AV MAGAZINE

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The State of Animal Research: Over 100,000,000...and Counting

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Organized and established in 1883.

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CONTENTS

FEATURES

COLUMNS

Who Are We?

Founded in 1883, the American Anti-Vivisection Society (AAVS) is the oldest non-profit animal advocacy and educational organization in the United States dedicated to ending experimentation on animals in research, testing, and education. AAVS also opposes and works to end other forms of cruelty to animals. We work with students, grassroots groups, individuals, teachers, the media, other national organizations, government officials, members of the scientific community, and advocates in other countries to legally and effectively end the use of animals in science through education, advocacy, and the development of alternative methods to animal use.

AAVS has two main divisions, each involved in specific activities. Animalearn is the education program of AAVS, which focuses on ending vivisection and dissection in the classroom. From elementary through college levels, Animalearn helps countless individuals make their classrooms more humane. Animalearn operates the most aggressive dissection alternatives lending library in the country, The Science Bank; it provides alternatives to using animals, from basic dissection, through psychology experiments. Animalearn also participates in national teacher conferences and hosts workshops to help teachers learn ways of educating without harming other living creatures. Animalearn's National Humane Educators Network links interested parties with speakers across the country, bringing the message of humane education to thousands.

The Outreach division of AAVS educates the general public about animal issues through one of the top-rated literature collections in the animal advocacy movement and the informative AAVS website. Our quarterly publication, *AV Magazine*, and bi-monthly newsletter, *Activate For Animals*, provide comprehensive up-to-date information on the scientific and ethical dimensions of animal experiments and alternatives. Both publications encourage AAVS members and supporters to become actively involved in our campaigns. Outreach staff also travel to speaking engagements and conferences and place advertisements in national publications to spread the AAVS message across the country.

The Alternatives Research & Development Foundation (ARDF), an affiliate of AAVS, awards grants to scientists and educators working to develop non-animal methods of investigation. ARDF's unique program provides the necessary resources for the development of alternatives to the use of animals, and it advocates the use of alternatives through the internet and by participating in conferences and seminars. Through these endeavors, ARDF works to promote scientific solutions for today with humane visions for the future.

We ask you to become a member of AAVS and help us to end the use of animals in science through education, advocacy, and the development of alternative methods. It is only through the support of members and other individuals that we are able to continue our vital and successful programs.

American Anti-Vivisection Society

First Word

Although the area of alternatives development is expanding in practical use and acceptance, the number of animals utilized in research is increasing. This fact is especially true for *Mus musculus*, the type of mouse most commonly used in research and testing. It is estimated that upwards of 100 million mice and rats are bred for use in laboratory experiments, with none of them being afforded even the minimal standards of care afforded by the Animal Welfare Act. Because of this, we have chosen the mouse to grace the cover of this edition of the *AV Magazine*, which focuses on several types of research.

In this issue, the major areas of research are covered, including toxicity testing of cosmetics, household products, and drugs; biomedical research and the use of animals as 'models' of disease; military and space research; agriculture research; psychology and addiction research; and alternatives development and its application.

As an interesting complement to the release of this edition of the *AV Magazine*, earlier this year, the Nuffield Council on Bioethics, based in the United Kingdom, published a lengthy report entitled "The ethics of research involving animals." Although the report did not by any means call for the end of animal research, it did present a fairly balanced summary of recommendations to improve the well-being of animals used in research and testing, and acknowledges that moral justification should be an issue of consideration when analyzing the ethics of animal research, particularly on a case-by-case basis.

Additionally, in its consensus statement by the Council's Working Party, the report states, "the importance of the Three Rs (Refinement, Reduction, and Replacement), and especially the of the need to find Replacements, cannot be overstated." The Working Group goes on to note that "the potential of the Three Rs is far from being exhausted" and that questions regarding their availability and use must also be answered.

The report also discusses regulations, recommendations on how to refine them, and what additional information should be included in researcher disclosure, including a more practical description of the study being proposed so that the public can have a better understanding of the purpose, procedure, the number of animals used, and what happens to the animals during and at the conclusion of the experiment. It also states that "proper attention to the welfare of animals involved in research and the accountability of scientists who conduct research on animals cannot be achieved merely by having detailed regulations," meaning that the Working Party believes that good laboratory practices and quality care are imperative to good, reliable science.

Interestingly, the Working Party also states that whether or not an experiment can or should be justified should also be considered. This is an important point in light of the dog that was recently cloned in South Korea. Over 120 dogs were used in invasive experiments to obtain one cloned Afghan hound puppy, a breed that certainly is not commonly used in research. The future health of this puppy is uncertain since other cloned animals have been afflicted with serious ailments that have ended their lives prematurely. Although the scientists assert that cloning dogs will in some way benefit future biomedical research, in light of the unreliability and cost of this science, it is doubtful that this claim will ever come to fruition. To this end, AAVS remains diligent in carrying out its mission to end the use of animals in research, testing, and education.

Over 100,000,000...and Counting

By Crystal Schaeffer, M.A. Ed.,
AAVS Outreach Director

Dogs. Cats. Guinea pigs. Mice. Rabbits. Salamanders. Minks. Sea sponges. Macaques. Lizards. Turtles. Rats. Pigs. Sheep. Fruit flies. Fox. Deer. Chimpanzees. Hamsters. Tamarins. Venomous snakes. Coral. Chickens. Salmon. Baboons. Frogs. Zebrafish. Ferrets. Cows. Cockroaches. Gerbils. Chinchillas. Honeybees. Trout. Squid. Pigeons. Goats. Horses. Squirrel monkeys. And the list goes on.

According to the United States Department of Agriculture (USDA), well over 1.1 million warm-blooded animals (i.e., dogs, rabbits, chimpanzees) who are covered by the Animal Welfare Act (AWA), legislation outlining minimal standards of care and treatment of animals in laboratories, zoos, circuses, rodeos, etc., were utilized in biomedical research and testing in 2002. Add to this figure the number of birds, mice, and rats (who are not covered by the AWA) used in research, the latter two of whom have been estimated to number upwards of 100,000,000, according to *What Animals Want: Expertise and Advocacy in Laboratory Animal Welfare Policy* by veterinarian Larry Carbone. While this marks an almost inconceivable nine figure tally of animals used in research and testing, it still does not include cold-blooded animals (i.e., insects, fish, amphibians, etc.), who are also not covered by the AWA.

This presents an ever-growing concern of animal advocates. Because only approximately one percent of animals utilized in research are covered by the Animal Welfare Act, upwards of 99 percent of those animals used in research and testing have *no* legal right to minimum standards of care and treatment. And just as importantly, the general public has virtually *no knowledge* of what species are used in biomedical research and testing, how many individuals are involved, what exactly happens to them over the course of a study, and their fate at the conclusion of the experiment. In short, experimenters who utilize mice and rats, birds, cold-blooded animals, and other animals excluded from the AWA (i.e., farmed animals used in agriculture research like cows and pigs) have no public accountability regarding the research they are conducting.

This quandary alone could spur a heated discussion regarding the ethical issues and debacles involved in animal research. And if information regarding such modes of scientific investigation were more widely known, the general public would command a better understanding of the reality of the situation, leaving little doubt that there would be greater debate over the 'necessity' of animal experimentation.

Likewise, animal advocates, as well as many scientists, have also come to question the validity and reliability of data construed through animal research. In order to fully appreciate this notion, consider these facts: acetaminophen is a therapeutic in humans but poisonous to cats; mice and rabbits are physiologically unable to vomit (which is why they are often used in oral lethal dose toxicity tests); oral contraceptives increase a human's risk of developing blot clots, while they prolong blood clotting times in dogs; women process anesthesia an average of four minutes faster than men, causing them to wake up from surgery much more quickly; penicillin is toxic in guinea pigs but a highly important drug in the history of human medicine; while men experience 'classic' chest pain that radiates down the arm when having a heart attack, women suffer atypical chest pain, abdominal pain, nausea, and fatigue; and morphine causes hyper-excitement in cats, yet it has quite the opposite

effect in calming human patients. These are just a handful of tangible examples representing the physiological and metabolical disparities that exist among different species and sexes. Similar differences can also be found among different breeds, age and weight ranges, and ethnic backgrounds.

With the breadth of such discrepancies, accurately assimilating and processing data derived from animal experiments and accurately extrapolating that information to human patients can be an exercise of speculation, with no one really knowing the true outcome of the investigation until the treatment in question is prescribed clinically and is found to improve a human condition, make it worse, or catalyze the manifestation of an otherwise completely unrelated condition. In essence, despite years of investigation, the sacrifice of thousands of animals, millions of dollars spent, and federal government approval to market a particular therapy, researchers are often still unsure of what fate actually awaits human patients who become the first to test their new drug or treatment.

A fair question to then ask is, "With such uncertainty, why does the biomedical research community and its allies revere investigational methodologies that utilize animals?" The 'justifications' for animal research vary from cost (especially for small animals such as mice and rats who are easy to house, have short lifespans, and reproduce quickly), 'necessity,' since few non-animal alternatives exist (although alternatives development is one of the fastest growing areas of investigation, and great strides in medical history have been made based on clinical and epidemiological studies), and a claimed unwillingness to test on humans (despite the fact that, as we have already discussed, humans are subject to unproven treatments, and humans are also utilized as voluntary experimental participants and even involuntary participants in some cases in the Third World). But perhaps the most powerful influence has been tradition.

Today's practice of using animals in biomedical research has its roots entrenched in the 19th century, when physiologists such as the renowned Claude Bernard, who published *Introduction to the Study of Experimental Medicine* and popularized the artificial production of disease in animals, laid the foundation for the biomedical industry's current reliance on animal models in research. Bernard regarded the vivisection laboratory as a "true sanctuary of medical science" and considered it much more important than the clinical study of hospital patients. The underlying theme of Bernard's teaching continues in today's classrooms as animal dissection and vivisection are the traditional, if not archaic, mode of learning basic anatomy and physiology.

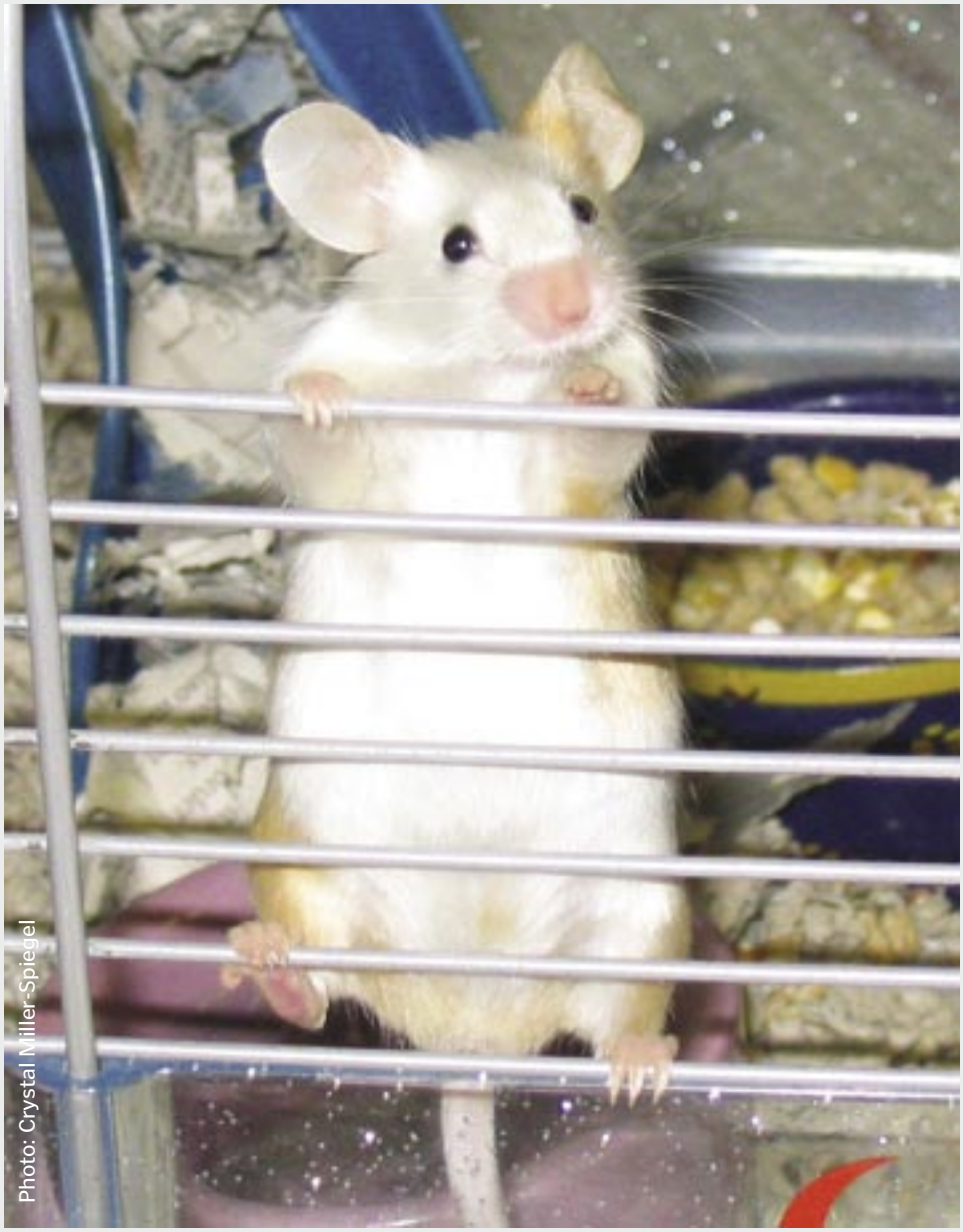
Photo: Crystal Miller-Spiegel

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However, despite the growing popularity of animal research in the 19th century, social reformers such as Edwin Chadwick in Britain and Lemuel Shattuck in the U.S., both of whom played leading roles in implementing sanitary reform, cited human epidemiological studies, not animal research, which revealed that people who lived and worked in dirty, overcrowded, and unsanitary conditions with little food or clean water were much more likely to die of infectious diseases such as tuberculosis, diphtheria, and typhoid. This led to the establishment of a sanitary waste removal system, resulting in improvements in public health that were chiefly responsible for the increase in life expectancy over the 19th century.

It is also important to note that these reforms occurred much earlier than specific treatments and vaccinations to fight infectious diseases which became available in the mid 20th century. And as a testament to the impact of sanitary reform, in 1971, the President of the Infectious Disease Society of America, Edward Kass, stated that the decline of infectious disorders, correlated with improving socio-economic conditions, is "the most important happening in the history of the health of man."

Despite the impact of this event, research involving animals continued through the 20th century, and today the majority of the biomedical industry considers it the dominant form of biological investigation. Most likely this notion has taken such a stronghold because early scientists like Bernard considered it an 'education tool' in learning more about animal and human anatomy and physiology. As such, animal use became and has remained commonplace in the biology classroom and the graduate-level laboratory, laying an unconscious foundation in the minds of budding scientists who are trained to rely on animals to study bodily functions in living organisms.

