

June 5, 2007

The Honorable Edward M. Kennedy
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
644 Dirksen Senate Office Building
Washington D.C. 20510

The Honorable Mike Enzi
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
379A Russell Senate Office Building
Washington D.C. 20510

Dear Chairman Kennedy and Senator Enzi:

On behalf of millions of consumers, workers, patients, employers, insurers and health care companies, we are writing to thank you for your commitment to mark-up legislation by June 13th that will give the FDA authority to approve safe and effective, more affordable biogeneric drugs and to pass this legislation this year. We look forward to working with you to ensure that this pathway is truly a workable pathway and moves forward on your timeframe. Failure to do so allows for the unacceptable continuation of monopoly pricing for biotech products.

Ensuring that all products on the market are safe is of the utmost importance and is of course the number one concern for all of our organizations. We believe that any workable pathway for biologenerics should be science-driven and prioritize patient safety.

Specifically, we urge you to move forward with legislation that:

- 1) Empowers the FDA to use its expertise to determine on a case by case basis what scientific data they need to approve comparable and interchangeable products.
- 2) Does not include administrative barriers that impede FDA's ability to approve safe and effective biologenerics.
- 3) Provides a clear framework for interchangeability that is immediately operative and does not require additional congressional action.
- 4) Ensures predictability for when scientifically-proven, safe and effective biologenerics can enter the marketplace.
- 5) Provides a clear and timely resolution to patent disputes and prohibits frivolous suits that restrict access to biologenerics and delay competition in the marketplace.
- 6) Creates a balanced process that encourages innovation by both brand and generic companies and expands access to prescription medications for consumers.
- 7) Does not create a system of endless monopoly pricing and no opportunity for competition to enter the marketplace.

We represent a broad array of interests who have come together to support making safe and effective life-improving and life-saving care available and more affordable to millions of Americans. To that end, we stand ready to work with you and your Colleagues as you pass legislation to create a workable, abbreviated pathway this year.

Sincerely,

Aetna Inc	IBM
AARP	International Union, United Auto Workers
AFL-CIO	Kaiser Permanente
American Federation of State, County and Municipal Employees	Kentucky Retirement Systems
Apotex	Kentucky Teachers' Retirement System
AT&T	Medco Health Solutions
Barr Laboratories	Momenta Pharmaceuticals, Inc.
Ben Venue	Mylan Labs
Blue Cross Blue Shield Association	National Association of Chain Drug Stores
CalPERS	National Association of Health Underwriters
Caterpillar, Inc.	National Consumers League
Centene	Ohio Public Employees Retirement System
Colorado Public Employees' Retirement Association	Pennsylvania Public School Employees' Retirement System
Consumers Union	PepsiCo
Costco	Pharmaceutical Care Management Association
Cummins Inc.	Public Health Roundtable
CVS Caremark	Raytheon
DaimlerChrysler Corporation	SEIU
Deere & Company	Sodexo
Department of Professional Employees, AFL-CIO	Sony BMG Music Entertainment
Eastman Kodak Company	Sony Electronics
ERISA Industry Committee	Teva Pharmaceuticals USA
Express Scripts, Inc.	The Board of Pensions of the Presbyterian Church (USA)
Families USA	The Dow Chemical Company
FedEx	The National Business Group on Health
Ford Motor Company	TRW Automotive
FreedomWorks	U.S. Public Interest Research Group
General Motors Corporation	Walgreen Company
Generic Pharmaceutical Association	Waste Management, Inc.
Hercules Incorporated	Watson Pharmaceuticals
Hospira, Inc.	Wellpoint, Inc.
HR Policy Association	Wendy's International, Inc.
Humana	Whirlpool Corporation
Council for Citizens Against Government Waste	Xerox Corporation

cc: The Honorable Harry Reid, Senate Majority Leader

cc: The Honorable Mitch McConnell, Senate Republican Leader