Free Executive Summary

Scientific and Humane Issues in the Use of Random Source Dogs and Cats in Research

Committee on Scientific and Humane Issues in the Use of Random Source Dogs and Cats for Research; National Research Council

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*Scientific and Humane Issues in the Use of Random-Source Dogs and Cats in Research examines the value of random-source animals in biomedical research and the role of Class B dealers who acquire and resell live dogs and cats to research institutions. Findings include that, while some random-source dogs and cats may be necessary and desirable for National Institutes of Health (NIH)-funded research, there is no clear need to obtain those animals from Class B dealers. Several options for random-source animal acquisition already exist and additional options are recommended, which would further ensure the welfare of these animals and foster a positive public image for NIH. While the scientific community has recognized and responded to concerns for humane treatment of animals in research, government oversight has thus far been unable to fully enforce the Animal Welfare Act in regard to Class B dealers of live animals. Although the animals acquired by Class B dealers are destined for research--and NIH research in particular--the standard of care while in the possession of some Class B dealers requires an inordinate amount of government enforcement and is not commensurate with the policies of most NIH-funded research laboratories. This dichotomy of standards reflects poorly on public perceptions of NIH and jeopardizes animal welfare. This book will be crucial for NIH and other groups using random-source animals in research, including veterinary schools and research facilities. Animal welfare advocates, policy makers, and concerned pet owners will also find this a vital and informative work for reconciling the needs of research with the welfare of animals. *

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Summary

BACKGROUND

Biomedical research uses various types of laboratory animals, known as animal models, to advance both human and veterinary medical knowledge. Most laboratory animals used in research today are rodents; a relatively small number are dogs and cats, most of which are either "purpose-bred" specifically for research by licensed commercial breeders (known as Class A dealers), or bred and raised in research colonies. Another smaller percentage of research dogs and cats, and the focus of this study, are commonly referred to as "random source" animals. Most, but not all, of these are provided by licensed dealers, known as Class B dealers (see below for a definition of the type of Class B dealer relevant to this report), which acquire dogs and cats from random sources, such as individual owners, small hobby breeders, and pounds and shelters.

Random source dogs and cats may possess a variety of desirable characteristics for research, including anatomic features, age, genetic diversity, and naturally occurring infectious disease, among others. However, they may also have undesirable features, such as unverifiable health status, zoonotic diseases, and inconsistent research qualities (such as temperament). In Chapter 3, this report provides detailed overviews of the characteristics of random source animals as they relate to the suitability of such animals for biomedical research.

Class A and Class B dealers are subject to federal regulation under the Animal Welfare Act (AWA) and are licensed by the United States Department of Agriculture's Animal and Plant Health Inspection Service (USDA/

APHIS). The AWA has been revised, amended, and increasingly refined since its original passage in 1966. Enforcement of the AWA is the responsibility of the USDA/APHIS, which has also repeatedly revised its Animal Welfare Regulations (AWR).

In general, the American public is supportive of the use of animals in research. However, the public is also concerned about the humane treatment of these animals. This concern has contributed to the evolution of federal laws, principles, and policies that guide the use of animals in biomedical research; for example, concern over lost or stolen pets was a major impetus that shaped the AWA when it first passed in 1966. Despite increasingly effective (but still incomplete) enforcement of the law, public concern continues, especially with respect to the use in biomedical research of random source dogs and cats that are obtained from pounds and shelters and may have come from the general pet population. Recent failure of the AWA and USDA/APHIS to prevent abuses by some, but not all, Class B dealers who buy and sell random source dogs and cats for research have re-stimulated public concerns, particularly in regards to lost or stolen pets.

In response to a request of Congress, the National Institutes of Health (NIH) charged the National Academies to critically examine the general desirability and necessity of using random source dogs and cats in NIH-funded research, and the specific necessity of using dogs and cats from Class B dealers for such research.

MANDATE AND STATEMENT OF TASK FOR THE REPORT

As a result of the Fiscal Year 2008 House Appropriations Committee Report 110-231 and Fiscal Year 2008 Senate Appropriations Committee Report 110-107 regarding appropriations to the Department of Health and Human Services, with the Pet Safety and Protection Act of 2007 as an additional impetus, Congress charged the NIH with determining the humane and scientific issues associated with the use of random source[1] dogs and cats in research. NIH in turn asked the National Academies to assemble a committee of experts to prepare a report that addresses the following statement of task:

> The National Academies will form an expert committee (entitled "**Scientific and Humane Issues in the Use of Random Source Dogs and Cats for Research**") to address the use of Class B dogs and cats in research funded by the National Institutes of Health (NIH). Specifically, the committee will:

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[1] Research animals that come from the general population, rather than from commercial breeders, are "random source" animals. See **Characteristics of Random Source Animals for NIH-Funded Research,** below.

