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Meat Animal Research Center: The Animal Welfare Act and Farm Animal Research

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Summary

On January 19, 2015, the *New York Times* (NYT) published an exposé of research activities at the Roman L. Hruska U.S. Meat Animal Research Center located near Clay Center, Nebraska. The Center is a U.S. Department of Agriculture (USDA) facility overseen by USDA's Agricultural Research Service (ARS). A veterinarian, who had worked at the Center for 24 years, approached the newspaper after his concerns about animal welfare conditions apparently went unanswered by the Center. The news article described "unsanitary housing and brutal treatment of pigs; violent forced mating between bulls and cows; and hormonal experiments conducted on sheep," among other animal welfare issues.

The NYT article raised significant public concern about animal welfare standards at the Center and other federal research facilities, especially because farm animals and federal research institutions are exempt under the Animal Welfare Act, the major federal statute governing animal research activities and other animal well-being conditions. In response to the article, the Secretary of Agriculture ordered USDA staff to deliver an updated Animal Welfare Strategy plan for the center and other ARS laboratories. In addition, ARS announced the appointment of the first ever Animal Welfare Ombudsman to coordinate a USDA review of animal welfare at the Center and other ARS laboratories.

The Secretary of Agriculture established an Animal Handling and Welfare Review Panel and charged it with reviewing ARS-wide research animal care and welfare policies. Following a three-day site visit to the Center in February and a public commentary period, the Panel published its final report on March 30. The Panel issued findings from its investigation of the Center and made several recommendations, including improving animal welfare training of the Center's employees and establishing clearer lines of authority in the Center's cooperative agreement with the University of Nebraska regarding oversight of animal care and use in research and teaching activities. The report also emphasized that the Federation of Animal Science Societies *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (Ag Guide) should be the primary document for policies guiding animal care and well-being. While this document is cited by ARS as a guiding document in its own Directive for animal welfare, the Panel noted failures to adhere to some of the Ag Guide's standards. The most significant recommendations of the Panel concerned the inadequacy of the Institutional Animal Care and Use Committee (IACUC) at the Center. An IACUC is a requirement under the Animal Welfare Act and is responsible for oversight of research activities involving animals.

On September 28, 2015, USDA's Office of Inspector General (OIG) published its interim review of the Meat Animal Research Center. The OIG reviewed 33 statements in the original NYT article, interviewed key individuals, and conducted a performance audit of the Center. On completing its fieldwork, the OIG will issue a final report.

Bills have been introduced in Congress to address some of the issues raised by the NYT article. The Animal Welfare in Agricultural Research Endeavors Act (AWARE; H.R. 746 and S. 388) was introduced on February 5 in the House and Senate. The identical bills would amend the AWA to include under its jurisdiction farm animals being used in agricultural research at federal facilities.

On June 18, 2015, the House Appropriations Subcommittee on Agriculture, Rural Development, and Food and Drug Administration approved an FY2016 appropriations bill that prohibits obligating \$56,123,000 of the total ARS appropriation until the Secretary of Agriculture certifies in writing to both the House and Senate Appropriation Committees that ARS has updated its animal care policies and that all ARS research facilities at which animal research is conducted have a fully functioning IACUC, including all appropriate and necessary record keeping.

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Background

On January 19, 2015, the *New York Times* (NYT) published an exposé of research activities at the Roman L. Hruska U.S. Meat Animal Research Center (the Center) located near Clay Center, Nebraska.¹ The Center is a U.S. Department of Agriculture (USDA) facility overseen by USDA's Agricultural Research Service (ARS).² The NYT article was reportedly initiated when a veterinarian, who had worked at the Center for 24 years, approached the newspaper after his concerns about animal welfare conditions apparently went unanswered by the center. The news article described “unsanitary housing and brutal treatment of pigs; violent forced mating between bulls and cows; and hormonal experiments conducted on sheep,” among other animal welfare issues.

The research practices reported in the NYT article raised significant public concern about animal welfare standards at the Center. It prompted the Secretary of Agriculture on January 26 to order USDA staff to deliver an updated Animal Welfare Strategy plan for the Center and other ARS laboratories within 60 days. In addition, on January 27, ARS announced the appointment of the first ever Animal Welfare Ombudsman to coordinate USDA's review of animal welfare at the center and other ARS laboratories.

The Center was authorized by Congress in 1964 and opened in 1966. It currently houses nearly 30,000 animals and operates with approximately 117 staff. Units at the Center conduct research in animal health, environmental management, genetics and breeding, meat safety and quality, nutrition, and reproduction. The Center is operated under a cooperative agreement with the University of Nebraska-Lincoln. Other land-grant universities also have cooperative research and training arrangements with the center.

