Committee on Energy and Commerce
U.S. House of Representatives

Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)

1. Your Name: Robert J. Meyer, MD		
2. Are you testifying on behalf of the Federal, or a State or local government entity?	**Yes**	**No** x
3. Are you testifying on behalf of an entity that is not a government entity?	**Yes**	**No** x
4. Other than yourself, please list which entity or entities you are representing: None, my testimony has a disclaimer to that effect.		
5. Please list any Federal grants or contracts (including subgrants or subcontracts) that <u>you or the entity you represent have received</u> on or after October 1, 2011: Not applicable (none)		
6. If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing:		
7. If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?	**Yes**	**No**
8. If the answer to the question in item 3 is "yes," please list any Federal grants or contracts (including subgrants or subcontracts) that were received by the entities listed under the question in item 4 on or after October 1, 2011, that exceed 10 percent of the revenue of the entities in the year received, including the source and amount of each grant or contract to be listed:		
9. Please attach your curriculum vitae to your completed disclosure form.		

Signature [redacted] **Date: <u>July 7, 2014</u>**

CURRICULUM VITAE

I. PERSONAL DATA

A. Name: **Robert James Meyer, M.D.**

B. [redacted] [redacted]

Business Address: **Dept. of Public Health Sciences**
Hospital West Complex, Room 3231
PO Box 800717
Charlottesville, VA 22908-0717

C. [redacted] [redacted]

Business Telephone: **(434) 982-3288**

II. EDUCATION

School	Date	Major/Minor	Degree
Lehigh University Bethlehem, Pa	1980	Natural Sciences	BA
Univ. of Connecticut, School of Medicine Farmington, CT	1984	Internal Medicine	MD
Post-Graduate Medical Education			
Univ. of Connecticut, School of Medicine			
Univ. Program in Internal Medicine (UCONN/Newington VAMC)	7/84-6/87 7/87-6/88	Internship/Residency Chief Medical Resident	
Univ. of Vermont, School of Medicine Burlington, VT	7/88-6/91	Fellowship in Pulmonary & Critical Care Medicine	

III. EMPLOYMENT HISTORY (most recent first)

Title	From - To
University of Virginia, School of Medicine	
Director, Virginia Center for Translational and Regulatory Sciences	03/13 - present
Associate Professor, Public Health Sciences	03/13 - present
Affiliate Faculty, Center for Public Health Genomics	02/14 - present
Fellow, Center for Health Policy	2013 - present
Merck Research Laboratories, North Wales, PA	
Vice President, Global Regulatory Strategy, Policy and Safety	11/09 – 01/13
Vice President, Global Strategic Regulatory Development	02/08 – 10/09
Executive Director, Worldwide Regulatory Affairs	10/07 - 02/08

Food & Drug Administration, CDER, Rockville, MD

Director, Office of Drug Evaluation II	06/02 -09/07
Coordinator of Strategic Planning for Counterterrorism	12/01 - 02/02
Director, Div. of Pulmonary & Allergy Drug Products	08/99 - 06/02
Acting Director, Div. of Pulmonary Drug Products	05/99 – 08/99

National Naval Medical Ctr., Bethesda, MD

Volunteer Staff Physician, Div. of Pulmonary & Critical Care Medicine	1995 – 1998

Food & Drug Administration CDER, Rockville, MD

Medical Team Leader, Div. of Pulmonary Drug Products	02/96 – 08/99
Acting Medical Team Leader, Div. of Pulmonary Drug Products	10/95 – 02/96
Medical Reviewer, Div. of Pulmonary Drug Products	07/94 – 02/96

IV. PREVIOUS ACADEMIC EXPERIENCE

Oregon Health Sciences University, Portland, Oregon

Assistant Professor of Medicine	08/91 – 06/94
Co-Medical Director Of Lung/Heart-Lung Transplantation	08/91 – 06/94

University of Vermont, School of Medicine

Instructor in Clinical Medicine	07/90 – 06/91

V. NOTABLE TRAINING (additional to formal education)

Source	Date	Type
Tufts University, New England Epidemiology Institute, Medford, MA	1993	Summer Series in Epidemiology
Tufts Ctr. For the Study of Drug Development	1995	Postgraduate Course in New Drug Development
Food & Drug Administration Chantilly, VA	1995	F.A.M.E. Course Leadership Skills I
Food & Drug Administration Chantilly, VA	1997	F.A.M.E. Course Leadership Skills II
Council for Excellence in Government	1998-1999	Leadership Fellows Program

VI. SOCIETY MEMBERSHIPS / ACTIVITIES (offices held and when)

- University of Virginia School of Medicine Strategic Planning Steering Committee (2014 -)
- FasterCures Benefit-Risk Advisory Council (2014 -)
- Covance Scientific Advisory Board (2014 -)
- United States Pharmacopeia Convention's Expert Committee on Therapeutic Information and Formulary Support [advises CMS on model medication guidelines] – 2013 to present
- United States Pharmacopeia Convention – Official Delegate on behalf of the University of Virginia's School of Medicine (2013 – present)

