# **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:			
	Rick Bright			
2.	Your Title:			
	Deputy Assistant Secretary for Preparedness and Response			
	Director of the Biomedical Advanced Research and Development Authority			
1000000	3. The Entity(ies) You are Representing:			
HHSASPR/BARDA				
4.	Are you testifying on behalf of the Federal, or a State or local	Yes	No	
	government entity?	X		
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5.	, , , , , , , , , , , , , , , , , , , ,			
	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.			
			2 2	
NONE				
6. Please attach your curriculum vitae to your completed disclosure form.				
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218	nature Date: 03/0	26/12		

Name: Address:



**Education:** 

**ADVAC** Advanced Course in Vaccinology, Annecy, France **2010** (Fondation Merieux and University of Geneva)

**Emory University** 

Atlanta, Georgia 30322 **Degree: Ph.D., 2002** 

Immunology and Molecular / Viral Pathogenesis (Virology)
Division of Biological and Biomedical Sciences, School of Medicine

PhD Dissertation: Studies on Pathogenicity and Control of Influenza A (H5N1) Viruses

Auburn University - Montgomery Montgomery, Alabama 36117-3596

Degree: Double Major B.S., magna cum laude, 1997

Majors: Biology GPA: 4.00/4.00; Physical Science (Chemistry) GPA: 3.96/4.00

**Interests:** 

Vaccines: Discovery, development, international capacity building Policy: Global health, vaccine introduction, access, use and distribution Therapeutic intervention: Discovery, development, resistance surveillance Emergency preparedness and response. Point-of-care diagnostics.

### **Professional Experience:**

2010 – Present **US Dept. Health and Human Services** 

**Assistant Secretary for Preparedness and Response** 

Biomedical Advanced Research and Development Authority (BARDA)

Director, BARDA (11/2016 – Present)

Deputy Assistant Secretary for Preparedness & Response (11/2016 – Present) Incident Commander, ASPR/BARDA Zika Response (02/2016 – 11/2016) Director, Influenza and Emerging Diseases Division (12/2014 – 11/2016) Acting Director, Influenza and Emerging Diseases Division (11/2013 – 12/2014) Deputy Director, Influenza and Emerging Diseases Division (06/2011 – 12/2015) Chief (Acting), Influenza Antiviral Drug Advanced Development (02/11 – 12/11) Program Lead, BARDA International Programs (10/2010 – Present)

- Responsible for leading the organization to support advanced development and procurement of medical countermeasures against an array of threats to national security and the public's health, including chemical, biological, radiological, nuclear threats and pandemic influenza, and emerging infectious diseases
- Recommends strategic and practical plans to the HHS Assistant Secretary for Preparedness and Response to resolve issues that require complex negotiations with interagency and other USG and non-USG stakeholders

- Coordinates domestic and international systems that combine product development with policies for introduction, uptake and access to newly developed products
- Champions and leverages innovations in vaccine science and serves as a global strategic partner to the vaccine franchise to raise awareness and collaboration for development and implementation of this innovation
- Leads and manages technical and administrative teams responsible for management oversight and execution of government contracts and acquisitions according to Federal Acquisition Regulations, exceeding \$7 billion USD in value
- Manages an average annual budget of approximately \$1.2 billion USD
- Developed detailed strategic, financial and staffing plans to support countermeasurespecific procurement through all stages of acquisition and advanced development
- Led the BARDA international program working in 12 developing countries in areas of technical transfer for manufacturing capacity building, advanced biomanufacturing training, adjuvant development, clinical capacity building, vaccine licensure and introduction in emerging markets. Provided oversight, vision, direction and leadership to projects and team members to achieve successful timeline and budgetary milestones within each project. Pandemic vaccine manufacturing capacity in developing countries has expanded to over 500 million doses from this program.
- Coordinated international efforts within ASPR, BARDA, OGA, DoD, NIH, CDC, NSC, DoS, USAID, UNICEF, WHO, PAHO, PATH, IDRI, DARPA, DTRA, BMGF, Wellcome Trust, as well as USG and other government agencies and officials to ensure smooth communication and collaboration to achieve strong international partnerships towards goals of global vaccine development and health diplomacy
- Represented HHS, ASPR, BARDA and the Influenza and Emerging Diseases
  Division in departmental and interagency technical, strategic and policy teams,
  including the BARDA Leadership Team, Enterprise Executive Committee,
  Countermeasure Steering Committee, Flu Risk Management Meeting, and Disaster
  Leadership Group
- Co-Chairs the PHEMCE-wide Influenza Risk Management IPT
- Attends domestic and international conferences and meetings to represent BARDA, ASPR, HHS and USG, providing advice on initiatives, policies, rules, and collaborative opportunities
- Led and coordinated medical countermeasure development activities through BARDA for the 2014 MERS outbreak and the 2016 Zika Response (Incident Commander), including USG-wide and international coordination of activities to develop vaccines, diagnostics and therapeutics as well as engagement with international collaborators and stakeholders in foreign governments, industry, academic and non-governmental organizations
- Participates on the WHO R&D Blueprint Advisory Group to develop and implement strategies to coordinate an international response plan to emerging infectious diseases
- Serves as USG representative in international delegations to meet with foreign government officials to discuss and develop strategies to coordinate policy and MCM development to address pandemic influenza and emerging infectious diseases
- Represents ASPR/BARDA in briefings to US congressional members and staff

