



July 12, 2007

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, D.C. 20549-1090

RE: PCAOB Rulemaking Docket Number 021

Dear Chairman Cox and SEC Commissioners:

On behalf of its members, the Biotechnology Industry Organization ("BIO") is pleased to provide comments on the proposed rulemaking by the Securities and Exchange Commission ("SEC") and the Public Company Accounting Oversight Board ("PCAOB") to clarify, reform and amend the guidance to public companies and their auditors on implementation of Section 404 of the Sarbanes-Oxley Act of 2002 ("SOX" or "Sarbanes-Oxley").

BIO represents over 1,100 members, including over 850 private and public biotechnology companies of all sizes, as well as academic centers, state affiliates and related organizations. Together, BIO members are advancing the vision of using biotechnology to improve health, feed a growing population and develop more efficient manufacturing processes and sustainable energy sources.

BIO appreciates the SEC and PCAOB's recognition that the implementation of Sarbanes-Oxley Section 404 has created problems for many companies, including confusion and substantially greater than expected regulatory costs. BIO commends both agencies' efforts to improve the implementation of this provision.

Indeed, there are some areas where significant improvement has been made. For instance, there is improved commonality in definitions used by both the SEC and the PCAOB. A multiplicity of standards and definitions that differ from those commonly employed in the area of financial reports themselves has contributed to the burdens

associated with implementation of Section 404. BIO member companies have raised concerns that after changing auditors, they experienced different interpretations of “material weakness”. Even within the context of a principles-based approach to auditing, some further clarification on this guidance was needed. We believe the clarification in the PCAOB adopted rule should accomplish this and laud the PCAOB for doing so.

BIO also commends the PCAOB for recognizing that its earlier standard — that an internal control deficiency had more than a “remote likelihood” of causing a misstatement—was vague, confusing and resulted in unnecessary costs and auditing burdens. BIO is pleased that both the SEC and PCAOB have adopted uniform definitions of “materiality”, “significant deficiency” and “material weakness”.

However, BIO believes that the changes promulgated by the two agencies are well-intended, though they appear modest in effect, and much more must be done to reduce compliance costs for small companies. There has been considerable rhetoric from both the SEC and PCAOB that has accompanied these rules, and we appreciate the recognition of the many problems caused by the poor implementation of Sarbanes Oxley Section 404. Ultimately, the rhetorical promises offered can only be kept if there is an on-going, consistent effort and commitment to reducing unneeded audit and compliance costs.

BIO fully appreciates and agrees with the Congressional intent behind Section 404 — to enhance investor protection and confidence. BIO members strongly support this goal. However, Section 404 has gone awry in its implementation. Many emerging biotech companies are directing precious resources from core research and development of new therapies for patients due to overly complex controls or unnecessary evaluation of controls. This legislation was not intended to be a windfall for auditors, nor a pile on the compliance costs for companies. Indeed, the Senate Banking Committee report on the legislation specifically stated that with respect to Section 404, “the Committee does not intend that the auditor’s evaluation be the subject of a separate investigation or the basis for increased fees.”

The scale of the problems that Section 404 has created, however, suggests that more needs to be done so its original intent is achieved. It is critical to ensure that these new rules are scaled properly for small public companies.

- 1. While BIO commends both the SEC and PCAOB for taking steps to address the compliance problems that Section 404 audits have been creating, there is serious concern that the final rules have removed any type of definition for a small company.**

While we BIO appreciates the PCAOB adopting a “top down, risk-based” approach in AS-5, we believe the PCAOB has taken a significant step backwards between the proposed rulemaking and the final rule, specifically as it relates to scaling the audit for “smaller companies.”

In the proposal released last December, PCAOB directed the auditor to evaluate for “size and complexity” of the company “when planning and performing the audit for internal control.”¹ The proposal goes on to note that the “final report of the SEC Advisory Committee on Smaller Public Companies indicates that market capitalization and annual revenue are useful indicators of a company’s size. In light of the Advisory Committee’s report, as well as the SEC’s definition of “large accelerated filer,” *companies with a market capitalization of approximately \$700 million or less, with reported annual revenue of approximately \$250 million or less, should be considered smaller companies.*” (emphasis added)²

We believe that an objective definition for “smaller company” and/or “size” is necessary to provide auditors meaningful direction in scaling the audit. Unfortunately, PCAOB has deleted any and all definitions as to what constitutes a “smaller company” in the final rule and have failed to define or describe what magnitude of “size” can affect the scaling of an audit.

