Susan Silk found a wonderful statement made by John of Salisbury in 1159 that serves as a theme for this presentation. Salisbury said, “We are like dwarfs sitting on the shoulders of giants. We see more, and we see greater distances than they did, not because our sight is superior or because we are taller than they, but because they raise us up, and by their great stature add to ours.”

Figure 1 shows acknowledged “giants” in the research enterprise of laboratory animals. They are rightly known in the field as “founding fathers.” They were the first persons to insist that the quality of veterinary medicine taught in US colleges and universities must be improved and special additional training be given to laboratory animal veterinarians, because the skills required of them go beyond those of other veterinarians and the knowledge expected of them is more sophisticated than that of veterinarians in other fields.

Dr. Bennett Cohen, on the right, was widely recognized as the leader of the group. He is revered by every senior veterinarian in America for his contributions to their professional discipline. I had the opportunity to spend some time with him only once. I was so impressed by him that my knees were trembling. To be in his presence was a great privilege. His influence has touched the lives of every person in this room. I think he would be justifiably proud of advances made in the care and use of laboratory animals since his time.

Other leaders have come to the fore in more recent times (Figure 2). Most of you know Dr. John Miller on the left and Dr. Nelson Garnett on the right. The man in the middle is Dr. Alan Sandler who worked in the Office for Protection from Research Risks (OPRR) for many years. Alan was our silent enforcer. He spoke very softly to many institutions informing them that if they did not improve their animal programs their Assurances would be withdrawn and their programs closed. A number of institutions failed to heed his warnings. Two of the most notable were Columbia University in New York and the City of Hope in California. Alan spoke to institutional officials at both and said, “We are withdrawing your Assurance. You may do no more research involving animals until you come into full compliance with the Animal Welfare Act and the PHS Policy on Humane Care and Use of Laboratory Animals.”

Figure 1  Four of five “Founding Fathers” of laboratory animal veterinary care. From left to right: Dr. Nathan R. Brewer, Dr. Eilhu Bond, Dr. Robert J. Flynn, Dr. Bennett J. Cohen. Missing: Dr. Robert J. Schroeder

Figure 2  Three “giants” in the field of research animal care: Dr. John Miller, Dr. Alan Sandler, and Dr. Nelson Garnett
Laboratory Animals.” He was a short man with a soft voice, but he carried a big stick that he wielded with high moral principle. He attended many meetings, but always remained on the fringe of each meeting. So far as I know, he never delivered a public talk or lecture. He was welcomed by veterinarians who operated sound programs, and he was feared by veterinarians in institutions with defective programs. I recall one instance when Alan spoke to the Vice President for Research at the University of Pennsylvania. He said, “Here is a list of violations that I found in your caging areas. If they are not corrected immediately, OPRR will withdraw your Assurance and you will be unable to carry out any laboratory animal research.” The vice president replied, “Thank you for the warning; we will make all these corrections within a month.” Alan replied, “You were warned some time ago. I am leaving in the morning, but before I leave I am going to come here to see if the problems are corrected. If this laboratory is not in compliance by tomorrow morning, your Assurance will be withdrawn.” Indeed the laboratory was transformed by the following morning and met the standards of the PHS Policy and the USDA Regulations.

I will comment later about the outstanding contributions of Drs. John Miller and Nelson Garnett. This country owes a debt of gratitude to all three of these outstanding public servants.

Federal regulation of laboratory animals began in 1966. The sad story of a mistreated Dalmatian named Pepper led to the passage of the first version of the Animal Welfare Act that year. The cruel events in Pepper’s life were pictorially illustrated in Life magazine. Life was the Twitter of its day—virtually everyone in America read the stories and viewed the pictures in Life every week. When a picture of Pepper, forlorn and emaciated, appeared on the cover of Life, millions of Americans were thunderstruck. Pepper was a family pet stolen by a dealer in Pennsylvania, resold to a dealer in New York, and sold again to Montefiore Hospital for research. The commercial sale of animals was, until that time, unregulated. The tragic picture on the cover of Life was sufficient to persuade the Congress to enact the first version of the Animal Welfare Act. It was signed immediately by President Lyndon Johnson.

