

S 3004

Dormant Therapies Act of 2014

Congress: 113 (2013–2015, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Dec 11, 2014

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. (Dec 11, 2014)

Official Text: <https://www.congress.gov/bill/113th-congress/senate-bill/3004>

Sponsor

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

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

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Bennet, Michael F. [D-CO]	D · CO		Dec 11, 2014

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Dec 11, 2014

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Dormant Therapies Act of 2014 - Requires the Department of Health and Human Services (HHS) to designate medicines being, or intended to be, investigated to address unmet medical needs as dormant therapies. Gives a dormant therapy a 15-year protection period during which no drug can be approved by relying on the approval of the dormant therapy absent a right of reference from the holder of the approved application for the dormant therapy.

Requires the sponsor of a potential dormant therapy to have a clinical plan to investigate the medicine and intend to file an application for approval or licensure of the medicine as a new drug or biological product. Prohibits the active moiety of the medicine from being the same as an active moiety in a drug or highly similar to one in a biological product for which an application has been submitted.

Requires the sponsor of a potential dormant therapy to list their patents that apply to the medicine and waive rights to those patents at the end of the dormant therapy protection period if the medicine is approved.

Allows a sponsor to withdraw a dormant therapy designation request unless the medicine has been approved or licensed.

Entitles the sponsor of a dormant therapy to extend patents that apply to the medicine to the end of the protection period.

Prohibits a dormant therapy from receiving specified protections that apply to pediatric, infectious disease, or rare disease or condition medicines.

Directs HHS to require a sponsor to certify that the clinical plan for a dormant therapy has been completed and that approval was based on investigations in the clinical plan.

Actions Timeline

- **Dec 11, 2014:** Introduced in Senate
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