

Steven E. Linberg, PhD

9601 Medical Center Drive  
Rockville, MD 20850

22401 Rolling Hill Lane  
Laytonsville, MD 20882

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**PROFESSIONAL SUMMARY:**

Dr. Linberg has worked for over 35 years in academic clinical research and commercial drug and biologics development, with particular attention to the strategy of overall development programs, to individual clinical trial design, execution and reporting, and to regulatory interactions with the FDA. Over the course of that time, Dr. Linberg participated in the design, conduct, reporting and/or oversight of well over 100 clinical trials. Dr. Linberg has held senior positions in the drug and biologics industry and at contract research organizations. Dr. Linberg is the principal editor of, and a contributing author in the text *Expediting Drug and Biologics Development*, now in its 3<sup>rd</sup> edition, and developed and taught graduate-level courses in *Drug and Biologics Development*, *Clinical Trial Design*, and *Clinical Trial Operations* for the Johns Hopkins University, and *An Overview of Clinical Research* for the University of Maryland.

**EDUCATION:**

1978	Ph.D., Physiology	Pennsylvania State University
1975	M.S., Physiology	Pennsylvania State University
1973	B.A., Biology	University of Delaware

**PROFESSIONAL EXPERIENCE:**

2013-Present Consultant, S.E. Linberg Consulting, LLC  
Providing consulting to companies on clinical development strategies, clinical trial planning, operations and reporting, and FDA interactions including formal meetings and Advisory Committee preparation.

2011-Present Co-Founder, Member, Airway Therapeutics, LLC.  
2011-2012 President and Chief Executive Officer  
Developed the clinical program necessary for the approval of rhSP-D for the treatment and prevention of bronchopulmonary dysplasia in very premature neonates. Planned and conducted the Pre-IND Meeting with the FDA for rhSP-D. Secured the initial seed round of funding for the company.

2009-2010 Managing Director, Vice President, Treasurer, Chiesi Pharmaceuticals Inc.  
2002-2009 Managing Director  
Oversaw all aspects of the US subsidiary of Chiesi Farmaceutici S.p.A. Directly responsible for the US development plans for Chiesi products identified for development in the US. Participated in the clinical trial planning and review of those same products in worldwide development.

2001-2002 Managing Director, Senior Vice President, Cato Research Limited  
1996-2001 Vice President, Clinical Development  
Responsible for directing and managing all aspects of the Washington area office. Planned, managed and conducted business development activities on behalf of the company. Served as

Coalition Exhibit 1017A  
Coalition v. Biogen  
IPR2015-01136

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2001-2002 Managing Director, Senior Vice President, Cato Research Limited

1996-2001 Vice President, Clinical Development

Responsible for directing and managing all aspects of the Washington area office. Planned, managed and conducted business development activities on behalf of the company. Served as

principal contact for selected sponsors working with the company. Planned and managed FDA interactions on behalf of sponsors. Directed and participated in the design of clinical development programs, and the design, conduct and reporting of individual clinical trials. Directed the conduct and reporting the US clinical program for Duoneb®, and the design, conduct and reporting of the first US clinical trial of Curosurf®.

1995-1996 Vice President, Clinical Development, Collaborative Clinical Research, Inc. Responsible for directing and managing all aspects of the Washington area office. Planned, managed and conducted business development activities on behalf of the company. Served as principal contact for selected sponsors working with the company. Directed and participated in the design of clinical development programs, and the design, conduct and reporting of individual clinical trials. Designed, directed and participated in the development program for Duoneb® (combination albuterol sulfate and ipratropium bromide), and directed and participated in the submission of the New Drug Application. Directed the design of the US clinical program for Duoneb®.

1992-1995 Consultant, Linberg Research, Inc.  
Provided consulting to companies on clinical development strategies, clinical trial planning, operations and reporting.

1992-1992 Director, Clinical Research, Univax Biologics, Inc.  
Oversaw the clinical trial program for vaccine products, and directed and participated in the design, conduct and reporting of individual clinical trials.

1986-1992 Associate Director, Clinical Research, Boehringer Mannheim  
Served as US Project Leader for Demadex® (torsemide), directed and participated in the design of the clinical development program, the design, conduct and reporting of individual clinical trials, and participated in the submission and defense of the successful New Drug Application.

1985-1986 Project Leader and Clinical Research Scientist, Burroughs Wellcome Co.  
Managed and participated in the design of the clinical development program for Zyloprim® (allopurinol) for the prevention of ischemia-reflow injury coincident with renal transplants.

1980-1984 Assistant Professor of Pathology, University of Maryland, School of Medicine  
1978-1984 Clinical Physiology Research Associate, Shock Trauma - Maryland Institute for Emergency Medical Services Systems, University of Maryland  
Responsible for designing and conducting clinical trials aimed at improving the outcomes of patients suffering from the sequelae of hemorrhagic and septic shock.

#### **ADDITIONAL EXPERIENCE:**

2014-Present Member of the Advisory Board  
Center for Rehabilitation Sciences Research  
Uniformed Services University of the Health Sciences  
Center for Rehabilitation Sciences Research, and the  
Henry M. Jackson Foundation for the Advancement of Military Medicine

2010-2012 Chairman of the Advisory Board

2009-2013 Member of the Advisory Board  
School of Arts & Sciences

The University of Delaware

- 2002-2008 Member of the Board of Directors  
Graduate School Alumni Society  
The Pennsylvania State University
- 1998-Present Adjunct Graduate Faculty  
Krieger School of Arts and Sciences  
Johns Hopkins University
- 1992-Present President and Founder  
Research Fund, Inc. (501(c)(3) Charitable Foundation)

**HONORS:**

Distinguished Alumnus 2014, Department of Biological Sciences, University of Delaware  
Outstanding Alumni Award 2013, University of Delaware Alumni Association  
Alumni Achievement Award 2013, College of Arts & Sciences, University of Delaware

**PUBLICATIONS:**

Available upon request.