The Act was designed to prevent the use or sale of stolen dogs or cats for research. It remedied a serious problem in this country. The history of laboratory animal research up to that time was “peppered” with cases of theft, abuse, and neglect of laboratory animals. I am happy to say that the purchase and treatment of research animals is on a far higher moral plane today than it was in those days. The Animal Welfare Act was amended and expanded in 1970, 1976, 1985, and 1990. The 1976 version set standards for animal dealers, exhibitors, circuses, and the import of animals. The Act prohibited animal fighting. In the first three revisions the law required “engineering” standards—that is to say, it set forth measurable standards for cage sizes, nutrition, temperature, air changes, and many more. Finally in 1990 the Act was amended to include “performance” standards, requiring human judgment related to the animal’s habitat, comfort, and well-being. The Act excluded coverage of rats, mice, birds, and farm animals; some of those exclusions still hold.

I would like to call your attention to the PHS Policy of 1979, because that is the first policy pertaining to animals that I promulgated. I know nothing of earlier policies. I confess to you that I had little knowledge or training in animal research when I was appointed to be Director of OPRR. Dr. Donald Chalkley, my predecessor, had suffered a severe stroke and was forced to retire.

Dr. Tom Malone, NIH’s Deputy Director, chaired the committee that selected me to succeed Dr. Chalkley. He briefed me on my new responsibilities and talked to me at length about human subjects and protections that must be afforded to them. As I was leaving his office he said, “Oh, by the way, you will also be responsible for the humane care and use of laboratory animals.” That was the only instruction given to me concerning laboratory animals.

When I returned to OPRR, I looked up and read the only PHS Policy that was under consideration at that time. It was still in draft form. It had been drafted primarily by Dr. Chuck McPherson. Because of his illness, Dr. Chalkley had never promulgated the Policy. One of my first acts in OPRR was to publish the McPherson Policy—although I had only a little understanding of what I was doing! Colleagues assured me that McPherson was an honest man, a good vet, and a wise regulator. In many ways it was a wonderful Policy: it emphasized good animal husbandry, appropriate housing, appropriate feeding, clean water, air circulation, clean cages, and competent veterinary care. However, I soon came to realize that the Policy had a serious shortcoming: it lacked enforcement authority for OPRR and [articulated] no authority for the institutional veterinarian or an institutional committee.

As I became familiar with my new responsibilities, I found many violations of the Policy. But I also found authority built into the Policy for enforcement. Dr. Chalkley had implemented sound practices only by the force of his own personality. He wrote long-hand letters to university presidents and directors of research centers, saying: “There are serious abuses going on in your institution. You have failed to meet your moral obligation to correct them. This office is holding you personally responsible.” The letters were blunt and often offensive. His letters would provide details of the abuses and give directions for correcting them. Typically the university presidents would write to the Director of NIH and say, “Who is this fellow Chalkley who has told me how I am to run my university? He has insulted me.”

When complaints about Chalkley’s letters reached a crescendo, Dr. Ronald Lamont-Havers, Associate Director for Extramural Affairs, called me to his office and instructed me to stay every evening after hours and rewrite Chalkley’s letters. I was instructed to take all the insults out of them, remove all of the direct blame heaped on university presidents, readdress letters to persons directly in charge of laboratory animals, and say very politely, “There may be some shortcomings in your program for the care and use of laboratory animals, and say very politely, “There may be some shortcomings in your program for the care and use of laboratory animals.”
animals. Please review the allegations (detailed below) and if you confirm any shortcomings please improve your program as soon as possible. NIH stands ready to assist you.” With this strategy, negative mail in the NIH Director’s Office diminished. I am not sure that my efforts did much for the well-being of animals, but I think they advanced my career. At least the McPherson Policy gave us standards that institutions were required to follow. After we promulgated the Policy cases began to flood into our office.

