

June 15, 2012

Honorable Fred Upton  
Chair, House Committee on  
Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

Honorable Henry A. Waxman  
Ranking Member, House Committee on  
Energy and Commerce  
2322A Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman:

Our organizations are pleased that the House passed H.R. 5651, the Food and Drug Administration Reform Act of 2012. This legislation would reauthorize the Food and Drug Administration's (FDA's) user fee programs. We are especially pleased with the provisions in Title IX, 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 Senate companion, S. 3187, we urge the House to **insist on adoption of 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 902<sup>1</sup> of the House bill *requires* the FDA to make this information public; section 1001(a)<sup>2</sup> 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)<sup>3</sup> and 907<sup>4</sup> 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 903<sup>5</sup> 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.

Additionally, we urge the House to **recede to the Senate on 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)<sup>6</sup> of the Senate bill expressly covers ‘sterile injectable product[s]’; section 901(a)<sup>7</sup> 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’<sup>8</sup>, ‘outside stakeholders’<sup>9</sup> and ‘external stakeholders’<sup>10</sup>. Sections 905(c)<sup>11</sup> and 906(10)<sup>12</sup> 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)<sup>13</sup> 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.

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](mailto: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

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