PIONEER HEALTH

The Negative Impact of COVID-19 Upon the Biopharmaceutical Sector

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WHITE PAPER
No. 207 | May 2020

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PUBLIC POLICY RESEARCH

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Introduction

The emerging conventional wisdom is that the coronavirus pandemic will generally have a beneficial impact upon biopharmaceutical companies that may have commercial opportunities with vaccine and treatments for the virus and may also improve the image of the industry with the public. [1,2] This paper argues the opposite.

First, like many industries, the biopharmaceutical sector is experiencing disruptions in their business operations, including research and development, sales and clinical trials. Potential mergers and acquisitions have slowed and a number of companies revised their financial forecasts downward for the rest of the year.

Second, while there certainly will be huge commercial opportunities in treatments for COVID-19 with literally worldwide demand, many of these potential treatments will require massive investments in clinical development and manufacturing. Moreover, when new treatments actually come to market, political pressures on pricing may make these investments unprofitable. No matter where the price points land for future COVID-19 treatments, they are unlikely to satisfy industry critics. Not only will there be downward political pressure on prices, there will be calls to strip patents and make any new therapy available at low cost worldwide. These political pressures are likely to be most acute in the area of vaccines, where the federal government is providing grants to companies such as Johnson & Johnson and Moderna. Many policy makers will likely see any new vaccine that emerges from research that was partially funded by the government as public property.

The pressure for very low prices will be so intense that, if one were to set aside humanitarian concerns and consider only the business impact of the current pandemic, one could argue that, in the current political environment, it is not in the interest of shareholders for biopharmaceutical companies to pursue COVID-19 treatments. The politicization of any pricing decisions will be pervasive and persistent.

Finally, the inevitable pricing controversies are very likely to dissipate any good will that the industry has accrued in the current "honeymoon" phase, when they are seen as committing significant resources and expertise to find COVID-19 treatments and vaccines. Many prominent members of the nation's political class have conducted a decades-long propaganda campaign against the biopharmaceutical industry; there is little reason to think that this campaign will be put on hold. In fact, there is good reason to suspect that the campaign will turn particularly vitriolic as successful treatments emerge.

The impact of all this upon the industry therefore will be largely negative. While many biopharmaceutical companies are profitable and will not need government assistance, many companies will emerge commercially weaker, with delays in new product launches and with fewer resources to invest in research and development. Smaller, newer companies will have particular difficulty launching trials and getting to market. More ominously, the lesson companies may learn from the coming political attacks will be that they should shy away from investing in treatments for diseases that are major public health challenges. Companies may decide that treatments for "lifestyle" issues or for less serious conditions are more likely to drive shareholder value. If, post-pandemic, biopharmaceutical research makes a turn in this direction, it would be a significant setback for the public health.

The Pandemic and Disruption of the Biopharmaceutical Business

Like other industries, the pandemic has created commercial and research challenges for biopharmaceutical firms. Many of these challenges are significant, from regulators who are not in their offices to fewer "medical tourists" traveling to the US for treatment. But biggest ones fall into several distinct categories:

- Disruption of clinical trials
- Declining sales due to fewer patient-physician interactions
- A pause for the in-person sales representative model
- Supply chain and distribution challenges
- Widespread share price declines

Disruption of Clinical Trials

The potential disruption in research and development activities, clinical trials in particular, is substantial. As one Evaluate Vantage report described the situation: "Most drug makers have delayed the start of new trials; with populations in lockdown, hospitals no-go destinations and doctors and labs re-prioritised, the logistics required to get studies up an running have become impossible in many locations."[3]

> While biopharma companies may not need government assistance, many will emerge commercially weaker, with delays in product launches and fewer resources to invest in R&D.

This same study reported that there are 315 phase III studies, costing $20 billion and having 172,104 patients enrolled, which were supposed to be completed this year. More than half of these trials were still recruiting patients when the pandemic hit. Those studies that need to enroll more patients are going to see their deadlines extended much further into the future.

Evaluate Advantage completed a further analysis by examining clinical trial entries that are registered on "clinicaltrials.

gov" by public biopharmaceutical companies and found that 6,461 trials had been registered with an estimated total cost of $291 billion.

Most of these trials will still likely proceed, although their completion is likely to be delayed significantly, with the largest impact upon smaller companies for which the firm's future depends upon a successful trial.

The pandemic has created commercial and research challenges for biopharmaceutical firms, as it has for other industries.

