

Laboratory Animals: An Executive, Legislative, and Judicial Narrative & Research Guide

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Are the animals most widely used in laboratory research really animals at all, that is, within the meaning of the Animal Welfare Act ([AWA](#)) and its regulations? The controversy hinges on the definition of “animal” in the statute, currently found at [7 U.S.C. § 2132 \(g\)](#) (2004), and in the Animal and Plant Health Inspection Service ([APHIS](#)) regulations promulgated under AWA authority, at 9 C.F.R. § 1.1. The debate over the level of protection offered rats, mice and birds used in research provides an instructive example of all three branches of government at work, if not always in perfect harmony, for nearly forty years, and demonstrates a few nuances of federal legislative and regulatory history research. This Guide contains some legislative history of the AWA (§§ I & III, V-VI, VIII-IX); the evolution of the regulatory definition of “animal” (§§ II, IV & X); and some important court challenges (§§ VII).

I would like to acknowledge the valuable assistance of Sue A. Leary, President, [Alternatives Research & Development Foundation](#), who kindly provided documents that helped me fill in many gaps and bring the controversy up to date.

- I. The purposes of the Animal Welfare Act (AWA) (originally known as the Federal Laboratory Animal Welfare Act), Pub. L. No. 89-544, 80 STAT. 350 (1966), codified as amended at 7 U.S.C. § 2131 et seq. (2004), originally were:
 - A. To protect the owners of dogs and cats from the theft of such pets;
 - B. To prevent the sale or use of dogs and cats which have been stolen;
 - C. To insure that certain animals intended for use in research facilities are provided humane care and treatment.
 1. See Congressional statement of policy, 7 U.S.C. § 2131 (2004) for the current language.

2. An article by Joseph Mendelson, III, *Should Animals Have Standing? A Review of Standing Under the Animal Welfare Act*, 24 B.C. ENVTL. AFF. L. REV. 795, 796-801 (1997), gives a short history of the AWA through the 1985 amendments.
- D. The definitions section of the enacted law, § 2(h), stated: “The term 'animal' means live dogs, cats, monkeys (nonhuman primate mammals), guinea pigs, hamsters, and rabbits...”
- E. The legislation appears to have had an arduous journey through Congress, one that began at least six years earlier when Mr. Cooper introduced what he believed to be the first bill in the Senate to provide for humane treatment of laboratory animals. See 112 CONG. REC. S13895 (June 22, 1966) (statement of Senator Cooper).
1. See Dael Wolfle, *Humane Treatment of Animals*, 132 (3418) SCIENCE 7 (July 1, 1960), for an editorial attack on S. 3570, 86th Cong. (1960).
 2. But see a response by the same title in a letter by Professor Bradley T. Scheer, at 132 (3430) SCIENCE 851-52 (Sept. 23, 1960) (“[I]t seems to me that the requirements [of S. 3570] are not greatly beyond those now in force.... I hope that all of us who publish results of animal experiments do at least the amount of record keeping specified by the bill.... In sum, I cannot find in this bill the evils which the National Society for Medical Research or *Science* profess to see....”).
- F. “Something like” 60 or 70 bills (“at least”) were introduced to the House alone in the 89th Congress (1965-66) to regulate the transportation, sale, and handling of dogs and cats for commerce or research. See 112 CONG. REC. H9210 (April 28, 1966) (statement of Rep. Poage).
1. In fact, according to the CCH CONGRESSIONAL INDEX (an invaluable source of information on bills, enacted or not, going back to 1937), 82 bills were introduced

during the 89th Congress (1965-66), 73 in the House, 9 in the Senate. (Topic: *Science & research, animals.*)

- a. See *Concentration Camp for Dogs—Pets are up for sale cheap—and no questions asked*, LIFE, Feb. 4, 1966, at 22, which graphically documented thefts of pet dogs to supply research facilities and laboratories, which “now need almost two million dogs a year.... the Humane Society of the U.S. estimates that 50 percent of all missing pets have been stolen by ‘dognapers,’.... Some dealers keep ... dogs in unspeakably filthy compounds that seem scarcely less appalling than the concentration camps of World War II. ... Stirred by revelations to a House subcommittee of such outrages and prodded by the continuing raids on these camps by humane societies, Congress already has eight bills pending, any of which would outlaw these shameful conditions.” *Id.* The photographs, of a Humane Society raid on a compound in Maryland, are utterly heartbreaking.
2. The article may have influenced Congress’ introduction and passage of H.R. 13881 and was mentioned in the CONGRESSIONAL RECORD. See, e.g., 112 CONG. REC. H9222 (April 28, 1966) (statement of Rep. Boland) and 112 CONG. REC. H9227 (April 28, 1966) (statement of Rep. Helstoski).
3. Editorials in support of legislation to require humane treatment of research animals were published in newspapers across the country (e.g., the WASHINGTON POST, SACRAMENTO BEE, NEW YORK TIMES), and were reproduced at 111 CONG. REC. 10574-10576 (May 14, 1965).
 - a. Several commented that one bill, Senator Clark’s S. 1071, was modeled after an English law from 1876.