### 02/2008 - 10/2010 **PATH**

Director, Vaccine Manufacturing Capacity Building in Viet Nam Scientific Director, Influenza Vaccine Project Global Vaccine Development Program

- Developed, championed and managed scientific strategies of the global influenza vaccine program, funded by the Bill and Melinda Gates Foundation
- Managed \$40 M program portfolio to identify and accelerate innovative influenza vaccine technologies
- Established and directed program to enhance technical and clinical capacity to produce, evaluate and introduce pandemic influenza vaccines in Viet Nam: 3 teams in U.S. & Vietnam. Received a \$7.9 M grant from the USG to support the program
- Established and managed technical scientific teams in the United States and Vietnam
- To respond to the 2009 H1N1 influenza pandemic, was seconded to the World Health Organization to serve on the H1N1 Vaccine Task Force. Organized and chaired two urgent consultations with industry, NGOs, government agencies and international policy stakeholders on the safety and use of adjuvanted vaccines and live attenuated vaccines during the pandemic.
- Served on the DoD DARPA Scientific Advisory Board for Accelerated
   Manufacturing Program and for the Blue Angel Program for development of vaccines
- Liaised with international stakeholders, including US CDC, WHO, EU, US HHS, DARPA, BARDA, US DoD, Regulatory Authorities, & Ministries of Health
- Conducted analyses of innovative vaccine technologies that could be available, affordable and accessible to people in developing countries
- Collaborated with domestic and international vaccine development partners from industry and academia to advance vaccines from early development through clinical evaluation. Provided both technical and management support to these projects.
- Raised over \$16M in the form of grants and contracts to support and diversify vaccine development programs

### **2006 – 2008 Novavax, Inc., Rockville, MD**

A clinical stage vaccine company
Vice President, Global Influenza Programs
Vice President, Vaccine Research
Vice President, Vaccine Development

- Executive Team Leader for two vaccine candidates, directing development progression from early discovery through late stage clinical development
- Chaired the Product Development Strategy Team for influenza vaccines
- Integrated all functional areas of the vaccine development process, including financial, discovery, manufacturing, quality, analytical, pre-clinical, clinical, regulatory, business development, and marketing to develop the vision and strategy of the influenza vaccine program
- Recruited and supervised a successful scientific and senior management team
- Served as an ambassador for the company to introduce and champion a unique technology and pipeline to global audiences including scientific, political, financial and international government / non-government organizations

- Established and maintained partnerships in Hong Kong, China, India and Taiwan
- Participated on WHO committees: vaccine development and pandemic preparedness

### 2003 – 2006 Centers for Disease Control and Prevention, Influenza Division, Strain Surveillance Branch, Atlanta, GA Immunologist/Virologist

- Led project team for the influenza antiviral drug program; responsible for development of research and drug resistance surveillance team
- Represented the CDC Influenza Division on matters of avian influenza, vaccine development and antiviral drug resistance at global congresses
- Accountable for the surveillance of influenza isolates for resistance to influenza antiviral drugs, including H5N1 viruses in BSL3+ high containment laboratories
- Recipient of 3 year grant from Antimicrobial Resistance Working Group
- Supervised a research team of MS- and PhD-level scientists. Trained over 15 international visiting scientists. Mentored 4 graduate and undergraduate students
- Recipient of Charles C. Shepard award for scientific excellence

# 2002 – 2003 Altea Therapeutics, Atlanta, GA Clinical stage biopharmaceutical company Senior Research Scientist & Project Leader Vaccine and Immunology Programs

- Created a new vaccine research program to show feasibility of transdermal delivery of vaccines, using a novel thermal-based microneedle delivery system
- Co-chaired the grant development committee to generate \$1 million in annual funding
- Authored and negotiated a cooperative research agreement with US CDC; enhanced research capabilities, scientific integrity, and access to vaccines for the company
- Managed a team of 18 scientists across 4 research sites in the U.S. and Canada

