

Introduction

Animal experimentation is an issue that has raised controversy for decades. Animal rights activists have held hundreds of protests on this issue. The pro-experimentation lobby opposes any new regulation of the field.

However, one of the most controversial issues about animal experimentation is the direction in which it is going. No one seems to know if animal experimentation is increasing or decreasing. Are more animals being experimented on today than ten years ago, or are fewer animals imprisoned in laboratories? Is more money being spent on animal experimentation? Are more projects being funded? Definitive answers to these questions are difficult to obtain. Accuracy is difficult because reporting requirements do not currently cover many of the most commonly used species. Therefore, we are left with a very incomplete picture.

Reports issued by the USDA/APHIS (the government agency charged with enforcing the Animal Welfare Act) on an annual basis are difficult to assess. While they seem to indicate trends, these trends are often fraught with uncertainty. The exclusion of the most commonly used species (rats, mice, birds, amphibians, etc.) from the regulatory process is one concern. Additionally, there seems to be a constant problem with reporting. Many labs simply seem not to file the necessary forms in time for their statistics to be included in this report. In the six-year period between 1996 and 2001 there was not a single year when all facilities reported. With significant amounts of experimentation centered in certain large labs, non-reporting by even a few labs can substantially skew national totals. Additionally, major reporting inconsistencies have been uncovered regarding both the compilation process used by the USDA and the accuracy of the reports filed by major facilities. Therefore, it is highly likely that the USDA statistics often utilized as a basis for examinations of animal experimentation trends may be flawed beyond repair.

Where does that leave us? Unfortunately, nowhere. No other reports provide data which give a picture that is any more accurate about how many animals are actually in laboratories. Therefore we have undertaken a different method of assessing the direction of animal experimentation.

Unfortunately, it is not possible to assess every aspect of animal experimentation. Private labs are often not particularly forthcoming with information, and government agencies can take months to turn over documents.

The CRISP (Computer Retrieved Information on Scientific Projects) database catalogues every research project funded by seven different parts of the federal government via a grant, whether it involves animals or clinical research. Evaluation of this database provides a good indication of animal experimentation within these agencies and, by generalization, throughout the rest of the government. This can then potentially be generalized to represent animal experimentation as a whole.

This report is based on fiscal 2005 information from the NIH CRISP system. It will address overall trends in animal experimentation funding as well as funding estimates for specific facilities. Several areas of highly duplicative research will also be discussed, and the duplication issue will be related to specific facilities.

Audit Scope and Methodology

This evaluation is based on searches of the CRISP system for 2005 using terms that describe 26 separate species of animals. Terms used to examine small animal use include: mouse, rat, guinea pig, hamster, gerbil and rabbit. Primate species names used include: macaca (Latin species name for macaque monkeys), saimiri (Latin species name for squirrel monkeys), baboon, chimpanzee, aotus, mangabey, cercopithecidae, and callithricidae. Companion animal species examined include: dog, cat, and ferret. “Farm” animals species examined include cow, horse, sheep, pig, and goat. Birds discussed include songbirds, chickens, and pigeons. Other species which were not discussed include chiroptera (bats), lizards, and fish. The tendency of this report has been to be conservative, and avoid overstating the situation.

Searches run on these terms will bring up a list of all funded grants using these animals. This will not give us any information on specific animal use numbers, but it should reveal the number of different experiments that these government agencies fund which utilize these species.

This system will not yield a foolproof measure of animal experiments. The results are from a limited number of government agencies including: the National Institutes of Health (NIH), Substance Abuse and Mental Health Services (SAMHSA), Health Resources and Services Administration (HRSA), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDCP), Agency for Health Care Research and Quality (AHRQ), and Office of Assistant Secretary of Health (OASH). This evaluation does not cover any experiments within the National Science Foundation, the United States Department of Agriculture, National Aeronautics and Space Administration, the Department of Defense, and many other governmental agencies. Also, in some instances species names have been eliminated from CRISP reports. This examination also ignores privately funded experiments. This investigation is meant only to reveal trends in the most general terms. However, there is no reason to believe that other entities, whether public or private, are moving in any other direction.

Funding estimates are derived by simply multiplying the number of grants in a specific category or for a specific facility by the average grant amounts published by the National Institutes of Health for the relevant year. The only exception to this methodology is in reference to eight research facilities. These eight laboratories (University of Wisconsin, University of Washington, University of California – Davis, Tulane, Emory, Harvard, Oregon Health Sciences University and the Southwest Foundation for Biomedical Research) publish the amount of funding they receive for primate experimentation in a progress report. The amount from this progress report has been substituted for the amount that would have been derived by multiplying the primate species numbers by the average grant amount. Even though the grant quantities used in the computation process are relevant to 2005, the most recent average grant amount published by the NIH is from 2004. This allows for an even more conservative total because the average grant amounts posted on the NIH website tend to increase by 4 – 6% per year.

