



Hearing Testimony
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On Behalf Of
The Biotechnology Industry Organization

Before the Small Business Committee
U.S. House of Representatives

“Sarbanes Oxley Section 404: What Is The Proper Balance Between Investor Protection
And Capital Formation For Smaller Public Companies?”

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Chairman Manzullo, Ranking Member Velazquez, and the Members of the Small
Business Committee:

Thank you for providing the opportunity to testify before you today on Sarbanes-Oxley
Section 404 and finding the proper balance between investor protection and capital
formation needs of smaller public companies.

My name is James Burns, President and CEO of EntreMed, a public biotechnology
company in Maryland. I have been involved in leading the development of
biotechnology companies and products for over 20 years. Founded in 1991, EntreMed is
a clinical-stage pharmaceutical company focusing on the development of next generation
multi-mechanism oncology and anti-inflammatory drugs that target disease cells directly
and the blood vessels that nourish them. Our focus is on the development of drugs that
are safe and convenient, providing the potential for improved patient outcomes. Our
Company has three drug candidates currently in clinical trials for cancer, as well as others
in preclinical development for oncology and non-oncology indications. Our Company
has no product sales, and will depend on continued investment capital for the foreseeable
future to maintain its clinical development programs.

Today, I am here to testify on behalf of the Biotechnology Industry Organization (BIO), an organization representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in 50 U.S. states and 31 other nations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The majority of BIO member companies are small, research and development oriented companies pursuing innovations that have the potential to improve human health, expand our food supply, and provide new sources of energy. My Company has a profile that is typical of the high-risk, capital-intensive, long lead-time, regulated business environment of the biotech industry.

As a representative of one of the most innovative high growth sectors of our nation's economy -- one in which the United States maintains a global leadership position—my testimony is tailored to the issues faced currently, or that will be faced, by emerging companies in the biotech sector – the microcap and smallcap companies who are among the driving forces of our Country's innovation leadership and competitiveness in the global market place.

One Size Does Not Fit All

Let me start by saying that we fully appreciate and agree with the Congressional intent behind Section 404 – ensuring that companies have in place effective policies, procedures and controls to protect against material misstatements in financial reports, and to protect against fraud. However, where Section 404 has gone awry is in the implementation of the requirements.

The current implementation of Section 404 is not tailored, and does not work, for smaller public companies. The one-size-fits-all approach of Section 404 is highly burdensome to smaller companies, and such companies are bearing disproportionate costs on a relative basis. This has been recognized, and documented, by the SEC Advisory Committee for Smaller Public Companies (Advisory Committee) in its Final Report, and by the 18-3 vote by the Advisory Committee in favor of Section 404 reform.

The reason for the increased cost burden is the imposition of an inflexible Section 404 on companies with fewer personnel, little or no revenues and minimal resources. Simply put, if the current 404 implementation continues to be imposed, or, in the case of non-accelerated filers, is imposed in the future, microcap and smallcap companies in our industry will be forced to endure internal processes and organizational changes that are completely contrary to the rapidly changing and highly-competitive markets in which we operate.

The Costs of the One-Size-Fits-All Approach to the Industry and U.S. Competitiveness

For most biotechnology companies, the actual costs of Section 404 compliance, including both internal costs as well as external auditor costs, are substantial. In fact, the opportunity costs of Section 404 for smaller companies can be even greater, impeding the

ability to invest in and even sometimes, to continue ongoing, critical research and development activities. Biotech companies are at the forefront of developing new treatments for many diseases, and biotech companies presently are engaged in over 350 clinical trials for over 200 diseases, from cancer to multiple sclerosis.

Under the requirements of Section 404, significant time and money are spent to put in place complex systems and processes dictated by the Auditing Standard No. 2 (AS2) and required by external auditors. If the current system is not changed, these effects will also be felt by non-accelerated filers as they prepare for compliance next year, as well as private companies preparing for an initial public offering of their stock.

