December 22, 2008

Federal Trade Commission
Office of the Secretary
Room H-135 (Annex 5)
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

Re: Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901

Federal Trade Commission:

On behalf of our more than 40 million members, AARP appreciates the opportunity to provide comments on the Federal Trade Commission's (FTC's) November 21, 2008, roundtable on follow-on biologic drugs. Specifically, we will limit our comments to the panel on the likely market effects of follow-on biologic drug competition.

As the largest organization representing individuals aged 50 and older, our members are particularly affected by rising prescription drug prices. Generic drugs have proven to be one of the safest and most effective ways for consumers to lower their prescription drug costs. We encourage our members to use generic drugs whenever possible to do so. Unfortunately, as the Commission is aware, there is currently no pathway for the approval of generic versions of biologic drugs. AARP has endorsed the Access to Life-Saving Medicines Act (H.R. 1038/S. 623) 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.

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. However, these treatment therapies can be very expensive – costing tens to hundreds of thousands of dollars a year. Many individuals are prescribed biologic drugs to treat chronic conditions.

Under-insured and uninsured persons who are prescribed biologic treatments may find these treatments 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. Most Medicare Part D plans have implemented a specialty tier for high-priced drugs, including biologics. In the 2009 plan year, 82% of Medicare

Part D prescription drug plans, and 97% of Part D MA-PD plans, will use higher-cost specialty tiers.[1] In 2009, some Part D plans will require a co-insurance amount of 40 percent (Humana Standard) or 50 percent (Member Health/ Community CCRx). High co-payments for expensive drugs puts a tremendous financial burden on beneficiaries and their families, made particularly onerous in these troubling economic times.

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. One study, which applied Medicare spending projections from the CBO and the SMI Trustees, estimated that Medicare's cost-savings from the enactment of the Access to Life-Saving Medicine Act would average $1.41 billion to $1.49 billion per year, or $14.1 billion to $14.9 billion over the 10-year period from FY2007-FY2016.[2]

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. For example, earlier this year, the Congressional Budget Office estimated that the Biologics Price Competition and Innovation Act would reduce total spending on biologic drugs in the United States by $25.2 billion between FY2009 and FY2018.

AARP believes that there needs to be a clear pathway for the approval of comparable and interchangeable biologics. We believe that legislation creating a follow-on biologics pathway should not create administrative barriers that hamper the FDA's ability to approve comparable and interchangeable biologics that are safe and effective.

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.

Finally, AARP believes that it is important that the follow-on biologics pathway 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

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[1] Jack Hoadley, Presentation to the Medicare Payment Advisory Commission, December 5, 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).

those who can so demonstrate. Again, the FDA should be granted the flexibility to determine – based on scientific evidence – in which cases a designation of interchangeability is appropriate.

Thank you for allowing us the opportunity to present our views on this very important health care issue. We look forward to working with the Commission on this issue. 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
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Government Relations and Advocacy