

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: <i>Kay Holcombe</i>		
2. Your Title: <i>Senior Vice President, Science Policy</i>		
3. The Entity(ies) You are Representing: <i>BIO (Biotechnology Innovation Organization)</i>		
4. Are you testifying on behalf of the Federal, or a State or local government entity?	Yes	No <i>X</i>
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.		
<i>None</i>		
6. Please attach your curriculum vitae to your completed disclosure form.		

Signature [REDACTED] Date: 3/1/17

Biographical Sketch – Kay Holcombe

Kay Holcombe is currently Senior Vice President for Science Policy at BIO, the Biotechnology Innovation Organization. She works with the BIO CEO and Board, and BIO's health policy, reimbursement, government affairs, and alliance development staff to formulate, develop, and advance BIO principles, programs, and strategies relating to science policy matters that are of interest to and affect BIO member companies. Most recently, Kay served as the lead negotiator for BIO in the PDUFA and BsUFA negotiations with FDA.

Prior to this, as Senior Policy Advisor and Vice President for Government Relations at Sanofi-Genzyme, Kay worked with government relations and regulatory affairs staff, and with principals of Genzyme and Sanofi, to develop and implement corporate policies and appropriate responses to government initiatives in the regulatory and health policy arenas. She worked with members of Congress and their staffs as well as with officials in the Food and Drug Administration and other agencies whose actions had impact on the corporation and the biopharmaceutical industry.

Before joining Genzyme in 2006, Kay spent 8 years as Executive Vice President of Policy Directions Inc., a government relations firm specializing in strategic planning and legislative and regulatory advocacy regarding health care and related issues. She represented a variety of clients in the pharmaceutical and biotechnology, food, and consumer products industries, providing strategic advice and assistance and advocacy at federal regulatory and funding agencies and in the U.S. Congress.

Earlier, she served as professional health legislative staff and senior health policy advisor for the House of Representatives Committee on Energy and Commerce; health legislative staff for the Senate Committee on Labor and Human Resources; Deputy Associate Commissioner for Legislative Affairs, U.S. Food and Drug Administration; Executive Vice President of the Foundation for Biomedical Research (advocating on behalf of the appropriate and necessary use of animals in research); Associate Director for Public Health Legislation, Office of the Assistant Secretary for Legislation, U.S. Department of Health and Human Services; Deputy Associate Administrator for Planning, Evaluation, and Legislation, Health Resources and Services Administration, U.S. Public Health Service; Special Assistant to the Director, Division of Legislative Affairs, National Institutes of Health; Executive Secretary, National Heart, Lung, and Blood Institute National Advisory Council; and researcher, National Heart, Lung, and Blood Institute, National Institutes of Health.

Kay was selected as a founding member of the board of the congressionally mandated Reagan-Udall Foundation and still serves in that capacity, and is a member of the board of the National Blood Clot Alliance.

She received her B.S. in chemistry education from the University of Illinois and her M.S. in chemistry from the University of Virginia. She graduated with honors and was elected to Phi Beta Kappa, Phi Kappa Phi, and Iota Sigma Pi.