



March 11, 2009

The Honorable Henry A. Waxman  
U.S. House of Representatives  
Washington, D.C. 20515

The Honorable Nathan Deal  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Chairman Waxman and Representative Deal:

AARP is pleased to endorse the “Access to Life-Saving Medicine Act.” Your bill will create a much needed pathway for the approval of safe, biosimilar and interchangeable versions of biologic drugs.

As the largest organization representing individuals aged 50 and older, our members are particularly affected by rising prescription drug prices. Biologic drugs hold the promise of treating some of the most serious diseases – such as multiple sclerosis, arthritis, cancer and others – that often affect older populations. Biologics now account for about one out of eight prescriptions written, and sales of biologics were over \$40 billion in 2007.

Unfortunately, these treatment therapies can be very expensive – costing tens to hundreds of thousands of dollars a year. Consumers and other payers – including employers and public programs like Medicare and Medicaid – cannot afford to continue paying these astronomical prices. Under-insured and uninsured persons who are prescribed biologic treatments may find the drugs unaffordable and decide to forgo them completely. Biologic treatments may also be too expensive for individuals fortunate enough to have health insurance; even well-insured individuals may face high co-insurance amounts. The high levels of cost-sharing associated with biologic drugs put a tremendous financial burden on consumers and their families, made particularly onerous in these troubling economic times.

Your legislation would create a pathway for FDA approval of less-costly, safe, and interchangeable biological products. It will ensure that consumers have greater access to many of the biologic therapies that may be currently financially out of reach and, in doing so, will improve the quality of life for millions of Americans. In addition, lower cost biologics will save both the federal and state governments – as well as employers -- billions of dollars in prescription costs.

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We look forward to working with you and your colleagues on both sides of the aisle to enact this critical legislation this year. If you have any further questions, please feel free to contact me, or have your staff contact Anna Schwamlein Howard of our Government Relations and Advocacy staff at 202-434-3770.

Sincerely,

A handwritten signature in black ink, appearing to read "Nancy LeaMond". The signature is written in a cursive style with a large initial "N" and a distinct "L" and "M".

Nancy LeaMond  
Executive Vice President



**Ken W. Cole**  
Vice President  
Global Public Policy  
and Government Relations

March 11, 2009

The Honorable Henry A. Waxman  
Chairman, Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

General Motors Corporation  
25 Massachusetts Avenue, N.W.  
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Washington, D.C. 20001  
Tel 202-775-5090  
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The Honorable Nathan Deal  
United States House of Representatives  
2133 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Waxman and Representative Deal:

On behalf of General Motors Corporation, I am writing to endorse "The Promoting Innovation and Access to Life Saving Medicines Act of 2009." This legislation would provide a clear and definitive pathway at the Food and Drug Administration for the approval of safe and effective biogenerics. The legislation appropriately gives full discretion to the FDA to use its scientific expertise to determine the safety and efficacy of biogenerics, an approach which will increase the accessibility and affordability of these life-saving medicines to millions of Americans.

GM is committed to improving access to safe, and affordable pharmaceuticals for the one million employees, retirees, and family members who are beneficiaries of GM health plans. As an automobile company, GM is also a leader in safety and innovation. We support this legislation because it ensures patient safety while striking the right balance between incentives for innovation and promoting competition in the pharmaceutical market.

General Motors commends you for your leadership and bipartisan efforts to craft this important legislation. We look forward to working with you to advance this legislation.

Sincerely,



**OFFICE OF THE PRESIDENT**

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March 10, 2009

The Honorable Henry Waxman  
Member of Congress  
2204 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Waxman:

On behalf of the California Public Employees' Retirement System (CalPERS), which represents over 1.6 million California public employees, retirees and their families, we write to applaud your continued leadership to bring safe, effective, and more affordable generic biopharmaceuticals to millions of Americans. Your bipartisan legislation, "*The Promoting Innovation and Access to Life-Saving Medicines Act*," achieves a balance between incentives for innovation and the competition that is required to reduce costs for patients and purchasers such as CalPERS. We are pleased to endorse your legislation and look forward to working with you to achieve its passage.

At a time when the nation is rightly focused on the need to find ways to constrain costs and ensure quality, affordable coverage for every American through long overdue health reforms, the legislation you are introducing could not be more timely. We were pleased to note that President Obama included a proposal in his recent budget proposal that seems to be completely consistent with the policy you are introducing. We believe your bipartisan legislation sends an important and welcome signal that the time to act to establish a biogeneric pathway has come.

As you know, CalPERS is the largest purchaser of public employee health benefits in California and the second largest public purchaser in the nation after the federal government. This year, CalPERS will spend more than \$5.7 billion to purchase health benefits for nearly 1.3 million active and retired state and local government public employees and their family members. Of that amount, CalPERS will spend over \$1.15 billion on our members' prescription drugs. CalPERS strongly supports legislation designed to help improve quality of care and slow the rate of growth in health care costs.