As a specific example, one of BIO's member companies had five employees working on Section 404 compliance at a cost of approximately \$1 million per year. This company estimated that its controller spent approximately 35% of his time on Section 404, while the CFO spent approximately 20% of his time. To complete the mandated internal control processes and the "checklist" dictated by AS2, the company had to increase its accounting staff by 40%. Further, this company reports only a 7% decrease in costs in year two as compared to its first year of compliance.

Another public company member's experience shows the opportunity costs of Section 404 compliance. This company not only spent approximately \$500,000 on its external attestation of internal controls but also had to endure additional costs in terms of (i) the reassignment of laboratory research personnel to perform internal control work dictated by AS2 and the company's external auditors, (ii) the postponement of the hiring of 5-10 additional researchers, and (iii) the delay of promising R&D programs. Such diversion of resources away from research activities can delay critical product development and has, in turn, a deleterious effect on a company's ability to raise capital. To say the least, this is clearly an unintended and unfortunate consequence of Section 404.

It is the experience of BIO members that the current problems with Section 404 are not merely growing pains where the costs and burdens will decrease once the auditors and companies become more familiar with the process and requirements. The current implementation of Section 404 imposes the same requirements, steps and reviews on all companies, by the same individuals year after year. As a result, the costs are fixed and ongoing, impacting the long-term investment resources of microcap and smallcap companies.

For the investors, their confidence and trust in public companies may have increased as a result of the passage of SOX as a whole in spite of Section 404 and not necessarily because of it. The other provisions in SOX include whistleblower protections, increased enforcement powers, such as the SEC's increased ability to obtain officer and director bars, auditor independence requirements and, perhaps most importantly, CEO and CFO certifications of company financial statements under section 302 of SOX. As we saw in the first and second years of Section 404 implementation, investors and the market generally had no market reaction when a company reported a "material weakness" in

internal controls under Section 404.¹ As we discussed further above, the costs of the implementation of Section 404, particularly for smaller public companies, clearly outweigh any benefits that are directly related to Section 404.

The impact of Section 404 costs on the U.S. economy and our industry's competitiveness abroad is also of great concern. As many Members on the Committee may have undoubtedly heard and read, there is evidence that foreign firms, the largest of which will be subject to Section 404 compliance beginning July 15, 2006, are foregoing the U.S. markets and listing overseas due, in large part, to Section 404, not necessarily because of SOX in general. In addition, it is the experience of our private company members that an initial public offering is becoming less and less the optimum path to liquidity for their investors due to the timing issues associated with accessing the market while at the same time ensuring readiness for Section 404. This issue has been previously noted by the recently-appointed head of the Division of Corporation Finance at the SEC.² Further, there have been reports of increases in the number of companies "going private" or deregistering from the SEC in order to avoid the continued compliance burden of Section 404.

As currently implemented, we suspect the actual beneficiaries of Section 404 may be the large public auditing firms. Due to Section 404, audit firms now have a required audit process, entirely separate from the typical financial statement audit process, for which they charge fees almost equal to what they charge on a financial statement audit. This is rather ironic since this was clearly not the intent of Congress. The Senate Committee Report on Section 404 was specific: "The Committee does not intend that the auditor's evaluation be the subject of a *separate engagement or the basis for increased charges or fees* [emphasis added]". Such windfall is attributable not only to the process imposed by the large accounting firms but also to the AS2, as promulgated by the Public Company Accounting Oversight Board (PCAOB). The current standards are very prescriptive in the procedures auditors must go through to perform the separate attestations, with little room for auditor judgment.

