UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COALITION FOR AFFORDABLE DRUGS VII LLC
Petitioner

v.

POZEN INC.
Patent Owner

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Case No. IPR2015-01718
Patent No. 8,945,621

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DECLARATION OF ROBERT W. MAKUCH, PH.D.

IN SUPPORT OF PATENT OWNER'S RESPONSE

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I, Robert W. Makuch, Ph.D., hereby declare and state as follows:

I. INTRODUCTION AND SUMMARY OF QUALIFICATIONS

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. I have been retained as an expert opinion witness on behalf of Patent Owners Pozen Inc. and Horizon Pharma Inc. for the above-captioned *inter partes* review ("IPR"). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is $625 per hour.

3. I have no financial interest in, or affiliation with, the Petitioner or the Patent Owners. My compensation is not dependent upon the outcome of, or my testimony in, the present *inter partes* review or any litigation proceedings.

4. My background, qualifications, and experience relevant to the issues in this proceeding are summarized below. A full description of my background and qualifications is set forth in my *curriculum vitae*, attached hereto..

5. I am a tenured Full Professor in the Department of Biostatistics at the Yale University School of Medicine. I am also currently Director of the Regulatory Affairs Track Yale University School of Medicine.

6. I possess nearly 38 years of experience in a variety of areas including but not limited to identification, evaluation, and interpretation of clinical endpoints and other clinical events. My research has focused primarily on the design, conduct, analysis, and interpretation of clinical and pre-clinical data obtained from pre-clinical experiments, clinical trials, and epidemiologic studies.

7.   My activities include, but are not limited to, serving as: 1) Special Government Employee (SGE) to the U.S. Food and Drug Administration (FDA); 2) consultant/advisor to numerous government and pharmaceutical-sponsored clinical and pre-clinical studies; and 3) author or co-author of over 200 peer-reviewed publications in the medical and regulatory affairs literature.

8.   I received my M. Phil. and Ph.D. from Yale University in 1976 and 1977, respectively.

9.   I received my M.A. degree from University of Washington in 1974 and my B.A. degree from University of Connecticut in 1972.

10.   In 1977 I became an investigator and was subsequently promoted to Senior Investigator at the National Cancer Institute. In 1983 I was again promoted to Section Head of the biostatistics and data management section. I held that position until 1986.   Many of my activities in these roles involved the design, conduct, analysis, and interpretation of clinical trials and pre-clinical studies.

11.   In 1986, I joined the faculty of Yale University in the Division of Biostatistics as an Associate Professor. I was tenured in 1990 and promoted to Full Professor in 1995 which I continue to hold today.

12.   From 1996-2003, I was the Acting Division Head, and then the Division Head, for the Division of Biostatistics, Yale University School of Medicine.

13.   I am also Director of the Regulatory Affairs Program and Chairman of the Regulatory Affairs Advisory Board at Yale University. I am Director of the Certificate Program in Regulatory Affairs for Senior Delegations of the Chinese Food and Drug Administration

(CFDA), and an Invited Member of the Dean's Advisory Board at the University of Connecticut for the College of Liberal Arts and Sciences.

14.   I currently teach two courses at the graduate level at Yale: Fundamentals of Clinical Trials and Introduction to Regulatory Affairs.

15.   I am an author or co-author on over 200 peer-reviewed publications, most of which relate to the design, conduct, analysis, and interpretation of clinical and pre-clinical studies, and have given numerous presentations on these topics at national and international meetings, universities, and government locations.

16.   I was nominated and appointed to serve as a Special Government Employee (SGE) to the FDA from 2002 to 2007. In this capacity, I performed a number of activities at the request of the FDA including serving on Advisory Committees and providing expert advice to the FDA on a variety of topics.

17.   Honors and awards I have received for teaching and research include the Connecticut Public Health Association Award for AIDS Research (1987). This award was given for my above-mentioned activities, and led to my selection to serve on The Stewart B. McKinney Foundation Advisory Board, a Foundation in honor of Congressman Stewart B. McKinney of Connecticut. I was also nominated and received the honor of becoming a Fellow of the American Statistical Association (ASA) (2003), a superlative honor that, under the Association by-laws, may be bestowed on no more than one-third of one percent of the total ASA membership (roughly 18,000 members currently). I was nominated and became a Fellow of Silliman College at Yale University. A complete list of my memberships on numerous academic, professional, and scholarly societies is found in my *curriculum vitae*.

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