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S. RES. 97

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

IN THE SENATE OF THE UNITED STATES

APRIL 15, 2013

Mr. COBURN (for himself, Mr. SCHUMER, and Mr. MCCONNELL) submitted the following resolution; which was referred to the Committee on Health, Education, Labor, and Pensions

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RESOLUTION

Expressing the sense of the Senate 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 products 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 efforts to reduce the level of abuse of opioid drug products are dependent on the widespread adoption of new technologies and approaches to the safer formulation of these drugs; and

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: Now, therefore, be it

Resolved, That it is the sense of the Senate that the Food and Drug Administration should exercise its acknowledged authority to—

(1) refuse to approve generic versions of non-abuse-deterrent opioid products that have been replaced in the market with abuse-deterrent formulations recognized by the Food and Drug Administration as effective; and

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

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