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August 30, 2016

Brent J. Fields  
Secretary  
Securities and Exchange Commission  
100 F Street NE  
Washington, DC 20549-0609

To whom it may concern:

The Advanced Medical Technology Association (“AdvaMed”) is pleased to provide the following comments to the Securities and Exchange Commission (“SEC”) on File No. S7-12-16, its proposed rule to amend the smaller reporting company (“SRC”) definition. The SEC’s issuer classifications directly impact AdvaMed members, which include companies that both currently trade on the public market or are seeking an IPO to fund the development and commercialization of life-changing medical technologies. We are hopeful that the final rule will reform the small company definitions under Regulation S-K, Rule 12b-2, and Rule 405 in such a way that fulfills the SEC’s mission to protect investors; maintain fair, orderly, and efficient markets; and perhaps currently most important to small medtech companies – facilitate capital formation.

AdvaMed is the world’s largest trade association representing medical device and diagnostics manufacturers. AdvaMed's member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 300 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed Accel is the division within AdvaMed dedicated to addressing the unique needs and challenges of these smaller medical device and diagnostics manufacturers – the lifeblood of the medical technology industry. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

The medical technology industry is heavily skewed toward small companies—the kind of companies that begin with a scientist or doctor with an idea to improve patient care. More than two-thirds of the medical technology firms in the U.S. have fewer than 20 employees – the majority of these companies being in pre-revenue or early revenue stages. A high proportion of the breakthrough products in our industry come from these small, often venture-capital funded companies. The long-term health of the whole industry depends on the continued success of these small firms and their access to the capital necessary to develop the breakthrough products of the future. Access to this capital is further dependent on the ability of investors to recoup their investment through an exit event (an IPO being one important path) – allowing for reinvestment and continued capital flow into this vital industry. If the United States is to remain competitive, there must be policies in place to incentivize financial investment in promising next generation medical technology companies to create breakthrough products and high-quality jobs. In



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recent years, investment in these companies has been declining significantly – a disturbing trend for our industry. Amendments to the SRC definition will aid in reversing this trend.

***AdvaMed supports the proposed reforms to the smaller reporting company definition.***

The proposed rule would allow companies with a public float below \$250 million to qualify as SRCs, a significant change from the current \$75 million public float cap. In the absence of public float, the proposed rule would allow companies to qualify based on a \$100 million revenue test, an increase from the \$50 million test in the existing definition. AdvaMed believes that these changes, which would increase the number of small companies eligible to provide scaled disclosures under Regulation S-K and Regulation S-X, would more accurately reflect the nature of emerging businesses and allow them to tailor their compliance obligations accordingly. In an industry subject to increasing regulations from various government agencies across the globe, resource efficiency is key to emerging and early-growth medtech companies. Resources required for complying with such regulations are typically pulled from research and development efforts, hindering the progress of medical technology. AdvaMed believes that these proposed standards appropriately balance capital formation and investor protection and would also promote capital formation and liquidity.

We appreciate that the SEC has acknowledged that the \$75 million public float marker in the current SRC definition is inaccurate and overly restrictive. We also encourage the SEC to apply the same reasoning to the non-accelerated filer definition.

***AdvaMed urges the SEC to adopt reforms to the non-accelerated filer definition in order to expand eligibility for the permanent exemption from Sarbanes-Oxley Section 404(b) established by Dodd-Frank.***

AdvaMed applauds the SEC for taking the encouraging first step of proposing an increased public float threshold for the SRC definition, and we urge the SEC to also extend this reform to the non-accelerated filer definition. We also support an alternative revenue test for both definitions to ensure that pre-revenue companies, who may be highly valued, are not improperly classified.

The SRC and non-accelerated filer definitions are vital components of the SEC's framework for small company regulation. By providing growing businesses with scaled disclosure opportunities, these issuer categorizations allow for important cost savings that decrease the amount of innovation capital diverted to reporting compliance from research and development activities. As such, AdvaMed commends the SEC for considering expansions of these classifications in order to “promote capital formation and reduce compliance costs for smaller registrants while maintaining investor protections.”

SOX Section 404(b) is extremely costly for emerging businesses. Congress recognized this reality when it exempted non-accelerated filers from SOX 404(b) compliance in Dodd-Frank, and again when it exempted emerging growth companies (“EGCs”) in the JOBS Act.<sup>1</sup> AdvaMed believes that the SEC should apply any reforms it makes to the SRC definition to the non-accelerated filer definition in order to broaden the exemption from Section 404(b)'s costly external auditor attestation requirement.

AdvaMed recommends that all companies with a public float below \$250 million be considered both SRCs and non-accelerated filers.

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<sup>1</sup> Note that the EGC definition (and associated SOX 404(b) exemption) set by Congress – annual revenues below \$1 billion and public float below \$700 million – is much more far-reaching than any proposed definition for SRCs or non-accelerated filers.

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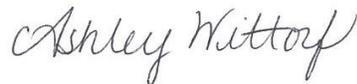
***AdvaMed supports an alternative revenue test for highly valued pre-revenue companies to qualify as SRCs and non-accelerated filers.***

AdvaMed believes that the SEC should institute an alternative revenue test for both the SRC and non-accelerated filer definitions so as to avoid stifling the advancement of emerging growth medtech companies that face costly compliance burdens like SOX 404(b), which often serve as roadblocks on the decades-long path to commercializing a new medical technology.

In conclusion, we commend the SEC for being willing to re-examine the SRC classification, and we encourage the SEC to extend this effort to the non-accelerated filer definition to more accurately reflect America's small businesses. As the SEC considers how to craft the SRC and non-accelerated filer definitions, AdvaMed urges it to consider the impact that costly regulations can have on emerging growth companies. Reforming the SRC and non-accelerated filer definitions, and including revenue as a component in that determination, would represent a positive change in our members' ability to access capital on the public market and utilize that capital to deliver life-changing technologies to the patients that need them most.

Please contact me with any questions or comments.

Sincerely,

A handwritten signature in cursive script that reads "Ashley Wittorf".

Ashley Wittorf