- UVa-Coulter Translational Research Partnership, Oversight Committee (2013- present)
- LaunchPad (Biomedical Innovations in Diabetes); Grant Review Committee (2013 – present)
- Member, Food and Drug Law Institute
- Member, Drug Information Association
- Member, Virginia BIO
- Member, FDA Alumni Association
- PhRMA PDUFA V negotiation team member for review and financial teams/subteams 2009 – 2010
- Peer Reviewer "Clinical Pharmacology and Therapeutics, 2009 – present
- Peer Reviewer “Food and Drug Law Institute Journal” 2014 - present
- Merck Research Laboratories – Late Stage Development Committee, Early Stage Development Committee, Gold Track Development Committee, Safety Review Committee – Member during 2007-2013 employment; Development Policy Committee – Chair (2010 – 2013)
- Biomarkers Consortium; Steering Committee on Endocrinology (2006 – 2007)
- Drug Safety Oversight Board (alternate OND representative in 2005, primary member as OND representative 2006 onward) – FDA, 2005 to 2007.
- United Nations Environmental Program (UNEP), Technical Options Committee on Aerosols, 1998 – 2004
- United Nations Environmental Program (UNEP), Technical Options Committee on Medical Aerosols, 2005 – 2008
- National Asthma Education and Prevention Program Coordinating Committee, 2001 - 2007
- National Asthma Education and Prevention Program Expert Panel 3, 2004 - 2007
- Medical Policy Coordinating Committee of the Center for Drug Evaluation and Research, 2000 – 2001; 2002 - 2007
- Center for Drug Evaluation and Research, MPCC CFC Work Group, 1996 - 2007 (Work Group Chair since 1997)
- PDUFA III - Risk Management Work Group on Risk Assessment (Chair), 2002 to 2007
- Center for Drug Evaluation and Research, Health Related Quality of Life / Patient Reported Outcome Work Group, 1996 - 2007
- Peer Reviewer for the "Archives of Internal Medicine," 1993 - 2007
- Peer Reviewer for "Critical Care Medicine," 1999 - 2007
- Peer Reviewer for "Clinical Evidence (British Medical Journal Series)", 2001 - 2007
- Member of US Delegations to UNEP meetings related to the Montreal Program (technical advisor to Dept. of State and EPA) 1997, 1998, 1999
- Volunteer Clinical Faculty, Bethesda National Naval Medical Center, 1995 - 1999
- Division of Pulmonary Drug Products, Work Group on Inhaled Corticosteroid Labeling, 1995
- Division of Pulmonary Drug Products, Work Group on Beta Agonist Labeling, 1995
- Division Coordinator, Pulmonary and Allergy Drug Products Advisory Committee, 1995 - 2000
- FDA PDUFA Reauthorization Team, Review Issues Subgroup, 2001 - 2002
- FDA Crisis Management Staff and Strategic Planning Staff, Dec. 2001 - March, 2002

VII. ACADEMIC AND PROFESSIONAL HONORS

- FDA Outstanding Service Award, 2007
- CDER Leadership Excellence Award, 2007
- US Environmental Protection Agency Team Award, 2007: The FDA MDI Transition Team For Leadership in the Transition to Ozone-Safe Metered Dose Inhalers
- United Nations Environmental Programme “Exemplary Contribution to the protection of the Ozone Layer as a member of the Aerosol Techical Options Committee under the Montreal Protocol
- CDER Group Recognition Award, 2006 – Omnitrope Review and Regulatory Team
- CDER Special Recognition Award, 2006 – Unapproved Drugs Compliance Policy Guide/Carbinoxamine Team
- Commissioner’s Special Citation, 2006 – FDA Hurricaines Katrina/Rita Response Team
- CDER Team Excellence Award, 2002 Pulmonary Inhalation Product Assurance Post 9/11 Team, “For exceptional performance in communication and collaboration in assuring that there were sufficient supplies of pulmonary inhalation drugs after the September 11, 2001 attacks.”
- CDER Team Excellence Award, 2002 Soltara review team
- FDA Group Recognition Award, 2001 to the Sterile Manufacturing of Aqueous Inhalation Drug Products Team for "exceptional dedication and perseverance in the investigation of product failure and preparation of a regulation requiring sterility of drug solutions for inhalation."
- FDA Commendable Service Award, 2000 "For exceptional teamwork that contributed to the protection of the public health through assuring a safe, adequate supply of albuterol in the market place."
- CDER Team Excellence Award, 2000 "For outstanding work in informing the public about the safe and appropriate use of influenza drugs."
- CDER Special Recognition Award, 1999 "For exceptional leadership in the review and approval of the first drug for the treatment of influenza A and B"
- Secretary of the Department of Health and Human Services Award for Distinguished Service, The Secretary's Asthma Initiative Working Group,1999
- United Nations Environmental Program Citation for contribution to the 1998 Scientific, Environmental Effect, and the Technological and Economic Assessments under the Montreal Protocol on Substances that Deplete the Ozone Layer
- CDER Team Excellence Award, 1998 "For extraordinary efforts in identifying, characterizing and communicating to the public the association between anti-asthma drugs and the systemic eosinophilic vasculitis known as Churg-Strauss Syndrome."
- CDER Director's Certificate of Appreciation, 1998 "For outstanding commitment to the review process"
- Commendable Service Award, 1997 from FDA for service on the CFC Work Group of the MPCC
- Chief Medical Residents' Teaching Award for Outstanding Contributions To Housestaff Training, Oregon Health Sciences University, 1993
- Finalist, Cecile Lehman Mayer Research Award, ACCP, Toronto, Canada, 1990
- American College of Chest Physicians / Parke-Davis Research and Training Fellowship, 1990
- John Boylan Clinical Excellence Award, University of CT, 1987
- Chief Medical Resident, University of CT, 1987-88

