MassBio
MASSACHUSETTS BIOTECHNOLOGY COUNCIL

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Testimony of Glenn Batchelder

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Joint Committee on Healthcare Financing

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Good morning, Chairman Welch, Chairman Sanchez and members of the committee. My name is Glenn Batchelder and I am the immediate past Chairman of the Board of Directors at MassBio. I have also had the opportunity to serve as CEO to a number of small biotech startups based here in Massachusetts, including most recently Civitas Therapeutics based in Chelsea.

I'm here today to share what the actual implications of Senate 1048 will be on life sciences startups, a key element of Massachusetts economic engine and a source of important new treatments for patients everywhere.

In considering Senate 1048, I hope that providing an example of the decades long and unpredictable process of discovering, developing, and ultimately bring new therapies to patients might illustrate some of the unintended consequences. I think it is important to understand that the accounting and reporting required in this bill are impractical for most early stage companies. This could also create a barrier to funding and disincentives to pursuing the fastest and lowest cost paths in developing new important medicines.

Starting in 2009, I served as co-founder and CEO of Civitas Therapeutics, a venture capital backed start-up. We founded Civitas with the goal of creating a new therapy for Parkinson's disease that we called CVT-301. To make Civitas and CVT-301 possible we acquired the AIR technology and the Chelsea manufacturing facility from Alkermes, a biotechnology founded in Massachusetts during the early 1990's.

The AIR technology and the associated 90,000 square foot commercial manufacturing facility were largely the result of collaboration between Alkermes and Eli Lilly during the early 2000's. Together they invested over $500 million dollars to develop an inhaled form of insulin for diabetes patients. Lilly stopped the program in 2008 leaving Alkermes with the AIR technology and an idle Chelsea facility. The Alkermes/Lilly investment and the AIR technology were essential to make Civitas and CVT-301 possible.

But how would we determine what portion of their investment should be attributed to CVT-301?

No good historic records exist. Alkermes and Lilly would have no interest spending the many hours required to document this even if it were in fact possible.

Further complicating the calculations, the original AIR technology was invented by an MIT spinout, Advanced Inhalation Research, which Alkermes acquired back in 1998. I am confident no records exist as to how funds were spent back then, let alone how they should be allocated to CVT-301.

This illustrates the complexity determining the costs associated with the critical enabling technology, let alone the final approved drug.

Back to Civitas: Our founding hypothesis was that the AIR technology developed for insulin could be repurposed to deliver an anti-Parkinson's medication. By delivering this agent to the lungs we could potentially solve one of the biggest challenges facing Parkinson's patients as they struggle to maintain independent productive lives.

Me and my two co-founder launched Civitas at the beginning of 2011 after working for more than a year to obtain venture funding. We then built the team, ran three clinical studies and raised over $100 million across three rounds of venture financing, and ultimately proved CVT-301 could be an important therapy for Parkinson's patients. We also invested significant amounts in a number of other early stage programs. In building any biotech company a large portion of the effort involves hiring people, raising the next round of financing, exploring potential development partnerships with larger companies.

These were all critical tasks to keep CVT-301 advancing, but how would we accurately allocate the costs to CVT-301 vs. other earlier products?

After completing the first three trials, we estimated we still needed well over a hundred million dollars in additional capital to complete the final trials require for FDA approval and launch of CVT-301. Venture capitalists are generally do not invest at this stage.

Our choices were:

Sell the company to a bigger company or raise the money by taking the company public, an IPO.

We ended up selling the company to Acorda Therapeutics who is completing the major activities required for FDA approval and plans to manufacture CVT-301 in Chelsea once it is approved. This is a Massachusetts biotech success story; over 50 manufacturing jobs being created in Chelsea, the investors will reinvest their funds in more early stage companies, and again Massachusetts will deliver another important new therapy for patients.

It is worth noting the unsuccessful stories far outnumber the success stories in this unpredictable business.

How might Senate 1048 have made this a different story?

First, I do not believe we could calculate with any precision the true cost of developing CVT-301.

Given the substantial resources required to capture the historic data or track the costs going forward, venture capitalists might not have invested.

Alkermes might not have licensed Civitas the technology. Retaining those historic costs on their ledger to accurately reflect the total cost of their existing products would likely have been more attractive than assigning them to a risky start-up.

If tracking and justifying development costs was an important part of determining the value of CVT-301, Acorda might not have acquired Civitas.

If Civitas wasn't acquired by Acorda, an IPO would likely have been our only means to fund CVT-301. The administrative efforts and expense required to transition a start-up into public market ready company entity are already daunting. For Civitas, the added burden of filing accurate costs for CVT-301 in the SEC filing could very well have foreclosed that option.

Potentially Senate 1048 could have stopped CVT-301 from ever being conceived, let alone reaching patients.

Having lived this example I have a hard time understanding how Senate 1048 would benefit patients or the Commonwealth as a whole.

I am now at the beginning of my fourth company, XyloCor, focused on gene therapy. Over the weekend I was sitting with a potential investor and to my surprise her central concern was how legislation like Senate 1048 would impact the viability of XyloCor. Civitas and XyloCor are not unique.

I would urge you to carefully consider the potential unintended consequences of this bill:

- Adding significant costs to the process of developing new drugs
- Inhibiting new company formation
- Increasing barriers to securing critical capital from both VC's and the public markets
- Discouraging large companies from acquiring technology and therapies from smaller companies
- And ultimately resulting in fewer new important therapies for patients

In summary, Senate 1048 would require companies to attribute spending throughout the organization—not just R&D cost, but also acquisition costs, administrative costs, manufacturing costs—to specific products reaching the market.

But without knowing how the research will play out, how would an early stage company retroactively categorize their expenses?

How would this intricate reporting appropriately account for all of the potential products that failed at some stage of the process?

In the bigger picture, how would the very real costs of failed programs and failed companies in our ecosystem be taken into account in the value equation?

At the very least, the language in Senate 1048 would require companies to invest money in much more complex accounting support, diverting critical early stage cash from the research. And overly burdensome regulatory requirement will continue to push critical venture capital out of life sciences and into other less risky industries.

From my perspective the risks to the Massachusetts economy are real. More importantly, it is not clear to me how adding these costs and complexities would benefit patients. The success of our life sciences ecosystem rests on a robust and healthy startup environment.