PRI CENTER FOR MEDICAL ECONOMICS AND INNOVATION

ISSUE BRIEF

Affordability Without Safety or Innovation

The improper compounding of GLP-1s harms patients and stifles the development of new medicines

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Executive Summary

GLP-1s, the latest blockbuster medicine, are efficacious treatments for Type 2 diabetes, weight loss, cardiovascular diseases such as heart attacks and strokes, obstructive sleep apnea, chronic kidney disease, and liver disease. Researchers are currently investigating the possibility that GLP-1s will help patients living with addiction and neurodegenerative diseases.

Due to the high demand for these medicines, a GLP-1shortage was declared during the Spring of 2022, which allowed, under specific conditions, compounding pharmacies to provide these medicines to patients for as long as the shortage lasted.[1] Their authority to continue selling compounded versions of GLP-1s lapsed when the shortage ended in February 2025. Troublingly, these sales persist. The prevalent but unauthorized compounding of GLP-1s poses a safety risk for patients and threatens to undermine future drug innovations.

As the FDA has stated, compounded drugs are not approved by the FDA, and their unauthorized use creates safety risks for patients.[2] Compounders generally operate under lower safety, quality, and regulatory standards compared to pharmaceutical manufacturers. The quality of compounded medicines is often compromised due to problems such as inappropriate storage temperatures, dosing errors, the use of active pharmaceutical ingredients (API) of dubious quality, and outright fraudulent or counterfeited compounded products.

These quality issues can have severe health consequences. As of July 2025, the FDA "received 605 reports of adverse events associated with compounded semaglutide" Novo Nordisk's GLP-1 and "545 reports of adverse events associated with compounded tirzepatide" Eli Lilly's GLP-1.[3] Compounded versions of semaglutide have been linked with at least 100 hospitalizations and 10 deaths. The lower advertising standards for compounded GLP-1s also raise concerns.[4]

Because innovative manufacturers reinvest one-third of their total revenues into future research and development,[5] unauthorized compounding will reduce the revenues available for future research and development efforts should the current trends persist. The current revenue per patient for a GLP-1 (which differs from the actual patient cost) is between $2,322 and $2,936.

The innovative drug industry invests, on average, 33.2 percent of its revenues back into R&D.[6] Across the estimated 1.5 million patients currently receiving compounded GLP-1 products and accounting for the remaining market exclusivity timeframes,[7] unauthorized compounding risks reducing total R&D investments by between $9.3 and $11.8 billion.

The reduction in R&D efforts diminishes the expected number of new therapies that will be developed in the future. Based on a 2023 study examining the impact of lost revenues on the development of innovative drugs and the estimated cost of developing new treatments from a 2016 study, these estimated lost revenues for GLP-1s will directly result in the loss of 4 to 5 innovative drugs.[8]

The total impact on new innovative treatments is likely to be worse than these direct impacts indicate. The U.S. has become the leader in pharmaceutical innovation because it fosters the necessary scientific knowledge, maintains well-developed capital markets, and imposes a sound regulatory framework that includes enforcing innovators' government granted temporary market exclusivity.

Ensuring that innovators have an opportunity to recoup the large capital costs associated with developing new medicines is essential. Developing a new drug can take up to 15 years, cost $2.6 billion each (or $2.9 billion

including post-approval costs), and entails significant financial risks. In fact, less than 7% of new drugs entering Phase I trials are ultimately approved. The pharmaceutical sector's ability to develop the next generation of innovative therapies is compromised without the opportunity to cover these costs. This is enabled by the temporary market exclusivity.

Unauthorized compounding undermines these rights that the government rightfully grants to innovative manufacturers. If tolerated, these actions will make it more difficult for innovative manufacturers to cover their cost of capital. This disincentive will further reduce the number of future drug innovations that will be created, to the detriment of patients.

The pharmaceutical industry developed nearly 900 novel medicines between 2000 and 2024.[9] Americans have access to 74 percent of these, which is greater access than any other country. In Germany, the country with the next highest access rate, only 52 percent of these medicines are available. Canadians and Britains have access to a mere 28 percent and 43 percent, respectively.

Greater accessibility has improved American health outcomes. A 2020 *Health Affairs* study estimated that 35 percent of the 3.3-year increase in U.S. life expectancy between 1990 and 2015 was due to pharmaceuticals.[10] That's the equivalent of one additional year of life expectancy because U.S. patients have greater access to new and better drugs.