G. The legislative history includes the following:

1. For consideration of H.R. 13881, see 112 CONG. REC. H9207-31 (April 28, 1966) (“[T]he Committee on Agriculture has received over 30,000 letters and cards; heard or received statements from some 150 witnesses; considered 45 bills...” (statement of Rep. Dague)); H.R. 13881 was read into the Record at 112 CONG. REC. H9224-25, and committee amendments followed; alternative bills covered all vertebrate animals used in federally financed scientific research, not only dogs and cats (see 112 CONG. REC. at H9219 (comparison chart), and H9223 (statement of Rep. Cleveland)); 112 CONG. REC. S13885-98 (June 22, 1966).
2. H.R. Rep. No. 89-1418 (1966) (to accompany H.R. 13881).
3. S. Rep. No. 89-1281, 89th Cong., 2d Sess. (1966), 1966 U.S.C.C.A.N. 2635 (to accompany H.R. 13881).
4. H.R. 13881 was passed in the House with 352 votes for, 10 against, and 70 abstaining (112 CONG. REC. H 9230 (April 28, 1966)); and passed unanimously in the Senate (112 CONG. REC. S13897 (June 22, 1966)).
 - a. However, the Senate had amended the House bill, and thus the Houses had passed different bills with the same number. A conference committee was formed.
5. H.R. Conf. Rep. No. 89-1848 (1966), 1966 U.S.C.C.A.N. 2649 (to accompany H.R. 13881).
6. On August 17, 1966, the Senate followed the House’s example and passed the substitute H.R. 13881. See 112 CONG. REC. S19753-54.

- H. The Laboratory Animal Welfare Act was signed into law as Pub. L. No. 89-544, on August 24, 1966.
- II. On December 15, 1966, the Agricultural Research Service published a Notice of Proposed Rule Making, at 31 Fed. Reg. 16110, in response to the enactment of the AWA. It proposed “to issue regulations and standards to appear as a new Subchapter A in Chapter I, Title 9, Code of Federal Regulations, to be designated ‘Laboratory Animal Welfare,’...”
- A. Section 1.1(l) of the Definitions section simply read: “‘Animal’ means any live dog, cat, nonhuman primate mammal, guinea pig, hamster, or rabbit.”
 - B. The new rules were finalized at 32 Fed. Reg. 3270, on February 24, 1967.
- III. In 1970 the AWA was amended to protect *all warm-blooded animals*, with an important administrative caveat: “[T]he term ‘animal’ ... includes any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animals *as the Secretary may determine* is being used, or intended for use, for research... .” Pub. L. No. 91-579, § 3 (3) (g), 84 STAT. 1560, 1561 (Dec. 24, 1970) [emphasis supplied].
- A. See also H.R. REP. No. 91-1651; 116 CONG. REC. 40152-59 (Dec. 7, 1970), considered and passed the House; 116 CONG. REC. 40460-62 (Dec. 8, 1970), considered and passed the Senate.
 - 1. The expansion in coverage to all warmblooded animals was praised by several representatives who rose in support of the legislation.
 - a. See, e.g., Representatives Foley (at 116 CONG. REC. 40154); Montgomery and May (id. at 40156); Kleppe (id. at 40157); Mayne (id. at 40158); Mizell, Matsunaga, and Price (id. at 40159); and Senator Cotton (id. at 40460).

