



BIOTECHNOLOGY  
INDUSTRY  
ORGANIZATION

July 21, 2003

Dear Member of Congress:

As members of the Board of Directors for the Biotechnology Industry Organization (BIO), we are writing to express our strong opposition to H.R. 2427, the Pharmaceutical Market Access Act of 2003, which would significantly weaken regulation on the importation of prescription drug products. BIO represents more than 1,000 members of the biotechnology industry. We understand that the House may consider the bill next week, and we urge you to vote against it.

The law already, in fact, allows "reimported" and imported drug products, subject to certification by the Secretary of Health and Human Services (HHS) that the products are safe and that consumers will receive the benefit of any cost savings on the products. The obstacle to such imports is not the current law, but the fact that there is no way to ensure product safety, according to the nation's preeminent health officials: the Secretaries of Health and Human Services in both the previous and current Administrations, FDA Commissioners in both Administrations, and eight former FDA Commissioners. H.R. 2427 would eliminate safety certification, surely a dangerous change for American consumers, who probably would not be informed their medicines were coming from a foreign source not subject to FDA oversight.

H.R. 2427 attempts to thwart obvious temptations to counterfeiters by introducing new "anti-tampering" and "anti-counterfeiting" packaging requirements. But such technology, where it exists, is new and has no track record as a viable approach to ensuring the safety of drug products. Even technology already in common use in the industry, such as holography, is not foolproof. Companies find they must change holograms many times a year, as counterfeiters are adept at duplicating them quickly.

1225 EYE STREET, N.W., SUITE 400  
WASHINGTON, D.C. 20005-5958

202-962-9200  
FAX 202-962-9201  
<http://www.bio.org>

Biologic products in particular are highly dependent – for both their effectiveness and their safety – on the conditions and temperatures in which they are stored and handled. Because biologics are injected or infused, their ingredients go straight into the bloodstream, making patients especially vulnerable to the adverse effects of any contaminants.

Counterfeiting is already a problem with these sensitive products. In May 2002 the FDA determined a lot of Serostim®, a growth hormone product of Serono Laboratories used to treat patients afflicted with HIV/AIDS, contained no active ingredient and did not originate from Serono. Similarly, in the spring of 2002, Amgen, Inc. became aware of a potential counterfeit of its product, Epogen®, which is used in the treatment of anemia associated with renal failure. Extensive laboratory analysis showed suspect vials contained only a clear liquid with about one-twentieth the concentration of active ingredient indicated on the label. There can be no doubt that such incidents would multiply – even with a biologics exemption – if the government were to permit a largely unregulated import trade in prescription medicines.

American citizens today have the safest supply of medicines in the world. Despite the occasional counterfeiting incident, we are nowhere near the 8 percent worldwide rate of counterfeit drugs (25 percent in poorer countries). In this country, pharmaceuticals are tracked and tightly regulated from manufacturer to consumer. We cannot afford to risk this gold-standard system of safety. With no guarantee that reimportation/importation will even provide any cost savings to consumers, we stand to place American patients at risk with no commensurate benefit if H.R. 2427 passes. We, the Board of Directors for BIO, therefore implore you to vote against H.R. 2427, the Pharmaceutical Market Access Act of 2003.

Sincerely,

Frank Baldino, Jr., Ph.D  
Chairman & CEO  
Cephalon, Inc.  
West Chester, PA

Andrew Baum  
President & CEO  
SemBioSys Genetics, Inc.  
Calgary, AB Canada

Alexis Borisey  
CEO & President  
CombinatoRx, Inc  
Boston, MA

Nancy Chang  
CEO  
Tanox  
Houston, TX

F.W. Corrigan  
Executive Vice President  
Cargill, Inc.  
Wayzata, MN

Dennis M. Fenton, Ph.D  
Executive Vice President  
Amgen  
Thousand Oaks, CA

Heinrich Gugger  
President & CEO  
Paradigm Genetics, Inc.  
Research Triangle Park, NC

Susan Desmond-Hellman  
Executive Vice-President & Chief  
Medical Officer  
Genentech,  
South San Francisco, CA

Kenneth C. Carter  
President & CEO  
Avalon Pharmaceuticals  
Germantown, MD

Robert Chess  
Chairman  
Nektar Therapeutics  
San Carlos, CA

Douglas A. Doerfler  
President & CEO  
MaxCyte, Inc.  
Rockville, MD

Thomas A. Glaze  
Vice-Chairman  
Metabolex, Inc.  
Hayward, CA

Richard Hamilton  
CEO  
Ceres, Inc.  
Malibu, CA

William D. Johnston  
President & CEO  
Inhibitex, Inc.  
Alpharetta, GA

Dennis H. Langer  
Senior Vice President  
GlaxoSmithKline  
King of Prussia, PA

John C. Martin, Ph.D  
President & CEO  
Gilead Sciences, Inc.  
Foster City, CA

Jennie Mather  
CEO  
Raven Biotechnologies, Inc.  
South San Francisco, CA

Ben McGraw  
Chairman, President & CEO  
Valentis, Inc.  
Burlingame, CA

Steven J. Mento  
President & CEO  
Idun Pharmaceuticals  
San Diego, CA

Walter H. Moos  
Chairman & CEO  
MitoKor, Inc.  
San Diego, CA

H. Stewart Parker  
President & CEO  
Targeted Genetics Corporation  
Seattle, WA

Richard F. Pops  
CEO  
Alkermes, Inc.  
Cambridge, MA

Edwin C. Quattelbaum  
President & CEO  
MetaMorphix, Inc.  
Savage, MD

Hollings C. Renton  
Chairman & CEO  
Onyx Pharmaceuticals, Inc.  
Richmond, CA

Norbert G. Riedel, Ph.D  
Corporate Vice President & Chief  
Scientific Officer  
Baxter International  
Roundlake, IL

David E. Robinson  
Chairman, President & CEO  
Ligand Pharmaceuticals  
San Diego, CA

Duane Roth  
Chairman, President & CEO  
Alliance Pharmaceutical Corp.  
San Diego, CA

Una S. Ryan, Ph.D  
President & CEO  
AVANT Immunotherapeutics, Inc.  
Needham, MA

Leonard S. Schleifer, M.D, Ph.D  
President & CEO  
Regeneron Pharmaceuticals, Inc.  
Tarrytown, NY

Joseph C. Scodari  
Company Group Chairman  
Biopharmaceuticals  
Johnson & Johnson  
New Brunswick, NJ

Mark Skaletsky  
Chairman & CEO  
Essential Therapeutics  
Waltham, MA

John P. Walker  
Chairman – CEO  
Bayhill Therapeutics, Inc.  
Palo Alto, CA

Robert R. Ruffolo, Jr.  
President  
R& D Development  
Wyeth Pharmaceuticals  
Collegeville, PA

Mitchel Sayare, Ph.D  
CEO  
Immunogen, Inc.  
Cambridge, MA

Toni Schuh, Ph.D  
President & CEO  
Sequenom, Inc.  
San Diego, CA

Stephen A. Sherwin, M.D.  
Chairman & CEO  
Cell Genesys, Inc.  
South San Francisco, CA

Henri A. Termeer  
Chairman & CEO  
Genzyme Corporation  
Cambridge, MA

Barbara H. Wells  
President & CEO  
ArborGen LLC  
Summerville, SC