



Honorary Co-Chairs

Former President George H W Bush
Former President Jimmy Carter

Co-Chairs

The Honorable Robert D. Ray, J.D.
The Honorable Robert W. Edgar

President

Henry E. Simmons, M.D., M.P.H.,
F.A.C.P.

Chief Executive Officer

Ralph G. Neas

Board of Directors

Robert D. Ray
Former Governor of Iowa

Robert W. Edgar
Former Congressman
President & CEO
Common Cause

Henry E. Simmons
President
National Coalition on Health Care

Frank Carlucci
Chairman Emeritus
Carlyle Group

Bill Crist
Emeritus Professor of Economics
California State University

George Diehr
Board Member
California Public Employees'
Retirement System

Commissioner Israel L. Gaither
National Commander
The Salvation Army

William J. Grize
Former President & CEO
Ahold USA, Inc

Cheryl G. Heaton
President & CEO
American Legacy Foundation

John H. McArthur
Dean Emeritus
Harvard Business School

John Rother
Executive Vice President, Policy and
Strategy
AARP

John Seffrin
CEO
American Cancer Society

John Sweeney
President
AFL-CIO

John Wilson
Executive Director
NEA

July 8, 2009

The Honorable Edward M. Kennedy
Chairman, HELP Committee
317 Russell Senate Building
Washington D.C. 20510

The Honorable Michael Enzi
Ranking Member, HELP Committee
379A Russell Senate Building
Washington, D.C. 20510

Dear Chairman Kennedy and Ranking Member Enzi:

As you continue your work drafting comprehensive health care reform legislation, The National Coalition on Health Care strongly urges you to consider the inclusion of an effective and timely approval process for more affordable versions of biotech medicines. Founded in 1990 by Dr. Henry Simmons, its current President, the National Coalition on Health Care is the largest, broadest, most diverse coalition working to achieve comprehensive health care reform. It is an alliance of 79 organizations representing business, unions, health care providers, associations of religious congregations, minorities, people with disabilities, pension and health funds, insurers, and groups representing patients and consumers. Our member organizations represent more than 150 million Americans. They speak for a cross-section, and a majority, of our population.

Biologics are among the most expensive and most important drugs available to patients today. They account for 25% of all new drug products approved by FDA and cost on average 22 times more than chemical drugs. Yet, there is no competition in this critical marketplace.

Twenty-five years ago, Congress passed the Hatch-Waxman Act that allowed for competition and greater access for chemical drugs. At that time biologic drugs were in their infancy and were not included in the legislation. Now, there is an opportunity to yield substantial savings to the health care system by creating a generic pathway for high quality biologics as part of comprehensive health care reform. The Coalition's principles and specifications address the need for rigorous cost containment provisions as part of system-wide and systemic reform. As a result, the Coalition -- with its member organizations representing more than 150 million Americans -

enactment of the "Promoting Innovation and Access to Life-Saving Medicine Act" (H.R. 1427). [for Senate letter S. 726]

In formulating language to create a generic biologic program at Food and Drug Administration (FDA), it is important to balance the incentives that are necessary for innovator companies to invest in developing new biologic drugs with the patients and healthcare providers' interest in generic drugs being available at the earliest possible time. In light of its tremendous success, we urge the Committee to use the Hatch-Waxman Act as a model for generic biologics legislation. Under Hatch-Waxman, innovation of brand drugs has accelerated, as demonstrated by a dramatic increase in research and development spending. At the same time, patients, taxpayers and federal and state governments have enjoyed hundreds of billions of dollars in consumer savings from generic alternatives. In fact, over the past 25 years available data indicates that the percentage of the U.S. prescription drug market occupied by generic drugs has risen from 19% to 68%.

H.R. 1427 would create a program at FDA similar to the program created by the Hatch-Waxman Act, authorizing the Agency to approve generic versions of biologics that are safe and effective. In connection with the Committee's consideration of a generic biologic program, we would like to highlight the issue of exclusivity for innovator products. Some of the bills that have been introduced would provide that innovator biologics would be entitled to 12-14 years of exclusivity, a period of time during which generic competition would be barred. We urge you to oppose generic biologics legislation that contains excessive periods of exclusivity or that contains other unnecessary and significant barriers to generic, biologic competition.

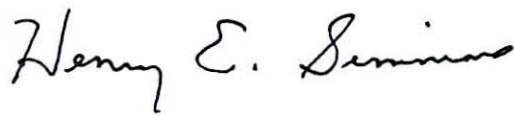
With regard to the exclusivity issue, we refer you to the Federal Trade Commission's recent report, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* (June 2009) (at 26, 35), which found that "the patent system has a proven record of protecting and stimulating biotechnology innovation." It also found that "pioneer biologic drugs are covered by more and varied patents than small-molecule branded products [the drugs covered by Hatch-Waxman], including manufacturing and technology platform patents." The FTC stated that "a twelve- to fourteen-year exclusivity period is unnecessary to promote innovation by pioneer biologic drug manufacturers." (capitalization and bold omitted) (p. vi).

The five year period of exclusivity provided in H.R. 1427 follows the Hatch-Waxman model and is the appropriate period of exclusivity. An unnecessarily long period of exclusivity would significantly delay the entry of generic versions of biologics and thus would delay the savings to the health care system from a generic biologic program at FDA. It would also diminish the incentives for other companies to continue innovating, actually resulting in less innovation over time.

Prescription drugs accounted for almost \$300 billion in 2008 and biologics accounted for almost \$45 billion. Many of the most expensive drugs on the market today are biologics and the national bill for biologic drugs is expected to grow significantly in the coming

years. Increased use of generic drugs have dramatically reduced drug costs for chemical drugs and have the potential to do the same for biologic drugs. For this reason, we urge you to include the key provisions of H.R. 1427 in national health care legislation.

Our nation is experiencing a massive health care cost and economic crisis. Increasing the availability of generic biologics will be a critical element of a comprehensive necessary health care cost containment strategy.



Henry E. Simmons, M.D., M.P.H.,
F.A.C.P.
President



Ralph G. Neas
Chief Executive Officer

Cc: The Honorable Christopher Dodd
The Honorable Tom Harkin
The Honorable Barbara Mikulski
The Honorable Jeff Bingaman
The Honorable Patty Murray
The Honorable Jack Reed
The Honorable Bernard Sanders
The Honorable Sherrod Brown
The Honorable Robert Casey
The Honorable Kay Hagan
The Honorable Jeff Merkley
The Honorable Sheldon Whitehouse

The Honorable Judd Gregg
The Honorable Lamar Alexander
The Honorable Richard Burr
The Honorable Johnny Isakson
The Honorable John McCain
The Honorable Orrin Hatch
The Honorable Lisa Murkowski
The Honorable Tom Coburn
The Honorable Pat Roberts