

Report on Research Compliance Volume 19, Number 3. February 24, 2022 In This Month's E-News: March 2022

By Theresa Defino

◆ Since the start of the year, the Animal and Plant Health Inspection Service (APHIS) has issued notices of alleged violations of the Animal Welfare Act (AWA) to one university and to a health system in Oregon. Both were belatedly issued. In a warning notice of alleged violation dated Jan. 14, APHIS said it “has evidence” the University of Louisiana at Lafayette violated the AWA on Aug. 26, 2021, related to standards for housing facilities, specifically water and electric power. “The housing facility must have reliable electric power adequate for heating, cooling, ventilation, and lighting, and for carrying out other husbandry requirements in accordance with the regulations in this subpart. The housing facility must provide running potable water for the nonhuman primates’ drinking needs. It must be adequate for cleaning and for carrying out other husbandry requirements,” the notice said.

Also dated Jan. 14 is a notice of alleged violation issued to Legacy Health of Portland related to standards for attending veterinarian and adequate veterinary care. APHIS cited provisions in the AWA that require research facilities to “establish and maintain programs of adequate veterinary care that includes: (b)(4) Guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia.” APHIS said evidence shows this provision was violated Sept. 23, 2021. Unlike in previous years, APHIS now withholds details from warning notices that would indicate the specific type of animal involved—such as the kind of nonhuman primate—and any details about the alleged violations. Both notices state that if “APHIS obtains evidence of any future violation of these federal regulations, APHIS may pursue civil penalties, criminal prosecution, or other sanctions for this alleged violation(s) and for any future violation(s).” (2/17/22)

◆ The Office of Science and Technology Policy (OSTP) should make a number of revisions to its Jan. 4 *Guidance for Implementing National Security Presidential Memorandum–33*, the Council on Governmental Relations (COGR) said in a Feb. 15 letter to the agency. Areas of general concern include the lack of attention to adopting a risk-based approach, lack of consistency within the guidance itself and among granting agencies, inappropriate standards for fundamental research, and a need to reduce the “unreimbursed institutional costs” of compliance, among others.

COGR also provided specific feedback, proposing substitute language for the “exceptionally broad” definition of foreign government-sponsored talent recruitment programs, noting that some of the enforcement mechanisms for violations exceed those allowed, offering suggestions for training programs and materials; and pointing out that institutions already have cybersecurity programs in place, so any “mandated cyber security standards specific to research should permit institutions the ability to leverage their compliance with these other federal standards. The research security program also should allow them to determine applicability to institutional components based on risk assessment,” COGR said. (2/17/22)

◆ Jason Edmonds, who the government said was a research biologist for the U.S. Army Combat Capabilities Development Command Chemical Biological Center, has been indicted on charges of conspiracy and bribery for allegedly accepting \$40,000 in cash and directing a center award to John Conigliaro, owner and CEO of EISCO

Inc., the U.S. Attorney's Office for the District of Maryland announced Feb. 8. Conigliaro "was separately charged with conspiracy in an Information" earlier in the month. The center is "the primary Department of Defense technical organization for non-medical chemical and biological defense," according to its website.

From 2012 to 2019, "Edmonds accepted cash and other financial benefits...in exchange for favorable action on CB Center contracts. For example, the Indictment alleges that in July 2013, Edmonds directed a \$300,000 CB Center project to EISCO," officials said. Conigliaro then "gave Edmonds \$40,000 in cash so that Edmonds could purchase two rental real estate properties. Once Edmonds purchased the rental properties, the Indictment alleges that Conigliaro paid for thousands of dollars of renovations to the rental properties. The Indictment alleges that Edmonds executed a 'Promissory Note,' in which Edmonds wrote that he repaid Conigliaro a portion of the funds that Conigliaro had given him with CB Center projects." The government added that, "from 2016 to 2018, Edmonds directed four CB Center projects to EISCO. Over that same time period, Conigliaro allegedly paid for more than \$30,000 in renovations to Edmonds' personal residence." A conspiracy conviction carries a sentence of up to five years, while bribery may result in a term of up to 15 years. (2/10/22)

◆ **A new version of H.R. 4521, the America Creating Opportunities for Manufacturing, Pre-Eminence in Technology, and Economic Strength (COMPETES) Act of 2022, introduced Jan. 25, is garnering praise from the Association of American Universities (AAU).** In a Jan. 26 statement, AAU President Barbara Snyder offered a "welcome" to the bill, calling it "an important step toward reauthorizing the National Science Foundation (NSF), the Department of Energy's Office of Science, and other research and STEM [science, technology, engineering and math] education programs vital to sustaining our nation's leadership role in science and innovation."

According to Snyder, "the House bill helps bolster the United States' global scientific and technological leadership and economic competitiveness by balancing the need to secure critical federally funded university research with the need to grow and attract both domestic and international STEM talent." Snyder noted that the Senate had already passed its version of the bill, and that the two will need to be reconciled. "As the House considers this legislation, we hope it achieves strong bipartisan support and moves quickly to floor approval" and reconciliation, she added. Snyder noted that in addition to this legislation, Congress needs to adopt appropriations "for the programs it authorizes to maintain U.S. preeminence in science, health, national security, and economic competitiveness." However, AAU also reported in its Jan. 28 weekly newsletter that Rep. Frank Lucas, R-Okla., said the bill "undoes more than a year of bipartisan work by the House Science Committee to develop and pass comprehensive legislation to double investment in basic research." Lucas is the ranking member of the House Science, Space, and Technology Committee. (2/3/22)

◆ **Awardees with funds from NIH's Small Business Innovation Research and Small Business Technology Transfer programs will be able to "withhold applicable data for 20 years after the award date," according to new FAQs about NIH's data management and sharing (DMS) policy.** In a Jan. 25 blog post, Lyric Jorgenson, acting director of the NIH Office of Science Policy, said the first set of nine FAQs will be followed by additional resources in the future. Other FAQs addressed noncompliance with the policy, which goes into effect a year from the blog post (Jan. 25, 2023). NIH may terminate an award or add special terms and conditions, which it did not specify. Awardees that aren't found to have complied with their DMS plan may find that used against them when they apply for funding in the future, according to an FAQ on enforcement.

Jorgenson explained that NIH's goal is to make "sharing the norm," and noted that while some organizations may already have policies in place, "prospective planning for how to share data (i.e., developing plans, requesting NIH funds) may be new for some." During the year, NIH plans to issue "tips for developing budgets in Plans describing data management and sharing," "updated information on principles for protecting research participant privacy and de-identification to help guide sharing of research participant data," "educational resources including webinars and potentially sample Plans," and "plans for further harmonizing NIH's data

management and sharing expectations, particularly with reducing duplicative plan submissions,” Jorgenson wrote. (2/3/22)

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