



PETA

PEOPLE FOR THE ETHICAL
TREATMENT OF ANIMALS

501 FRONT ST.
NORFOLK, VA 23510
Tel. 757-622-PETA
Fax 757-622-0457

PETA.org
info@peta.org

December 4, 2003

William H. Donaldson, Chairman
U.S. Securities and Exchange Commission
450 Fifth St., NW
Washington, DC 20549

Dear Mr. Donaldson:

People for the Ethical Treatment of Animals (PETA) is the world's largest animal rights charity, with more than 750,000 members and supporters dedicated to alleviating animal suffering. You may or may not know that some of the methods we use to educate people about animal issues are quite extraordinary and often controversial. This complaint letter is not one of them. I know from my 10 years with Merrill Lynch prior to these last 15 years with PETA that the SEC sometimes receives frivolous or downright bogus complaints from people who wish that they had never met their brokers or become accustomed to the lounge-lizard lifestyle. I would like to ask that you take this complaint and our request for remedy seriously and not brush it off as a gadfly action, which you may initially be tempted to do. Please give this some thought.

On May 9, 2001, Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX), of Tarrytown, N.Y., issued a press release about an experimental drug, dehydroascorbic acid (DHA), that the company claimed "significantly decreased brain damage and neurological deficits when administered as long as three hours after a stroke in an animal model." The press release identified E. Sander Connolly Jr., M.D., from Columbia University, as a "co-author of the scientific presentation." Connolly's experiments are funded by the National Institutes of Health (NIH). He is quoted in the news release as saying, "The positive outcome of this study underscores the potential of DHA to protect patients against the debilitating consequences of stroke."

The study referred to in the press release is Connolly's stroke experiments on baboons which resulted in the filing of a serious complaint by a Columbia University veterinarian, who claimed that the baboons received inadequate or no veterinary care. The complaint was filed in October 2002, and on June 30, 2003, Columbia admitted to the complaining veterinarian that "based on records of care, inadequate or questionable veterinary care was rendered to 11 of the 23 animals about which [she] expressed concerns."

AN INTERNATIONAL
ORGANIZATION DEDICATED
TO PROTECTING
THE RIGHTS OF ALL ANIMALS

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I am enclosing our January 10, 2003, letter to the federal Office of Laboratory Animal Welfare (OLAW) about this matter. As you can see, the baboons, whose left eyes were cut out of their sockets to allow access to their brains so that Connolly could clamp off blood flow and induce a “stroke,” were severely debilitated—unable to eat, drink, or hold themselves upright. Many of them were simply found dead in their cages by animal-care staff, even though the experimental protocol called for round-the-clock attention by the researchers themselves if the baboons could not self-care after the stroke was induced.

As you can see, the first baboon medical record that we mention in our January 10, 2003, letter to OLAW is dated September 19, 2001, but the same DHA experiments on baboons were taking place long before Progenics’ May 9, 2001, news release. We believe that the baboon records dated prior to the May 9, 2001, news release should be examined by experts to determine whether fraud or shabby science or animal care is as evident in those records as it was in those we address in our letter to OLAW. If such is the case, Connolly and Progenics may have provided unscientific—or perhaps even misleading—information to the investing public about DHA. On May 8, 2001, Progenics opened at \$10.24 and its volume was 128,900 shares. On May 9, 2001, the stock closed at \$13.18 with a volume of 46,300. On May 29, 2001, Progenics closed at \$22.14.

In August, we received an expert opinion provided by Nicholas Dodman, DVM, a former professor of veterinary anesthesiology at Tufts University who currently heads Tufts’ veterinary school’s Department of Clinical Sciences. Much to our horror, after reviewing Connolly’s experimental baboon protocol for DHA, Dr. Dodman pointed out that the baboons did not even receive adequate anesthesia for the removal of their eyes and the occlusion of their brain blood vessels. Excessive stress caused by unmitigated pain would alter data from experiments to the point where they would not be usable.

I have also enclosed opinions from two neurology experts who are highly critical of Connolly’s baboon experiments. Robert S. Hoffman, M.D., writes, “The major point I wish to make is that this project is only the latest of a very large number of similar studies of potential neuroprotective agents done over the pasty twenty years. Over thirty such agents, which were found beneficial in animal models, were then tested in humans. Not a single one showed benefit in the human trials (Ovbiagele B et al, “Neuroprotective agents for the treatment of acute ischemic stroke,” *Curr Neurol Neurosci Rep.*, January 2003, 3(1): 9-20).”

Dr. Hoffman also criticized the DHA study because “less than 25% of human strokes are of the type that is being studied. ... [Tying off one or more large cerebral arteries] is not applicable to the vast majority of human strokes. Most are due to emboli (traveling clots), microvascular disease (closure of microscopic arteries), or other mechanisms. Another reason, of course, is that although nonhuman primates are closer than other animals to humans in some respects, their nervous systems are still very different. Many human strokes, for example, involve language dysfunction (aphasia) or impairment of higher cortical functions, i.e., those not present or testable in nonhuman primates.”

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We broach the issue of the irrelevance of animal studies to human health, knowing full well that all pharmaceutical and biotech companies are required by regulators to conduct tests on animals. Even so, we believe that it may be time for the SEC to consider the irrelevance factor when biotech or pharmaceutical companies make announcements that may have a profound effect on investor confidence. Perhaps the SEC should require full disclosure by companies, which would include providing statistics such as those provided above by Dr. Hoffman, so that investors would have a more complete picture before they choose to invest in a company based on an announcement such as the one issued by Progenics in May 2001. The "forward-looking statements" disclaimer at the end of Progenics' news release is simply too vague to be useful or meaningful.

We certainly hope that the SEC will request records of DHA experiments on baboons from Progenics and Columbia University so that experts can examine them. We also hope that the SEC, even though it already has an extremely heavy burden without taking on extra duties, will look more closely at what it allows to be fed to the consuming public by biotech and pharmaceutical companies using inherently unreliable data from animals. Thank you for your time. We look forward to hearing from you.

Sincerely,

A handwritten signature in cursive script that reads "Mary Beth Sweetland".

Mary Beth Sweetland, Senior Vice President
Director, Research & Investigations Department

cc: The Honorable Eliot Spitzer
Office of the Attorney General, Department of Law
The Capitol
Room 220
Albany, NY 12224-0341