

November 14, 2007

Mr. Daniel Levinson
Inspector General
Department of Health and Human Services
330 Independence Ave
S.W., Room 5250
Washington, DC 20201

Via mail and facsimile to 202-401-3196

Re: Misuse of biodefense funds for chimpanzee antibody production

Dear Mr. Levinson,

People for the Ethical Treatment of Animals (PETA) sent the enclosed letter to Dr. Zerhouni, Director of the National Institutes of Health (NIH), to express the concerns of our 1.8 million members and supporters over experiments being performed at the National Institute of Allergy and Infectious Disease (NIAID). We ask that you launch an investigation into NIH's failure to honor the Animal Welfare Act in allowing this redundant experimentation on animals and the misappropriation of potential biodefense funding.

PETA has learned that chimpanzees are being used to produce antibodies against several pathogens for which successful immunotherapeutics already exist.^{1,2} Because several of these pathogens are classified as potential bioterrorism threats by the Center for Disease Control and Prevention (CDC),³ critical biodefense funds are being misdirected towards these redundant efforts. In fact, funding from NIH, the Centers for Disease Control and Prevention (CDC), and the Department of Health and Human Services (DHHS) has already directly contributed to the development, manufacturing, and stockpiling of several of the available, non-chimpanzee based immunotherapies by other researchers.⁴⁻⁹

The NIAID researcher's assertion that this work is necessary because chimpanzees allow more "flexibility" than human volunteers¹ is undermined by the fact that many of the FDA-approved therapeutic antibodies, including those against the very pathogens on which these researchers are focused, are from humans.^{10,11} The antibodies being produced by NIAID are neither novel nor necessary since effective therapeutics have already been developed without the use of chimpanzees. In a specific example, two companies have already been contracted to supply human-derived Anthrax immunotherapeutics to the Strategic National Stockpile,⁴ and three other companies have human derived or humanized Anthrax antibodies in clinical trials³.

There is a clear ethical and scientific need to halt this extraneous experimentation so that more chimpanzees do not suffer and biodefense funds do not continue to be funneled into this misguided approach.



PETA

PEOPLE FOR THE ETHICAL
TREATMENT OF ANIMALS

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I look forward to hearing from you on this important matter.

Sincerely,



Nancy Douglas, PhD
Regulatory Testing Division

Enclosure: NIH letter

¹ Zhaochun Chen, Suzanne Emerson, Robert Purcell. Monoclonal Antibodies Derived From Chimpanzees: A New Approach to Immunoprophylaxis and Immunotherapy. Presentation at the Protein Engineering Summit, Boston, Mass., May 2007. This presentation listed 15 target pathogens/antigens: Hepatitis (A, C, E) dengue, smallpox, anthrax, Japanese encephalitis, polio, tick-borne encephalitis, rabies, Norwalk, West Nile, lupus, measles-mumps-rubella, botulism. Published references:

Kabrane-Lazizi Y, Emerson SU, Herzog C, Purcell RH (2001) Detection of antibodies to HAV 3C proteinase in experimentally infected chimpanzees and in naturally infected children. *Vaccine* 19(20-22):2878-83.

Schofield DJ, Satterfield W, Emerson SU, Purcell RH (2002) Four chimpanzee monoclonal antibodies isolated by phage display neutralize hepatitis a virus. *Virology* 292(1):127-36.

Yu C, Engle RE, Bryan JP, Emerson SU, Purcell RH (2003) Detection of immunoglobulin M antibodies to hepatitis E virus by class capture enzyme immunoassay. *Clin Diagn Lab Immunol* 10(4):579-86.

Schofield DJ, Purcell RH, Nguyen HT, Emerson SU (2003) Monoclonal antibodies that neutralize HEV recognize an antigenic site at the carboxyterminus of an ORF2 protein vaccine. *Vaccine* 22(2):257-67.

Men R, Yamashiro T, Goncalves A, Wernly C, Schofield DJ, Emerson S, Purcell RH (2004) Identification of Chimpanzee Fab fragments by repertoire cloning and production of a full length humanized immunoglobulin G1 antibody that is highly efficient for neutralization of Dengue Type 4 virus. *Journal of Virology* 78(9): 4665-4675.

Yu MY, Bartosch B, Zhang P, Guo ZP, Renzi PM, Shen LM, Granier C, Feinstone SM, Cosset FL, Purcell RH (2004) Neutralizing antibodies to hepatitis C virus (HCV) in immune globulins derived from anti-HCV-positive plasma. *PNAS* 101(20): 7705-7710.

Chen Z, Moayeri M, Zhou YH, Leppla S, Emerson S, Sebrell A, Yu F, Svitel J, Schuck P, St Claire M, Purcell R (2006) Efficient neutralization of anthrax toxin by chimpanzee monoclonal antibodies against protective antigen. *J Infect Dis* 193(5):625-33.

Chen Z, Earl P, Americo J, Damon I, Smith SK, Yu F, Sebrell A, Emerson S, Cohen G, Eisenberg RJ, Gorshkova I, Schuck P, Satterfield W, Moss B, Purcell R (2007) Characterization of

chimpanzee/human monoclonal antibodies to vaccinia virus A33 glycoprotein and its variola virus homolog in vitro and in a vaccinia virus mouse protection model. *Journal of Virology* 81(17):8989-95.

² Available non-chimpanzee-based antibody therapies:

Hepatitis A – fda.gov/cber/summaries/ig042507es.pdf, 10/3/2007

Hepatitis B – <http://www.cangene.com/products-hepagam-b.htm>, 10/3/2007

Vaccinia (smallpox) – Cangene.com/biodefense.htm, 9/12/2007

Rabies – FDA consumer magazine, wikipedia passive immunity, 10/3/2007

Botulism – <http://www.fda.gov/cber/sba/igivcdhs102303S.pdf>, 10/3/2007

West Nile – <http://www.macrogenics.com/pipeline>, 10/3/2007

Lupus - http://www.lupusresearchinstitute.org/press_article.php?epratuzumab, 9/12/2007

Anthrax –see references 4-9

³ www.fbo.gov/servlets/Documents/R/589030, 9/12/2007

⁴ www.upmc-biosecurity.org, 9/12/2007

⁵ www.hhs.gov/aspr/barda/mcm/medcountmeas.html, 9/12/2007

⁶ www.Cangene.com/biodefense.htm, 9/12/2007

⁷ Avanir (AVP-21D9), www.avanir.com/products/xenerex.php, 9/12/2007

⁸ Elusys (Anthim), www.elusys.com/technology_mc_anthrax.php, 9/12/2007

⁹ Medarex (Valortim), www.medarex.com/development/pipeline.htm, 9/12/2007

¹⁰ Waldmann TA (2003) Immunotherapy: past, present and future. *Nature Medicine* 9: 269–277.

¹¹ <http://www.pharmadd.com/StrategicBriefings/MAbs.asp>, 10/3/2007