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June 7, 2012

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 Chairman Harkin, Ranking Member Enzi, Chairman Upton, and Ranking Member Waxman:

On behalf of the physician and medical student members of the American Medical Association (AMA), I would like to thank you for your leadership and commitment to seeking broad consensus in order to achieve passage of S. 3187, the "Food and Drug Administration Safety and Innovation Act" in the U.S. Senate and H.R. 5651, "Food and Drug Administration Reform Act of 2012," in the U.S. House of Representatives. As Congress reconciles S. 3187 and H.R. 5651, the AMA would like to share the following comments:

User Fee Agreements

The AMA broadly supports the drug, generic, biological product, and medical device user fee provisions in both bills which will ensure that the Food and Drug Administration (FDA) has the essential resources needed to provide timely review and oversight of brand and generic drugs, biological products, and medical devices. We are particularly pleased with the passage of the new generic drug user fee provisions which would reduce FDA review and approval time for such products from an average of thirty months to nine months. Processing the significant back log of generic drug applications will reduce costs throughout the health care delivery system, facilitate the availability of affordable treatments to patients, and help address the current drug shortage crisis.

Unique Device Identifier

The AMA supports the establishment of a national unique device identification (UDI) system as an important means to promote patient safety. Although the Food and Drug Administration Amendments Act of 2007 required the FDA to implement a mandatory national UDI system, the agency has not released final implementing regulations. We appreciate that both S. 3187 and H.R. 5651 contain a provision that would require the FDA to take the necessary steps to move forward in order to implement a national UDI system. We recommend that the conference agreement include the S. 3187 provision directing the FDA to finalize the regulations within six months following the close of the comment period, and to implement a national UDI system within two years after issuance of the final regulation. A national UDI system will improve clinical care and lead to an estimated \$16 billion reduction in medical supply chain costs.

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Generating Antibiotic Incentives Now

Antibiotic resistance represents a serious and growing public health risk, even more so as the number of manufacturers developing next generation antibiotics has dramatically dwindled. We appreciate the inclusion of meaningful and necessary regulatory modifications in S. 3187 and H.R. 5651 to incentivize research, development, and manufacture of such antibiotics. The AMA supports S. 3187/H.R. 5651 provisions that would extend market exclusivity for next generation antibiotics. In addition, the AMA supports additional regulatory incentives such as priority review and fast track product status as contained in S. 3187 in the final conference agreement. The AMA also supports a study evaluating the impact of any new regulatory incentives and a reassessment in five years consistent with H.R. 5651.

Averting and Mitigating Drug Shortages

The AMA applauds your leadership and efforts to combat drug shortages that increase health care costs and compromise the health and well-being of patients. The current widespread shortages of clinically important drugs has generated a cascade of clinical problems and costs that have consumed tremendous resources and undermined the ability of physicians to help patients achieve or maintain positive health outcomes. We are encouraged that both bills contain provisions that will expand the authorities available to the FDA to avert or mitigate drug shortages and engage relevant stakeholders that are able to work with the FDA and others when shortages occur.

We urge you to require manufacturers to provide the FDA notice of an anticipated shortage or production cessation of a drug or biological that is life-supporting, life-sustaining, intended for use in the prevention of a debilitating disease or condition, a sterile injectable product, or used in emergency medical care or during surgery, consistent with S. 3187. The AMA also strongly recommends the exclusion of any explicit exceptions to the foregoing criteria. We urge you to include manufacturers of biological products upon enactment of the final legislation.

While S. 3187 provides the FDA with the authority to include biologicals through agency rule-making, the typical process is lengthy and will hinder the agency's ability to avert or mitigate biological shortages in the interim.

In the conference agreement, the AMA also urges the inclusion of provisions of H.R. 5651 that would require the U.S. Drug Enforcement Agency (DEA) to work with the FDA to avert or ameliorate drugs shortages where the manufacturers of shortage drugs are limited by a DEA quota. FDA and DEA cooperation is needed in the development of quotas for manufacturers producing drugs that are subject to the Controlled Substances Act and are vulnerable to shortages.

