

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)
TECHNET
TELECOMMUNICATIONS INDUSTRY ASSOCIATION (TIA)
ELECTRONIC INDUSTRIES ALLIANCE (EIA)
SEMICONDUCTOR INDUSTRY ASSOCIATION (SIA)
ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (ADVAMED)
MEDICAL DEVICE MANUFACTURERS ASSOCIATION (MDMA)
ASSOCIATION OF BIOSCIENCE FINANCIAL OFFICERS (ABFO)
CALIFORNIA HEALTHCARE INSTITUTE (CHI)

September 12, 2006

Chairman Christopher Cox
Commissioner Paul S. Atkins
Commissioner Roel C. Campos
Commissioner Annette L. Nazareth
Commissioner Kathleen L. Casey
U.S. Securities and Exchange Commission
100 F Street, NE
Washington, DC 20549

Re: Concept Release Concerning Management's Reports on Internal Control Over Financial Reporting (File No. S7-11-06, Release No. 34-54122);

Internal Control Over Financial Reporting In Exchange Act Periodic Reports Of Non-Accelerated Filers and Newly Public Companies (File No. S7-06-03, Release No. 33-8731).

Dear Mr. Chairman and Commissioners:

On behalf of the biotechnology, healthcare technology, high technology, information and communications technology, electronics, and semiconductor industries, we urge the Securities and Exchange Commission to expeditiously adopt Section 404 reforms, in the form of a rule, based on a reform framework that is cost effective, "scaled", and "proportional" to the size and complexity of corporate structures.

Our member companies include the management of a majority of microcap and smallcap companies in the U.S. high-growth sectors. As we indicated in our letter to the Commission on April 3, 2006, we fully support the original goals of the Sarbanes-Oxley Act (SOX) and recognize the need for responsible internal control standards that create meaningful and transparent financial reporting for investors.

The implementation of the SOX Section 404 requirements, however, continues to have a significant impact on smaller public companies that is disproportional to its benefits for the investors. The result has been a negative impact on America's ability to innovate and maintain its

global competitiveness in the high-growth sectors of our nation's economy. For these reasons, we urge the Commission to expeditiously adopt Section 404 reforms as described below.

We welcome this opportunity to provide comments on the Concept Release and appreciate the Commission's recognition of the compliance challenges and costs faced by small businesses as detailed in the Final Report of the Advisory Committee for Smaller Public Companies (Advisory Committee) and the April 2006 report of the U.S. Government Accountability Office (GAO). It is our hope that the changes proposed by the Commission and the Public Company Accounting Oversight Board's (PCAOB) plans to provide further Auditing Standard #2 (AS2) reforms will be critical steps towards fundamental reform of Section 404 that addresses the significant compliance burdens on smaller public companies and supports innovation.

The Reform Framework Should Be Principles-Based

For the high-growth industries, the implementation of SOX Section 404 has had a significant impact on the long-term competitiveness of American companies and the U.S. capital markets. Section 404 has imposed cost burdens on high-growth companies and their management far beyond what Congress intended and what is needed to protect investors against corporate fraud. These disproportional compliance burdens have been described to the SEC and the PCAOB by participants in the Section 404 Year Two Roundtable discussions and were well documented in the Final Report by the Advisory Committee.¹

As currently implemented by the Commission and through the guidance provided by AS2, Section 404 places disproportional cost burdens on America's smaller companies, while specific benefits are difficult to identify.

As the Advisory Committee recommended after its year-long review of Section 404 impacts, without a revised implementation framework, the current "one-size-fits-all" approach of Section 404 and AS2 will continue to hamper the ability of smaller public companies to invest in research and development and to gain access to public capital markets, thereby jeopardizing the competitiveness of smaller companies.

To ensure the continued innovation and vitality of America's public companies, including the smaller companies engaged in the high-growth industries -- high technology, biotechnology, medical devices, electronics, telecommunications and semiconductors, as well as the American institutions that provide access to public capital -- **a principles-based reform framework should be adopted in the form of a rule by the SEC to be implemented through AS2 revisions.**

The Reform Framework Should Be Based On The Following Principles:

- Reforms must reflect rational cost/benefit balance. Cost burdens imposed by increasing complexity of required internal controls must yield increased benefits in assuring greater investor confidence.

¹ During the May 2006 SEC Roundtable on SOX Section 404 Year Two Compliance, the former SEC Commissioner Joe Grundfest also recommended fundamental Section 404 reforms for smaller public companies. Mr. Grundfest suggested that the Commission and PCAOB amend AS2 to incorporate many of the findings made by the Advisory Committee. He also recommended that AS2 reforms should redefine the objective of the control audit process so as to reduce auditors' incentive to examine controls that are unlikely to have material impact on smaller public companies. Fixing 404 by Joseph A. Grundfest, Stanford Law School, May 1, 2006.