The Federal Animal Welfare Act

In the wake of the NYT article, alleged conditions at the Center raised questions about possible violations of the federal Animal Welfare Act (AWA; 7 U.S.C. 2131 et seq.). The AWA is the major federal statute governing the welfare of animals used in laboratory research.³ Select animals used in research are subject to AWA standards and oversight by USDA's Animal and Plant Health Inspection Service (APHIS). In particular, dogs, cats, non-human primates, guinea pigs, hamsters, rabbits, and some other species come under regulation. Birds, rats, and mice bred for research; horses not used for research; and farm animals are exempt from AWA regulation.

Regulatory standards for laboratory animal welfare were strengthened in the Food Security Act of 1985 (P.L. 99-198, 1985 farm bill), which amended the AWA. It established minimum requirements for care and treatment of regulated animals in research facilities. Veterinary schools, research universities, medical schools, diagnostic laboratories, pharmaceutical firms, and other facilities that use regulated animals for research, teaching, or exhibition must register with USDA and be inspected by APHIS.

¹ “U.S. Research Lab Lets Livestock Suffer in Quest for Profit: Animal Welfare at Risk in Experiments for Meat Industry,” *New York Times*, January 19, 2015, <http://www.nytimes.com/2015/01/20/dining/animal-welfare-at-risk-in-experiments-for-meat-industry.html>.

² For more information on the U.S. Meat Animal Research Center, see http://www.ars.usda.gov/main/site_main.htm?modecode=30-40-05-00.

³ CRS Report RS22493, *The Animal Welfare Act: Background and Selected Animal Welfare Legislation*, by (name redacted).

In addition to setting regulatory standards for animal welfare at research facilities, the AWA requires that research facilities using regulated animals establish an Institutional Animal Care and Use Committee (IACUC). IACUCs are composed of at least three members, one of whom is the Attending Veterinarian of the research facility and one of whom is not affiliated in any way with the facility other than as a member of the committee. The chief executive officer of the research facility appoints the IACUC members. The AWA charges the IACUC with evaluating the care, treatment, housing, and use of animals and certifying compliance with AWA standards by the research facility. The IACUC of a non-federal research facility reports compliance problems to APHIS.

However, the regulations implementing the AWA provide certain exemptions for federal research facilities. Federal agencies that conduct animal research are not required to register with USDA, nor are they inspected by APHIS. However, AWA regulations require that federal facilities establish an IACUC that reports deficiencies to the head of the federal research agency rather than to APHIS.

ARS's Humane Animal Care Policy Covers Farm Animals

Although the AWA explicitly exempts farm animals from regulation under the act, ARS's own guidelines for research practices cover all vertebrate animals, including livestock and farm animals, in all its locations under its Humane Animal Care and Use policy.⁴ Animal welfare standards in this ARS policy are virtually the same as those of the AWA.

Additionally, ARS policy requires that all ARS locations using agency funds, personnel, or physical resources and engaging in research and testing on vertebrate animals establish an IACUC. ARS policy also includes oversight by an IACUC of non-ARS animals at ARS locations or at a non-ARS location using either ARS funds or personnel. The Center had established an IACUC composed of five members and chaired by the Center's Attending Veterinarian.

Semi-annual reports of the IACUC are required under ARS's animal care policy. These reports must contain a description of and the reasons for any major deviations from the requirements outlined in ARS policy. In cases of major deviations, the IACUC chair and Attending Veterinarian can immediately suspend the activity, request immediate correction of the deviation, or, ultimately, terminate the activity.

Animal Handling and Welfare Review Panel

After publication of the NYT article on the Center, the Secretary of Agriculture established an Animal Handling and Welfare Review Panel and charged it with reviewing ARS agency-wide research animal care and well-being policies.⁵ The Panel established a two-phase review process. Phase 1 was a review of the Meat Animal Research Center and its activities.⁶ Phase 2 charged the Panel with reviewing an additional three to five ARS locations where animal research is conducted. The Phase 2 review is currently being planned.

⁴ USDA, *Humane Animal Care and Use*, Directive 635.1, August 1990, <http://www.afm.ars.usda.gov/ppweb/pdf/635-01.pdf>.

⁵ The establishment of the Panel is authorized under Section 1409(a) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (P.L. 95-113; 7 U.S.C. 3124a(e)).

⁶ The Animal Handling and Welfare Review Panel did not specifically investigate the various allegations of animal abuse made in the *New York Times* article. USDA's Office of Inspector General is currently planning an investigation of those particular allegations.