1. Determine the important biomedical research questions and common research topics in contemporary NIH-funded research where Class B dogs and cats are desirable/necessary as well as the frequency of these various research topics (i.e., number of grants where the potential exists or the source of the animal is identified as coming from a Class B source).
2. Describe the specific characteristics, such as physiological, anatomical, or genetic characteristics, of the animals that make them particularly well-suited for the types of research described under Task #1.
3. Make recommendations, if necessary, for new or revised scientific parameters to guide their use, if these Class B dogs and cats are deemed to be necessary for research.

The NIH, as the sponsor of this report, negotiated the Statement of Task with the National Academies, which, through its Institute for Laboratory Animal Research (ILAR), appointed an authoritative committee of experts in biomedical research, animal behavior, animal welfare, and veterinary medicine.

This is a highly nuanced report, since its deliberations and recommendations pertain only to the desirability/necessity of random source dogs and cats, and specifically random source dogs and cats from Class B dealers for NIH-funded research (not for other purposes, such as teaching, veterinary research, or research by industry). The animals that fall under these narrow definitions are relatively few in number, but may have potentially high value for advancing medical knowledge. They also profoundly impact public perceptions about humane treatment of all research animals, protection of pets from theft or loss, and public attitudes toward animal-related research funded by NIH.

CHARACTERISTICS OF RANDOM SOURCE ANIMALS FOR NIH-FUNDED RESEARCH

Random source animals (those that come from the general population rather than from Class A dealers) represent potentially important models for research on naturally occurring diseases such as cancer, infectious diseases, and age-related diseases because they may provide research scientists with a genetically diverse study group. They may also exhibit characteristics not available in purpose-bred animals; for example, random source dogs may be larger (especially useful for the study of heart disease) and/or older (desirable for research on the processes of aging).

Most random source animals come from Class B dealers who are exclusively licensed to buy and sell animals for research (Class A dealers breed animals, called purpose-bred, on their own premises and sell them to various entities, including research institutions; they do not buy animals

except to replenish their breeding stock). However, random source animals can also be obtained directly by research institutions through the same sources from which Class B dealers obtain them (e.g., pounds, shelters, and individual owners).

Because random source animals come from various sources, they are more likely to be associated with undesirable aspects such as infectious disease, occupational health (zoonotic) hazards, and inconsistent health and welfare standards. These undesirable aspects may limit their value for research purposes and place additional burden on institutions resulting from increased health and welfare surveillance.

Cost may be a factor in the decision to use random source animals for research, as they are less expensive than most purpose-bred dogs and cats. However, there are often additional costs associated with conditioning the animals to make them suitable for research, including quarantine, treatment for parasites, vaccination, de-worming, and other procedures. These costs for research institutions, as well as those incurred by the federal government (USDA) related to inspection and enforcement of Class B dealers, tend to equalize the costs compared to purpose-bred animals. Furthermore, cost alone should not be the sole determinant of the appropriateness of a particular animal model used in research.

TRENDS AND STATUS OF CLASS B ANIMALS AND DEALERS

There are more than 1,000 Class B dealers operating in different USDA-designated capacities such as distributors of animals for the pet industry, animals for exhibit purposes, and animals used in laboratory research. The specific group of interest for this study is the latter, which buys and sells live random source dogs and cats for biomedical research.

It is important to emphasize that this report addresses only those few Class B dealers—11 of them at last count—that acquire and sell live random source dogs and cats for research and teaching. Not all of these 11 dealers provide animals for NIH-funded research; and one has a suspended license and is not likely to resume activity. Furthermore, the demand for and use of random source as well as purpose-bred dogs and cats in research has fallen significantly over the last 30 years, as has the number of Class B dealers. These developments suggest that for a variety of reasons (research trends, alternate animal models, institutional policies, animal welfare, public opinion, animal rights pressure, regulatory and financial burden), the Class B dealer system may eventually become unavailable.

Although these facts narrow the focus of this report, the necessity of Class B dealer-derived dogs and cats must be assessed both (1) from the perspective of the general desirability and necessity of random source dogs and cats for biomedical research and (2) in the broader context of all of the

following factors: U.S. law (AWA); USDA/APHIS interpretation of the law (AWR); *U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research and Training*; *Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals*; the National Academies' *Guide for the Care and Use of Laboratory Animals*; and widely accepted voluntary assurance mechanisms for compliance of high standards of laboratory animal care through the *Association for Assessment and Accreditation of Laboratory Animal Care* (AAALAC) *International*.[2] These various laws, regulations, principles, policies, guidelines, and compliance mechanisms are inextricably intertwined and had a significant impact upon the Committee's deliberations.

