# Reporting Requirements Under the Animal Welfare Act: Their Inadequacies and the Public's Right to Know

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## Introduction

The Animal Welfare Act is the only federal statute designed to protect animals used in laboratory research. Under this law, research facilities are required to register with the U.S. Department of Agriculture (USDA) and to meet minimum standards of housing, care, and treatment for most warm-blooded animals. The Act is administered by the Animal and Plant Health Inspection Service (APHIS), an agency of the USDA.

The Animal Welfare Act established by law

> *The human ethic that animals should be accorded the basic creature comforts of adequate housing, ample food and water, reasonable handling, decent sanitation, sufficient ventilation, shelter from extremes of weather and temperature, and adequate veterinary care, including the appropriate use of pain-killing drugs.* [emphasis added]

The petitioner considers all provisions of the Animal Welfare Act important, but none more so than those that concern animals used in painful experimentation. The number of animals used in such procedures is great, and has increased over the years from 65,301 in 1974 to 122,650 in 1980, according to APHIS (1975, 1981) reports. (These figures are cited for comparative purposes only since their reliability is questionable.)

Since 1970, congress has required research facilities to show that during actual research and experimentation, pain-relieving drugs are used "appropriately" and in accordance with "professionally acceptable standards" of care. To this end, congress established the Research Facility Annual Reporting System.

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> *[T]he Secretary [of Agriculture] shall require, at least annually, every research facility to show that professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, during experimentation are being followed by the research facility during actual research or experimentation* (7 USC 2143 — emphasis added).

Under current regulations, research facilities must file an Annual Report with APHIS showing the number of types of animals used in "actual research, testing, or experimentation," and indicating which tests involved "accompanying pain or distress to the animals." In instances when animals were used in painful procedures but were given no pain-relieving drugs, the Annual Report must include "a brief statement explaining the reasons for the same" (9 CFR 2.28 (a) (2)-(4)).

The Reporting System, functioning properly, should provide APHIS with information sufficient to demonstrate that researchers are using pain-relieving drugs "appropriately" and in accordance with "professionally acceptable standards." This was congress' intent and the System is, in fact, the only means by which APHIS can obtain such information on a regular and cost-effective basis. Effective administration of the Reporting System, therefore, is crucial to enforcement of this most important provision of the Animal Welfare Act. We therefore undertook an analysis of the reports from 1,211 facilities for FY 1979.

We conclude from the analysis that the Reporting System, as presently administered, fails to achieve its primary statutory objective: it does not provide APHIS with information sufficient to demonstrate that researchers have used pain-relieving drugs "appropriately" and in accordance with "professionally acceptable standards." The chief reasons for this failing are (1) regulations and guidelines do not define "pain" or "distress," (2) regulations and guidelines do not adequately define "routine procedures," and (3) regulations and guidelines do not require meaningful explanations for the withholding of pain-relieving drugs in procedures acknowledged to cause pain.

The Reporting System, as presently administered, for the same reasons, also fails to achieve a secondary — but nonetheless important — objective: it does not generate reliable and meaningful information to the public about the use of animals in research. When congress passed the Animal Welfare Act amendments in 1970, it declared that animals used in research "deserve the care and protection of a strong and *enlightened* public" (H. Rep. No. 91-1651, 91st Cong., *reprinted in,* (1970) U.S. Code Cong. & Ad. News 5103, 5104 — emphasis added). The analysis also revealed serious transcription errors, involving tens of thousands of animals, by APHIS staff.

## Statement of the Problem

> *Current regulations and guidelines do not define "pain" or "distress." Without such definitions, researchers appear to apply conflicting standards in interpreting these terms.*

Current regulations require research facilities to report annually to APHIS on the use of animals in "actual research, testing, or experimentation," and to indicate which tests involved "accompanying pain or distress to the animals" (9 CFR 2.28(a)). APHIS supplies researchers with a specific form for submitting the Annual Report ("Annual Report of Research Facility," VS Form 18-23) and has also issued instructions for completing the Report form ("Instructions for Submitting the Research Facility Annual Re-

port Form," VS Memo. 595.19) (1975) (Appendix B)).