The Review Panel was composed of four members and an ex-officio member appointed by the Secretary of Agriculture. In its review of the Center, the Panel was charged specifically with the following responsibilities:

- A review of ARS policies and procedures for care and well-being of animals used in research;
- A field visit to the Center and inspection of areas where animals are housed or where they are involved in experimentation;
- A review of the Center's IACUC, records of its meetings, evaluation of its compliance with ARS policies and procedures used to select research topics, and evaluation of the experimental design and protocols under the IACUC;
- An assessment of the Center's animal care and well-being training for staff with responsibility for handling animals;
- Preparation of a report for the Secretary and the Under Secretary for Research, Education, and Economics that summarizes the Panel's findings; reaches conclusions regarding compliance with ARS policies and procedures; and makes specific recommendations for the Center to improve compliance with ARS standards and, where necessary, industry standards.

On March 30, 2015, the Panel published its final report on Phase 1, the review of the Center.⁷ The report's findings are discussed below.

Review Panel Report Findings and Recommendations

With respect to ARS policies and procedures for care and well-being of animals, the Panel noted that ARS identified the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (Ag Guide) by the Federation of Animal Science Societies (FASS) as the primary document guiding its use of agricultural animals at ARS facilities.⁸ While the ARS Directive for animal care cites the Ag Guide as a primary document, the Panel reinforced use of the Ag Guide as the guiding source for the care and use of animals at ARS facilities.

The Panel found the Center's grounds, pastures, and physical facilities were adequate and appropriate for animal care and handling, and that animal handling equipment was consistent with current industry practices. Obsolete equipment had been removed, and new animal handling facilities (e.g., new swine barns) had been designed and constructed. The Panel observed no visible signs of neglect or mistreatment of animals; animals were treated with care and professionalism, according to the Panel. The observed absence of stress among the Center's animals, their calmness at handling, and their nutritional status were noted by the Panel as "indicative of regular and high-quality animal management and care."

The Panel did note that, while handling and veterinary care were adequate to the Center's operation, the Ag Guide states that while those responsible for handling and care of animals are qualified to do so through their training and experience, the Panel saw no evidence of a "clearly defined animal handling training program with a corresponding method for documenting the

⁷ Findings and Recommendation on the Animal Care and Well-Being at the U.S. Meat Animal Research Center to the Secretary of Agriculture and the REE Under Secretary, March, 2015, http://www.ree.usda.gov/ree/news/USMARC-AWHR-Panel-Report_FINAL%20FINAL.pdf.

⁸ Federation of Animal Science Societies, *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, Tenth Edition (2010), http://www.fass.org/docs/agguide3rd/Ag_Guide_3rd_ed.pdf.

completion of appropriate training” as recommended by the Ag Guide. Accordingly, the Panel recommended the development and implementation of an appropriate training and documentation program for all individuals involved with the handling and use of animals in research. As part of such training, the Panel noted that animal handlers should know how to report welfare concerns and should be knowledgeable of “whistleblower” policies. Consistent with improvements in staff training, the Panel further suggested development of means to recognize individuals with excellent animal care skills by implementing a tiered classification system for animal care technicians at the Center.

Of particular note, the Panel concluded that the Center’s IACUC was not adequately fulfilling its research oversight responsibilities. The IACUC is responsible for reviewing, approving, requiring modifications, or denying proposed research activities involving animals. The IACUC was not compliant with ARS policies and procedures that call for the facility to follow Ag Guide standards. The Center’s IACUC relied on a research review and consultation system that the Panel found lacked a process for formal review and approval. Nor were there regularly convened meetings of the IACUC as recommended by the Ag Guide. The Ag Guide states the various responsibilities of the IACUC regarding research protocols, objectives of research or teaching, and other activities involving the use of animals. While the Panel did not find any research projects that should not have been approved by the IACUC, the Panel concluded that the Center’s IACUC was not adequately fulfilling its responsibilities, particularly its duty “to review and approve or disapprove protocols and other proposed activities related to animal care and use.” Nor had the IACUC followed formal ARS procedures in approving Center research projects.

Based on these observed IACUC shortcomings, the Panel recommended that (1) the Center develop and implement processes that “promote a robustly functioning IACUC that is consistent with the Ag Guide and with current practices in the field of animal research;” (2) that no proposed research or facility inspections be conducted unless a properly constituted IACUC is in place; (3) that the Attending Veterinarian should not serve as the Center’s chair of the IACUC; and (4) that the use of all vertebrate animals (e.g., rodents) should be reviewed and approved by the IACUC.

The Panel also investigated the Center’s administrative and operational structure. The Center and the University of Nebraska operate under a cooperative agreement. The animal care program consists of two integrated components: (1) livestock production and (2) active research programs. The livestock production program supports the research program by providing animals that may be used in research, as well as providing animals for evaluation of livestock production management practices. Under the cooperative agreement, University of Nebraska employees operate and oversee the livestock production operations, while the Center’s staff conduct and oversee the research program. The Panel noted that this cooperative agreement did not directly address oversight of animal care and welfare, particularly the specific responsibilities of the IACUC of the Center and the IACUC of the University of Nebraska.