Perhaps no case was more vexing than the so-called Silver Spring Monkey Case. It was that case that made me acutely aware that the PHS Policy, although it set wise standards for the care and use of laboratory animals, contained virtually no investigative or enforcement provisions. When the Silver Spring case broke in 1983, I was in Los Angeles investigating a major abuse of human subjects. A research investigator had forged a fake approval of his research project by an IRB and was conducting research in dying cancer patients. He was injecting spinal stem cells into leukemia patients without approval from the local IRB or consent from the subjects. All of the 18 patients died. We believe their lives were shortened by the illicit research procedures. I started going through records before 6:00 AM and spent a long day interviewing nurses, doctors, and IRB members. I sought in vain someone to defend the accused.

I remember returning to my hotel with a headache from a long, discouraging day. I turned on the TV to ABC News and saw photos of a police raid on a primate laboratory in Silver Spring, Maryland, only a mile from my home. Tired as I was, I realized that I was not watching a movie but that somehow the cameraman was already inside the laboratory when the police raid began. That indicated to me that the raid was set up from inside the laboratory. The commentator stated that the laboratory was filthy and smelly. The animals there were deafferented—the nerves in one of the shoulders of each of the primates had been severed. This process simulated the results of a stroke, and the purpose of the research was to determine which, if any, treatments could restore or rebuild any muscular activity in the inactive shoulders and arms. The cages were filthy and covered with rust. ABC cameras were panning all around the laboratory even as the police were confiscating records attached to each cage.

Before I went to bed that night I contacted OPRR and, with help from Bill Dommel, planned a site visit to the Silver Spring laboratory. That was a long eventful day for one person simultaneously struggling to enforce Regulations for the Protection of Human Subjects and the PHS Policy on Humane Care and Use of Laboratory Animals. Although the violation of the rights of humans seemed to be even worse than the deafferentation of primates, the press put the primates on page 1 of the LA Times and the story about abuse of humans on page 19.

The research investigator in the Silver Spring Case was Dr. Edward Taub. The person who admitted the cameraman ahead of the raid was Mr. Alex Pacheco, one of the founders of People for the Ethical Treatment of Animals (PETA). Taub had hired Pacheco as a summer employee to care for the animals in the Silver Spring lab. Pacheco took many photos of the handicapped monkeys. The animals were taken to the apartment of Ingrid Newkirk, another of the founders of PETA. This was a clear violation of zoning laws and good animal husbandry. It endangered the health of residents and the health of the primates. It turned out that the investigating police officer was also a member of PETA. Ironically, a short time later, the animals were stolen from Newkirk’s apartment. Eventually, following an agreement not to press charges for theft with another group sympathetic to research animals, the animals were returned by truck to NIH where they were temporarily housed in animal facilities in Poolesville, MD.

Dr. William Raub, then Deputy Director of NIH, took over the case. It was often called the Raub-Taub Case. Disputed issues were tried in court six or seven times. The case finally went to the Supreme Court. Dr. Taub was found guilty of failure to consult a veterinarian at periods required by the PHS Policy. Taub contended that he knew more about the care of primates than any veterinarian. Clearly that was not the case. The courts never decided whether the neglect of the laboratory and the poor condition of the animals was Dr. Taub’s fault. Many believed that he had been “set up” by PETA. Eventually the animals were shipped to a laboratory in Mississippi where they lived out their lives.

The Silver Spring investigation was hampered from the beginning by the need to get Taub’s permission to examine his laboratory and documents and by lack of cooperation from the Maryland police. OPRR learned the value of including enforcement procedures in the animal welfare policy. The Silver Spring Monkey Case stimulated OPRR to consider revisions to the PHS Policy—it was clear that it required more “teeth” to permit investigations and sanctions of violations of the Policy. It was also clear that someone or some group at each institution must have authority over research involving laboratory animals.

In 1984, the self-styled Animal Liberation Front (ALF) broke into the University of Pennsylvania Baboon Head Trauma Laboratory. They trashed the laboratory and stole 60 hours of videotape of animals involved in a "whiplash injury study." ALF turned the tapes over to PETA, which edited them down to about 20 minutes and produced a film called “Unnecessary Fuss.” The title came from the NIH Director, who had used those words to describe the fact that PETA created an unnecessary fuss by refusing to turn over the tapes to OPRR and by showing an inaccurate altered version to congressmen and senators as well as to state officials and private associations of various kinds. PETA twisted the director’s words to mean that concern about cruelty to animals was an “unnecessary fuss.” The 20-minute tape was narrated by Ingrid Newkirk.

