

# 2017 Rising Leaders Conference on Healthcare Policy

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COALITION FOR HEALTHCARE COMMUNICATION

## AGENDA

National Press Club  
Washington, D.C.

Monday, May 15, and Tuesday, May 16, 2017

### MONDAY EVENING, MAY 15 | 6:00 pm

Networking reception and dinner



#### KEYNOTE SPEAKER

##### Dr. Robert Califf

Former FDA Commissioner and professor of medicine at Duke University

Dr. Califf will share his perspective on the role and programs of the Food and Drug Administration, the initiatives he launched as commissioner, and the process for developing and approving innovative drugs.

### TUESDAY, MAY 16 | 8:45 am

Continental breakfast with time for networking;  
Program begins at 9:30 am



#### INTRODUCTION AND OVERVIEW

##### Jon Bigelow

Conference chair; President, Thayer Pond Solutions

A new President and Republican-controlled Congress bring new players in key roles, new perspectives on key areas of policy, and new proposals – sometimes contradictory – for major changes at the FDA and CMS, in the ACA, and throughout the healthcare system. What do these proposals mean and how might they play out? An overview of the program.



#### HEALTHCARE POLICY IN THE TRUMP ERA

##### Kate Rawson

Senior Editor, Prevision Policy and The RPM Reports

An experienced inside-the-beltway observer of healthcare policy will offer insights on the key players in the new administration and in Congress, and the impact of their agendas on drug pricing, budget cuts, regulation limits, next steps in the ACA “repeal and replace” process, and other issues.

### Panel: Clashing Visions of the FDA



#### WHAT TO WATCH FOR AT THE FDA THIS YEAR AND NEXT

##### Kay Holcombe

Senior VP for Health Policy, BIO

Approved late in 2016, the 21st Century Cures Act included new funding and initiatives for the FDA. Now in 2017, the FDA has a new commissioner-designate, the Trump administration has proposed major changes in user fees and mandated cutting regulations, and PDUFA VI legislation requires Congressional action by September. Ms. Holcombe—who has been involved in PDUFA legislation since the first bill and from the perspectives of Congress, the FDA, and industry—will outline the issues on the table and what to expect.



#### THE FDA APPROVAL PROCESS: WHAT ARE THE POSSIBLE CHANGES?

##### Wayne Pines

President for Healthcare, APCO Worldwide; former FDA Associate Commissioner for Public Affairs

In recent months, new ideas—such as greater reliance on surrogate markers or allowing new molecules on the market based on safety before efficacy is proven—have been floated by people influential with the Trump administration. A leading FDA authority will look at ways in which the current approval process may evolve, special approval pathways, and other changes behind the scenes.



#### OPDP AND OFF-LABEL REGULATION

##### Mit Spears

Attorney; former EVP and General Counsel, PhRMA; former General Counsel, Federal Trade Commission

In the wake of the IMS v Sorrell and Caronia decisions, declining numbers of enforcement letters, and new FDA personnel, a close observer of the FDA's Office of Prescription Drug Promotion (OPDP) will discuss the outlook for regulation of off-label information and implications for health communicators.

### Luncheon



#### KEYNOTE SPEAKER

##### Senator Chris Murphy (D-CT)

Member of the Senate Health, Education, Labor and Pensions Committee and the Senate Appropriations Committee

Senator Murphy was the sponsor of the Mental Health Reform Act of 2016 that was enacted as part of the 21st Century Cures legislation. He will offer his perspectives on such current issues as access to healthcare, the role of the FDA and of the pharma industry in drug innovation, and strategies for ensuring medicines are affordable.



#### TAX REFORM AND PHARMA

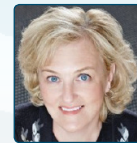
##### Dick O'Brien

Executive VP for Government Relations, American Association of Advertising Agencies

With corporate tax reform considered a priority initiative for both President Trump and Speaker Ryan, Mr. O'Brien will consider the content and prospects of proposals with special significance to the advertising and communications fields.

### How Knowing What Happens in Washington (and Why) Matters in Your Career

Leaders with background across advertising, medical communications, public relations, and digital strategy will emphasize what they see as the most important topics raised during the conference and relate them to attendees' careers: why staying abreast of Washington developments enables us to better serve our clients and make more substantial contributions to our companies and the health communications field.



##### Sharon Callahan

CEO, TBWAWorldwide; chair, Coalition for Healthcare Communication



##### Laura Schoen

President, Global Healthcare Practice and Chair for Latin America, Weber Shandwick



##### J.D. Cassidy

Managing Director, Saatchi & Saatchi Wellness

### The Coalition's Mission and 2017 Priorities



##### John Kamp

Executive Director, Coalition for Healthcare Communication

The mission and key priorities for the Coalition in supporting the open and accurate communication of health information.

### CLOSING COMMENTS

##### Jon Bigelow

Conference chair; President, Thayer Pond Solutions