

**THE STATEMENT OF THE
BIOTECHNOLOGY INDUSTRY ORGANIZATION ON
Sarbanes-Oxley Section 404: New Evidence on the Cost for Small Companies
BEFORE THE HOUSE SMALL BUSINESS COMMITTEE**

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**BIOTECHNOLOGY INDUSTRY ORGANIZATION
1201 MARYLAND AVENUE, SW, SUITE 900
WASHINGTON, D.C. 20024
(202) 962-9200
www.bio.org**

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide the perspective of its members on the implementation of Section 404 of the Sarbanes-Oxley Act. BIO represents over 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. The promise of biotechnology is immense, as our members combine biology and technology to deliver new treatments for unmet medical needs, improved crops that are more drought resistant and have reduced environmental impact, and create cheaper, more environmentally friendly fuels and consumer products. Biotech is one of the most innovative high growth sectors of our nation's economy, and one in which the United States maintains a global leadership position.

In 2003, the Sarbanes-Oxley Act of 2002 ("SOX" or "Sarbanes-Oxley") was signed into law providing a number of new requirements for financial reporting. While BIO members strongly support the Congressional intent behind SOX Section 404—to enhance investor protection and confidence—the implementation of Section 404 has unfortunately caused problems for many emerging biotechnology companies, including confusion and substantially greater than expected compliance costs.

For many emerging biotechnology companies, funds that would otherwise be spent for core research and development of new therapies for patients are instead used for overly complex controls or unnecessary evaluation of controls. Diversions of resources away from research activities can delay critical product development and have a detrimental effect on a company's ability to raise capital. 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 continue ongoing, critical research and development activities for treatments of an array of diseases, from cancer to multiple sclerosis.

The current problems faced by emerging biotechnology companies are not merely growing pains in which costs and burdens decrease as auditors and companies become more familiar with the process and requirements of Section 404. Rather, costs and burdens are fixed and ongoing, impacting the long-term investment resources of all microcap and smallcap including those on the forefront of developing new treatments for many diseases. Much of the implementation costs of Section 404 are a result of the SEC and PCAOB imposing the same requirements, steps and reviews on all companies, regardless of size. As a result, costs are disproportionately burdensome for emerging biotechnology companies that often have little or no product revenue to devote to additional compliance costs. Therefore, this shifts shareholder equity from core research functions to outside auditors.

SEC and PCAOB's New Standards

BIO commends both the Securities and Exchange Commission (SEC) and the Public Company Accounting Oversight Board (PCAOB) for taking steps to address some of the compliance problems that Section 404 audits had been creating for public companies. However, BIO remains concerned that the agencies' guidance, particularly to auditors, with respect to smaller public companies, may not live up to the high expectations the SEC and PCAOB have placed upon the new rules and guidance.

In July 2007, the SEC approved the PCAOB's Auditing Standard Number 5 (AS-5) to replace the old AS-2 standard in an attempt to mitigate the implementation costs of Section 404. Despite the previous recommendations of the SEC's Advisory Committee on Smaller Public Companies, as well as comments from a variety of industry groups including BIO, the SEC approved AS-5 without revisions necessary to ensure that smaller public companies will have the benefit of scaled audits. While BIO applauds the intent of AS-5, it does not appropriately give smaller companies the intended relief that will reduce compliance costs while maintaining the core principals of SOX.

Definition of Smaller Public Company

In removing all objective definitions of "smaller company" in AS-5 guidance, the SEC and PCAOB have failed to give smaller public companies any deference to be deserving of a scaled audit but rather have empowered auditors to continue to look at all companies the same, regardless of size. As recommended by the SEC's own Advisory Committee on Smaller Public Companies, a "smaller company" would include

"companies with a market capitalization of approximately \$700 million or less, with reported annual revenue of approximately \$250 million or less."

Removal of any reference to market capitalization or annual revenues deleted the only objective criteria for scalability. As a result, the final determination of "size and complexity of a company in planning and performing the audit" lies heavily on the shoulders of the auditor, thereby creating unfortunate conflicts of interest. First, auditors have an economic incentive to maximize profits by determining a company, independent of its size, as complex and therefore requiring a more extensive audit. Second, auditors currently face unlimited exposure to legal liability. This exposure understandably places their incentives in line with an overly ambitious audit of internal controls. Third, due to a lack of any penalties for being overly aggressive and creating unnecessary costs in an audit, there is no incentive for an auditor to be looking for ways to scale the audit.

To its credit, the PCAOB nevertheless continues to discuss smaller public company issues throughout the rule—at least thirteen times by our count. Yet it is a startling failure on PCAOB's part that it chose to no longer provide any definition of smaller company, while maintaining the subjective definition of less complex companies.

BIO and our member companies believe that an objective definition of "smaller company" is the best way to mitigate against the current auditor incentives toward unnecessarily burdensome and costly audits.

Product Revenue

BIO consistently advocates for scalability indicia that are most reflective of complexity. BIO supports the PCAOB's work to include the scalability criteria and guidance throughout the auditing standard. In order to achieve the benefits of the scalable approach, it is imperative that the auditors be encouraged to apply the criteria throughout the audit. In doing so, they minimize the combined threat of litigation and PCAOB examination based upon terms and definitions that are mandatory and inflexible, and discourages auditors from using the maximum degree of checklist compliance.

BIO believes that product revenue is the best indicator of complexity which could be used in conjunction with various attributes of smaller companies, such as market capitalization and overall revenue, and independently as proxies for complexity. The SEC Advisory Committee Final Report on Smaller Public Companies also recommended that a "revenue filter" be used as a tool to define a smaller public company when scaling an audit. However, the SEC and PCAOB chose not to include this objective criteria in its final AS-5 guidance.

Rather than limiting auditor judgment by linking various attributes of smaller companies such as market capitalization and overall revenue, the SEC and PCAOB should be looking for ways to provide the indicia to auditors that operate both in conjunction and independently as proxies for complexity.

Economic Cost-Benefit Studies

Lastly, BIO strongly believes that a rigorous economic study of the costs and benefits associated with implementation of Section 404 is imperative to understanding if the current reform proposals are meeting their objectives. Specifically, the SEC Office of Economic Analysis should be required to provide a quantitative annual cost estimate of the costs of complying with Section 404, for all companies, but specifically broken down between large companies, and "smaller companies" using the definition of the SEC Advisory Committee. These studies should be used annually in reassessing the usefulness and necessity for an audit of internal controls.

Conclusion

BIO appreciates the efforts that both agencies have taken to improve SOX implementation. It is unclear, however, whether these reforms will fully match the rhetoric surrounding their adoption. BIO remains hopeful that this is just the first of several steps both the PCAOB and the SEC will take in reducing the unnecessary burdens of Sarbanes-Oxley on America's emerging and innovative companies. Consistent oversight into the application of these new rules and consequent appreciation of how they are continuing to impact capital formation particularly for small companies will be critical to restoring the U.S. to its proper primacy in the global capital markets.