Finally, delays in clinical trials have a significant long-term financial impact upon the industry. Typically, companies file a patent before any therapies are placed into clinical trials. Therefore, significant delays in clinical trials eat up valuable patent life and limit the period when a drug can be sold under patent and not copied by generic companies.

Declining sales for some non-COVID treatments because of fewer physician visits

According to very recent data from IQVIA, a pharmaceutical marketing analytics firm, healthcare provider-patient interactions dropped more than 60 percent from early March to early April.[4] In early April, increased telehealth claims helped flatten out the steep decline in physician interactions, albeit at a much lower level.

Even if companies can shift successfully to some form of online marketing, sales will inevitably decline during the pandemic due to patients avoiding physicians' office and hospitals for fear of contracting the virus. As IQVIA pointed out: "it is expected that delays in treatment will negatively affect volume growth in the short term, especially in hospital sectors."[5]

IQVIA notes that it is very common in nations experiencing the pandemic for patients and physicians to postpone non-urgent treatments that will inevitably weaken biopharmaceutical sales for non-COVID therapies.

Typical weekly prescription volume is in the range of 79 million but the last week of April saw volume drop to 68.9 million.

This decline in provider-patient interactions has indeed led to a steep decline in the number of prescriptions. During March, there was a surge in patient stockpiling of medicines compared with the eight week pre-COVID period ending February 28th. Since about mid-March, the volume of prescriptions has plummeted for both retail and mail order sales. Typical weekly prescription volume is in the range of 79 million but the last week of April saw volume drop to 68.9 million.

The decline in prescription drug sales was particularly acute for those treatments that must be administered in the physician's office. For example, for the week ending April 10 (and compared with an eight-week period ending February 28), claims for in-office COPD treatments were down 86 percent, vaccines were down 72 percent and asthma treatments were down 71 percent.

This loss of sales for new drugs will be partially offset by patients who want to make certain that they have an adequate supply of their chronic medications and are diligently refilling their prescriptions. For example, when reporting their earnings recently, Eli Lilly & Company pointed out that revenues had surged 15 percent in Q1 due to "increased inventory across the supply chain including at the patient level." Lilly's CEO David Ricks, however, pointed out that "the COVID-19 pandemic is likely to have a negative impact on our business in the future."[6]

So even companies with solid portfolios of medications for chronic diseases, such as diabetes, are projecting that the reduced ability to market their products will have a disruptive impact.

Finally, some of the non-COVID data is very troubling when you look at certain specialties.[7] For cancer treatment, for example, 74 percent of oncologists indicated that they had delayed cancer surgeries while 48 percent of indicated that they have delayed administering chemotherapy. One new study indicates that cancer screening for breast, colon, and cervix cancers were down about 90 percent in March.[8]

A Pause in In-Person Sales and Marketing

While pharmaceutical marketing to physicians has received some legitimate criticism in the past, one can argue that when it is properly employed, this form of marketing is one of the most efficient ways to effectively transfer technology from the laboratory to the patient. When the FDA approves a new drug, that drug is "launched" into the market by a literal army of sales representatives who are trained to educate physicians on every aspect of the efficacy and safety data from the clinical trials for that new drug. Many busy physicians, especially primary care ph dysicians, simply do not have the time to read all the published clinical data from the dozens of new drugs approved each year. In a 30-minute lunch and presentation from a company sales representative, physicians can learn all the important facts about a new therapy.

The pandemic has disrupted this entire marketing and technology transfer apparatus. Both physician offices and pharmaceutical companies want to keep their employees safe, so in-person marketing has been suspended. While sales forces are attempting to shift their marketing of physicians

to online platforms, this shift will undoubtedly cause major disruptions in sales, particularly for those companies launching new drugs.

Another significant challenge for companies attempting to market to physicians is the loss of national and regional medical conferences where biopharmaceutical companies can create a "buzz" about their products by releasing data, distributing marketing material, promote their R&D pipelines, and otherwise mingle with key medical opinion leaders.

Supply Chain and Distribution Challenges

Like any business, biopharmaceuticals depend upon a supply and distribution chain that has been disrupted by the pandemic. The supply chain issue to receive the most attention during the pandemic is the vulnerability of America's supply of generic drugs and Active Pharmaceutical Ingredients (APIs) from foreign nations such as India and China. This vulnerability is particularly acute in the area of antibiotics.

