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

Chairman Mark W. Olson
Member Kayla J. Gillan
Member Daniel L. Goelzer
Member Bill Gradison
Member Charles D. Niemeier
Public Company Accounting Oversight Board
1666 K Street, NW
Washington, D.C. 20006-2803

RE: SEC File Number S7-24-06
PCAOB Rulemaking Docket Matter Number 021

Dear Chairman Cox and Chairman Olson:

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.

Dramatic advances in these fields require substantial investment, and biotechnology companies are heavily dependent on well-functioning capital markets. We are therefore committed to working with both the SEC and the PCAOB toward the development of a regulatory framework that enhances the strength, depth and integrity of these markets. In that spirit, we offer the following comments on the SEC's proposed interpretive guidance and the PCAOB's draft Auditing Standard No. 5.

BIO applauds both the SEC and PCAOB for acknowledging that implementation of Section 404 should be scaled to the size of the company and proportionate to the complexity of underlying corporate structures. Regrettably, implementation to date of the simple policy objective of Section 404 demonstrates the risks inherent when the burden of compliance far exceeds any benefit to the company, the capital markets or to the stated public policy objective. The critical test for these reform proposals will not be the words written in the final approved rules package, but how these reform proposals are implemented by auditors and enforced by the SEC and the PCAOB. **Going forward, BIO strongly urges both agencies to undertake a series of steps to monitor how well the objectives of "scalability" and "proportionality" are being achieved.**

BIO member companies are engaged in the development of new products that are at the cutting edge of innovation in the health care, energy and agricultural fields. In health care, the development of new therapies to treat disease is a high risk, capital intensive, and long lead-time process that requires strong capital markets to support the necessary research and development. However, a regulatory regime that is inflexible or one in which costs exceed benefits means that resources that could otherwise go to pursuing new cures for disease are instead dedicated to overly burdensome compliance costs. This ultimately weakens and diminishes the very markets and companies that are the engines of American economic growth and innovation.

1. **While BIO commends the efforts of the PCAOB to include revenues to define smaller companies, the SEC should recognize product revenue as a strong indicator of complexity, and the PCAOB should direct auditors to consider it as an important factor in scaling audits for smaller companies.**

One of the key elements of "scalability" is the basis on which the company is being judged. As described above, biotechnology companies frequently are in the position of having little or no revenues for an extended period of time, even while publicly owned. During this period of time, these biotech companies have large research and development expenses as well as overhead, and are generally straightforward from an accounting and internal controls standpoint. However, due to investor sentiments, biotech companies may have high market capitalizations during this same period.

BIO recommends that the SEC and PCAOB follow the spirit of the recommendation of the SEC's Advisory Committee on Smaller Public Companies: "The concept we are trying to convey in providing relief for small cap companies with less than $10 million in annual product revenues is that full Section 404 compliance is not

appropriate for uncomplicated business organizations with much potential but simple current operations from an accounting standpoint." While the Advisory Committee's recommendation was for exemptive relief, we urge that the SEC and PCAOB nonetheless implement the intent of the Advisory Committee: that companies with little or no product revenues should have scaled, more appropriate implementation.

Product revenue, rather than market capitalization, is a far better metric for organizational complexity and the challenges that management could face with respect to internal controls for financial reporting. Product revenues suggest that the organization may face revenue recognition, inventory management, and product manufacturing issues that would not be the case for an emerging biotech firm that remains in the research and development phase, but nevertheless has a several hundred million dollar market cap.

In our September 12, 2006 comment letter to the SEC on Release No. 34-54133 and Release No. 33-8731, BIO, along with several other trade groups representing biotechnology, healthcare technology, information and communications technology, electronics and semiconductor industries, strongly supported the recommendation of the SEC's Small Business Advisory Committee that a more appropriate test for inclusion in this smaller company category should be based upon a "revenue filter," or product revenues. In that letter, we noted:

> 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.

Indeed the Advisory Committee itself suggests that while it would "defer to the SEC as to how the term "product revenue" should be defined... We would assume that the SEC would define the term similarly to the way it provides for the disclosure of product and services revenue in Section 5-03 in SEC Regulation S-X, 17 CFR 210.5-03, but exclude 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."[1] BIO supports the recommendation of the Advisory Committee.

[1] See page 46, Footnote 106 – Final Report of the Advisory Committee on Smaller Public Companies to the Securities and Exchange Commission (April 23, 2006).