In 2007, you invited Priya Mathur, a member of the CalPERS Board of Administration to testify on this important issue before your Committee on Oversight and Government Reform. She testified that "The high cost of biopharmaceutical products presents an unsustainable challenge to CalPERS and to our entire health care system." In 2007, despite representing less than one percent of all CalPERS prescriptions, specialty drugs represented ten percent of our spending. Our experience shows that improving access to generic drugs dramatically reduces health care costs. We believe that this would be particularly true in the growing field of biopharmaceuticals.

The Honorable Henry Waxman  
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Thanks to the significant scientific advances made in the biotechnology industry, the science exists for the Food and Drug Administration (FDA) to establish a pathway that will enable them to ensure the safety and efficacy of biogenerics. Your bill creates a pathway that will operate efficiently and effectively, ensure the safety and efficacy of biogenerics, and produce consistent and timely reviews so that consumers can obtain the benefit of a robust and competitive pharmaceutical market.

For CalPERS, the safety and health of our members comes first in any decision we make about any policy. We strongly support your legislation which appropriately gives FDA clear authority to use its expertise to review and, where appropriate, approve both biosimilar and interchangeable biogenerics. We also share your goal that the FDA is best positioned to determine what testing is needed to approve biosimilar and interchangeable biological alternatives, and that they continue to assure the safety of all prescription drug products. Furthermore, we support the exclusivity periods included in the bill which are based on those in the current Hatch-Waxman law.

CalPERS believes that safe and effective biogenerics will bring billions of dollars of savings to consumers, state and federal governments and the health care community. We urge you to include the "Access to Life Saving Medicine Act" in this year's health care reform legislation.

CalPERS is proud and honored to add our support to the growing list of workers, seniors, patient groups, businesses, health plans, health care providers, pharmacy benefit managers and countless others who support your legislation to open the door to biogeneric competition. We thank you for your leadership and look forward to supporting your efforts on this and other reforms to improve quality, expand access and enhance value within the health care system.

Sincerely,



ROB FECKNER  
President, CalPERS Board of Administration



ANNE STAUSBOLL  
Chief Executive Officer

cc: The CalPERS Board of Administration  
Executive Staff



March 10, 2009



The Honorable Henry Waxman  
Chair, House Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Waxman:

SEIU is pleased to support the *Life-Saving Medicine Act of 2009*, and we will work with you and President Obama to enact this important and necessary “ingredient” for comprehensive healthcare reform this year. In a recent poll reported in *Health Affairs*, 94 percent of respondents said that drug prices are too high, and 56 percent agreed that Americans should use more generic drugs. According to IMS Health, generic drugs account for two-thirds of prescriptions filled but less than 13 percent of total drug spending. The choice of safe and affordable generic drugs has been an important option for patients and healthcare payers to contain the ever-growing costs of healthcare, thanks in large part to your original Hatch-Waxman legislation.

President Obama has identified a strategy for containing drug costs in his healthcare reform budget reserve proposal, and his budget pledges that “the administration will accelerate access to make affordable generic biologic drugs available through the establishment of a workable regulatory, scientific and legal pathway for generic versions of biologic drugs.” The *Life-Saving Medicine Act of 2009* would accomplish the President’s goal of holding down drug costs while promoting safe and effective “biogeneric” products. The bill gives the FDA authority to approve applications for “biosimilar” and “biogeneric” products, including the authority to require the applicant to conduct clinical studies and post-market safety studies. The bill also provides reasonable exclusivity periods and extensions, and establishes a procedure for resolving patent disputes. It strikes the proper balance between rewarding innovation and promoting competition and choice.

Drug costs will continue to be a major driver in pushing up overall healthcare costs if we do not take action such as establishing a workable and safe pathway for generic biologic drugs. Official CMS national health spending projections indicate that drug costs will accelerate to more than 8 percent annually in large part because the generic dispensing rate will level off after the

ANDREW L. STERN  
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ANNA BURGER  
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next five years. Patients and healthcare payers urgently need Congress to establish a pathway for approval of safe and effective biogeneric drugs to promote choice while holding down costs for patients and for the overall healthcare system. SEIU applauds your leadership in this area and looks forward to working with you to build support for this important ingredient of comprehensive healthcare reform in 2009.

If you have questions or need additional information, contact Michelle Nawar, SEIU's Deputy Director of Legislation, at 202-730-7232 or [michelle.nawar@seiu.org](mailto:michelle.nawar@seiu.org).

Sincerely,

A handwritten signature in black ink that reads "Anna Burger". The signature is written in a cursive, flowing style.

Anna Burger  
International Secretary-Treasurer

AB:AK:gmb

opeiu#2  
afl-cio, clc



March 11, 2009

The Honorable Henry A. Waxman  
Chairman  
Committee on Energy and Commerce  
United States House of Representatives  
Washington, DC 20515

The Honorable Nathan Deal  
Ranking Member  
Subcommittee on Health  
Committee on Energy and Commerce  
Washington, DC 20515

The Honorable Frank Pallone, Jr.  
Chairman  
Subcommittee on Health  
Committee on Energy and Commerce  
Washington, DC 20515

The Honorable Jo Ann H. Emerson  
Ranking Member  
Subcommittee on Financial Services and Government  
Committee on Appropriations  
Washington, DC 20515

Dear Chairman Waxman and Representatives Deal, Pallone and Emerson:

The Coalition for a Competitive Pharmaceutical Market (CCPM) applauds your leadership in introducing “The Promoting Innovation and Access to Life Saving Medicines Act,” bipartisan legislation that will bring safe, effective and more affordable biogeneric drugs to millions of Americans. Representing some of the largest purchasers, distributors and manufacturers of prescription drugs in the nation and proudly employing or serving tens of millions of Americans, we are pleased to endorse this landmark legislation. We appreciate your leadership and look forward to working with you to pass and enact this legislation in this Congress.