Audit Findings

National Trends

In general, the overall national trend appears to be towards an increase in animal experimentation. The total of all of funded projects involving the listed 26 species of animals for fiscal 2005 is 30,426. The total for 1995 (a ten year comparison) was 18,251. This is an increase of 59% or 10,686 grants. Grants funded using fifteen of the twenty-six measured species increased, with the most significant increases involving virtually all species of primates – an overall increase for this category of 345 grants or 40%, rats & mice – a combined increase of 100% or 11,520 grants.

Using this data it is possible to develop a very general approximation of how much these government agencies spend on animal experiments per year. The NIH publishes average dollar amounts per grant. For the year 2004 (newest available statistic), the average grant was \$413,109 (this has been rounded to 413,000 for this report). This approach generates an estimated 2005 animal experimentation funding total of \$11,950,981,000 or approximately \$12 billion. This should be compared with a 1994 funding level of \$5,128,531,000. In a ten year span the increase in animal research funding was \$6,822,450,000 or 133%. Appendix A contains the national statistics broken down by species for both 2005 and 1995.

Every day the National Institutes of Health (NIH), Substance Abuse and Mental Health Services (SAMHSA), Health Resources and Services Administration (HRSA), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDCP), Agency for Health Care Research and Quality (AHRQ), and Office of Assistant Secretary of Health (OASH) spends over \$33,396,161 on animal experiments.

Statistical Highlights

- **2005 funding for animal experimentation -- \$12 Billion**
- **10-year increase of \$6,822,450,000 or 133%**
- **Over \$32,742,413 spent daily by the federal government for animal experiments.**

Research Duplication

The finding of a significant increase in the number of grants funded by the agencies which are catalogued in the CRISP system leads to several questions. Perhaps the most important of these questions deals with the issue of duplication. Are all of these research projects necessary? Are they unique and innovative? Are any of these grants redundant? Are those researchers who are being trusted by the NIH et al to perform medical research defrauding the American taxpayer?

While it is not within the scope of this audit to fully answer questions of this nature, certain conclusions can be drawn from a relatively limited number of additional searches that have been run using the CRISP system. Eight species were used to examine addiction experimentation: rats, mice guinea pigs, rabbits, pigeons, macaque monkeys, squirrel monkeys, and baboons (chosen to illustrate the range of species used). The results of these searches were very disturbing. There are currently (for fiscal 2005) 1200 separate projects (costing a potential \$495,600,000 per year) that examine addiction experiments in these species. 1100 (92%) of these projects are centered in just three species – rats, mice and macaque monkeys. Clearly, there is a high level of duplication in this area.

778 projects study neural information processing, an even more specialized area, in 11 species costing an estimated \$321,314,000. Again, the majority of experiments (644 or 83%) are done in only three species – rats, mice & macaque monkeys.

Several questions arise from these findings? Are these studies based on science or finance? Are these species used chosen for scientific reasons or simply for convenience? Why are we spending almost ½ billion per year making drug addicts out of animals when humans often cannot find treatment programs for lack of federal funding? Details of these duplication issues are contained in Appendix B.

Duplicative areas of experimentation were examined at many of the top 30 facilities (see the list below), and it is a major concern. In only these two areas of duplicative research, addiction and neural information processing, many projects are underway at the top 30 labs. The top facilities for duplication which also made the top 30 list are:

Facility	# Projects in two areas of duplication	Cost of Duplication
Emory	18	\$7.4 million
Vanderbilt	17	\$7 million
Johns Hopkins University	15	\$6.2 million
Harvard	15	\$6.2 million
NYU/Mt. Sinai	14	\$5.8 million
Washington University (MO)	12	\$5 million
University of Michigan	12	\$5 million
Scripps	11	\$4.5 million
University of TX, Dallas	11	\$4.5 million
Yale	9	\$3.7 million
Total	134	\$55 million

These ten facilities alone wasted \$55 million on 134 potentially duplicative projects in only two areas of experimentation. When the over 1000 research facilities in the U.S. and the dozens of areas of possibly duplicative research are considered, the potential for the waste of both federal funding and animals' lives is staggering.