The Report form is organized by species of animal covered by the Animal Welfare Act and by type of experiment. Experiments fall into three categories (in Category A, the species used is identified):

*Category B:* Experiments or tests involving no pain or distress

*Category C:* Experiments or tests involving pain or distress where appropriate anesthetic, analgesic, or tranquilizers were used

*Category D:* Experiments or tests involving pain or distress but where anesthetic, analgesic, or tranquilizers were *not* used.

Clearly, a registrant's determination as to whether an animal was caused "pain" or "distress" is essential to the proper completion of the Annual Report form. However, neither the regulations, nor the APHIS instructional memorandum, nor the Annual Report form itself defines these terms.

The result is that research facilities appear to apply different and conflicting standards in assessing the responses of animals used in similar procedures. Two examples are discussed below.

*1. Eye and skin irritation studies*

The Monsanto Company (Reg. No. 43-33), of St. Louis, MO, which performs eye and dermal testing of products, reported that it used 1,044 rabbits in Column D of the form, "Pain-No Drugs," and explained: "These studies by their nature cause distress to the rabbits." Similarly, Unilab Research (Reg. No. 93-154) of Berkeley, CA, reported eye and skin irritation studies in 1,150 rabbits, 50 of which were listed in Column D. The explanation attached to the Annual Report stated: "Some materials, based on the response in the test animals, are classified as 'corrosive.' During exposure to these corrosive substances, and during the subsequent evaluation period, the animal may experience pain or distress."

In contrast, Revlon Research Center, Inc. (Reg. No. 21-43) of Bronx, NY, reported that 2,371 guinea pigs and 2,210 rabbits were used in "Draize Eye Irritation Studies" and "Primary Skin Irritation Studies" and yet listed all animals in Column B—"No Pain."

A more ambiguous approach was reflected by the Report of ALZA Corp. (Reg. No. 93-56) of Palo Alto, CA, which listed all of the animals it used in Columns B or C. The report stated that ALZA used New Zealand white rabbits "to study potential ocular and/or cutaneous compounds." The company explained that the use of pain-relieving drugs would "preclude meaningful interpretation of these test results," *and* that the animals did not undergo "procedures of an acutely painful nature requiring chemical restraint or analgesia." The former statement suggests drugs were indicated; the latter denies their necessity. The explanation continued, "Therefore, due to the experimental nature of the work, the number of rabbits experiencing pain or distress would be difficult to determine or construe in the given context." However, after having explained how and why pain-relieving drugs were *not* used, 180 rabbits were listed in Column C—"Pain and Drugs," and 397 rabbits were listed in Column B—"No Pain." No animals were listed in Column D.

*2. Pyrogen testing*

Pyrogen testing is the screening for preparations that might raise body temperature to a dangerous degree. Ortho Diagnostics, Inc. (Reg. No. 22-64) of Raritan, NJ, listed 819 rabbits in Column B ("No Pain") and explained "Animals are used for antibody production and pyrogen testing. When euthanized, appropriate drugs are used." Similarly, Burron Medical Products, Inc. (Reg. No 23-59) of Bethlehem, PA, listed 250 rabbits in Column B and explained, "Pyrogen and Intacutaneous [sic] Reactivity Testing as

per USP XIX does not involve pain or distress to the rabbits."

In contrast, John Hopkins University (Reg. No. MD-R-11) of Baltimore, MD, listed 300 rabbits in Column D—"Pain-No Drugs." The explanation attached to the Report stated: "Anesthesia not used for intravenous or interperitoneal injections or for pyrogen assay. Anesthetics would inhibit the response to pyrogens."

