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Congress Takes Aim at Animals in Research; Requires New Center, Better Data, Reporting

By Theresa Defino

NIH will create a new Center for Alternatives to Animals in Research and Testing to “promote” ways to reduce animals used in studies and make other related efforts, as required by Congress under new funding legislation that keeps the government afloat for the balance of this fiscal year (FY), which ends Sept. 30. And in something of a twist, Congress found a way in the new legislation to combine its interest in combating foreign influences with its animal research concerns.

President Biden signed into law H.R. 2471, the Consolidated Appropriations Act, on March 15.^[1] It boosts NIH funding by \$2.25 billion for a total of \$44.959 billion. Congress passed three continuing resolutions for FY 2022 before enacting H.R. 2471. As it often does, Congress also included explicit instructions to NIH about how it wants funds spent—or not spent, as the case may be. Congress’ intentions are spelled out in a 524-page report by the House Appropriations Committee,^[2] a 197-page explanatory statement^[3] and in the text of the law itself.

And apparently animal research was on the list this year. In addition to establishing a new center, Congress has asked NIH for more data on animal use in research and for a plan to increase public knowledge about such studies.

Congress Wants Numbers on Animals

The explanatory statement notes that “Congress has expressed an interest in reducing the use of nonhuman animals in NIH-funded research and replacing animals with valid and reliable non-animal alternatives when appropriate for the science” as far back as 1993. In that year, “Congress first requested that the agency create a plan for doing so. The [funding] agreement also recognizes the scientific community’s stated commitment to the ‘three Rs of replacement, reduction, and refinement.’”

The House report makes a brief mention of the center; it is not included in the explanatory statement nor in the text of H.R. 2471. According to the House report, NIH is to “submit a plan not later than 180 days after enactment of the Act for the establishment of a Center for Alternatives to Animals in Research and Testing within NIH, for the purposes of (1) developing, promoting, and funding alternatives to animal research and testing, and (2) developing a plan for reducing the number of animals used in Federally funded research and testing.”

Under a section called “Humane Research Alternatives,” the explanatory statement also requires NIH to create a new working group on animal research.

“Recognizing that humane, cost-effective, and scientifically suitable non-animal methods are available for certain research models, the agreement directs NIH to appoint a working group to make recommendations for encouraging the use of non-animal models where appropriate in NIH intramural and extramural research, including epidemiological and clinical studies, cell-based methods, computer modeling and simulation, and human tissue studies, with consideration for complexity of the biomedical research area, and the current

applicability and translatability of the non-animal model,” it states.

Congress wants the working group to “report on effectively moving research away from methods that rely on poorly-defined animal models to methods that rely on validated non-animal alternatives,” and is requiring it to “review and recommend means of encouraging greater reliance on validated human-relevant non-animal methods/approaches that are appropriate for identified research areas.”

The explanatory statement also addresses the makeup of the working group, stating that it “should include individuals with proven knowledge of/experience with non-animal research methods; with proven knowledge of/expertise with animal research models; with expertise in evaluating the adequacy of justifications described in research applications and proposals for why the research goals cannot be accomplished using an alternative model; and with knowledge of research animal welfare, and relevant scientific limitations.”

The committee wants to receive a “report of the working group’s findings within 180 days of enactment of this Act.”

The statement also addresses “animal model validation,” although this section is less a mandate and more of a suggestion. “The agreement encourages NIH to provide a report to the Committees no later than one year after enactment outlining the progress of its efforts to improve animal model validation, support the development of models to improve translation, and what additional funding may be required,” the explanatory statement says.

Congress also asked both NIH and the U.S. Department of Agriculture (USDA) to beef up data on animals used in research and associated funding. The appropriations committee noted that an “accurate counting of animals used in research and testing and the accurate reporting of NIH funding dedicated to projects involving animals” is “integral” to determining whether the number of animals used in research is declining.

According to Congress, “it has been NIH’s policy since 1985 to collect an ‘average daily inventory’ of vertebrate animals housed in research facilities that wish to receive agency funding.” Additionally, domestic facilities also file a federalwide assurance every four years that includes the inventory, but “copies of the documents are available to the public only through Freedom of Information Act requests.”

The agencies will have to do better, and in the future, institutions also may be required to report more details.

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