Despite a lack of definitions, the PCAOB uses the term “smaller” 32 times in the final rule and the term “size” 12 times. What is considered a “smaller company” to one auditor may not be “smaller” to another and will certainly vary from one to the other. Likewise, what magnitude or threshold of “size” of company are auditors actually to consider when scaling the audit? Is it by market capitalization, annual revenues, number of personnel? The final rule has made these questions more ambiguous, not less.

While the PCAOB has not defined “less complex” they have at least described factors that contribute to it, i.e., fewer business lines, more centralized accounting functions, etc.). This is not the case for the term “smaller.”³

In effect, the PCAOB has removed “smaller” as a clear trigger for an auditor to scale the audit, and by deleting any objective definition therein, the SEC and the PCAOB are really saying is that the audit is being scaled for “less complex” companies – and not smaller companies.

As a result, BIO believes the lack of reasonable objective criteria will result in the AS-5 failing to meet its objective of reducing costs by providing auditors with clear direction as to when they should be providing an audit appropriately scaled to the company. With no objective criteria or definitions, the auditors are the judge and jury of what is a “smaller company.”

Maintaining the market capitalization and revenue criteria would have alleviated concerns with the potential conflict of interest relating to the incentives of the auditor

¹ See Paragraph 9, PCAOB Release No. 2006-007. http://www.pcaob.org/Rules/Docket_021/2006-12-19_Release_No_2006-007.pdf

² Ibid.

³ See Paragraph 9, PCAOB Release No. 2007-005

http://www.pcaob.org/Rules/Docket_021/2007-06-12_Release_No_2007-005A.pdf

who is charged with evaluating the “size and complexity of a company in planning and performing the audit ”and also being the company profiting from the providing the work. In pursuing its incentive to maximize profits, an auditor has an economic incentive to determine companies to be large and complex, thus requiring an extensive audit with additional hours of billing, etc. Furthermore, an auditor has a significant legal incentive in today’s litigious environment to pursue a path of work that treats each company with the highest level of complexity as possible.

Some suggest that an objective criteria is not useful or not indicative of risk or complexity. BIO profoundly disagrees.

The underlying public policy objective to be achieved by reforming Section 404 in the first place was to ensure that the substantial problems of implementation by the PCAOB – and the auditors subject to its examination – would be rectified by creating a system in which **both** smaller and less complex companies would receive audits appropriately scaled in size and scope. “Smaller” and “less complex” are not synonyms for one another. They are related characteristics of companies that Congress, the SEC and PCAOB have all agreed were subjected to unwarranted burdens and costs associated with Section 404 costs. The experiences leading to that unified policy conclusion have clearly demonstrated that unless auditors are given clear and specific instructions to avoid imposing such unneeded costs and burdens upon specific types of corporations, they will not refrain from doing so. By removing the clear instructions to auditors with respect to smaller companies, BIO members’ experiences suggests that the cost savings promoted and promised by PCAOB and the SEC in finalizing these rules are unlikely to be realized. This is not an academic or theoretical exercise and we strongly urge SEC not treat this as one.

As such, BIO strongly urges the SEC to reinsert the definition of what constitutes a “smaller company” pursuant to its original proposal on management guidance and the SEC Advisory Committee Final Report on Smaller Public Companies.⁴ Specifically, the definition of a “smaller company” should be inserted in the definitions portion of AS-5, Appendix A – Definitions. It should read:

“A **smaller company** refers to companies with a market capitalization of approximately \$700 million or less, with reported annual revenues of approximately \$250 million or less.”

2. While objective criteria, market capitalization and market revenue are not as substantial an objective measure as product revenue.

BIO has consistently advocated for scalability indicia that are most reflective of complexity. BIO supports the PCAOB’s work to include the scalability criteria and

⁴ See Footnote 44, P. 17, SEC Proposal 33-8762. <http://www.sec.gov/rules/proposed/2006/33-8762.pdf>; and p. 15 of the Final Report of the Advisory Committee on Smaller Public Companies to the United State Securities and Exchange Commission (April 23, 2006) <http://www.sec.gov/info/smallbus/acspc/acspc-finalreport.pdf>

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 recognizes the efforts made by both the SEC and PCAOB to affirmatively attempt to reduce the audit and compliance burdens by evaluating the complexity of each company individually. However BIO believes by removing all objective measures established in the proposals, AS/5 has withdrawn one of the most positive aspects the small business section of the proposal brought to the table.

