

## Introduction

Animal experimentation is an issue that raises controversy whenever it is discussed. It has been the center of 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 five years ago, or are fewer animals imprisoned in laboratories? 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 commonly used species (rats, mice, birds, 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 recently 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 better. 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 National Institutes of Health (NIH) will be used as the basis for this assessment because the NIH is the largest single funding agency for animal experimentation in the U.S. The CRISP (Computer Retrieved Information on Scientific Projects) database catalogues every project that the NIH (and some other parts of the Department of Health and Human Services) funds via a grant, whether it involves animals or clinical research. Evaluation of this database should give us a good indication of animal experimentation within the NIH and, by generalization, throughout the rest of the government. This can then potentially be generalized to represent animal experimentation as a whole. However, the CRISP system deals only with NIH grants. NIH research contracts are not part of this system. However, it is believed that trends in the contract system would closely resemble trends in the grant system.

## **Audit Scope and Methodology**

This evaluation is based on searches of the CRISP system for 2002 using the following terms: mouse, rat, macaca (Latin species name for macaque monkeys), saimiri (Latin species name for squirrel monkeys), dog, cat, rabbit, guinea (to bring up grants involving guinea pigs without using the potentially confusing term pig), and hamster. While these terms will not give us an exhaustive picture, they should certainly suffice to provide a good measure of trends because these are often the most commonly used species in animal experimentation. Certain species were purposely not counted in these totals in an effort to compensate for potential duplication. The tendency here has been to be conservative, and avoid overstating the situation.

Searches run on these terms will bring up a list of all NIH-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 the NIH funds which utilize these species.

This system will not yield a foolproof measure of animal experiments. The results are from only one government agency. This evaluation totally ignores 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. 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.

## **Audit Findings**

### **National Trends**

In general the trend appears to be towards an increase in animal experimentation. The total of all of the National Institutes of Health-funded projects involving the listed animals (macaca, saimiri, rat, mouse, dog, cat, guinea pig, hamster& rabbit,) for fiscal 2002 is 33,014. The total for 2001 was 29,699. This is an annual increase of 11%. Grants funded using seven of the nine measured species increased significantly. The remaining two species (hamsters and squirrel monkeys) had only minor changes (See Appendix A for national species by species totals for 2002, 2001, 1998, &1993 – providing the basis for one-year, five-year, and ten-year comparisons).

The total for 1998 (a five-year span) is 26,408. The increase from 1998 to 2002 is 6,606 new grants, or an increase of 25%. The 1993 total is 20,675. Using this number we now have a ten-year span to examine. This shows an increase of 12,399 projects or 59.7% for a ten-year period. This trend does not overtly examine dollars spent or animals used. It examines only the actual number of grants awarded by the NIH. However, a ten-year increase of approximately 60% is very high.

Using this data it is possible to develop a very general approximation of how much the NIH spends on animal experiments every year. The NIH publishes average dollar amounts per grant. For the year 2002, the average grant was \$309,225. For the sake of dealing in more round numbers, and to keep the estimates in this report conservative this will be rounded down to \$300,000. This approach generates an estimated 2002 NIH animal experimentation funding total of \$9,904,200,000, or approximately \$10 Billion.

### **Research Duplication**

The finding of a significant increase in the number of grants funded by the National Institutes of Health 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 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.

In order to deal with this potential for duplication within the NIH grant system some basic searches were performed via the CRISP system. Three species were used: rats, mice and macaque monkeys (chosen to illustrate both ends of the evolutionary scale). The results of these searches were very disturbing. There are currently (for fiscal 2002) 187 separate projects (costing a potential \$56,100,000 per year) that examine neural information processing in macaque monkeys. Since neural information processing could still be a potentially large area, the topic was refined further.

Visual neural information processing in macaque monkeys brought up 130 separate projects within the CRISP system (costing \$39,000,000 annually). 284 projects study cocaine in rats (\$85,200,000), 110 projects study cocaine in mice (\$33,000,000), and 51 projects study cocaine in macaque monkeys (\$15,300,000). This is a total of 445 projects studying cocaine in three different species. This gives us an estimated total of \$133,500,000 annually spent on 445 cocaine addiction research experiments in only three species of animals. Using these same three species as a basis we can

find 85 studies examining heroin (\$25,500,000), 51 that examine marijuana (\$15,300,000) and 44 that study phencyclidine (\$13,200,000). Studies in heroin, marijuana, and phencyclidine (PCP) in these species use a total of \$54,000,000 per year. One must wonder if the best way to deal with the substance abuse problem facing the U.S. is to continue to manufacture drug-addicted rats, mice, and primates.

Alcoholism is another problem that plagues our society. The National Institutes of Health has responded to this problem by funding 657 concurrent animal studies which examine alcohol in rats, mice, and macaque monkeys. This leads to an estimated annual expenditure of \$197,100,000 for animal studies involving alcohol. How many humans could be helped with the combined \$384,600,000 that is currently being spent on animal studies in alcohol, cocaine, marijuana, PCP, and heroin?

It must also be noted that some of these grants have been in existence for decades. Specifically, several of the grants in the area of neural information processing in macaque monkeys have been in existence for over 30 years, with one reaching 39 years of age. This type of information spawns several further questions. If this area has been studied by dozens of researchers for decades, why are new grants which often utilize essentially the same methodology continually appearing in this field? If decades of study have not garnered worthwhile information, why are more grants being approved? If the decades-old grants are not sufficient to examine the field, necessitating new grants, why do the old grants continue to be renewed? Why is all of this research happening? To answer this question, the funding of animal experimentation within specific facilities will be examined.

