

Committee on Energy and Commerce
U.S. House of Representatives
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

1. Your Name: M. Michelle Berrey, M.D., MPH		
2. Your Title: President and Chief Executive Officer		
3. The Entity(ies) You are Representing: Chimerix, Inc.		
4. Are you testifying on behalf of the Federal, or a State or local government entity?	Yes	No X
5. Please list any Federal grants or contracts, or contracts or payments originating with a foreign government, that you or the entity(ies) you represent have received on or after January 1, 2015. Only grants, contracts, or payments related to the subject matter of the hearing must be listed.		
U.S. Department of Health and Human Services HHSO100201100013C (as modified)		
In February 2011, Chimerix entered into a contract with BARDA for the advanced development of brincidofovir as a medical countermeasure in the event of a smallpox release. Under the contract, Chimerix may receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees over the performance of 1 base segment and 4 option segments. Exercise of each option segment is solely at the discretion of BARDA. Currently, option segments 1 through 3 have been completed. Chimerix is currently performing under the second and third option segments of the contract during which Chimerix may receive up to a total of \$21.6 million and \$11.6 million in expense reimbursement and fees, respectively. The second and third option segments are expected to end on September 30, 2018.		
6. Please attach your curriculum vitae to your completed disclosure form.		

Signature: _____

Date: _____

04 June 2018

M. Michelle Berrey, MD, MPH

2505 Meridian Parkway

Suite 100

Durham, NC 27713



Employment

2014-present President and Chief Executive Officer, **Chimerix**

2012-2014 Chief Medical Officer, **Chimerix**

Leads operations and strategic direction for publicly- traded biopharmaceutical company developing antiviral therapeutics in areas of unmet medical need. Member of the company's Board of Directors.

2007-2012 Chief Medical Officer, **Pharmasset, Inc.**

Led the development strategy of the company's drug candidates for Hepatitis B and Hepatitis C. Oversaw the company's clinical development strategy and medical governance by planning, designing and directing first-in-human, clinical pharmacology, dose-ranging, and pivotal trials toward international registration, including post-marketing trials.

2006-2007 Vice President, HIV & Antiviral Clinical Development, US, **GlaxoSmithKline**

Led development of Phase 2b/3 and 3b/4 development for eight antiviral products in Phase 2b through life cycle management; included clinical strategy and medical governance, matrix input to Regulatory Strategy, Business Development, and Commercial Strategy.

2004-2006 Vice President, Viral Diseases, Clinical Pharmacology & Discovery Medicine
GlaxoSmithKline

Responsibilities included early development and clinical strategy for Phase 1-2a for new targets against viral infections as well as for hepatic fibrosis; oversaw strategy and medical governance of all Clinical Pharmacology/Phase 1 studies (First-In-Human, drug-drug interactions, hepatic and renal impairment, etc) for later phase and marketed antiviral compounds. Authored INDs for novel and precedented antiviral and antifibrotic targets, authored sNDAs for dose and population updates to package insert; attended face-to-face meetings for pre-

IND, end of Phase 2, Type C, and other relevant meetings with Viral and GI Divisions within CDER.

- 2002-2004 Director, Viral Diseases
Discovery Medicine, MV CEDD, **GlaxoSmithKline**
- 2001-2002 Director
HIV Clinical Development, **GlaxoSmithKline**
- 2000-2001 Senior Clinical Research Program Head
HIV & Opportunistic Infections Clinical Development, **GlaxoSmithKline**
- 1999-2000 Senior Clinical Research Physician
HIV & Opportunistic Infections Clinical Development, **GlaxoWellcome**

Postgraduate Training

- 1996-1999 Senior Fellow in Infectious Disease Medicine
Division of Allergy and Infectious Diseases
University of Washington, Seattle WA
- Research in HIV transmission and acute HIV infection; viral dynamics and immunologic responses in natural history of acute HIV with and without therapeutic intervention
- 1993-1996 Intern and Resident in Internal Medicine
University of North Carolina, Chapel Hill NC