This supply chain issue is of enormous public health importance and commercial complexity. However, it involves the unique requirement for low-cost manufacturing by the generic drug industry. Currently, there are only anecdotal reports of specific drug shortages, but if the pandemic persists for a lengthy period, China and India could choose to reserve key APIs and medicines for their domestic populations, sparking price spikes or even major shortages in other nations.

However, even the branded drug industry must worry that their manufacturing and distribution systems could be disrupted by the pandemic. One McKinsey report recommends that these companies "take a forensic view of your supply chain and operations to derisk key elements such as in-market supply."[9] McKinsey points out that certain treatments related to COVID could see "huge spikes in demand that are putting pressure on supply chains." IQVIA reports that there has been a huge spike in demand for certain over-the-counter medications with many consumers stockpiling "immunity enhancing treatments, vitamins, analgesics (especially paracetamol), anti-infectives, and cough and cold medications."[10]

Financial Markets' Reaction to Biopharmaceuticals and COVID-19

Given the business disruptions outlined above, it is not surprising that, in general, the markets have reacted negatively. Evaluate Advantage studied the first quarter stock market trends for 600 global drug companies and found that "every market cap bracket fell in the first quarter.[11] The biggest drop was for large cap pharmaceutical companies and the smallest for companies with market caps of between $250 million and $5 billion. But the market trended downward for the entire sector.

For the biotechnology sector specifically, biotech shares have been volatile but have generally declined. That said, however, the Nasdaq portfolio of biotech stocks has outperformed the S&P 500. A handful of biotech stocks that have surged on the basis of potential treatments or vaccines, such as Regeneron, Gilead, Moderna and BioNTech, which partnered with Pfizer in mid-March on a potential vaccine.

Within the large cap pharmaceutical sector, average share prices have declined but stock performance depended upon the nature of the company's portfolio. As has been mentioned, Ely Lilly, with its portfolio of diabetes treatments, saw an upside as diabetes patients stockpiled their treatments. Merck, on the other hand, cut their revenue estimates for 2020 by $2.5 billion because two-thirds of its portfolio is physician-administered treatments such as vaccines, which generated over $8 billion in sales during 2019, as well as their blockbuster cancer drug Keytruda.

Evaluate Advantage studied stock market trends for 600 global drug companies and found that "every market cap bracket fell in the first quarter."

However, the most interesting "canary in the coal mine" on the stock market came right after Gilead announced its first successful controlled trial for Remdesivir. One would have thought that Gilead's stock would have risen in a straight line. However, after Gilead announced that they would spend $1 billion to ramp up their Gilead franchise, their stock fell 5 percent. A number of Wall Street analysts remarked that the reason for the drop was fears that political pressure would lead to very low prices or even threats to Gilead's patent. As one analyst put it, "once Gilead starts charging for the product, we expect calls for the exercise of march-in rights and compulsory or no-cost licensing to become louder."[12] These policy challenges are discussed in more detail below.

Treatment Opportunities

The number of treatments and vaccines in development for COVID-19 is staggering given how recent the pandemic flared. In Massachusetts alone, the Boston Business Journal reports that more than two-dozen companies are working on COVID-19 treatments.[13] As of late April, one report indicated that: "More than 140 experimental coronavirus treatments and vaccines are under development worldwide, including 11 in clinical trials.[14] Another 254 clinical trials are underway for coronavirus treatments or vaccines derived from drugs already approved to treat other diseases."

This paper therefore cannot serve as a comprehensive account of the massive research & development efforts around COVID-19, but can simply highlight major areas of research that may provide commercial opportunities for the industry.

Vaccines

There is broad agreement among public health authorities that a safe and effective vaccine is the ultimate solution to the pandemic. Many entities—large pharma companies, smaller biotech companies, universities, foundations and the federal government—have all jumped into vaccine research.

In Massachusetts, two efforts are worth discussing. Cambridge-based Moderna Therapeutics is working on a so-called mRNA vaccine. This cutting-edge technology involves injecting "dummy" viruses, i.e. not live or dead virus but artificial creations that resemble the virus, into the body in the belief that the body's immune system will recognize the real virus, if it appears, and destroy it. On May 5th, Pfizer and BioNTech jointly announced that they had begun injecting human subjects with their mRNA vaccine candidate; they simultaneously announced that they would begin expanding their manufacturing network "at risk" to prepare for large-scale production. (An "at risk" investment means they will ramp up manufacturing investments before they have definitive clinical evidence of the vaccine's safety and efficacy.)