GENERAL CONCLUSIONS

The Committee determined that although the number of random source dogs and cats used in research is small and declining, they represent an important but relatively small asset to biomedical research (in 2007 to 2008 approximately 4 percent of dogs and 1 percent of cats used in research were acquired from Class B dealers with a smaller percentage of those being random source animals from pounds and shelters). The principal question posed to the Committee was not whether such animals should be used in research but whether dogs and cats from Class B dealers are necessary. Animals with similar qualities are available from such alternate sources as direct acquisition from pounds and shelters, Class A dealers of purpose-bred dogs and cats, existing research colonies, and owner-donated animals. The Committee therefore determined dogs and cats from Class B dealers are not necessary for NIH-funded research. Regardless of the source however, if NIH deems animals with random source qualities to be important, proactive mechanisms to assure continued access to alternative sources, as well as consideration of additional options, are essential for the advancement of both human and animal research. One argument for the use of random source dogs and cats is that they come from a genetically diverse base within the general dog and cat populations and comprise many highly valuable genetic models of human disease. Class B dealers do not play a significant role in discovering and acquiring these models; rather, they have largely been discovered and acquired through NIH-funded programs that foster cooperation between the animal breeder community, private owners, the veterinary community, and NIH. Furthermore, as access to random source animals from pounds and shelters becomes increasingly limited, Class B animals are becoming more and more similar to those provided by Class A breeders because Class B dealers increasingly acquire animals from

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[2] These guidelines and regulations also apply to Class A dealers.

hobby breeders. The Committee recognizes, however, that Class B dealers may still provide a benefit in acquiring dogs and cats from diverse sources and conditioning them before resale for research.

The Class B dealer system, as originally intended by federal law, would be desirable for the reasons stated above. But the Committee found that, despite over 40 years of regulations resulting from the AWA, the Class B dealer system does not operate consistently as intended. The USDA invests increasing efforts in enforcing the AWR with Class B dealers, primarily in tracebacks (the process of verifying the origins and, to a lesser extent, the standards of care of these animals). Standards of care for the animals at the remaining 11 Class B dealers appear to vary greatly. Some Class B dealers subscribe to the full intent of the law while others jeopardize the industry. Furthermore, the Committee noted that although dogs and cats acquired by Class B dealers are destined for research, including NIH-related research, the standards of care for these animals at some dealers are discordant with the standards set forth in the *U.S. Government Principles*, *PHS Policy*, and the *Guide*. Class B dealers and their facilities however, are governed only by the AWR. Although in principle these various standards are similar, in practice they are not. The AWR are difficult to enforce outside the PHS circle of influence: standards at a PHS-assured institution tend to be scrutinized more carefully because that institution's assurance is periodically reviewed and the institution's NIH funding is in jeopardy if the assurance is violated (including violations of the AWR), whereas non-PHS-assured entities are not subject to the same kinds of scrutiny or penalties. Moreover, some institutions that accept PHS funds also have AAALAC International accreditation adding another layer of animal welfare guidance. This dichotomy of standards colors public perceptions of the NIH and USDA, and brings into question the welfare of these animals.

CONCLUSIONS AND RECOMMENDATIONS

The Committee concluded that under some circumstances, dogs and cats with qualities of random source animals may be desirable and necessary for NIH-funded research. The Committee was unable to specifically identify research projects that used Class B animals, since NIH does not maintain records of the specific sources or numbers of research animals nor of grants that use Class B animals, and individual grants and publications do not identify sources of animals. However, the Committee found that it is not necessary to obtain random source dogs and cats for NIH research from Class B dealers, provided that alternative sources of animals with similar characteristics can continue to be assured.