2. H.R. Rep. No. 91-1651, reprinted in 1970 U.S.C.C.A.N. 5103, states that H.R. 19846, the enacted bill, “includes within its definition all warm-blooded animals designated by the Secretary with only limited and specifically defined exceptions” (id. at 5104), and that “[u]nder this section... it would be expected that the Secretary would designate *additional* species of those animals not previously covered as permitted by available funds and manpower.” [emphasis supplied] (id. at 5108).
 - a. A letter from the Under Secretary of Agriculture, included in the report at 1970 U.S.C.C.A.N. 5105-06, predictably expressed concern over the expansion of coverage to all warm-blooded animals. Mr. Campbell suggested that the proper agency to administer the act would (surprisingly) be HEW, and that “regulating the humane care and handling of animals by exhibitors and pet dealers should be the responsibility of State and local agencies rather than the Federal Government.” (Apparently he hadn’t reviewed the Commerce Clause recently. See U.S. CONST. art. I, § 8, cl. 3) In any case, the letter was written about an earlier version of the bill and Mr. Foley felt that Mr. Campbell’s concerns had been satisfied. See 116 CONG. REC. 40155.
 - b. The General Statement at the beginning of the report states that H.R. 19846 “is an effort to demonstrate America’s humanity to lesser creatures while maintaining and promoting the national enlightenment in medicine for the care of all mankind. It is a bill which initially was controversial, but which, by virtue of good reason and good will and deliberation and discussion by many persons of divergent views, was able to command the unanimous approval of the Committee on Agriculture as well as the joint sponsorship of the entire membership of the Livestock and Grains Subcommittee.” 1970 U.S.C.C.A.N. at 5104.

Was the committee dissembling, intending the agency to put the breaks on and thereby leaving members of Congress with their halos intact? Or were they sincere, and was their clearly stated intent deliberately thwarted by the agency? Stay tuned.

- B. The level of discretion Congress gave to the Secretary to determine the definition of the word “animal,” and the judicial reviewability of the exclusion, is discussed at *ALDF v. Yeutter*, 760 F. Supp. 923, 928-29 (1991) and *ALDF v. Madigan*, 781 F. Supp. 797, 800-01 (1992). See *infra* §§ VII (B) & (C)).

IV. However, despite this arguably clear legislative intent, the Secretary of Agriculture determined on some pretty sweeping exclusions in the regulations.

- A. 9 C.F.R. § 1.1, definitions of terms, was amended in 1971, certainly as a response, and possibly as a defensive measure, to the congressional requirement that the Act protect all warm-blooded animals.

1. See 36 Fed. Reg. 20472 (October 22, 1971) for the notice of proposed rule making, and 36 Fed. Reg. 24,917, 24,919 (December 24, 1971) for the final rule.
2. In his comments to the NPRM, F.J. Mulhern, then-Acting Administrator of the Agricultural Research Service, stated that the “revision of the previous legislation necessitates or makes appropriate certain adjustments in, and additions to, the regulations and standards governing the humane care and handling of certain animals” and that “[t]his proposed revision of the regulations and standards also reflects certain other changes which are proposed to update, clarify, or editorially correct present wording in the interest or [sic] normal progress.” 36 Fed. Reg. 20472 (1971).
3. The Statement of considerations to the final rule stated that comments were received from 352 persons, and divided the comments into 11 topics, one of

which was the definition of “animal.” However, the final rule didn’t elaborate on comments that specifically dealt with the definition any further. See 36 Fed. Reg. 24917 (1971).

- a. “Regulatory history” (as opposed to “legislative history”) is not easy to find, to say the least, and it took many phone calls and emails to officials at APHIS (the successor agency to the Animal and Plant Health Service) ostensibly in charge of records retention to learn whether those 33-year-old comments are still extant and, if so, where they could be found.
- b. An email from Judy L. Lee at AHPIS, Sept. 22, 2004, stated: “[T]he archives have destroyed all records over 30 years old because they don’t have the space to keep the records.”
- c. However, a subsequent email from Cynthia Howard, Chief, Regulatory Analysis and Development at APHIS, received on Sept. 28th, 2004, stated that: “In most cases, our records are retained for *20 years* and then destroyed,” [emphasis supplied], and that she would check on the records’ possible existence. On the 30th she wrote again and said: “After checking our files and archive records, we have determined that we no longer have the comments you requested. In accordance with standard procedures, the files for this rulemaking were most likely destroyed at the Archive Center in 1991, 20 years after publication of the final rule.”
 - (1) I was disappointed, but must admit that twenty years is a surprisingly long time. Other agencies might have a different retention policy. But the fact that comments are retained at all might be useful for you to know.

d. Whether the agency relied on those comments in the final rule is probably unknowable at this point, as the only way to uncover that information is to contact someone who works at the agency, was involved in the rulemaking, and has a very good memory.

4. It was at this time that the word “Laboratory” was deleted from the title of Subchapter A, as the revised Act also included regulation of animals intended for exhibition or for pets, as well as research animals.

5. The revised language read: “‘Animal’ means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or any other warmblooded animal, ...and is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes or as a pet. *Such term excludes birds, ... rats and mice, ...*” 36 Fed. Reg. 24919 (1971) [emphasis supplied].