Education

- 1993 Doctor of Medicine, Medical College of Georgia, Augusta GA
- 1992 Master of Public Health, Behavioral Sciences and Health Education
Rollins School of Public Health, Emory University, Atlanta GA
- 1988 Bachelor of Arts, English, Emory University, Atlanta GA
- 1986 Associate of Arts, Oxford College of Emory University, Oxford GA

Certification

- 1994 Diplomate, National Board of Medical Examiners, No. 433023
- 1996 Diplomate, American Board of Internal Medicine, No. 167574
- 1998 Diplomate, Infectious Diseases, ABIM, No. 167574

Awards

1991 CIBA-GEIGY Community Service Award
1995 Chairman's Award, University of North Carolina

Licensure

1994 State of North Carolina, Active 1994-1998; Inactive 1998-present
1996 State of Washington, Active 1996-1999; license # MD00034189 (inactive)

Professional Organizations

American College of Physicians, Member
American Association for the Study of Liver Diseases, Member
Washington State Medical Society
Infectious Diseases Society of Washington
North Carolina Medical Society
American Society for Microbiology
American Association of Pharmaceutical Physicians

Mentoring and Volunteer Work

1991-1993 Director, Medical College of Georgia Homeless Health Clinic
1998 UW Residents' Career Retreat – "Finding a Fellowship"
Faculty Advisor, UW School of Medicine
2002-2008 Troop Leader, Girl Scouts Troop 219, NC Area 9
2003-2007 GSK Women in Science Scholars Program

Board Service

2017-present Planned Parenthood South Atlantic
2015-present NC Biotechnology Center
2014-present Board of Directors, Chimerix
2012-present Carolina Headache Foundation

Publications

Ferris DG, **Berrey MM**, Ellis KE. The optimal technique for obtaining a Papanicolaou smear with the Cervex-Brush. *Journal of Family Practice* 1992;34(3):276-80

Berrey MM, Shea T. Oral sex and HIV transmission [letter]. *Journal of AIDS & Human Retroviruses* 1997;14(5):475.

Berrey MM, Corey L. Diagnosing oral manifestations of sexually transmitted diseases. *Consultant* 1997;37(5):1243-4.

Berrey MM, Shea T, Corey L. Cotton wool spots in primary HIV infection [letter]. *Journal of AIDS & Human Retroviruses* 1998;19(2):197-8.

Chun TW, Engel D, **Berrey MM**, Corey L, Fauci T. Early establishment of a pool of latently infected resting CD4+ T cells during primary HIV-1 infection. *Proc Natl Acad Science USA* 1998;95:8869-8873.

Corey L, **Berrey MM**. Antiretroviral Therapy in Primary HIV *Advances in Experimental Medicine & Biology*. 1999;458:223-7.

Chun TW, Engel D, Mizell SB, Hallahan CW, Fischette M, Park S, Davey RT, Dybul M, Kovacs JA, Metcalf JA, Mican JM, **Berrey MM**, Corey L, Lane HC, Fauci AS. Effect of interleukin-2 administration on the pool of latently infected, resting CD4+ T cells in HIV-1 infected patients receiving highly active antiretroviral therapy. *Nature Medicine* 1999;5(6):651-55.

Berrey MM. Acute HIV-1 infection. *Current Treatment Options in Infectious Disease* 1999;1(1):31-38.

Malhotra U, **Berrey MM**, Huang Y, Markee J, Musey L, Schacker T, Corey L, McElrath JE. Effect of combination antiretroviral therapy on T cell immunity in acute human immunodeficiency virus type 1 infection. *J Infect Dis* 2000;181(1):121-31.

Smith D, **Berrey MM**, Robertson M, Perrin L, Clumak N, Lazzarin A, Markowitz M, Corey L, Cooper D. Virological and immunological effects of combination antiretroviral therapy during primary HIV-1 infection. *J Infect Dis* 2000; 182:950-954.

