

April 23, 2018

The Honorable Lamar Alexander
Chair, Senate Committee on
Health, Education, Labor, and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member, Senate Committee on
Health, Education, Labor, and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

On behalf of our 161,000 dentist members, we would like to express our support for S. 2315, the Over-the-Counter Drug Safety, Innovation, and Reform Act. We are particularly enthusiastic about the provision that would reform the Food and Drug Administration's (FDA) 40 year-old process for considering approval of submissions that would allow certain drugs to be sold over-the-counter (OTC) with administrative approval by the FDA.

Under current law, non-prescription drugs may be marketed OTC without FDA pre-approval if they are tested, manufactured, and labeled in accordance with an appropriate drug monograph. Each drug monograph is subject to a three-phase public rulemaking process that can take years (and sometimes decades) to complete.

S. 2315 would empower the FDA Commissioner to approve a submission by sponsors via administrative order in lieu of following a laborious rulemaking process. The agency would have to supply a detailed justification for issuing the order, and the order itself would be subject to 45 days of public comment and a reasonable period of judicial review, if requested. But the approval process would be much more nimble and far more effective than the one now in place.

Streamlining the approval process will, among other things, allow for the submission of non-narcotic pain relievers with a combination of two or more active ingredients, which is particularly important in the context of preventing opioid abuse.

For example, dental patients are often advised to treat post-operative pain with acetaminophen and ibuprofen in lieu of a prescription pain medication. The current regulatory scheme prohibits these active ingredients from being combined into one pill/tablet, meaning patients have to buy them separately and take different numbers of different pills at different times of day.

In this case, the reforms in this bill would establish a pathway for a single, strength-controlled acetaminophen-ibuprofen combination drug to be considered for approval to be sold OTC. These types of combination drugs could be a safe, effective, and convenient alternative to opioid pain relievers.

S. 2315 is an important step towards alleviating the scourge of opioid abuse that has been devastating our families and communities. We urge the Committee to issue a favorable report so it may be considered for a floor vote by the Senate.

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We applaud Sens. Johnny Isakson and Bob Casey for introducing this important legislation and are pleased to offer our enthusiastic support. If you have any questions, please contact Ms. Natalie Hales at 202-898-2404 or haesn@ada.org.

Sincerely,

/s/

Joseph P. Crowley, D.D.S.
President

JPC:KTO:rjb

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director