The Committee concluded that alternative options are currently available to fill the majority of NIH needs for various types of research dogs and cats:

- **Direct Acquisition from Pounds and Shelters.** Albeit in diminishing numbers, animals can still be obtained directly from the few states that mandate pound seizure and from some municipal shelters in states that have no formal policy prohibiting such acquisition.
- **Donation Programs.** Direct acquisition of animals from small breeders, hobby clubs, and individual owners is a practice already in use by research institutions and accounts for a significant percentage of animals currently being acquired by Class B dealers.
- **Cooperative Pre-clinical Consortia.** The current use of pet animals with owner consent for NIH-supported comparative pre-clinical investigations for cancer research is a viable model for advancing both human and veterinary medical research. Cooperative efforts can capitalize on the rich genetic diversity and variety of cancers that arise in the canine population as well as on anatomic and disease characteristics that are more accurately reflective of the human condition than those of rodents. In addition, they ensure outstanding clinical care of the animals, and they are not constrained by human phase I, II, and III clinical trial designs. Such consortia could be readily developed for virtually any comparative disease research of interest to categorical institutes of NIH.
- **Class A Dealers.** Class A dealers of purpose-bred dogs and cats can accommodate many research needs, including, for example, larger animals, genetically diverse animals, and older animals. If a greater number of these animals are needed, Class A vendors could provide them, albeit at a greater cost. Moreover, the number of cats provided by Class B dealers is so small that they are likely to be available through other mechanisms such as Class A dealers.
- **NIH-Supported Resource and Research Development.** Programs such as the *Referral Center for Animal Models of Human Genetic Diseases* at the University of Pennsylvania School of Veterinary Medicine (Chapter 4) directly address the needs of NIH for discovery, accurate characterization, and access to these incalculably valuable dog and cat models of human disease that arise in the general dog and cat population. This program serves as an example in which the public willingly contributes animals for research in order to advance both animal and human health, and fosters a positive public image for NIH.

In order to assure continued availability of various types of dogs and cats in the absence of Class B dealers, the Committee recommends that NIH undertake an effort to explore new potential sources of random source dogs and cats to meet important biomedical research needs, including the following options:

- **NIH Request for Proposal.** Various NIH categorical institutes commonly use the Request for Proposal (RFP) mechanism to acquire needed items (including research animals) or to perform research and development on a contractual basis, including through contracts to provide or develop specific animal models. A variety of laboratory animals, ranging from rodents to nonhuman primates, are the subject of RFPs, and since the RFPs are NIH-supported, all such animals fall under the *PHS Policy*. Thus, the RFP mechanism is already in place and is quite suitable for fulfilling this need.
- **Coordination and Support of Private Research Animal Colonies.** Several academic and commercial entities maintain purpose-bred colonies of research dogs and cats, supported by NIH or private funding. These colonies already provide some animals to other research institutions, and with additional RFP-type cooperative agreements that provide NIH support, this source of animals could be assured and better coordinated.

IMPACT OF RECOMMENDATIONS

The numbers of dogs and cats used in research are very small, and justification for use of dogs and cats from Class B dealers is largely (but not entirely) based on anatomic features (e.g., size) that can also be provided by Class A dealers, or other sources. However, the discontinuation of Class B dealers may affect not only NIH but also other research and teaching activities that may use such animals, such as veterinary medicine and private industry. Furthermore, it is important to emphasize that the Committee's recommendations pertain only to Class B dealers of live random source dogs and cats for NIH-funded research, and not the other types of Class B dealers or animals, which may or may not be desirable or necessary.

CONCLUDING STATEMENT

Although the statement of task for this Committee initially appeared straightforward, the Committee soon realized that its task is deeply entwined with perceptions of both the public and scientific communities, increasing but as yet not completely effective efforts by USDA to assure the public trust, declining trends in the use of dogs and cats in research, and declining trends in the numbers of Class B dealers. Although random source dogs and cats represent a very small percentage of animals used in biomedical research, this small number is not commensurate with their potential value, and it is desirable to assure continued access to animals with random source qualities. This access can be accomplished with existing alternative mechanisms other than Class B dealers and can be assured with additional effort.

The Committee thus determined that Class B dealers are not necessary for supplying dogs and cats for NIH-funded research.

GLOSSARY OF ABBREVIATIONS USED IN THIS REPORT

AAALAC Association for Assessment and Accreditation of Laboratory Animal Care (International)
APHIS   Animal and Plant Health Inspection Service, a division of USDA
APS   American Physiological Society
ASPCA   American Society for the Prevention of Cruelty to Animals
AVMA   American Veterinary Medical Association
AWA   Animal Welfare Act
AWI   Animal Welfare Institute
AWR   Animal Welfare Regulations
HSUS   Humane Society of the United States
IACUC   Institutional Animal Care and Use Committee
ILAR   Institute for Laboratory Animal Research (National Academies)
MISMR   Michigan Society for Medical Research
NABR   National Association for Biomedical Research
NIH   National Institutes of Health
OLAW   Office of Laboratory Animal Welfare/NIH
PHS   Public Health Service
SOP   Standard Operating Procedure
USDA   United States Department of Agriculture
WHO   World Health Organization
3R's   Overarching principles of animal-based research: replacement, refinement, and reduction