# 1998 – 2002 Centers for Disease Control and Prevention, Influenza Branch, Immunology and Viral Pathogenesis Section, Atlanta, GA

- Developed and characterized novel influenza vaccine candidates for seasonal and pandemic influenza in a BSL3<sup>+</sup> high containment facility
- Analyzed in vivo and in vitro mechanisms and molecular correlates of pathogenicity of influenza A(H5N1) viruses

## 1997 – 2000 Emory University, Vaccine Research Center, Yerkes Regional Primate Research Ctr Immunology/Molecular Biology Department, Atlanta, GA

- Developed and characterized DNA-based vaccines for influenza
- Developed and characterized DNA expression vectors for human vaccine use. Co-inventor on patents for expression vectors for HIV, influenza, and measles vaccines

### 1994 – 1995 Alabama Reference Lab, Montgomery, AL Research Assistant, Flow Cytometry Department

1990 – 1992 **Osborn Laboratories, Inc., Olathe, KS** 

Product Manager, R&D Department

**Committees:** WHO R&D Blueprint for Action to Prevent Epidemics – Advisory Group

CEPI – Coalition for Epidemic Preparedness Innovations – Scientific Advisory Cmte International Society of Influenza and other Respiratory Viruses – Prior Board Member

Global Health Security Initiative – Pandemic Influenza Working Group

WHO International LAIV Joint Committee Working Group ACIP Novel Influenza Vaccines Working Group (ad hoc)

WHO Global Action Plan for Influenza Vaccines

WHO H1N1 (2009) Vaccine Task Force

**Awards:** Hutchinson High School Wall of Honor Recipient, 2017

Top 40 Graduates in 40 years of history – Auburn University-Montgomery, 2010

Centers for Disease Control Charles C. Shepard Science Award for Scientific Excellence,

2007 (Highest scientific award given at the CDC)

Nakano Citation for the best scientific publication at CDC, 2007 Nakano Citation for the best scientific publication at CDC, 2006

National Center for Infectious Diseases Honor Award for Public Health Epidemiology

and Laboratory Research, 2005

Who's Who Among Students in American Universities, 1997 Who's Who Among Students in American Universities, 1996

The Honor Society of Phi Kappa Phi, Inducted 1997 Omicron Delta Kappa - Leader of the Year, 1997

Alabama Academy of Science Top Research Award, 1997

Omicron Delta Kappa, National Leadership Honor Society, Inducted 1995

Alpha Epsilon Delta Honor Society, Inducted 1994

### **Publications:**

- 1. Arabi, Y, Fowler, R, **Bright RA**, Kerkhove M (2016). Knowledge gaps in therapeutic and non-therapeutic research on the Middle East respiratory syndrome. The Lancet Respiratory Medicine Jan;4(2):93-94.
- 2. Gessner BD, Brooks WA, Neuzil KM, Vernet G, **Bright RA**, Tam JS, Bresee J, Monto AS (2013). Vaccines as a tool to estimate the burden of severe influenza in children of low-resourced areas. Vaccine. Jul 11;31(32):3222-8.
- 3. Wathen MW, Barro M, **Bright RA** (2013). Antivirals in seasonal and pandemic influenza future perspectives. Influenza Other Respir Viruses. Jan;7 Suppl 1:76-80.
- 4. Neuzil KM, **Bright RA**, Nyari LJ, Boslego JW (2012). PATH Influenza Vaccine Project: Accelerating the development of new influenza vaccines for low-resource countries. Expert Review for Vaccines. Aug;11(8):939-47.

