

## S 1509

### Orphan Products Extension Now Accelerating Cures and Treatments Act of 2017

**Congress:** 115 (2017–2019, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Jun 29, 2017

**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. (Jun 29, 2017)

**Official Text:** <https://www.congress.gov/bill/115th-congress/senate-bill/1509>

### Sponsor

**Name:** Sen. Hatch, Orrin G. [R-UT]

**Party:** Republican • **State:** UT • **Chamber:** Senate

### Cosponsors (5 total)

| Cosponsor                    | Party / State | Role | Date Joined  |
|------------------------------|---------------|------|--------------|
| Sen. Menendez, Robert [D-NJ] | D · NJ        |      | Jun 29, 2017 |
| Sen. Nelson, Bill [D-FL]     | D · FL        |      | Aug 2, 2017  |
| Sen. Scott, Tim [R-SC]       | R · SC        |      | Aug 2, 2017  |
| Sen. Rubio, Marco [R-FL]     | R · FL        |      | Jan 30, 2018 |
| Sen. Donnelly, Joe [D-IN]    | D · IN        |      | Jul 31, 2018 |

### Committee Activity

| Committee                                        | Chamber | Activity    | Date         |
|--------------------------------------------------|---------|-------------|--------------|
| Health, Education, Labor, and Pensions Committee | Senate  | Referred To | Jun 29, 2017 |

### Subjects & Policy Tags

#### Policy Area:

Health

### Related Bills

| Bill        | Relationship | Last Action                                                 |
|-------------|--------------|-------------------------------------------------------------|
| 115 HR 1223 | Related bill | <b>Mar 3, 2017:</b> Referred to the Subcommittee on Health. |

## **Orphan Products Extension Now Accelerating Cures and Treatments Act of 2017**

This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to extend by six months the exclusivity period for an approved drug or biological product when the product is additionally approved to prevent, diagnose, or treat a new indication that is a rare disease or condition (also known as an orphan disease). The FDA may revoke an extension if the application for the new indication contained an untrue material statement. The FDA must notify the public of products that receive this extension and patents related to those products. Products may receive only one of these extensions. This extension is in addition to other extensions. Only products approved after enactment of this bill for a new indication that is a rare disease or condition are eligible for an extension.

For a medication to be approved as an orphan drug with seven years of marketing exclusivity when it is the same medication for the same condition as an already approved orphan drug, the sponsor of the new medication must demonstrate that the new medication is clinically superior to the approved medication.

The bill expands to cover brand name drugs provisions that allow generic drugs to be approved and marketed without labeling for pediatric indications when the pediatric indications are protected by patent or marketing exclusivity.

### **Actions Timeline**

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- **Jun 29, 2017:** Introduced in Senate
- **Jun 29, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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