- Internal control requirements should be “scaled” and “proportional” to the size of product revenues and complexity of corporate structures.
 - Scaled and proportional reform should be based on the principle that the level of risk and product revenues are intricately tied; product revenues drive the complexity of corporate structures and the corresponding need for more rigid and established internal control processes.
 - Reforms should support management’s incentive to maintain an effective and integrated system of internal controls to produce accurate financial reports, which are most important to investors. The internal controls necessary to meet Section 404 should be “integrated” and consistent with the level of controls necessary to meet the CEO and CFO certifications of company financials as required under Section 302 of SOX.
- Reforms should provide clear rules that are risk-based and material to the integrity of the financial statements.
 - The rules must provide a clearly defined scope of required assessments with a focus on entity-level controls material to financial statements.
- Frequency of internal control testing should be determined by changes in established baseline controls and not merely by the calendar.

1) Reforms Must Achieve Cost/Benefit Balance.

We fully appreciate the Congressional intent behind Section 404 – ensuring that companies have in place effective policies, procedures and controls to protect against material misstatements in financial statements, and to prevent fraud. However, as currently implemented, AS2 does not require a cost/benefit balance as part of its objectives.

The majority of smaller public companies simply do not have the manpower or the resources to perform the requirements under AS2. As most do not have more than one or two dedicated staff to the internal audit function, these companies are forced to either hire additional internal audit personnel or engage external consultants to perform the management assessments necessary to meet the requirements of AS2. As a result, many of our companies are incurring additional consulting fees in addition to external auditing fees. Many smaller companies, in order to complete the mandated internal control processes and the “checklist” dictated by AS2, are required to increase their accounting staff by as much as 50% in addition to hiring additional consultants.

Smaller public companies have limited resources, leaner staffs and tighter budgets. Given the disproportionately high cost of Section 404 compliance for smaller companies, it is our experience that many are forced to redirect funding from other investments, including R&D and the hiring of additional engineers or scientists, all of which are critical for continued innovation and survival of a company. For example, a small company with \$150 million in market capitalization but no product revenues recently paid more than \$1 million for costs associated with Section 404 compliance. Such costs are typical and often do not include a company’s indirect costs of complying with Section 404, or the costs associated with non-accounting staff performing the internal control work due to the shortage of available resources.

Due to Section 404, audit firms now have a required audit process, entirely separate from the typical financial statement audit process, generating fees almost equal to or greater than the charges for a financial statement audit. This was clearly not the Congressional intent. 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”. Such windfall is attributable not only to the process imposed by the large accounting firms but also to AS2, as promulgated by the PCAOB. The current standards require very prescriptive procedures that auditors must follow to perform the separate attestation, with little room for an auditor’s judgment.

Investor confidence and trust in public companies has increased as a result of the passage of SOX as a whole in spite of Section 404 and not necessarily because of it. Important and effective provisions of 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. 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 404.² Thus, we believe the costs of the implementation of Section 404, particularly for smaller public companies, clearly outweigh any benefits that are directly related to Section 404.

2) Reforms Must Be “Scaled” And “Proportional” To The Level of Product Revenues.

In achieving scaled and proportional reforms that are risk based, it is critical that Section 404 reforms establish a concrete basis for the required levels of internal controls. As recognized by the Advisory Committee in its Final Report and strongly supported by our members, Section 404 reform should be based on a “revenue filter” or revenue metric, particularly product revenues. This approach reflects corporate reality in that product revenues drive the complexity of corporate structures and the corresponding need for increased internal controls to protect against financial fraud.

Scaling Section 404 requirements, in part, on product revenues is critical to smaller companies in our industries. Biotech and other innovative start-up companies generally have very low revenues compared to their market capitalizations. For example, it is not uncommon for an early stage public biotech company with a market capitalization of \$700 million to have product revenues of \$1 million or less.

For smaller public companies, as defined by the level of product revenues, the reform framework should focus on the internal controls necessary for CEO and CFO certifications of company financials as currently required under Section 302 of SOX. The proposed reform supports management’s incentive to maintain effective systems of internal controls and produce accurate financial reports which are most important to financial markets and 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. Under section 302, each CEO and CFO must certify that the financial statements fairly present in all material respects the financial condition of the company, and disclose all

² 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.

weaknesses in the internal controls that could adversely affect the company's ability to record, process, summarize and report financial information, among other things.