B. See Henry Cohen, *The Legality of the Agriculture Department’s Exclusion of Rats and Mice from Coverage Under the Animal Welfare Act*, 31 ST. LOUIS U. L.J. 543 (1987) for the legislative history of the 1970 amendments’ definition of “animal,” at 544-46. Mr. Cohen argues that the exclusion of rats and mice is “inconsistent with the Act and is therefore illegal.” *Id.* at 543.

1. NB: Mr. Cohen, at note 9, gives an incorrect Federal Register cite (42 Fed. Reg. 31,025 (1977)) for the first regulatory promulgation of the exclusion of rats and mice.

V. The AWA was amended again in 1976...

A. See Animal Welfare Act Amendments of 1976, Pub. L. No. 94-279, 90 STAT. 417 (codified as amended at 7 U.S.C. §§ 2131 et seq).

- VI. And amended again, on December 23, 1985, by ISLAA, the Improved Standards for Laboratory Animals Act, within the Food Security Act of 1985, Pub. L. No. 99-198, Title XVII, Subtitle F, 99 STAT. 1354, 1645.
- A. See Esther F. Dukes, *The Improved Standards for Laboratory Animals Act: Will It Ensure that the Policy of the Animal Welfare Act Becomes a Reality?*, 31 ST. LOUIS U. L.J. 519, 523-24 (1987).
- B. Section 1751, at 99 STAT. 1645, stated that Congress found that alternative methods of testing were being developed that were preferable (faster, less expensive, more accurate) to animal experiments, and that “measures that eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds.” *Id.* at § 1751 (2) and (3).
- VII. Litigation ensued.
- A. Two years later, in March 1987, APHIS proposed to amend 9 C.F.R. Part 1, definitions of terms, to comply with the 1985 AWA amendments. See 52 Fed. Reg. 10292. (“All warmblooded animals are covered by the Act [since the 1970 amendments, *supra* § III], however, the Department will still exclude from regulation ...laboratory-bred species of rats and mice....” *Id.*) Concerned individuals (over 1000 of them) stated in their comments that the “definition should encompass all warmblooded animals, including rats, mice, birds,...” but, two years later, in a request for supplemental comments, USDA refused.
1. In its refusal the agency stated: “... Neither are we changing our definition of ‘animal’ to include birds, rats and mice. We do have the authority to regulate these animals, though except for wild rats and mice, we have never covered them in our regulations. However, in response to the comments we received, we are considering developing regulations and standards for them. Development of new regulations and standards ... is a time-consuming process. We do not

believe it would be in the best interests of animal welfare in general if we were to delay promulgating the regulations we have proposed. Therefore, we are not changing our proposed definition of 'animal' to include birds, rats and mice in this rule. ... We do want to note that wild rats and mice are covered by our proposed definition, though laboratory-bred rats and mice are not. We are revising the definition of 'animal' to clarify this point." 54 Fed. Reg. 10,823-24 (Mar. 15, 1989).

a. So the proposed rule read: "'Animal' excludes: Birds, rats and mice bred for use in research..." 54 Fed. Reg. 10832 (Mar. 15, 1989).

2. The regulation was finalized at 54 Fed. Reg. 36112 (Aug. 31, 1989). The agency repeated much of the above-quoted language, and revised the language of the definition to be more specific still in its exclusion, which read for the first time and ever since, more or less: "'Animal'... excludes: Birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, ..." Id. at 36120.

3. Then, "...two animal welfare organizations filed a petition with the USDA for a rulemaking to amend the regulation [referring to the exclusion of rats, mice and birds]. When the USDA denied the petition in June 1990, the plaintiffs filed this suit." *ALDF v. Yeutter*, 760 F. Supp. 923, 925 (1991), see *infra*. However, I can find no evidence of either the petition or the denial.

B. In *Animal Legal Defense Fund (ALDF) v. Yeutter*, 760 F. Supp. 923 (D.D.C. 1991), plaintiffs ALDF, the Humane Society of the United States, and two individuals, alleged that the defendants, the USDA and the administrator of APHIS, had violated the mandate of the Federal Laboratory Animal Welfare Act by failing to define rats, mice, and birds as "animals" and including them in their regulations. They sought, *inter alia*, declaratory judgment and an injunction preventing defendants from excluding birds, rats, and mice from the definition of 'animal' in applying and enforcing the Act. Defendants filed a motion to dismiss, claiming that plaintiffs did not have constitutional standing to sue and had

failed to state a claim on which relief could be granted. The court held that the plaintiffs did have standing to sue, and that the regulation at issue, 9 C.F.R. § 1.1, was reviewable.