> "To address the problem of unauthorized compounding, regulators should adhere to a simple premise–compounding is for individualized care when personalization is needed, not scaled manufacturing."

To address the problem of unauthorized compounding, regulators should adhere to a simple premise–**compounding is for individualized care when personalization is needed, not scaled manufacturing.** Compounders who violate this rule, or misleadingly label mass production efforts as personalization, need to be held accountable. Additionally, compounders should be required to meet equivalent FDA safety standards as drug manufacturers. It is also imperative that the federal government protects the market exclusivity rights that are legally granted to innovative manufacturers from unauthorized compounding by enforcing all violations.

To address larger questions of affordability, systemic reforms to the third-party payer system are required. These reforms should empower patients to control their own spending through Health Savings Accounts and Individual Coverage Health Reimbursement Accounts. These accounts would enable families to purchase the combination of health insurance and healthcare services (such as subscription based primary care models) that best suit their individual needs.

Empowered to control the spending on their behalf, insurers and providers would be incentivized to directly serve patients, not third-party intermediaries. The result would be higher quality and lower cost healthcare services. Health insurance services, as distinct from healthcare services, could then focus on their core function of managing the financial risks of requiring high-cost medical services.

It is also important to establish an effective healthcare safety net to ensure people have access to both healthcare and health insurance. Reforms should transform the current healthcare assistance programs into a

cash-based system that sufficiently funds Health Savings Accounts to ensure that families have the resources necessary to purchase the insurance and healthcare services they need. Further, such income support ensures that the healthcare system incorporates the values and needs of lower-income patients and provides greater consistency of care.

The existence of a temporary drug shortage should not become an excuse to overlook otherwise troubling actions. Unauthorized compounding raises safety and supply chain vulnerabilities and discourages the development of the next generation of medicines. Due to these high costs, regulators should clearly state that compounding is for individualized care and protect innovative manufacturers' patent rights.

Reforms should, consequently, empower patients to control their own spending and enable them to purchase the combination of health insurance and healthcare services that best suits their individual needs.

"Unauthorized compounding raises safety and supply chain vulnerabilities and discourages the development of the next generation of medicines."

Introduction

There are many problems that afflict the U.S. healthcare system, but drug innovation is not one of them. It is one of our system's strengths. We are living longer and healthier lives because exceptional pharmaceutical innovations are occurring. GLP-1s are simply the latest "miracle drug" that innovative manufacturers have developed.

Scientists first discovered the important role that hormones play in our Gastrointestinal (GI) tract nearly 50 years ago. Specifically, the Glucagon-like peptide-1 hormone was identified as a vital component for regulating our metabolism, blood sugar, and appetite. GLP-1 medicines mimic this natural hormone in the body.

Researchers spent decades researching GLP-1s, with the original goal of finding a better treatment for Type 2 diabetes. Beyond an efficacious diabetes treatment that helps patients better control their blood sugar levels, GLP-1s have shown tremendous efficacy as a popular weight loss drug by suppressing people's appetites.[11]

