

November 15, 2018

The Honorable Mitch McConnell  
Senate Majority Leader  
S-230 United States Capitol  
Washington, DC 20510

The Honorable Chuck Schumer  
Senate Minority Leader  
S-221 United States Capitol  
Washington, DC 20510

Dear Majority Leader McConnell and Minority Leader Schumer:

On behalf of our 161,000 dentist members, we urge you to call a floor vote on S. 2315, the Over-the-Counter Drug Safety, Innovation, and Reform Act. This bill will modernize the federal government's 40 year-old system for considering whether new drugs with ingredients that are generally accepted as safe and effective may be sold over-the-counter.

Under current law, drug products with ingredients that the FDA already considers safe and effective for self-use may bypass the rigorous and expensive new drug application process if they are tested, manufactured, labeled, and reviewed in accordance with an appropriate drug monograph. A drug monograph is a predetermined checklist covering acceptable ingredients, formulations, testing methods, packaging, labeling, and more.

The monograph drug approval process is generally less expensive and more efficient than filing a new drug application. However, it can take years and in some cases decades to review and update a drug monograph to account for more modern methods of scientific testing, and ingredients and formulations that were brought to market after 1972.

S. 2315 would authorize the FDA Commissioner to update a drug monograph by administrative order instead 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 monograph revision process will inspire confidence that the drugs available over-the-counter have met the most recent testing standards for quality, safety, and effectiveness. It will also foster more innovation in developing new over-the-counter drugs. This is particularly important in the fight against opioid abuse.

For example, dental patients are often advised to treat post-operative pain with a combination of 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 the wrong combinations, these medications could be harmful even though they are generally considered safe.

The reforms in this bill would establish a pathway for a single, strength-controlled acetaminophen-ibuprofen combination drug to be developed and made available over-the-

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counter. These types of combination drugs, which are already used in some countries, would be a safe, effective, and easily accessible alternative to opioid pain relievers.

S. 2315 will improve the safety and effectiveness of over-the-counter drugs and foster innovation in the development of new pain medications. We urge you to bring this bill to the floor so that it may be considered by the full Senate.

We applaud Senators Johnny Isakson and Robert Casey for introducing this important legislation. If you have any questions, please contact Ms. Natalie Hales at 202-898-2404 or [halesn@ada.org](mailto:halesn@ada.org).

Sincerely,

/s/

Jeffrey M. Cole, D.D.S.  
President

/s/

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

JPC:KTO:rjb