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Life Sciences Mergers and Acquisitions (M&A): Myths vs. Facts

Mergers and acquisitions (M&A) allow life sciences companies of all sizes to bring together the resources, investment and expertise needed to develop and deliver new treatments and cures for patients. Decades of pro-innovation policies have helped catalyze this by incentivizing M&A and establishing it as an important tool. Recently, federal regulators have proposed a new, more far-reaching approach to prevent and deter M&A that would disrupt the unique and world-class American life science ecosystem.

Myth 1: The life sciences industry is consolidating.

America's life sciences industry is unique for its vibrant competition between companies of all sizes, each aiming to find a new, better way to treat disease. More than 2,300 biopharmaceutical companies are headquartered in the U.S.,[1] and hundreds more start every year.[2] Altogether, these companies employ over two million people and operate out of more than 120,000 business establishments in all 50 states.[3] Current innovation and competition policies ensure that no one company has a monopoly on treating disease, which is why the world looks to the U.S. and its novel competitive ecosystem to lead the way in life sciences innovation.

The U.S. life sciences industry is among the most competitive globally in large part due to longstanding bipartisan innovation policies – such as the *Hatch-Waxman Act*,[4] *Orphan Drug Act*,[5] *Bayh-Dole Act*,[6] and *21st Century Cures Act*.[7] Together, these and other policies incentivize research and development (R&D) into therapies for complex and emerging health conditions while promoting a competitive market with a wide range of treatment choices for patients. These policies also support a constant pipeline of newer and more advanced approaches to help treat and cure many serious health concerns.

Myth 2: M&A leads to lower R&D investment and reduced innovation.

Research consistently shows that M&A fosters increased R&D and greater innovation by enabling a broad and efficient allocation of resources across the life sciences ecosystem. Delivering an innovative new therapy to patients requires an immense investment of time, expertise and resources – carrying a price tag exceeding $2.6 billion and taking 10-15 years, on average.[8] Between the many anticipated "failures," the lengthy regulatory approval process and the significant manufacturing and distribution infrastructure necessary to deliver doses to patients, most companies are unable to go it alone.

With more than 8,000 potential new treatments and cures on the horizon across dozens of disease areas,[9] leading experts, such as the American Bar Association[10] and Congressional Budget Office[11], have rightly acknowledged that M&A can help life science companies overcome these difficulties. By combining their complementary resources, M&A enables companies of all sizes to unlock efficiencies that help them deliver more innovations to more patients. For example, on the back of 10 years of increased M&A activity, the rolling five-year average of new therapies approved by the FDA more than doubled – rising from 24 in 2010 to 49 in 2022.[12]

Unlike many other industries, about 80 percent of biopharmaceutical companies operate without a profit.[13] Outside funding from venture capital (VC) and other sources plays a unique, central role to advancing promising new innovations through the development pipeline. M&A can be a major factor in drawing critical investment to new life sciences innovations, creating the potential for investors to recover their investment while offsetting the risks of early-stage R&D. By fueling this investment, M&A ultimately unlocks the resources necessary to bring innovative treatments and cures to patients in need.

Myth 3: M&A leads to higher health care and consumer costs.

Critics who assert M&A activity is the culprit behind high drug prices fail to consider the role and impact of insurers and pharmacy benefit managers (PBMs) in determining the price that patients pay for their medicines. According to recent coverage in the *Wall Street Journal,* "In the name of keeping down drug costs, PBMs decide which medicines a patient's health plan will pay for and how much the patient will have to contribute to the cost, in the form of out-of-pocket expenses like deductibles and coinsurance." Yet, this control exercised by PBMs has resulted in markups of more than 100 times the actual cost for some medications.[14]

Further, as life sciences M&A activity has remained constant over the last five years,[15] brand name drug prices have been on the decline. After adjusting for inflation and factoring in manufacturer discounts and rebates, net prices for brand name prescription medicines dropped nearly nine percent in 2022.[16]

Unlike other health care markets, competition policy in the life sciences has long struck a delicate balance between incentivizing extensive R&D to treat emerging, complex health conditions and ensuring patient access to therapies. Policies like Hatch-Waxman create important pathways for generic and biosimilar competition as a means of providing patients with a range of affordable treatment options and promoting the sustainability of the health care system.

Myth 4: Antitrust authorities need to broaden their notions of anticompetitive behaviors in the life sciences.

Current standards of antitrust enforcement are rooted in decades of evidence that life sciences M&A has benefits for patients and serves a critical, unique role in advancing innovation across the ecosystem. These balanced, bipartisan policies have long defined our nation's commitment to promoting life science innovation and protecting patient access to therapies. However, the broad and aggressive antitrust agenda being pursued by the Federal Trade Commission (FTC) ignores the successes of these policies and risks upending this balance.

M&A policies that allow life sciences companies to combine their complementary resources are key to advancing new innovations that benefit patients – a reality reaffirmed by our courts and other leading experts for decades. In 2021, the Congressional Budget Office acknowledged that, "In making [an] acquisition, a large company might bring a drug to market more quickly than the small company could have or might distribute it more widely."[17] Further, by smoothing the path for life sciences innovators to deliver their new treatments to patients in need, one small life science company noted that mergers "simply mark a turning point in the natural evolution of the drug development process."[18]

However, the FTC's recent suggestions that even speculative or theoretical harm to competition should be sufficient to invalidate an M&A deal flies in the face of this long-established precedent. Such a drastic policy shift introduces new uncertainty and risk to an already high-stakes process for life science companies and patients alike. Critically, it could slow or even stop new treatments and cures from reaching patients.

The FTC must continue to acknowledge the importance of balanced and bipartisan policies that reflect the unique competitive dynamics of the U.S. life sciences ecosystem. Short-sighted, partisan policies that speculate without a basis in fact and threaten to derail innovation should not be taken lightly.

Myth 5: M&A is anti-competitive and harms U.S. global leadership in innovation.

As a result of the unique policy frameworks that motivate innovation across the American life science ecosystem, biopharmaceutical R&D spending in the U.S. outpaces that of Europe by more than $25 billion annually.[19] Our world-class life sciences ecosystem brings together public and private researchers and academics as well as life sciences companies of all sizes. M&A helps to facilitate this collaboration across the ecosystem by bringing to bear the right resources and expertise, to advance the right therapies, at the right time.

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