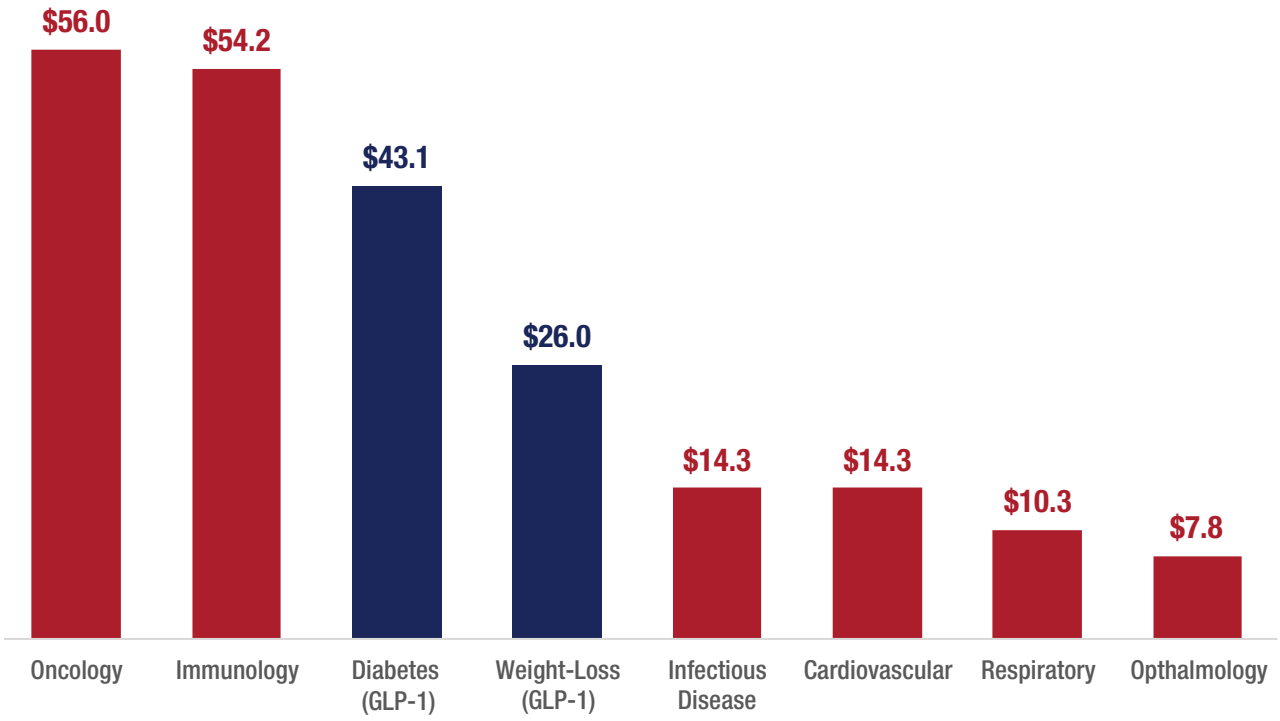
> "Researchers spent decades researching GLP-1s, with the original goal of finding a better treatment for Type 2 diabetes."

Other conditions these medicines have been approved to treat include cardiovascular diseases such as heart attacks and strokes, obstructive sleep apnea, chronic kidney disease, and liver disease. There are hopes that GLP-1s can help patients living with addiction and neurodegenerative diseases due to their impact on inflammation and amyloid plaque.

The FDA approved the first GLP-1, Byetta, in 2005 to treat type 2 diabetes.[12] In 2014, the FDA approved the first GLP-1 for weight management, Saxenda (liraglutide).[13] As is typical with drugs, researchers did not stop investigating and improving GLP-1s. The fruits of these efforts are reflected in the revolutionary benefits that semaglutide and tirzepatide now provide a wide range of patients.

Due to the benefits these medicines create for a wide range of patients, PwC estimates that between 8 percent and 10 percent of U.S. adults are taking GLP-1s, or up to around 34 million Americans.[14] As a reflection of the value created by GLP-1s, these medicines are now among the best-selling drugs as measured by Biospace, see Figure 1.[15] Figure 1 presents the spending on the top selling drugs by disease area, which shows that total GLP-1 sales revenues are consistent with the spending on other innovative medicines.

Figure 1. Spending on Top Selling Drugs by Disease Area



Source: Biospace

Patients have access to these efficacious medicines because the U.S. implements a regulatory environment that promotes biopharmaceutical innovation. Unfortunately, due to the success of GLP-1s, a new threat to the innovative U.S. drug system has arisen: compounders.

Most patients using GLP-1s sold by compounders are likely unaware that these compounded medicines are "now illegal to produce" and are not FDA approved therapies.[16] There are also significant safety concerns with many of these compounded medicines.

Worsening their negative impact, the continued unauthorized compounding of GLP-1s directly diverts resources that, based on current capital allocations, would have been re-invested in researching the next generation of medicines. The unauthorized compounding of GLP-1s also undermines the incentives that fostered the development of hundreds of innovative medicines such as GLP-1s.

"Most patients using GLP-1s sold by compounders are likely unaware that these compounded medicines are "now illegal to produce" and are not FDA approved therapies."

Affordability is a crucial issue, of course; but the issue of affordability arises because of the inherent flaws in the U.S. third-party payer system. Consequently, the most efficient way to improve access to cutting edge GLP-1s is through effective patient-driven payment reforms. Ignoring the unauthorized compounding of GLP-1s imposes net costs on patients and undermines a core comparative advantage of the U.S. healthcare system.

Unauthorized Compounding Creates Patient Safety Risks

Before discussing the significant concerns regarding the illegal and unauthorized compounding of GLP-1s, it is important to recognize the essential functions that drug compounding serves in the healthcare system. Compounding pharmacies provide valuable options for patients that need variations of medications that are not commercially available. This could be a medicine with a non-standard strength, a medicine that does not contain a preservative or inactive ingredient that the FDA-approved version contains, or a combination of drugs compounded into a single medication.