On the other hand, the AMA is concerned that overly prescriptive requirements that direct the FDA to conduct expedited reviews for drugs or biologicals in shortage as provided in H.R. 5651, could overwhelm FDA resources and siphon them away from shortages that could be averted or turned around. We urge you to ensure that the FDA retains the maximum discretion and flexibility to respond to anticipated or actual shortages.

Finally, the AMA applauds the provision in both bills that direct the Comptroller General to examine and prepare a report on the causes that contribute to drug shortages. We urge a broad examination of the issue consistent with what should also include a review of the factors that lead to the stockpiling and the grey market that exacerbates shortages.

Changes in the Controlled Substances Act

The AMA supports the inclusion in the conference agreement of the provision in S. 3187 that would place various synthetic chemical substances in Schedule I of the Controlled Substances Act. Adding these substances 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, but in addition have led to self-mutilation, violent behavior and deaths. There is no known medicinal use for these harmful synthetic stimulants and hallucinogenic substances, which have been banned in several countries, as well as in numerous states and municipalities.

The AMA has significant concerns with the inclusion of a provision in S. 3187 to reclassify hydrocodone containing combination products from Schedule III to Schedule II controlled substances. While we strongly support efforts to prevent the abuse of such products, we fear that this approach will unintentionally limit patient access to legitimately needed pain treatment. This reclassification will be especially problematic for nursing home and hospice patients in need of immediate pain care.

Due to unresolved regulatory hurdles, many patients today experiencing acute pain in nursing and hospice care facilities are facing significant delays in getting needed Schedule II medications. For example, physicians are often not on site at these care settings and are therefore at times unable to provide written prescriptions (as required for Schedule II drugs) in a timely manner. The reclassification of hydrocodone-containing combination products will only serve to expand the scope and severity of this problem resulting in more patients suffering from untreated pain. The AMA and a coalition of stakeholders continue to raise these concerns with the DEA and possible solutions are under consideration within the relevant Committees of jurisdiction in Congress.

The AMA welcomes the opportunity to continue working closely with Congress to develop a multi-pronged strategy to combat the epidemic of prescription drug abuse and diversion. However, we also urge you to give full consideration to the potentially harmful consequences of reclassifying hydrocodone-containing combination products to ensure that vulnerable patient populations do not lose access to effective medicines that help alleviate their pain.

Combating Prescription Drug Abuse and Diversion

The AMA is pleased with the inclusion of key provisions in S. 3187 and H.R. 5651 that will add to the arsenal of strategies needed to combat prescription drug abuse and diversion. We have strongly supported and led efforts to curb the epidemic of prescription drug abuse. The complexity and geographic variability of this crisis requires concerted engagement of a diverse array of stakeholders at the federal and state level. We are committed to working with Congress (and others) to identify and implement effective measures that address this national crisis. Since the early 1990s, the AMA has advocated for tools that physicians are able to use at the point-of-care to identify patients who are engaged in a pattern of medication misuse or diversion. The AMA continues to promote a broad range of strategies, including the passage of H.R. 866, the "National All Schedules Prescription Electronic Reporting Reauthorization Act of 2011" (NASPER 2011), with a public health focus and full appropriations. Therefore, we strongly support the provisions in both bills that require the U.S. Department of Health & Human Services (HHS) to identify gaps and opportunities to ensure the safe use and disposal of prescription drugs. We also strongly support the provisions in both bills that require HHS to identify and share prescription drug monitoring program best practices including those related to interoperability and to leverage existing resources in new ways. The AMA supports a public health approach to S. 3187.

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Tanning Bed Notice and Disclosures

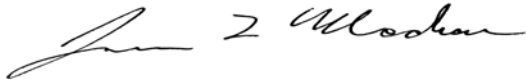
The AMA supports the language in S. 3187 that would require the Secretary of HHS to determine whether warning labels on tanning beds need to be strengthened to clearly convey the risks such products pose for the development of irreversible damage to the eyes and skin, including skin cancer.

Deterring Rogue Online Pharmacies

The AMA supports the S. 3187 provision that requires the Comptroller General to evaluate and prepare a report on the problems posed by pharmacy rogue online pharmacies that violate federal or state law. We urge the inclusion of this provision in the conference agreement.

We applaud your efforts and appreciate your consideration of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and a stylized "M".

James L. Madara, MD