No vaccine has been approved utilizing these mRNA technologies but they have stirred excitement because of their potential to come to market faster than technologies that use live viruses.

There is also considerable talk of the efforts by Johnson & Johnson to develop a vaccine targeting the SARS-CoV-2's spike protein, a fragment on the surface of the virus shaped like a crown that could be easily recognizable by the body's immune system. The J&J effort received a significant investment from the U.S. Department of Health and Human Services, representing a very large public-private partnership.[15]

Drug maker AstraZeneca is partnering with scientists at Oxford University to develop a vaccine based upon a weaker version of the virus that nonetheless may spur the body's immune system to recognize more dangerous form of the virus and attack it.[16] Oxford had already begun testing their vaccine candidate in humans and their partnership with AstraZeneca will help them to ramp up large, later-stage testing.

Finally, two huge vaccine makers, Sanofi and GlaxoSmithKline, announced a partnership to develop a vaccine by combining their respective companies' expertise: Sanofi's expertise with so-called recombinant DNA and GSK's technologies that help boost the immune system.

Anti-Virals

After decades of research on SARS, MERS, HIV, Ebola and malaria, the biopharmaceutical research sector has developed considerable expertise in technologies that may inhibit the virus.

Gilead, for example, had developed Remdesivir as a treatment for Ebola after it showed promise in animals. It did not prove terribly effective in humans, but scientists did notice that it has more activity against coronaviruses such as SAR and MERS. So when COVID-19 appeared in Wuhan, Chinese researchers reached out to Gilead to begin studies. After one of the first COVID-19 patients appeared in the U.S. in Washington state, he was given Remdesivir and his fever dropped and he no longer required supplemental oxygen. While their trials in China were not definitive because the pandemic ebbed and trial enrollment dropped, Gilead has launched major U.S. trials. The first of those controlled trials reported last week and demonstrated some efficacy in reducing the length of hospital stays and a slight drop in mortality. There are numerous other Gilead trials yet to report.

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One older malaria drug promoted by President Trump, hydroxychloroquine, has proven to be the most controversial treatment. The drug has proven effective in the lab in preventing viruses from infecting cells, but the evidence was not as persuasive in actual human subjects. Hydroxychloroquine has been prescribed off-label many times by ICU physicians with very sick patients but no definitive consensus has emerged on its effectiveness. However, some major pharmaceutical companies such as Novartis and Sanofi have launched large, blinded and controlled trials that are likely to settle questions about its safety and effectiveness.

Numerous other anti-virals and influenza treatments are being testing such as Favipiravir, a flu treatment that a Japanese company, Toyama Chemical, has put into trials.

Immune System and Antibodies

Finding ways for the immune system to secure antibodies against the virus is considered one of the most promising treatments against it. Much attention has been given to "convalescent plasma" or using blood plasma from recovered patients to infuse sick patients with antibodies. Assisted by New York's Mount Sinai Hospital, one of the largest efforts to collect blood with antibodies was launched by the non-profit New York Blood Center. The FDA is permitting doctors to use experimental plasma on the sickest patients.

New York biotech company Regeneron has generated considerable interest for it its research into animal-generated antibodies that might he effective in humans. Regeneron expects

to begin testing some of these antibody treatments in humans during June.[17]

Very recently, there is reporting about a breakthrough on antibodies in Israel. Scientists at Israel's Institute of Biological Research have isolated a 'monoclonal neutralizing antibody' that could potentially neutralize the virus after infection.[18]

Other Treatments

Biopharmaceutical companies and university laboratories are researching many, many existing treatments for cancer, HIV, inflammation, and other conditions that may have a beneficial impact upon some aspect of the problems created by the coronavirus. Research into these existing treatments has the advantage of working with a therapy with a clear safety profile.

Larger companies and university labs also have libraries of drug molecules and compounds that are being scoured to find a compound that may work effectively against the virus. An entire ecosystem of partnerships has developed between large companies and smaller companies, government and the private sector, private foundations and public companies and between academia and the private sector. The amount of money, effort and scientific expertise being deployed against this virus is truly astonishing.

Commercial Prospects for COVID-19 Treatments

Despite the worldwide market, it seems unlikely that companies that bring successful COVD-19 treatments to market will enjoy significant financial rewards. It is a truism of American political life: companies that provide products that are essential to people's daily lives find that their pricing decisions become highly politicized. For this reason, pharmaceuticals, oil and health insurance companies, and to some degree airlines and cable companies, find themselves regularly criticized by politicians for their prices.

