



HEARING STATEMENT

United States Senate Committee on Banking, Housing, and Urban Affairs

“Spurring Job Growth Through Capital Formation While Protecting Investors”

December 1, 2011

Executive Summary

- The Biotechnology Industry Organization (BIO) represents more than 1,100 innovative biotechnology companies, along with academic institutions, state biotechnology centers, and related organizations in all 50 states.
- BIO supports S. 1544 and H.R. 1070, the Small Company Capital Formation Act. This would increase the eligibility threshold of SEC Regulation A from \$5 million to \$50 million while maintaining the same disclosure requirements.
- BIO supports S. 1824 and H.R. 2167, the Private Company Flexibility and Growth Act, which would raise the reporting trigger under the Securities Exchange Act of 1934 by increasing the shareholder limit and exempting employees from the count.
- BIO supports S. 1831 and H.R. 2940, the Access to Capital for Job Creators Act, which would require the SEC to revise Regulation D to permit general solicitation of accredited investors in private offerings under Rule 506.
- BIO supports legislation to relieve small companies from the unnecessary burden and expense of conducting an audit under Section 404(b) of Sarbanes-Oxley (SOX). H.R. 3213, the Small Company Job Growth and Regulatory Relief Act, would provide companies with a public float of \$350 million or less an exemption from Section 404(b). BIO supports the addition of a revenue test with regard to the exemption from Section 404(b).

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December 1, 2011

Thank you for the opportunity to submit a written statement to the Senate Committee on Banking, Housing, and Urban Affairs. BIO represents more than 1,100 innovative biotechnology companies, along with academic institutions, state biotechnology centers, and related organizations in all 50 states. Entrepreneurs across the biotech industry are conducting groundbreaking science and are deeply invested in treating the severe illnesses that families around the nation and world face.

Biotechnology has incredible potential to unlock the secrets to curing devastating disease and helping people to live longer, healthier, and more productive lives, but the barriers that small biotech companies encounter on a daily basis raise some important questions: Would we rather see the next generation of breakthrough cures discovered by researchers in New Jersey or New Delhi? Do we want the jobs associated with this groundbreaking science to go to workers in San Francisco or Shanghai? If we want more scientific breakthroughs that allow us to enjoy a high quality of life – indeed, breakthroughs that save the lives of our loved ones – then shouldn't we put in place policies that encourage innovation?

Biotech leaders must deal with the day-to-day challenges of running small businesses. Of great import in the biotechnology industry is the constant struggle to find working capital. It takes eight to 12 years for a breakthrough company to bring a new medicine from discovery through Phase I, Phase II, and Phase III clinical trials, on to FDA approval of a product. The entire endeavor costs between \$800 million and \$1.2 billion. For the majority of biotechnology companies that are without any product revenue, the significant capital requirements necessitate fundraising through venture capital firms. Unfortunately, due to the high-risk nature of our industry, venture capital firms are turning elsewhere to make their investments.

A recent survey conducted by the National Venture Capital Association found that 41 percent of venture capital firms have decreased their investments in the biopharmaceutical sector in the past three years. Additionally, 40 percent of venture capitalists reported that they expect to further decrease their biopharma investments over the next three years. Therapeutic areas that affect

millions of Americans will be hit by this change in investment, including cardiovascular disease, diabetes, and cancer.

Additionally, venture capital firms are affected by the commitment that other countries are putting into their biotech industries. Forty-two percent of venture capitalists surveyed said they already have healthcare investments outside of the United States, while 44 percent foresee significant investment increases forthcoming in emerging powers in Asia. Such a decline in venture capital will hinder our companies from making it onto the public markets where later stages of research are funded for large-scale and expensive clinical trials. Fewer initial public offerings will result in a decrease in job growth.

While the biotechnology industry faces significant challenges, we nonetheless have the ability to deliver the next generation of cures and treatments to the bedsides of patients who desperately need them while at the same time creating a healthier American economy. The 1.42 million Americans directly employed by biotech are driven to treat and heal the world, but in order for them to be able to do so, Congress must remove the barriers to innovation that we face. Innovation in biotechnology leads to the medical breakthroughs that cure and treat devastating diseases like cancer and Alzheimer's and allow real people to see their grandkids graduate from college or walk their daughters down the aisle.

Congress has the opportunity to help speed lifesaving cures and treatments to patients by removing burdens to innovation in our industry. Below are some proposals that Congress has been considering that will help alleviate some of the financial struggles that our companies face.

SEC Regulation A (Direct Public Offerings)

Regulation A, adopted by the SEC pursuant to Section 3(b) of the Securities Act of 1933, was created to provide smaller companies with a mechanism for capital formation with streamlined offering and disclosure requirements. Updating it to match today's market conditions would provide an important funding source for small biotechnology companies.