Herein lies the importance of humane education, an approach to learning that encourages students (in all grade levels from elementary to graduate school) to challenge not the status quo but rather themselves, using critical thinking that enables them to explore different methodologies of investigation to answer the same biological questions. Such an approach will lead to more of a willingness to utilize alternative methods and approaches, which will also help create a broad dialogue regarding scientific investigation among regulating agencies, researchers, educators, and students alike. This is especially important as the number of animals used in research continues to climb. Although for the most part the number of so-called 'higher life forms' like dogs, cats, and chimpanzees have decreased, overall, animal usage has been dramatically increasing due in part to a growing popularity and reliance on genetic engineering, which often involves mice who are not covered by the AWA. In addition, the number of monkeys used in laboratories continues to grow since they are commonly used in bioterrorism/infectious disease research and drug toxicity testing.

So, as is often the case in social issues, education plays a pivotal role in effecting change in how the public and scientists view animals. If we as advocates are to hope to instill change in how scientists approach their research, then we must put sufficient effort into promoting and utilizing humane education curricula to inspire the researchers of tomorrow. And it is imperative that all advocates act now...over 100,000,000 animals are counting on it. **AV**

So, as is often the case in social issues, education plays a pivotal role in effecting change in how the public and scientists view animals.

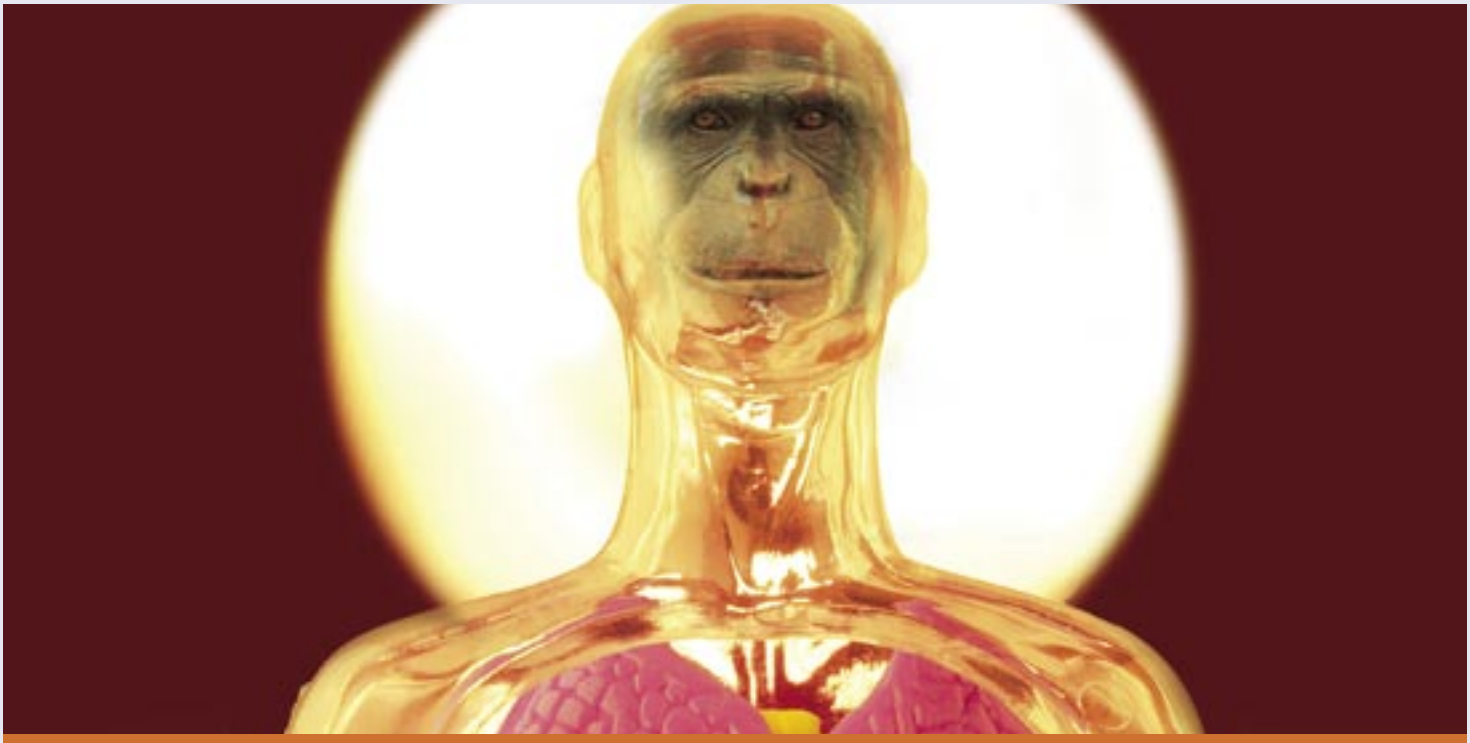
National Institutes of Health:
Tax Dollars to Fund Animal Cruelty

The National Institutes of Health (NIH), established in 1887, is one of eight health agencies of the Public Health Service, which is part of the United States Department of Health and Human Services. The goal of NIH is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability. NIH funds research and education programs in schools, hospitals, and research institutions throughout the world. It also aids in the instruction of researchers and fosters communication of medical and health science information.

While NIH portrays itself as an agency that is dedicated solely to the well-being and understanding of living creatures, its methods can sometimes be unnecessary and inhumane. For example, in an experiment exploring cocaine addiction that was performed in its Bethesda, Maryland laboratory, NIH conducted a study using 286 rats, 109 mice, and 55 macaques, all to the same end. With an endless amount of funds, it is not uncommon for NIH to perform experiments and surgeries again and again with the same results. Yet the merit of such redundancy is questionable, especially considering that there are millions of people who are voluntarily exploring cocaine addiction on a personal level.

In addition to its own research, NIH also uses tax dollars to fund animal research and coursework in universities around the country. At the University of Arizona, research is performed where primates are confined to restraint chairs with electrode devices screwed into their skulls, while being forced to perform various behavioral tasks to get water. They only are given water during the experiment, leaving them without it for up to 19 hours a day. Similar experiments with comparable findings were also performed at Emory University, the University of California-Los Angeles, and the California Institute of Technology. Ohio State University (OSU) offers a course where the students surgically expose the spinal cords of mice and rats and then drop weights on the animals in order to simulate human spinal cord injuries. During a three-week period, the 269 mice and rats used are subjected to additional surgeries, invasive laboratory procedures, and rigorous behavioral exercises before they are eventually killed. OSU claims that this method is crucial for teaching students about spinal cord injury; however, using human neural cell lines, impact studies on human cadavers, and clinical trials in place of using mice and rats are equally as effective, while averting cruelty. NIH has awarded a grant to OSU to fund this course for the next five years.

In addition to its extensive history of funding and conducting research/experiments involving animals, NIH is also responsible for a significant number of studies that do not involve animals. Hopefully, NIH will continue in this vein regarding its work and will embrace alternatives to the use of animals that are more cost effective, accurate, and humane in its other experiments AV



INHERENT SUFFERING:

NON-HUMAN 'MODELS' OF HUMAN DISEASES AND CONDITIONS

By Crystal Miller-Spiegel, MS, AAVS Senior Policy Analyst

These days, it seems that researchers will attempt to induce into nonhuman animals virtually any conceivable human disease that exists, many of which do not even naturally occur in the species of animals being used. Animals are manipulated to cause or mimic diseases through genetic tinkering (i.e., inserting, deleting, or otherwise inactivating the function of genes, etc.) or physical, chemical, and/or biological means. In other cases, naturally affected animals are bred to produce more animals with a specific disease or trait. Researchers try to use these animals, or so-called 'models,' to learn about the dynamics of diseases, lifestyle or environmental effects on the disease, or treatment methods, and hope that the findings will relate in some way to people. Because the onset of the disease is intentional, and researchers want to understand its process, the animals are not usually treated as human patients would be. Their suffering is often part of study protocols.

Many researchers, companies, and academic institutions have also sought patents on not just the methods used to make animals suffer from a disease but also the animals themselves. Patents on actual animals can be very lucrative if they become in demand for biomedical and testing laboratories. For example, the first patent issued on an animal came in 1988 and was granted to Harvard University for "Transgenic non-human mammals" (U.S. Patent Number 4,736,866), involving mice genetically manipulated to develop cancers mimicking human diseases. These mice have been trademarked as the "Oncomouse" and marketed widely by DuPont, which funded the Harvard research and, hence, owns rights to the patent. DuPont has also worked with Charles River Laboratories, one of the world's largest breeders and dealers of animals for research and testing, to continue developing the Oncomouse and other cancer-prone mice.

Indeed, such animals have proven to be big business for companies like Charles River, which has an online "research models" catalog from which researchers can order a variety of animals under such headings as, "Disease Models" and "Immunodeficient Models." Charles River's Disease Models Program offers 11 types of animals who can have one or more health problems related to their cardiovascular systems, metabolism, renal function, or oncology (i.e., development of cancer). Animals are labeled as "Diet Induced Obesity [DIO] Rats," "Spontaneously Hypertensive Heart Failure [SHHF] Rats" and "Stroke Prone Rats," to name a few. As with the Oncomouse, many animals sold by Charles River and other companies have resulted from experiments done at universities, government institutions, and private companies.

Another large dealer, The Jackson Laboratory, states on its website, "Each year, the

Laboratory supplies approximately 2 million JAX® Mice to the global research community from more than 2,700 varieties, 97% of which are available only from The Jackson Laboratory." The Jackson Laboratory maintains an extensive website database of mice who are available for purchase or are "under development." The disclaimer to those ordering animals states, "...[W]e cannot guarantee a strain's phenotype will meet all expectations.... ...[W]e suggest ordering and performing tests on a small number of mice to determine suitability for your particular project."

Other major companies that sell 'animal models' to laboratories include Taconic and Harlan. Taconic sells over 50 lines of transgenic animals and also sells surgically-modified rats and mice, including animals whose glands or organs have been removed or whose brains have been injected with a neurotoxin to cause damage in order to study the neurodegenerative disease process related to Parkinson's Disease. According to its website, Harlan "offers over 200 stocks and strains of mice, rats, hamsters, guinea pigs, gerbils, rabbits, cats, and dogs."

Animals have been altered in countless ways in attempts to learn more about human diseases and conditions, and such studies are commonly funded by the U.S. government. Searches for rabbit, non-human primate, and mouse 'models' using the National Institutes of Health's Computer Retrieval of Information on Scientific Projects (CRISP) database of federally-funded research for the year 2005 produced studies of wide-ranging topics.

For example, a search under the phrase "rabbit model" yielded 72 research projects (a search under "rabbit" resulted in 1521 hits). Rabbits are used in studies to model human syphilis, carpal tunnel syndrome, intoxication of ricin and Shiga toxin, Lyme Disease, tuberculosis infection, periodontal disease and diabetes (in combination), liver cancer, heart failure, and genetic heart disorders, among others.

"Primate model" yielded 137 hits (searching for a particular species, such as *Macaca mullata* resulted in 573 hits, "monkey model" returned 35 projects, and "primate" yielded 693). The "primate model" search demonstrated that monkeys are used in government-funded experiments as 'models' for AIDS and tuberculosis (both as separate and combined diseases), cocaine addiction, genital ulcers, brain damage, fetal alcohol syndrome, and the list goes on and on.

For mice, a search under "murine model" produced 434 studies ("mouse model" found 1652, and "mouse" yielded a whopping 15,144 studies, though some of them did not involve live animals but utilized cells, tissues, or other samples). A quick glance at the list of funded projects shows that mice are used as 'models' for monkey B virus infections, HIV, hepatitis C, asthma, Chlamydia and arthritis (combined), pancreatic and prostate cancer, squamous cell carcinoma (with human tumors transplanted into mice), West Nile virus, *Escherichia coli* infection, peanut allergies, and many, many more.

Scientists in laboratories continually overstep the boundaries of nature. The creation of chimeras—non-human animals who are comprised of two or more cells or tissues of different genetic composition (i.e., of different species)—has only recently gotten attention from the media but has in fact been happening for years. In the April 2005 National Academy of Sciences report, *Guidelines for Human Embryonic Stem Cell Research,* "interspecies mixing," or the transfer of human stem cells into animals, is discussed, and it appears that, for the authors of the report, the more 'human' the animal, the more cause for concern. Some examples of chimeras include: mice with human brain cells, pigs with human blood, and the transplantation of human fetal organ tissue derived from aborted human fetuses into young, immunocompromised mice.

In analyzing attempts to model human diseases and conditions by using non-human animals, some scientists do admit the difficulty in applying results from animals in laboratories to everyday people. As author Timothy A. Cudd of Texas A&M University stated in the June 2005 issue of *Experimental Biology and Medicine*, "Because prenatal alcohol exposure causes damage by multiple mechanisms, depending on dose, pattern, and timing of exposure, and because no species of animal is the same as the human, the choice of which animal model to use is complicated."

In a carefully titled review paper, "Why Do Animal Models (Sometimes) Fail to Mimic Human Sepsis?" in the journal *Critical Care Medicine* published in 2004 (Vol. 32, No. 5), Charles T. Esmon stated, "...[S]ome of the differences between animal models and humans preclude direct extrapolation from the animal studies to the [human] patient...." He also cited several factors related to this, in his words, "failure": the use of different infective agents, age differences (i.e., young adult animals are used in experiments, but many human patients are either neonates or older adults), secondary health problems in the human patient that are not present in the animals (e.g., high blood pressure, cancer, diabetes, immune suppression), treatment timing, dosage differences, organ infection vs. blood infection, "different dose-dependent efficacies," "differences in the use and effectiveness of antibiotics," and *"lack of intensive care in the animal studies"* (emphasis added.) Esmon also notes confounding environmental conditions in laboratories that are not present in human hospitals: "...[R]odents and baboons are housed in feces-contaminated environments. Many of the animals used for studies of sepsis are coprophagous (i.e, ingest their own feces), potentially allowing the development of resistance [to induced infections]...."

Researchers from the Vanderbilt University Medical Center also describe problems with animal 'models' in their aptly but not concisely titled article, "The Use of Animal Models in the Study of Complex Disease: All Else is Never Equal or Why Do So Many Human Studies Fail to Replicate Animal Findings?" published in the journal *Bioessays* in 2004 (Vol. 26, No. 2). Though they support the use of animal 'models,' the authors cite the following problems: "...[T]he design of animal studies automatically controls many variables that can confound human studies"; "...[I]n human studies, it is impossible to control for many intrinsic (i.e., genetic) and extrinsic (i.e., environmental) factors"; "...[T]he phenotypes studied in animals are not truly identical to human disease but are limited representations of them"; "...[G]enetic manipulations in animal models are often extreme—gene titration or knockouts may be more severe than one would see in most human populations"; and "In most cases, animal studies do not assess the role of naturally occurring variation and its effects on phenotypes."