SCIENTIFIC AND HUMANE ISSUES IN THE USE OF RANDOM SOURCE DOGS AND CATS IN RESEARCH

Committee on Scientific and Humane Issues in the Use of
Random Source Dogs and Cats in Research

Institute for Laboratory Animal Research

Division on Earth and Life Studies

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v

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viii

Preface

The ancient Indian fable of the Blind Men and the Elephant describes a group of blind men who each touch a different part of an elephant and, when they compare their individual impressions of the animal before them, discover that they are in complete disagreement. While assorted versions of this fable vary about the contentiousness of the debate and how it is resolved, the primary lesson is that opinions can differ among individuals. The secondary message is that differences must be resolved in order to reach consensus. Such were the challenges of this committee.

The National Academies endeavor to appoint committees that represent a broad range of perspectives and expertise in order to accomplish a fair and balanced study, and this committee was no exception. But what seemed to be a relatively straightforward task in determining the desirability and necessity of random source dogs and cats from Class B dealers for National Institutes of Health (NIH) research turned out to be far more complex than the committee initially realized. The complexity goes back to the very origins of medical research and the animal protectionist movement, and is steeped in the American public's emotional ties to dogs and cats (which Frank Loew[1] termed "America's Sacred Cows") and changing trends in public attitudes toward research using these familiar animals. The American public has insisted that their pets be protected, resulting in pas-

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[1] Personal communication from the late Franklin Loew, DVM, PhD, Diplomate of the American College of Laboratory Animal Medicine, member of the Institute of Medicine, former Dean of Tufts School of Veterinary Medicine and Cornell School of Veterinary Medicine, past President of Becker College, research scientist, and advocate for research animal welfare.

sage of the original Animal Welfare Act in 1966, with several subsequent revisions. The enforcement arm of the Act, the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), has also repeatedly amended its Animal Welfare Regulations to better enforce the Act. Despite these efforts, infractions continue, including recent egregious ones that sparked renewed concern by the public and Congress, which was the impetus for convening this committee.

In contrast to the emotion and conviction that pervade public sentiment toward dogs and cats, the scientific community views the "elephant" rationally. The U.S. dog and cat population, with its many breeds and numbers, represents a rich resource for advancing medical knowledge through discovery and use of models with homology to many human diseases.

The panel of experts on this committee represented a broad spectrum of perspectives, and endeavored to approach its task without bias, despite strong and admittedly emotional personal opinions. As Chairman of this committee, I was impressed that its members set aside their individual differences in order to reach consensus, and as a result were able to factually describe the entire elephant, with all of its complexity.

The committee acknowledges with appreciation a number of individuals who provided input and testimony from their varied perspectives for the committee's deliberations. At the first meeting, in Washington, DC, on October 7, 2008, the following individuals presented information to the committee:

Kimberley Cohen, Covance
W. Ron DeHaven, American Veterinary Medical Association (AVMA)
Jerry DePoyster, USDA/APHIS
David A. Kass, Johns Hopkins University
Cathy Liss, Animal Welfare Institute
Stacey Pritt, Covance
Margaret Snyder, NIH sponsor and contact person
Bill Yates, University of Pittsburgh

The following additional individuals presented information to the committee during its January 12, 2009, meeting in Washington, DC:

Stephen O'Brien, National Cancer Institute, NIH
Robert Willems, USDA/APHIS

Others who provided invaluable assistance to the committee include:

Chester Gipson, USDA/APHIS
Jodie Kulpa-Eddy, USDA/APHIS

The committee also received written material submitted for consideration by the American Physiological Society, the Humane Society of the United States, and individuals with business or personal interests in the subject of the committee's deliberations. In addition, the committee received information from several Class B dealers in response to specific questions posed by the committee.

The draft of this report was reviewed by individuals chosen for their diverse perspectives and expertise, in accordance with procedures approved by the Report Review Committee of the National Research Council (NRC). The purpose of this independent review is to provide candid and critical comments that will assist the committee in making its published report as sound as possible, and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberation process. The committee thanks the following individuals for their review of the draft report:

B. Taylor Bennett, Management Consultant
Larry Carbone, University of California—San Francisco
Jerry Collins, Yale University
Linda Cork, Stanford University
W. Ron DeHaven, American Veterinary Medical Association
Betty Goldentyer, U.S. Department of Agriculture
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Appointed by the NRC, these individuals were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring Committee and the institution.

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Dogs and Cats in Research

Contents