The Drug Quality and Security Act (DQSA), which was passed in 2013, increased the FDA's oversight over compounding pharmacies and outsourcing facilities. Congress passed the DQSA in response to a national meningitis outbreak that occurred in September 2012. The outbreak was caused by contaminated steroid injections that the New England Compounding Center (a compounding pharmacy) produced because of the facility's poor sanitary conditions and negligence in sterilization standards. Due to these poor practices, the contaminated injections ultimately infected more than 750 people and killed 64.[17]

The DQSA established two classifications for compounders – 503A compounding pharmacies, which prepare patient-specific compounded medications pursuant to individual prescriptions, and 503B outsourcing facilities, which may compound sterile drugs in larger batches for healthcare facilities under heightened FDA oversight. During declared shortages, the FDA allows, under specific conditions, certain compounded versions of otherwise commercially available drugs to enter the market.[18]

> "When the shortage was declared to be over, compounders lost their authority to continue selling GLP-1s. Although the GLP-1 shortage is officially over, sales of compounded versions, which are now unauthorized, persist.

Semaglutide and tirzepatide GLP-1s were declared to be in shortage during the Spring of 2022 and 2023 respectively.[19] As a result, compounders were allowed to provide these medicines to patients for as long as the shortage lasted. Which they did.

Despite this ability to produce drugs during a shortage, the FDA still "recommends patients be prescribed an FDA-approved drug when available and appropriate for the patient."[20] However, "when a drug is on FDA's drug shortages list, compounders may be able to make a compounded version of that drug if they meet certain federal law conditions and requirements."[21]

The GLP-1 shortage was declared to be completely over by early 2025.[22] The shortage for tirzepatide (Mounjaro and Zepbound) ended in December 2024 and the shortage for semaglutide (Ozempic and Wegovy) ended in February 2025.[23]

When the shortage was declared to be over, compounders lost their authority to continue selling GLP-1s. Although the GLP-1 shortage is officially over, sales of compounded versions, which are now unauthorized, persist. Compounders will argue that these versions are still authorized because they are making individualized adjustments to dosage, formulations, or prescribing practices for specific patients. This argument rings hollow.

There are legitimate instances where personalized compounding serves an important medical purpose, particularly when a patient has a documented clinical need that cannot be met by a commercially available product. However, individualized compounding was intended to address limited, clinically necessary patient-specific circumstances — not serve as a source for routine, large-scale production and marketing of FDA-approved GLP-1 medicines. In practice, the widespread use of "mass personalization" is functioning as a parallel commercial market operating outside the FDA approval process. The FDA has stated its concern regarding unauthorized compounding by announcing that it

> *is aware that some patients and health care professionals may look to unapproved versions of GLP-1 (glucagon-like peptide-1 (GLP-1) receptor agonists) drugs, including semaglutide and tirzepatide, as an option for weight loss. This can be risky for patients, as unapproved versions do not undergo FDA's review for safety, effectiveness and quality before they are marketed.*[24]

Because compounded drugs are not approved by the FDA and generally operate under lower safety, quality, and regulatory standards compared to pharmaceutical manufacturers, the agency has specific concerns regarding the compounded medicines. For example, the FDA notes that

> *Injectable GLP-1 drugs require refrigeration as indicated in their package inserts. FDA has received complaints that certain compounded GLP-1 drugs have arrived warm or with inadequate ice packs to keep the drug at recommended storage temperatures.*[25]

This improper storage can compromise the quality of the compounded drug. Other concerns expressed by the FDA include dosing errors, the use of active pharmaceutical ingredients (API) of dubious quality, and outright fraudulent or counterfeited compounded products.

These quality issues can have severe health consequences for patients and there are numerous documented cases of patients experiencing significant health complications due to the use of unauthorized compounded GLP-1s. The FDA "received 605 reports of adverse events associated with compounded semaglutide" and "545 reports of adverse events associated with compounded tirzepatide" as of July 2025.[26]

"These quality issues can have severe health consequences for patients and there are numerous documented cases of patients experiencing significant health complications due to the use of unauthorized compounded GLP-1s.

