July 28, 2016

Dr. Elizabeth Goldentyer, DVM Director, Operations U.S. Department of Agriculture Animal and Plant Health Inspection Service Animal Care 920 Main Campus Dr., Ste. 200 Raleigh, NC 27606-5210

Via e-mail: Betty.J.Goldentyer@usda.gov

Dear Dr. Goldentyer:

I am writing on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 5 million members and supporters to request that the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) investigate possible violations of the Animal Welfare Act (AWA) related to the use and treatment of animals at the laboratories of MPI Research, Inc. (MPI; #34-R-0031, #34-B-0171), located at 54943 N Main Street in Mattawan, MI.

PETA was recently contacted by an anonymous whistleblower who attested to the following problems at MPI:

- Failure to ensure that procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals [9 C.F.R. §2.31(d)(1)(i)]; and
- 2. Failure to ensure the psychological well-being of nonhuman primates [9 C.F.R. §3.81].

I. Failure to ensure that procedures will avoid or minimize discomfort, distress, and pain to animals

Section 2.31(d)(1)(i) of the Animal Welfare Regulations (AWRs) specifies that in its review of activities involving animals, the Institutional Animal Care and Use Committee (IACUC) must ensure that the proposed activities "avoid or minimize discomfort, distress, and pain to the animals."

However, the insider informed PETA that MPI maintains a colony of approximately 18 dogs who are used to study the delivery of drugs across the blood-brain barrier and are subjected to procedures where discomfort, distress and pain to the dogs is not minimized. According to the informant, the dogs have metal ports surgically implanted into their bodies and an attached catheter is run up to the lower part of the spinal column to facilitate multiple collections of cerebrospinal fluid (CSF). The ports are flushed every two weeks with saline solution. The informant stated that staff members in MPI's pharmacokinetics department conduct the lumbar punctures and port-flushes. Staff members carry

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

PETA ,

Washington, D.C.

1536 16th St. N.W. Washington, DC 20036 202-483-PETA

Los Angeles

2154 W. Sunset Blvd. Los Angeles, CA 90026 323-644-PETA

Norfolk

501 Front St. Norfolk, VA 23510 757-622-PETA

Oakland

554 Grand Ave. Oakland, CA 94610 510-763-PETA

Info@peta.org PETA.org

Affiliates:

- PETA Foundation (U.K.)
- PETA Asia-Pacific
- PETA India
- PETA Germany
- PETA Netherlands

out the punctures and flushes quickly. This and/or possibly other procedural problems make the process especially uncomfortable for the dogs, who clearly show in their behavior that they are experiencing intense pain, which can be long-lasting. In some instances, the dogs experience seizures. They shake violently and their eyes roll up in their heads. The insider informed PETA that the dogs are not anesthetized prior to the procedure and they are given analgesia only if they experience a seizure—and only after staff members receive approval from supervisors.

The insider told PETA that as with humans, dogs can experience migraines during lumbar puncture. That humans may suffer side effects including incapacitating headaches from lumbar puncture is well-documented in the human medical literature; and there are also cases of humans who have experienced seizures after an epidural injection. Principle IV of the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training advises that "investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals." However, the insider informed PETA that nothing is done to alleviate the dogs' pain and discomfort.

The insider also told PETA that the dogs are euthanized when they are 3 or 4 years old and replaced by young puppies who are approximately three to five months of age. The whistleblower reported that one of the new puppies who was subjected to a lumbar puncture was screaming and flailing through the process.

We contacted with Dr. Daniel Smeak, DVM, Professor and Chief of Small Animal Surgery at Colorado State University, who stated that he had consulted on a project similar to the one that we described but he did not witness any adverse signs during CSF collection; and that if a small amount of saline is used and administered at a slow rate, there should be no changes in behavior or heart rate and there should not be any other signs of discomfort or anxiety during the saline flush.

Additionally, the veterinary literature recommends specific elementary refinements that may reduce the pain and discomfort experienced by dogs who are subjected to lumbar injections, including proper placement of the catheter¹ and avoiding high speed injections.² These refinement techniques are apparently not being used. The human medical literature documents that accidentally injecting air into a catheter can cause headaches, dizziness, and seizures.³

The failure on the part of MPI's IACUC to ensure that the distress, discomfort, and pain experienced by dogs used in the protocol described above was minimized appears to constitute a failure on the part of the facility to comply with Section 2.31(d)(1)(i) of the AWRs.

II. Failure to ensure the psychological well-being of nonhuman primates

¹ Swalander, David, et al. (2000). Complications associated with the use of indwelling epidural catheters in dogs: 81 cases (1996-1999). *Journal of the American Veterinary Medical Association, 216* (3), 368-370.

² Son, WG et al. (2014, September). The effect of epidural injection speed on epidural pressure and distribution of solution in anesthetized dogs. *Veterinary Anaesthesia and Analgesia*, 41 (5), 526-533.

³ Arora, Dheeraj, Yatin Mehta, Aashish Jain, and Naresh Trehan (2012). Headache and seizures after cervical epidural injection in a patient undergoing coronary artery bypass grafting. *Annals of Cardiac Anesthesia*, *15* (3), 244-246.

Section 3.81 of the AWRs stipulates that "facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological wellbeing of nonhuman primates."

The insider informed PETA that several monkeys at MPI are caged alone and exhibit signs of psychological distress, pacing in their cages. The informant stated that some of the monkeys have "picked themselves raw" and one monkey who is caged alone has pulled out much of his hair. The informant did not believe that special attention was provided to this monkey, in contravention of Section 3.81(c)(2).

We urge you to investigate the concerns summarized in this letter and, if the claims are substantiated, to take swift and decisive action that includes citing MPI for violations of the AWA and levying fines against the facility.

If you have any questions, please contact me at 202-829-0974 or <u>AlkaC@peta.org</u>. Thank you for your time and consideration.

Sincerely,

Alka Chade

Alka Chandna, Ph.D. Laboratory Oversight Specialist Laboratory Investigations Department People for the Ethical Treatment of Animals