The test procedures discussed (eye and skin irritation, and pyrogen testing) were evaluated by the different registrants as causing differing amounts of pain and/or discomfort. The same protocols were used, and in many cases similar substances were introduced into test animals, yet there are inconsistencies among facilities in regard to the research category chosen on the Annual Report. Anecdotal evidence obtained by us provides further examples of inconsistency. For example, Dr. G.L. Enold, DVM, Director of Veterinary Medicine at ICI Americas, Inc., in a telephone conversation on February 4, 1981, bluntly told one of us (M.S.) that *all* toxicology work falls within the "No-Pain" classification. Dr. Enold's remark may have been in reference to work conducted at ICI Americas only, but even if that were the case, his statement would constitute a rather sweeping proclamation.

The inconsistencies surrounding the definition of "pain" and "distress" are further complicated by the current definition of "routine procedures," a problem that is addressed below.

*The current definition of "routine procedures" is inadequate, as evidenced by inconsistent application of the exemption by both researchers and APHIS officials.*

Current regulations provide that "routine procedures" performed on animals do not have to be reported on Annual Report forms. Regulations do not formally define "routine procedures," but offer three examples of procedures that are intended to fit into this category: "injections, tattooing, and blood sampling" (9 CFR 2.28(a) (2)-(4)). Neither the APHIS instructional memorandum nor the Annual Report form itself offers further guidance as to how this term is to be applied, and a large number of cases were found in which the "routine procedures" exemption was inconsistently applied.

For example, challenge testing involves the injection of a vaccine or bacterin into a group of animals followed by injection of a selected disease agent to determine whether the animal has been immunized. (A control group receives the virus or bacteria, but not the vaccine or bacterin.) The cases discussed below involve challenge testing for *Leptospira* bacterin. Quoted statements are from the registrants' 1979 Annual Reports.

In the first case, Burns Biotec Laboratories, Inc. (Reg. No. 47-10) of Elkhorn, NE, listed 1,275 hamsters used in challenge testing. Though the bacterin was administered by injection, the registrant evidently did not consider this a "routine procedure" and listed all the animals in Column D—"Pain-No Drugs." The report explained, "The hamsters were used in *Leptospira* bacterin potency tests according to applicable 9 CFR 113 methods and for maintenance of *Leptospira* challenge cultures."

The second case in point concerns Jensen-Salsbery Laboratories, a division of Burroughs Wellcome (Reg. No. 48-12), of Kansas City, KS. In 1979, this registrant reported that it had used more than 32,000 animals in various types of challenge testing. This included 15,868 hamsters used in *Leptospira* challenge tests, just as Burns Biotec (noted above) had done. As noted by Solomon (1981), the 1979 annual report had been altered so that the numbers of animals listed as having been used under Category D—"Pain-No Drugs"—had been moved into Category C—"Pain and Drugs." Solomon stated that:

*When informed of the discrepancy, Mr. J.A. McKeown, Production Manager and signatory on the report, stated that he had not changed the reports and had not been told by the USDA of any alterations. The USDA, responding to further enquiries, provided the following information.*

*In late 1979 or early 1980, Dr. Robert Whiting, then USDA-APHIS Chief Staff Veterinarian, contacted his area office in Kansas to enquire about the Jensen-Salsbery reports. After consulting with that office, Dr. Whiting relisted the numbers from Column D to Column C. He justified the action by referring to information he obtained from attachments to the reports, which...were of "challenge testing"....Dr. Whiting (personal communication — March 25, 1981) reasoned that because the tests involved injections, which are considered under the regulations to be routine procedures, there was no need to report them. He added that he felt the research facilities had misinterpreted or were unaware of the exemption. Dr. Whiting maintained that these particular inoculations cause, at most, only minor and temporary pain although he did concede that the infections induced in the control group, as well as in those animals that might receive an ineffective vaccine or bacterin, could cause considerable pain.*

*The disease agents used in the Jensen-Salsbery challenge tests were* Leptospira, *rabies virus and anaerobic bacteria. The attachments to the reports note specifically that in each instance, no pain-relieving drugs were administered. Mr. McKeown assumed that infections which cause pain and distress in untreated humans cause similar pain and distress in untreated laboratory animals. Therefore, to comply with regulations, Jensen-Salsbery listed the animals in Column D.*

The cases discussed above illustrate the practical problems that can result from the current definition of "routine procedures."