Regulation A allows companies to conduct a direct public offering valued at less than \$5 million while not burdening them with the disclosure requirements traditionally associated with public offerings. The intent of Regulation A was to give companies which would benefit from a \$5 million influx (*i.e.*, small companies in need of capital formation) an opportunity to access the public markets without weighing them down with onerous reporting requirements.

However, the \$5 million offering amount has not been adjusted to fit the realities of the costs of development and Regulation A is mostly not used by small companies today. The current threshold was set in 1992 and is not indexed to inflation, pushing Regulation A into virtual obsolescence. As it stands, a direct public offering of just \$5 million does not allow for a large enough capital influx for companies to justify the time and expense necessary to satisfy even the relaxed offering and disclosure requirements.

Regulation A could have a positive impact for small biotechnology companies if its eligibility threshold was increased from \$5 million to \$50 million while maintaining investor protections.

This increase would allow companies to raise more capital from their direct public offering while still restricting the relaxed disclosure requirements to small, emerging companies. Regulation A reform could provide a valuable funding alternative for small biotech startups, giving them access to the public markets at an earlier stage in their growth cycle and allowing them to raise valuable innovation capital.

The Small Company Capital Formation Act, H.R. 1070, which would raise the Regulation A eligibility threshold from \$5 million to \$50 million, passed the House in November. Senators Tester and Toomey have introduced companion legislation, S. 1544, in the Senate. This bill would provide an important avenue for small biotech companies to raise innovation capital. BIO thanks both Senators for championing this issue, and we look forward to working with them to pass this meaningful legislation.

SEC Reporting Standard (Shareholder Limit)

Although the SEC in general monitors public companies, the agency also keeps tabs on private companies when they reach a certain size. Modifying the SEC's public reporting standard would prevent small private biotechnology companies from being unnecessarily burdened by shareholder regulations.

Once a private company has 500 shareholders, it must begin to disclose its financial statements publicly. Biotechnology companies are particularly affected by this 500 shareholder rule due to our industry's growth cycle trends and compensation practices. Currently, the IPO market is essentially closed to biotechnology, leading many companies to choose to remain private for at least 10 years before going onto the public market. This long timeframe can easily result in a company having more than 500 current and former employees, most of whom have received stock options as part of their compensation package. Under the SEC's shareholder limit, a company with over 500 former employees holding stock, even if it had relatively few current employees, would trigger the public reporting requirements. Exempting employees from any shareholder limit is a minimum necessary measure to ensure growing biotech companies are able to hire the best available employees and compensate them with equity interests, allowing them to realize the financial upside of a company's success.

Also, including accredited investors in the private company shareholder count does not serve the intended purpose of protecting retail investors. The SEC recognizes that accredited investors are a unique class that does not require the same level of protection as other investors. By including them in the 500 shareholder limit, growing private companies are forced to rely primarily on institutional investors because they need to maximize funding without triggering the limit. This excludes retail investors, whom the SEC was originally trying to protect, from taking part in this process.

Increasing the shareholder limit above 500 would relieve small biotech companies from unnecessary costs and burdens as they continue to grow. As it stands, the limit encumbers capital formation by forcing companies to focus their investor base on large institutional investors at the expense of smaller ones that have been the backbone of our industry. Further, it

hinders a company's ability to compensate its employees with equity interests and negatively affects the liquidity of its shares.

BIO applauds Senators Toomey and Carper for introducing S. 1824, the Private Company Flexibility and Growth Act, which would increase the shareholder limit from 500 to 2000 and exempt employees from the count. Representative Schweikert has introduced similar legislation, H.R. 2167, in the House. Increasing the shareholder limit and exempting employees are measures that, together, would remove significant financing burdens from small, growing companies.

SEC Regulation D (Ban on General Solicitation)

Another potential avenue for capital formation in the biotech industry is SEC Regulation D. Under Rule 506 of Regulation D, companies can conduct offerings to accredited investors without complying with stringent SEC registration standards. This exemption allows companies to access accredited investors (who do not need as much SEC protection) without burdensome disclosure requirements. However, the upside of this fundraising avenue is hindered by the ban on general solicitation in Rule 506. Companies are limited in their investor base by this Rule, meaning that a vast pool of investors remains untapped. If the ban on general solicitation were lifted, growing biotech companies would be able to access funds from the entire range of wealthy SEC accredited investors without undergoing the full SEC registration process.

BIO supports S. 1831 and H.R. 2940, the Access to Capital for Job Creators Act, which would require the SEC to revise Regulation D to permit general solicitation in offerings under Rule 506. If enacted, this legislation would enhance fundraising options for growing biotech companies searching for innovative cures and treatments.