The research study involved animals given simulated whiplash injuries. Whiplash is an injury to the neck and shoulders of humans involved in rear-end automobile collisions. The purpose of the study was to learn how best to treat whiplash in baboons and ultimately in humans. When an animal was subjected to a sudden jolt pictures of the animal’s
head were taken from many angles to develop an understanding of what muscles and nerves were injured in whiplash accidents.

The 20-minute film claims to show that a large number of animals were subjected to whiplash procedures. Eventually OPRR was able to obtain the original unedited tapes. The master tapes demonstrated that only one animal had been subjected to whiplash injury, although pictures of that animal were taken from many angles. Many believe that inflicting whiplash on even one baboon was not justified. All agree that PETA was dishonest in editing the film in such a way as to make it appear that the injury was repeated over and over again. Many erroneous statements were included in the commentary associated with the edited film.

Films from another camera focused on the surgical table in the laboratory and showed several surgical procedures. The camera was fixed on the table so that it was not possible to see the faces of those conducting the surgery. In reviewing those films, OPRR noticed that puffs of cigarette smoke often billowed across the operating table. Clearly that created a danger for the surgical patients (baboons), but also for the humans involved because oxygen tanks were nearby. We also noticed that the smoker (whose face we could not see) extracted the cigarette from a pack in the hip pocket of his trousers. Of course University of Pennsylvania rules prohibit smoking in all surgical units on the campus. When OPRR interviewed Dr. Thomas Gennarelli, he reached into the left-hand hip pocket of his trousers and extracted a cigarette. He lit it while standing under a “No Smoking” sign in the conference room. It was clear that he had lied about not smoking in the surgical unit.

OPRR found indisputable evidence that PETA had deliberately altered the evidence and repeatedly lied about it in public and before Congress. PETA also withheld evidence from OPRR for many months. OPRR used that information to discredit PETA with the members of Congress. We also found that Dr. Gennarelli had deliberately lied about smoking in the surgery to OPRR investigators. Eventually under pressure from OPRR, the University of Pennsylvania closed the Head Injury Laboratory. OPRR moved on to revise the PHS Policy.

The difficulties we had with these cases made us acutely aware that the PHS Policy needed revision. Because President Reagan was strongly opposed to issuing any regulation not required by law, we did not even consider attempting to create PHS regulations. Reagan had imposed a 5-year moratorium on hiring. The moratorium left OPRR with the responsibility of overseeing the care and use of laboratory animals throughout the country, but we did not have even one veterinarian on our staff. Consequently OPRR turned to Drs. Tom Wolfe and Bob Whitney who, among their many other responsibilities, were in charge of the NIH laboratory animal facility in Poolesville, MD. Over a period of several years, they answered every request submitted to them by OPRR.

I have asked Drs. Whitney and Wolfe to join me on the podium. Clearly they rank among the “giants” on whose shoulders rested the implementation of the PHS Policy. Their concern for making sure that programs throughout the country were in compliance with the PHS Policy made it possible for OPRR to meet its responsibilities.

OPRR assembled a small committee to review the PHS Policy. Our experience with the Silver Spring Monkey Case and with the University of Pennsylvania Head Injury Case and dozens of other less publicized cases made us acutely aware that we needed to establish local authority in each institution that conducted research involving laboratory animals.

OPRR formed a drafting committee to create a revised PHS Policy. Carol Wigglesworth, a young staff person in OPRR, served as secretary for that group. Wolfe, Whitney, and Wigglesworth did the heavy lifting. Eventually Carol produced a final draft of the Policy. For that work, and for her subsequent leadership as Director of the Office of Laboratory Animal Welfare, I consider Carol to be another one of the “giants” of the laboratory animal community. I served as Committee Chairperson, but they did the work.

