

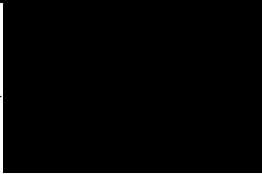
Committee on Energy and Commerce

U.S. House of Representatives

Witness Disclosure Requirement - "Truth in Testimony"

Required by House Rule XI, Clause 2(g)(5)

1. Your Name: Michael Werner		
2. Your Title: Partner, Holland & Knight; Policy Advisor to PASS Coalition		
3. The Entity(ies) You are Representing: Public Access to SunScreens (PASS) Coalition		
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. None		
6. Please attach your curriculum vitae to your completed disclosure form.		

Signature:  Date: 09/11/2017

Michael J. Werner

Speaker Biography



Michael Werner is a partner in Holland & Knight's Washington, D.C. office and a co-leader of the firm's Healthcare & Life Sciences Industry Team. He has almost three decades of healthcare law, lobbying, regulatory, reimbursement and policy development experience in Washington. He focuses on issues affecting biotechnology and pharmaceutical companies, medical research and research institutions, physicians and patients. His specific areas of knowledge include legislation and FDA regulations regarding drug/biological product, approval, and distribution; biosimilars; Medicare reimbursement strategy and issues; FDA and NIH oversight of clinical trials including registries

and reporting of trial results; approval and marketing of orphan drugs; stem cell research and regulation of cell therapy, gene therapy, tissue engineering and regenerative medicine products; the Physician Sunshine Act; human subject protection issues such as IRB review and informed consent, as well as conflicts of interest and other bioethics issues arising from research and uses of new technologies.

Mr. Werner is the co-founder and Executive Director of the Alliance for Regenerative Medicine, a Washington, DC-based organization whose mission is to advocate for federal funding, regulatory and reimbursement policies that will advance regenerative medicine research and product development.

Before joining Holland & Knight, he was president of The Werner Group, a Washington, D.C.-based firm that provided lobbying, regulatory, and bioethics consulting services for biotechnology and pharmaceutical companies, physicians, health plans, investors, and patient advocacy groups. Prior to founding The Werner Group, he was chief of policy for the Biotechnology Industry Organization (BIO), representing over 1000 biotechnology companies in the U.S. and other countries. In that role, he was responsible for virtually all major issues affecting biotech companies including: drug evaluation and review by FDA; CMS policies and reimbursement, Medicare, intellectual property, stem cell research and other sensitive bioethics issues.

Mr. Werner is also a founding member of the Board of Directors of the Coalition for the Advancement of Medical Research (CAMR), an organization of over 100 nationally-recognized patient organizations, universities, scientific societies, foundations and individuals that advocate for the advancement of breakthrough research and technologies in stem cell research and related fields.

Before BIO, he spent six years as counsel for legislation and policy for the American College of Physicians where he performed legal analysis and congressional and regulatory advocacy on

such issues as Medicare reform, liability reform, integration and delivery system re-structuring, quality improvement and end of life care.

Mr. Werner was senior healthcare advisor to U.S. Senate Majority Leader George Mitchell, a congressional investigator for the U.S. Senate Special Committee on Aging and senior advisor to Maryland Governor William Donald Schaefer.

He is a heavily sought-after speaker for meetings and conferences, and the author of over 40 published articles. Mr. Werner is a frequent media commentator and has appeared in The Wall Street Journal, Science, Scientific American, The Washington Post, BIOWorld, Congressional Quarterly and The Baltimore Sun, as well as on many TV and radio news programs. In 2013, he was named one of the Top 50 Global Stem Cell Influencers by Total BioPharma.

Honors & Awards

Top 50 Global Stem Cell Influencers, Total BioPharma,

2013 Memberships

National Academies of Sciences, Engineering and Medicine's Forum on Regenerative Medicine
Biomedical Engineering Society, Ethics Committee

University of Michigan Alumni Club of Washington, D.C., Board of Directors

Read more: <https://www.hklaw.com/Michael-Werner/>