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Direct Impact on Animal Welfare Among Noncompliance in Studies

By Theresa Defino

In recent years, half of the incidents of noncompliance discovered during semi-annual inspections and reported to the NIH Office of Laboratory Animal Welfare (OLAW) involved “direct impacts on animal welfare,” with issues related to euthanasia and pain medications among the more common problems.

During a recent webinar^[1] in which federal officials discussed plans to implement changes stemming from the animal research provisions in the 21st Century Cures Act,^[2] OLAW Director Patricia Brown gave some details about the small percentage of serious noncompliance issues spotted during inspections.

Other speakers were Betty Goldentyer, deputy administrator of the Animal Care program at the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) and Brianna Skinner, a senior regulatory veterinarian with the Food and Drug Administration (FDA).

Brown’s remarks were part of an explanation as to why the agency is sticking with its requirement for semiannual inspections, rather than dropping that down to annual as some had requested (others were opposed).

‘Critical’ Role for Inspections

In September, OLAW, USDA and the FDA jointly issued a report^[3] describing burden-reducing actions they would take as part of compliance with a Cures Act requirement to facilitate animal research. The report followed a request for comments on a draft version.

In stating it would continue to require semiannual inspections by institutional animal care and use committees (IACUCs), OLAW noted that “approximately 7% of the self-reported noncompliant incidents were identified” during such inspections.

Semiannual inspections remain a “critical” part of oversight, Neera Gopee, director of OLAW’s Division of Policy and Education, said during the Q&A portion of the webinar. Gopee then posed a question to Brown submitted prior to the webinar: “What percent of the 7% actually involved animal welfare?”

Brown said that 89% of the reported noncompliance found in semiannual inspections had the “potential” to affect animal welfare, and that 50% more clearly did.

She presented a pie chart, showing data from Jan. 1, 2017, to March 1, 2019. Brown said that in 13% of the reports any possible direct impact on animals was “unclear.”

But, she added, “the nature of the noncompliance that was reported had a very high risk of impacting animal welfare. An example is use of expired drugs and, in particular, the use of expired analgesics.”

Another type of noncompliance that could affect animal welfare is “failing to give post-op analgesia when no clinical signs of pain were reported, but there was still certainly a potential for observable impact on animal

welfare, because failing to give analgesics post-operatively has a high probability of increasing pain,” said Brown. “A similar example would be failure to apply aseptic technique. Not having dehiscence [wound separation] or infection may be due to luck or to the use of antibiotics, but it is a high potential risk to animal welfare that would qualify.”

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