The introduction to the PCAOB's proposed Auditing Standard No. 5, in discussing factors to identify smaller companies appears to emphasize market capitalization as a threshold factor in choosing to use the scaled down approach, while the proposed audit standard itself mentions in a note both market capitalization and revenues to define "smaller companies."[2] BIO commends this effort to include revenues as a test for scalability of an internal controls audit, with a specific level of revenues. However, this should be drawn out and not simply made part of a note. Furthermore, depending on the application of these two standards, a combination of the two may still unfortunately penalize companies in the implementation of the audit. BIO urges that the test should be market capitalization OR product revenues, not both.

Applying a market capitalization or revenue standard will alleviate concerns with the potential conflict of interest relating to the incentives of the auditor who is charged with evaluating the "size and complexity of a company in planning and performing the audit" and also being the company providing the work.[3] In pursuing its incentive to maximize profits, an auditor has an economic incentive to determine a company too large and too complex, thus requiring an extensive audit mandating additional hours of billing, etc. While we are aware previous guidance required two Independent Auditor opinions, we believe that retaining the opinion on internal controls without an objective bright line test will not significantly decrease audit fees.

In addition, some – like SEC Chief Accountant Conrad Hewitt as well as principals of the big accounting firms - have suggested auditors currently face unlimited exposure to legal liability and thus should receive some sort of limitation or cap on such liability.[4] While we make no policy judgment on that issue at this time, the mere consideration does suggest an auditor has great incentive to be overly ambitious with its internal control opinion in an effort to protect itself from such liability and the costs associated with litigation.

Combined, these two incentives provide auditors powerful reasons to require excessively detailed internal controls. Such actions may benefit and protect the auditor, but do not necessarily serve the purpose of this proposal or the marketplace. Neither do such actions coincide with Congressional intent. The Senate Committee's report on Section 404 is clear: "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."[5]

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[2] P. A1-7-Standard indicates that companies with a market capitalization of approximately $700 million or less, with reported annual revenues of approximately $250 million or less, "should be considered smaller companies."

[3] See page 28 of the proposal. Proposal-2006-00 http://www.pcaobus.org/Rules/Docket_021/2006-12-19_Release_No._2006-007.pdf.

[4] See Taub, Stephen. CFO.com "SEC's Hewitt: Indemnify the Big Four," CFO.com, Stephen Taub 26 January 2007; and www.pwc.com, "Global Capital Markets and the Global Economy: A Vision from the CEOs of the International Audit Networks" November, 2006.

[5] S. Rep. No. 107-205, at 31 (2002).

For these reasons, BIO strongly believes that the goal of making implementation of Section 404 appropriate to the size and complexity of individual companies would be best served by implementing a standard specifically referencing a threshold for product revenues (or at least total revenues) in the discussion of smaller companies.

2. BIO commends efforts to draw out materiality standards by both SEC and PCAOB, but there needs to be significant improvements in implementation to reduce inconsistency in application.

One of the continuing concerns about implementation of Section 404 to date has been the multiple and vague standards to which management is held in determining that a company has sufficient internal controls on its financial reporting. BIO commends the SEC and PCAOB for their efforts to address the definition of "materiality" to make it both more reasonable and more consistent.

In particular, BIO congratulates the PCAOB for recognizing that it's earlier standard - that the an internal control deficiency had more than a "remote likelihood" of causing a misstatement of the financial statement – was vague, confusing and resulted in unnecessary costs and audit burdens, especially for small companies. BIO is pleased and encouraged that both the SEC proposal and the PCAOB proposal now use the same standard of materiality: " A material weakness is a deficiency, or combination of deficiencies, in ICFR such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis by the company's ICFR."[6]

However, even this important reform may not go sufficiently far to provide certainty and consistency in its application.

First, while BIO respects that both auditors and corporate managers require flexibility in making determinations as to what is or isn't material, we remain concerned that there is still a great deal of inconsistency in its application. For example, we have heard concerns from member companies, who after changing auditors, experience new interpretations of what is the definition of a material weakness. Even within the context of a principals-based approach to auditing, some clear guidance on this point would be useful.

Second, we would also note that PCAOB guidance itself can be confusing because the same definitions are not uniformly used throughout in guiding auditors in what they should be looking for. The PCAOB uses the term "materiality" as it currently applies to a public company's annual financial statements, but also uses other terms such as "control deficiency" and "significant deficiency." Further on, the PCAOB uses the phrase "deficiency or combination of deficiencies" without any either previously stated modifiers of "control" or "significant."

