

National Trends in Animal Welfare Act Violations by Laboratories

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Contents

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| Introduction | 1 |
| National Trends in Violations of the AWA | 2 |
| Violation Trends in the 10 Worst U.S. facilities | 3 |
| Executive Summary & Key Statistics | 4 |
| Recommendations | 6 |
| Appendix A | 7 |

Introduction

While the use of animals in laboratories has been a controversial subject for decades, virtually everyone concerned with this subject agrees that animal experimentation should be regulated. This regulation began in 1966 with the advent of the Animal Welfare Act (AWA). This law regulates many situations in which animals are used including exhibition, sale, transportation, and experimentation. The act has been amended several times in the intervening years to require exercise for dogs and environmental enhancement for primates. The AWA is enforced by the Animal Care division of the Animal and Plant Health Inspection Service of the United States Department of Agriculture (USDA/APHIS/AC).

The existence of this law is not in question. However, the enforcement of this law is open to discussion. A recent audit of USDA/APHIS/AC by the Office of the Inspector General (OIG) found:

“Due to a lack of clear National guidance, AC’s Eastern Region is not aggressively pursuing enforcement actions against violators of the AWA.² We found that regional management significantly reduced its referrals of suspected violators to IES from an average of 209 cases in fiscal years (FYs) 2002-2003 to 82 cases in FY 2004. During this same period, regional management declined to take action against 126 of 475 violators that had been referred to IES.³ In contrast, the Western Region declined action against 18 of 439 violators.”

This finding is cause for concern because many large and well-known laboratories are located in the Eastern Region of the U.S. This report was dated September of 2005, but it dealt with information from the 2002 – 2004 time period. The elapsed time since this report should have allowed USDA/APHIS/AC to implement changes which could improve AWA enforcement. Improvements in enforcement should, theoretically, result in fewer AWA violations by laboratories. This report will examine the reality of trends in this area.

This report examines national trends in compliance/non-compliance with the Animal Welfare Act by U.S. laboratories for the period 2002 – 2006 by analyzing violations data provided by the USDA.

National Trends in Violations of the AWA

The number of violations of sections of the Animal Welfare Act (AWA) which are specifically relevant to laboratories increased during 2006, reaching a total of 2,107 violations. This total represents an 18.4% in one year and by 90.5% (1001 violations) for the five-year period since 2002 (1,106 violations).

The rate at which violations occur is also increasing. For the period from 2002 – 2004 the number of infractions climbed from 1101 – 1491, a change of 35%. This rate accelerated for the period from 2004 – 2006, with the change running from 1491 – 2107, or a 41% increase. Apparently, not only are more violations of the Animal Welfare Act occurring, but the rate at which they are occurring is increasing.

During 2006 the majority (58.2%) of these violations were in the areas of Institutional Animal Care & Use Committees (1,226). The second most frequently violated category was Veterinary Care with 522 infractions. There were also 110 non-compliances involving unqualified personnel, 105 violations relevant to the filing of annual reports, 16 non-compliances regarding facility registration, and 91 violations of a miscellaneous nature. For details of these violations see Appendix A.

However, these violations do not represent the totality of AWA violations relevant to research facilities. This is a result of the way in which AWA regulations are written. The violations listed above are in categories which can only be relevant to laboratories. However, many sections of the Animal Welfare Act are written in such a way as to apply to all animal users, of whom labs comprise only a part. In areas such as animal handling, feeding and watering, facilities, sanitation, etc. the same regulations apply regardless of the variety of the facilities in question.

A survey of the violations of the AWA by 100 laboratories reveals one important trend. Violations of the non-facility specific portions of the AWA account for just over one third of the violations committed by laboratories. In other words, the violations of sections of the Animal Welfare Act which are specific to laboratories probably account for only 66% of the AWA violations actually committed by labs. Therefore, the total for AWA violations by the research community likely reaches approximately 3160. In other words the AWA is violated by a laboratory over 9 times every day in the U.S.

Violation Trends in the 10 Worst U.S. facilities

SAEN staff authored a report on the enforcement of the Animal Welfare Act in 2003 titled: Breaking the Law: Animal Care in U.S. Labs. This report compiled AWA violation information for many of the largest laboratories in the U.S. During 2006, a follow-up report with a larger scope was prepared, which contained AWA violations data for over 200 labs.

