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February 28, 2011

Mary L. Schapiro, Chairman  
Securities and Exchange Commission  
100 F Street, N.E.  
Washington, DC 20549

RE: SEC Initiatives under the Dodd-Frank Act---Special Disclosures Section 1502 (Conflict Minerals)

Via email: [rule-comments@sec.gov](mailto:rule-comments@sec.gov)

Dear Chairman Schapiro:

On behalf of its members, AdvaMed is writing to provide 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, 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". It states that our regulatory system "must identify and use the best, most innovative and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements."

AdvaMed has endorsed the comments provided to you by the National Association of Manufacturers (NAM). We provide the following additional information and comments on issues of particular interest to AdvaMed members.

To achieve the goals of the law without placing undue burdens on industries or undermining the diplomatic efforts underway in the region, AdvaMed believes that the SEC needs to:

1. state clearly the legal standard for compliance (i.e., that an audit of a company's due diligence efforts is acceptable in place of a product-based or materials certification approach);
2. adopt a set of transition rules that recognizes the current infrastructure limitations;
3. minimize unnecessary or unwarranted harm to company brands through inexact designation of products;
4. apply the regulation only to those issuers that have control over production and supplier sourcing; and
5. allow issuers to furnish a separate report to the SEC in lieu of adding conflict mineral disclosures to the annual report.

*Use of conflict minerals in medical devices*

Given the wide variety of medical devices, it is unavoidable that conflict minerals will be used as part of US FDA approved medical devices. For example, tin and gold are used for soldering metals; tungsten and tantalum are used for their radiopaque characteristics in implantable medical devices. Tantalum capacitors are used in many electronic medical devices. As there are currently no substitutes for these minerals, the continued sourcing of these minerals is necessary to ensure the safety and efficacy of medical devices.

Although conflict minerals are used in these medical devices, medical device manufacturers are far removed from the source of the conflict minerals. As the manufacture of medical devices are tightly controlled due to their inherent quality requirements, medical device companies specify to their suppliers the materials which are required to be present in purchased parts. Conflict minerals are specified for certain parts based upon their characteristics which are essential for the appropriate function and safety of the device. Typically, medical device companies may source parts with conflict minerals in a sub-assembly or part which is then incorporated within the larger medical device. The supplier of these parts is likely a distributor who buys these parts from many manufacturers who subsequently purchases the material (e.g., conflict mineral containing solder, wire, etc.) from another manufacturer who may source from a smelter.

*Transition Period for Implementation*

As a result of the complexity of the supply chain, we firmly believe that the SEC should establish transition rules for implementation of the regulation. Specifically, we believe a transition period is needed for the disclosure requirements. Many medical device companies have initiated requests within their supply chain as to the geographical source of conflict minerals. Many distributors (the source of the parts or subassemblies purchased) do not have information as to the source of the conflict mineral present in the part/subassembly. It will take time and education throughout the supply chain to obtain this information. A transition period should be implemented which first documents conflict minerals that are derived from metal smelted on or after January 1, 2012.

Such a transition would accomplish several purposes. It would provide issuers an opportunity to put in place smelter verification programs covering a greater portion of the smelting industry, thus limiting the need to report unknown origins due to having material in inventory that entered the downstream flow prior to having any visibility of the origin of ore used by the smelters. Similarly, it would allow issuers time needed to communicate through their supply chains the expectation that conflict-supporting minerals will not be provided, and to work through the system inventories of metal whose origin is not known. The medical device industry would utilize this transition period to ensure Tier 1 supplier contracts include a commitment that they maintain a policy requiring identification of the source of the materials, and that they do not purchase from conflict areas. In addition, the medical device industry routinely audits their suppliers as part of their supplier quality program and will further communicate and train suppliers as to the conflict mineral requirements.

This transition period is not prohibited by the law and would result in a practical implementation of the rule while minimizing undue burden and cost to industry. Without a phased-in approach, all levels in the supply chain would be duplicatively attempting to obtain the same information, wasting effort, time and cost. It would also recognize that the needed infrastructure and capacity to comply with the regulation does not yet exist, which makes it practically impossible for issuers to comply with the proposed rule. Requiring the medical device industry to query their supply chain for the origin of conflict minerals at this time would likely result in reports of unknown origins as distributors and manufacturers actually utilizing the conflict minerals have not yet had the opportunity to educate their supply chain and obtain the needed information.

The proposed phase-in schedule is consistent with the statutory requirements. All issuers will be held accountable for the information they provide to the SEC. If they knowingly or willfully provide false information, the issuer would be subject to SEC penalties.

Subsequently, in 2012-2014, medical device companies should disclose to the SEC based upon one of three options:

1. **Negative Determination:** If the conflict minerals are not from the DRC or adjoining countries, the issuer would furnish to the SEC a separate disclosure to

the SEC stating that based on its reasonable inquiry to its supplier the minerals were not sourced from the DRC or adjoining countries.