### **Specific Facilities**

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

After examining information relevant to many well-known facilities, a list of twenty-six has been developed. These are very likely to be the top 26 facilities in the U.S. for NIH annual funding of animal experimentation. All of these facilities received over \$100 million a year from the NIH for performing animal experiments during fiscal 2002, with funding amounts for some labs exceeding \$200 million (please see Appendix B for funding estimates for specific facilities).

The top ten facilities nationally for the receipt of funds from the National Institutes of Health for the performance of animal experimentation are: the University of Washington, Seattle (\$270,845,000); the University of Pennsylvania (\$215,700,000); Johns Hopkins University (\$191,400,000); the University of Michigan (\$185,400,000); Yale (\$173,400,000); Washington University (\$173,400,000); Baylor (\$162,300,000); the University of California, San Francisco (\$159,600,000); the University of California, Los Angeles (\$144,900,000); and the University of California, San Diego (\$142,800,000).

These ten facilities averaged \$181,974,500 per year for the performance of animal experimentation, as received from the NIH. 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 NIH-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.

I believe that this entirely misses the point. The fact is that 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. Only the interests of the animals, who are unable to speak, 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 that the NIH spends every year 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.

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 hundreds of millions 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.

## 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 (33,014 for 2002 projects in target species, a 59.7% 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 \$9.9 billion.

26 nationally known laboratories receive more than \$100 million annually for the performance of animal experimentation (see Appendix B for individual facility totals), 8 of these facilities receive over \$150 million per year, and two have eclipsed the \$200 million mark. The average annual funding amount per facility is \$139,805,731. 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 will continue to increase.

Several specific areas of experimentation have been examined to study the issue of experimental duplication. 187 separate projects study neural information processing in macaque monkeys, with 130 of these studying visual neural information processing. Additionally, 445 NIH grants study cocaine in rats, mice or macaque monkeys potentially using more than \$133 million annually. The NIH is also currently funding 657 animal studies on alcohol in rats, mice or macaque monkeys that consume an estimated \$197,000,000 each year. These two areas of addiction research expend \$384,600,000 annually. Should we consider re-directing this funding towards programs that directly benefit humans suffering from substance abuse?

Experimental duplication is evidently very high, leading to the waste of hundreds of millions in federal tax dollars, and the unnecessary deaths of tens of thousands of animals. 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 \$330 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 \$10 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 NIH spends over \$27,000,000 on animal experiments. Shouldn't we be examining this whole process much more closely?

A radical restructuring of the NIH 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 should be required to compile an annual report detailing, the amount of funding directed at animal experimentation, the amount of funding directed at alternatives development, the number of animal used in experimentation, etc.

Congress should commission a General Accounting Office audit of the National Institutes of Health grant system, 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 NIH system.

The NIH 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 NIH 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 an internet accessible database of all funded projects to prevent inter-agency project duplication.

## Appendix A

### National Totals for

### NIH Grants Awarded

2002

Species	2002	2001	1998	1993
macaque monkey	1119	1013	958	680
squirrel monkey	105	104	112	77
dog	646	574	667	738
cat	498	465	557	694
rat	8762	8037	7999	6632
mouse	18631	16372	12009	6893
guinea	461	438	546	658
rabbit	2455	2355	3068	3715
hamster	337	341	492	588
<b>Total Grants</b>	<b>33014</b>	<b>29699</b>	<b>26408</b>	<b>20675</b>

## Appendix B

### 2002 Facility Funding Totals for Animal Experiments

Facility Name	Number of NIH Grants	Other NIH Funding*	Facility Total NIH Funding
1. U. of WA, Seattle	531	111,545,000	270,845,000
2. U. of Pennsylvania	719		215,700,000
3. Johns Hopkins U.	638		191,400,000
4. U. of Michigan	618		185,400,000
5. Yale	578		173,400,000
6. Washington University (MO)	578		173,400,000
7. Baylor	541		162,300,000
8. UCSF	532		159,600,000
9. UCLA	483		144,900,000
10. UCSD	476		142,800,000
11. Oregon Health Sciences U.	279	55,000,000	138,700,000
12. Vanderbilt	428		128,400,000
13. Massachusetts General Hospital	421		126,300,000
14. Scripps Research Institute	399		119,700,000
15. Emory U.	294	25,375,000	113,575,000
16. U of NC, Chapel Hill	396		118,800,000
17. U. of Pittsburgh	386		115,800,000
18. Stanford	380		114,000,000
19. Duke	369		110,700,000
20. Columbia	364		109,200,000
21. U. of WI, Madison	298	17,057,000	106,457,000
22. Brigham & Women's Hospital (MA)	354		106,200,000
23. U. of CO	344		103,200,000
24. Case Western	342		102,600,000
25. U of AB, Birmingham	338		101,400,000
26. Harvard	204	38,972,000	100,172,000
<b>Totals</b>	<b>11290</b>		<b>3,634,949,000</b>

**Average Funding per facility**

**139,805,731**

\*Amounts in this column are fiscal 2000 NIH support for primate research as reported in the Primate Center Annual Progress Reports