Statistical Highlights

- **Research Duplication Waste in only two areas of \$817 million annually in addiction and neural information processing research.**
- **\$495,600,000 spent annually by the federal government on 1200 grants regarding drug and alcohol addiction experiments in rats, mice and macaque monkeys.**
- **\$321,314,000 spent annually on highly duplicative neural information processing experiments in eleven species.**
- **10 universities wasted \$55 million in only two areas of duplicative research in one year. When this concept is expanded to cover all labs in all areas of experimentation the waste is likely in the billions.**

Specific Facilities

If specific institutions are examined using the same method as was used to develop an estimated national total for the overall funding of animal experimentation, it is possible to arrive at estimates for the annual funding received by specific laboratories for the performance of animal experimentation.

After examining information relevant to many well-known facilities, a list of thirty has been developed. These are very likely to be the top 30 facilities in the U.S. for annual federal funding of animal experimentation, accounting for 39% of all animal research grants for the nation. These facilities range from over \$440 million a year to just over \$116 million per year in funding from the National Institutes of Health (NIH), Substance Abuse and Mental Health Services (SAMHSA), Health Resources and Services Administration (HRSA), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDCP), Agency for Health Care Research and Quality (AHRQ), and Office of Assistant Secretary of Health (OASH). (Please see Appendix B for funding estimates for all fifty facilities).

The top 30 facilities nationally for the receipt of funds from the agencies in question for the performance of animal experimentation are listed in the table below. They are listed in order of dollars received from the government agencies in question, with the top lab listed first.

Facility	Annual Funding	Rank
Harvard University	\$441,273,869	1
University of Washington, Seattle	\$418,889,748	2
Oregon Health Science University	\$274,916,502	3
Johns Hopkins University	\$256,886,000	4
University of Pennsylvania	\$256,060,000	5
Emory University	\$239,303,364	6
University of Michigan	\$216,825,000	7
Washington University	\$215,999,000	8
University of California, San Francisco	\$203,196,000	9
Yale	\$199,066,000	10
Southwest Found. for Biomedical Research	\$195,268,215	11
University of California, Los Angeles	\$194,110,000	12
Tulane	\$183,978,003	13
University of Pittsburgh	\$183,372,000	14
NYU/Mt. Sinai	\$175,525,000	15
Baylor	\$173,047,000	16
Vanderbilt	\$170,982,000	17
Massachusetts General Hospital	\$165,613,000	18
Stanford	\$164,374,000	19
Duke	\$162,309,000	20
University of North Carolina, Chapel Hill	\$154,875,000	21
University of California, San Diego	\$153,223,000	22
Brigham & Women's Hospital (MA)	\$151,984,000	23
Columbia University	\$147,028,000	24
University of California, Davis	\$142,033,026	25
University of Wisconsin, Madison	\$141,655,452	26
University of Texas, Dallas	\$126,378,000	27
Scripps Research Institute (San Diego)	\$124,726,000	28
University of Colorado	\$118,879,000	29
University of Alabama, Birmingham	\$116,053,000	30

These thirty facilities averaged an estimated \$195,527,939 per year for the performance of animal experimentation, as received from the relevant agencies. The availability of sums of money of this magnitude must begin to raise questions about the facilities that receive it. Are the experiments performed by these facilities internally approved because they have the potential to further scientific knowledge, or because they have become budgetary necessities? Are university faculty pressured to perform research projects simply to justify (i.e. pay for) their own positions? Are university professors in the sciences viewed primarily as teachers or as procurers of grants? Are research projects proposed to obtain scientific knowledge, or simply to procure government funding? In essence, we must begin to wonder if the research that is underway at many universities is worthwhile in any sense other than monetary. Are funded research projects unique and innovative, or simply just re-treads of existing projects designed to bring in ever more funding?

It has already been demonstrated that a significant amount of duplication exists in many areas of animal experimentation. How can this duplication be interpreted? What does it tell us about the system of which animal experimentation is a part?

A grant system that is fraught with unnecessary duplication and redundancy would seem to indicate that the goal is not to obtain new and useful scientific knowledge, but simply to perform research. Where could such a system reveal itself? It may be revealed in the grant approval process.

Plous and Herzog (1) have performed an examination of the Institutional Animal Care & Use Committee (IACUC) system. The IACUC is the internal body that performs the first step in the approval process for each research project. The findings of this investigation were that unaffiliated IACUCs usually did not approve projects that had previously been examined and approved by the IACUC from the institution where the grant originated. The authors attempted to explain this finding by saying that it was based on familiarity with the researcher who originated the protocol in question.