Serody JS, **Berrey MM**, Albritton K, O'Brien SM, Capel EP, Bigelow SH, Weber DJ, Gabriel Wiley JM, Schell MJ, Gilligan PH, Shea TC. Utility of obtaining blood cultures in febrile neutropenic patients undergoing bone marrow transplantation. *Bone Marrow Transplantation* 2000; 26(5):533-8.

Berrey MM, Schacker T, Collier AC, Shea T, Brodie SJ, Mayer D, Coombs R, Chun T-W, Fauci AS, Corey L. Clinical impact of early treatment of primary HIV infection with zidovudine, lamivudine, and indinavir. *J Infect Dis* 2001; 183:1466-75.

Berrey MM, van Burik J. Images in clinical medicine: Symmetric peripheral gangrene. *NEJM* 2001; 21(344):1593.

Boeckh M, **Berrey MM**, Bowden RA, Crawford SW, Balsley J, Corey L. Phase I Evaluation of the RSV-Specific Humanized Monoclonal Antibody Palivizumab (MEDI-493) In Hematopoietic Stem Cell Transplant Recipients. *J Infect Dis* 2001;184:350-4.

Malhotra U, Holte S, **Berrey MM**, Delpit E, Koelle DM, Corey L, McElrath JE. Role for HLA Class II molecules in HIV-1 suppression and cellular immunity following antiretroviral treatment. *J Clin Invest* 2001;107(4):505-17.

Truong HH, **Berrey MM**, Shea T, Diem K, Corey L. Concordance between HIV source partner identification and molecular confirmation in acute retroviral syndrome. *JAIDS* 2002;29(3):232-43.

Adkison KK, Shachoy-Clark A, Fang L, Lou Y, O'Mara K, **Berrey MM**, Piscitelli SC. Pharmacokinetics and Short-Term Safety of 873140, a Novel CCR5 Antagonist, in Healthy Adult Subjects. *AAC* 2005;49(7):2802-06.

Johnson BM, Song IH, Adkison KK, Borland J, Fang L, Lou Y, **Berrey MM**, Nafziger AN, Piscitelli SC, Bertino JS. Evaluation of the drug interaction potential of Atravirine, a novel HIV entry inhibitor, using a modified Cooperstown 5+1 cocktail. *Jrnl Clin Pharm* 2006;46:577-587.

Adkison KK, Shachoy-Clark A, Fang L, Lou Y, Otto VR, **Berrey MM**, Piscitelli SC. The effects of ritonavir and lopinavir/ritonavir on the pharmacokinetics of a novel CCR5 antagonist, atavirine, in healthy subjects. *Br J Clin Pharmacol* 2006;62:336-344.

White IR, Patel K, Symonds WT, Dev A, Griffin G, Tsokana N, Skehel M, Liu C, Zekry A, Cutler P, Gattu M, Rockey D, **Berrey MM**, McHutchison JG. Serum proteomic analysis focused on fibrosis in patients with hepatitis C virus infection. *Journal of Translational Medicine* 2007;5:33.

Gane EJ, Roberts SK, Stedman CAM, Angus PW, Ritchie B, Elston R, Ipe D, Morcos PN, Baher L, Najera I, Chu T, Lopatin U, **Berrey MM**, Bradford W, Laughlin M, Shulman NS, Smith PF. Oral combination therapy with a nucleoside polymerase inhibitor (RG7128) and danoprevir for chronic hepatitis C genotype 1 infection (INFORM-1): A randomised, double-blind, placebo-controlled, dose-escalation trial. *Lancet* 2010

Pogam SL, Sessaadri A, Ewing A, Kang H, Kosaka A, Yan J-M, **Berrey MM**, Symonds WT, De La Rosa A, Cammack N, Najera I. RG7128 Alone or in Combination with Pegylated Interferon- α 2a and Ribavirin Prevents Hepatitis C Virus (HCV) Replication and Selection of Resistant Variants in HCV-Infected Patients *Journal of Infectious Diseases* 2010

