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AdvaMed
Advanced Medical Technology Association

November 1, 2011

Elizabeth M. Murphy, Secretary
Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549

RE: File # S7-40-10 (SEC Initiatives under the Dodd-Frank Act---Special Disclosures Section 1502 – Conflict Minerals)

Via email: rule-comments@sec.gov

Dear Secretary Murphy:

On behalf of its members, AdvaMed is writing to provide additional comments in response to the Proposed Rule published by the Securities and Exchange Commission (SEC) to implement Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act).

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

We support the underlying goal of Sec. 1502 to address the atrocities occurring in the Democratic Republic of Congo (DRC) and adjoining countries, however, as we stated in our initial comments on Februrary 28, 2011, we believe the proposed rule is overly burdensome and could be modified to achieve the stated goal of the Dodd-Frank Act with less burdensome measures. We believe the SEC should be mindful of President Obama's Executive Order (Executive Order 13563) "Improving Regulation and Regulatory Review," as well as the SEC's own statutory mandate to consider the effect of any new rule on "efficiency, competition, and capital formation."

AdvaMed has already submitted comments in response to the proposed rule. We also endorsed the comments provided to you by the National Association of Manufacturers (NAM). In response to the re-opening of the comment period to address issued discussed during the October 18, 2011 SEC Round Table, we provide the following additional information and comments on issues of particular interest to AdvaMed members.

*Costs of Initial and Ongoing Compliance*

During its October 18 Round Table, SEC officials specifically asked that comments address the cost of compliance. Since the close of the initial comment period, several new cost estimates have been released from a variety of sources, and every estimate far exceeds the SEC's own cost estimates for industry compliance. This month, a Tulane University report estimated the total cost to industry at $7.9 billion.[1] A more conservative estimate, calculated by Claigan Environmental Consulting, still puts the cost to industry near or at $1 billion. The SEC has a statutory mandate to consider the effect of any new rule on "efficiency, competition, and capital formation."[2] In view of that mandate, as well as the fact that, by several independent accounts, the SEC has drastically underestimated the cost of compliance, we urge the SEC to re-examine the true costs that the proposed rule will have on industry as a whole.

*Costs and Implications for Medical Device Manufacturers*

The Claigan Environmental Consulting estimate referenced above is based on an assumption that most companies will spend a minimum of 0.05% of annual revenues on initial compliance with the rule. That number could jump to 0.5% if companies are required or encouraged to dispose of current inventories of minerals of undetermined origin. Actual, documented costs of compliance with RoHS, a European Union Directive in effect since 2006, are closer to 0.8% of annual revenues.[3]

In the United States, publicly traded manufacturers of medical technology had combined revenues of $205 billion in 2010.[4] Using even the most conservative estimates from above (0.05% of revenue), this would result in $103 million in initial compliance costs for the medical technology industry – an industry already under increasing pressure from Congress, the Administration, and the public to constrain costs. Using estimates from other sources, the true costs could be drastically higher. Though it is difficult to assign a particular percentage of the total cost to the medical device industry using the Tulane methodology, it is safe to assume that a reasonable calculation would far outweigh both the SEC's initial cost estimates as well as the Claigan calculations.

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[1] Bayer, et. al., *A Critical Analysis of the SEC and NAM Economic Impact Models and the Proposal of a Third Model*, Tulane University Law School, Oct. 17, 2011 (available at: http://www.payson.tulane.edu/assets/files/3rd_Economic_Impact_Model-Conflict_Minerals.pdf).
[2] 15 U.S.C. §§ 78c(f). This statutory provision was at issue in *Business Round Table v. SEC*, 647 F.3d 1144 (2011), in which the U.S. Court of Appeals for the District of Columbia Circuit struck down an SEC rule for "fail[ing] adequately to assess the economic effects of a new rule."
[3] RoHS compliance costs are somewhat analogous; however RoHS contains a de minimis exception for small quantities of covered materials. Costs of compliance with Sec. 1502 could prove even higher given the lack of a similar de minimis exception.
[4] Ernst & Young, *Pulse of the Industry: Medical Technology Report 2011* (available at: www.lifechanginginnovation.org)

None of these estimates take into account the costs that a company would incur if forced to abruptly change suppliers in order to comply with the rule or if a supplier were to change a key material due to the rule. Such a scenario could have significant FDA regulatory implications, which bear their own significant costs. Medical devices may only be marketed in accordance with the specifications included in the manufacturer's FDA filings – this includes information pertaining to manufacturing processes and materials. Any alteration in the manufacturing process or materials could result in the temporary unavailability of a device, costly revisions and re-submission of data to the FDA, or both.