Scaled Reform Needed for Smaller Public Companies

As embraced by the Advisory Committee in its final recommendations, it is critical that the Section 404 reform framework establishes a risk-based approach that provides scaled reforms based on a "revenue filter" condition. This approach recognizes that the level of risk and the level of product revenues are clearly interrelated and that the level of product revenues should drive the level of internal control procedures. An approach that scales Section 404 requirements based on the level of product revenues also provides a risk-based approach, more appropriate for microcap and smallcap companies in our industry. Biotechnology start-up companies early in their histories often have very limited product

¹ See, e.g., Neil O'Hara, *An Analysis of the (Non) Impact of SOX 404*, Compliance Week, March 8, 2005. In addition, at the 2005 SEC and PCAOB Roundtable on Section 404, a representative of Moody's on one of the panels stated that, of the 71 companies disclosing material weaknesses they considered in detail, they ultimately issued a negative rating action on 12, or 20%, of the companies. Thus, credit rating agencies had no adverse reaction to approximately 80% of the companies.

² See, the letter from John W. White, the new and current head of the Division of Corporation Finance at the SEC, submitted in connection with the SEC's 2005 Roundtable on Section 404, available at <http://www.sec.gov/news/press/4-497.shtml>.

revenues compared to their market capitalizations. For example, it is not uncommon for a public biotechnology company to have a market capitalization of \$700 million or greater with product revenues of \$1 million, or less.

Thus, BIO has urged the Securities and Exchange Commission (Commission) and the Public Company Accounting Oversight Board (PCAOB) to, as expeditiously as possible, take the necessary steps to adopt the following reform framework as recommended by the Advisory Committee:

- As per the Advisory Committee's recommendations, establish risk-based, scaled Section 404 reform for smaller public companies based on the level of product revenues (as defined in Section 5-03 of SEC Regulation S-X, 17 CFR 210.5-03, excluding revenues from license fees, and research and development payments, milestone payments, and other payments received from an unrelated third party before product sales have commenced under the terms of a collaborative contractual agreement to develop a product).
 - Provide full Section 404 relief for smallcap companies with less than \$10 million in annual product revenues and microcap companies with less than \$125 million in annual revenues.
 - Provide relief from the auditor attestation requirements of Section 404 and AS2 for microcap companies with between \$125 million and \$250 million in annual revenues, and for smallcap companies with less than \$250 million in annual revenues, but greater than \$10 million in annual product revenues.
 - Require that in order to take advantage of the above reforms, microcap and smallcap companies would be required to (i) comply with the audit committee requirements under Section 10A-3 of the Securities Exchange Act of 1934, and (ii) adopt (and disclose) a code of ethics applicable to directors, officers and employees in addition to other required corporate governance standards.
- If the Commission and PCAOB ultimately determine that an auditor attestation requirement is necessary for microcap and/or smallcap companies, it is imperative that the PCAOB re-open AS2 to revise the standards to devise a cost-effective, risk based standard that is tailored to the product revenue size and the level of complexity of smaller companies.
- For the smaller public companies, as defined by level of product revenues, the above reform framework should focus on the internal controls necessary for CEO and CFO certifications of company financials as currently required under Section 302 of the Sarbanes-Oxley Act. The proposed reform supports management's incentive to maintain effective systems of internal controls and produce accurate financial reports which are most important to the investors. Section 13(b)(2)(B) of the Exchange Act requires, as it has since 1977, that public companies maintain a system of internal controls that provide reasonable assurances as to the accuracy of financial reports.

The proposed reforms, in effect, would provide added assurances to investors based on the degree of risk and cost effectiveness while providing Section 404 relief for smaller public companies.

With the submission of the Advisory Committee's final reform recommendations on April 23, 2006, time has come for the Commission to act on the recommendations. It is critical now more than ever that the Commission take expeditious action, before non-accelerated filers have to start gearing up on and around July 15, 2006, for their compliance deadline in 2007. Without reform, the current Section 404 framework will continue to impose substantial cost burdens on smaller companies as a result of external auditors continuing to apply the same standards and methods across all companies, large and small.

Thank you for your time and consideration of our views. We urge the Committee to request expeditious action by the Commission on the Advisory Committee's reform recommendations for smaller public companies, providing the continued opportunity for high growth sectors to lead, innovate, and compete in the global market place.