Therefore, as new COVID-19 treatments emerge, there are two possible pricing scenarios: one, companies preempt the political firestorm and price their products unprofitably or; two, companies price their products based upon the market and then lower prices after the inevitable political attacks. Under either scenario, the commercial prospects for these products are not strong.

To illustrate the political dynamic that occurs when a public health emergency arises, we should recall the hysteria in 2001 around the pricing for Cipro, the one antibiotic that is well suited to treat anthrax.

In the weeks after September 11, 2001, letters laced with anthrax began arriving in mailboxes around the country. The number of people exposed to anthrax was quite small but, tragically, five people died from their exposure and 17 others were treated for the infection.

Given the small number of people infected, there seemed little prospect that there would be a shortage of Cipro. The Centers for Disease Control recommendation for patients exposed to anthrax is to take Cipro twice a day for 60 days.[19] Therefore, at $1.83 per tablet, the price of a Cipro treatment would have been about $219 for each patient. While policy makers were not certain of the extent of the anthrax outbreak, all the patients who were exposed to anthrax could have been treated for a few thousand dollars.

Despite the worldwide market, companies that bring successful COVD-19 treatments to market are unlikely to enjoy significant financial rewards.

For some politicians, this relatively modest price was not low enough. Senator Charles Schumer (D-NY) forcefully argued that Bayer's patent for Cipro should be stripped by the federal government and given to a generic company so it could be sold at a cheaper price.[20] In response to the growing criticism, the Secretary of Health and Human Services, former Wisconsin Gov. Tommy Thompson, also threatened to take away Bayer's patent. In response, Bayer agreed to about a 50 percent price cut for Cipro.[21]

The Cipro controversy presages what will happen to companies who seek to price COVID-19 treatments based upon their value in the market.

Internationally, the preemptory calls to discard patents for COVID-19 treatments have already begun in earnest. In early April, Francis Curry, director-general of the World Intellectual Property Organization at the United Nations said that during a public health emergency, health and safety "trumps everything."[22] What Curry most wants to trump are intellectual property rights for COVID-19 treatments.

The Chilean and Ecuadorian governments have already announced that they are taking measures to permit "compulsory licenses" for COVID-19 treatments while two other nations that are generally more respectful of intellectual property rights, Germany and Canada, have passed legislation to make it easier to issue compulsory licenses.[23]

Perhaps most shockingly, the Institute of Virology in Wuhan, China filed a patent request for Gilead's drug Remdesivir.[24] Gilead themselves had filed for a Chinese patent on the drug in 2016. China does not have a strong tradition of protecting intellectual property, but it seems highly ironic that the laboratory that may have been the source of the pandemic would be the organization chosen to take away Gilead's intellectual property.

Likewise, in the United States, there have been numerous

calls to weaken the intellectual property rights for COVID-19 treatments and to make certain that these future products are not profitable for biopharmaceutical companies. On February 20th, 46 members of Congress wrote to President Trump urging him "not to provide an exclusive license to any private manufacturer for a coronavirus treatment… Providing exclusive monopoly rights could result in an expensive medicine that is inaccessible."[25]

Even before the results of Gilead's Remdesivir trial had been peer-reviewed, on May 1, the Institute for Clinical and Economic Review (ICER) announced that they had completed a cost-effectiveness review of Remdesivir.[26] While the headlines trumpeted ICER's conclusion that the drug could be cost effective at a price of $4,460, the fine print of the review indicated that, given the data in the just-announced trial, Remdesivir deserved only to be priced at $390.

Arguably, the largest anti-industry media platform can be found at STAT News. On May 5th, they offered a voice to activists who wanted to preempt any pricing decision by Gilead.[27] Senator Ron Wyden (D-OR) was quoted as saying that "Without tools to take on price gouging, America's strained health care system will be at the mercy of the pharmaceutical industry." Wyden's statement, of course, came before any price had been announced for Remdesivir.

The story also quoted an activist from Public Citizen who offered that the price of Remdesivir should be $1 per day.

Intellectual property experts point to two features of federal law that industry critics would use to strip pharmaceutical patents or threaten companies to lower their prices. The first is 1980 intellectual property law, the Bayh-Dole Act, that provides what are labeled "march in rights" that would permit the government to take a patent holder's intellectual property if important "health and safety needs" are not being met. This would allow the government to grant a license to a generic company to copy and sell the medicine. The exercise of march in rights would be permitted for any drug that was created with the use of federal funding. Because the federal government has been pouring billions of dollars into COVID-19 research, many treatments that emerge could become candidates for march in rights.

