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## Upgrading the Tax Code to Bolster Biotech

**A handful of minor adjustments to the US tax code would have a major effect on biotech funding and the development of critical new therapies.**

When the Supreme Court upheld the Affordable Care Act in late June, it validated an important tax incentive designed to spur innovation in biomedicine. Embedded in the 2010 law, the Therapeutic Discovery Project (TDP) created \$1 billion in grants and tax credits to help small companies defray R&D costs. Nearly 3,000 early-stage companies benefited, to the tune of \$220,000, on average, according to the Biotechnology Industry Organization. The program provided an important shot in the arm in troubled times, enabling many companies to conduct studies that led to subsequent funding by investors.

The TDP was relatively small—the \$1 billion total would barely cover the average start-to-finish development costs of a single novel drug. But this program hints at what the United States could accomplish with a few other adjustments to the US Internal Revenue Code.

At a time when small companies are struggling to finance the next generation of medical breakthroughs and match mounting competition overseas, tax reform is one of America's most powerful and underutilized policy assets.

Many economists say actions such as these should be

call for action. Then it will describe some current proposals and will also respond to some of the more salient objections.

Faced with regulatory uncertainties and poor prospects for IPOs, venture capitalists have been shunning biotech companies. A widely reported funding spike from 2010 to 2011 actually masked an overall 12 percent decline in the four years since 2007, according to the National Venture Capital Association (NVCA). Alarming, BioWorld recently reported that capital raised by private and public biotech firms fell 40 percent in the first half of 2012, compared with the same period last year.

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reserved for cases where market mechanisms have failed and a whole industry is on the precipice. I agree. As outlined below, in the case of the biotechnology industry, the TDP together with other policy steps are required to avert just such a debacle.

First, this article will review the conditions that justify this

First-time financings for life sciences companies at the end of last year stood at the lowest level since 1996, according to NVCA, based on data from Thomson Reuters.

The trend lines are likely to worsen before they improve. In a global venture-capital confidence survey that Deloitte and the NVCA released in July, 81 percent of respondents said they expected either no change in funding for drug research com-



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panies or a decrease over the next five years. Big Pharma continues to inject capital into biotech through acquisitions and other deals. But these large companies have their own budgetary woes, as waves of layoffs and plant closings attest. Between 2011 and 2018, they risk losing \$290 billion in revenues due to patent expirations, according to London-based consultants EvaluatePharma. Cuts in research staff are now taking their toll. Earlier this year, when analysts at Ernst & Young modeled the top 28 pharma companies' "fire power" to foster innovation, they concluded that capacity fell about 30 percent between 2006 and 2011.

A few judicious changes to the tax code could ease the flow of investment dollars. One involves the application of Section 382, the quite reasonable purpose of which is to block corporations from sheltering profits on financial statements by acquiring money-losing shell companies. Section 382 restricts the use of net operating losses (NOLs) by companies that have undergone an "ownership change." An unintended consequence of this wording is that this is interpreted to include changes in ownership that occur when companies receive new investor financing. Biotech companies typically must rely on a series of outside financings over the 10 or more years it takes to develop a drug, and thus can lose the benefit of their legitimate NOLs under Section 382. If small biotech companies were able to retain their NOLs and include them as tax attributes on the balance sheet, investors would value them more highly in advance of additional financing rounds, including mergers and IPOs. NOLs on R&D by small

### How important are small businesses to the US economy?

#### Small firms:

- Represent 99.7 percent of all employer firms.
- Employ about half of all private sector employees.
- Pay 43% of total US private payroll.
- Have generated 65 percent of net new jobs over the past 17 years.
- Create more than half of the non-farm private GDP
- Hire 43 percent of high-tech workers (scientists, engineers, computer programmers, and others).
- Are 52 percent home-based and 2 percent franchises.
- Made up 97.5 percent of all identified exporters and produced 31 percent of export value in FY 2008.
- Produce 16.5 times more patents per employee than large patenting firms.

**Source:** Small Business Association's Office of Advocacy, [archive.sba.gov/advo/research/rs299tot.pdf](http://archive.sba.gov/advo/research/rs299tot.pdf).

biotech companies ought to be exempt from Section 382.

There are also ways in which the tax code could encourage investors to take stakes in biotech companies earlier in development and to hold them longer. Section 1202 allows investors to exclude 50 percent of their gains when selling shares of a qualifying small company they have held for at least five years. Many small biotech companies are excluded due to assessments of their intellectual property (IP) and successive rounds of financing. But they would qualify if lawmakers agreed to raise the qualifying limit to \$150 million, index the cap to inflation, and exclude IP and follow-on financings from the test for gross assets.

A third proposal relates to how an acquiring company is allowed to amortize some of the target firm's intangible assets. This term refers to properties such as patents, copyrights, customer lists, and trade secrets. In

biotech, it's not uncommon for an early-stage company to receive investments from a strategic acquirer. If the buyer chooses to purchase certain intangible assets, specified under Section 197 of the tax code, it may amortize them over a 15-year period. Shortening this amortization period to five years would encourage partners to make their investments early in the development cycle, when the biotech company most urgently needs cash.