1. At note 3, the court noted that “[b]y some estimates, rats, mice, and birds are the subjects of more than half of all experimentation using animals,” and cited Cohen, *supra*, 31 ST. LOUIS U. L.J. 543 n.6 (1987).
2. The individual plaintiffs were Dr. Patricia Knowles and William Strauss, members of the plaintiff organizations.
 - a. Dr. Knowles was a psychobiologist who used rats and mice in her research; Mr. Strauss was an attorney and a member of an oversight committee of a facility registered under the AWA, as required by 7 U.S.C. § 2143 (b) (2004). *ALDF v. Espy*, 23 F.3d 496, 499-501 (1994).

C. Back in District Court, the next case was *ALDF v. Madigan*, 781 F. Supp. 797 (D.D.C. 1992).

1. The court gave more background to the litigation (but mistakenly stated that the exclusion of rats, mice and birds dates from the first regulations implementing the Act; as we have seen, it did not).
2. The court decided that plaintiffs successfully showed that the agency’s interpretation of the statute was arbitrary and capricious; it granted ALDF’s motion for summary judgment on the merits, and denied USDA and APHIS’s cross motion.
3. See *Lab Animal Protections Broadened*, THE WASHINGTON POST, Jan. 9, 1992, at A6, and correction, Valerie J. Stanley, *Broad Protections*, THE WASHINGTON POST, Jan. 28, 1992, at A20.

- D. On appeal, in *ALDF v. Espy*, 23 F.3d 496 (D.C. Cir. 1994), the circuit court vacated the district court and held that plaintiffs could not show both constitutional standing to challenge the USDA's exclusion of rats, mice and birds, and a statutory right to judicial review under the APA. The case was remanded with directions to dismiss.
1. See Joshua E. Gardner, NOTE: *At the Intersection of Constitutional Standing, Congressional Citizen-Suits, and the Humane Treatment of Animals: Proposals to Strengthen the Animal Welfare Act*, 68 Geo. Wash. L. Rev. 330, 348-49 (2000).
 2. See also Rick Weiss, *Rats, Mice, Birds: They're Not Animals?*, THE WASHINGTON POST, July 5, 1994, at Z5 (“...[T]he U.S. Court of Appeals has weighed in on the issue, and it looks as though laboratory rodents and birds will remain expelled from the animal kingdom.”).
 3. The huge constitutional issue of standing is outside the scope of this guide. However, you might be interested to know that in a later case, *Animal Legal Defense Fund v. Glickman*, 154 F.3d 426 (D.C. Cir.1998) (en banc), which concerned the AWA's standards for humane treatment of nonhuman primates, the court held that plaintiff's aesthetic injury was sufficient to establish the injury in fact, causation, and redressability prongs of constitutional standing, and that the complaint was within the zone of interests to be protected by the AWA, as required by prudential standing requirements. Thus, “the D.C. Circuit explicitly recognized the right to sue when an individual suffers an aesthetic injury by viewing an animal kept in allegedly inhumane conditions.” Gardner, 68 GEO. WASH. L. REV. at 331. See also Fiona M. St. John-Parsons, “*Four Legs Good, Two Legs Bad*”: *The Issue of Standing in Animal Legal Defense Fund, Inc. v. Glickman and its Implications for the Animal Rights Movement*, 65 BROOK. L. REV. 895 (1999).

- E. On April 29, 1998, the Secretary of Agriculture received a petition for rulemaking sponsored by several individuals and groups, including Alternatives Research and Development Foundation, which promotes alternatives to the use of animals in research, requesting that the definition of “animal” in 9 C.F.R. § 1.1 be amended to include rats, mice and birds. See *Animal Welfare; Notice of Petition and Request for Comments*, 64 Fed. Reg. 4356 (Jan. 28, 1999).
1. USDA’s comments elaborated on the “substantial financial impact on the affected entities and [stated] that the vast majority of rats, mice, and birds being used in biomedical research are already being afforded *certain* protections.” *Id.* at 4357 (emphasis supplied). It went on to describe a 1990 APHIS study of the potential effects of removing the exclusion. The study had found the estimated annual cost to inspect the additional facilities that would be covered by the AWA if the regulation were changed [about 2,324 research sites, in 1990, in addition to the 2,410 sites already regulated] “was at least \$3.5 million (in 1990 dollars), or roughly one-third of the current Animal Care budget.” *Id.* at 4357-58.
 2. Petitioners relied on the sections of the 1985 amendments quoted *supra* at § VI (B) and other statutory requirements that must be met whenever “animals” are used in research (such as the requirement that *animal* pain and distress be minimized), to emphasize the importance of the regulatory definition of “animal” and to support their claim that the definition must be changed to be consistent with congressional intent under the AWA. *Id.* at 4361.
 - a. At note 8, 64 Fed. Reg. 4362, petitioners quote a 1986 report from the Office of Technology Assessment entitled *Alternatives to Animal Use in Research, Testing, and Education*, that stated that, of the at least 17 to 22 million animals used in research in 1983, the majority, between 12 and 15 million, were rats and mice.

