Animal activists take aim at Columbia University's primate program

Columbia University's medical center is under fire from the People for the Ethical Treatment of Animals (PETA), which has alleged that the school's treatment of research primates violates New York state laws.

PETA's complaints have prompted investigations by the US Department of Agriculture and the US National Institutes of Health into the university's potential violations of the federal Animal Welfare Act. In March, PETA also filed a complaint against the medical center with the office of the Manhattan District Attorney.

PETA began an intense public awareness campaign in 2002 after veterinarian Catherine Dell'Orto, a former postdoctoral fellow at Columbia, went public with complaints about the treatment of baboons she had observed in several Columbia laboratories, particularly in the stroke therapy research of neurosurgeon E. Sander Connolly.

The study to test potential neuroprotective drugs in a baboon model of stroke involved removing an eye from each animal to allow technicians to clamp an artery and artificially induce a stroke. Dell'Orto reported that anesthesia was not administered to some baboon subjects, while others were left to die in their cages without being euthanized.

Sion Touhig/Getty Images

Monkey business: Columbia U is under investigation for potential violation of animal welfare laws.

Laboratories are generally exempt from New York animal cruelty laws, but scientists may be prosecuted in cases where experiments are "improperly conducted," says Mary Beth Sweetland, PETA senior vice president. PETA says Connolly and his staff failed to observe the research protocols and that the experiments "lacked any 'reasonable scientific justification'."

Also named in the complaint were members of the medical center's Institutional Animal Care and Use Committee, which evaluates animal research protocols. Mark Underwood, chairman of the committee, says an internal investigation turned up several "deficiencies," including incomplete documentation and insufficient post-operative veterinary observation. "Columbia University took the allegations very seriously and made immediate and appropriate corrective action," says Underwood, who was not named in the complaint.

Connolly, who did not respond to interview requests, has voluntarily suspended the stroke experiments, Underwood says, adding that Connolly and others who conduct animal research have the university's full support. "We feel that the research is of vital importance to the mission of saving lives and finding cures," Underwood says.

PETA and others were buoyed by a recent critique of animal research, which reported that much of the research is inapplicable to human models and is subject to significantly lower standards than clinical trials (*BMJ* **328**, 514–517; 2004). The authors concluded that "the contribution of animal studies to clinical medicine requires urgent formal investigation."

Bruce Diamond, New York

Collaboration may be the cure for what ails drug development

Pharmaceutical companies routinely sink millions of dollars into common diseases, hoping for a multibillion-dollar payoff from the next blockbuster drug. But for orphan diseases with a small market, there are few takers.

An emerging model for medical research—exemplified by the Cystic Fibrosis (CF) Foundation's approach to drug discovery—relies on collaborative efforts between pharmaceutical companies, academic researchers, physicians and patients to propel test tube discoveries to the clinic.

"There is not a lot of incentive for companies to invest in orphan diseases like cystic fibrosis," says Robert Beall, president of the CF foundation. "By funding CF drug discovery, we ensure that our pipeline of potential therapeutics is continuously fed."

At a conference held in March in Washington, DC, Elias Zerhouni, director of the US National Institutes of Health, said the foundation's model exemplifies the collaborative efforts described in his Roadmap for Medical Research (*Nat. Med.* **9**, 1335; 2003). Other organizations, such as the Juvenile Diabetes Research Foundation and the Institute for the Study of Aging, are following similar paradigms.

Developing a drug from concept to approval can cost up to a billion dollars. Using unconventional strategies designed to encourage companies to develop medicines at minimal financial risk, the foundation hopes to lower the cost to about $100 million.

In addition to funds, the foundation gives companies access to a network of 18 CF care centers and a patient registry. "The largest problem in the research of orphan diseases is the lack of centers with enough patients to enter into a trial," says Bruce Montgomery, chief executive officer (CEO) of Corus Pharma. "The care centers, by standardizing and centralizing care, help solve this problem." With financial support from the foundation, Corus is conducting a phase 2 clinical trial of an inhaled antibiotic for treating pseudomonal infections in CF patients.

The foundation supplies initial funding to companies in the form of awards and contracts and matches companies' investment in CF drug research. In return, companies must meet certain goals before they receive the next payment. The foundation typically helps fund phase 1 and phase 2 trials. "Once they've completed those successfully," Beall adds, "it's much easier for them to get additional sources of funding for the development of a phase 3 drug."

This integrated model of drug development is a "one-stop shop," says Ed Field, CEO of Inologic, Inc., which is developing a compound to improve the function of CF-struck lung cells. Apart from reducing financial risk for companies, Field says, the model also cuts clinical risk in terms of access to patients, centralized data management, academic researchers and protocols. "The foundation's integrated network makes it easy for a company like ours to plug in to," he says.

Another aspect of the model is finding companies with potential CF drugs already in their pipelines. For example, Inspire Pharmaceuticals had a drug that was originally targeted for sinusitis. Because some experts thought the drug might have applications in CF, the foundation gave the company $1.7 million to develop the drug for CF. The drug did not test well for sinusitis, but Inspire recently announced promising phase 2 results for its efficacy in CF.

Amy K Erickson, Washington, DC