An Overview of the Animal Welfare Act

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“GLP Forum” addresses topics of interest associated with good laboratory practices. We intend this column to be a useful resource for daily work applications. Reader comments, questions, and suggestions are needed to help us fulfill our objective for this column. Please send your comments and suggestions to column coordinator Steven Kuwahara at stevekuwahara@yahoo.com or to managing editor Susan Haigney at shaigned@advanstar.com.

KEY POINTS

The following key points are discussed:
• All workers who deal with animals need to be aware of the Animal Welfare Act regulations.
• The original intent of the act was to cover the handling, holding, and transportation of dogs and cats. Amendments have expanded the scope of the act to cover almost any type of animal that is commercially available.
• The act addresses humane care and treatment of animals in research or experimental purposes, or for exhibition or holding for sale as pets.
• US Food and Drug Administration investigators should be aware of Animal Welfare Act requirements.
• Public concern for treatment of animals is an important consideration for research facilities.
• Best practices for laboratory operations include standards established by the US National Academy of Sciences provided in the Guide for the Care and Use of Laboratory Animals. Personnel training by the American Association for Laboratory Animal Science should also be considered.
• Conscientious management must realize that good laboratory practice regulations are only minimal requirements for working with animals.

INTRODUCTION

Previous articles (1-3) in this column discuss the Animal Welfare Act (AWA) (4) and its basic requirements. This is an important regulation for pharmaceutical laboratories that work with animals under all conditions, including those studies based upon the good laboratory practice (GLP) regulations (5). Although the US Department of Agriculture (USDA) is primarily responsible
for its enforcement, the AWA is a US regulation and, therefore, applies to all work with animals conducted in the United States, including pharmaceutical studies. Earlier articles in this column address the Institutional Animal Care and Use Committee (IACUC) and the role it plays as an Institutional Review Board (IRB) for studies that use animals. The Winter 2011 issue of “GLP Forum” (3) covers the fact that rats and mice are exempt from the AWA regulations. These are some of the main points that are of concern to the pharmaceutical laboratory. The AWA also contains other provisions that will be of concern to pharmaceutical workers in certain specific situations.

This discussion addresses other matters covered by the AWA. It is impossible to cover the whole of the AWA within this article because of the many amendments that have been made to the Act. Also, the other agricultural laws have inserted specific regulations into the version found in Title 9 of the Code of Federal Regulations (CFR).

ANIMAL WELFARE ACT OVERVIEW
The AWA itself is actually a large set of regulations that covers much more than the IACUC. A more condensed version can be found in the Federal law, United States Code, Title 7, Agriculture (6). Most of the regulations cover commercial matters such as shipping and housing of animals held for sale. They have little immediate impact on the pharmaceutical laboratory. However, there are certain regulations that apply to specific situations or types of animals. These regulations are of concern to small, specific groups of workers but can create problems for workers who become subject to them without being aware of their requirements. This is often seen when a laboratory that normally had only rats and mice decides to incorporate guinea pigs or hamsters into its studies. Therefore, all workers who deal with animals need to be aware of the existence of these regulations. Supervisory personnel should make an effort to review the whole set of regulations found in Title 9 of the CFR (4).

INTENT OF THE ACT
The original intent of the act was to cover the handling, holding, and transportation of dogs and cats. However, there have been many amendments to the Act, and its scope has been greatly expanded to cover most types of animal commercially available. Livestock and animals held for food or as a source of animal products have been excluded from the Act; although, there are other, more specific, agricultural laws that apply to these animals.

The intent of congress in passing this act was given in the following statements:

• To ensure that animals intended for use in research facilities or exhibition purposes or for use as pets are provided humane care and treatment
• To assure the humane treatment of animals during transportation in commerce
• To protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen.

The Congress further finds that it is essential to regulate, as provided in this chapter, the transportation, purchase, sale, housing, care, handling, and treatment of animals by carriers or by persons or organizations engaged in using them for research or experimental purposes or for exhibition purposes or holding them for sale as pets or for any such purpose or use.

These statements regarding the use of animals for research and experimentation include the activities of pharmaceutical laboratories. In fact, some of the regulations concerning the theft of animals are directed at preventing stolen animals from being used as experimental subjects.