> *Some registrants provide no explanation for withholding pain-relieving drugs; others merely parrot language suggested by USDA, providing explanations that are perfunctory and unrevealing.*

By law, research facilities must show that during actual testing on animals, pain-relieving drugs are used "appropriately" and in accordance with "professionally acceptable standards" (7 USC 2143). Current regulations require Annual Reports to list:

> *The common names and approximate number of animals upon which experiments...were conducted involving accompanying pain or distress...and for which the use of [pain-relieving drugs] would adversely affect the procedures...and a brief statement explaining the reasons for the same* (9 CFR 2.28(a) (4)).

As the regulation indicates, pain-relieving drugs may be withheld from animals only if use of such drugs would "adversely affect" the test procedures. By *explaining* how this standard ("adversely affect") applies to each procedure, researchers can fulfill the statutory requirement of "showing" that professionally acceptable standards have been followed.

Animals used in painful tests without pain-relieving drugs are listed on the Annual Report form in Column D — "Pain-No Drugs." An instructional note at the head of Column D asks researchers to "Attach a brief explanation."

Further information for completing Column D is provided in the APHIS instruction memorandum:

> *List the number of animals used where pain or distress was involved but where anesthetic, analgesic, or tranquilizing drugs were not used. A brief explanation why drugs were not used must be attached, e.g., testing of toxic products required by FDA, use of anesthetic, analgesic, or tranquilizing drugs would interfere with test results. Many other reasons in addition to this may be listed* (VS Memo. 595.19 (1975) at p. 4).

Several problems are associated with this aspect of the Reporting System. Two of these are:

*1. Failure to provide an explanation*

The analysis revealed that a number of registrants recorded totals of animals in Column D—"Pain-No Drugs," but provided no explanation as to why pain-relieving drugs had been withheld. Nineteen facilities in 12 states using a total of 7,483 animals gave no explanations to accompany their Column D listings, and thus were in technical violation of reporting requirements (Table 1).

*2. Use of inadequate explanation*

Some research facilities also attempt to explain the withholding of pain-relieving drugs by merely parroting the suggested "explanations" offered by APHIS in its instructional memorandum. These "explanations" are: "testing of toxic products required by FDA," and "use of anesthetic, analgesic, or tranquilizing drugs would interfere with test results" (VS Memo. 595.19 (1975) at p. 4).

The parroting of these "explanations" is a serious problem, not only because they are so perfunctory and unrevealing, but because they do not "show," as required by law, that pain-relieving drugs have been used "appropriately" and in accordance with "professionally acceptable standards."

A conservative analysis of all explanations contained in or attached to 1979 Annual Reports shows that 31 facilities in 9 states that listed 27,331 animals in Column D—"Pain-No Drugs," used the exact explanations or wording that was very similar to that suggested in the APHIS instructional memorandum. In addition, research facilities using 7,483 animals in FY 1979 offered no explanation for withholding pain-relieving drugs from animals. The total number of animals used in painful research without sufficient explanation, therefore, was more than 34,800—a figure equal to approximately 32 percent of all animals reported to have been used that year in painful research without drugs.

## Legal Considerations

> *Present administration of the research facility annual reporting system violates both the letter and intent of the Animal Welfare Act.*

The original Animal Welfare Act of 1966 exempted from regulation the use of animals during actual research (80 Stat. 350, Sec. 18). In a Report accompanying the Act, congress stated that the determination as to when an animal is "in actual research" should be left to researchers to decide "in good faith" (S. Rep. No. 1281, 89th Cong., *reprinted in* (1966) *U.S. Code Cong. & Ad. News* 2635, 2639).

In 1970, a unanimous House Agriculture Committee added the assurance that "the research scientist still holds the key to the laboratory door" (H. Rep. No. 91-1651, 91st Cong., *reprinted in* (1970) *U.S. Code Cong. & Ad. News* 5103, 5104). Yet, in 1970, two important new elements emerged from congress' efforts to strengthen the Act.

