

April 15, 2008

The Honorable John Dingell
Chairman
House Energy and Commerce Committee
United States House of Representatives
Washington, D.C. 20515

The Honorable Joe Barton
Ranking Member
House Energy and Commerce Committee
United States House of Representatives
Washington D.C. 20515

Dear Chairman Dingell and Representative Barton:

On behalf of millions of consumers, workers, patients, employers, insurers and health care companies, we are writing to thank you for your interest in giving the FDA authority to approve safe and effective, more affordable biogeneric drugs. We remain committed to seeing legislation enacted as soon as possible and look forward to working with you to ensure that this pathway is truly workable. 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 biogenics should be science-driven and prioritize patient safety. Failure to do so allows for the unacceptable continuation of monopoly pricing for biotech products.

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 biogenics.
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 biogenics can enter the marketplace.
5. Provides a clear and timely resolution to patent disputes and prohibits frivolous suits that restrict access to biogenics 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	International Union, United Auto Workers
AARP	Kaiser Permanente
AFL-CIO	Kentucky Retirement Systems
America's Health Insurance Plans	Kentucky Teachers' Retirement System
American Federation of State, County and Municipal Employees	Medco Health Solutions
Apotex	Momenta Pharmaceuticals
AT&T	Mylan Labs
Barr Laboratories	National Association of Chain Drug Stores
Blue Cross Blue Shield Association	National Association of Health Underwriters
CalPERS	National Consumers League
Caterpillar, Inc.	National Women's Health Network
Centene	Ohio Public Employees Retirement System
Chrysler LLC	Pennsylvania Public School Employees' Retirement System
Cigna	Pharmaceutical Care Management Association
Colorado Public Employees' Retirement Association	Public Citizen
Consumer Federation of America	Public Sector Healthcare Roundtable
Consumers Union	Ranbaxy Pharmaceuticals
Council for Citizens Against Government Waste	Raytheon Company
Cummins Inc.	RESTAT
CVS Caremark Inc.	Rite Aid Corporation
Deere & Company	SEIU
Department for Professional Employees, AFL-CIO	Sony Electronics
Eastman Kodak Company	Spastic Paraplegia Foundation
ERISA Industry Committee	Teva Pharmaceuticals USA
Express Scripts, Inc.	The Dow Chemical Company
Families USA	The National Business Group on Health
Ford Motor Company	U.S. Public Interest Research Group
FreedomWorks	United Parcel Service
General Motors Corporation	Walgreen Company
Generic Pharmaceutical Association	Wal-Mart Stores, Inc.
Hospira, Inc.	Watson Pharmaceuticals
Humana, Inc.	Wellpoint, Inc.
Insmmed Incorporated	Whirlpool Corporation
	Xerox Corporation