KEY AMENDMENTS
In a 1985 amendment to the Act, Congress stated:

• The use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals
• Methods of testing that do not use animals are being and continue to be developed which are faster, less expensive, and more accurate than traditional animal experiments for some purposes and further opportunities exist for the development of these methods of testing
\textbf{Measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds.}

\textbf{Measures which help meet the public concern for laboratory animal care and treatment are important in assuring that research will continue to progress.}

These statements clearly address public concerns about the manner in which pharmaceutical studies are conducted. The statements are encouraging in that they show that Congress does understand the role that animal experimentation plays in pharmaceutical research and wishes to have it continue with due regard for public concerns.

With regard to specific animals, the AWA applies to horses that are used for research purposes, but excludes horses used for other purposes along with birds, rats, and mice. Other parts of the United States Code address matters such as dog fighting and cock fighting and the exhibition of animals. The last section of the AWA contains regulations related to the care of swine.

The AWA has many provisions regarding the sale and distribution of animals and the records that are required. For dogs and cats, an amendment made in 1970 added the following record keeping requirements for research facilities:

\textbf{Sec. 2140. Recordkeeping by dealers, exhibitors, research facilities, intermediate handlers, and carriers.}

Dealers and exhibitors shall make and retain for such reasonable period of time as the Secretary may prescribe, such records with respect to the purchase, sale, transportation, identification, and previous ownership of animals as the Secretary may prescribe. Research facilities shall make and retain such records only with respect to the purchase, sale, transportation, identification, and previous ownership of live dogs and cats.

Later considerations have suggested that the records for live dogs and cats should also apply to dead animals that are obtained by a research facility.

Records concerning the history of the animals employed in testing and research must be complete, if nothing more than to ensure that the animals were suitable for their intended use when acquired by the animal facility.

In 1976, the following amendment added a requirement for the identification of dogs and cats acquired by a research facility:

\textbf{Sec. 2141. Marking and identification of animals}

All animals delivered for transportation, transported, purchased, or sold, in commerce, by a dealer or exhibitor shall be marked or identified at such time and in such humane manner as the Secretary may prescribe: Provided, that only live dogs and cats need be so marked or identified by a research facility.

However for the laboratory operating under the GLP regulations, 21 CFR 58.90(d) states:

\textbf{(d) Warm-blooded animals, excluding suckling rodents, used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require the animals to be removed from and returned to their home cages for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification.}

Thus the GLP regulations extend the requirement for animal identification to all animals in these specific situations, but it should be noted that dogs and cats must be identified even if they are not handled in the manner described in 21 CFR 58.90(d).

\textbf{FDA AND THE ANIMAL WELFARE ACT}

There is an interesting statement found in 7 USC 2145(a):

\textbf{(a) The Secretary shall consult and cooperate with other Federal departments, agencies, or instrumentalities concerned with the welfare of animals used for research, experimentation or exhibition, or administration of statutes regulating the transportation in commerce or handling in connection therewith of any animals when establishing standards pursuant to section 2143 of this title and in carrying out the purposes of this chapter. The Secretary shall consult with the Secretary of Health and Human Services prior to issuance of regulations.}
This requirement is interesting in that it should ensure that the Department of Health And Human Services, and, by extension, the US Food and Drug Administration, should be aware of the requirements of the AWA. Many laboratories that employ animals in pharmaceutical research have commented that FDA investigators appear to be unaware of the AWA. During inspections or reviews of submissions, investigators or reviewers rarely ask to review the reports required under the AWA. It has been assumed that FDA personnel are expecting separate investigations by US Department of Agriculture (USDA) personnel of the Animal and Plant Health Inspection Service (APHIS), but some of these laboratories themselves are unaware of the USDA regulations and are definitely not registered with the USDA.

It appears that the high workloads of FDA and APHIS investigators have resulted in many pharmaceutical laboratories “falling into the cracks” with regard to regulatory monitoring of AWA-related activities. This is unfortunate in that monitoring and inspection is helpful in maintaining a high level of knowledge and awareness of the requirements of the AWA and the GLPs. It would seem that this is an area where inter-agency coordination and joint action would produce a more efficient outcome that would be beneficial to all concerned, including industry.