Though researchers acknowledge that humans are truly the gold standard when it comes to studying human diseases, there are variations within the human species as well. Fortunately, most people are protected from being used in invasive and harmful research, but animals obviously are not. Researchers view the use of non-human animals as a primary means of learning about human disease, but this can also lead them down the wrong path, resulting in more harm to people and other animals. **AV**

Product Testing in the United States: A Need for Change

By Rachel Menge, Administrator, and Michelle Thew, Chair, Coalition for Consumer Information on Cosmetics

While the European Union has seen some recent victories for animals on the product testing front, an unfortunate reality exists: product testing remains a common practice within the cosmetic and household product manufacturing industries worldwide. Familiar brands and popular companies still rely on the antiquated and cruel animal testing model. U.S. product testing practices account for much animal suffering and give rise to an urgent need for change.

Many conscientious and compassionate consumers believe that product testing is a thing of the past. Bottles and labels filling store shelves often boastfully claim, "We do not test on animals." With so many companies asserting such an animal testing policy, no wonder a consensus of confusion exists. Not only is product testing on animals more prevalent than imagined, the lack of labeling guidelines and numerous "cruelty-free" lists offer little relevant information about the current state of the product testing industry and its direct contribution to immense animal suffering.

Regrettably, although many products carry a "not tested on animals" claim or image implying a testing policy, these claims often refer to the finished product, not to that product's actual *ingredients*. Ingredient testing is where most animal testing occurs, rendering a final product claim virtually meaningless. A company's simple claim often masks the practices behind the final product, leaving consumers unsure of a company's actual animal testing policy, and whether that policy extends to the product's ingredients.

Common Product Testing Procedures on Animals

Conservative estimates place animals used in research at well over 100 million. However, no one knows how many animals are used in the United States today because legislation that requires animals to be counted in laboratories excludes birds, mice, and rats, with the latter two indisputably the most used animals in the industry. A staggering 100 million mice are estimated to be used in U.S. laboratories alone. It is further estimated that 10 to 20 percent of the animals used in laboratories are the subjects of safety testing of chemicals and consumer products. We can only speculate on the exact number and extent of animals used in this industry.

Animals continue to be subjected to a range of tests including, but not limited to, acute toxicity, chronic toxicity, repeat dose toxicity,

mutagenicity, carcinogenicity, teratogenicity, reproductive toxicity, toxicokinetics, and endocrine disruptors. Guinea pigs, mice, rats, rabbits, fish, and dogs are often the unfortunate test subjects. A few common product tests include:

Draize Test. Developed in 1944, this eye irritancy test aims to assess the acute irritancy of a substance when applied directly to the eye. Test substances range from cosmetic ingredients to oven cleaners. The albino rabbit is the typical test subject. Once the rabbit is immobilized by confinement in a head-holding device, the test substance is placed in one of the rabbit's eyes, usually without anesthetic, while the other eye serves as a control. Irritation is observed for up to 21 days, and scores are assigned by technicians observing damage to the eye.

Skin irritancy and corrosion testing. These tests assess the toxicity of a chemical applied to the skin. Patches of the animal's fur are shaved off, and the animal endures application of the test substance to the exposed skin. The skin is observed for reactions such as reddening, swelling, inflammation, and ulceration.

Lethal Dose Fifty Percent (or LD50). In an LD50 test (an oral poisoning test or 'toxicity test'), animals are forced to ingest measured lethal amounts of test chemicals to determine at what dose half of the animals die. Death comes only after the animal experiences the grisly effects of the poisoning. Sometimes the volume alone of the substance the animals are forced to ingest actually kills them. Other times the test measures the experienced ghastly effects of the chemical destroying the animal's internal organs until death.

Controversy surrounding product testing involves both ethical and scientific criticisms. While these tests represent only a small portion of those used to manufacture beauty and household products, they help demonstrate the immense and unnecessary suffering inflicted on animals. Validated alternatives (such as Corrositex) to animal testing exist, as well as a number of promising alternatives (i.e., Episkin, Epiocular, Epiderm) waiting in the wings, which are cheaper, more humane, and more reliable.

Legislative Mandates for Change

Recent legislative successes for animals in Europe help demonstrate a momentum of change in efforts to end this unnecessary practice once and for all. The European Union (EU) is currently leading the way in effectively ending product testing for cosmetics and household products. Legislation now passed in the EU will include: 1) a complete animal testing ban six years from the date the legislation passed (around 2009); 2) a sale ban from 2009 for the majority of animal tests; and 3) a sale ban from 2013, 10 years after the legislation passed, for additional test areas (toxicokinetics, reproductive toxicity, repeat dose toxicity).

The EU's officially sanctioned acceptance of non-animal based test methods draws global attention to the fact that the time is now for worldwide change in the regulatory authorities concerning product testing.

Currently, neither the U.S. Food and Drug Administration (FDA) nor the U.S. Consumer Product Safety Commission requires animal testing for cosmetics. However, while animal testing is not *required*, it remains *accepted* by regulatory agencies, and, therefore, the practice continues. With no mandates to utilize alternatives (even when deemed equivalent to animal-based tests), there is less of an incentive for manufacturers to invest in, or utilize, non-animal based testing.

Developments in Non-Animal Based Testing

What makes the continued use of tests, such as the Draize test, skin irritancy, or toxicity tests, additionally problematic are the existing alternative strategies and testing methods that could alleviate this senseless suffering.

Known safety data exist for common ingredients currently subjected to further animal testing practices. More than 8,000 ingredients are already deemed safe after years of testing. Additionally, huge strides have been made in non-animal based *(in vitro)* testing, which offer valid alternatives to antiquated (and arguably inapplicable) animal-based tests. Progressive companies use *in vitro* testing practices such as chemical assays, artificial skin systems, human volunteers, and computer models.

If these non-animal-based methods were mandated, in step with the European Union's achievements in this regard, the U.S. could see an end to animal testing for cosmetics and household products.

Consumer Power

Compassionate consumers in the U.S. can take a stand against animal testing. By purchasing cosmetics, personal care, and household products certified by the Coalition for Consumer Information on Cosmetics (CCIC), consumers send a message of support to those companies that make a voluntary decision to end animal testing throughout their manufacturing process. Companies that sign the CCIC Corporate Standard of Compassion for Animals must commit in writing that neither their products, nor the ingredients used in those products, are (or ever will be) tested on animals after a fixed date. These companies must verify that their suppliers and/or manufacturers are not only aware of the company's policy but have agreed to abide by the guidelines of the Standard. As a result of that pledge, these companies have made a commitment to end animal testing once and for all and to continue to monitor their suppliers as new products develop.

For more information on the CCIC and the leading animal groups comprising the Coalition, or to view a list of approved companies, please visit www.leapingbunny.org or call (888)546-CCIC. **AV**

Look for the CCIC leaping bunny logo, the only trademarked cruelty-free logo to ensure that the products you are purchasing are not tested on animals!

Perhaps one of the most defining characteristics of humankind is its inquisitive nature. In the biological sciences, one area of exploration and creativity that has helped to impact the development and growth of our society is drug and treatment discovery. Indeed, the discoveries of drugs such as morphine and penicillin (both founded primarily without the use of animals) not only greatly affected medicine by opening the door to novel approaches to treatment and care but also the quality and longevity of life of countless patients whether they be lying on an examination table in the 'old west,' in a foxhole in Normandy, resting comfortably at home, or recovering at a renowned university hospital.

Searching for Innovation: Drug Research

By Crystal Schaeffer, M.A. Ed., AAVS Outreach Director

In anyone's mind, scientist or not, it is astonishing to imagine the process that begins with a simple desire to help eliminate pain and suffering or fight disease; and continues by analyzing a bag of chemical compounds, understanding their structures and chemistry, picking which one will act like a key to unlock a medical mystery that lies within the interworkings of 206 bones, more than 600 muscles, countless organs, nine bodily systems that seem to work independently yet are completely interconnected, and no less than a million cells that perform specific functions; and ends, hopefully, with an effective drug that will help improve the lives of patients.

The breadth of drug discovery is infinite. However, according to the U.S. Food and Drug Administration (FDA), "The medical product development process is no longer able to keep pace with basic scientific innovation." In essence, our biological knowledge is growing, yet "...the gap between bench discovery and bedside application appears to be expanding," meaning that while scientists are continually learning more about our bodies, they are having difficulty producing drugs that help improve the human condition and in fact do not harm people. Many believe that this is symptomatic of research based on animal studies.

Regulating a Multi-Billion $ Industry

In 1862, then President Abraham Lincoln established the Bureau of Chemistry, which eventually evolved into the U.S. Food and Drug Administration, to assess adulterated food and drugs. Forty-four years later, the Food and Drug Administration Act of 1906 was enacted, requiring drugs to meet official standards of strength and purity and prohibiting the sale of misbranded food, drink, and drugs. However, the FDA gained little power from the Act, and quackery remained rampant.

Then, in 1937, 107 people died, many of them children, after taking a patented 'medicine' marketed as Elixir Sulfanilamide, which contained a known toxin, although the manufacturer was not aware of this. As a consequence of this tragic event, Congress enacted the Federal Food, Drug, and Cosmetic (FD&C) Act of 1938, marking the birth of the modern FDA. The FD&C Act required manufacturers to prove the safety of drugs *before* they could be marketed and established penalties for fraudulent claims and mislabeling. Years later, in response to the Thalidomide catastrophe, which led to over 12,000 babies being born in Europe who had flipper-like appendages instead of arms and legs, Congress toughened drug regulation in 1962 by passing the Kefauver-Harris Amendment, requiring drug manufacturers to provide evidence that their products are effective, as their labels state. Such actions have erroneously helped the animal research industry to gain a stronghold on drug development.

Today, drug regulation is an arduous process, as is drug development. It takes an average of eight and half years of research and testing and review by the FDA for a drug to finally reach the market, at an average cost of $500 million. The drug development process begins with scientists studying various chemical compounds and their effects on enzymes, cell cultures, and/or other substances that are believed to be important in the manifestation and progression of a disease or ailment. Much of the investigation at this early stage is *in vitro* research, although animals can also be used. Chemicals thought to be potentially effective are then tested in two or more species of animals, one rodent (usually rats and mice) and one non-rodent (often dogs and monkeys), in a rather archaic attempt to determine whether they can be used in humans, despite the fact that it is extremely difficult to extrapolate such findings to human patients. As a footnote to this fact, the widely respected medical journal *The Lancet* commented in 1962 that "We must face the fact that the most careful tests of a new drug's effects on animals may tell us little of its effect in humans." Despite this type of commentary, animal use continues in drug development, and according to the FDA, no more than five out of 5,000 compounds tested pass preclinical trials and are proposed to the FDA for clinical testing.

Once the FDA approves a drug for human testing, it enters "phase I" studies where the substance is administered to a small number of healthy volunteers to assess whether it causes adverse reactions. If no major problems occur, the drug enters "phase II," and its effectiveness in treating actual patients is measured. If successful, the drug moves on to "phase III" where its safety, effectiveness, and dosage are

determined through blind studies (i.e., one group of patients is given the drug while the other is given a placebo, with neither knowing in which category they fall). The results of phase III trials are submitted to the FDA, and if the agency determines that clinical testing demonstrates that the potential benefits of the drug outweigh the possible risks, it is approved for marketing.

Drug Failings

The FDA reports that "adverse events associated with drugs are the single leading contributor to preventable patient injury, and may cost the lives of up to 100,000 Americans, account for more than 3 million hospital admissions, and increase the nation's hospitalization bill by up to $17 billion each year." And the agency estimates that drug-related injuries outside the hospital add $76.6 billion to health care costs.

The FDA also stated in its 2004 report entitled "Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products" that an "inability to predict [adverse drug effects] before human testing or early in clinical trials dramatically escalates costs." For example, Pfizer reported last year that it has wasted more than $2 billion over the past decade on drugs that "failed in advanced human testing or, in a few instances, were forced off the market because of liver toxicity problems." This figure represents valuable funding (and does not include health care costs that may have arisen from drug complications) that otherwise could have been directed towards the development of a different, effective drug strategy. Interestingly, the FDA admits in its report that animal research is not as reliable as many want to believe, saying "Current available animal models, used for evaluating potential therapies prior to human clinical trials, have limited predictive value in many disease states."

This admission is important because it gives credence to the negative cyclic impact that animal-based studies can have on drug research development. While it can be argued that the number of drugs being removed from the market has declined, according to the FDA, so too has the number of drugs placed on the market, a figure which has been cut in half over the past decade. Some examples of drugs that were subject to animal testing and have been removed from the U.S. market in recent years due to adverse and/or unintended reactions include Vioxx (manufactured by Merck), which caused as many as 140,000 heart attacks and strokes in American men and was dubbed by the Associate Safety Director of the FDA as the "single greatest drug-safety catastrophe in the history of the world;" Posicor (Hoffman LaRoche), which caused liver problems; and Duract (Wyeth-Ayerst), responsible for at least 20 incidents of severe liver effects which lead to the deaths of four patients and eight requiring liver transplants. Additionally, the FDA acknowledges that many drugs removed from the market "posed greater health risks for women than for men." These include Seldane (Hoechst Marion Roussel) and Propulsid (Janssen Pharmaceutica), both of which caused irregular heart beats; Rezulin (Parke-Davis/Warner-Lambert), which caused liver failure; and Lotronex (GlaxoSmithKline), which caused intestinal inflammation.

Alternative Potential

The FDA's report also discusses the future of drug development research and urges the scientific community to move forward in finding innovative investigational methodologies. "If biomedical science is to deliver on its promise, scientific creativity and effort must also be focused on improving the medical product development process itself.... We must modernize the critical development path that leads from scientific discovery to the patient." Certainly, one way to do this is to look towards non-animal research techniques, which can be directly extrapolated to actual human patients.

Many may scoff at such a suggestion, claiming that animal research is responsible for many medical advancements. However, it is clear that drug development is in need of transformation, and the FDA points to the fact that non-animal approaches could be the answer. For example, the FDA stated in its report that "...there is hope that greater predictive power may be obtained from *in silico* (computer modeling) analyses such as predictive toxicology." Computer technologies include a recently developed 3-D computer modeling system that tests how drugs are broken down in the liver within hours instead of weeks as in animal testing and drug "Absorption, Distribution, Metabolism, Excretion, and Toxicity" (ADMET) data computer programs that use known biochemical and physical properties to generate qualitative and quantitative structure-activity relationships. Regarding the positive outcomes of computer technology, the FDA stated, "Some believe that extensive use of *in silico* technologies could reduce the overall cost of drug development by as much as 50 percent."

Another alternative approach that can play an important role in drug development is the National Cancer Institute's Developmental Therapeutics Program, which created the In Vitro Cell Line Screening Project, a program designed to provide high-volume drug screening for potential anti-cancer agents. Reportedly, the Project evolved from a "dissatisfaction with the performance of prior *in vivo* [animal] primary screens," and uses 59 human tumor cells lines to evaluate anti-cancer effects of potential drugs, and has replaced animal testing in this specific area at the National Cancer Institute.

