

113TH CONGRESS
1ST SESSION

H. RES. 161

Expressing the sense of the House of Representatives that the Food and Drug Administration should encourage the use of abuse-deterrent formulations of drugs.

IN THE HOUSE OF REPRESENTATIVES

APRIL 15, 2013

Mr. ROGERS of Kentucky (for himself, Mr. KEATING, Mr. WOLF, Mr. RAHALL, Mr. GRIMM, Mr. LYNCH, Mr. TIERNEY, and Mr. ADERHOLT) submitted the following resolution; which was referred to the Committee on Energy and Commerce

RESOLUTION

Expressing the sense of the House of Representatives that the Food and Drug Administration should encourage the use of abuse-deterrent formulations of drugs.

Whereas when abuse-deterrent formulations of a drug have been developed, approved, and recognized as effective by the Food and Drug Administration, the approval and marketing of generic versions that do not have abuse-deterrent features are likely to prevent achievement of the public health purposes of the efforts to develop such abuse-deterrent formulations;

Whereas the Office of National Drug Control Policy and the Food and Drug Administration have for many years strongly encouraged manufacturers of opioid drug prod-

ucts to develop abuse-deterrent formulations designed to prevent or discourage the abuse or misuse of those products;

Whereas in response, several opioid drug manufacturers have developed abuse-deterrent formulations;

Whereas helping to reduce the level of abuse of opioid drug products is dependent on the widespread adoption of new technologies and approaches to the safer formulation of these drugs;

Whereas the Commissioner of Food and Drugs has acknowledged that the Food and Drug Administration has the authority under current law to require generic versions of products that have been formulated or reformulated with abuse-deterrent features to have comparable features; and

Whereas fourteen Members of Congress in a bipartisan coalition have cosponsored the Stop Tampering with Prescription Pills (STOPP) Act, which would similarly promote abuse-deterrent technologies in addictive painkillers: Now, therefore, be it

1 *Resolved*, That it is the sense of the House of Rep-
 2 resentatives that the Food and Drug Administration
 3 should exercise its acknowledged authority to—

4 (1) refuse to approve generic versions of non-
 5 abuse-deterrent opioid products that have been re-
 6 placed in the market with abuse-deterrent formula-
 7 tions; and

- 1 (2) require generic versions of abuse-deterrent
- 2 opioid products to be formulated with comparable
- 3 abuse-deterrent features.

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