While national trends regarding Animal Welfare Act violations are significant, it is also important to address trends within specific facilities. Therefore, the data from these two reports has been cross-referenced, to obtain a list of facilities, and their violations data for both periods.

While variations exist from facility to facility, one clear trend has become apparent. Most of the facilities who led the nation in violations of the Animal Welfare Act in the 3-year period ending in 2003 are still leading the nation in this infamous category as of 2005.

The top 10 labs for AWA violations from the earlier report for whom more recent data was available, compiled a total of 158 new violations in the first nine months of 2005, for an average of almost 16 violations per facility in a nine-month period.

Apparently, enforcement actions taken by the USDA are ineffective because they do not have sufficient deterrent effect to prevent research facilities from continuing to violate federal law.

Executive Summary

The conclusions reached by this report are unavoidable. Violations of the Animal Welfare Act (AWA) by laboratories are increasing, having reached a high of 2107 for 2006 which represents a five-year increase of 90.5%. Additionally, for laboratories which have a history of AWA violations continue to violate the AWA, with the top 10 labs for AWA violations from the 2003 time period accumulating a total of 158 new violations during the first nine months of 2005.

The highest level of AWA violations by laboratories occur in the areas of Institutional Animal Care and Use Committees (IACUC – 1226 violations, or 58% of total), and Veterinary Care (522 violations, or 25% of total). These two areas account for 75% of all violations.

IACUC violations are extremely significant because these committees are responsible for approving research protocols and for enforcing the AWA within research facilities during the time period between USDA inspections. There are enough IACUC violations for every lab in the US to have violated this area of the AWA more than once a year. It is also quite apparent that animals do not receive adequate veterinary care on a regular basis, since there are sufficient violations of veterinary care to allow for every other lab to have an infraction in this area.

Additionally, the research facility specific sections of the USDA code typically account for only 2/3 of all violations, based on trends for 100 labs. Therefore, labs actually violate federal law 3160 times per year, or roughly 9 times per day.

These statistics clearly indicate that laboratories violate federal law on a very regular basis and that those violations are increasing. Therefore, the only conclusion that can be drawn is that the enforcement actions taken by the USDA are ineffective, having no real deterrent value.

In 2005, the Office of the Inspector General (OIG) of the USDA published an audit report which evaluated the Animal Care Division of the USDA (the part of the USDA which enforces the AWA). The findings of this report included:

“ . . . violators consider monetary stipulation as a normal part of the cost of conducting business rather than a deterrent for violating federal law.”

This statement can account for the lack of effectiveness of USDA/APHIS/AC enforcement actions. In other words, fines/stipulations, etc. are so small that the entities which are penalized are essentially unconcerned about paying them. This may be particularly relevant to animal laboratories because of the high level of federal funding which they receive for animal experimentation. Current estimates put the federal expenditure for animal experimentation by the National Institutes of Health at approximately \$12 billion annually. The typical size of USDA fines pale in comparison to this figure.

The 2005 OIG audit also states:

“During FYs 2002 – 2004 the number of research facilities cited for violations of the AWA has steadily increased from 463 – 600.”

When this statement is compared with the number of violations listed per year 1106 and 1491, respectively, we come up with an average of research specific violations rate of approximately 2.5 per facility. If this average is used to extrapolate to a new total, then an accurate estimate of the number of labs currently violating the AWA would be 843.

This 843 facility estimated total would account for an increase (over 5 years) of 82%. Additionally, with the total population of laboratories estimated at 1100, approximately 75% of all labs violate the AWA every year.

Key Statistics:

- **The Animal Welfare Act (AWA) is estimated to be violated by U.S. laboratories 9 times per day.**
- **The number of AWA violations has increased by 90.5% in the last five years.**
- **The estimated number of labs violating the AWA has increased by 82% in five years.**
- **Approximately $\frac{3}{4}$ of all labs violate federal law.**
- **Estimated total for AWA violations by labs reached high of 3160.**

Recommendations:

- 1. The average fine per violations should at least be doubled, to make the fines, stipulations, etc. imposed by the USDA more meaningful to laboratories that often receive over \$100,000,000 per year from the federal government for animal experiments.**
- 2. The USDA/APHIS/AC policy of discounting fines by 75% should be immediately eliminated, again, to make fines more meaningful and effective.**
- 3. USDA/APHIS/AC should be given the authority to shut down a research facility if said facility has a long history of AWA violations, without reform.**