Pharmacogenetics, the study of drug metabolism and responsiveness due to an individual's inherited or genetic traits, and pharmacogenomics, the study of genes that influence drug responses, have also shown great promise in helping to predict drug efficacy and toxicity. Such approaches can aid in streamlining clinical trials and have the potential to 'personalize' drug delivery for patients, limiting adverse drug reactions. Additionally, pharmacokinetics utilizes microdose studies that can be used to monitor minute drug levels in the blood and other bodily fluids of human volunteers using sensitive measuring technology that provides precise data.

While it may seem far off to expect drug development without the use of animals, it is not out of the realm of possibilities. Pharmagene is a drug development company (incidentally owned by Pfizer) "whose aim is to provide better drug discovery based on the use of *human* biological information." Pharmagene bases all its drug research on human cells and tissue, decrying the use of animals in its research. Its website states, "Pharmagene believes that no animal species is sufficiently similar to man to act as a wholly reliable surrogate. Indeed there is extensive evidence that the use of animal (non-human) tissue can result in the generation of potentially misleading information."

Conclusion

Drug development has certainly evolved over the last century, and we are sure to be amazed with what the future holds for drug treatment and discovery. Though animal testing once was believed to be the only way to study the effects of drugs, new technology is emerging that could have the potential to redefine this area of biomedical research. But until the time comes when animal research fades as a tool of the past, we must continue searching for innovation. **AV**

SEEKING SCIENTIFIC HEIGHTS WITH MORAL LOWS: VIVISECTION IN MILITARY & SPACE RESEARCH

By Cynthia M. Zipfel, AAVS Outreach Coordinator

Vivisection is everywhere. From clothing to cosmetics to food to medicine, animal experimentation is present in nearly all aspects of life. And while many are making great strides to eliminate the use of animals in science, there are countless others who still embrace the utilization of animals in their research. Two of the most recognized agencies to practice vivisection are the Department of Defense (DoD) and the National Aeronautics and Space Administration (NASA). In the fiscal year 2001, 330,149 animals, including birds, cats, dogs, ferrets, fish, goats, marine mammals, mice, pigs, primates, rabbits, rats, and sheep, were used in military and space related experiments, according to the DoD, and this total does not include animals used for breeding. Given the increased interest in bio-defense and infectious disease research after September 11, 2001, the numbers of animals used by the DoD have likely increased since then, although it is impossible to know for sure, since the DoD no longer makes its reports available for public viewing.

The United States military uses taxpayers' dollars to fund animal experiments that are aimed at furthering the development of new weapons, bio-terrorism tactics, and infectious disease control. Second only to the National Institutes of Health (NIH), the DoD and the Veterans Administration (VA) combined are the federal government's largest users of animals, accounting for nearly half of the total number utilized for research.

The military conducts animal experimentation in nearly all aspects of its research. For example, mice, monkeys, and dogs are frequently used for research involving radiation and disease control. The Armed Forces Radiobiology Research Institute in Maryland conducted two experiments to observe the effects of radiation. In one of the studies, nine rhesus monkeys were exposed to total body irradiation. Within two hours, six of the nine were hypersalivating and vomiting, and eventually died. The second experiment was similar but was performed on 17 beagles who were killed upon completion of the study, which lasted one to seven days. The 'finding' was that radiation adversely affects the gallbladder. In another study, pigs were subjected to severe burns in order to determine how large of a burn can be survived by 50 to 75 percent of the afflicted animals. In addition, medical students in the military often 'practice' surgery on animals who have been intentionally injured in an attempt to simulate wounds that people in combat may sustain. Even though many of the experiments conducted by the military cause significant pain and suffering to the animals involved, in many cases medicine is not administered, which would otherwise be essential to healing and survival.

"Wound labs" have been in use by the DoD since 1957. In these laboratory experiments, animals are often suspended with slings and shot by any number of potential new weapons. In 2003, the United States Naval Board tested Pulsed Energy Projectiles (PEPs) on animals to gauge their effectiveness in creating excruciating pain followed by temporary paralysis in its victims. The weapon is eventually going to be employed to immobilize rioters, and is estimated to be ready for use in 2007.

Many of the military's experiments also seem to draw conclusions on matters that have already been well-established either by past experiments on animals or with humans through epidemiological studies. For example, the aforementioned experiments that subjected rhesus monkeys and beagles which concluded that radiation has detrimental effects on the gallbladder seems unproductive when considering all that has been learned about this topic from the countless incidents of human exposure to radiation in history. Further, the use of cell cultures can be effectively employed to predict the effects of radiation on humans in place of using animals, according to *Alternatives to Pain In Experiments on Animals* by Dallas Pratt, M.D. The military also performs biomedical experiments on animals, such as those that investigate the effects of exposure to smoke inhalation, drugs, and alcohol. Yet there are endless numbers of epidemiological studies of people who have voluntarily participated in studying the effects of these chemicals in their bodies.

NASA has been using animals in its research since the birth of the agency in 1958, and the impressive technological advancements that are achieved every day in its work are not represented in its research methods regarding the use of animals. They are utilized in NASA's laboratories and aboard its shuttles in a wide variety of experiments, from studying the effects of microgravity to the susceptibility of astronauts contracting infectious diseases.

NASA employs animals of all types for its research. According to NASA, mice are frequently taken on board to explore the effects of microgravity on the nervous system of the animals. They are placed in 'lockers' containing food and water. However, the mechanisms are tightly sealed, and while the people on board can observe the mice, they do not have access to them for any treatment or manipulation. As a result, many die from starvation or other complications during the journey. In addition to mice, squirrel monkeys, fish, and baby mammals are taken aboard to note their tribulations as a result of the anti-gravity environment. For example, baby mammals tend to suffer in space because they crave warm, cuddled environments, which are impossible to achieve in an anti-gravity situation. They also have difficulty nursing because they cannot locate their mothers' nipples. In 1996, NASA was still conducting a multi-million dollar research project called Bion that involved sending monkeys whose tails were cut off and who were placed into apparel similar to straight-jackets with restraining rings screwed into their skulls and various electrodes implanted throughout their bodies into space for 14 days. The purpose of Bion was to study the effects of microgravity and radiation in living beings.

Animals are also used in NASA's ground-based laboratories. In one study that simulated microgravity, mice were injected with bacteria called *Salmonella typhimurium*. Many died from shock or major organ failure as a result of the procedure. In another study, newborn rats were subjected to a painful experiment where they were suspended upside down from their legs for periods of up to 45 days to explore the affects that an anti-gravity environment would have on muscle atrophy.

The study of military and space developments are undoubtedly two of the most advanced and technologically sophisticated areas of research that exist in modern science today. Throughout the 20th and 21st centuries, the strides that have been made in these subject areas have affected our world positively in countless ways, from defense to infectious disease control, to our exploration of other planets, to increasing our understanding of gravity and the importance it has on our healthy existence. Certainly these achievements are to be celebrated. But with all of the resources available to military and space research facilities, these agencies should be cautious not to abuse their powerful position, and should limit their research to only that which is absolutely necessary and covers new ground. Further, as leaders in technological development, it is crucial that these agencies set the standard by making every effort to avoid the suffering of animals at all costs, by embracing and developing alternatives that are more cost effective, accurate, and humane. **AV**

The Armed Forces Radiobiology Research Institute in Maryland conducted two experiments to observe the effects of radiation. In one of the studies, nine rhesus monkeys were exposed to total body irradiation.

Biotechnology and the suffering of farm animals

The chicken called; she wants her legs back.

By Tamiko Thomas, M.Sc.,
Animal Scientist,
Farm Animal Welfare,
The Humane Society of the United States

I remember one woman at a party quite earnestly trying to convince me that in this day and age, chickens without heads, wings, and legs, like growing meatballs, were being raised for food. I didn't ask her where drumsticks come from; I thought that would be rude. Instead, I smiled and nodded and said I had never heard that, nor did I think it was possible.[1] However, as the old adage goes, truth is stranger than fiction, and bigger—but certainly not better—things are afoot for animals raised for food.

Biotechnological applications such as cloning and genetic engineering of farm animals are opening up an infinite number of possibilities and allowing scientists unprecedented control over the substance of life, DNA. Identical genetic copies or clones are being made of particularly 'valuable' animals.[2] Others are having their genes altered to grow faster or to strengthen their resistance to certain diseases, to name just a few of the many applications envisioned for genetic engineering. The problem is that farm animals can—and do—suffer during these processes that have virtually no social value.

Animal Suffering

It has been approximately 30 years since the first farm animal was genetically engineered and eight years since the birth of Dolly, the first cloned animal generated from an adult cell. Yet, despite decades of development, genetic engineering and cloning have a bad animal welfare track record and extraordinarily high failure rates. Take the latest example of dairy cows whose genes were modified so that they would be more resistant to mastitis, an infection of the udder. Of 330 attempts, only 8 calves were born, and only 5 of those survived to adulthood, meaning a success rate, if one could call it that, of only 1.5 percent.[3] While the reasons for the deaths of almost half of the calves born were not given, other studies have cited a number of potential causes, and the list is unfortunately long, including heart failure, lameness, anemia, anal atresia (a condition in which the animal lacks a tail and anus), respiratory failure, skeletal defects, and gastrointestinal problems. Indeed, death and deformities in cloned and genetically engineered animals are the norm rather than the exception, and it is clear that some of these animals suffer horrible and lingering deaths.

Cloning and genetic engineering can also mean problems for the surrogate mothers. One of

the most common problems in cattle and sheep is Large Offsring Syndrome, or fetal overgrowth, which more often than not necessitates a Caesarian section. This invasive surgical procedure is sometimes performed repeatedly on the same animals[4]—not only to deliver the offspring but also so cells of interest can be harvested from the fetus. Hydrops, or abnormal fluid buildup in the fetus, can kill the mother in severe cases. Additionally, surrogates undergo invasive reproductive manipulations such as embryo transfer, which requires epidural anesthesia. These injections, if done repeatedly, can cause welfare problems such as chronic pain in the tail, head, and fused vertebrae, as well as post-operative pain.[5]

All these procedures raise the overall question of animal integrity and whether it is acceptable for living, sentient beings to be manipulated in such a manner. While animals are commonly used in industrial agriculture with little consideration for their welfare, society increasingly disfavors such animal abuse. There is a need for limits to the procedures to which animals can be subjected.

Who Will Benefit?

Who will benefit from these "brave new world" applications? Some argue that animals could if, for example, disease resistance applications are pursued. While this is possible, it makes little sense when far simpler and cheaper ways to prevent disease already exist, such as cleaning up the dirty, crowded, and stressful conditions common to factory farms that predispose animals to disease. These basic solutions to bettering farm animal health are more beneficial for animals in the long run and do not entail the suffering inherent in genetic engineering and cloning.

Furthermore, the development of more disease-resistant animals is not the pay-dirt application most likely to be adopted. One need look no further than the genetically engineered products currently or poised to be on the market to get an idea of what the biotechnological future holds. Currently, recombinant Bovine Somatotropin, a genetically engineered growth hormone meant to increase milk production in dairy cows, is used widely, despite animal welfare concerns,[6] and another application nearing approval is a fast-growing, genetically engineered salmon.

Will animal industries benefit from use of this technology? Increasingly, consumers are rejecting animal products or purchasing more humanely raised products after learning about the suffering of animals on factory farms. As well, people generally are opposed to the genetic modification of animals. Comprehensive polls on the subject found that 57 percent of those surveyed opposed research on the genetic modification of animals in 2003 and 58 percent in 2004. When asked in 2001 about genetically modifying fish, 65 percent of the public disagreed with this idea.[7] And, as there is already a glut in the animal protein market and potential food safety risks associated with cloned and genetically engineered animals, consumers are unlikely to gain any benefit from these technologies, further decreasing their desirability.

What You Can Do

For now, science marches on with little government oversight, little to no public input, and seemingly little consideration for ethical concerns. The federal Animal Welfare Act doesn't cover farm animals used in food and fiber research, and the U.S. Department of Agriculture, the agency responsible for the Act, actually produced the more mastitis-resistant cows mentioned above.[8] While the U.S. Food and Drug Administration (FDA) is charged with regulating genetically engineered farm animals destined for the food supply under its New Animal Drug Authority (NADA), it has not yet developed regulations or public guidance that provides a clear determination of how the NADA process will apply to these animals, nor will there be an opportunity for prior public review of or comment on applications as NADAs are by law confidential.[9] The FDA will also regulate clones, which are temporarily prohibited from the food supply, but its full risk assessment has not yet been released for public comment.

While animal safety is part of the FDA's remit, it is clear that the agency's primary concern is food safety. Indeed, what is missing from the regulatory process is protection for animals, as well as a critical cost-benefit analysis. European countries give greater importance to animal interests by disallowing some research because the potential costs to the animal subjects are too great or the benefit to humans too little.[10] Since the only people who really stand to gain by the selling of these animals are the personnel of a handful of biotech companies at an exorbitant cost paid by the animals themselves, this technology is simply indefensible.

This technology is at a crucial juncture, and it is imperative that the FDA and other government agencies hear from each one of us concerned about animal welfare. It may be in the best interest of these biotech companies for us to accept their costly and expensive 'solutions;' it certainly is not in the best interest of the public or animal welfare. **AV**

ALL THESE PROCEDURES RAISE THE OVERALL QUESTION OF ANIMAL INTEGRITY AND WHETHER IT IS ACCEPTABLE FOR LIVING, SENTIENT BEINGS TO BE MANIPULATED IN SUCH A MANNER.

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MediaWatch

Designer Pet Guarantee: Animal Suffering and Consumer Deception

California has become the hotbed for companies trying to create markets in 'designer pets'—cloned cats and dogs or so-called 'hypoallergenic' cats. The companies have seized emerging, yet inefficient, technologies and are already profiting from people who want to preserve their pets' DNA for cloning or are interested in buying genetically modified cats.

Yet, curiously, only a handful of cloned cats have survived and no cloned dog or 'hypoallergenic' cat exists anywhere in the world. What consumers may not know is that cloning and genetically modifying animals can cause great harm to those animals involved. Clone scientists consistently describe the common failures of animal cloning—miscarriage, deformities, diseases, and premature death. Even with supposed 'new and improved' techniques, the CEO of one California pet-cloning company confessed that up to 45 percent of the cloned kittens born alive will die within one month. There also is no guarantee that cloned or genetically modified animals will live average, healthy life spans or exhibit the desired traits (i.e., not causing allergic reactions in people).

Animals who are born but do not have the 'right' profile—they are unhealthy, do not look like they are supposed to, or exhibit unwanted genetic traits—are likely to be considered nothing more than byproducts. In addition, cloning one animal involves the invasive use of other animals behind laboratory doors. People who want to clone their pets probably want animals that look and behave like the originals. But cloned animals are not actually 'carbon copies' of the original animals. Every animal is unique.

Perhaps the most ironic aspect of this industry is that it targets animal lovers but actually does more harm to animals than good. These potential consumers presumably would want to prevent, not promote, animal suffering. And let us not forget the nearly one million cats and dogs that are euthanized each year—just in California—mostly from lack of homes.

State Assemblyman Lloyd Levine (D-Van Nuys) has introduced Assembly Bill 1428 to ban the sale and transfer of cloned and genetically modified household pets in California.

