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Law injected into animal testing Researchers cite obstacles if mice, rats and birds are protected

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Buried in the mammoth federal spending bill covering agriculture lies a mouse-size amendment that is causing a lot of roaring among biomedical scientists and animal welfare activists.

The bill, signed Saturday by President Clinton, contains language that requires the U.S. Department of Agriculture (USDA) to hold off a year before adding laboratory mice, birds and rats to the list of animals that are protected under the 1966 Animal Welfare Act.

They had long been excluded from the act, which regulates the living conditions of dogs, cats, rabbits, monkeys and other animals in laboratories. But in September, an animal rights group won a big victory when the USDA settled a long-running lawsuit by agreeing to include them.

Animal rights groups want the provisions because, they argue, unregulated research animals all too often live under cruel conditions not allowed by the law. They say a lack of oversight leads researchers to use animals more than necessary in medical research instead of looking for alternatives.

The research community, meanwhile, argues that extending the law to cover rats, mice and birds -- which make up about 95% of laboratory animals -- will require researchers to spend a fortune keeping track of redundant regulations, will generate thousands of pages of additional documentation and will open the door to further restrictions aimed at stopping fruitful medical research done with animals.

Researchers argue that extending the rules would end research efforts at community colleges, high schools and other institutions

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too poor to deal with federal regulations and inspections. Animal rights activists say institutions that can't comply shouldn't be doing research in the first place.

Adding to the controversy, Sen. Thad Cochran, R-Miss., added the postponement provision to the USDA's funding bill this month, preventing the agency from implementing the coverage of rats, mice and birds for a year.

"USDA decided to (settle the case and include the animals) without researchers' input. We felt this was the only possible way to get some of our concerns heard," says researcher David Dzielak of the University of Mississippi in Jackson. His institution, which uses about 5,100 rats and 1,100 mice a year, recommended the one-year delay to Cochran to allow researchers to take a role in the process, he says.

"We went through the system and followed the rules," says John McArdle of the Alternatives Research & Development Foundation (ARDF), one of the groups that sued the government to get the animals included under the law. "And they went through a sneaky, backdoor way to put off a judicial decision."

But the USDA's Susan McAvoy says the agency settled the lawsuit, agreeing to start a lengthy session of public meetings aimed at agreeing on new rules, just so that researchers' views could be heard. Losing the case would have meant immediate protection under the Animal Welfare Act for the more than 20 million mice, rats and birds that scientists use in biomedical research nationwide, without any discussion.

Under the act, inspectors visit labs once a year, looking at cage sizes, food and water dishes, and sanitation; checking the floor for holes and the walls for peeling paint; and randomly checking the health of animals.

Right now, 43 lab inspectors, all veterinarians, check labs holding animals that are covered by the act, including monkeys, hamsters and dogs, part of a \$ 10.1 million annual effort. Their inspections cover about 5% of lab animals, by some estimates.

McArdle points out that one benefit of an expanded act would be an accurate census of lab mice, rats and birds. And he suggests that researchers at the largest institutions have little to fear because most already meet U.S. Public Health Service standards that match the Animal Welfare Act standards.

"Then why do it at all?" asks researcher Richard Traystman, head of the animal welfare committee at Johns Hopkins University in Baltimore. "All this does is place an unbelievable burden of paperwork on researchers, raising the cost of finding new medicines."

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Food and Drug Administration regulations, for example, require the testing of drugs for toxicity in rodents and other animals, typically dogs, as part of the development of any drug.

Under the settlement, Traystman foresees yearly changes in regulated cage sizes, mandated "environmental enrichment" toys for lab rats and researchers filling out individual forms for each of the 42,000 mice used at Johns Hopkins.

Such requirements have limited the numbers of monkeys and other covered animals used in research, Traystman says.

Rabbits, for example, require lab temperatures kept steadily between 68 and 72 degrees and have costlier air-conditioning systems than human offices, he says.

But the Agriculture Department says the law's requirements change only once every 10 years or so. McArdle says only two pieces of paperwork would be added to researchers' burden, and his group would be happy if mice, rats and birds were tracked by cage or lot, not individually.

"We really just want researchers to consider more alternatives" to mice, rats and birds, he says.

The furor comes as the mouse stands poised to be the research animal of choice for the genetic age. Celera Genomics of Rockville, Md., the private company involved in sequencing the human genome, announced this month that it has deciphered at least 95% of the genes that make up a mouse, which Celera calls a key move toward figuring out what those genes do in people.

Also this month, the Jackson Laboratory of Bar Harbor, Maine, received a \$ 14 million grant from the National Institutes of Health to study the mouse genetics involved in heart, lung, blood and sleep disorders. More than 60% of the genes of mice and men are the same, by common estimate. "How will we ever determine what these (human) genes do without the mouse?" Traystman asks.

In addition to learning how humans and mice share genes, researchers have figured out powerful ways to delete, add or switch on genes in mice. An entire generation of researchers has learned how to uncover a gene's function using "transgenic" mice as the tool of first resort, Traystman says.

"Truthfully, animal-rightists have the public believing scientists can't wait to go to their labs every morning and torture animals. And that's the furthest case from the truth," Traystman says.

As mice become more important to gene-tracing efforts, their care and cost will increase, even without the law. Animal care and use committees at most major institutions will look hard at projects

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for alternatives to mice for just that reason, he adds.

Advocates of alternatives question that common assertion.

"Committees often don't have the latest information about new testing methods," says Rodger Curren of In Vitro Sciences in Gaithersburg, Md.

His company, which joined the lawsuit, tries to inform researchers, animal rights advocates and federal regulators about alternatives to using animals for research, such as using cell cultures.

From his experience, he compares animal use committees to the overworked, underfinanced and widely criticized institutional review boards that oversee human research.

"Probably researchers can walk all over them if they really want to," Curren says.

Much of the real concern driving researchers' outcry over the settlement derives from the fear that it will lead to more regulations. The real goal of the animal rights movement, says **Frankie Trull** of the National Association for Biomedical Research, is further unwarranted tightening of the use of animals in medical research until it ends.

"We're against animal testing across the board," says Lisa Lange of People for the Ethical Treatment of Animals. Despite the drugs approved every year by the FDA, all of which went through animal testing, she says, "it doesn't really work." Many researchers increasingly see alternatives as a better choice for drug development, she suggests. Economic concern from "the animal testing industry" drives much of the resistance, she adds.

Curren suggests that many more companies are looking for alternatives. Use of lab animals, both as subjects of toxicity tests and as sources of monoclonal antibodies, a type of immune cell useful in medical research, has dropped in recent years. But Curren says animal testing is unavoidable in some cases.

Others agree, arguing that ultimately animals suffer in some cases so that people don't. "Who wants to see another thalidomide go on the market without animal testing?" asks Jackson Laboratory head Ken Paigen. Thalidomide caused birth defects in Europe while the FDA prevented its use here in the 1960s. Testing will take place in patients when drugs go on the market without animal tests, he says.

"The fact is, the mouse is an imperfect model of the human being. If it was perfect, it would be a person," Paigen says. "I don't think we have much choice."

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