AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Tom Harkin
Chairman
Senate Committee on Health, Education,
Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Michael Enzi
Ranking Member
Senate Committee on Health, Education,
Labor and Pensions
835 Hart Senate Office Building
Washington, DC 20510

The Honorable Fred Upton
Chairman
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
House Energy & Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairmen Harkin and Upton, and Ranking Members Enzi and Waxman:

On behalf of the physician and medical student members of the American Medical Association (AMA), I would like to offer our support for the final version of S. 3187, the "Food and Drug Administration Safety and Innovation Act." The AMA commends the bipartisan effort in both the U.S. House of Representatives and Senate on developing strong legislation to ensure the Food and Drug Administration (FDA) has the necessary resources to provide timely review and oversight of new drugs and medical devices. The AMA broadly supports the various user fee provisions. The AMA also appreciates that the legislation includes other provisions essential to patient access to safe and effective health care, including:

Generating Antibiotic Incentives Now

The AMA strongly supports the inclusion of meaningful and necessary regulatory modifications to incentivize research, development, and manufacture of next generation antibiotics.

Averting and Mitigating Drug Shortages

The AMA applauds the expansion of FDA authorities to avert or mitigate drug shortages. These provisions represent significant work to advance a consensus position. The legislation would also allow the Secretary to include biologicals/biosimilars through rulemaking.

Prescription Drug Abuse and Diversion

The AMA strongly supports the provision that tasks the Secretary of Health and Human Services (HHS) with reviewing and reporting on current Federal initiatives and identifying gaps and opportunities with respect to ensuring the safe use of prescription drugs with the potential for abuse.

The AMA also applauds the inclusion of provisions that would place various synthetic chemical substances in Schedule I of the Controlled Substances Act. Adding these substances, sometimes referred to as "bath salts," to Schedule I would eliminate their legal sale and manufacture in the United States. These chemicals, when inhaled or injected, cause some effects similar to those caused by cocaine and methamphetamine, including paranoia, hallucinations, and suicidal thoughts, and in addition have led to self-mutilation, violent behavior and deaths.

Addressing Hydrocodone Abuse

The AMA is pleased that S. 3187 requires the Secretary of HHS to hold a public meeting to solicit recommendations regarding drugs containing hydrocodone. While we strongly support efforts to prevent the abuse of such products, we believe that all stakeholders must take a careful science-based approach to ensure that policy changes would appropriately address abuse and diversion, while not unintentionally limiting patient access to legitimately needed pain treatment. The AMA looks forward to the opportunity to work with Congress, the FDA, and other stakeholders to develop a multi-pronged strategy to combat the prescription drug abuse and diversion epidemic.

Online Rogue Pharmacies

The AMA strongly supports the provision that requires the Comptroller General to evaluate and prepare a report on the problems posed by rogue online pharmacies that violate federal or state law.

Laboratory Developed Test FDA Regulation

The AMA applauds the provision that prohibits the FDA from issuing guidance on the regulation of laboratory developed tests unless it notifies the Committee of its intent to take such action 60 days prior to the issuance of the guidance.

We applaud your leadership on all of these issues and urge all members to support passage of this important legislation.

Sincerely,

James L. Madara, MD