Please urge your legislator to support this bill which will prevent the welfare of animals from being compromised at the expense of those who love them.

Crystal Miller-Spiegel,
AAVS Senior Policy Analyst
Eureka Reporter
March 20, 2005

Cloned Pet Ban Rejected Law : Would Have Been Nation's First

State lawmakers Tuesday turned away a bill that could have brought a first-in-the-nation ban on pet cloning, moved less by a host of scientific and ethical arguments than by photos of wide-eyed, copy-cat kittens.

The 4-2 vote against the bill with four abstentions by members of Assembly Business and Professions Committee on AB1428 by Assemblyman Lloyd Levine, D-Van Nuys, came after a brief discussion that touched on everything from free enterprise to mad science—all triggered largely by a pioneering Bay Area firm's willingness to replicate pet owners' favorite cat or dog.

Levine, who sponsored the Bill, framed pet cloning as a needless scientific incursion in a world where millions of needy animals are euthanized each year. He further stated that with the practice lacking federal or state regulation, cloning could not only lead to deformities in the laboratory, but to unintended consequences in society.

"Life is more than a commodity," Levine said, "and this is where we draw the line. Just because we can doesn't mean we should."

Crystal Miller-Spiegel, policy analyst with the American Anti-Vivisection Society, said pet owners should realize that "animals can't be replaced like a printer." She called Levine's legislation "not anti-science, not an animal-rights bill, and not based on emotion. It's simply common sense."

San Francisco Chronicle
May 4, 2005

IT'S NOT A SALE IF NO ONE'S BUYING

The website related to Ron Seely's Saturday news story entitled "Going rate for a cloned cat? Now only $32,000," is www.NoPetCloning.org, and it was created in 2004 by the American Anti-Vivisection Society to educate the public about the reality behind pet cloning. AAVS has significant concerns about animal welfare, consumer fraud, ethics, and science relating to this emerging industry and finds that these issues are not well-characterized by the media.

It is odd that a pet-cloning company would already announce a "sale" on the cost of cloning a cat when it has failed to fulfill the five $50,000 orders that it received last year. To date, the company has sold only two cloned cats.

What is actually happening to the cats in this lab? The company CEO has admitted to the Associated Press that up to 45 percent of the cats who survive birth in his laboratory will die within the first four weeks of life. Surely, people who love their cats and dogs enough to want to clone them would be horrified by this reality.

Despite these serious shortcomings, the company continues to profit from grieving pet lovers who feel that they can preserve their companion animals' qualities by banking their DNA for future cloning. Yet, no dog has ever been cloned successfully, and only a handful of cloned cats have been born. There's no telling if they will lead normal, average life spans.

Let's hope that this company's 15 minutes of unwarranted fame are nearly expired and that Waunakee realtors will soon have a vacant laboratory on their hands.

Crystal Miller-Spiegel,
AAVS Senior Policy Analyst
Wisconsin State Journal
March 24, 2005

Hello Kitty, Hello Clone

The cloning and sale of pets has its critics, who call it wasteful and inhumane. Some point to shelters bursting with pets in need of homes, or remind buyers that cloning is still a relatively new process, with the health of future generations of offspring still unknown. And the $32,000 lavished on one kitten clone would certainly pay for the care of many a needy animal.

Crystal Miller-Spiegel, senior policy analyst at the American Anti-Vivisection Society, in Jenkintown, Pa., a Philadelphia suburb states, "We are concerned about what's happening to cats in laboratories. They are harming animals for no reason." The Society is a founding member of Californians Against Pet Cloning, a group that supports legislation to ban the sale of genetically modified and cloned animals in California.

New York Times
May 28, 2005

RE: Hello Kitty, Hello Clone

Associate philosophy professor Lori B. Gruen might feel that some concerns about the suffering of animals involved in pet cloning can be addressed "with an appropriate oversight body," but the fact remains that Genetic Savings & Clone, the pet cloning company highlighted in your article, continues to operate without any federal oversight. Every other laboratory that uses cats and dogs in experiments must abide by our nation's Animal Welfare Act, which sets modest standards of animal care and use and provides some verifiable public accountability.

Furthermore, this company is failing to meet its mark. According to its website, hundreds of cats and dogs have been used in its laboratory, and yet it has reported the 'successful' births of only six cloned cats and two sold to the public, despite promising a cloned cat to each of five paying clients by November 2004.

What's happening to these animals?

Crystal Miller-Spiegel,
AAVS Senior Policy Analyst
New York Times
Submitted May 30, 2005

Another Missy: Can Dog Cloning Be Far Off?

While "Another Missy: Can Dog Cloning be Far Off?" (May 29) mentions that the American Anti-Vivisection Society (AAVS) is opposed to pet cloning, it fails to correctly describe our reasons. AAVS is also not alone in its opposition: a 2004 national survey showed that 80% of adults are opposed to cloning pets.

According to the Genetic Savings & Clone website, hundreds of cats and dogs have been used in its laboratory, and yet it has reported the 'successful' births of only six cloned cats and two sold to the public. It promised a cloned cat by December 2004 to each of five paying clients, yet failed to fulfill four orders. AAVS and others are deeply concerned about the health and well-being of these animals—including the 'clones' and the 'surrogate mothers' (females bought from animal dealers and used to bear cloned offspring). Cloning scientists themselves repeatedly state in published studies that animal cloning is "inefficient" and plagued by high death rates. This company also is unregulated, operating without any federal oversight or verifiable public accountability.

Surely, people who love their pets enough to consider cloning them would be horrified by this reality. Animal cloning doesn't help animals; it harms them.

Crystal Miller-Spiegel,
AAVS Senior Policy Analyst
San Francisco Chronicle Magazine
June 26, 2005

NewsNet

Pushing the Limit: Giving Mice Human Intelligence

Irving Weissman, a molecular biologist at Stanford University, and his team of researchers have injected human brain cells into the fetus of mice, resulting in animals who are approximately one percent human. Conducting a type of research known as chimeric experimentation, Weissman has said that his ultimate goal is to create mice whose brains are 100 percent human. When concerns were expressed about the possibility of these animals escaping into nature and the repercussions that could ensue as a result of their 'new intelligence,' Weissman simply stated that if the mice appeared to pose any danger, he would kill them.

The first chimeric experiment occurred years ago when scientists in Edinburgh, Scotland fused the embryos of a sheep and goat: two species who are completely unrelated and incapable of breeding with each other. The outcome of the experiment was what scientists had termed a geep: an animal born with the head of a goat and the body of a sheep.

Researchers who advocate this chimeric study say that the more human they can make an animal, the more accurate their research will be investigating human diseases, treatments, and organ transplantation. However, what these scientists fail to mention is that there are alternatives to these severe manipulations of nature that hold even more potential for success, while being much less invasive or risky, including computer modeling, *in vitro* tissue culture, nanotechnology, and artificial substitutes for human tissues and organs. AV

Rats Get a Laugh Out of Being Tickled

Laughing has almost always been considered an action that is exclusive to humans. It is a very natural response that can decrease stress, lower blood pressure, reduce the risk of heart attack and stroke, as well as help the brain to retain information. However, a recent discovery has proven that humans are not the only species reaping the benefits of laughter. Apparently, rats are getting the joke, too.

It has been found that when they are tickled, rats emit a 'chirp,' similar to laughing. The sound hadn't been previously discovered because it cannot be heard with the human ear. It is shown to be an ultrasonic tone that is about five times higher than can be detected with the naked ear. The chuckles of a rat are likely kept at these ultrasonic levels so as not to be heard by a predator. In fact, the sounds are so delicate that a mere blade of grass can deflect it. As a result, rats are free to play and laugh without fear of being caught by a nearby predator. Studies have shown that primates and dogs are capable of laughing as well. AV

Human Embryonic Stem Cells Developed Without Animals

Stem cell research is at the forefront of medical technology and could save the lives of millions of people, since they have the remarkable potential to develop into many different cell types in the body. As such, the use of stem cells could serve to treat countless diseases, conditions, and disabilities such as Parkinson's and Alzheimer's diseases, spinal cord injury, stroke, burns, heart disease, and diabetes. In the past, human embryonic stem cells (ESCs) were developed only with the use of mouse 'feeder cells' and animal-derived serum, a method that poses the risk of animal contamination, which could trigger a transplant rejection of the cells. Recently, Paul De Sousa and his team at the Roslin Institute in Scotland developed ESCs without the use of animals by using 'feeder' layers of human neonatal foreskin cells in place of the mice. Other scientists throughout the world have also developed alternatives to using animals, with success. Non-animal options are not only beneficial to animals who are spared the suffering that would be involved in developing ESCs, but they also eliminate the concern of transplant rejection as a result of animal contamination, opening the door to saving even more lives. AV

Killer Tree-Ants Capture Prey Using Complicated System

Allomerus decemarticulatus are small tree-dwelling ants who reside in the forests of the northern Amazon. They live in only one type of plant, the *Hirtella physophra*, where they build 'galleries,' or refuge areas, underneath the stems. While many ants use similar space as sanctuaries between their nests and scavenger areas, *Allomerus decemarticulatus* use it to trap their prey.

These tiny ants form the traps by weaving together hairs from the *Hirtella physophra* and reinforce the structure with a fungus, producing a platform containing pitted holes. Using the hairs not only gives the ants something from which to build their gallery, but it also makes the plant a more smooth, soft surface, which is inviting to other unsuspecting insects. The ants hide under the holes with their jaws open, so that when an insect lands, they can immediately grab the legs and antennae of the unsuspecting creature. The ants pull off the appendages to immobilize their victim, allowing the worker ants to bite and sting their prey repeatedly until the creature dies. Finally, the dead insect is severed into smaller pieces and taken back to the leaf pouch to be consumed.

Until recently, it was believed that only social spiders engaged in such a complex method of capturing their prey, using the silk they produce instead of the hairs of a plant. The complex capturing system that *Allomerus decemarticulatus* have devised allows them to eat insects who are much larger than they could ever catch with ordinary methods. Larger insects not only supply the colony with a substantial amount of food but also provide a significant amount of nitrogen, crucial to the ants' diet. **AV**

Animal Cloning Corporation Creates Company to License its Technology

The Geron Corporation, parent company of the Roslin Institute famous for cloning Dolly the sheep, has announced that it will be joining forces with Exeter Life Sciences, Inc. to form a new company called Start Licensing, Inc. The deal will enable Geron to profit immensely from its technological advancements while allowing its employees to stay focused on the company's primary focal points: oncology and stem cell-based research.

Start Licensing, Inc. will utilize animal reproductive technology along with agricultural biotechnology to manipulate animal genomes so that they produce human therapeutics. Geron plans to breed animals whose bodies will serve as 'factories' for a desired human antibody that can be derived from milk or blood. These animals will also be used to 'produce' tissues and organs for xenotransplantation, animal to human transplantation. To date, there has never been a successful whole organ transplant from an animal to a human.

Geron is being paid four million dollars initially by Exeter Life Services, Inc. for the deal and will continue to receive undisclosed milestone payments in the future. In addition to its own research, Geron grants licenses to other animal cloning companies, furthering its profit margin. AV

The Parliament Turns Back on Vivisection

The Associate Parliamentary Group for Animal Welfare (APGAW), an all-party parliamentary group made up of MPs, Peers, and associate animal welfare organizations that aims to promote and further the cause of animal welfare to the Parliaments at Westminster and in Europe, recently issued a report that could reopen debates about vivisection. The report states that vaccine testing on animals involves significant suffering and has proven to be less than conclusive with regard to human safety. The document has also revealed that vaccines are currently being tested for a third time in the United Kingdom, a clear violation of the European Union law that states a vaccine can be tested only twice. The scientists claim that their reason for continued testing of the vaccines is due to variable responses in animals and unsatisfactory results. This point is in direct correlation with what the APGAW has pointed out about animal testing proving unreliable with respect to human safety.

Adolfo Sansolino, Chief Executive of the British Union for the Abolition of Vivisection (BUAV), has stated that the report is a positive step toward the end of vivisection, addressing the most important issues concerning animal testing: the suffering of animals and the unreliability of these experiments. Sansolino went on to say that he hopes the necessary financial and material resources will be used to address these issues so that the report's efforts will not prove fruitless. AV