2. The court held that plaintiffs did indeed have standing to sue based on a serious aesthetic injury (for which it relied heavily on the binding precedent in *ALDF v. Glickman*, 154 F.3d 426, 432 (D.C. Cir.1998), discussed supra § VII(D)(2)), and held that the agency's action was not insulated from judicial review; it refused to grant defendants' motion.
- G. USDA, fearful of the outcome if the case went to trial on the merits, as an adverse judgment by the U.S. District Court was "a very real possibility," reached a settlement with ARDF to resolve the lawsuit. The agreement, filed with the U.S. District Court for the District of Columbia on September 25, 2000, officially ended the case. Under it, USDA agreed to grant plaintiffs' petition for rulemaking filed on April 29, 1998; to propose and finalize a rule (in a "reasonable time") to regulate rats, mice, and birds under the AWA; to keep plaintiffs' counsel informed of the procedural status of the rulemaking process; and to pay part of plaintiffs' legal fees. See *Rats, Mice and Birds Settlement Agreement*, synopsis available at <http://www.aphis.usda.gov/ac/q4.html> (visited 1/17/05). However, as the site also states, the legislature nearly immediately mooted these good intentions. See infra § VIII.
1. Settlement agreements are not always subject to public disclosure, although with a federal agency as a party it would seem likely that this one would be.
 2. The D.C. District Court's Web page, <http://www.dcd.uscourts.gov/>, said to request documents only by U.S. mail or phone, not by email.
 - a. When I called, the gentleman in the Clerk's Office saw only the stipulation of dismissal, no settlement agreement, and believed that the case was on appeal, which tipped me off that there were subsequent cases to look for.

- b. He faxed me the docket sheet and I could see that the Stipulation of Dismissal was what I needed. (It appears that USDA's terminology was faulty on <http://www.aphis.usda.gov/ac/q4.html>, as well as most of its dates.)
 - c. The subsequent cases were *ARDF v. Veneman* [the new USDA Secretary], 262 F.3d 406 (D.C. Cir. 2001), and an unpublished order from the same day. After the district court denied USDA's motion to dismiss in *ARDF v. Glickman*, the National Association for Biomedical Research sought to intervene in the case. After the parties entered into the stipulation of dismissal, NABR had filed a motion to vacate the stipulation, and the district court had denied both the motion to intervene and the motion to vacate; the D.C. Circuit affirmed.
3. In my search for the settlement/stipulation agreement I contacted ARDF (from the information given at <http://www.ardf-online.org/>) and was delighted to receive a return email from its president, Sue Leary.
- a. Which goes to support one of my pet theories about research of all kinds, that contacting the individuals directly involved in a situation is the very best approach, if it is at all possible to do.
4. "The settlement was opposed by a coalition of research groups that included the National Association of Biomedical Research (NABR), the Association of American Medical Colleges, the Federation of American Societies for Experimental Biology, and the Association of American Universities." David Malakoff, *Research Groups Win Delay in Rules*, 290 Science 243 (Oct. 13, 2000).

VIII. Shortly after *ARDF v. Glickman* settled, the legislature got into the act.

- A. The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, Pub. L. No. 106-387, § 772, 114 STAT. 1549, 1549A-45 (Oct. 28, 2000) (NB: the act was signed into law exactly one month after the settlement agreement *supra* was filed), stated: *None of the funds appropriated or otherwise made available by this Act shall be used to issue a notice of proposed rulemaking, to promulgate a proposed rule, or to otherwise change or modify the definition of “animal” in existing regulations pursuant to the Animal Welfare Act.*
1. This exact language first appeared on Oct. 6, 2000, in H.R. 5426, § 772, introduced by Representative Joe Skeen (R-NM), which was referred to the House Appropriations Committee and immediately incorporated in the conference report (H.R. Rep. No. 106-948) on H.R. 4461, the enacted bill; the conference report was published at 146 Cong. Rec. H9461, and § 772, at H9499 (Oct. 6, 2000).
 - a. Several articles in the popular press claim that the provision was really introduced by Senator Thad Cochran (R-MS), who was at the time chair of the Senate subcommittee that oversees agriculture spending. See, e.g., David Malakoff, *Research Groups Win Delay in Rules*, 290 Science 243 (Oct. 13, 2000), which stated: “To achieve its ends, the coalition [see *supra* VII (G)(4)] enlisted Wallace Conerly, dean of the University of Mississippi Medical Center in Jackson. He telephoned Cochran, the third-ranking Republican on the Senate Agriculture Committee. Cochran responded by adding language to the agriculture appropriations bill that prevents USDA from drafting the new animal-care regulations during the 2001 fiscal year, which began on 1 October.” *Id* at 245.

