

January 8, 2019

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
H-232 United States Capitol
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
H-204 United States Capitol
Washington, DC 20515

Dear Speaker Pelosi and Minority Leader McCarthy:

On behalf of our 163,000 dentist members, we would like to thank you for bringing legislation to the floor that would modernize the federal government's outdated system for considering whether new drugs with ingredients that are generally accepted as safe and effective may be sold over-the-counter.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 generally recognizes as 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 monograph to account for ingredients, formulations and methods of scientific testing that were available in 1972.

The Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019 will 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.

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

Again, thank you for bringing legislation to the floor to improve the safety and effectiveness of over-the-counter drugs and promote development of new over-the-counter pain medications. We applaud your leadership on this issue 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/

Jeffrey M. Cole, D.D.S., M.B.A., F.A.G.D
President

/s/

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

JMC:KTO:rjb