

January 18, 2017

HHS Nominee Testifies at First Confirmation Hearing

Earlier this morning, the Senate Committee on Health, Education, Labor and Pensions (HELP) met to consider the nomination of Rep. Tom Price (R-GA) by President-elect Donald Trump (R) for Secretary of Health and Human Services (HHS). Rep. Price, an orthopedist, could be confirmed by the full Senate soon. Members of the committee, who have jurisdiction over HHS, questioned him for several hours over his outlook on the department's plans for the Affordable Care Act (ACA) as well as potential financial conflicts of interest. Rep. Price must next appear before the Senate Finance Committee, which is scheduled for Tuesday. For a recap of today's hearings, please see The Hill's "Five takeaways from Price's confirmation hearing."

As for other nominations, President-elect Trump has yet to pick a candidate to fill the top post at the U.S. Department of Agriculture (USDA) and the Director of the National Institutes of Health (NIH).

Be sure to watch for updates from NABR about any new announcements during the confirmation process.

NABR Submits Comments to FDA on GLP Proposed Rule

Last August, the Food and Drug Administration (FDA) published a proposed rule the in the Federal Register (Vol. 81, No. 164) titled, "Good Laboratory Practice for Nonclinical Laboratory Studies" [Docket No. FDA–2010–N–0548]. FDA has proposed amending the current regulations to require a complete quality system approach which they refer to as a GLP Quality System.

The proposed system would be required for safety and toxicity studies to support applications or submissions to the FDA. Proposed changes that would impact animal research facilities include additional management responsibilities, changes to SOP procedures and changes to address the management of multisite nonclinical laboratory studies.

NABR submitted comments to the FDA this afternoon, expressing concern that creating additional rules would be redundant with existing regulations and confusing for researchers, as research facilities are already governed by numerous other animal welfare requirements. A copy of our comments can be <u>found here</u> and NABR readers are encouraged to use them as a basis for filing their own at <u>www.regulations.gov</u>. Comments must be submitted by January 21, 2017.

Max Planck Society Paper Focuses on Importance of Animal Research

The Max Planck Society has published a white paper focusing on ethics in the animal laboratory environment and the resulting challenges faced by animal researchers. The paper emphasizes that the use of animals is critical to the process of discovering lifesaving cures in biomedical research, and the research community conducts its work ethically and responsibly. The paper reinforces the commonly accepted idea that researchers should carefully consider the "three R's," replace, reduce and refine, before performing an experiment.

Also emphasized in the report is the importance of open communication about projects between researchers and the public in an effort to promote a greater understanding of the need for animals in this lifesaving work.

Max Planck Society is a premier German research organization focusing on the life sciences and innovation, and its membership includes award-winning scientists and Nobel laureates. To read the full copy of the white paper, <u>click here</u>.

Animal Extremist Sentenced for Violating the AETA

As we <u>reported on January 4</u>, Nicole Kissane pled guilty to the charge of conspiracy to violate the Animal Enterprise Terrorism Act (AETA). Yesterday <u>she was sentenced</u> to 21 months in prison and \$423,000 in restitution. Her accomplice, Joseph Buddenberg, was sentenced in May of last year to two years in federal prison and to \$398,272 in restitution payments.

The two were arrested in July 2014 for their involvement in a months-long campaign of animal extremism by vandalizing property and illegally releasing mink from farms in five separate states. In 2008, Buddenberg was charged in California for alleged illegal activity against researchers, but the charges were dropped two years later.