Compassionate Conservation

Wildlife Research Can Save Wild Animals

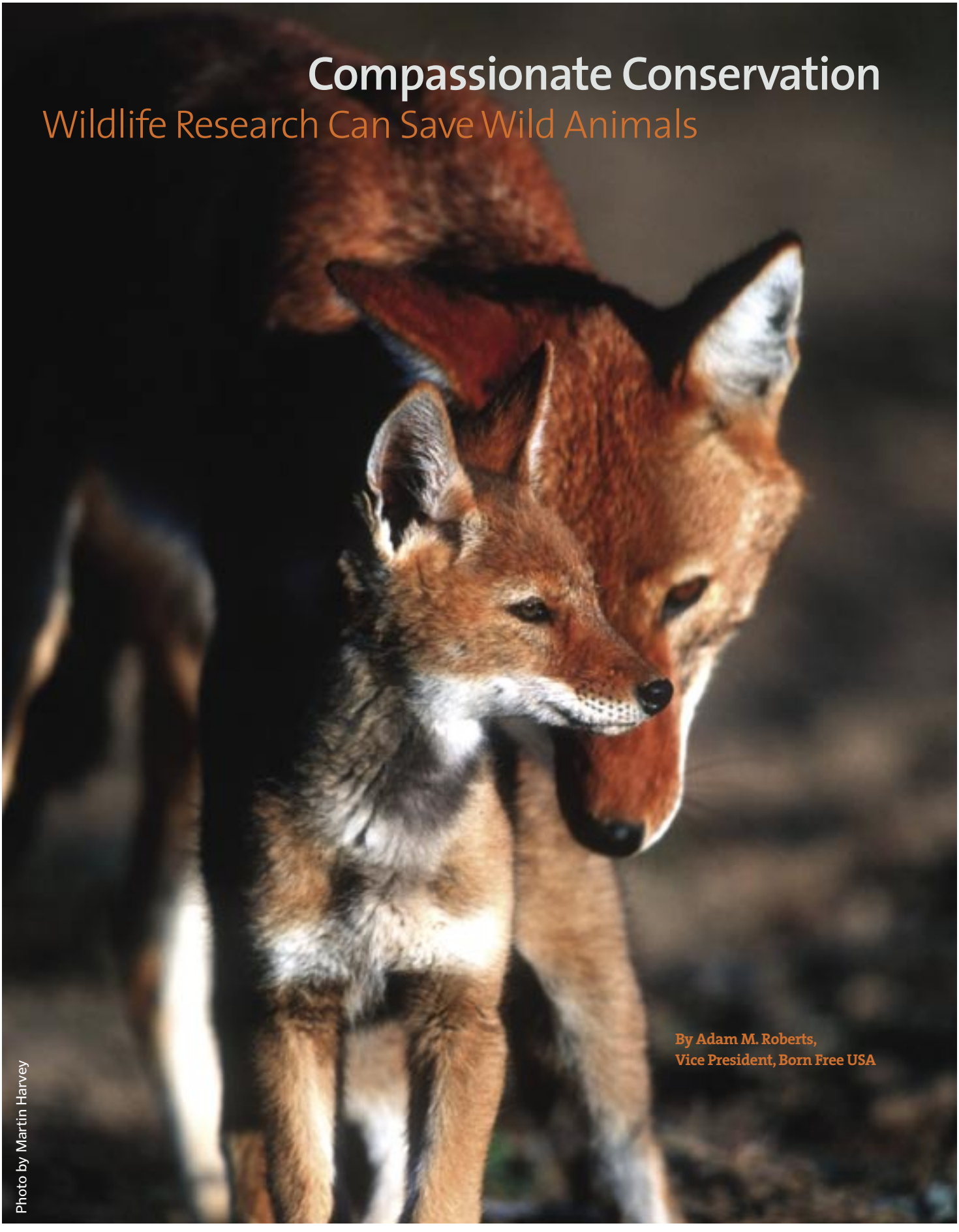
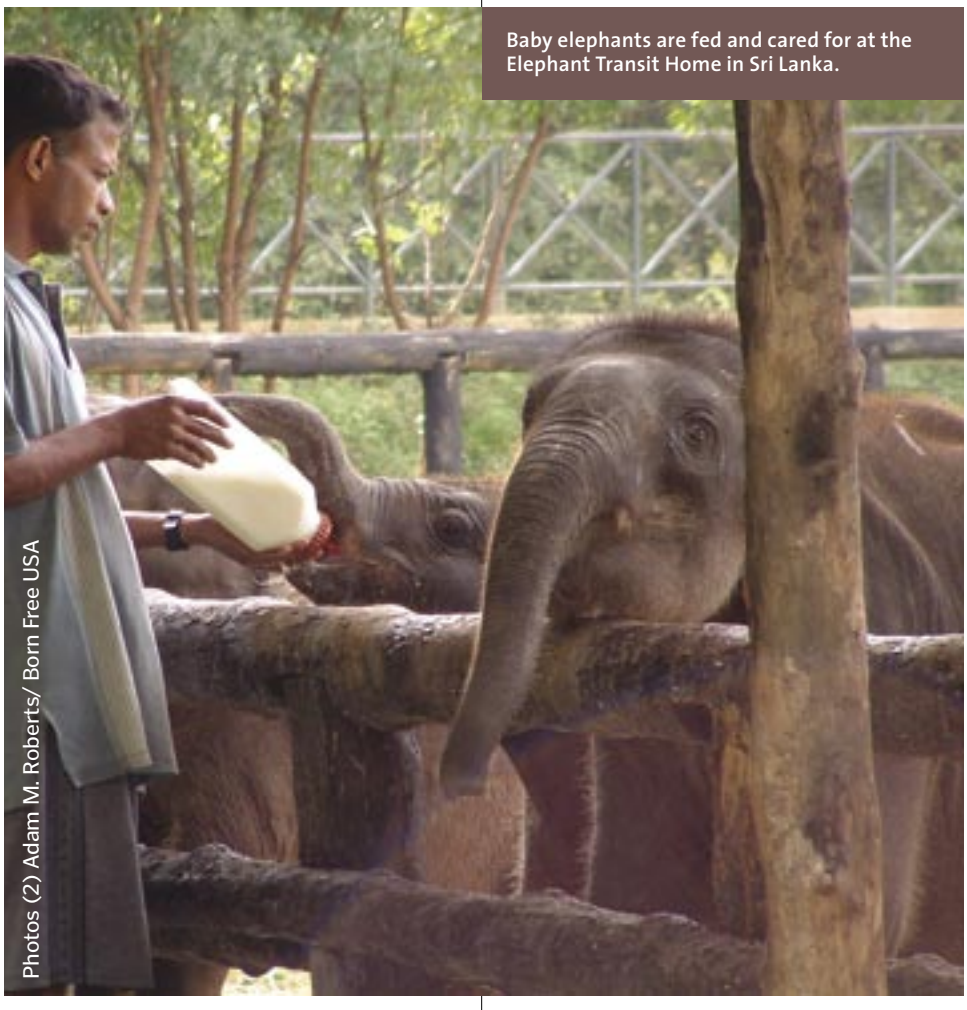


Photo by Martin Harvey

By Adam M. Roberts,
Vice President, Born Free USA

The individual matters—that's the bottom line. Animal welfare and wildlife conservation do not have to be mutually exclusive endeavors. In fact, wildlife research can be undertaken in a way that causes little or no harm to particular animals, while yielding valuable information to ensure the long-term viability of the species. If wildlife investigation is done right, the resultant information can lead to prevention of animal abuse, education of the public, and preservation of species in their natural habitats.

Born Free USA, and its British companion organization, the Born Free Foundation, support humane wildlife research to ensure that wildlife stays in the wild. Through hands-on conservation projects and scientific exploration in the field, we are learning valuable lessons about how best to ensure a better future for animals in need. Notably, these projects are always undertaken in partnership with local organizations, giving communities a stake in the ongoing protection of their resident wild animals.



Photos (2) Adam M. Roberts/ Born Free USA

Baby elephants are fed and cared for at the Elephant Transit Home in Sri Lanka.

The few case studies outlined below give an overview (by example) of the ways in which wildlife research can save individual wild animals and species' populations as a whole.

The New Three Rs?

Readers of the *AV Magazine* will be entirely familiar with Russell and Birch's profound introduction of the 'Three Rs' of animal research: Replacement, Refinement, and Reduction. Scientific research on wild animals frequently employs its own Three Rs: *Rescue, Rehabilitation, and Release.*

Take, for example, the Elephant Transit Home (ETH) in Udawalawe National Park, Sri Lanka. Sri Lanka is currently home to fewer than 4,000 wild Asian elephants, approximately 25 percent of the population present in 1900. An increasing human population and agriculture expansion create competition for habitat, which often leads to farmers killing adult elephants and orphaning their babies.

The ETH is equipped to care for young elephants orphaned by conflict with people (or other reasons) with an Intensive Care Unit to provide immediate veterinary treatment as needed and daily feedings to bolster the animals' strength. But the elephants are not kept there forever; the ultimate goal is to release them back to the wild. The scientific knowledge gained through the release study can be applied elsewhere in the region with replicable results that benefit the elephants—the alternative would be sending orphaned elephants to zoos or other captive facilities that cannot truly provide suitable care.

Once radio-collared and released, a research program monitors their progress. The most recent fieldwork was conducted on 11 rehabilitated juveniles who were released into the National Park on March 15, 2004. According to Deepani Jayantha, the project leader, study objectives include "gathering systematic data on ranging pattern, habitat use, general behaviour, interactions with wild herds, and body condition status of the released individuals." Ultimately, she hopes the research will result in "more knowledge and experience regarding elephant conservation in Sri Lanka."

Preliminary findings indicate that orphaned Asian elephants, even after a period in captivity, can be successfully released into a wild herd. Mihika, a female just over four years old at the time of release, has been observed for many months in the company of a wild adult female and her calf. St. Antonio, a male a few months younger than Mihika, was seen playing with a wild juvenile of the same size *on the day of his release.*

The research also examines habitat usage and ranging patterns. The study elephants were observed grazing and browsing for nearly 50 percent of the time they were observed. Contrast elephants in captivity who may actually spend more than that amount of time chained and fundamentally immobile. Whereas Mitsui ranged with wild herds over nearly 70 square kilometers (approximately 17,000 acres) after release,

the American Zoo and Aquarium Association *Standards for Elephant Management and Care* calls for outdoor elephant yards to be 167.2 square meters (approximately .04 acres) for a single adult elephant. Research on these wild elephants helps inform our perspective on elephants in captivity and the noble campaigns to keep them free.

Hands On

Wildlife research on Ethiopian wolves may provide the information vital to the survival of this highly endangered species. Approximately 500 individuals cling to life in the Afroalpine ecosystem of Ethiopia, a country where the environment and conservation have not historically been a high priority (although a commitment to conservation and wildlife law enforcement appears to be increasing of late). The wolves suffer from habitat loss and fragmentation, poisonings (especially in retaliation for livestock losses), road kills, and canid diseases such as rabies and distemper.

Researchers examine and treat an anesthetized Ethiopian wolf who was later safely released.

Photo: Mike Daines

The Ethiopian Wolf Conservation Project (EWCP), however, works hard to secure the wolf's ecosystem and counter threats to the species' survival. The EWCP, the leading conservation project in the country, melds scientific inquiry with conservation and advocacy. Moreover, in one town, the Project is actually the largest employer of local people.

Scientific research is undertaken to assess changes in the threats facing the animals, the prevalence of disease, the factors that affect pup survival, the effects of mating strategies on wolf genetic structure, and the efficacy of disease prevention vaccinations of Ethiopian wolves and the domesticated dogs living near them.

Community-Based Conservation

The Community-based Marine Turtle and Dugong Research & Habitat Protection Program works with members of the local communities in Tanzania to promote the long-term survival of marine turtles and dugongs through proactive community protection, awareness raising, wildlife monitoring, and research. The program is coordinated out of Dar es Salaam by the Project Coordinator, Catharine Muir, an East African-based biologist.

Tanzania's coastline provides feeding, breeding, and nesting habitats for all five turtle species found in the Western Indian Ocean: green, hawksbill, loggerhead, leatherback, and olive ridley. These turtles have experienced dangerous declines due to poaching of nesting females and eggs, captures in gillnets and by prawn trawlers, and disturbance of nesting beaches. The project has already identified nesting sites, recruited and trained local project assistants and protection officers, implemented a nest protection incentive scheme, translocated at-risk nests, started a turtle catch monitoring program, held meetings with village councils, and provided conservation education to thousands of school children.

Endangered dugongs are hunted for their meat and oil, are captured in fishing nets, and face habitat degradation. The dugong may be the most endangered large mammal in Africa. The project has collected data on dugong sightings and captures, interviewed local fishers along the Tanzanian coast to assess status, distribution, and threats to dugongs, circulated a report on dugongs throughout the region, and started development of dugong conservation strategies in various areas of concern.

The dugong project—even in its early stages—has already had a real impact. Twice in 2004, fishermen accidentally drowned dugongs in their nets, and both times they brought the carcass to the project staff, rather than eating or selling the meat,

A green turtle is measured with the help of local villagers. This information is used to help track turtle populations.

Photo: Tanzanian Turtle and Dugong Conservation Programme

which could have netted them some 100,000 Tanzania shillings, a large sum of money in this developing country. Education about the threats to the species and the importance of the project have fostered a cooperative and productive feeling among people in the relevant local communities.

Conclusion

Naturally, there is a broad portfolio of benevolent research projects in developing countries to save individual animals, conserve species, and educate the public. These research programs are incredibly significant and too robust to explore comprehensively on these pages.

What we have learned without question, however, is that there is a right and a wrong way to engage in research on wild animals. The right way considers the well-being of individual animals in addition to the conservation of the species; the right way includes community involvement and public education; the right way is the path to real conservation.

We need to learn about wildlife in order to save wildlife, and the best laboratory for conducting this research will always be the savannahs, rainforests, and oceans of the world. **AV**

To find out more about Born Free's global field projects, contact Adam at adam@bornfreeusa.org.

Animal Addiction Experiments in Psychology
Promises, Problems, and Prospects

By Paul F. Cunningham,
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Nobody really knows how many animals are used in psychology addiction experiments. Research universities are reluctant to report animal use because of fears about how the information will be used (Allen, 1994-1995). We do know that use of animals is substantial (Overmier & Burke, 1992), 90 percent of the animals used are rodents and birds (American Psychological Association, 1995), addiction experiments are among the most painful and distressing in all of behavioral science (National Research Council, 1992), administration of drugs to animals occurs in the undergraduate psychology classroom (Cunningham, 2003), and the continued use of animals in psychology research and education is 'justified' on the basis of its claimed benefits for human beings (Carroll & Overmier, 2001). We also know that there are serious scientific objections concerning the internal and external validity of laboratory animal experiments (Greek & Greek, 2002; LaFollette & Shanks, 1996; Shapiro, 1998). Animals are poor models for humans for the same reasons that humans are poor models for animals.

Factors Affecting Internal Validity or Certainty

The *internal validity* of an experiment is the extent to which the observed effect is actually caused by the planned experimental treatment. There are a tremendous number of biasing variables that operate within even the simplest animal experiment whose effects are rarely evaluated, which threaten the certainty of cause-and-effect inferences in animal psychology experiments, making them scientifically defective (Pratt, 1980). These include history bias caused by extraneous laboratory events; multiple-treatment interference, which may arise when animals are used in several different experiments; maturation bias that arises as animals age and mature; experimenter bias; animals' perceptions, which may cause them to react differently than expected; stress, pain, and/or discomfort, which may cause extreme biological and psychological reactions; selection bias, since all animals are individuals; instrumentation bias; and experimental mortality bias.

Every animal experiment is susceptible to these variable factors. If the variables are uncontrolled, or unrecognized or unreported, then the scientific value of the animal experiment is impaired because the researcher does not know whether the experimental treatment or uncontrolled factors produced the observed effect, and it becomes impossible for a later investigator to reproduce the experimental results. Even the claim that animals will benefit from research on animals becomes scientifically suspect because of the impossibility of controlling the many variables.

Factors Affecting External Validity or Generality

External validity, or generalizability of results, is the extent to which the specific subjects, research procedures, laboratory settings, experimental tasks, observed behaviors, and types of measurement reflect an accurate picture of human phenomena. Biasing variables that negate the value and ruin the application to the human condition of animal experiments include the manipulation of experimental treatments that ethically cannot be used on humans (which is why animals are used in the

first place) to create artificially-induced conditions in animals that correspond only superficially to the naturally occurring human condition. Animal behaviors are measured that have no apparent correspondence to human behaviors (e.g., rearing, freezing, pecking, switch-pressing, pacing, vocalization, pole-climbing, swimming, tail reflex, activity level, dominance) and whose construct, criterion, or content test validity are not established for human subjects.

Subject variables that interfere with

drawing animal-human comparisons are virtually endless and include genetic, biomolecular, metabolic, immunological, cellular, anatomical, physiological, reproductive, circadian, behavioral, cognitive, motivational, and social differences between species. Nonhuman animals are different not only from humans, but also from each other on these variables. Subtle systemic differences in biological organization between species can result in widely divergent responses to the same stimuli.

Most animal species used in psychology experiments are selected on nonscientific grounds (e.g., cost, reproductive capacity, ease of handling, size). Rodents, a favorite species used in psychology drug experiments, sleep 14-15 hours a day, live an average of 2-3 years, produce 8-10 litters a year, are completely colorblind and physically unable to vomit, have a four-day menstrual cycle and sexually mature in four months, possess no tonsils or gallbladder but a liver that regenerates, walk on four legs (quadruped), and have a natural aversion to tobacco, alcohol, and cocaine. Any student of psychology 101 knows that we cannot automatically generalize results of psychology experiments from one person to another, males to females, infants to elderly, Chinese to Americans, blacks to whites, poor to rich, Rhode Islanders to Californians, or even to the same individual at different stages of the lifespan. The problem is compounded when we want to generalize across species with different genetics and evolutionary histories.