2. **Positive Determination:** If the conflict minerals did originate from the DRC or adjoining countries, the issuer would furnish a separate CMR report on its due diligence to the SEC and publish the CMR on its company's website.
3. **Unknown Determination:** If the issuer is unable to determine the origin after a reasonable inquiry to its supplier, the issuer shall furnish a separate disclosure to the SEC and make it available on its website stating the following:
  - the company's conflict minerals policy
  - the company's reasonable inquiry to determine the origin
  - the conflict minerals used in its supply chain

Such disclosure would be subject to the Commerce Department's review to determination if the issuers' statement is unreliable.

It is likely that the majority of information reported by the medical device industry will likely be 'unknown determination' until the supply chain has been able to obtain and process the information. However, as the legislation is communicated throughout the supply chain, 'unknown determinations' should diminish over the course of three years (approximately 2015).

Our phase-in proposal is also consistent with the requirements of the law. Sec. 1502 (b) requires companies:

"to disclose annually whether conflict minerals that are necessary... did originate in the Democratic Republic of the Congo...and in cases in which such conflict minerals did originate [to] submit to the Commissioner a report.."

It is our position that such language only requires and creates an affirmative obligation to disclose and submit a conflict minerals report if the issuer knows that the minerals in its products originated in the DRC or adjoining countries. If the issuer does not have actual knowledge that the minerals originated from the DRC, the authorizing statute creates no further obligation for the issuer. Therefore, it is within the SEC's discretion to create a third category for an unknown determination.

#### Recycled Materials

The final rule should include an alternative approach for recycled or scrap sources but the approach as proposed requiring issuers using conflict minerals from recycled or scrap sources to furnish a CMR including a certified independent private sector audit is unworkable and will significantly discourage the use of recycled materials. Issuers who purchase metals as raw material should be able to determine based on a reasonable inquiry if the metals are

recycled or scrap. 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. 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.

Subjecting recycled materials to the same requirements as “conflict full” material intrinsically does not make sense. By the very nature of the material, an issuer using recycled material will not be able to provide any of the details required in a CMR. Recycled materials may be weeks or decades old. In any event, the origin is impossible to determine. Instead, issuers should have a reasonable basis for believing the material is recycled and maintain auditable records to support the determination.

We urge the SEC to reconsider its treatment of scrap and recycled conflict minerals. There is not a statutory requirement for issuers to execute due diligence and create a CMR for recycled or scrap conflict minerals. We believe recycled conflict minerals should have parity with conflict minerals originating from a conflict-free mine so as to encourage manufacturers to use recycled and scrap materials, to reduce the demand for minerals that would support armed groups in the DRC and adjoining countries, and to maintain a fair market for metals and minerals. This could be accomplished by providing that after a manufacturer conducts a reasonable inquiry into the source of its conflict minerals no further action is required if either: (1) the minerals were determined to originate not from the DRC or adjoining countries, or (2) the minerals originated from a scrap or recycled source.

#### *De Minimis Standard*

The conflict minerals identified by the legislation are used in a vast number of products in varying quantities and for various purposes. It is generally impossible for companies to trace the minerals in every product in which they are used. Furthermore, companies that utilize small quantities of these materials will have to deploy a disproportional amount of resources to comply with the regulation. We believe a *de minimis* standard is critical. We acknowledge that how such a standard is created and applied is difficult but by working together with industry and other governmental agencies, the SEC should craft a standard that recognizes the diversity of products that contain the minerals and the uses for the minerals without diminishing the impact of the legislation on the overall cause. Typically, if the legislation doesn't specifically prohibit the agency from creating a *de minimis* standard then it is at the discretion of the agency to do so. We encourage the SEC to develop an appropriate *de minimis* standard.

In numerous other regulations in which companies are required to trace raw materials, a *de minimis* standard is created (e.g., REACH, RoHS, the Barry Amendment). A *de minimis* standard is not a loophole or exemption, and it will not decrease efforts to increase supply chain transparency. Rather, it allows the SEC and issuers to focus on the products containing a significant amount of the conflict minerals in a manner that will change supply chain behavior.

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A *de minimis* threshold is needed to alleviate the need for companies to trace truly “insignificant” amounts that would be virtually impossible to trace. To try to trace these small amounts would be prohibitively costly, and even after spending significant time and financial resources would still in all likelihood be untraceable.

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 the comments provided by the National Association of Manufacturers and our specific issues. We also restate our request that the SEC review this proposed rule and subsequent revisions in compliance with Executive Order 13563.

Sincerely,

A handwritten signature in blue ink that reads "Ruey C. Dempsey". The signature is fluid and cursive, with a long horizontal stroke at the end.

Ruey C. Dempsey RAC  
Director  
Technology and Regulatory Affairs