The federal government has never exercised march in rights, and some legal experts argue that the provision was never intended as a tool to lower drug prices.[28] However, in a crisis, many politicians would likely seek to exercise it.

The second and probably more powerful legal tool to seize patents is found in the famous Section 1498 of the U.S. Code which allows the federal government to seize a patentee's intellectual property if the owner is provided with "reasonable" compensation.[29] It was thought that Secretary Thompson threatened to use this provision in 2001 to obtain a lower price for Cipro. Unlike Bayh-Dole, this provision is explicitly used by the government to lower prices and is not limited to treatments that have been funded in some way with federal money.

While the government has powerful tools to threaten patents and reduce prices, it is still unclear how biopharmaceutical companies will react to the emerging threats. They could simply write off their investments in potential COVID-19 treatments and sell these products at a loss, or price them based upon their value and thereby risk a mountain of opprobrium. One company, Abbvie, concluded that the potential criticism is not worth any commercial benefit that may arise and announced they would not enforce their patents on the HIV treatment Kaletra, which is being tested for its anti-coronavirus potential.

There are humanitarian reasons why companies may choose not to profit from their treatments but there are also arguments that threats to intellectual property create significant disincentives for companies to invest in treatments.

This paper is not offering moral judgments about what is the correct strategy for companies to adopt and is only offering the conclusion that COVID-19 treatments are not likely to be profitable for the industry because of the current policy environment. There are humanitarian reasons why companies may choose not to profit from their treatments but there are also arguments that threats to intellectual property create significant disincentives for companies to invest in treatments.

Therefore, industry critics may wish to be sensitive to the fact that some investors and some industry leaders may conclude from this situation that R&D investments in treatments for major public health emergencies are financially suspect and they should be avoided. Better to research lifestyle treatments or medicines for less serious conditions where threats to intellectual property and agitation for lower prices are less prominent. As one investment banker said of the Gilead dilemma on Remdesivir, "If a company that has maintained the capability and product library to respond to this kind of massive infectious disease threat is then saddled with mandatory licensing and zero profit, it would have to impress even the most misinformed lawmakers as a negative signal to the rest of the industry."[30]

Impact of COVID-19 Upon the Massachusetts Biopharmaceutical Industry

The biopharmaceutical sector is one of the most dynamic components of the Massachusetts economy. According to the Massachusetts Biotechnology Council (MBC), employment growth in this sector was 35 percent over the last decade with

industry growth surging by 6.4 percent during 2018 alone.[31] Moreover, the Massachusetts biopharmaceutical industry is R&D-intensive, as job growth in R&D over the past decade has been 47 percent.

However, as the MBC report points out, tabulating private sector job growth severely underestimates the size of the huge life sciences ecosystem that exists here. Massachusetts institutions secure the second highest amount of funding from the National Institutes of Health, totaling nearly $3 billion in 2018. Private venture capital firms invested $4.8 billion in Massachusetts life sciences companies during 2018. This government as well as private sector funding helps support one of the finest clusters of life sciences research in the world. This life sciences ecosystem of small biotech companies, large pharmaceutical companies and world-class universities and hospitals—this staggering collection of medical expertise is arguably the crown jewel of the Massachusetts economy.

Patent life on these products should be extended by the period that clinical trials were delayed because of the pandemic.

While private-sector life science companies have higher margins than many service sector companies and will not see a comparable level of immediate layoffs, there is no doubt that COVID-19 will create strains for the Massachusetts biopharmaceutical sector.

First consider the disruptions that are taking place within the research laboratories of private companies, academic laboratories, and at research hospitals. Much of non-COVID-19 research has been put on hold. During 2019, Massachusetts' private sector-companies had 2,253 drug candidates in various stages of pre-clinical and clinical testing, trials that were costing billions of dollars and were largely paused. In the academic sector, for example, much post-doctoral laboratory work has been frozen unless the work is related to COVID-19. Academic medical centers likewise have had to postpone many non-COVID-19 clinical trials, as hospitals may not be open to non-COVID-19 patients or trial subjects.