IX. PUBLICATIONS AND PATENTS

Patents: none

Book Chapters:

Meyer, RJ. Regulatory Perspective on Outcomes Research, Advancing Health Outcome Research Methods and Clinical Applications; edited by William Lenderking and Dennis Revicki (ISOQOL), 2005

Gilbert-McClain, L, **Meyer**, RJ. A Concise Review of Montelukast Therapy, Harrison's Textbook of Internal Medicine On-Line (McGraw-Hill), 2001

Osborne, M, **Meyer**, RJ. The Epidemiology of ARDS. from the text: ARDS: Acute Respiratory Distress Syndrome in Adults. Haslett, C, Evans, T - Editors. Chapman & Hall Medical Publishers, 1996

Publications in Peer-Reviewed Journals:

Meyer RJ – "The Role of Academic Medical Centers in Advancing Regulatory Sciences" Clinical Pharmacology and Therapeutics; 2014 May; **95** (5): 471–473

Beakes-Reid V, **Meyer RJ** - "With respect to new molecular entities with abuse potential, should FDA's recommendations for Controlled Substances Act scheduling be immediately effective upon FDA approval?" FDLI's Food and Drug Law Policy Forum; 2013 Nov 13, Vol 3, Issue 19

Rex JH, Eisenstein BI, Alder J, Goldberger M, **Meyer R**, Dane A, Friedland I, Knirsch C, Sanhai WR, Tomayko J, Lancaster C, Jackson J**.** A comprehensive regulatory framework to address the unmet need for new antibacterial treatments. Lancet Infect Dis.; 2013 Mar;13(3):269-75

Meyer, RJ Regulatory Considerations for Determining Postmarketing Study Commitments J Clin Pharm Ther; 2007 Aug;82(2):228-30

Hendeles, L, Colice, E, and **Meyer, RJ** **"**Withdrawal of albuterol inhalers containing chlorofluorocarbon propellants" N Engl J Med 2007;356:1344-51.

Meyer, RJ U.S. Regulatory Perspective on the Minimal Clinically Important Difference in Chronic Obstructive Pulmonary Disease COPD: Journal of Chronic Obstructive Pulmonary

Purucker,ME, Rosebraugh,CJ, Zhou,F, and **Meyer**, RJ Inhaled Fluticasone Propionate by Diskus in the Treatment of Asthma: A Comparison of the Efficacy of the Same Nominal Dose Given Either Once or Twice a Day Chest 2003 124: 1584-1593
Disease 2005, 2 (1): 47 - 49

Mann, M, Chowdhury, B, Sullivan, E, Nicklas, R; Anthracite, R, **Meyer,** RJ Serious Asthma Exacerbations in Asthmatics Treated With High-Dose Formoterol Chest 2003;124:70-74

Lesko LJ, Salerno RA, Spear BB, Anderson DC, Anderson T, Brazell C, Collins J, Dorner A, Essayan D, Gomez-Mancilla B, Hackett J, Huang SM, Ide S, Killinger J, Leighton J, Mansfield E, **Meyer** R, Ryan SG, Schmith V, Shaw P, Sistare F, Watson M, Worobec A - Pharmacogenetics and pharmacogenomics in drug development and regulatory decision making: report of the first FDA-PWG-PhRMA-DruSafe Workshop. J Clin Pharmacol 2003 Apr;43(4):342-58

Meyer, RJ FDA "Black Box" Labeling. Ann Emerg Med. 2003 Apr;41(4):559-60.

