# S 4016

Access to Life-Saving Medicine Act

**Congress:** 109 (2005–2007, Ended)
**Chamber:** Senate
**Policy Area:** Health
**Introduced:** Sep 29, 2006
**Current Status:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
**Latest Action:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Sep 29, 2006)
**Official Text:** https://www.congress.gov/bill/109th-congress/senate-bill/4016

## Sponsor

**Name:** Sen. Schumer, Charles E. [D-NY]
**Party:** Democratic • **State:** NY • **Chamber:** Senate

## Cosponsors (3 total)

| Cosponsor | Party / State | Role | Date Joined |
|---|---|---|---|
| Sen. Clinton, Hillary Rodham [D-NY] | D · NY | | Sep 29, 2006 |
| Sen. Leahy, Patrick J. [D-VT] | D · VT | | Sep 29, 2006 |
| Sen. Stabenow, Debbie [D-MI] | D · MI | | Sep 29, 2006 |

## Committee Activity

| Committee | Chamber | Activity | Date |
|---|---|---|---|
| Health, Education, Labor, and Pensions Committee | Senate | Referred To | Sep 29, 2006 |

## Subjects & Policy Tags

**Policy Area:**

Health

## Related Bills

| Bill | Relationship | Last Action |
|---|---|---|
| 109 HR 6257 | Related bill | **Oct 2, 2006:** Referred to the Subcommittee on Health. |

## Summary (as of Sep 29, 2006)

Access to Life-Saving Medicine Act - Amends the Public Health Service Act to establish a process for the approval of a comparable biological product based on its similarity to a previously licensed biological product (the reference product). Allows a person to file an abbreviated comparable product application with the Secretary of Health and Human Services that includes: (1) data demonstrating that the product is comparable to the reference product; (2) information to show that the conditions or conditions of use prescribed, recommended, or suggested in the labeling proposed for the comparable product have been previously approved for the reference product; and (3) information to show that the route of administration, the dosage form, and the strength of the comparable product are the same as those of the reference product.

Sets forth conditions for approval of such an application by the Secretary.

Allows an applicant to request that the Secretary make a determination as to the interchangeability of a comparable product and the reference product. Provides market exclusivity to such an interchangeable product.

Requires the Secretary to establish requirements for the efficient review, approval, suspension, and revocation of comparable biological product applications.

Sets forth provisions governing patent infringement claims against the license holder of a comparable product.

## Actions Timeline

- **Sep 29, 2006:** Introduced in Senate
- **Sep 29, 2006:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.