## TABLE 1 Column D — "Pain-No Drugs," No Explanation

| Registrant | Reg. No. | Number/Name of Animals Used |
|---|---|---|
| SANDOZ, Inc.<br>East Hanover, New Jersey | 22-9 | 3 dogs<br>20 rabbits<br>4 primates |
| New Jersey College of Medicine & Dentistry<br>Newark, New Jersey | 22-20 | 125 guinea pigs<br>117 rabbits |
| Rutgers, The State University<br>Piscataway, New Jersey | 22-25 | 50 guinea pigs<br>10 hamsters<br>50 rabbits |
| Trustees of Columbia University in the City of New York<br>New York, New York | 21-35 | 4 dogs |
| Children's Hospital<br>Columbus, Ohio | 31-13 | 4 guinea pigs<br>2 primates |
| CDC Research, Inc.<br>Clarks Summit, Pennsylvania | 23-80 | 50 guinea pigs<br>120 rabbits |
| Texas A & M University<br>College Station, Texas | 74-12 | 239 dogs<br>7 cats |
| Regents of the University of Wisconsin<br>Madison, Wisconsin | 35-1 | 6 guinea pigs<br>1 rabbit |
| University of South Alabama<br>Mobile, Alabama | 64-8 | 200 hamsters |
| Los Angeles County Harbor-UCLA Medical Center<br>Torrance, California | 93-16 | 4 primates |
| Cutter Laboratories, Inc.<br>Berkeley, California | 93-18<br>Site I | 3195 guinea pigs |
| State of California<br>Berkeley, California | 93-25 | 35 hamsters |
| Stanford Research Institute<br>Menlo Park, California | 93-26 | 20 guinea pigs<br>133 rabbits |
| Alpha Therapeutic Corporation<br>Los Angeles, California | 93-155 | 525 guinea pigs |
| Colorado State University<br>Fort Collins, Colorado | 84-3 | 20 guinea pigs |
| Eli Lilly & Company<br>Indianapolis, Indiana | 32-3 | 1450 guinea pigs<br>417 rabbits<br>17 primates |
| Boston University Medical School<br>Boston, Massachusetts | 14-17 | 1 primate |
| Toxicity Research Laboratory<br>Muskegon, Michigan | 34-54 | 630 guinea pigs |
| University of Nebraska<br>Lincoln, Nebraska | 47-04 | 24 rabbits |

First, the unanimous house Committee boldly declared that laboratory animals deserve the care and protection of "a strong and enlightened public" (H. Rep. 91-1651, 91st Cong., *reprinted in* (1970) *U.S. Code Cong. & Ad News* 5103, 1504). Second, congress expanded the definition of "adequate veterinary care" to include "appropriate use" of pain-relieving drugs during "actual research and experimentation" (84 Stat. 1560, Sec. 14). Further, every research facility would not be required "to show annually" in a report to the Secretary of Agriculture that "professionally acceptable standards" of care are followed in the administration of pain-relieving drugs (84 Stat. 1560, Sec. 14).

Thus, the "good faith" of the 1966 Act was replaced in 1970 by an Annual Reporting system that had at least two important functions: (1) to provide researchers with a means to demonstrate that pain-relieving drugs are used appropriately and in accordance with professional standards, and (2) to further "enlighten" the public about the use of animals in biomedical research. To be sure, the researcher still "holds the key" to the laboratory door, but by virtue of the 1970 amendments, that door was intended to have a "window" in it.

However, administration of the Reporting System is flawed to the extent that neither of these two goals can be met at present. Without adequate definitions of "pain," "distress," and "routine procedures," researchers cannot be said "to show" that pain-relieving drugs are used appropriately. Researcher's parroting of stock phrases supplied by APHIS to explain withholding of pain-relieving drugs compounds the problem.

