

May 8, 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

On behalf of our 161,000 dentist members, we would like to express our support for H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018. 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.

H.R. 5333 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. We believe these non-regulated combinations may lead to unsafe drug use, which can potentially cause harm to the patients.

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

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H.R. 5333 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 House of Representatives.

We applaud Representatives Bob Latta, Michael Burgess, Gene Green, Diana DeGette, Brett Guthrie and Debbie Dingell 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 halesn@ada.org.

Sincerely,

/s/

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

/s/

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

JPC:KTO:rjb