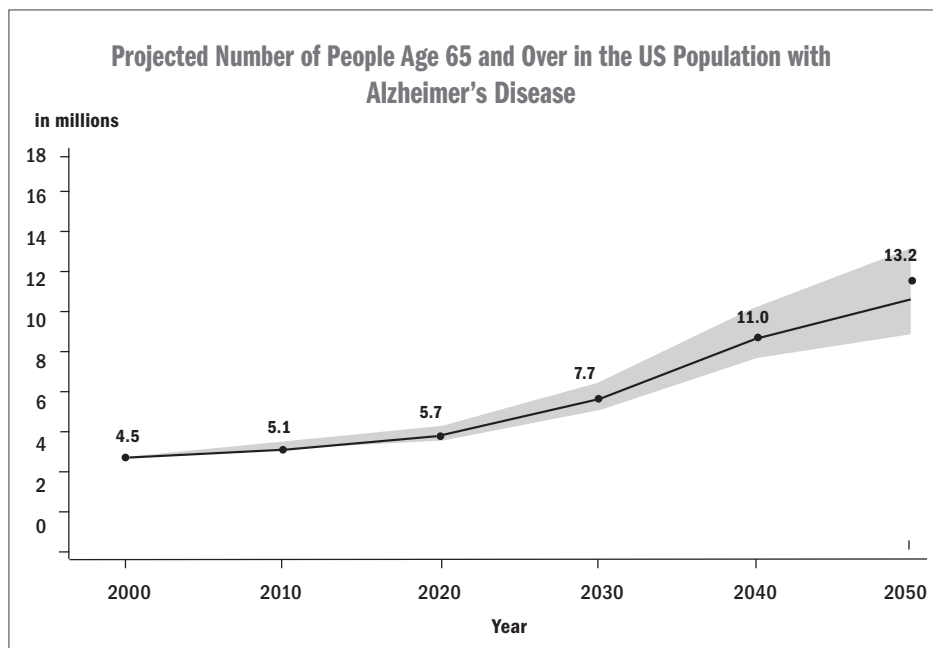
Proposals such as these don't sit well with some economists and lawmakers. Some cringe at picking industrial "winners and losers," or see tax credits as a form of corporate welfare. Sometimes the counter-argument is about fairness. Under a progressive tax system, individuals with higher incomes pay more in taxes. The fear, in this case, is that the benefits of a tax break may show up as an increase in after-tax earnings that flow through to the small business owner.

Incentives shouldn't enrich one class of small business owner over another, the argument goes.

Critics of tax incentives like those I have proposed also question two key precepts: that small businesses create more jobs than large ones, and that they are the rightful guardians of technical innovation. The arguments for and against are clearly laid out in a March 2009 report titled "Small Business Tax Benefits: Overview and Rationale," from the Congressional Research Service. While it's true that small businesses employ roughly half of all US workers (table on page 2), some studies show that they shed as many jobs as they create. And no one disputes that many large companies also excel at innovation.

Perhaps most persuasively, critics of tax restructuring say that measures like the ones I've described are only justified when market forces fail, thus harming smaller firms that may function in ways big companies can't duplicate.

These critiques fail to account for the unique role biotech plays in our economy and society, and the unique challenges that confront this industry. In medicine, small companies now account for the majority of cutting edge therapies in development. The coming treatments and cures for diseases like cancers, Alzheimer's disease, heart failure, kidney disease, diabetes, multiple sclerosis, and arthritis are more likely to emerge from small biotechnology companies than from large pharmaceutical firms. The failure of these biotech companies would have economic as well as health consequences. Consider that caring for Alzheimer's patients alone in 2012 is expected to cost Medicare



\* Numbers indicate middle estimates per decade. Colored area indicates low and high estimates per decade.

Source: Alzheimer's Association, "2012 Alzheimer's Disease Facts and Figures," Created from data from L. E. Hebert, P. A. Scherr, J. L. Bienias, and D. A. Bennett, "Alzheimer Disease in the US Population: Prevalence Estimates Using the 2000 Census," *Archives of Neurology*, 60 (8) 1119-1122 (2003).

more than \$100 billion, and the number of patients is projected to continue to rise (figure above). If a new drug could delay the onset by just five years, cost savings could be \$50 billion a year, according to Research!America's "Facts about Alzheimer's Disease."

Roughly 72 million Americans will be 75 or older in the year 2030. That's almost one out of every five citizens. Our hopes of treating these illnesses with truly novel medicines that can also curb costs in an aging society will rest, increasingly, on biotech.

Yet most of America's 2,500 biotech companies are struggling. The regulatory burdens on biopharmaceutical development are heavier than those of virtually any other industry; it now requires an average of 12-15 years and approximately \$1.3 billion to develop a single

new drug successfully. Only about one in 5,000 molecules proposed for development as a new medicine actually makes it all the way through the process to commercialization. Therefore, to an extent unmatched in other industries, investors in biotech are likely to curtail funding in times of economic stress. In fact, as noted earlier in this article, they have done precisely this over the past several years.

Further, this has occurred just at a time when global competition in biotechnology has become formidable: in 2011, China named biotech as one of seven industries that will receive \$1.7 trillion in government funding over the next five years, and India's Bioconnect initiative has funded more than 200 new biopharma projects. The shift in power is reflected in IP. At

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present, the United States holds more patents in biotech than any other nation; however, in a 2010 report Battelle prepared for the Council for American Medical Innovation, China and India were first and second in a ranking of the top 23 countries filing new biotech patents. The United States came in at 20.

Thus, the issue is not one of picking winners or losers, nor is

it an issue of corporate welfare. Rather, it is a matter of our society recognizing that we place unique burdens on our biopharmaceutical industry based on the special nature of its products to affect lives. These burdens can be shouldered by well-established companies with the kind of cash flow that enables ongoing investment in product development. But they become

a severe handicap to smaller, development stage companies that must rely on investor capital for periods exceeding a decade at a time. In such cases, our economic and medical self-interest calls for judicious relief where possible, to incentivize investors and small companies to fund the next generation of biomedical discoveries. 