As reported by CNN in November 2024, "compounded versions of semaglutide, the active ingredient in approved diabetes and obesity drugs Ozempic and Wegovy, have been associated with at least 100 hospitalizations and 10 deaths, the chief executive of Ozempic maker Novo Nordisk warned."[27]

The unauthorized compounding of GLP-1s also raises safety concerns due to the sources of the active pharmaceutical ingredients (APIs). As the Partnership for Safe Medicines notes,

> *the origin of the active ingredients (also known as active pharmaceutical ingredients or API) used in compounded GLP-1s has also become a primary source of concern and criticism. Indeed, 93% of respondents in our public opinion poll were concerned about knockoffs from unknown or uncertain places of origin, like China. Compounders are required to obtain their API from FDA-registered facilities, and*

> *both FDA and the branded GLP-1 manufacturers have expressed concern that some drug compounders use API from unauthorized foreign sources.*[28]

Confirming these concerns, the Partnership for Safe Medicines found that

> *After studying 2,465 shipments from September 2023 to January 2025, we identified 239 problematic shipments of semaglutide or tirzepatide that were from unregistered entities that do not have any semaglutide or tirzepatide products listed with FDA. Many of these shipments were allowed to enter the U.S. anyway, a violation of federal law. Sixty of these shipments originated from China or Hong Kong, 42 from India, and 49 from Canada.*
>
> *Especially disturbing were the number of shipments explicitly marked for compounding.*[29]

On top of all these risks, there are also concerns because compounders adhere to different advertising standards. "Typical pharmaceutical ads must follow strict guidelines about sharing a drug's side effects and risks to inform and protect patients," wrote Shabbir Safdar, the Partnership's executive director. "Compounders operate on the outskirts of drug safety regulations and don't face the same stringent requirements."[30]

The FDA is taking action in light of these abusive actions and unnecessary risks. In a February 2026 announcement, the FDA stated it was taking action to restrict GLP-1 active pharmaceutical ingredients used in unapproved compounded drugs.[31] Additionally, following warning letters that were sent in 2025, the FDA also took "steps to combat misleading direct-to-consumer advertising and marketing."[32] Specifically, the FDA stated,

> *In promotional materials, companies cannot claim that non-FDA-approved compounded products are generic versions or the same as drugs approved by FDA. They also cannot state compounded drugs use the same active ingredient as the FDA-approved drugs or that compounded drugs are clinically proven to produce results for the patient.*[33]

Along with the announcement, the FDA sent warning letters to 30 telehealth companies regarding their

> *"illegal" sales of compounded GLP-1s, building off increasing pressure to tamp down on the sale of these unapproved medications.*
>
> *According to the FDA, the companies they contacted made "false or misleading claims" about the GLP-1 products they sold on their websites, including implying "sameness with FDA-approved products and obscuring product sourcing."*[34]

In other words, with the shortage declared over, compounders are not allowed to sell GLP-1s for mass market purposes. Compounders' proper role is to serve the small niche of patients who legitimately require personalized prescriptions. Yet, as evidenced by compounders' ubiquitous advertising, sales of compounded GLP-1s to the mass market continue. The companies argue that by tailoring doses, adding vitamins or other ingredients, or altering administration forms for individual patients, their compounded products are legally distinct from FDA-approved medicines. However, FDA actions and warnings from patient safety organizations have raised concerns that these practices increasingly amount to "mass personalization" used to justify the large-scale marketing of copies of FDA-approved therapies outside the FDA approval framework.[35]

Such practices are not only demonstrably deceptive and raise significant patient safety concerns, but these actions also pose a real threat to future innovation.

Unauthorized Compounding Is Diverting the Resources from the Next Generation of Medicines

Unauthorized compounding is tangibly reducing the revenues that innovative manufacturers of GLP-1s can devote toward future research and development efforts. And due to the reduction in resources devoted toward R&D, the expected number of new therapies that will be developed is lower. Based on the assumptions and calculations presented below, the unauthorized compounding of GLP-1 will potentially cause patients to lose access to between 4 and 5 new innovative treatments.

According to a PwC survey, "anywhere from 8 percent to 10 percent of Americans are currently taking GLP-1s, while 30 percent to 35 percent of Americans are interested in using them."[36] Based on the 8 percent to 10 percent estimates and the size of the U.S. population as of 2025, there are between 27.3 million and 34.2 million Americans currently using GLP-1s.

