# S 3056

CREATES Act of 2016

**Congress:** 114 (2015–2017, Ended)
**Chamber:** Senate
**Policy Area:** Health
**Introduced:** Jun 14, 2016
**Current Status:** Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights. Hearin
**Latest Action:** Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights. Hearings held. (Jun 21, 2016)
**Official Text:** https://www.congress.gov/bill/114th-congress/senate-bill/3056

## Sponsor

**Name:** Sen. Leahy, Patrick J. [D-VT]
**Party:** Democratic • **State:** VT • **Chamber:** Senate

## Cosponsors (11 total)

| Cosponsor | Party / State | Role | Date Joined |
|---|---|---|---|
| Sen. Grassley, Chuck [R-IA] | R · IA | | Jun 14, 2016 |
| Sen. Klobuchar, Amy [D-MN] | D · MN | | Jun 14, 2016 |
| Sen. Lee, Mike [R-UT] | R · UT | | Jun 14, 2016 |
| Sen. Collins, Susan M. [R-ME] | R · ME | | Jun 21, 2016 |
| Sen. McCaskill, Claire [D-MO] | D · MO | | Jun 21, 2016 |
| Sen. Blumenthal, Richard [D-CT] | D · CT | | Jul 14, 2016 |
| Sen. McCain, John [R-AZ] | R · AZ | | Jul 14, 2016 |
| Sen. Vitter, David [R-LA] | R · LA | | Sep 13, 2016 |
| Sen. Whitehouse, Sheldon [D-RI] | D · RI | | Sep 13, 2016 |
| Sen. Cotton, Tom [R-AR] | R · AR | | Sep 22, 2016 |
| Sen. Durbin, Richard J. [D-IL] | D · IL | | Sep 22, 2016 |

## Committee Activity

| Committee | Chamber | Activity | Date |
|---|---|---|---|
| Judiciary Committee | Senate | Hearings By (subcommittee) | Jun 21, 2016 |

## Subjects & Policy Tags

**Policy Area:**

Health

## Related Bills

*No related bills are listed.*

## Summary (as of Jun 14, 2016)

**Creating and Restoring Equal Access to Equivalent Samples Act of 2016 or the CREATES Act of 2016**

This bill permits the developer of a drug or biological product to bring a civil action against the license holder of an approved medication alleging that the license holder: (1) declined to make available sufficient quantities of the approved medication for the developer's testing; or (2) failed to agree on, or refused to allow the developer to join, a single, shared system of elements to assure safe use (ETASU) of the medication. (Under current law, a generic version of a medication with ETASU must join the brand name medication's system of ETASU unless the developer of the generic has a waiver from the Food and Drug Administration.) The bill does not apply to medications for which there is a shortage, unless the shortage will not be promptly resolved.

In a civil action regarding the availability of sufficient quantities of a medication, it is an affirmative defense that the license holder: (1) is not manufacturing or marketing the medication and does not have access to a supply of the medication to make available, or (2) sells the medication without restrictions through other entities and the developer can purchase sufficient quantities of the medication from those entities.

## Actions Timeline

- **Jun 21, 2016:** Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights. Hearings held.
- **Jun 14, 2016:** Introduced in Senate
- **Jun 14, 2016:** Read twice and referred to the Committee on the Judiciary. (Sponsor introductory remarks on measure: CR S3862-3863)