birds from AWA protection; both made it through the conference committee and into H.R. 2646, the enacted bill, and can be found at 147 CONG. REC. S13504 (Dec. 18, 2001). See Rick Weiss, *PETA Says Tape Shows Rat Research Violations*, THE WASHINGTON POST, April 19, 2002, at A23 (“PETA is one of several groups trying to kill a farm bill amendment, introduced by Sen. Jesse Helms (R-N.C.), that would keep rats, mice and birds from coming under the protections of the the Animal Welfare Act. Helms and others have claimed that rodents and birds are adequately protected by other federal and institutional rules.”).

A. Helms’ first amendment, SA 2664, was to make the regulatory exclusion of rats, mice and birds a statutory one by amending the AWA to include it. See H.R. CONF. REP. NO. 107-424, § 10301, Definition of Animal Under the Animal Welfare Act.

1. This amendment was enacted as Pub. L. No. 107-171 § 10301, 116 STAT. 134, 491 (May 13, 2002), codified at 7 U.S.C. § 2132 (g) (2004).
2. Mr. Helms discussed this amendment at 148 Cong. Rec. S612, S616-17 (Feb. 12, 2002). He sought “to clarify once and for all” the question of rats, mice and birds and to follow “Congressional intent” (which as we have seen was by no means clear) by amending the AWA to exclude them from the definition of “animal.” He described the USDA as “weary and browbeat [sic] into submission by numerous lawsuits and petitions by the so-called ‘animal rights’ crowd” and that it had finally given “notice of its intent to add rats, mice, and birds under the regulatory umbrella,” to the astonishment of the medical research community. He spoke in glowing terms of medical research, and of his desire that it should not be “compromised by the regulatory shenanigans” of the USDA. He described the animal rights groups as “professional activists who delight in creating mischievous controversies like this” and stated that “their mischief-making in this case has serious real-life complications for the life-saving research in laboratories all over America.” If USDA promulgated the new rule, the “additional

reporting requirements and paperwork will cost the researchers up to \$280 million annually.” He hoped that the Senate “will resist the extremism of activists and deliver a richly deserved rebuke to the methods of these people who are protesting so mightily. It is time to definitively settle this matter, to end the debate, and to approve the pending amendment....”

3. And so they did.
 4. The definitions section of the AWA, 7 U.S.C. § 2132 (g) (2004), now reads: “The term ‘animal’ means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet; but such term excludes (1) birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, (2)....”
 5. ...and conforms with the revised C.F.R., which reads: “Animal means any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warmblooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research;...” This version, from LexisNexis, was current through Nov. 18, 2004.
- B. Helms’ second amendment, SA 2665, required the Secretary of Agriculture to submit to the agriculture committees of both Houses a report to be completed with the “input, consultation, and recommendations from the Secretary of Health and Human Services and the Institute for Animal Laboratory Research [sic] within the National Academy of Sciences...” on the implications of including rats, mice and birds within the AWA’s

definition of animal. See H.R. CONF. REP. NO. 107-424, § 10304, Report on rats, mice, and birds.

1. This amendment was enacted as Pub. L. No. 107-171 § 10304, 116 STAT. 134, 492-93 (May 13, 2002), codified at 7 U.S.C. § 2132 note (2004).
 - a. The conference committee report, H.R. Rpt. No. 107-424 (2002), and the enacted language, Pub. L. No. 107-171 § 10304, codified at 7 U.S.C. § 2132 note, read: “Not later than 1 year after the date of enactment of this Act, the National Research Council shall submit ... a report ... with input, consultation, and recommendations from the Secretary of Agriculture; the Secretary of Health and Human Services; and the Institute for Animal Laboratory Research [sic] within the National Academy of Sciences; ...” Thus at some point the NRC was given primary responsibility for production of the study.
 - b. The report was instructed to estimate the number and types of entities that use rats, mice and birds for research, and which of those are regulated by the DOA, HHS, or which “voluntarily comply with the accreditation requirements of the Association for Assessment and Accreditation of Laboratory Animal Care....”
 - c. It was to estimate the numbers of rats, mice and birds used by such facilities and the increase in costs “incurred by breeders and research facilities resulting from the additional regulatory requirements needed in order to afford the same level of protection to rats, mice, and birds as is provided for species regulated by the Department of Agriculture, detailing the costs associated with individual regulatory requirements...” and contain recommendations for minimizing such costs....