In total there was an estimated $75.9 billion in GLP-1 sales in 2025.[37] Dividing the total estimated sales revenues by the estimated patient population prescribed GLP-1s provides an estimate for the revenues per patient. Note, it is important to distinguish between revenues per patient and actual patient costs, which will differ from these estimates based on their insurance coverage and use of any patient assistance programs. Overall, the current revenue per patient for a GLP-1 is between $2,322 and $2,936.

> "Consequently, the continued large-scale sale of compounded GLP-1s diverts billions of dollars in revenue from innovative manufacturers that will severely diminish the capital available to invest in the next generation of medicines.

As cited in a note by Fidelity, an estimated 1.5 million patients are currently receiving compounded GLP-1 products.[38] As discussed above, except in limited patient-specific circumstances, compounded GLP-1s are not intended to function as substitutes for FDA-approved medicines once shortages have been resolved. Consequently, the continued large-scale sale of compounded GLP-1s diverts billions of dollars in revenue from innovative manufacturers that will severely diminish the capital available to invest in the next generation of medicines.

A paper on biopharmaceutical and pharmaceutical profitability I recently co-authored documented that

> *the innovative drug industry invests 33.2 percent of its revenue into research to develop the next generation of therapies. The next most research-intensive healthcare industry – the healthcare products industry, which includes manufacturers of medical equipment and hospital supplies – invests one-fourth the amount into R&D as the drug industry. The healthcare support services industry invests one-tenth of one percent. For comparison, the average industry invested 3.8 percent of their sales into R&D.*[39]

Based on the range of revenue per patient and the assumption that approximately one-third of the lost revenues would have been devoted toward research and development, compounding inappropriately reduced innovative manufacturers annual R&D spending by between $1.2 billion and $1.5 billion.

Without a consistent regulatory framework governing the commercialization of compounded copies of FDA-approved medicines, innovative manufacturers will continue to face significant erosion of the market exclusivity that supports long-term research and development investment. Using the patent expiration for semaglutide (2031) and tirzepatide (2036) as the duration of the losses and using the interest rate for a AAA rated corporate bond as of February 2026 as the discount rate (5.3 percent), the total present value of the potential lost revenues due to unauthorized compounding is between $9.3 billion and $11.8 billion. Such a large reduction in R&D expenditures will likely have a meaningful impact on the number of new medicines that will be developed.

A 2023 study by ITIF found that reforms that "would have increased pharmaceutical sales revenue globally by $254.1 billion" would have resulted "in $56.4 billion of additional R&D expenditures and 25 new drugs annually."[40] Applying this ratio to the lost revenues due to unauthorized compounding indicates that between 4 and 5 fewer drugs will be developed due to these activities, see Table 1. These lost therapies are also consistent with the estimated lost therapies based on the DiMasi et al. (2016) cost estimates of $2.6 billion per drug, excluding post-authorization costs.[41]

Table 1 Estimated Lost Innovations Due to Unauthorized Compounding

	LOW-PATIENT EST.	HIGH PATIENT EST.
Lost Revenues (in billions)	$28.1	$35.5
Lost R&D Spending (in billions)	$9.3	$11.8
Lost Therapies (ITIF)	4.1	5.2
Lost Therapies ($2.6 billion cost)	3.6	4.5

Source: Author calculations based on ITIF and DiMasi et al. (2016)

Unfortunately, these direct losses are only part of the story.

Unauthorized Compounding Undermines the Policy Environment That Transformed the U.S. Into the "World's Medicine Chest"

The rest of the story accounts for the broader adverse impacts the unauthorized compounding of GLP-1s has on the vibrant pharmaceutical and biopharmaceutical industry in the U.S.

The pharmaceutical industry has developed nearly 900 novel medicines between 2000 and 2024.[42] Americans have wide access to these medicines; more access than any other country. A 2022 Rand Study examined the availability of new drugs across OECD countries as of the end of 2022.[43] Americans had access to 74 percent of all new drugs, which is significantly greater availability than any other country. Patients in Germany, the country with the next highest access rate, only had access to 52 percent. The availability for Canadians and Britains was a mere 28 percent and 43 percent, respectively.

Importantly, this accessibility improves health outcomes. According to a 2020 *Health Affairs* study, life expectancy in the U.S. increased by 3.3 years between 1990 and 2015.[44] According to the analysis, 35 percent of this gain was due to pharmaceuticals. That's the equivalent of one additional year of life expectancy because U.S. patients have greater access to new and better drugs.

As is often the case, too many people take these achievements for granted. Consistent development of new therapies that create better and more efficacious treatments for patients is now expected. It's the norm. But establishing the right environment that incentivizes the creation of innovative medicines is anything but ordinary.