- 5. Perdue M, **Bright RA** (2011). United States of America Department of Health and Human Services support for advancing influenza vaccine manufacturing in the developing world. Vaccine 29(Suppl 1):A48-A50.
- 6. Mochalova L, **Bright R**, Xu X, Korchagina E, Chinarev A, Bovin N, Klimov A (2010). Shift in oligosaccharide specificities of hemagglutinin and neuraminidase of influenza B viruses resistant to neuraminidase inhibitors. Glycoconj J. Apr;27(3):321-7.
- 7. **Bright RA**, Neuzil KM, Pervikov Y, Palkonyay L (2009). WHO meeting on the role of neuraminidase in inducing protective immunity against influenza infection. Vaccine 27(45):6366-9.
- 8. Neuzil KM, **Bright RA** (2009). Influenza vaccine manufacture: Keeping up with change. The Journal of Infectious Diseases 200:835–837.
- 9. TM Ross, Mahmood K, Crevar CJ, Schneider-Ohrum K, Heaton PM, **Bright RA** (2009). A trivalent virus-like particle vaccine elicits protective immune responses against seasonal influenza strains in mice and ferrets. PLoS One 4(6):e6032.
- 10. VM Deyde, Nguyen T, **Bright RA**, Balish A, Shu B, Lindstrom S, Klimov AI, Gubareva LV (2009). Detection of molecular markers of antiviral resistance in influenza A (H5N1) viruses using a pyrosequencing method. Antimicrob Agents Chemother 53(3):1039-47.
- 11. TR Maines, Szretter KJ, Perrone L, Belser JA, **Bright RA**, Zeng H, Tumpey TM, Katz JM (2008). Pathogenesis of emerging avian influenza viruses in mammals and the host innate immune response. Immunol Rev. 225:68-84.
- 12. K Mahmood, **Bright RA**, Mytle N, Carter DM, Crevar CJ, Achenbach JE, Heaton PM, Tumpey TM, Ross TM (2008). H5N1 VLP vaccine induced protection in ferrets against lethal challenge with highly pathogenic H5N1 influenza viruses. Vaccine 26(42):5393-9.
- 13. TG Sheu, Deyde VM, Okomo-Adhiambo M, Garten RJ, Xu X, **Bright RA**, Butler EN, Wallis TR, Klimov AI, Gubareva LV (2008). Surveillance for neuraminidase inhibitor resistance among human influenza A and B viruses circulating worldwide from 2004 to 2008. Antimicrob Agents Chemother 52(9):3284-92.
- 14. R Maines, Szretter KJ, Perrone L, Belser JA, **Bright RA**, Zeng H, Tumpey TM, Katz JM (2008). Pathogenesis of emerging avian influenza viruses in mammals and the host innate immune response. Immunol Rev. 225:68-84.
- 15. M Rahman, **RA Bright**, BA Kieke, JG Donahue, RT Greenlee, M Vandermause, A Balish, A Foust, NJ Cox, AI Klimov, DK Shay, EA Belongia (2008). Adamantane-resistant influenza infection during the 2004–05 season. Emerg Infect Dis 14(1):173-76.
- 16. **RA Bright**, DM Carter, CJ Crevar, FR Toapanta, JD Steckbeck, KS Cole, NM Kumar, P Pushko, G Smith, TM Tumpey, TM Ross (2008). Cross-clade protective immune responses to influenza viruses with H5N1 HA and NA elicited by an influenza virus-like particle. PLoS ONE 3(1): e1501. doi:10.1371/journal.pone.0001501.

- 17. **RA Bright**, DM Carter, S Daniluk, FR Toapanta, A Ahmad, V Gavrilov, M Massare, P Pushko, N Mytle, T Rowe, G Smith, TM Ross (2007) Influenza virus-like particles elicit broader immune responses than whole virion inactivated influenza virus or recombinant hemagglutinin. Vaccine 25(19):3871-8.
- 18. P Pushko, TM Tumpey, N Van Hoeven, JA Belser, R Robinson, M Nathan, G Smith, DC Wright, **RA Bright** (2007). Evaluation of influenza virus-like particles and Novasome adjuvant as candidate vaccine for avian influenza. Vaccine 25(21):4283-90.
- 19. H Chen, **RA Bright**, K Subbarao, C Smith, NJ Cox, JM Katz, Y Matsuoka (2007). Polygenic virulence factors involved in pathogenesis of 1997 Hong Kong H5N1 influenza viruses in mice. Virus Res. 128(1-2):159-63.
- 20. VM Deyde, X Xu, **RA Bright,** M Shaw, CB Smith, Y Zhang, Y Shu, LV Gubareva, NJ Cox, AI Klimov (2007). Surveillance of resistance to adamantanes among influenza A(H3N2) and A(H1N1) viruses isolated worldwide. J Infectious Diseases 196(2):249-57.
- 21. A Klimov, A Balish, A Foust, B Kieke, E Belongia, M Vandermause, **RA Bright** (2006). Clinical characteristics of Adamantane resistant influenza in Wisconsin during the 2004-05 season. Conference paper, Infectious Diseases Society of America 2006 Annual Meeting.
- 22. **RA Bright,** D Shay, J Bresee, A Klimov, N Cox, J Ortiz (2006). High levels of adamantane resistance among influenza A(H3N2) viruses and interim guidelines for use of antiviral agents United States, 2005-06 influenza season. Morbidity and Mortality Weekly Report, Jan. 2006.
- 23. **RA Bright**, Shay DK, Shu B, Cox NJ, Klimov AI (2006). Adamantane resistance among influenza A viruses isolated early during the 2005-2006 influenza season in the United States. JAMA 295(8):891-4.
- 24. **RA Bright,** M Medina, X Xu, G Perez-Oronoz, T Wallis, XM Davis, L Povinelli, NJ Cox, and AI Klimov (2005). Increasing incidence of adamantane resistance among influenza A(H3N2) viruses, isolated globally from 1994 to 2005: A cause for concern. The Lancet 366:1175-81.
- 25. M Hoelscher, S Garg, D Bangari, J Belser, X Lu, I Stephenson, **RA Bright,** J Katz, S Mittal, and S Sambhara (2005). An adenoviral vector-based pandemic influenza vaccine confers protection against antigenically distinct human H5N1 strains. The Lancet 367:475-81.
- 26. N Bhat, JG Wright, and Members of the Influenza Special Investigations Team (**RA Bright**) (2005). Deaths in children associated with influenza, United States, 2003-04. New England Journal of Medicine 353(24):2559-2567.
- 27. PC Crawford, EJ Dubovi, WL Castleman, I Stephenson, EPJ Gibbs, L Chen, C Smith, RC Hill, P Ferro, RA Bright, M Medina, CM Johnson, CW Olsen, NJ Cox, AI Klimov, JM Katz, and RO Donis (2005). Interspecies transmission of equine influenza virus to dogs. Science 310(5747):482-5.
- 28. RO Donis and Members of the World Health Organization's Global Influenza Program and Collaborating Laboratories (**RA Bright**) (2005). Avian influenza virus H5N1 evolution. Emerging Infectious Diseases 11(10): 1515-21.