- d. It should estimate the additional funding that APHIS would need to be able to ensure that the level of compliance with respect to other regulated animals was “not diminished by the increase in the number of facilities that would require inspections if a rule extending the regulatory definition of animal to rats, mice, and birds were to become effective...”
- e. And it should recommend ways to minimize the regulatory burden on facilities subject to DOA or HHS regulation, or to the accreditation requirements of the Association for Assessment and Accreditation of Laboratory Animal Care.

C. Two years after the Farm Bill’s enactment, in 2004, I searched zealously, but unsuccessfully, for that report. In desperation, I contacted both congressional agriculture committees and the National Research Council, but only the latter responded. Ms. Joanne Zurlo, Ph.D., Director of the Institute for Laboratory Animal Research (ILAR) within the National Academies (which includes the National Research Council), explained that while Congress mandated the study, it neglected to appropriate funds for it. ILAR and the National Academies requested funds from NIH and USDA but did not receive them. The agencies then decided that there was no need for the study, as the Farm Bill contained language that excluded coverage of rats and mice used for research anyway. Ms. Zurlo pointed out that ILAR relies on external funds to perform studies. Her email of June 4, 2004, is on file with the author.

1. The National Academies are “private, nonprofit institutions that provide science, technology and health policy advice under a congressional charter.” See <http://www.nationalacademies.org/nrc/>.
2. So the order to prepare the report is now in in the Code, at 7 U.S.C. § 2132 note, and without contacting someone at ILAR or the NRC who is familiar with the

situation, other researchers in search of the nonexistent report will be condemned to the same frustration I experienced. See supra VII(G)(3)(a).

X. Postscript; further developments.

A. On June 4, 2004, APHIS published a final rule, at 69 Fed. Reg. 31513, in response to the Farm Security & Rural Investment Act of 2002, to make 9 C.F.R. § 1.1 consistent with the amendment to the AWA. As of June 5, 2004, the term animal “...excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research;...” 69 Fed. Reg. 31514. That is, the earlier regulation excluded *all* birds; the new one excluded *only* birds bred for use in research.

1. Actually you have to read the punctuation very carefully to understand the difference. 9 C.F.R. § 1.1 *formerly* read “This term excludes: Birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, and horses...” Two commas make a world of difference, to the feathered, anyway.

B. On the same day, June 4, 2004, in the same issue of the Federal Register, at 69 Fed. Reg. 31537, APHIS published an Advance Notice of Proposed Rulemaking. It requested comments to aid the agency in developing regulations and standards that would be appropriate for birds other than those bred for use in research, and for comments on whether the “humane handling, care, treatment, and transportation of rats and mice covered by the Act” should have specific standards or should continue to be regulated under the general regulatory standards. *Id.*

1. At page 31539, the ANPRM stated that it followed the notice of petition and request for comments published at 64 Fed. Reg. 4356 (Jan. 28, 1999), that immediately preceded *ARDF v. Glickman*. Remember that petitioners’ original petition for rulemaking was filed on April 29, 1998, almost exactly 6 years earlier. See supra § VII (E).

2. Comments were also requested on the potential economic effects on affected entities if standards were established for birds, rats, and mice not specifically excluded from AWA coverage.
 3. When APHIS determines how to regulate birds not bred for use in research, and what specific standards, if any, should be established for rats and mice that are covered by the Act, a proposed rule will be published in the Federal Register and public comments will be requested. 69 Fed. Reg. 31539, 31540 (June 4, 2004).
- C. On July 21, 2004, the comment period was extended to November 1, 2004, at 69 Fed. Reg. 43538.
1. To update further, I searched in volume 70 of the Federal Register, and in the [2004 Semiannual Regulatory Agenda](#), which outlines the actions that all federal agencies are planning or have recently completed; they are a part of the Unified Agenda of Federal Regulatory and Deregulatory Actions, and are published in the Federal Register. Typically the Agendas are published in April and October but in 2004 they appeared in December. The Final Action from 69 Fed. Reg. 31513 was there, at 69 Fed. Reg. 72920, and the ANPRM from 69 Fed. Reg. 31537 & 43538, at 69 Fed. Reg. 72911 (both on Dec. 13, 2004). The date of the promised Notice of Proposed Rulemaking is listed as "To Be Determined."
- D. As of January 26, 2005, no notice of proposed rulemaking had yet appeared. But it seems as if some good might eventually come out of all of this after all.