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[6] See page 13 of the proposal. Release 33-8762 http://sec.gov/rules/proposed/2006/33-876d2.pdf

If, as stated in the proposal that the "auditor is not required to search for deficiencies that, individually or in combination, are less severe than a material weakness"[7] why are other standards used elsewhere in the guidance?

The ultimate concern with regard to vague or multiple standards is that the auditors will come in and determine those standards for our companies. This could result in a continuation of the lack of uniformity and create standards that are far too burdensome and far too costly. We view this as a significant risk to capital formation and the ability of the management of our companies to execute their respective duties.

3. Auditors should be required to use the work of others such as management monitoring and testing that is done in accordance with SEC guidance.

BIO has urged the SEC and PCAOB that any reforms to Sarbanes-Oxley be risk-based. This orientation is critical for ensuring the appropriate level of both management and auditor oversight to internal controls processes. BIO commends both SEC and PCAOB's mindfulness of this principle in developing their proposals.

BIO supports the SEC's guidance that management may use evidence from on-going monitoring and its own direct testing of controls, particularly in lower-risk areas.[8] Specifically, the SEC's interpretive guidance describes that "a small company with less complex business processes that operate on a centralized basis and with little change in the risks or processes, management's daily involvement with the business may provide it with adequate knowledge to appropriately identify reporting risks."[9] Indeed, for the vast majority of BIO's companies, which are engaged in project-oriented research over long time horizons funded generally by a combination of venture capital plus public investment, the complexity tends to be relatively low.

However, BIO is concerned that there are inconsistencies between the SEC proposed guidance and the PCAOB proposals. Confusion or conflicts between the two rules create uncertainty with corporate management as to which is the appropriate standard to follow.

For example, efficiencies created by the SEC guidance to management could potentially be offset by the PCAOB's proposed auditing standard "Considering and Using the Work of Others in an Audit." To guard against this result, we believe the

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[7] See page A1-27 of Appendix 1 of the proposal. Proposal-2006-00-http://www.pcaobus.org/Rules/Docket_021/2006-12-19_Release_No._2006-007.pdf.

[8] See page 36 of the proposal. Release 33-8762 http://sec.gov/rules/proposed/2006/33-876d2.pdf.

[9] See page 24 of the proposal. Release 33-8762, http://sec.gov/rules/proposed/2006/33-876d2.pdf

PCAOB should revise this proposed standard to make it clear to auditors that they may rely on management monitoring and testing done in accordance with SEC guidance.[10]

In addition, the PCAOB proposal, while ostensibly allowing auditors to use the work of others, (e.g., corporate management) in making evaluations of internal controls, requires that the auditor first take into account the "objectivity of the individuals who performed the work."[11]

Reconciling this type of inconsistency is particularly important to ensure that the primary goal of these new proposals is met. BIO urges PCAOB to make explicit that management testing that is in conformity with the SEC guidance may be relied upon by auditors in evaluating a company's internal controls. Furthermore, BIO urges that a risk-based approach is not just described in preambles, but actually implemented.

4. BIO urges both the SEC and the PCAOB to continue to work cooperatively to eliminate these seeming disparities, and is pleased that both organizations have worked together to address the many problems that BIO and other organizations have raised regarding the implementation of Section 404 of SOX.

The SEC proposal provides that "an evaluation that complies with the interpretive guidance is one way to satisfy [its] rules."[12] However, to the extent that there is conflict between two regulatory interpretations, it is unclear where that resolution is fully met. While one may construe that the resolution will necessarily occur at the firm's audit committee, nevertheless such a committee may have difficulty resolving two equally valid views – those of management and those of its auditor – based on two separate regulatory interpretations. In short, if there is a conflict between the SEC guidance and PCAOB rules, how does that conflict get resolved?

The execution and coordination of policy implementation between the SEC and PCAOB is critically important to achieve the stated objectives and resolve conflicts inherent in the two proposals.

There is substantial interplay between the two proposals that are the subject of this comment letter. The SEC proposal provides broad and general guidance, and embodies a principle-based approach to compliance with Section 404 of SOX, while the PCAOB proposal is far more specific and detailed. However, in some cases, the PCAOB proposal, through its implementation by auditors, may in some cases conflict with the policy intentions outlined by both agencies. For example, one of the objectives of these

[10] See A2-10, A2-15 of Appendix 2 of the proposal. Proposal-2006-00-http://www.pcaobus.org/Rules/Docket_021/2006-12-19_Release_No._2006-007.pdf.

