HR 486

Stop Tampering of Prescription Pills Act of 2013

Congress: 113 (2013–2015, Ended)
Chamber: House
Policy Area: Health
Introduced: Feb 4, 2013
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Feb 8, 2013)
Official Text: https://www.congress.gov/bill/113th-congress/house-bill/486

Sponsor

Name: Rep. Keating, William R. [D-MA-9]
Party: Democratic • **State:** MA • **Chamber:** House

Cosponsors (15 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Buchanan, Vern [R-FL-16]	R · FL		Feb 4, 2013
Rep. Hanabusa, Colleen W. [D-HI-1]	D · HI		Feb 4, 2013
Rep. Lynch, Stephen F. [D-MA-8]	D · MA		Feb 4, 2013
Rep. Rahall, Nick J., II [D-WV-3]	D · WV		Feb 4, 2013
Rep. Rogers, Harold [R-KY-5]	R · KY		Feb 4, 2013
Rep. Aderholt, Robert B. [R-AL-4]	R · AL		Mar 13, 2013
Rep. Markey, Edward J. [D-MA-5]	D · MA		Mar 13, 2013
Rep. Tierney, John F. [D-MA-6]	D · MA		Mar 13, 2013
Rep. Kennedy, Joseph P., III [D-MA-4]	D · MA		Mar 14, 2013
Rep. Kingston, Jack [R-GA-1]	R · GA		Mar 14, 2013
Rep. Rooney, Thomas J. [R-FL-17]	R · FL		Mar 14, 2013
Rep. Wolf, Frank R. [R-VA-10]	R · VA		Mar 21, 2013
Rep. Grimm, Michael G. [R-NY-11]	R · NY		Apr 11, 2013
Rep. McGovern, James P. [D-MA-2]	D · MA		Feb 4, 2014
Rep. Schakowsky, Janice D. [D-IL-9]	D · IL		Jul 10, 2014

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 8, 2013

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Feb 4, 2013)

Stop Tampering of Prescription Pills Act of 2013 - Amends the Federal Food, Drug, and Cosmetic Act to prescribe new drug application requirements for abuse-deterrent drugs: (1) containing as an active moiety (the part of the drug that makes it work the way it does) a controlled substance classified as opium, an opiate, or a derivative; (2) formulated for oral administration; (3) exhibiting physicochemical properties making them significantly more difficult or ineffective in altering the drug's characteristics for purposes of misuse or abuse; and (4) containing one or more additional ingredients intended to deter abuse through potential pharmacological effects.

Requires the Secretary to refuse a new drug application for any new (brand name) drug containing opium, an opiate, or a derivative as an active moiety that is not abuse-deterrent if an abuse-deterrent drug containing the same active moiety has been approved and has not been discontinued from marketing. Authorizes the Secretary to approve an application failing to meet such requirements, however, if approval is necessary to prevent or alleviate a drug shortage or otherwise address a significant unmet public health need.

Requires an abbreviated new (generic) drug application for an abuse-deterrent drug to include testing information demonstrating that the generic drug resists manipulation or the effect of manipulation to a degree at least comparable to the listed drug. Authorizes the Secretary to deny approval of a generic application if the listed drug is abuse-deterrent and one or more of the generic drug's active moieties differ in any material respect from those of the listed drug.

Declares that an approved generic drug shall not be considered bioequivalent to, or as having the same therapeutic effect as, a listed drug if the listed drug becomes abuse-deterrent unless and until the generic drug demonstrates that it resists manipulation or the effect of manipulation to a degree at least comparable to the listed drug.

Prescribes requirements governing when a drug which is not abuse-deterrent may have its approval withdrawn or suspended.

Actions Timeline

- **Feb 8, 2013:** Referred to the Subcommittee on Health.
- **Feb 4, 2013:** Introduced in House
- **Feb 4, 2013:** Referred to the House Committee on Energy and Commerce.

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