CCPM is an organization of large national employers, health plans, pharmacy benefit managers, chain pharmacies, generic drug and biopharmaceutical manufacturers committed to improving consumer access to high quality, affordable generic medicines and promoting a vigorous, competitive prescription drug market. Experience shows that improving access to generic medicines will dramatically reduce health care costs thus expanding access to care. This is particularly true in the growing field of biopharmaceuticals. While biopharmaceuticals hold tremendous promise, their high costs – on average \$20,000 to \$200,000 annually – too often make this promise unavailable to millions of Americans. That is why access to biogenerics is so important.

Thanks to the significant scientific advances made in the biotechnology industry over the past twenty years, the science exists for the Food and Drug Administration (FDA) to ensure the safety and efficacy of biogenerics. Your bill creates a pathway that will operate efficiently and effectively, guarantees the safety and efficacy of biogenerics, and eliminates the current effective marketing monopoly of brand biotech pharmaceuticals which will create competition and choice – something that always has driven innovation. Additionally, by granting a period of marketing exclusivity that mirrors the current Hatch-Waxman law (up to eight years), it ensures substantial revenues to the innovator companies and, in so doing, supports research and development for new products.

We also strongly support your legislation because it appropriately gives FDA clear authority and resources to use its expertise to review and, where scientifically justified, approve both comparable and interchangeable biogenerics. We share your belief that the FDA is best positioned to determine what testing is needed to approve comparable and interchangeable biological alternatives, and their science and review process for biogenerics should not be statutorily mandated by the Congress.

Safe and effective biogenerics will bring billions of dollars of savings to consumers, state and federal governments and the healthcare community. According to a study conducted on behalf of the Pharmaceutical Care Management Association (PCMA), creating a clear pathway for approval of biogenerics would save an estimated \$14 billion over ten years for the Medicare Part B program alone. This amount represents the tip of the iceberg of potential federal savings and does not include the vast majority of medications covered by Medicare, Medicaid, the Federal Employee Health Benefit Plan and other publicly financed health programs. Moreover, business and workers covered by private health plans would stand to save billions of dollars as well.

Passage of “The Promoting Innovation and Access to Life Saving Medicines Act” should be a high priority for this Congress as it is critical to making safe and effective life improving and life saving care available and more affordable to millions of Americans. We thank you again for your leadership and look forward to working with you throughout the legislative process to increase competition in the healthcare marketplace and to bring more affordable biogenerics to consumers.

Sincerely,



Annette Guarisco  
Chairman

Christopher B. Begley

Chairman and Chief Executive Officer



March 11, 2009

The Honorable Henry Waxman  
U.S. House of Representatives  
Chairman  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Nathan Deal  
U.S. House of Representatives  
Ranking Member, Subcommittee on Health  
Committee on Energy and Commerce  
2133 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Waxman and Congressman Deal:

Hospira, Inc. enthusiastically supports your efforts to help make biopharmaceuticals more affordable and more accessible to patients in the United States. The introduction of the "Promoting Innovation and Access to Life-Saving Medicines Act" represents a critical step toward creating a legal pathway that works for biogenerics to enter the U.S. market.

Headquartered in Illinois, with nearly 14,000 employees, Hospira is the only U.S. company selling a biogeneric drug in Europe today. Hospira's Retacrit® (epoetin zeta), a treatment for anemia associated with chronic kidney failure and chemotherapy-induced anemia, is available in more than a dozen European countries. As the global leader in generic injectable pharmaceuticals, we are also dedicated to helping reduce the overall costs of healthcare – improving both the affordability of care for patients and the financial strength of the global healthcare system.

We believe that the "Promoting Innovation and Access to Life-Saving Medicines Act" offers a real opportunity to increase patient access to safe, effective and affordable medications. Safe and effective biogenerics are scientifically possible, and Hospira is confident that we can bring these products to market given the opportunity. To that end, we are supportive of your efforts to provide a framework for the FDA to create a well-defined process – rooted in science – to ensure the safety and efficacy of generic biologic products.

We are confident that establishing an approval pathway will lead to significant savings for consumers, state and local governments and healthcare providers.

Your leadership in this area has been instrumental and is very much appreciated. Hospira stands ready to help you in your efforts.

Regards,

A handwritten signature in blue ink, appearing to read "Chris Begley", is written over a light blue horizontal line.

Chris Begley  
Chairman and CEO



March 11, 2009

The Honorable Henry A. Waxman  
Chairman, Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

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The Honorable Nathan Deal  
United States House of Representatives  
2133 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Waxman and Representative Deal:

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