
December 14, 2011

Office of the Secretary
Public Company Accounting Oversight Board
1666 K Street NW
Washington, D.C. 20006

RE: *PCAOB Docket Matter Number 37, Concept Release on Auditor Independence and Audit Firm Rotation*

Dear Members and Staff of the Public Company Accounting Oversight Board:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the *Concept Release on Auditor Independence and Audit Firm Rotation*.

BIO is a not-for-profit trade association that represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in 31 other nations. BIO members are involved in the research and development of healthcare, agriculture, industrial, and environmental biotechnology products.

BIO fully appreciates and agrees that strong auditing standards can enhance investor protection and confidence. BIO members strongly support this goal. However, unnecessary and burdensome auditing standards can have a negative impact on a biotechnology company. Overregulation can force an emerging public biotech company with little or no product revenues to divert its limited cash and internal resources away from innovation development. This could lead to research programs being curtailed or delayed. If compliance costs of additional regulations such as mandatory auditor rotation are substantial, it would have an unnecessary and negative impact on the limited financial resources of microcap and small cap companies at the forefront of developing new treatments for severe diseases. Furthermore, mandatory audit firm rotation will shift corporate governance away from internal audit committees tasked with oversight of auditors and audit quality.

BIO believes that mandatory audit firm rotation would not enhance audit quality and would instead unnecessarily burden our companies. During this difficult economic climate, lawmakers are seeking more effective ways for emerging companies to flourish, and a required audit firm rotation goes against the heart of those intentions. In October of 2011, the IPO Task Force reached the same conclusion, stating that audit firm rotation would "threaten to increase costs even further for emerging growth companies."

BIO has the following concerns with the *Concept Release on Auditor Independence and Audit Firm Rotation*.

1. **There is minimal evidence that mandatory audit firm rotation would improve the quality of the audit.**

In the concept release, the PCAOB states that "preliminary analysis of [inspection] data appears to show no correlation between auditor tenure and number of comments in PCAOB inspection reports." Furthermore, it appears unclear as to whether the PCAOB's findings constitute actual audit failures. The data covers potential audit deficiencies as well as instances where there is not reasonable assurance that a financial statement is free of material misstatement; however, these problems do not necessarily amount to audit failures. Despite this discrepancy, the PCAOB prescribes audit firm rotation as a way to decrease the frequency of audit failures.

When Congress passed the Sarbanes-Oxley Act of 2002 (SOX), it visited the idea of auditor rotation and decided more information was necessary before formally recommending mandatory audit firm rotation. We believe that there is a lack of clear evidence in the PCAOB findings to correlate audit deficiencies and the lack of audit firm rotation. It would be inappropriate to implement audit firm rotation without strong evidence of definitive benefits, and as a result, to subject smaller companies in the biotech industry to the additional burden of audit firm rotation.

2. **Mandatory audit firm rotation would present significant resource and cost burdens for small emerging biotechnology companies, and could diminish the quality of the audit.**

Small emerging biotechnology companies, in general, have limited internal resources and staff in their accounting departments. As noted above, these companies have limited or no product revenues and incur substantial research and development expenses and net operating losses; as a result, they incur administrative expenses for personnel and services judiciously to conserve cash. Growing biotechnology companies face a constant struggle to find working capital. It takes 8 to 12 years for a breakthrough company to bring a new medicine from discovery through Phase I, Phase II, and Phase III clinical trials and on to FDA approval of a product. The entire endeavor often costs between $800 million and $1.2 billion. Diverting critical funds from research and development can lead to research programs being curtailed or delayed. Therefore, burdening these limited resources with educating and acclimating a new audit firm to the company periodically will be disruptive. Companies may even need to hire more personnel to avoid disruption of day-to-day operations, which would further unnecessarily increase costs.

BIO is especially concerned that audit fees will increase with the implementation of audit firm rotation as firms may pass through the additional costs of learning a new client and reviewing the prior auditor's work. In addition, public companies are prohibited from using their auditors for certain non-audit services, either because it taints their independence or is prohibited by the company's audit committee. As a result, audit firm rotation may also result in mandatory rotation of other firms for non-audit services, resulting in additional burdens on our companies' limited staff as well as potentially higher costs due to the change in firms.

Finally, BIO believes that retaining auditors over an extended period enables the auditor to provide a higher quality audit, given their cumulative audit knowledge obtained regarding the company's business, operations, and accounting policies.

Audit firms have also suggested that audit firm rotation could increase the challenges and costs to maintain high quality personnel. This could also result in higher turnover in their staff. The cost associated with these scenarios would be transferred to the company while making relationships between the audit firm and the company more difficult to establish. This environment could severely hamper overall audit quality.

**3. Mandatory audit firm rotation will shift corporate governance away from internal audit committees tasked with determining audit quality.**

Audit committees are responsible for ensuring that companies retain an appropriate and proficient independent auditor to provide assurance that the company's financial statements are free of material misstatement. After choosing a firm, the audit committee must continue evaluating audit quality and make determinations on whether the audit firm continues to serve in the best interest of the company, users of the financial statements, and investors. Implementing a mandatory audit firm rotation would unnecessarily force an audit committee to engage a new firm when their current auditor was already providing outstanding value-added service while maintaining a high level of audit quality at competitive costs.

Audit firm expertise is crucial in the biotech industry due to the unique business model of biotechnology companies. It is important for companies to retain audit firms that understand the nature of the company and the industry. Audit committees are well-equipped to make that determination. Additionally, the number of auditing firms from which a biotech company may choose is limited by firms' expertise in our industry. Furthermore, as biotech companies become publically traded and grow into mid-size or larger public companies, the "Big Four" auditing firms are best equipped to, and there is an expectation by investors that they will, conduct their audits. Mandatory audit firm rotation would eliminate one of these firms from performing an audit, further shrinking an already limited pool of auditors.

In summary, while BIO appreciates the PCAOB's concern about audit quality, we are not in favor of mandatory auditor rotation, principally for the reasons described above. BIO would appreciate the PCAOB reconsidering the unintended adverse consequences on companies in our industry that would result from implementing this Concept Release. If you have further questions or comments, please contact Tooshar Swain, Policy and Research Manager, at (202) 962-9200.

Sincerely,

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