Once recent survey of biotechnology companies found that, "Over three quarters of the 99 survey respondents said their ability to start new trials or to continue active trials has been hindered by the coronavirus outbreak."[32] Another survey indicates that more than half of biotech companies report that "all new" R&D projects are being delayed or cancelled.[33] These research dislocations are likely to ripple through and disrupt company pipelines for years to come.

Moreover, this disruption in research can be financially problematic for certain companies. Those, for example, whose future depends upon completing a key clinical trial will find that a difficult task in the current environment. That disruption may cause the company to lose value or even lose investors.

The pandemic is taking the harshest toll on some of the most innovative companies in this sector—small biotech startups. STAT News reports that a Bernstein bank survey indicates a number of small biotech firms are running out of cash and "a growing number of these companies are coping by reducing staff, slashing compensation, or cutting spending on pre-clinical program."[34] Massachusetts, and Cambridge is particular, is a hotbed of these types of small, startup companies. For example, 35 percent of all U.S.-based biotech companies that went public in the first half of 2019 were Massachusetts companies.[35]

However, even larger companies are feeling the strain of the pandemic, with the same Bernstein survey reporting that 31 percent of profitable biotech companies have laid off staff and 34 percent are reducing compensation.

While the economic disruption to Massachusetts' biopharmaceutical companies will not be as immediately severe as other industries have experienced, the longer-term damage to the industry is likely to be significant. Industry employment is likely to shrink during 2020 but maybe more importantly, key research projects on promising therapies are likely to be disrupted, delayed or even cancelled.

Key Policy Recommendations

Currently, the biopharmaceutical industry is not in need of cash bailouts or other forms of direct assistance. However, because the industry is now diverting a huge portion of their research efforts to COVID-19 and, as described above, they are unlikely to profit significantly from these efforts, some policy options should be considered.

1. Regulators should demonstrate significant flexibility in reviewing data from clinical trials that have been disrupted or delayed. Such flexibility would include allowing changes in clinical protocols without undue process and the use of telemedicine in trials. Keeping these trials on track is important to both public health and the commercial success of the industry.
2. Congress should consider ways to extend the patent life of therapies that were patented but clinical trials were then delayed. Patent life on these products should be extended by the period that clinical trials were delayed because of the pandemic. Restoring a reasonable period of exclusivity would be a way for the government to assist the industry without extending a bailout.
3. Companies that make significant investments in COVID-19 treatments should be able to secure a reasonable return on their investments. For example, if a company invests $1 billion to create manufacturing capacity for a new vaccine, that vaccine should be priced in a way so the company can recoup that investment. Failure to reward such investments will create large disincentives

for companies to tackle public health crises in the future.

4. State officials should make it a priority to increase the ability of patients to secure treatments where access has been disrupted by the pandemic. For example, pharmacists might be given a larger role in administering vaccines or other treatments that currently can only be administered in physicians' offices. Likewise, regulatory hurdles to telemedicine should be lifted to allow easier prescribing from online platforms. These reforms will not only help patients to remain healthy, but will help mitigate the sales downturn some companies are experiencing.
5. Likewise, state regulators should seek ways to increase access to medicines for older Americans who are most vulnerable during COVID-19. Access to medicines could be increased by: making 90-day refills easier to obtain, reducing high out-of-pocket costs, and easing burdensome prior authorization or step therapy requirements. Increased access to medicines for older Americans will make them as healthy as they can be and also increase sales for the industry at a time when they are making significant COVID-19 investments.
6. An expert commission should be formed to make recommendations on improving the supply chain for medicines. Thankfully, there was no major crisis in accessing certain key drugs during the current pandemic, although shortages of some drugs were reported. However, a lengthier or different type of pandemic could indeed have created a crisis in the drug supply. A commission could examine the vulnerability of the supply chain in key therapeutic areas and make recommendations to the President and Congress.

Conclusion

The biopharmaceutical industry sector, as well as the other components of the life sciences ecosystem such as academia and hospitals, is one of the most dynamic and important American national treasures. During this pandemic, its importance and expertise should be obvious to all. Policy makers should pay careful attention to the strains and disruptions taking place with this ecosystem and make changes that will strengthen it. As we look to erase the current pandemic and look to the next one, we want our nation's and our world's arsenal of medicines to be even stronger.

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About the Author

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Pioneer Institute is an independent, non-partisan, privately funded research organization that seeks to improve the quality of life in Massachusetts through civic discourse and intellectually rigorous, data-driven public policy solutions based on free market principles, individual liberty and responsibility, and the ideal of effective, limited and accountable government.

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