ADA American Dental Association®

1111 14th Street, N.W.
Suite 1200
Washington, DC 20005

T 202.898.2400
F 202.898.2437
www.ada.org

October 30, 2019

The Honorable Lamar Alexander
Chairman, 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 163,000 dentist members, we are writing to express our support for S. 2740, the Over-the-Counter Drug Safety, Innovation, and Reform Act of 2019. This bill would modernize the federal government's outdated system for considering whether new drugs with ingredients that are generally accepted as safe and effective may be sold over-the-counter.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 than were available in 1972.

The Over-the-Counter Drug 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.

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.

We urge the Committee to favorably report S. 2740 so it may be considered for a vote by the full Senate. It is an important step toward modernizing the FDA's monograph drug approval process.

Thank you for bringing this bill to the Committee, and for your leadership on this issue. If you have any questions, please contact Ms. Natalie Hales at 202-898-2404 or halesn@ada.org.

Sincerely,

Chad P. Gehani, D.D.S.
President

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

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