

June 15, 2012

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

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

Dear Chairman Harkin and Ranking Member Enzi:

Our organizations are pleased that the Senate passed S. 3187, the Food and Drug Administration Safety and Innovation Act. This legislation would reauthorize the Food and Drug Administration's (FDA's) user fee programs. We are especially pleased with the provisions in Title X, which would help mitigate the increasing number of drugs in chronic shortage.

Dentists are experiencing chronic shortages of sedatives, anesthetics, analgesics and anti-inflammatory drugs used to treat patients in their offices. Drugs such as propofol, dexamethasone, meperidine, fentanyl, lorazepam, midazolam and morphine are in dangerously short supply and are badly needed to help dentists manage pain, infection and anxiety in their patients.

As you begin conferencing this legislation with its House companion, H.R. 5651, we urge the Senate to **insist on adoption of the following provisions in S. 3187:**

- ***Sterile injectable products.*** The House and Senate bills both require drug manufacturers to notify the FDA at least six months prior (or as soon as practicable) whenever certain drugs will be discontinued or their manufacture will be interrupted. Section 1001(a)¹ of the Senate bill expressly covers 'sterile injectable product[s]'; section 901(a)² of the House bill does not.

One might assume from the language that both bills cover the various sedatives, anesthetics, analgesics and anti-inflammatory drugs used in the dental office. However, the term 'sterile injectable product[s]' in section 1001(a) of the Senate bill makes clear that those products are covered.

- ***Stakeholder definitions.*** The House and Senate bills both provide for a number of plans, studies and reports to be developed. Both bills direct that these plans, studies and reports be developed in consultation with relevant stakeholders.

The Senate bill uses broad language to identify the relevant stakeholders, such as 'healthcare providers'³, 'outside stakeholders'⁴ and 'external stakeholders'⁵. Sections 905(c)⁶ and 906(10)⁷ of the House bill identify physicians, pharmacists and other health care specialties without the specific mention of 'dentists'.

No health care profession should be given undue preference as a relevant stakeholder. While we do not believe either bill would preclude dentists from participating, we support the Senate language on stakeholders because it is broad enough to help prevent such occurrences from happening.

- **Reporting by other entities.** Section 1001(a)⁸ of the Senate bill would establish a mechanism for health care providers to report evidence of a drug shortage. The House bill does not include such language.

A third-party reporting system may help identify shortages that have previously gone unreported by manufacturers.

Additionally, we urge the Senate to **recede to the House on the following provisions in H.R. 5651:**

- **Public access to shortage information.** The House and Senate bills both establish mechanisms for the FDA to maintain a list of drugs in shortage, document the reasons for the shortages and publish an estimate of when the shortages should be resolved. Section 902⁹ of the House bill *requires* the FDA to make this information public; section 1001(a)¹⁰ of the Senate bill does not.

Providers need to know what drugs are in shortage so they can quickly locate the best alternative drugs to treat their patients. By *requiring* the FDA to make this information public, section 902 of the House bill does more to ensure patient care will not be interrupted.

- **Coordination between HHS and DOJ.** Sections 901(a)¹¹ and 907¹² in the House bill require coordination between the Department of Health and Human Services (HHS) and the Department of Justice (DOJ) on controlled substances that are in short supply.

Additionally, section 903¹³ allows the HHS Secretary to request an increase in DOJ's aggregate and individual controlled substance production quotas. The Attorney General must also justify any decision against raising such quotas.

Dentists rely on sedatives, anesthetics, analgesics and anti-inflammatory drugs to alleviate pain and anxiety associated with dental procedures and oral surgery. Dentists are experiencing chronic shortages of these controlled substances even though many are subject to quotas. It is, therefore, vital that HHS and the DOJ work together to ensure the availability of these drugs for our patients.

We applaud both chambers for taking up this important issue. If you have any questions, please contact Ms. Jeanne Tuerk at the American Association of Oral and Maxillofacial Surgeons. Jeanne can be reached at 800-822-6637 or jtuerk@aaoms.org.

Sincerely,

Academy of General Dentistry
American Academy of Oral and Maxillofacial Pathology
American Academy of Pediatric Dentistry
American Association of Oral and Maxillofacial Surgeons
American Association of Orthodontists
American College of Prosthodontists
American Dental Association
American Society of Dentist Anesthesiologists
Hispanic Dental Association

References

- ¹ S. 3187, sec. 1001(a), page 308, line 21.
- ² H.R. 5651, sec. 901(a), page 274, line 24.
- ³ S. 3187, sec. 1001(a), page 313, line 5.
- ⁴ S. 3187, sec. 1001(a), page 311, line 2.
- ⁵ S. 3187, sec. 1001(a), page 311, line 21.
- ⁶ H.R. 5651, sec. 905(c), page 285, line 12.
- ⁷ H.R. 5651, sec. 906(10), page 288, line 14.
- ⁸ S. 3187, sec. 1001(a), page 313, line 3.
- ⁹ H.R. 5651, sec. 902, page 280, Line 13.
- ¹⁰ S. 3187, sec. 1001(a), page 317, line 12.
- ¹¹ H.R. 5651, sec. 901(a), page 276, line 7.
- ¹² H.R. 5651, sec. 907, page 288, line 22.
- ¹³ H.R. 5651, sec. 903, page 281, line 4.