Sarbanes-Oxley Section 404(b) Exemption

As you know, the Sarbanes-Oxley Act was passed in 2002 with the intent of protecting public investors from corporate fraud. At the time, President Bush praised it as a collection of "the most far-reaching reforms of American business practices since the time of Franklin D. Roosevelt." While we can all agree that investors benefit from greater transparency, some of the regulations found in SOX, namely Section 404(b), are unnecessarily burdensome on smaller companies, and often involve onerous compliance with little to no benefit to investors or the general public. In fact, many biotech companies facing their first few years on the public market are forced to divert funds from scientific research and development to the stringent Section 404(b) auditing requirements. The opportunity cost of this compliance can prove damaging, resulting in already limited resources being driven away from a company's search for cures and treatments.

The biotechnology sector is especially disadvantaged by the compliance burden of Section 404(b) due to the unique nature of our industry. The long, capital-intensive development period intrinsic to biotechnology often causes companies to have a relatively high market capitalization (caused by multiple rounds of venture financing prior to going public) but little to no revenue. All public companies with market caps greater than \$75 million are forced to comply with

Section 404(b), even though most biotech companies in a cash-strapped financial position can ill afford to pay for expensive external attestation of internal financial controls.

The main problem that these regulations cause for emerging public biotechnology companies is the need to divert resources away from innovation development to compliance for Section 404(b). The compliance costs are fixed and ongoing, and have a severe impact on the long-term investing of microcap and small cap companies at the forefront of developing new treatments for severe diseases. These small companies are the most affected by SOX at a time when they often have little or no product revenue to devote to compliance costs and must, as a result, shift funds from core research functions. This can lead to research programs being shelved or slowed as compliance takes precedence.

Further, the true value of biotech companies is found in scientific milestones and clinical trial advancement toward FDA approvals rather than financial disclosures of losses incurred during protracted development terms. Investors often make decisions based on these development milestones rather than the financial statements mandated by Section 404(b). Thus, the financial statements required do not provide much insight for potential investors, meaning that the high costs of compliance far outweigh its benefits.

Section 989G of the Dodd-Frank Wall Street Reform and Consumer Protection Act is an important acknowledgment by Congress that Section 404(b) of Sarbanes-Oxley is not an appropriate requirement for many small reporting companies. Dodd-Frank sets a permanent exemption from Section 404(b) for companies with a public float below \$75 million. This provision is particularly important because it provides consistency to companies who now have a clear understanding as to whether or not they are exempt. However, it is too narrow in practicality and must be raised. Because of the business model of innovative industries like biotechnology, companies generally have very low revenues compared to their market capitalizations. For example, it is not uncommon for a newly public biotech company to have a market capitalization in excess of \$600 million but have product revenues of \$1 million or less. Such a company would be required to fully comply with Section 404(b) despite its lack of revenue with which to pay for compliance.

In 2006, the SEC Small Business Advisory Board recommended that the permanent exemption be extended to companies with public floats of less than \$700 million to better fit the business model of industries like biotechnology. The Advisory Board's proposed ceiling would allow small innovative companies to focus on speeding cures and treatments to patients rather than SOX compliance.

The Advisory Board also realized that public float alone does not fully portray the complexity and risk associated with a reporting company, and suggested a revenue test to paint a fuller picture. Revenue should be a critical consideration when determining the appropriateness of Section 404(b) compliance, along with public float. The addition of a revenue test would better serve the congressional intent behind Sarbanes-Oxley by reflecting the truly small nature of companies with little or no product revenue. Public companies with a public float below \$700 million and with product revenue below \$100 million should be permanently exempt from Section 404(b), allowing them to focus their resources on critical research and development.

BIO strongly supports Congressman Fincher’s efforts to raise the public float exemption to a more practical level. H.R. 3213, the Small Company Job Growth and Regulatory Relief Act, would provide companies with a public float of \$350 million or less an exemption from Section 404(b). In conjunction with raising the public float exemption, BIO supports the use of a revenue test that exempts companies with product revenues below \$100 million.

Additionally, BIO supports the concept of an IPO “on ramp”, particularly as it provides relief from 404(b) requirements for newly public companies. BIO looks forward to reviewing upcoming legislation that addresses this issue.

The U.S. biotechnology industry remains committed to developing a healthier American economy, creating high-quality jobs in every state, and improving the lives of all Americans. Additionally, the medical breakthroughs happening in labs across the country could unlock the secrets to curing the devastating diseases that affect all of our families. There are many pitfalls and obstacles endemic to this effort, including scientific uncertainty and the high costs of conducting research. Congress has the opportunity to support and inspire biotechnology breakthroughs by unburdening startup companies and allowing innovators and entrepreneurs to continue working toward delivering the next generation of medical breakthroughs – and, one day, cures – to patients who need them.