and direct spending from the collection and spending of fines, but CBO estimates that any such effects would be insignificant for each year.

Basis of estimate: At present, CBO understands that the National Institutes of Health (NIH) is the only federal agency that provides financial support for research that involves the use of great apes, namely chimpanzees, for invasive research. NIH also supports research that involves the use of chimpanzees for behavioral and observational studies. Under the bill, chimpanzees intended for use in invasive research would be retired; other chimpanzees would remain available for behavioral and observational research. Based on a 2011 report by the Institute of Medicine and

National Research Council of the National Academies, CBO estimates that about 440 government-owned chimpanzees are available for use in invasive research.

Implementing S. 810 would require start-up expenditures to establish a suitable sanctuary with sufficient capacity to accommodate the retired chimpanzees and transport them to the sanctuary, as well as ongoing costs for the care of the chimpanzees in the sanctuary. In addition, the budgetary effect of S. 810 would include any difference between the cost to NIH of invasive research that uses chimpanzees and the cost of alternative methods of conducting such studies.

For this estimate, CBO assumes that S. 810 will be enacted near the end of calendar year 2012 and that the necessary amounts will be appropriated near the beginning of calendar year 2013 and near the start of each subsequent fiscal year. CBO estimates that implementing S. 810 would cost $56 million over the 2013–2017 period, assuming appropriations of the necessary amounts.

It is unclear whether S. 810 would authorize appropriations for the existing sanctuary program for retired great apes. The amount authorized for that program is capped at a cumulative total of $30 million. CBO expects that cap will be reached by 2014. This estimate reflects the incremental cost of expanding the existing sanctuary program to accommodate chimpanzees retired under S. 810, but does not incorporate the cost of continuing to operate the existing program after the cumulative cap on funding is reached.

The bill would allow civil monetary penalties against any person who violates the bill three or more years after the date of enactment. Also, it would permit the expenditure of the amounts collected without subsequent appropriation action. For this estimate, CBO assumes that the affected chimpanzees would be retired and housed in a suitable sanctuary by that deadline. As a result, CBO estimates that any increases in both revenues (from civil monetary penalties) and direct spending from the amounts collected would be insignificant.

Construction and transportation costs

The bill would require that all retired apes be placed in suitable sanctuaries as outlined in the Chimpanzee Health, Improvement, Maintenance & Protection (CHIMP) Act of 2000. CBO has identified only one existing sanctuary that meets the requirements of the CHIMP Act. However, that sanctuary has space for less than one-quarter of the chimpanzees expected to retire under the legislation. CBO estimates that expansion of that facility and transportation of the retired chimpanzees to the facility would cost about $30 million over three years, beginning in 2013. (Transportation costs account for less than $500,000 of that amount.)

If a new sanctuary were established instead of expanding the existing sanctuary, the construction costs could be substantially higher and the three-year deadline for complying with the requirements of S. 810 probably would not be met. Non-compliance could result in the collection of substantial civil monetary penalties and direct spending of the amounts collected.

Cost of caring for chimpanzees

Under S. 810, CBO assumes that all chimpanzees would be moved to the sanctuary by December 2015. The estimate assumes that there is space for less than one-quarter of the chimpanzees estimated to be retired under the bill. Those chimpanzees could be moved immediately to the sanctuary upon enactment of the bill. The remaining chimpanzees would be moved as suitable living space becomes available. In addition, the estimate assumes that the costs for care of the chimpanzees will rise with inflation, but that the population of retired chimpanzees will decline as a result of chimpanzee mortality. CBO estimates that caring for the retired chimpanzees in the sanctuary would cost about $26 million over the 2013–2017 period, assuming the appropriation of the necessary funds.

Cost of alternatives to invasive research

By many estimates, chimpanzees and humans share approximately 98 percent of their DNA and are susceptible to many of the same infections. As a result, for some disease research, the chimpanzee is the only established non-human, animal model in which to test innovative new medicines and to understand the immune response to those medicines. While the National Institutes of Health could seek an exception for the use of a chimpanzee model in such circumstances from the Great Ape Research Task Force established under S. 810, it is unclear if an exception would be granted. The cost of developing and using alternative models for such research would probably exceed the cost of testing with existing chimpanzee models. However, because NIH is not required to develop alternative models and could either prolong the development of such models or shift their research priorities, CBO cannot determine what the net change in research spending might be over the next five years. As a result, CBO estimates that the provision that would prohibit invasive research using chimpanzees would not have a significant net effect on research spending by NIH.

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. CBO estimates that the net changes in revenues and direct spending that are subject to those pay-as-you-go procedures under S. 810 would be insignificant.

Intergovernmental and private-sector impact: S. 810 would impose intergovernmental and private sector mandates as defined in UMRA by prohibiting invasive research on great apes unless authorized by the research task force established in the bill. Public and private entities, including research institutions, that use, breed, house, or transport great apes for invasive research would be prohibited from continuing those activities. Based on information from public and private research institutions, CBO estimates that the cost of the mandate would be small and would not exceed the annual thresholds established in UMRA for intergovernmental or private-sector mandates ($73 million and $146 million, respectively, in 2012, adjusted annually for inflation).

Estimate prepared by: Federal costs: Jamease Miles and Martin von Gnechten; Impact on state, local, and tribal governments: Me-

lissa Merrell and Sandra Trevĩno; Impact on the private sector: Danielle Parnass and Amy Petz.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

CHANGES IN EXISTING LAW

Section 12 of rule XXVI of the Standing Rules of the Senate requires the committee to publish changes in existing law made by the bill as reported. Passage of this bill will make no changes to existing law.

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