



AMERICAN ACADEMY OF  
ORTHOPAEDIC SURGEONS

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ORTHOPAEDIC SURGEONS

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August 7, 2014

Margaret A. Hamburg, MD  
FDA Commissioner  
Food and Drug Administration (FDA)  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Dr. Hamburg:

On behalf of more than 18,000 board-certified orthopaedic surgeons, the American Academy of Orthopaedic Surgeons (AAOS) thanks the FDA for the opportunity to comment on the 'Use of Innovative Packaging, Storage, and/or Disposal Systems to Address the Misuse and Abuse of Opioid Analgesics'.

The AAOS shares the concerns of the FDA regarding inappropriate use of opioid medications and is aware that opioid consumption in the United States (US) is increasing and patterns of use are different than other countries. The AAOS believes developing better means of disposing unused opioid analgesics is one way to reduce opioid diversion, misuse and abuse.

National Drug-Take Back Events have worked in disposing countless unused medicines, but legal restraints limit take-back events from accepting controlled substances, including opioids. FDA currently recommends that some medicine, including unused opioids, be disposed of by flushing down the toilet—a practice that leaves much to be desired.

In 2010, the Secure and Responsible Drug Disposal Act (Disposal Act) was enacted. The legislation sought to create a paradigm in which end-users (patients) would be able to safely and responsibly dispose unused, unwanted or expired medications. Regulations outlined by the Drug Enforcement Administration expanded entities to which patients may transfer unused, unwanted, or expired controlled substances for the purpose of disposal, as well as the methods by which such controlled substances may be collected<sup>1</sup>. But, all of the proposed collection methods are voluntary and no person is required to establish or operate a disposal program<sup>1</sup>.

The Disposal Act regulations go on further to say that DEA also proposes to authorize certain registrants (manufacturers, distributors, reverse distributors, and retail pharmacies) to be "collectors". The AAOS lauds the effort to create the means by which patients can safely dispose medications, but is concerned that the



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efforts do not go far enough to ensure that opioid diversion is mitigated. The AAOS supports creating incentives for manufacturers and other relevant stakeholders to develop systems to safely dispose unused, unwanted and expired opioids.

Significant time, resources and commitment of regulatory, legislative, health policy and medical professional organizations will be needed to create the societal changes needed to transform patterns of US opioid consumption. The AAOS recommends that the FDA work with the AAOS and other important stakeholder organizations to implement a comprehensive opioid medication use/misuse program needed to change US cultural norms and behaviors.

For additional information or clarification please do not hesitate to contact the Medical Director in our Washington office, William O. Shaffer, MD, at (202) 546-4430 or [shaffer@aaos.org](mailto:shaffer@aaos.org).

Sincerely,

A handwritten signature in black ink that reads 'Frederick M. Azar'.

Frederick M. Azar, M.D.  
President, American Academy of Orthopaedic Surgeons

1. <https://www.federalregister.gov/articles/2012/12/21/2012-30699/disposal-of-controlled-substances#h-10>