E. Lawitz · M. Rodriguez-Torres · M.T. Cornpropst · J.M. Denning · D. Clemons · L. McNair · L. Fang · **MM Berrey** · W.T. Symonds The effect of hepatic impairment on the pharmacokinetics and antiviral activity of PSI-7977 in hepatitis C infected subjects treated for seven days. *Journal of Hepatology* 2012

M.T. Cornpropst · J.M. Denning · D. Clemons · T.C. Marbury · H. Alcorn · W.B. Smith · M. Sale · L. Fang · **MM Berrey** · W.T. Symonds The effect of renal impairment and end stage renal disease on the single-dose pharmacokinetics of PSI-7977. *Journal of Hepatology* 2012

Maribel Rodriguez-Torres · Eric Lawitz · Kris V Kowdley · David R Nelson · Edwin Dejesus · John G McHutchison · Melanie T Cornpropst · Michael Mader · Efsevia Albanis · Deyuan Jiang · Christy M Hebner · William T Symonds · **MM Berrey** · Jay Lalezari Sofosbuvir (GS-7977) plus peginterferon/ribavirin in treatment-naïve patients with HCV genotype 1: A randomized, 28-day, dose-ranging trial. *Journal of Hepatology* 2012

Jill Denning · Melanie Cornpropst · Stephen D Flach · **MM Berrey** · William T Symonds Pharmacokinetics, Safety, and Tolerability of GS-9851, a Nucleotide Analog Polymerase Inhibitor for Hepatitis C Virus, following Single Ascending Doses in Healthy Subjects. *Antimicrobial Agents and Chemotherapy* 2012

Eric Lawitz · Maribel Rodriguez-Torres · Jill M Denning · Efsevia Albanis · Melanie Cornpropst · **Michelle Berrey** · William T Symonds Pharmacokinetics, Pharmacodynamics, and Tolerability of GS-9851, a Nucleotide Analog Polymerase Inhibitor, following Multiple Ascending Doses in Patients with Chronic Hepatitis C Infection Dec 2012 · *Antimicrobial Agents and Chemotherapy*

Kris V Kowdley · Eric Lawitz · Israel Crespo · Tarek Hassanein · Mitchell N Davis · Michael Demicco · David E Bernstein · Nezam Afdhal · John M Vierling · Stuart C Gordon · Jane K Anderson · Robert H Hyland · Hadas Dvory-Sobol · Di An · Robert G Hindes · Efsevia Albanis · William T Symonds · **M Michelle Berrey** · David R Nelson · Ira M Jacobson. Sofosbuvir with pegylated interferon alfa-2a and ribavirin for treatment-naïve patients with hepatitis C genotype-1 infection (ATOMIC): An open-label, randomised, multicentre phase 2 trial. Mar 2013 · *The Lancet*

Lawitz E, Lalezari JP, Hassanein T, Kowdley KV, Poordad FF, Sheikh AM, Afdhal NH, Bernstein DE, Dejesus E, Freilich B, Bzowej NH, Hyland RH, Symonds WT, **Berrey MM**, Muir A. Sofosbuvir in combination with peginterferon alfa-2a and ribavirin for noncirrhotic, treatment-naïve patients with genotypes 1, 2, and 3 hepatitis C infection: a randomised, double-blind, phase 2 trial. *Lancet Infect Dis.* 13:401-408.

Gane EJ, Stedman CA, Hyland, Ding X, Svarovskaia E, Symonds WT, Hindes RG, **Berrey MM**. Nucleotide Polymerase Inhibitor Sofosbuvir plus Ribavirin for Hepatitis C. *New Engl J Med* 2013; 368:34-44

EJ Lawitz · M Rodriguez-Torres · J Denning · A Mathias · H Mo · B Gao · M T Cornpropst · **MM Berrey** · WT Symonds. All-oral therapy with nucleotide inhibitors sofosbuvir and GS-0938 for 14 days in treatment-naïve genotype 1 hepatitis C (NUCLEAR) *Journal of Viral Hepatitis* 2013
