USDA gives ground over lab animals

Animal rights activists and their opponents are both declaring victory in the wake of a legal settlement between the US Department of Agriculture (USDA) and the Minnesota-based Alternatives Research and Development Foundation (ARDF). The ARDF had sued the agency in an effort to expand the scope of animal care regulations. Under the terms of the agreement, the USDA will now begin the process of extending its animal welfare rules to cover rats, mice and birds, which make up 90–95% of the US population of laboratory animals.

The dispute began in 1970, when Congress passed the Animal Welfare Act and directed the USDA to establish regulations for laboratory animal care. At the time, the agency decided to exclude rats, mice and birds from the regulations, a decision that has been attacked repeatedly by animal rights groups. The agency and many researchers have argued that an existing system of voluntary accreditation, in addition to rules established by funding agencies like the National Institutes of Health (NIH), make USDA regulation of these species redundant. Some argue that redundant regulation is precisely what the ARDF is hoping to establish. "It's not about animal welfare—it's about pricing us out of existence," says Barbara Rich, executive vice president of the National Association for Biomedical Research (NABR). Rich describes the USDA settlement as "a capitulation...to people who want to abolish animal research." According to NABR estimates, the USDA will need to add $10 million to its budget to enforce the expanded regulations, and the additional administrative costs for research institutions could reach into the hundreds of millions of dollars.

John McArdle, director of the ARDF, responds that the NABR estimates are "incredible," adding that any facility that complies with current NIH guidelines "is going to see almost no change. When the USDA sets regulations for care...I'm expecting it will be absolutely identical to what the NIH has right now." McArdle concedes that this means USDA involvement will have little or no effect on the way animals are cared for at major research centers, but asserts that the change is still worthwhile. Under the current system, researchers and animal breeders who are not NIH-funded and use only rats, mice or birds are essentially unregulated, and may have to upgrade their facilities. Although the settlement calls for the USDA to begin the rule-making process immediately, clarifications made in a 6 October hearing on the case reassured the NABR that "it was an open question whether or not there would be a final rule," or what form that rule might take, according to Rich. Before the hearing, the NABR had feared that the settlement would force the agency into adopting a specific set of regulations without adequate input from researchers, in violation of federal NIH making procedures, which require an agency to consider input from the public before proposing and implementing a specific rule change. If the USDA ultimately decides not to regulate rats, mice and birds this time around, though, it is likely that the agency will be headed back to court: McArdle stresses that the ARDF still retains the right to sue the agency in the future.

In a separate effort, the USDA is now considering adopting new standards for measuring distress in laboratory animals, a change that could have a considerable effect on the administrative requirements for animal care. At present, agency regulations offer no clear definition of distress for laboratory animals, and no quantitative scale to assess the level or duration of pain experienced by the animals.

Alan Dove, Philadelphia

NIH gives money for orphan development

Sometimes companies have potential products in their portfolios that, for whatever reason, are not a high priority. They may be 'orphan' drugs that will be used only by a small number of people, or their market may be in developing countries that lack the money to buy them. Whatever the reason, a new National Institutes of Health (NIH) grant program has been established to provide companies with the financial incentive they need to accelerate the development of certain drugs.

The new Challenge Grants program has announced funding for nine projects—new malaria and tuberculosis (TB) drugs, and vaccines against TB, influenza and dengue fever.

"The aim of this program is to promote joint ventures between government and industry," says Pamela McInnes, acting deputy director of the Division of Microbiology and Infectious Diseases at the National Institute for Allergy and Infectious Diseases (NIAID). "It involves one-on-one matching of dollars, and the goal is research that would have commercial potential."

But why give government money to private industry? NIAID Deputy Director John LaMontagne explains that what is needed in these areas goes beyond basic research: "If you want to develop a product for any of these difficult problems that are of low market potential, then you have to go where the talent is." He adds that whereas academic departments have "wonderful skills in basic research, [industry can] work out problems of manufacturing and quality control."

Steven Reed, CSO of Corixa of Seattle, which has received a $2.3 million Challenge Grant for development of a TB vaccine, says "It's true that it helps to prioritize the program at a higher level. And it's definitely true that for big companies, such as our partner, SmithKline, these kinds of grants are important to provide the validation and momentum to drive the product to the clinic." Corixa will use the funds to develop their chimeric molecule vaccine composed of antigens that "are important for human immune responses," combined with a safe adjuvant. Reed expects that clinical trials will begin by the end of 2001.

Thomas Monath, vice president for research and medical affairs at Massachusetts-based OraVax, which received $1.8 million for development of a dengue vaccine, does not believe that the products supported by the Challenge Grants are true orphans. "Industry's just waking up to the fact that there are substantial markets [for dengue, malaria, and TB]," he says. He believes the world's markets for such products, even in developing nations, "are undergoing significant changes," which will include