As stated in our February 2007 comment letter, BIO believes that both the SEC and PCAOB should recognize product revenue as an important indicator of complexity in its own right. Rather than limiting auditor judgment by linking various attributes of smaller companies such as market capitalization and overall revenue, both agencies should provide for auditors to provide the indicia both in conjunction and independently as proxies for complexity.

3. BIO urges the SEC to provide an additional exception for non-accelerated filers.

BIO believes that there must be clarification as to whether small companies will have to comply with the AS-5 auditing and management evaluation standards. Small companies need additional time to evaluate and adjust to new auditing standards. Although small public companies regularly submit annual financial reports to the SEC, the internal controls reporting process is time intensive by adding the requirements of identifying processes, assessing risk levels, and documenting and testing the internal controls. Small companies are at a disadvantage in complying with Section 404 because they have less structured processes and fewer personnel and accountants. Many small companies are paying a significantly higher percentage of their total expenses for legal and audit fees than larger companies.

Providing an additional exception for non-accelerated filers will allow small companies to remain competitive and innovative while they prepare to adopt these new regulations.

4. Auditors should be required to use the work of others in an integrated audit.

In our February 2007 comment letter, BIO urged the SEC and PCAOB to include in any reform of Section 404, that auditors be required to rely on the work of others such as management monitoring and testing that is done in accordance with SEC guidance.

BIO supports the PCAOB's work in agreeing to the use of one standard in evaluating the use of others work and by adopting a rule that allows auditors to use the work of

others in the audit of internal controls over financial reporting as well as the integrated audit of financial statements. In addition, the PCAOB made progress in adopting a rule that allows for recognition of work of internal auditors, company personnel (other than internal auditors) and third parties working under the direction of management or the audit committee.

BIO does, however, remain concerned that the burden of determining the competency and objectivity of others work is placed solely in the hands of the auditor. This leaves a great deal of subjective evaluation by the auditor in determining the competency and objectivity of others work. BIO believes that given the nature and structure of accounting firms, there remains no clear incentive for the auditor to recognize the work of others in conducting their audit of internal controls.

5. An economic study of the costs and benefits associated with implementation of Section 404 is imperative to understanding if the current proposals are meeting their objectives.

BIO believes that the cost-benefit studies contained in the SEC proposal is wholly qualitative and lacks a quantitative analysis. BIO further notes that the PCAOB did not even contemplate an economic or qualitative evaluation of its proposed standard. Both agencies should be willing to engage in a true economic analysis of the cost and benefits associated with these proposals. We commend SEC Commissioner Atkins in his questioning of the Commission's economic analysis and hope that he will continue to highlight this weakness during the Commission's consideration of AS/5.

BIO urges the SEC to utilize its Office of Chief Economist to provide sound economic analysis. While pure economics should not be the sole driver of auditing standards and practices, the economic consequences of adopting these rules should not be ignored. A faithful effort in this area would help to ensure that certain auditing rules and regulations are meeting their primary objectives for the shareholders.

Conclusion

BIO believes that PCAOB's new rules are a marginal improvement over the current system of internal control audits but would note that the current system is so bad that any change is a marginal improvement. It is unclear, though not entirely likely, that these reforms will match the rhetoric surrounding their adoption.

BIO urges both the SEC and the PCAOB to continue to work cooperatively to eliminate the disparities noted in this comment letter, and is encouraged by the fact that both organizations have worked together to address many of the issues that BIO and other organizations have raised regarding the implementation of Section 404 of SOX. **However, it appears necessary that to ensure policy consistency and reduced compliance burdens, the SEC should use its authority to amend PCAOB rules under Section 107(b)(5) of Sarbanes-Oxley.**

BIO appreciates the efforts of both the Commission and the PCAOB and looks forward to continuing to work with both agencies to ensure a workable implementation of Sarbanes-Oxley.

Sincerely,

/s/

Alan F. Eisenberg
Executive Vice President
Emerging Companies and Business Development
Biotechnology Industry Organization (BIO)

Cc:
Public Company Accounting Oversight Board Members
Chairman Mark W. Olson
Member Kayla J. Gillan
Member Daniel L. Goelzer
Member Bill Gradison
Member Charles D. Niemeier