3) Reforms Must Be Risk-Based.

The prescriptive nature of AS2 in its current form deters both management and auditors from taking a risk-based approach to prioritizing key financial controls under Section 404. As currently implemented, for smaller companies, management has little say in determining the scope and identification of necessary internal controls. Often, management implements extensive assessment plans developed by their auditors. As currently required, AS2 provides limited opportunity for management or external auditors to take a risk-based approach. AS2 thereby limits the ability of management and auditors to focus on the necessary controls, especially at the entity-wide level, which ultimately could have a material impact on their financial statements as required under Section 302. In short, the management and auditors are compelled to focus on the breadth of controls rather than the depth of necessary controls.

In fact, most small companies currently match their internal reviews to the requirements of the external reviews. They do not see how it could work any other way. If companies were truly performing their own internal audits for fraud and accuracy, they would not follow the current AS2 internal control requirements because many of these processes evaluate items that are immaterial for smaller companies.

Just to provide two examples of processes lacking a rational basis: a biotech company's management was required to sign off on every page of its Controller's 150-page close book; and the same company also received a deficiency because its accounting software did not require passwords to be alpha-numeric. Additionally, for smaller public companies, cross-training and interchangeability of staff is often more valuable than the strict segregation of duty that is required under Section 404, sometimes to a point of dysfunction.

Other examples include a lack of rationale in addressing certain information technology (IT) controls. The current external auditor-driven approach requires extensive testing of internal controls over IT as it relates to entire company and not just IT systems related to financial reporting. Under the current system, company management cannot rely on the capabilities of external service providers (i.e. payroll providers, tax firms and transfer agents) if no SAS 70 reports are in place. Thus, most companies are left to either pay for the external service provider to obtain the SAS 70 or put extensive controls in place surrounding the information that the service providers provide, including extensive manual recalculations.

Under AS2, auditors are so focused on the detail and the shear breadth of the internal controls and testing that there is little room for judgment and clear perspective over the overall process goals. Additionally, management has such extensive compliance requirements, including sign offs, recalculations and documentation, that many company managers have less time to evaluate the reasonableness of their disclosures.

As previously discussed, the opportunity cost of time spent on complying with documentation, testing and review of internal controls is time that could be directed toward functions that add value to the company and its shareholders (i.e. training staff, forecasting, modeling, monitoring, bringing in-house tasks done by external parties).

4) Frequency Of Internal Control Assessments Should Be Determined By Material Changes In Key Financial Controls.

Frequency of internal control testing should be determined by changes in established baseline entity-wide controls. As currently implemented, AS2 fails to recognize the value of cumulative knowledge and relevance of changes in key control areas that matter to the reporting of financial statements. Periodic testing or testing when a material change has occurred could alleviate the excessive duplication year after year that further adds to the high cost and burdens imposed by Section 404.

5) Additional Deferrals For Non-Accelerated Filers And Newly Public Companies Should Be Provided Until A New Reform Framework Is Implemented.

We fully support the Commission's proposal to provide further implementation deferrals for non-accelerated filers (small companies under \$75 million in market capitalization) and for newly public companies. In light of the current uncertainties due to the anticipated reforms by the Commission and the PCAOB and potential changes to AS2 requirements, we believe it is critical to further delay both the management assessment and external auditor attestation requirements for non-accelerated filers as well as newly public companies until a settled guidance can be provided and revised AS2 rules have been implemented for a reasonable time. In fact, non-accelerated filers and newly public companies should not be required to comply with Section 404 until a full assessment can be made by the GAO on the cost/burden impact of the newly revised AS2 rules.

Conclusion

As representatives of the high-growth sectors of the U.S. economy, we appreciate this opportunity to comment on the concept release. We believe that principles-based reforms that focus on cost effectiveness, that are risk based, and that are scaled and proportional to the level of product revenues and complexity of corporate structures will achieve the original intent of Section 404 – achieving internal controls that provide investors with the optimal level of confidence in the financial integrity of a public company.

We thank you for your consideration of our views and we urge you to expeditiously adopt a reform framework that provides fundamental relief to smaller public companies and that supports innovation in the U.S. high-growth sectors. We look forward to working with you to achieve these important goals.

Sincerely,



James C. Greenwood
President and CEO
Biotechnology Industry Organization



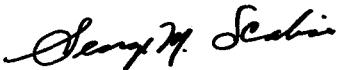
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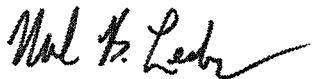
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