> "Developing innovative medicines is an exceptionally long and expensive endeavor.

The U.S. has served as a successful drug incubator for many years because it nurtures the complex ecosystem required for an innovative drug industry to thrive. This includes ensuring that the talent and scientific infrastructure exist to discover and develop cutting edge treatments. But just having the scientific know-how is insufficient.

Developing innovative medicines is an exceptionally long and expensive endeavor. On average, it can take up to 15 years to develop a new therapy and cost upwards of $2.9 billion, including post-approval expenditures.[45] This is why having well-developed capital markets is also essential. The U.S.' efficient capital markets ensure that developers of innovative medicines have the financial resources necessary to turn their scientific discoveries into efficacious medicines that are available to patients.

Still, more is needed. Discovering new efficacious drugs and treatments is also very risky. A 2024 analysis showed that the likelihood of approval "for new assets entering Phase I is now just 6.7%, down from 7.9% three years ago."[46] In other words, more than 93% of new drugs entering Phase I trials are not ultimately approved.

Given the large financial investments required for many years, innovative firms bear a great deal of risk over a long period of time. However, once an innovation has been created, copying that technology is relatively cheap. After all, imitator firms do not need to invest the same amount of capital to produce a knockoff of an innovation. They can simply copy the innovator firm's new technology.

This reality creates a huge disincentive against innovation, which is not unique to drugs. It is a pall hanging over all potential innovators. Without the need to invest billions of dollars into creating the new technologies, imitator firms have a large pricing advantage relative to innovative firms. When imitator firms set prices, they only need to account for the costs of producing the new products whereas innovator firms must set prices that cover the costs of production and invention.

Since innovators need to cover the additional (very expensive) cost of invention but imitators do not, there is a naturally powerful disincentive to engage in entrepreneurship. After all, why risk the time and costs to create a product only to see some other firm reap the rewards. This is why a legal system that grants and protects exclusivity rights (i.e., patents) and avoids price controls is just as important as having a vibrant scientific base and well-developed financial infrastructure.

"Without the need to invest billions of dollars into creating the new technologies, imitator firms have a large pricing advantage relative to innovative firms.

Once a safe and efficacious treatment has been discovered and approved by the FDA, the U.S. has done a relatively good job ensuring that innovators have the opportunity to recoup the capital costs invested into developing the therapy. This has included avoiding price controls and enforcing a regulatory system that secures innovators' intellectual property rights through well-defined and secure patents. This exclusivity period grants innovators an opportunity – and it is only an opportunity – to recover their cost of capital. This opportunity alone provides a powerful incentive for drugmakers to continue investing in new cures. As I argued in my 2014 analysis,

> *The purpose of patents is to provide the innovator company with market exclusivity to create an opportunity for the company to cover its R&D capital costs. A competitive rate of return on capital, adjusted for risk, ensures that investors will be willing to put their money into the pharmaceutical industry, a business where failure is the norm, and a small number of medicines pay for all of the R&D.*[47]

There have been so many innovative drugs developed and approved in the U.S. over the past quarter of a century because the U.S. has traditionally done well across all these areas. There is undoubtedly room for improvement, but we have created a better innovation ecosystem that more efficiently encourages pharmaceutical innovation compared to all other countries. The proof: the U.S. has become *The World's Medicine Chest*.[48]

Incentivizing innovation is not the only material policy goal, however. Affordability matters too. Due to the need to balance these two sometimes conflicting goals, market exclusivity is not, and should not, be granted in perpetuity. This is why patent rights expire. With the loss of exclusivity, competitive generic and biosimilar medicines are empowered to enter the market and compete. Currently in the U.S.

> *this occurs after a branded pharmaceutical has been on the market around 10–12 years. Typically after 11.5 years, patents for branded pharmaceuticals expire. Once the patent has expired, generic companies can copy the medicine, and use the data developed by the innovator company for free. Competition from generics typically drives prices down toward the marginal cost of production.*

This patent cycle has two major benefits for patients and the healthcare system. It allows investors to receive a return on their capital, incenting innovation. Afterward, the patent cycle empowers the establishment of a vibrant generic market. This market allows for the treatment of many of the highest incidence diseases, including heart disease, depression, and even some cancers, with lower cost drugs.[49]

In other words, the combination of temporary market exclusivity followed by a competitive environment helps the U.S. promote two potentially conflicting goals: continued drug innovation and broad-based affordability.