Lastly, we would echo the recent submission of the Small Business Administration, in which the SBA stated that the SEC's initial regulatory flexibility analysis underestimated the cost to small businesses, as well as the number of small businesses potentially affected by this rule. A large portion of AdvaMed's membership consists of smaller, emerging growth companies; these companies, along with small businesses that supply all affected issuers, will face significant hurdles in complying with the proposed rule.

As we stated in our February 28, 2011 comment letter, it is unavoidable that tin, tungsten, tantalum, and gold will be used as part of FDA-approved medical devices. There are currently no substitutes for these minerals, used in a variety of implantable and electronic medical devices, and their continued use is vital to ensure the safety and efficacy of medical devices. In addition, medical device manufacturers are far removed from the source of the conflict minerals, making compliance potentially even more costly. Given the necessity of using tin, tungsten, tantalum, and gold in these life-saving and life-sustaining devices, combined with the lengthy supply chain between a medical device manufacturer and the original smelter and mine, we urge the SEC to re-examine the proposed rule and make compliance a less costly endeavor for manufacturers of medical technology.

*Transition Period for Implementation*

As we advocated in our February 28 letter, we firmly believe that the SEC should establish transition rules for implementation of the regulation. We would refer you to that letter for our specific suggestions. Based on discussion during the October 18 Round Table however, we would emphasize the need for a three-year period during which companies may disclose that, after a reasonable inquiry, they are unable to determine the origin of conflict minerals used in manufacturing. Concurrent to these disclosures, manufacturers would communicate over that three-year period the need for up-stream suppliers and smelters to put in place tracking and verification programs so that companies will be able to make a more definite determination on the source of the minerals used in manufacturing following the transition period.

The transition period would serve two important goals. First, as stated, it would allow up-stream suppliers the time to put programs in place so that issuers will be able to certify to the source of conflict minerals with much more confidence. Second, it would address the fact that many manufacturers and suppliers have large stockpiles of conflict minerals and inventories of products containing conflict minerals on hand – for most of these minerals, it will be impossible to determine the source.

*Recycled Materials*

As stated by many of the panelists during the October 18 Round Table, the final rule should include an alternative approach for recycled or scrap sources. The same standard for determining that the minerals did not originate from conflict mines in the DRC or adjoining countries should apply to recycled materials, and if the minerals are determined to be recycled or scrap minerals, the issuer should be permitted to end the inquiry at that point – without submitting a Conflict Minerals Report and undertaking the associated audit. Under such a system, issuers are still accountable to the SEC for providing fraudulent information and thus cannot simply state that their metals are recycled without inquiring of the origin.

*Standardized Reporting Requirements*

Finally, we urge the SEC to clarify the standard that companies should use in determining the presence of conflict minerals in manufactured products. Often, medical device manufacturers receive components from first-tier suppliers with declarations based on information contained within safety data sheets from second and third-tier suppliers. These declarations may not list the presence of conflict minerals as the concentrations are not sufficient to be declared on the safety data sheets (less than 0.1% of the material for toxic substances and less than 1% for hazardous substances). It would be unreasonable to expect companies to report the presence of minerals in such minute quantities, and we would recommend that materials below the 0.1% threshold not be subject to reporting.

AdvaMed appreciates this opportunity to provide comments on the proposed rule to implement Sec. 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. We encourage you to carefully consider these comments, as well as our prior comments and the prior comments submitted by the National Association of Manufacturers. We also restate our request that the SEC review this proposed rule and subsequent revisions in compliance with Executive Order 13563.

Sincerely,

Andrew Van Haute
Associate General Counsel