[11] See A2-10, A2-15 of Appendix 2 of the proposal. Proposal-2006-00-http://www.pcaobus.org/Rules/Docket_021/2006-12-19_Release_No._2006-007.pdf.

[12] See page 1 of the proposal. Release 33-8762 http://sec.gov/rules/proposed/2006/33-876d2.pdf

proposals is to reduce the unnecessary compliance burden, it is unclear how PCAOB will address overly conservative applications of its new Auditing Standard No. 5 (when implemented) which create undue costs for management. The PCAOB should examine both the inadequate and the unduly aggressive applications of its standard and discourage both in its examination of auditors.

BIO urges both the SEC and the PCAOB to continue to work cooperatively to eliminate these seeming disparities, and is pleased that both organizations have worked together to address the many problems that BIO and other organizations have raised regarding the implementation of Section 404 of SOX. **However, should it be necessary to ensure policy consistency and reduced compliance burdens, BIO encourages the SEC to use, if necessary, its authority to amend PCAOB rules under Section 107(b)(5) of Sarbanes-Oxley.**

Cost/Benefit Analysis

In our aforementioned September 12, 2006 letter, BIO urged that any reforms reflect a rational cost/benefit balance. Unfortunately, there is little formal discussion of costs and benefits in either the SEC or PCAOB's proposal. Given the disproportionately high cost of Section 404 compliance for smaller companies, it is critical that both proposals review modifications under the light of costs and benefits.

BIO urges the SEC to utilize its Office of Chief Economist to provide sound economic analysis of the costs and benefits of the SEC's guidance the implementation of that guidance under AS5. Neither the SEC nor the PCAOB has subjected their proposals to a rigorous cost/benefit analysis performed by an economist. While we applaud the intent of both proposals, we would note that the SEC's cost/benefit analysis[13] is wholly qualitative and is lacking in any quantitative analysis. The PCAOB proposal lacks any attempt to measure the costs and benefits associated with its rules. Pure economics should not be a driver of auditing standards and practices, but to wholly ignore the economic consequences of adopting certain rules is equally inappropriate and may help explain how many observers believe that certain auditing rules and regulations are divorced from reality.

A true and meaningful cost/benefit analysis going forward may assist both agencies in determining further reforms that may be necessary to reduce unnecessary compliance costs, particularly for smaller companies with limited product or other revenues. BIO strongly urges the SEC to utilize its Office of Chief Economist to perform, on an ongoing basis, quantitative analysis of the costs associated with its proposed guidance and measure those costs against the incremental public policy benefits qualitatively spelled out in the release.

[13] See page 54-59 of the proposal. Release 33-8762 http://sec.gov/rules/proposed/2006/33-876d2.pdf.

Additional Deferrals for Non-Accelerated Filers

BIO commends the SEC for its action regarding the extension of deadlines for both filing the management's assessment and the auditor attestation to fiscal years for non-accelerated filers that was taken on December 15, 2006. Many BIO member companies fall into this category of company, and the regulatory burdens of Section 404 have hit these companies perhaps most acutely. Accordingly, as the SEC and PCAOB seek to make adjustments to the implementation of Sarbanes-Oxley, it is fully appropriate that the implementation timeline for these emerging companies should be delayed while new standards are set and procedures established.

CONCLUSION

BIO strongly urges the SEC and the PCAOB to move expeditiously to finalize these rules with any changes necessary to improve or clarify the proposals. BIO welcomes the recognition by both agencies that previous implementation of Section 404 of Sarbanes-Oxley was rigid, overly burdensome and inappropriate for smaller companies. The net effect of the previous implementation was not to reduce corporate fraud or improve the accuracy of financial statements but, in fact, to deter companies from seeking financing from public markets, weaken the US competitiveness in a global economy and drive scarce corporate resources away from job creation, growth and investment and into compliance and audit fees.

We hope that the stated desire to adopt more flexible, scaled and proportionate rules for the audit of internal controls succeeds in achieving its aims. Continued attention by both agencies to the success of these proposals will be integral to making that determination and to understanding what further steps should be taken to make sure that our capital markets and public companies operate with the integrity and efficiency required by truly global economy.

Sincerely,

Alan F. Eisenberg
Executive Vice President
Emerging Companies & Business Development