



**BEFORE THE US FOOD AND
DRUG ADMINISTRATION**

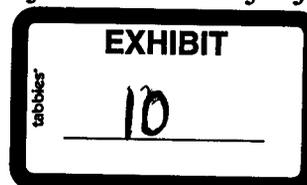
**ANTIBODY SYSTEMS, INC., §
CITIZEN PETITION §**

AFFIDAVIT

**STATE OF FLORIDA §
COUNTY OF Escambia §**

BEFORE ME, the undersigned Notary Public on this day personally appeared George L. Stewart, Ph.D, known to me, and having been duly sworn stated and deposed upon his oath the following:

1. My name is George L. Stewart. At present I am a resident of Baldwin County, Alabama. I am Professor and Chair of the Department of Biology of The University of West Florida, Pensacola, Florida. I hold the degree of Doctor of Philosophy. I am over the age of 21 years and am fully capable in law and fact to make this affidavit. Each of the statements made in this affidavit are based upon my personal knowledge unless otherwise stated.
2. This Affidavit is made in connection with what I understand is a Citizen's Petition being filed by Antibody Systems, Inc., and Terry Fredeking following his receipt of a warning letter from FDA in 2003 concerning the North Texas Institutional Review Board.
3. In 1991 the North Texas Institutional Review Board (NTIRB) was formed. The Chairman of the NTIRB was Dr. Neil Dishon, MD., head of student services at the University of Texas at Arlington.
4. I became a full voting member of the NTIRB in 1991. At the time I was employed full-time by The University of Texas at Arlington and a member of the faculty in the Department of Biology and Director of the Center for Parasitology.
5. It is my understanding that following a December, 2002, inspection of the NTIRB by investigators of the US Food and Drug Administration the Establishment Inspection Report (EIR) states that while serving as a voting member of the NTIRB I was an employee of Antibody Systems,



Inc., and further that this created a conflict of interest since during my tenure on the IRB we reviewed proposed clinical trials of Antibody Systems, Inc. The statement that I was an employee of Antibody Systems, Inc., while serving on the NTIRB is not correct. At no time have I ever been an officer, director, or employee of Antibody Systems, Inc. If I had I would never have joined the IRB.

5. My doctor of philosophy degree and my professional field of study is parasitology. In that capacity I did conduct research on parasites under grants funded by Antibody Systems, Inc. I was co-author of articles published on this parasite research and did put on my resume that I was Director of Research and Development for Antibody Systems, Inc. That term was intended to refer only to the scientific research publications I published jointly with Antibody Systems, Inc. As is my practice, I also disclosed on my resume the fact that Antibody Systems, Inc., had supported some of my research along with all the other sponsors of research I have conducted, the largest by far of which was a \$117,424 grant from the National Institutes of Health in 1985. None of this research in parasitology had any connection with any study ever reviewed by the NTIRB and upon which I voted. In my resume I also listed Antibody Systems, Inc., as one of 28 firms and institutions to which I have served in a consultant capacity

7. To the best of my knowledge the NTIRB discontinued operations approximately five years ago.

Dated this 5 day of April, 2005.


George L. Stewart, Ph. D

Subscribed and sworn to before me, on the 6th day of April, 2005, to certify which, witness my hand and official seal.


Notary Public in and for
the State of Florida

My Commission Expires:

1-13-06

Joyce K. Boyce
Notary's Printed Name