This entirely misses the point. IACUCs have a vested interest in approving every research project that comes before them. Every experiment, every project, potentially brings hundreds of thousands of dollars into the facility where it is performed. Investigators prestige and financial well-being are often connected to the successful completion of government-funded experiments. Institutional budgets are substantially subsidized by the income from government research grants.

The bottom line is that substantially more incentives exist for grant approval than for disapproval. Financial, prestigious, and bureaucratic motivations lead to the potentially unjustified approval of research projects. The interests of the animals (who are unable to speak) and the public (who are under-represented on IACUCs) contradict this drive for approval.

This is the system that has led to an ever-increasing tide of redundant research projects. For what better way to insure approval of a project, than to make only minor modifications in a paradigm that has already been accepted? If the goal is to bring in more money, not gain new knowledge, why gamble with unknown cutting-edge technology when tried-and-true (and previously-approved) methodologies are available? The safest thing is to engage in parametric tinkering, using a well defined and understood approach to measure some obscure aspect of an area of "basic science." This approach may well guarantee approval of a proposed research project. It also guarantees that many essentially useless and extremely redundant research projects will be performed over and over again.

From a governmental point of view this kind of duplication is potentially financially catastrophic. The hundreds of millions of dollars spent every year by these seven agencies to fund medical research using animals may well be going into a bottomless pit of duplication that accomplishes nothing other than funneling hundreds of millions of tax dollars into the coffers of nationally known laboratories. For their own part, these laboratories have literally become fiscally dependent on animal experiments. What laboratory could afford to lose an average amount of \$195,527,939 in federal funding? Losses of this magnitude would be fiscally catastrophic, potentially leading to laboratory closures and staff reductions. Every indication points to the primary motivation for the performance of animal research to be monetary, not scientific.

We may be told that this funding system is well supervised and that the system does not allow for waste. However, animal based experimentation brings billions of dollars into U.S. laboratories every year. In light of the fact that these institutions receive so much federal funding, it is highly likely that duplicative experimentation is funded on a regular basis with the primary purpose of filling out the budgets of local colleges and universities.

At the facility level, the membership of Institutional Animal Care & Use Committees (who are responsible for institutional protocol approval) are heavily weighted with people who either perform animal experiments or individuals who otherwise have a vested interest (i.e. -- institutionally affiliated veterinarians) in the performance of animal experimentation. Do they have any real motivation for declining to approve a project? It appears that these bodies are substantially biased toward grant approval because each additional grant brings more money into the laboratory. The grant approval process probably has more to do with job security and the prevention of budget shortfalls than with science.

At a time when projections for the federal budget include deficits for many years to come, the funding of animal experimentation should be closely examined.

Statistical Highlights

- **The average facility in the top 30 U.S. laboratories received an average of over \$195,527,939 per year for the performance of animal experiments, or \$53,569 per day/per facility.**
- **The top 30 labs in the US account for 39% of all animal experimentation grants funded through the National Institutes of Health.**

Animal Welfare Act (AWA) Enforcement Within the top 30 labs

A previous report (2) discussed the violation of federal law by laboratories within the United States. This report reveals that the violation of federal laws by animal labs is increasing: laboratories violated the AWA 1,780 times during the 2005 reporting year. During the 2002 reporting year the same regulations were violated 1,106 times. The 2005 violation total for laboratories represents a three-year increase of 60.9%.

Have the top 30 facilities contributed to these violations? Within the last two years Johns Hopkins University (#4), the University of California (San Francisco #9), and the University of California (Davis #25) have all been fined by the USDA for major violations of the Animal Welfare Act. Major issues have been raised at other facilities regarding animal care issues including the University of Wisconsin (Madison #26 primates killed in cage washer). Internal records from Harvard (#1), Oregon Health Sciences University (#3), University of Alabama (Birmingham #30) and UCLA (#12) indicate major primate care issues including self-injurious behavior, etc. (3) Additionally, 11 of the top 30 labs were ranked in the top 25 labs nationally for violating the Animal Welfare Act (4).

Statistical Highlights

- **The Animal Welfare Act was violated 1780 times by laboratories during the 2005 reporting year, a three-year increase of 60/9%.**
- **3 of the top 30 labs have been fined by the USDA for Animal Welfare Act violations within the last two years. In the most recent ranking, 11 of the top 30 labs were in the top 25 for Animal Welfare Act violations.**

2. **2005 Enforcement of the Animal Welfare Act: Whose Side is the USDA on?** available at:
<http://www.all-creatures.org/saen/articles-2005enf-ex.html>

3. **The Primate Experimentation Scandal, 2005: An Investigative Report** available at:
<http://www.all-creatures.org/saen/articles-rep-pes05.html>

4. **Breaking the Law: Animal Care in U.S. Labs** available at:
<http://www.all-creatures.org/saen/articles-rep-btl.html>

Summary

In summary, it appears that the current system for grant approval has been constituted in such a way as to provide for the approval of almost any grant for an animal experimentation project, with few motivations for a project to be disapproved. The individuals involved in the approval process often have a vested interest in approving grants, with little or no incentive to disapprove grants.