- 29. **RA Bright,** TM Ross, K Subbarao, JM Katz, and HL Robinson (2003). Impact of glycosylation on the immunogenicity of a DNA-based influenza H5 hemagglutinin vaccine. Virology 308(2): 270-278.
- 30. **RA Bright,** DS Cho, T Rowe, and JM Katz (2003). Mechanisms of pathogenicity of influenza A (H5N1) viruses in mice. Avian Diseases 47:1131-4.
- 31. JA Mitchell, TD Green, **RA Bright**, and TM Ross (2003). Induction of heterosubtypic immunity to influenza A virus using a DNA vaccine expressing hemagglutinin-C3d fusion proteins. Vaccine 21: 902-914.
- 32. T Rowe, DS Cho, **RA Bright**, LA Zitzow, and JM Katz (2003). Neurological manifestations of avian influenza viruses in mammals. Avian Diseases 47:1122-6.
- 33. TM Ross, Y Xu, **RA Bright,** and HL Robinson (2000). C3d enhancement of antibodies to hemagglutinin accelerates protection against influenza virus challenge. Nature Immunology 1(2): 127-31.

### **Book Chapters:**

- 1. Sang-Moo, Pushko P, **Bright RA**, Smith G, Compans RW (2009). Virus-like Particles for Pandemic Influenza Vaccines. Current Topics in Microbiology and Immunology, (Edtrs Compans RW, and Orenstein W)
- 2. Pushko PM, **Bright RA**, Tumpey TM, Smith G (2008). Engineering Better Influenza Vaccines: Traditional and New Approaches. Medicinal Protein Engineering, (Edtr Khudyakov YE)

### **Patents:**

- 1. Harriet L. Robinson, et al. DNA Expression Vectors and Methods of Use (US 7795017; 08506967)
- 2. Gale Smith, et al. Novel M2 Vaccines for Influenza (EPO 1998814-A2, US Application pending)
- 3. Gale Smith, et al. Functional Influenza Virus Like Particles (VLPs) (US 08080255)
- 4. Various applications on the development and use of virus-like particles as vaccines

**Presentations:** Over 250 presentations and invited lectures at national and international conferences, workshops, symposiums and panels on emerging infectious diseases, human and avian influenza virus evolution, pathogenesis, diagnostics, vaccine development, new vaccine technologies, antiviral drug susceptibility, vaccine manufacturing and global supply/distribution of vaccines, policy, preparedness and response for pandemic influenza and other emerging diseases. Includes the organization and chair responsibilities for several WHO consultations on vaccine development, vaccine safety, adjuvant use and safety and vaccine development for developing countries.

Editorial Boards: Expert Review of Vaccines, ISIRV Journal

**Ad hoc reviewer:** The Lancet, Vaccine, J Virology, Virology, Emerging Infectious Diseases, Human Immunology, Medical Virology, J Infectious Diseases, ISIRV, Expert Review Vaccines, PNAS.