I was very busy in those days giving speeches and leading workshops that combated the philosophy that it was immoral to use animals in research. If that philosophy had been translated into a governing policy, it would have dealt a mortal blow to biomedical research. OPRR took a middle ground.

It strongly opposed any activity that imposed unmitigated pain on laboratory animals. On the other hand, OPRR strongly opposed unnecessary and crippling restrictions on research involving animals. Many groups insisted that all research involving laboratory animals should be forbidden. That position, had it prevailed, would have undermined medical progress for both humans and animals. My liberal arts training in philosophy proved to be exceedingly valuable. We made it clear that OPRR stood for protection of the rights of human research subjects and for the well-being and proper care of laboratory animals used in research. That approach is now widely accepted.

As soon as the Policy was drafted, OPRR began to implement it. Before coming to OPRR, I had served as a legislative liaison to Congress in the NIH Division of Legislative Analysis (DLA). I knew a few members of Congress and had worked with many congressional staff members. Working through staff, I was able to persuade Congressman Doug Walgren to allow us to test the Policy for a year before it was added to the Public Health Service Act. He said something like this: “I think that is a splendid idea. Try the Policy first, report back to me how it works, and then we will change the law to incorporate the tested Policy.” We did try the Policy, which included for the first time the requirement that each affected institution establish an IACUC. True to his word, in 1985 Rep. Walgren shepherded amendments to the Public Health Service Act through the Congress, establishing the PHS Policy which required institutions to establish IACUCs.

That same year, 1985, Congress amended the Animal Welfare Act. The new law required the USDA to issue revised regulations. It also required the USDA to consult with DHHS. After several failed attempts by the USDA to publish
regulations that met the spirit (as well as the letter) of the AWA Amendments, Dr. John Miller took the matter into his own hands.

John had come to OPRR only a short time before. At last the hiring freeze was over and OPRR was able to recruit a veterinarian. Dr. John Miller came for an interview. I had written about 24 questions to be answered by candidates for the position. He informed me that he thought he could tolerate working with me, and he told me a joke. I laughed so hard I could not finish the interview. John turned out to be another “giant.”

Dr. Miller secretly redrafted the failed USDA regulations; persuaded affected government agencies to endorse (without actually seeing the draft) his revised version of regulations, which emphasized performance standards; and won the approval of the Office of Management and Budget, which, in turn, persuaded the Secretary of Agriculture to publish Miller’s draft for comment. Public comment strongly favored the Miller version, and it became the final Animal Welfare Act Regulation that is operative today.

If John Miller had done nothing but draft the USDA Regulations, he would be worthy to be called a giant on whose shoulders laboratory animal veterinarians and scientists are able to see untold future opportunities. USDA had struggled for 4 years to draft and promulgate acceptable regulations. USDA failed. John Miller single-handedly accomplished the task for them in a matter of a few weeks. His performance was unprecedented and amazing.

John Miller accomplished many wonderful tasks at OPRR, and one of them was to bring soft-spoken Dr. Nelson Garnett on board. Nelson eventually replaced Miller (who moved to AAALAC) as the Director of the Animal Division of OPRR, and then succeeded in separating the Animal Division from the Human Subjects Division. He was the first Director of OLAW. The new office quickly became known as a helper and teacher. Institutions began to bring their problems to OLAW instead of hiding them. The smooth transformation of the Animal Welfare Division into OLAW qualifies Nelson Garnett as one of the giants in our field.

In closing, I wish to salute Nathan Brewer, Elihu Bond, Robert Flynn, Bennett Cohen, Robert Schroeder, Alan Sandler, Carol Wigglesworth, Helen Gordon, John Miller, and Nelson Garnett. Each of these persons made “giant” contributions to the humane care and use of laboratory animals.

I was privileged to work with most of these giants. They are among the best public servants I have ever encountered. It is my privilege tonight to recall and brag about the wonderful people who have made it possible for all of us to celebrate the 25th anniversary of the Public Health Service Policy. Thank you.

Acknowledgment

I should like to acknowledge my dear friend Amy Chuang, who prepared the PowerPoint slides for this presentation.