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May 2, 2008

Representative Frank Pallone, Jr.
Chairman, Energy and Commerce Health Subcommittee
2125 Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Representative Nathan Deal
Ranking Member, Energy and Commerce Health Subcommittee
2125 Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Pallone and Ranking Member Deal:

On behalf of AARP's nearly 40 million members, thank you for the opportunity to respond to the stakeholder questions sent to those groups interested in the creation of a pathway for the approval of comparable and interchangeable biologics. As the largest organization representing those age 50 and older we have focused on those specific questions where we have the most expertise. AARP has endorsed the Access to Life-Saving Medicines Act (H.R. 1038) because we believe that it will provide for the creation of a much needed workable pathway for the approval of comparable and interchangeable biologic products.

Generic drugs help improve the quality of an individual's life by providing safe and effective lower-priced treatment options. Studies also demonstrate that individuals who begin prescription drug regimens with generics have a much greater chance of staying on their medications compared to those who begin on higher-cost medications.

Biologic drugs hold the promise of treating some of the most serious diseases – such as Multiple Sclerosis, arthritis, cancer and others – that may afflict older adults more than younger patients. In addition, more and more research and development is focused on biologics. Unfortunately these therapies can be very expensive – costing tens to hundreds of thousands of dollars a year. Some are fortunate to have insurance coverage for these treatments. However, even those with prescription drug coverage may be faced with high co-insurance amounts. Under-insured and uninsured persons who are prescribed biologic treatments may find these treatments are unaffordable, and may be likely to forgo them completely.

Erik D. Olsen, President
William D. Novelli, Chief Executive Officer

The high price of these treatments not only has adverse effects on consumers, but also on other health care payers including employers, private health care plans, and public programs like Medicare and Medicaid. Creating a pathway for the approval of comparable and interchangeable forms of biologics will help make these treatments more affordable not only for consumers, but for the entire U.S. health care system.

Science/Safety

Although price is an important consideration, no prescription drug – whether it is a traditional prescription drug or a biologic – should be allowed on the market unless it is safe and effective. AARP believes that scientific determinations should be left to the entity best equipped to address them – the FDA. Common sense tells us that an agency that has the scientific knowledge to approve a brand-name biologic surely has the ability to approve comparable and interchangeable versions of the same product.

Congress certainly has the responsibility for overseeing the FDA, the agency charged with ensuring that products are safe and effective. However, we do not believe that Congress should be in the business of legislating science. As technology has developed over the years, we have seen advances in areas never before imagined. It is important that any legislation that is enacted will help to spur – and not limit – scientific discovery. Thus, AARP believes that the FDA should be granted the authority to use its expertise on a case-by-case basis to determine what scientific data is necessary to approve comparable and interchangeable products.

Regulatory/Administrative

AARP believes that there needs to be a clear pathway for the approval of comparable and interchangeable biologics. In addition, legislation should not create administrative barriers that hamper the FDA's ability to approve safe and effective comparable and interchangeable biologics.

AARP does not believe that clinical trials should be statutorily mandated. Clinical trials may be necessary for some products, but not for all. The FDA should be granted the authority to decide which scientific studies are necessary and when to ensure the safety and effectiveness of comparable and interchangeable biologic products. AARP also believes that the FDA should be granted appropriate resources to be able to fully implement a pathway for the approval of comparable biologics.

Interchangeability

AARP believes that it is important that legislation allow for the FDA to approve biogenerics as interchangeable to the reference product. Not all comparable biologics will be able to demonstrate interchangeability, but the FDA should be able to grant such designation for those who can so demonstrate. Again, the FDA should be granted the flexibility to determine – as science dictates – in which cases a designation of interchangeability is appropriate.

Patents and Incentives/Exclusivity/Investment

AARP believes that any generic biologics legislation should include provisions on the timely resolution of patent disputes. Excessive and unnecessary litigation in this area will delay market entry of comparable and interchangeable biologics and will increase health care costs.

It is also important that any legislation strikes a balance between encouraging innovation and allowing for competition. Our members want and need drug research and development to continue to thrive in this country – just as it has since the passage of the Hatch-Waxman bill. Creating a workable pathway for the approval of comparable and interchangeable biologics will help to spur both innovation and will provide lower prices through competition.

Economic Impact

As the Committee is aware, there have been numerous studies demonstrating significant savings from the enactment of legislation that would create a pathway for the approval of comparable and interchageable biologics. A recent study supported by Insmed estimated that generic versions of the top 12 categories of biologic treatments with patent protections that have expired or are due to expire in the near future could save Americans, in net present value, $67 billion to $108 billion over the next 10 years and $236 billion to $378 billion over the next 20 years.[1] Another study, which applied Medicare spending projections from the CBO and the SMI Trustees, estimated that cost-savings from the enactment of the Access to Life-Saving Medicine Act would be on average $1.41 billion to $1.49 billion per year, or $14.1 billion to $14.9 billion over the entire 10-year period from FY2007 - FY2016.[2]

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[1] R.J. Shapiro, K.Singh, and M.Mukim, "The Potential American Market for Generic Biological Treatments and the Associated Cost Savings," Insmed Corporation, February 2008.

[2] Engel & Novitt, LLP. "Potential Savings That Might Be Realized By the Medicare Program From Enactment of Legislation Such As The *Access to Life-Saving Medicine Act* (H.R. 6257/S. 4016) That Establishes a New cBLA Pathway For Follow-on Biologics," Pharmaceutical Care Management Associates (January 2007).

Conclusion

The Hatch-Waxman Act created a pathway for the FDA to approve generic prescription drugs. Twenty-four years later, the time has come for the FDA to approve comparable and interchangeable biologics. The Waxman bill provides the FDA with the authority to produce a safe, comparable or interchangeable version of a biologic. This FDA pathway is simply a first step toward more available, affordable options for people with diseases that can be treated with biologic drugs. No medicine can be effective if those who need it cannot afford to pay for it.

Thank you for allowing us the opportunity to present our views on this very important health care issue. We look forward to working with members of the Committee to enact this legislation. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard of our Government Relations Department at 202-434-3770.

Sincerely,

David P. Sloane
Senior Vice President
Government Relations and Advocacy