The animal research establishment emphasizes surface structure similarities between human and nonhuman animals (e.g., all animal species share the same genetic material, and phylogenetically related animals, such as mammals, have all evolved from the same ancestral species) that make it *appear* at first glance that nonhuman animals are nothing more than humans dressed up differently. Yet further examination reveals that very small differences in the arrangement of genetic material can be of enormous biological significance between species who have adapted to different ecological niches through the process of evolution and demonstrate why in fact we cannot use animals as surrogates of humans (LaFollette & Shanks, 1996). The canon of scientific method states that the sample must be selected from the *same* population to which one wants to generalize results. "Similar" is not good enough.

Alcohol-Addiction Animal Experiments in Psychology: Major Scientific Flaws and Fallacies

Alcohol-addiction studies illustrate some of the major scientific flaws of animal experiments and fallacies of interspecies comparisons (Cohen & Young, 1989). First, there is the problem of species variation. Many different animal species are used in alcohol-addiction research because no single animal reflects all aspects of the human phenomena of alcohol dependence and withdrawal. Ethanol, the alcohol used in animal studies and the major ingredient of alcoholic beverages, exerts different effects in different species because of variations in absorption, distribution, storage, excretion, and biotransformation of the drug across species.

Beyond the genetic and evolutionary differences that make human-to-animal analogies break down and become disanalogous, there are the inevitable psychosocial factors of 'set' and 'setting' to consider. A person's private experience of drug addiction happens in the context of his or her purposes, expectations, and intents and, basically, cannot be separated from his or her psychological well-being and biological health status, religious sentiments and philosophic beliefs, socioeconomic status and cultural environment, political realities, and linguistic community. Drug addiction must be seen in the light of all these factors and cannot be understood unless they are considered in this far greater context that falls completely outside the animal model altogether.

Alcohol dependence and withdrawal, like the dynamics of health and illness, can never be understood from a biological, environmental, or behavioral standpoint alone. Yet this is the framework that the animal model approach presupposes in both theory and practice. The context in which animal researchers visualize human problems and pathology becomes constricted to that which they can see in animals Our psychological reality, however, is so sweepingly different from that of other animals (e.g., verbally structured thought, capacity for reflection, imaginative capacity, range and number of aesthetic and moral desires) that we inevitably show a wider variety of biological and behavioral reactions to the same stimuli.

Second, there is the problem of artificially-induced independent variables. Nonhuman animals do not like alcohol and left alone do

not seek it. In order to study alcohol dependence and withdrawal in humans, animals who have a *natural aversion* to alcohol (e.g., baboons, rodents, dogs, cats, fish) are forced into addiction, genetically altered, or operantly conditioned to 'prefer' alcohol over other fluids. The frequency and duration of drug exposure, the dosage levels, and the conditions under which laboratory animals are exposed to the substance (e.g., inhalation, force feeding through tubes, infusing directly into jugular vein or stomach, made hungry by food deprivation then trained to drink alcohol to obtain food) can never be made to parallel human alcohol intake and bears little relationship to the conditions under which humans are exposed to alcohol in the natural context of human life.

Why It Persists

Given the scientific flaws and fallacies that plague animal psychology experiments, why do they persist? It seems to be largely a matter of social conditioning in a human culture that condones various forms of harm to animals (e.g., hunting, trapping, zoos, circuses, classroom dissection, factory farms, product testing, roadkill) (Fox, 1990). Animal experimenters are not bad or 'evil' persons but are doing what they are trained to do and what thousands of their colleagues do in pursuit of what they think of as 'the good' for human beings (Cohen, 1990). Philosophy cannot be divorced from action. Distorted philosophies dealing with survival of the fittest, the end justifying the means, and the 'natural' subordinate position of animals that are believed in fervently and repeated often enough with the best of intentions by revered mentors during their early years of scientific training become accepted uncritically by animal researchers and act like strong hypnotic suggestions that trigger particular actions strongly implied by the beliefs. No longer examined, these socially conditioned beliefs are taken for literal truth and appear to be statements of fact, proven 'true' by the simple process of excluding anything else that seems contradictory, until, finally, animal experimentation appears as the only logical kind of method of study that can so well and exactly identify the mechanisms by which nature and nurture are believed to produce consciousness, mind, and behavior in human and nonhuman animals alike.

Standing solely on the side of intelligence and reason, logical thought, and objectivity, animal researchers are trained to be unemotional, to stand apart from their experience, to separate themselves from the animal, and to view with an ironical eye any emotional sensitivity or identification with the animal they are about to experiment upon and later kill and dissect. The animal research laboratory environment of non-feeling objectivity mirrors the standard for scientific ideas and behaviors. In their scientific training, animal researchers become desensitized and taught how to distance themselves emotionally from animals, to conceptually isolate the animal from all influences that may individualize or 'animate' them. The animal loses his vital individualism and living quality in the researcher's eyes so that he or she can number, categorize, dissect, and examine the animal's body portions without qualm and without being aware of the living voice that protests.

In animal laboratory experimentation, we have a situation in which one species definitely takes advantage of other species, and a classic case of a society using ends to justify means. In pursuit of the ideals of protecting the sacredness of human life, promoting the genetic betterment of humankind, and improving the quality of our own lives, the quality of other kinds of life is destroyed (Rollin, 1995). Conscience is encountered and conquered once and for all by the unrestricted and detached desire to know and understand as the death of thousands of animals become justified if it is a means toward the goal of survival of the human species, regardless of the consequences.

The Human Cost of Animal Experimentation

All of us, in one way or another, hope for scientific progress in the laboratory, safe drugs in the clinic, and quality education in the classroom, and wonder what methods might best help us achieve those ends. While some good to some human beings and some animals may have arguably been achieved by the use of animals in psychology research (Miller, 1985), much unnecessary and dangerous biological and spiritual tampering has also been accomplished that has had unfortunate consequences for both human and nonhuman animals alike (Sharpe, 1994; Greek & Greek, 2000, 2002).

Certainly there is nothing more stimulating and worthy of actualization than our ideals. We become fanatics, however, when we consider the possibility of killing in pursuit of those ideals, when we are not willing to examine the worthiness of our methods to achieve those ideals, or when we refuse to search for non-animal alternative methods because we are afraid to do so.

Must we kill in pursuit of our ideals? Is it reasonable to believe that we can learn one iota about the inner reality of human life, mind, and consciousness when our search leads us to destroy it in animals? Or does such destruction presuppose a misunderstanding of life to begin with? When we no longer treat animals as possessors of living consciousness and ignore the fact that the overall consciousness of animals has its own purposes and intents, then we lose any true conception of the great sacredness of all life and of our relationship within it (Scully, 2002). The field of psychology will forever escape opening up into any great vision of the meaning of life as a consequence. **AV**

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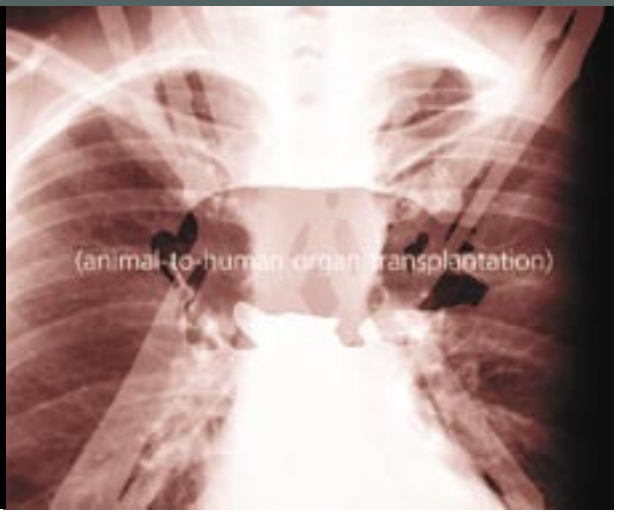
XENOTRANSPLANTATION

MISMATCHED SCIENCE, NOT SCIENTIFIC MIRACLE

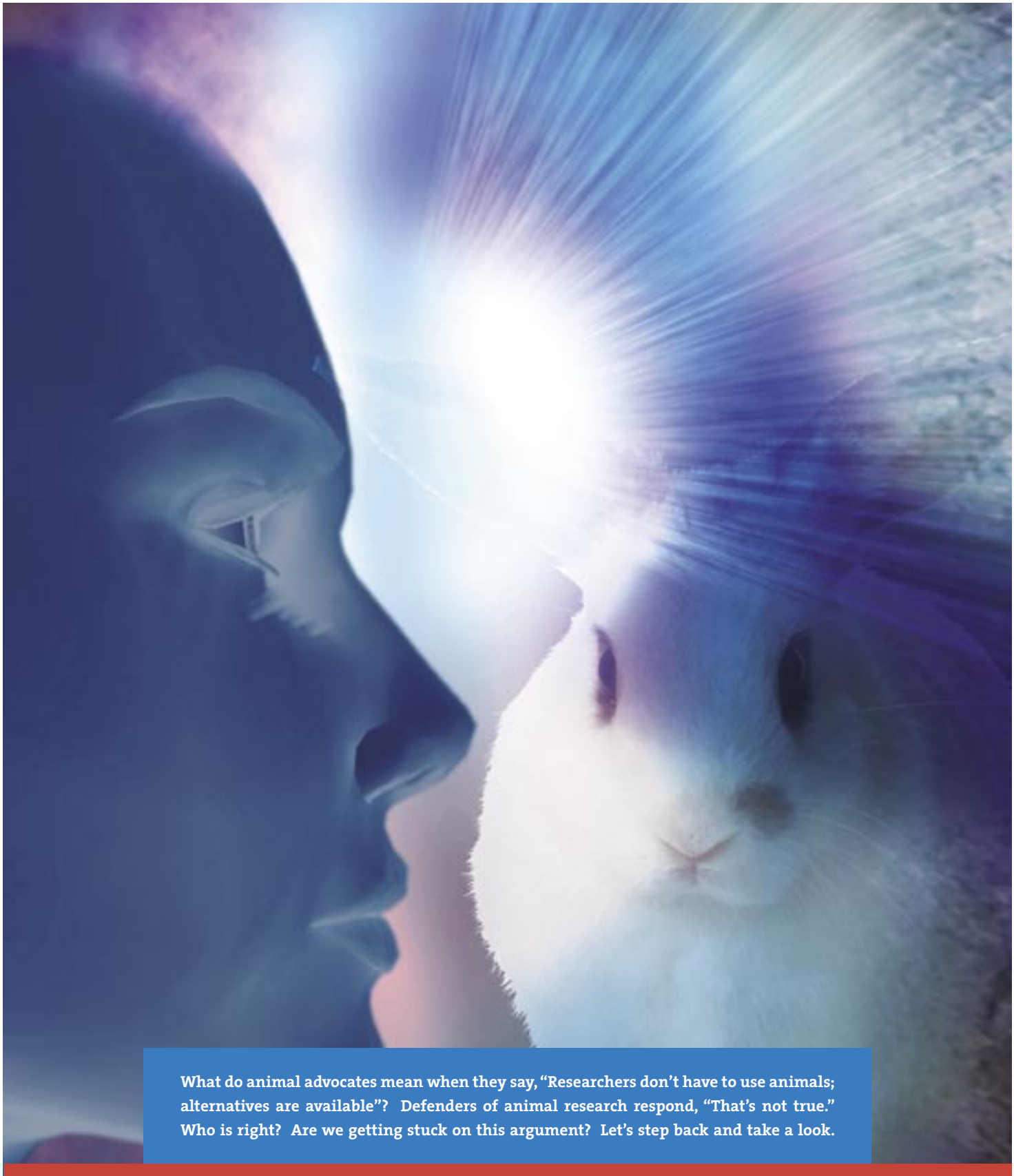
Xenotransplantation, the transplanting of cells, tissues, or organs from one species to another, began in the early 1900s. Since its inception, there has never been a successful whole organ animal to human transplant. Human xenigraft recipients generally die within hours to weeks of the transplant, and the procedure is not only ineffective and costly but can also prove extremely dangerous to humans worldwide.



The problems that arise from xenotransplantation are numerous. First, the risk of the procedure causing a hyperacute rejection, a life-threatening reaction to the transplanted part, or an acute vascular rejection causing an inflammation of the blood vessels is extremely likely. Second, organ transplants from animal to human can create the potential for exposing the patient to deadly viruses, including retroviruses. These not only may negatively affect the recipient, but there is also the possibility that such viruses could spread to other people. Although many scientists claim to 'screen' for retroviruses, there is always the impending risk of exposure to undetected viruses. Additionally, no matter how much preparation is done, it is almost impossible to have completely pathogen-free animals for xenotransplantation. Finally, the use and continued development of xenotransplantation is extremely costly, and millions of tax dollars are allocated to this 'technology' every year. This money could be put to better use developing alternatives to transplants that are successful, such as producing artificial organs and funding programs for preventative treatments to avoid the need for transplants completely.

The biggest argument for xenotransplantation is the lack of donated organs available in the United States. However, the problem is not a lack of organs but rather a lack of donors. Currently, only 20 percent of people who die with viable organs have made arrangements to have their organs donated. In Austria, Spain, Belgium, and Singapore, a "presumed consent" policy is in place, which assumes that citizens will donate their organs after death unless they specify otherwise. This law has allowed for a greater number of transplants to be available, and if the United States would institute a similar rule, the organ shortage would be much less severe.

The lack of viable organs in this country is a huge problem. However, the solution is not xenotransplantation; but rather, it is people becoming educated on the benefits of a healthier lifestyle, and signing up to be organ donors. For more information on organ donation, contact The United Network for Organ Sharing (UNOS) at www.unos.org. UNOS is an organization dedicated entirely to matching donors with those in need of transplants, as well as educating patients and physicians about transplant issues and policies. AV



What do animal advocates mean when they say, "Researchers don't have to use animals; alternatives are available"? Defenders of animal research respond, "That's not true." Who is right? Are we getting stuck on this argument? Let's step back and take a look.

Straight Talk about Alternatives

By Sue Leary, AAVS and ARDF President

What are 'Alternatives'?

There are two ways to consider what people mean by 'alternatives.'

First, they might be referring to specific *methods* that do not involve whole animals. In other words, when you peek through the laboratory door, instead of seeing rows of animal cages, you see an incubator with rows of little Petri dishes or cylinders whose contents are not visible.

Alternative methods include a variety of cell and tissue cultures, computer simulations, and epidemiological studies, research that relies on information that human volunteers report about themselves or that is gathered clinically. These are all widely used, and modern research investigation could not exist without them.

In fact, many of these methods should not be considered alternatives because animals would not be used anyway. In some cases, as the alternative becomes the method of choice, it is forgotten that it was originally developed as an alternative to animal use. Now it's not an alternative; it's just better.

