STAT

Why the U.S. needs a public benefit biopharma industry

By Barbara Handelin *and* Sandra HeibelOct. 13, 2022

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The biopharma industry is failing Americans, economically and medically.

U.S. biotechnology and pharmaceutical companies, like all for-profit corporations, have a primary duty baked into their corporate charters: maximize profits and shareholder value. Unlike companies in other industries, however, biopharma companies have a special advantage: their products have market exclusivity upon Food and Drug Administration approval, which can be leveraged to maximize pricing for a specified period. During that time, they do not need to worry about competition on product pricing, quality, or supply capacity in order to maximize profits.

That means biopharma companies have had little incentive to reduce research and development or operating costs, especially in bull markets. Shareholders have had a happy ride as the industry has delivered high returns on investment[2], despite the touted high R&D risks and costs[3].

Because most disease indications are not blockbuster markets, the industry produces a narrow sector of all the "cures" needed. There are no treatments for 90%[4] of all known diseases, and the health care economy is crumbling beneath the cost of the drugs that are produced. Moreover, few methods exist for prevention and early detection of common killers, and the industry has all but abandoned low-margin products like vaccines and antibiotics[5] — until a crisis causes a stampede of reckless investment to push emergency development of products, as has occurred during the Covid-19 pandemic with testing, vaccines, and antiviral treatments.

The country needs a public benefit biopharma industry.

Not just a bear-market problem

The frailty of the current business model is amplified by today's bear market, causing company closures, retractions, and lost time and effort toward R&D as the burden of shareholder demands come back to roost[6] in the C-suite and on Wall Street. As one biotech exec wrote in STAT[7], "Biotech leaders must focus on the aspects of their business they can control to safeguard their companies and development pipelines."

Yet even if these companies are rescued, the country is still faced with the legacy of lack of productivity and the overwhelming burden of cost stemming from the biopharma industry.

Regulating prices only "moves the cheese"

New drug-pricing legislation in the Inflation Reduction Act allows the government to negotiate prices for some drugs covered by Medicare, but doesn't directly affect the 211 million[8] people with private insurance. The act's drug-pricing provisions could cause drug makers to try to recoup some lost revenue[8] in the private market.

This begs a social and economic question: Should Americans be relying upon high-profit markets to fulfill our most basic and precious need for prevention, diagnosis, or effective treatments for their ailments?

The case for financial innovation in the biomedical innovation industry

While some pharmaceutical companies can trace their roots[10] to the 1600s, the biotech industry emerged in the 1970s[11], financed with high-stakes venture capital and avid public financial markets. The list of market failures in today's biopharma business model (more on that in a minute) points to underappreciated investment opportunities that can generate global impact in the treatment of a broad spectrum of human diseases — beyond the classic neglected and rare disease — with commensurate returns, and indicate a need right now for financing innovation.

The business model for the biopharmaceutical industry has peculiar characteristics that drive the need to maximize prices rather than compete on operational efficiencies:

- biopharma companies rely on the majority of their profits from just a few products
- the vast majority of existing drugs are never repurposed for a second or third use despite hundreds of millions of dollars invested in research and development
- legacy batch manufacturing[12] methods are inefficient[13] — and create significant toxic waste[14] — and are centralized in only a few locations with deficient regulatory oversight[15], creating a vulnerable supply chain
- sales and distribution account for 50% to 75% of operating costs for medicines that have no real competition because patients are a captive market

A business model that reduces risk and delivers more productivity

Innovation in the business and financing of biopharma companies is arising from seasoned leaders in research and development, business development, intellectual property, and sales and marketing who are rejecting the limitations of their legacy industry and building new companies with compelling business models. Companies like these are in operation today, with varying financial and corporate structures. Examples include Bridge Therapeutics, Medicines Development for Global Health, Medicines For All, OWP Pharmaceuticals, reVision Therapeutics, Sequella, and others.

This new generation of companies expects to operate leanly, think beyond patent protections, compete on quality and price, cut out middlemen, keep their focus on the purpose of the industry, and let the profits follow in measure. As management consultant guru Peter Drucker famously said, “No financial man will ever understand business because financial people think a company makes money. A company makes shoes, and no financial man understands that. They think money is real. Shoes are real. Money is an end result.” Financial women may also be so limited in their thinking!

Just as hardware stores carry many items that no one customer will ever need, and no two or three items could sustain the store’s revenue requirements for a vibrant business, so too will companies in the new model facilitate the development of broad and profitable portfolios.

If they meet the objective of addressing many untreated conditions, the sum of these many will support sustainable, robust companies. But the time and scale for returns does not match the current investment algorithms.

New-model companies have one thing in common: finding aligned capital investment is rate limiting, preventing them from generating margins on steady revenue with high medical value products addressing unmet medical needs.

Financing a new biopharma sector

We propose a systematic solution to the financing conundrum. It will serve as a model that can unlock billions of already invested capital, both dollars and intellectual. Companies built on this model can provide returns on investment for investors that are risk-adjusted with an old-fashioned business plan that requires them to be cost and time efficient with the customers' interests in focus: good medicine at sustainable cost. The financing blueprint should meet the following requirements:

- provide capital for companies or projects with a range of commercial potential — no reliance on blockbusters
- incentivize companies to pursue drugs that already have some proof in humans of safety and/or potential effectiveness and shorten the time to reach patients
- support advanced innovations in manufacturing to reduce costs, enhance quality, and create a secure drug supply chain
- create incentives for companies to develop strategic commercial contracts for more direct — meaning less costly — distribution of their drug products
- reward long-term sustainability, in all aspects of the term "sustainable"
- deliver effective medicines at price points that are accessible for all

This kind of investment market presents investors with returns on investment commensurate with reduced risks. This is in accordance with the standard investment rubric, which posits that risky investments offer a chance of high returns while low-risk investments yield low but almost guaranteed returns.

To achieve this goal, we have established a commission[19] on financing a public benefit biopharma industry to shape the new financial curve. The inaugural meeting, held on Oct. 10, brought together seven financial innovators from a range of backgrounds, including bank executives, investors, former pharma business executives, incubator directors, and academic institute leaders. The meeting clarified that the purpose of the commission is not to tear down the extant industry, but rather to foster a new channel to fill gaps left by the legacy biotech/pharma enterprise.

We believe that establishing companies with long-term, triple-bottom-line investment — people, profits, and the planet valued equally — provides the world with a robust and sustainable biopharma industry that truly benefits the public.

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