Temple RJ, **Meyer** R Continued need for placebo in many cases, even when there is effective therapy. Arch Intern Med 2003 Feb 10;163(3):371-3

Meyer RJ Bringing new nebulizer technologies to market: regulatory issues. Respir Care. 2002 Nov;47(11):1334-6.

Chowdhury B, **Meyer** RJ - Intramuscular versus subcutaneous injection of epinephrine in the treatment of anaphylaxis . J Allergy Clin Immunol. 2002 Apr;109(4)

Chowdhury B, **Meyer** RJ - Role of mometasone furoate nasal spray as an adjunct treatment of acute sinusitis. J Allergy Clin Immunol. 2001 Jul;108(1):148-9

Meyer RJ - Comment on call for worldwide withdrawal of BAC from nebulizer solutions. J Allergy Clin Immunol. 2001;108(3):469-70

Meyer RJ - A United States regulator's perspective on the ongoing chlorofluorocarbon transition. J Allergy Clin Immunol 1999; 104(6):236-238

Meyer, MM, **Meyer**, RJ - Nitrofurantoin-induced Pulmonary Hemorrhage. Journal of Urology, 1994; 15 2:93 8-40

El-Malik R, Abrams J, **Meyer** RJ - Suicidal Sodium Azide Ingestion. Annals of Emerg. Med., 1987, 16:1378-80

Talks/Presentations at National Meetings

Annual Flu Meeting (PhRMA-FDA-CDC-WHO); Moderator, December 2013

DIA CHINA, 2013 – Shanghai, China “Risk-Benefit Determinations at the US FDA”, May 2013

DIA CHINA, 2012 – Shanghai, China “Handling Scientific Disagreements at FDA”, May 2012

DIA Annual Meeting, 2012 – PDUFA V negotiations, the Industry Perspective

DIA Annual Meeting, 2009 – Washington DC; "Quality by Design, the Industry Clinical Perspective"

NIH Meeting on Usual Care: “FDA Perspectives on Usual Care Control Groups in Regulatory Decision Making”, Nov, 2005

ECRI’s 13th Annual Conference on Using Evidence in Practice and in Public and Private Policymaking - Chronic Pain as a Health System Priority: How Evidence Could Inform Policy and Practice, “Regulation of Drugs for Chronic Pain, A Brief Clinical View,” Plymouth Meeting, PA, Nov, 2005

American Thoracic Society: “Pharmacogenomics in Drug Development: Challenges and Opportunities,” Orlando, FL May, 2004

Keystone Conference: “Clinical Trial Design Considerations in Using Genomic Biomarkers of Safety and/or Efficacy.” Santa Fe, NM February, 2004

American Academy of Allergy, Asthma, and Immunology Annual Meeting, "Update from FDA" FDA symposium on Allergy/Asthma Drugs and Biologics Denver, CO, March 2003

American Thoracic Society: "The US CFC transition; and, Current Issues and Initiatives in the Pulmonary Division at FDA" – Seattle, WA May, 2003

The European Federation of Pharmaceutical Scientists Meeting on "Getting the Dose Right;" Basel, Switzerland, December 2002

The Aerosol Society of Great Britain, Drug Delivery to the Lungs XIII on "Regulatory Perspective on Dose Counters for MDIs" London, UK, December 2002

American Association of Pharmaceutical Scientists Annual Meeting, "PK/PD studies In Regulatory Decisions: Clinical Perspective" Denver, 10/2001

American Academy of Allergy, Asthma, and Immunology Annual Meeting, "Update from FDA - 2001" FDA symposium on Allergy/Asthma Drugs and Biologics. New Orleans, LA, March 2001

American Academy of Allergy, Asthma, and Immunology Annual Meeting, Key Note Speaker at the AAAAI Annual Business Meeting, San Diego, CA, March 2000

American Medical Association Press Briefing: "Breathing Easier: Advancements in Treating and Managing Asthma." New York City, May 1998

American Academy of Allergy, Asthma, and Immunology Annual Meeting, "CFC Phase-out, the US perspective." Orlando FL, March 1999

International Society for Quality of Life Research (ISOQOL) 7th Annual Meeting, "HRQOL measures in clinical trials - What do they add?" and "Satisfaction with Drug Therapy." June 1998: "Clinical Endpoints for Respiratory Drug Development."

Pharmaceutical Educational Research Institute (PERI) Course on Respiratory Drug Development, Annapolis MD, March 1996; May 1997

International Conference on Ozone Protection Technologies, Baltimore MD, 11-97: "CFC Phase-Out and MDIs: The FDA Perspective"

CHEST Annual Conference 1996, San Francisco: "CFC Phase-out and MDIs: The FDA Perspective."

American Thoracic Society Annual Meeting 1996, New Orleans LA: "Regulatory Perspective on Clinical Science."

CHEST Annual Conference 1990, Toronto, Ontario, Canada: "Hyperoxia protects endothelial cells against hydrogen peroxide."