The existing system has led to a steady climb (28,937 for 2005 projects in target species, a 59% increase for a ten-year period) in the number of animal experimentation projects funded by the NIH over the last ten years. A conservative estimate of the current annual expenditure for animal based experimentation as it is funded by the National Institutes of Health exceeds \$12 billion which is a 133% increase for a ten-year period.

30 nationally known laboratories account for receive an average of roughly \$195 million annually for the performance of animal experimentation, or \$53,000 per facility per day receiving 39% of all animal experimentation grants in the US. All of these facilities receive over \$100 million per year, with the top 10 at approximately \$200 million or more. The top two labs, Harvard and the University of Washington, have eclipsed the \$400 million mark annually. Since laboratories have a monetary interest in performing as much experimentation as possible, it is expected that without radical changes to the grant approval process these numbers of animal experiments will continue to increase. Eleven of these top labs for receiving federal funding for animal experimentation are also among the 25 offenders for violating federal laws regarding animal care, and three have been fined by the USDA for Animal Welfare Act violations in the last two years.

Several specific areas of experimentation have been examined to study the issue of experimental duplication. 778 separate projects study neural information processing primarily in macaque monkeys, rats and mice using almost \$500 million per year in federal funds. Additionally, 1200 grants study addiction to various drugs primarily in rats, mice or macaque monkeys potentially using more than \$321 million annually. When combined these two areas potentially waste over \$800 million per year.

The consumption of this funding in animal experiments may also prevent U.S. citizens from accessing the social programs that they need. How many people could be funded in substance abuse programs with the \$495 million that is currently directed at animal experiments in addiction? How many of them will die for lack of treatment? What will the cost be to our society in health care, criminal justice and other programs because these people weren't treated? What is more important keeping multi-million dollar laboratories open, or keeping U.S. citizens alive?

It is time that we end the process of writing the research community a \$12 billion blank check every year for the purpose of performing animal experimentation with little more than a vague hope that any real benefits will result. Every day the National Institutes of Health (NIH), Substance Abuse and Mental Health Services (SAMHSA), Health Resources and Services Administration (HRSA), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDCP), Agency for Health Care Research and Quality (AHRQ), and Office of Assistant Secretary of Health (OASH) spends over \$33,396,161 on animal experiments. Shouldn't we be examining this whole process much more closely?

A radical restructuring of the grant approval system and the Institutional Animal Care & Use Committee system is necessary to prevent further waste of federal tax dollars and animal lives.

Recommendations

- The National Institutes of Health (NIH), Substance Abuse and Mental Health Services (SAMHSA), Health Resources and Services Administration (HRSA), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDCP), Agency for Health Care Research and Quality (AHRQ), and Office of Assistant Secretary of Health (OASH) should be required to compile annual reports detailing: the amount of funding directed at animal experimentation, the amount of funding directed at alternatives development, the number of animals used in experimentation, etc.
- Congress should commission a General Accounting Office audit of the grant system within these same agencies, also correlating research contracts data, to examine the issue of duplication within the system and to develop specific parameters to prevent excessive duplication and redundancy within the grant system. This information should also be correlated with information relevant to funding of research projects in other agencies including the Department of Defense, United States Department of Agriculture, Department of Energy, etc.
- The grant approval system, on the agency level, as well as the facility level, must be overhauled to put more community representation on Institutional Animal Care & Use Committees (IACUC) for all facilities that receive federal funding, and all IACUC meetings must be open to the public, and regularly announced.
- All branches of the federal government that perform animal-based experimentation should be required to maintain internet accessible databases of all funded projects to prevent inter-agency project duplication.
- All research projects at laboratories who are fined by the USDA for violations of the Animal Welfare Act (AWA) should be automatically suspended for a period six months. If a research facility is cited for 10 violations of the AWA within one year, the offending facility should be placed on probation for a one year period. If further violations occur during that year, then all federally funded research projects should be suspended. If after suspension, a facility has reason to be fined or suspended again, then all federally funded projects should be permanently terminated.