In the case of the production of monoclonal antibodies (MAbs), for example, we are in the midst of such a transition at this very point in time. Skilled laboratory technicians tend to grow MAbs in bioreactors or other artificial systems in which they can control and precisely measure what substances go in and what product comes out. They recognize the advantages over trying to produce MAbs inside a live mouse's belly, where the desired end product might combine with contaminants and have to be purified later. And this is aside from considering the mouse's suffering and her right not to be in that situation at all.

In the early stages of research and testing there has been a dramatically increased use and reliance on computers, or *in silico* methods. Because they are more efficient than using animals, computer programs are the method of choice for first run assessments of chemical formulations. However, the subsequent stages in product development, whether it is a drug, eyeliner, or weed killer, may involve the use of animals. While not entirely accepted, increasingly sophisticated series of *in vitro* tests are replacing animals at all stages. We should recognize that in some cases where animals were once used exclusively, they no longer are used at all. Now *that's* a successful alternative!

Alternatives—as an Approach

Alternatives can be another way of saying the '3Rs,' which are more principles than methods: *Replace* the use of animals, *Reduce* the numbers of animals being used, and *Refine* to use animals in a less invasive/harmful/painful way. In other words, alternatives is a way to approach a research program (e.g., testing many chemicals at a company) or a single research problem (e.g., examining a cancer researcher's plan or protocol) and apply principles that either eliminate animal use, determine the minimum number of animals who would produce statistically relevant results, or manage to conduct the research without causing pain or distress.

An alternatives approach to conducting experiments has the potential to prevent use, misuse, and abuse of animals on an enormous scale. It is more than a particular method—it is a shift in thinking and should be the foundation of all research, testing, and education that has traditionally used animals. Alternatives training courses at the Netherlands Center for Alternatives and the free online course through the Johns Hopkins University's Center for Alternatives to Animal Testing need to be required for anyone who wants to engage in research.

It will be a significant turning point when the alternatives approach becomes embedded in the research community.

How are Alternatives Used?

Education

For educational purposes alternative methods are used to demonstrate principles of biology. How the body works is a fascinating subject, but it is not necessary to dissect animals to learn.

There are extraordinary computer programs that simulate dissection and help young people learn to identify all the parts of the body, but there is also much more than that. A recent article in the *New Yorker* referred to incredibly sophisticated training manikins—like the famous "crash test dummies"—that are wired for surgical practice, with responses to drug administration and the slip of a scalpel. Their use results in dramatically improved confidence and surgical skills over the use of human cadavers and live animal surgery practice.

Leading educators now recognize that alternative methods are creative innovations that satisfy students' need for ethical learning. Consensus will grow, but meanwhile there is little doubt that using animals in education is unnecessary.

Product Testing

In product testing, the first phase of investigation is an in-house screening and development of new products. In a number of large and small companies alike, this phase no longer involves the use of a large number of animals. It may be the most dramatic example of how the alternatives approach can produce huge benefits. Tens of thousands of animals are now no longer needed for dripping toxic substances into rabbits' eyes, rubbing onto guinea pigs' backs, or blowing into beagle dogs' lungs simply to gauge the initial effects of the substance in question.

However, in the later phases of product development, when a drug or chemical is being tested for government approval, often the tables turn as many animals endure some of the worst situations imaginable. In the case of agricultural and industrial chemicals as well as pharmaceuticals, there are stricter regulatory requirements and an absence of direct consumer influence, so this area of testing has been slow to change. The good news is that this is generally recognized as an area ripe for improvement. Many of the tests commonly used, such as the Draize rabbit eye irritancy test, have been proven to provide results that simply are not reliable. They produce observations of what happens when a certain amount of a substance is applied for a specific time, at specific intervals on a particular species. But what we really want to know is the prediction of how humans will be affected, perhaps by small daily exposure over a long time, and/or in combination with exposure to all the other chemicals in our daily lives.

New designs for government toxicology programs give more attention to the welfare of animals in the analysis of costs and benefits. But there is a danger that they may still decide to hold on to animal use in large numbers. This is government in action and is by design conservative and slow to change. But there is a chance to teach by example.

In Europe, where the scientific establishment is not so adversarial to animal welfare, social outcry for more humane approaches and methods has received a better hearing. European governments have been more responsive, and some of the innovative non-animal tests that were developed of necessity for use in those countries are increasingly being used in the U.S. Because they have been essentially 'pre-approved' by our

scientific peers in other countries, they will have an easier path to widespread adoption.

Overall, the area of implementing alternatives in product testing has experienced tremendous momentum, although advocates for animals are key to continuing progress.

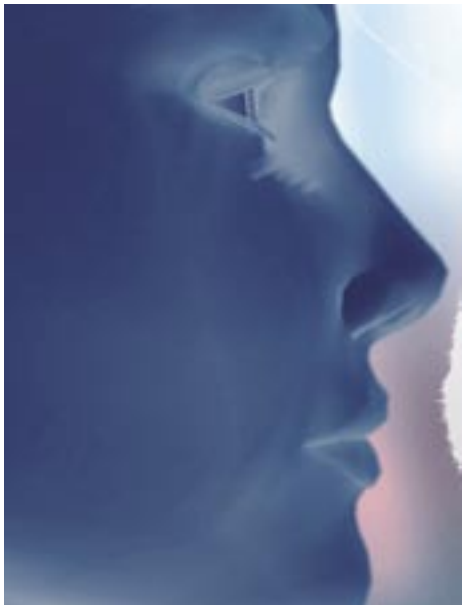
Basic Research

What about basic biomedical research? The search for new drugs and medical treatments, understanding paths and progression of diseases and accidents, exploring all the problems of the human condition—many of these are the worthy subjects for this kind of research.

For a number of reasons too extensive to explore here (such as the human emotion attached to disease research), this is the biggest challenge for advocates for alternatives. And from a fundamental perspective, it should be the easiest.

'Animal models' are problematic for predicting human response to many diseases. Drug addiction and mental illness, for example, involve more than substances' effects on brain chemistry. Infectious organisms have radically different effects on different species. And all the suffering and manipulation and breeding for crippling deformities is more than many can contemplate. But the attachment to the concept of animals as models of disease runs very deep in the scientific community, and biomedical research is a vast industry. So what is to be done?

Here is where rigorous implementation of the alternatives approach could be applied with more ease than attempting to proscribe particular methods. For example, researcher X at Big East University applies for a grant from the National Institutes of Health (NIH). Her protocol must pass through several stages of approval at her school, including ethics committees. What if those committees were well versed in alternatives? What if Dr. X was? What if NIH grant reviewers were? Then at each step along the way, that research proposal would be examined with an eye towards the 3Rs.



This is the challenging mission that AAVS's affiliate, the Alternatives Research & Development Foundation (ARDF), has set for itself: to draw members of the academic and basic research community into the field of alternatives through its grant program.

In one ARDF-funded project, a replacement for an animal's lungs was developed. It works by forcing air, saturated with chemical mists or particles, through a gas-permeable layer of cells grown from human lung cells. But our lungs are complex, with many layers and types of cells. Air reaches those cells at varying velocities. So our grantee envisioned a cascade system with a series of cell types and layers receiving differing densities of chemicalized air at different pressure. This simulated lung is intended to replace the use of dogs and guinea pigs.

Where do We Stand?

Alternatives are more easily applied when basic researchers are looking at small processes or junctures in a process, rather than whole systems. To see what is happening on the level of a gene or a cell, using a whole animal is not only unnecessary, but it can complicate matters.

In summary, opportunities to utilize alternatives in all types of research abound. Whether looking closely at particular methods or stepping back to see a broad approach, alternatives are everywhere in science, and they are here to stay. And animals' lives depend on advocates continuing to press for funding development and adoption of non-animal alternatives. **AV**

In Vitro Alternatives

Here are a few examples of alternatives that are in use today, all of which replace animals:

CORROSITEX® Assay; EpiDerm™; Episkin™; and other systems
Test for Skin Corrosivity and Irritation

ToBI (Toxin Binding Inhibition); ELISA (Enzyme Linked Immunosorbent Assay) for batch potency of vaccines
Test for vaccine effectiveness

3T3 NRU (Neutral Red Uptake)
Tests for phototoxicity (toxic reaction resulting from exposure to light)

EpiOcular™ Model
Tests for eye irritation, toxicity

Integra CELLine; miniPERM® bioreactor; TECNOMOUSE; i-MAb™ Gas-Permeable bags; and other cell culture systems
Grow monoclonal antibodies

Members

Dear Friends,

Just as there are endless forms of medical research, there are almost equally limitless charities that need your support, and AAVS is proud to call you a member. There was surely some research done on your part to make the decision to support our mission and work, and for that we are always grateful.

Don't let all your hard work and research go unnoticed! Please pass along your support of our work to friends and family who are federal employees since now is the time when AAVS is eligible for Combined Federal Campaign funds.

Many thanks,

Heather Gaghan

Assistant Director of Development & Member Services

Tributes

In loving memory of Pippin and Linus. You were the best feline friends a girl could have. It was devastating losing you both within a month of each other; I can only hope that you are both in a better place where you will always be young and carefree. I will never forget you!

Mr. Howard and Ms. Julie Sinnamon, Jenkintown, PA

In memory of Goliath, beloved companion of Howard Wagner, who went home to God March 22, 2005. Goliath, you leave paw prints on our hearts. Thank you for all you gave to us.

Ms. Bertha Festge, Cross Plains, WI

In memory of Little Girl—Lovey Dovey

Karen Wiggin, Danvers, MA

Remembering Berry, an extraordinary miniature sheepdog for 17 years and the companion of my dreams; Sophie Squirrel, a kindred spirit; and Rose Rogers, way ahead of her time who taught me respect and compassion for all creatures.

Carole Rogers, Clackamas, OR

AAVS Memorial Fund

This is a new and unique way of paying tribute to kindred animals and animal lovers while making a gift in their name to help stop animal suffering. All AAVS memorial gifts are used for continuing our mission's work of ending the use of animals in biomedical research, product testing, and education.

Memorial donations of any amount are greatly appreciated. With a donation of $50 or more, your memorial will also be acknowledged in a special recognition section of AAVS's Annual Report. At your request, we will notify the family member or other individual you have remembered as a memorial gift to AAVS.

Ways to Support AAVS

Combined Federal Campaign

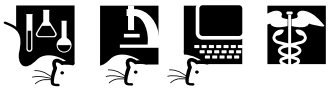
It's that time of year again when federal employees working around the globe can offer their generous support to AAVS through their local or the national Combined Federal Campaign (CFC). This is an easy way not only to offer support of our work for animals but *to become a new member of the oldest animal rights non-profit in the country.* By going to www.bestcfc.org and clicking on Animal Charities, you can choose to donate to AAVS (Agency Code #1859) with a "Give Now" card, and you can also become a member by clicking on the link to our website (www.aavs.org). Be sure to keep an eye out for AAVS in the 2005 Best of the CFC special supplement of the *Federal Times/Military Times* under the *Animal Charities of America Federation.* Just look for these logos:

CFC

ICA
Independent Charities of America
Share The American Way

Animal Charities of America

ARDF UPDATE



The Alternatives Research & Development Foundation's mission is to fund and promote the development, validation, and adoption of non-animal methods in biomedical research, product testing, and education. The primary mechanism for achieving that mission is the annual *Alternatives Research Grant Program*.

Each year, ARDF announces funding for projects that seek to find new ways of conducting science—without using animals. Applicants are advised that the ideal successful project will be:

- Significant in its effect to reduce or replace animals in laboratory procedures
- Innovative in applying alternatives to new areas of research
- Practical for application in the near future
- Applicable to other areas of investigation

Preference is given to individuals associated with U.S. institutions or organizations, since part of ARDF's goal is to expand the utilization of alternatives beyond the borders of Europe where alternatives research is well established. Certain stipulations have been put into place to assure that animal use is clearly not permitted.

Additional requirements include a documented effort to disseminate results to colleagues in order to promote consideration of alternatives in the broader scientific community and demonstrate their utility. Perhaps most importantly, publication of results will mean that when a future investigator is looking for a way to address a research question such as "How do we determine the effect of this drug on the healing of skin cells?" she or he can readily find that an alternative has already been developed, and then can choose not to use animals.

At press time, a record number of 42 proposals were received during the 2005 grant cycle. The next issue of the *AV Magazine* will contain a list of the successful applicants—stay tuned!

For more information, or to contribute to the 2005 Grant Fund, call ARDF at (215) 887-8076, or visit the website, www.ardf-online.org.

Readers of the *AV Magazine* are welcome to contact ARDF for additional information on any of the topics mentioned here. Please direct your comments by e-mail to info@ardf-online.org. AV

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One act of kindness can be your legacy, too.

Nearly 125 years ago, AAVS was founded by social visionary Caroline Earle White. Knowing that small acts of kindness can make a difference for animals, she tirelessly worked to improve the lives of those who were in need of loving homes, labored on city streets, and suffered in laboratories.

Make her legacy yours.

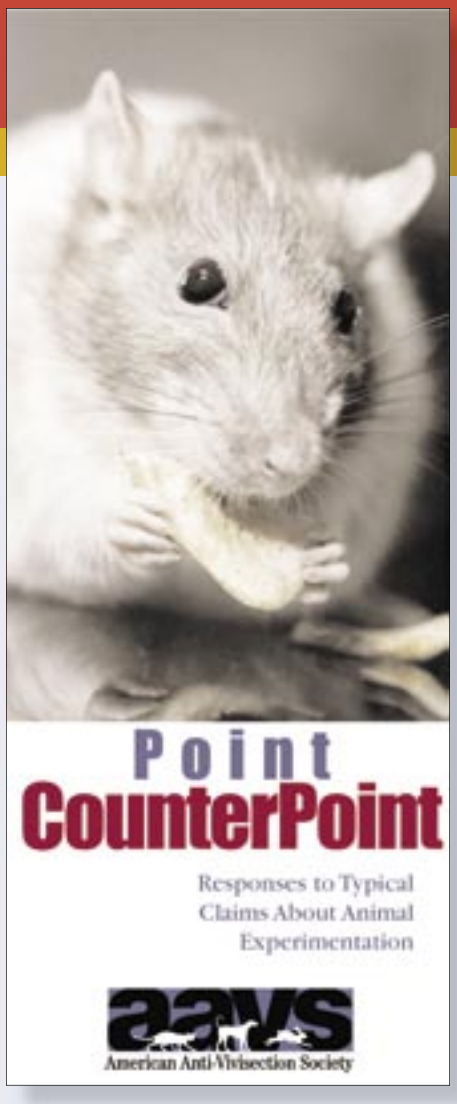
You can help ensure that Caroline Earle White's vision and the work of AAVS continues far into the future. For information on estate planning and becoming a member of the Caroline Earle White Society, please contact Heather Gaghan at hgaghan@aavs.org or (215)887-0816.

aavs

American Anti-Vivisection Society

Get the Facts!

Request your free Point CounterPoint brochure, an easy to use resource to reference when speaking up for animals in laboratories.



The American Anti-Vivisection Society
801 Old York Rd., #204
Jenkintown, PA 19046-1685
A Non-Profit Educational Organization
Dedicated to the Abolition of Vivisection