The Reporting System's secondary goal — to "enlighten" the public — is also hampered by these flaws. As long as key terms remain undefined, data gathered from Annual Reports will remain unreliable and misleading. Explanations for withholding of drugs could provide the public with important information about how animals are used in research. Instead, the mere repetition of stock phrases reveals little of substance.

Nearly 12 years after passage of the amendment, the USDA has not set *any* standards or guidelines for terms as crucial to the Reporting System as "pain" and "distress" (9 CFR Sec. 1.1(a)-(rr); VS Memo. 595.19 (1975)). Researchers can hardly be expected to demonstrate that pain-relieving drugs have been used in "painful experimentation" if there is no generally accepted definition of what a painful experiment is. This analysis clearly reveals that researchers performing similar procedures on similar test animals apply different and conflicting standards to determine pain or distress, and categorize animals differently on Annual Report forms, according to their own definitions. The result is that statistical data derived from Annual Reports are unreliable and cannot accurately reflect the use of animals in research.

The current state of scientific knowledge does not permit the setting of an all-encompassing, definitive standard for "pain" and "distress." Nevertheless, changes in regulations and guidelines can enhance the reliability and value of the Reporting System. The term "routine procedures" is also a crucial one in the Reporting scheme, for any procedure deemed to be "routine" is automatically exempt from all reporting requirements. (This procedure, in addition to the fact that rats and mice are excluded from the reporting requirements, explains why APHIS figures are so low.) The study by The Humane Society of the U.S. has revealed that, while some definition has been given this term, "routine," it is inadequate to assure uniform application. Indeed, the examples discussed earlier show that even among APHIS officials, there is disagreement as to whether some common test procedures are "routine" or not.

The 1970 Animal Welfare Act amendments direct that the Secretary of Agriculture "shall require" every research facility "to show" that pain-relieving drugs are used appropriately and in compliance with professionally acceptable standards. In practice, however, for nearly one-third of all animals used in painful research, no explanation (or an inadequate explanation) is provided. APHIS actually exacerbates this problem by encouraging research facilities to use stock explanatory phrases from the APHIS instructional memorandum that are legally inadequate.

Without information as to what kind of product is being tested, and in what way, the use of the suggested explanation is not a "showing," but, rather, a mere statement. For legal purposes, stating is simply alleging, while showing consists of the disclosure of facts. "To show" means "to make apparent or clear by evidence, illustration or other means" (*Kenyon* vs. *Crane,* 120 F. 2d, 380 (1941)). It has also been said that "showing" is more than a bare assertion; rather, it consists of special explanations and reasons (*Speer* vs. *Desrosiers* 361 So. 2d 722, 723 (1978)).

For example, the phrase "testing of toxic products required by FDA" is merely an assertion. It is not an explanation, as it does not tie a specific legal requirement of the Food, Drug and Cosmetic Act to the particular research activity of the registrant. Without such additional information, there is no "showing" and APHIS is unable to know whether the Animal Welfare Act is being complied with or not.

## *Conclusions*

If the reporting element of the Animal Welfare Act is to be properly enforced, APHIS will have to take the following actions.

First, APHIS must issue clear definitions of "pain" and "distress." It is suggested that an experimental procedure should be deemed to involve pain or distress if it includes induction of any pathological state, administration of toxic substances or substances in toxic doses, long-term physical restraint, aversive training procedures, or major operative procedures such as surgery and induction of physical trauma. While this may not cover all of the procedures that may involve "pain and distress," it at least gives substantially more guidance to the individual who must complete the Annual Report.

Second, APHIS should add a further explanatory section to the definition of "routine procedures." Such procedures may still include injections, tatooing, and blood sampling, but should specifically exclude those procedures where, for example, an injection may lead to the induction of a pathological state.

Third, APHIS should require additional information from those who do not use pain-relieving drugs. For example, research facilities should be asked to describe the type of experimental procedure (e.g., ocular toxicity, carcinogen testing, routine batch testing) and state how administration of pain-relieving drugs would have adversely affected the objectives of the research.