

# Generic Biologic Drugs: Myth vs. Fact



AARP believes that any final health care reform package must create an FDA approval process for generic biologic drugs so Americans can get these life-saving medicines at a price they can afford.

AARP supports the “Promoting Innovation and Access to Life-Saving Medicine Act” (H.R. 1427/S. 726), which is sponsored by Rep. Henry Waxman (D-CA) and Rep. Nathan Deal (R-GA) and Sen. Charles Schumer (D-NY) and Sen. Susan Collins (R-ME). This bill would create a pathway for the FDA approval of generic versions of biologic drugs that could not enter the market until five years after the brand name version became available.

There are several competing bills that would also create a pathway for the FDA approval of generic biologics. However, many of these bills will force consumers to wait an unacceptably long period of time before they can purchase the lower cost generic version of their biologic medicine.

For example, the “Pathway for Biosimilars Act” (H.R. 1548), introduced by Rep. Anna Eshoo (D-CA) and Rep. Joe Barton (R-TX), would not allow the FDA to approve generic versions of biologic drugs for twelve to fourteen years after the brand name version enters the market.

Click [here](#) for more information on Generic Biologics and how to contact your member of Congress.

Below are some myths the drug and biotech industries use to generate opposition to H.R. 1427/S.726, as well as the facts that debunk them.

**Myth #1:** H.R. 1427/S.726 will undermine manufacturers’ efforts to research and develop new life-saving medications.

**Fact:** The Federal Trade Commission (FTC) recently concluded that five years without generic competition is adequate to support continued innovation and that the twelve to fourteen years supported by the drug industry actually negatively impacts innovation.

**Myth #2:** Allowing generic versions of biologic drugs to enter the market “too soon” will jeopardize public safety.

**Fact:** If the FDA has the scientific knowledge to approve a brand-name biologic, it surely has the ability to approve safe generic versions of the same biologic.

**Myth #3:** H.R. 1427/S.726 would not provide manufacturers with enough time to recover the costs associated with biologic drug development.

**Fact:** Based on U.S. drug sales alone, many top selling biologics have recouped their manufacturer’s initial investment several times over in the last six years; often within a single year. In addition, the FTC has concluded that brand name manufacturers will continue to reap substantial profits even after generic versions enter the market.

### Join in on Health Care Reform Town Hall Meetings

AARP, SC Appleseed Legal Justice Center, SC Small Business Chamber of Commerce, and SC Fair Share to hold health care reform town hall meetings in July

July 2 Rep. John Spratt Rock Hill - Baxter Hood Center 4 p.m.  
July 6 Rep. James Clyburn Columbia - Drew Wellness Center 5 p.m.  
July 11 Rep. James Clyburn Charleston - Location and time TBA

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