Acknowledging what the Panel called “excellent communication” between the University of Nebraska and the Center, the Panel nonetheless noted the potential for confusion about lines of authority and oversight responsibilities. Although no incidences of deficiency in animal health or care due to uncertainty about current lines of authority were cited by the Panel, the Panel recommended that the Center develop and implement written agreements with the University of Nebraska (and any other research or teaching partners) to ensure optimum lines of responsibility for the oversight of animal care and welfare in research and teaching.

Public Response to the Review Report

An open comment period on the Panel’s report was announced on March 13, 2015.⁹ This announcement was followed by an open meeting of the Animal Handling and Welfare Review Panel on March 18 to discuss the draft report. Written comments were taken between March 13 and March 18. Verbal comments were taken at a March 18 public meeting. The final report included a summary of the public comments. Nearly 60,000 comments were received, including eight verbal comments made at the March 18 public meeting. Over 37,000 comments stated that all animals used in research at ARS facilities should be protected under the AWA. Over 20,000 comments stated that USDA should close the Meat Animal Research Center, require all USDA facilities funding animal research to comply with the AWA, and investigate all other USDA facilities to ensure animals were not being abused. Nearly 1,500 comments requested an Office of the Inspector General investigation and an end to the use of U.S. taxpayer funds for the Center’s research.

A wide range of animal welfare organizations provided comments on the Panel’s report. The Anti-Vivisection Society, while agreeing with all the recommendations, also pointed to long-standing problems with the oversight by IACUCs. The Humane Society of the United States and the American Society for the Prevention of Cruelty to Animals argued that the report did not go far enough in its investigation and ignored past abuses within other ARS facilities. The Animal Welfare Institute called for more unannounced inspections of ARS facilities by USDA. The American Veterinary Medical Association (AVMA) supported the recommendations of the Panel, especially the Panel’s recommendations on the importance of training for employees handling and caring for animals. The AVMA also called for increased veterinary oversight of all medical and surgical procedures. The North American Meat Institute and the Nebraska Cattlemen supported the Panel recommendations, praised the Center’s work, and emphasized the importance of ARS research to the meat industry.

USDA’s Office of Inspector General Interim Report

On September 28, 2015, USDA’s Office of Inspector General (OIG) published its interim review on the Center. The OIG review evaluated 33 statements in the original NYT article to make a determination of their veracity. The OIG review had no observation on 11 of the statements. On the other 22 statements, the review commented on whether evidence did or did not support the statements in the review. In general, the OIG report found that the activities discussed in the NYT article were “were generally in line with industry norms,” or the review found no confirmatory evidence of the article’s statements. As determined by the Review Panel’s findings discussed above, the OIG review also noted that the IACUC was not adequately fulfilling its intended role. The OIG review is preliminary, and the findings are subject to change in the final report to be issued when the fieldwork is completed.

Congressional Action

Bills have been introduced in Congress to address some of the issues raised by the NYT article. The Animal Welfare in Agricultural Research Endeavors Act (AWARE; H.R. 746 and S. 388) was introduced on February 5, 2015, in the House and Senate. These identical bills would amend the AWA to end the exemption for farm animals used in agricultural research at federal facilities. Farm animal research at nonfederal facilities is not addressed. H.R. 746 was referred to the

⁹ *Federal Register*, Vol. 80, No. 49, 13324, March 13, 2015.

Subcommittee on Livestock and Foreign Agriculture of the House Agriculture Committee, and S. 388 was referred to the Senate Committee on Agriculture, Nutrition, and Forestry.

While H.R. 746 and S. 388 would remove the AWA exemption for farm animals and livestock in federal research facilities, some policymakers are concerned that such an amendment could be a first step to on-farm regulation of livestock at commercial farms, dairies, ranches, and feedlots under AWA permit and inspection provisions. Other observers of animal care and welfare also have suggested that including farm animals housed exclusively in research facilities under AWA jurisdiction might not be disruptive to production agriculture and potentially address some of the alleged welfare abuses raised by the NYT article. Since APHIS currently does not inspect federal research facilities, Congress could also consider bringing such federal facilities under the same USDA registration and APHIS inspection as non-federal research facilities.

On June 18, 2015, the House Appropriations Subcommittee on Agriculture, Rural Development, and Food and Drug Administration approved an FY2016 appropriations bill that prohibits obligating \$56,123,000 of the ARS appropriation until the Secretary of Agriculture certifies in writing to both House and Senate Committees on Appropriation that ARS has updated its animal care policies and that all ARS research facilities at which animal research is conducted have a fully functioning IACUC, including all appropriate and necessary record keeping.

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