**PUBLIC CONCERN**

Even if these regulations do not apply directly to a laboratory or a laboratory is exempt from them, it is not wise to ignore all considerations of animal welfare. The problem here is that animal welfare is an area where public opinion can have severe consequences for a company that is viewed as violating regulations or not caring about the welfare of animals that it is using. The humane treatment of animals is of great public concern. The situation is further exacerbated by the existence of extremist groups who claim to be animal welfare activists. Some of these groups have been called urban terrorists by the Federal Bureau of Investigation, and the pharmaceutical laboratory that attracts their attention will have much about which to be concerned.

The following are some “voluntary” actions that laboratory management should consider taking to show that it is responsive to public concerns about animal welfare. While these actions are not strictly required by regulations, they will serve to demonstrate compliance with regulations and to show that a laboratory is willing to go beyond minimal regulatory compliance. In addition, they serve to demonstrate that a laboratory has adopted “best practices” for its operations.

**Guide for the Care and Use of Laboratory Animals**

The first is a voluntary standard that was prepared and published by the US National Academy of Sciences. It is known as the *Guide for the Care and Use of Laboratory Animals* (7). The most recent edition (8th) was published in 2010 and replaces the previous edition that was published in 1996. The previous edition was translated into Chinese (with a separate Taiwanese version), German, Turkish, French, Spanish, Korean, Portuguese, Japanese, and Russian. Presumably the 8th edition will also be translated into these languages.

The existence of this guide in so many languages is an indication of its wide acceptance, and the great international interest in demonstrating acceptance of the principles of animal welfare. The Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) employs the guide as a voluntary standard. AAALAC will certify a laboratory’s compliance with this standard and verify the maintenance of the compliance with periodic inspections of the laboratory. It is interesting to note that many major laboratories located in developing nations such as India and China have become certified as compliant organizations. Pharmaceutical companies that seek contract laboratories for work on products should only deal with organizations that have made the effort to comply with this standard.

**American Association for Laboratory Animal Science**

A second path that an animal research facility should take is to have its personnel trained and certified by the American Association for Laboratory Animal Science, AALAS (not to be confused with AAALAC). AALAS provides voluntary training and certification for laboratory animal technicians and corresponding supervisory staff. Although the training and certifica-
tion are voluntary, many companies have supported the training and certification of their personnel who work with animals. For a pharmaceutical company looking for a contracting facility, the knowledge that the facility’s personnel are trained and certified will provide confidence in the reliability of the results of their work.

Another consideration here is the requirement of 21 CFR 58.29(a) which states:

(a) Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

As there are not very many training programs at the secondary or college level that train workers on the care and handling of laboratory animals, the use of AALAS services can be helpful in meeting this requirement. It is somewhat curious that some facilities that are associated with hospitals or medical schools feel that a certification as a medical technologist somehow qualifies personnel to work with laboratory animals. The fact that working with humans is quite different from working with animals, especially because animals cannot verbalize their complaints, is not considered. In addition, there are many nutritional and physical needs that are significantly different between humans and animals. Therefore, a medical technician trained to work with humans and human specimens cannot possibly be considered to meet the requirements of 21 CFR 58.29(a).

FINAL THOUGHTS

Conscientious management must realize that, when working with animals, the requirements of GLP are only the beginning of a longer and complex path to conformance with all of the concerns that surround this work. Because of public concern, simple compliance with the regulations is not sufficient.

REFERENCES


6. United States Code, Title 7, Agriculture, Chapter 54 - Transportation, Sale, and Handling of Certain Animals, Section 2131 et seq.


ARTICLE ACRONYM LISTING

AAALAC Association for the Assessment and Accreditation of Laboratory Animal Care

AALAS American Association for Laboratory Animal Science

APHIS Animal and Plant Health Inspection Service

AWA Animal Welfare Act

CFR Code of Federal Regulations

FDA US Food and Drug Administration

GLP Good Laboratory Practice

IACUC Institutional Animal Care and Use Committee

IRB Institutional Review Board

USDA US Department of Agriculture

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