The introduction of nearly 900 new innovative medicines over the past quarter of a century attests to the ability of secure patents to incentivize innovation. Importantly, because a firm's market exclusivity is temporary, the current patent system also promotes affordability. The Association for Accessible Medicines document that 90 percent of all drugs filled are generic; with a total cost of $98 billion for 3.9 billion prescriptions, these medicines cost around $25 each.[50] The average patient receives an affordable medicine, consequently.

There are many success stories demonstrating the benefits from this process. Take statins as an example. These essential medicines for lowering people's cholesterol were once expensive. But once their market exclusivity expired, the introduction of generic statin competition saved an estimated $925.60 per individual.[51] Today, statins cost pennies per dose.[52] A similar story holds for Hepatitis C; a costly chronic disease that can now be cured for most patients because of the efforts to develop direct-acting antiviral medicines. Through the second quarter of 2020, net prices for these medicines fell 78 percent compared to the third quarter of 2014 when these medicines were first available.[53]

"Allowing the unauthorized compounding of GLP-1s sets a detrimental precedent by narrowing the opportunity for innovative companies to recover the large cost of capital required to develop new treatments.

And competition does not just come from generics and biosimilars. Innovative drugs will compete against one another. For example, semaglutide and tirzepatide, which are both patented medicines, compete against one another in the GLP-1 space. Consequently, competitive pressures will often exist even before market exclusivity expires and, as in the case of GLP-1s, cause prices to decline significantly even before generic or biosimilar competition is allowed to develop.

Allowing the unauthorized compounding of GLP-1s sets a detrimental precedent by narrowing the opportunity for innovative companies to recover the large cost of capital required to develop new treatments. As a consequence, tolerating the unauthorized compounding of GLP-1s undermines the efficiency of U.S. pharmaceutical ecosystem.

Innovative manufacturers will now have another risk that needs to be managed – once the long, risky, and expensive drug development process has been successfully navigated, innovative manufacturers must worry that the government will turn a blind eye to the sales of unauthorized compounded medicines. These greater risks will increase capital uncertainty. Greater uncertainty reduces the dollars invested into R&D, which will further dampen the number of innovative medicines developed.

Policy Solutions Can Ensure Pharmaceutical Innovation Continues

Addressing the problem of unauthorized compounding starts with a simple premise –compounding is for individualized care, not scaled manufacturing. Therefore, compounders who violate this rule, or misleadingly label mass production efforts as personalization, need to be held accountable. And there have been recent enforcement actions toward this end. For example, in February 2026 the "Department of Health and Human Services lawyers referred telehealth company Hims & Hers to the Justice Department… to investigate "potential violations" of federal drug law."[54]

Of course, compounding should be available for patients in those instances where personalization is needed. However, compounders should be required to meet equivalent FDA safety standards as drug manufacturers. It makes no sense to have different standards for medicines depending on whether it is compounded or manufactured.

> "Compounders should be required to meet equivalent FDA safety standards as drug manufacturers. It makes no sense to have different standards for medicines depending on whether it is compounded or manufactured.

It is also imperative that the federal government protects the market exclusivity and regulatory framework that support innovative manufacturers from unauthorized compounding. Predictable periods of market exclusivity are one of the core foundations that have helped the U.S. become the global leader in pharmaceutical innovation by enabling companies to invest in high-risk, long-term research and development. This leadership is not guaranteed, however, and actions that undermine these policies risk weakening the incentives that sustain future medical innovation.

Then there are the larger questions of affordability. While affordability concerns often focus on innovative medicines, the vast majority of healthcare services cost more in the U.S. healthcare system compared to other industrialized countries. It's not just drugs; it's doctors, hospital stays, emergency care, and surgeries. In other words, affordability is a systemic problem, not a drug problem. Creating a more affordable healthcare system that still promotes innovation and quality care requires systemic reforms to the third-party payer system, consequently.

Effectively addressing these problems that plague the healthcare system requires two separate reform efforts. The first set of reforms should recognize that health insurance and healthcare services are distinct from one another. Blending both services under the current third-party payer system creates many of the distortions that are inflating costs and reducing the quality of care. Reforms should, consequently, empower patients to control their own spending and enable them to purchase the combination of health insurance and healthcare services that best suits their individual needs.

Such a system would leverage health savings accounts and empower individuals and families to purchase the health care services (such as subscription based primary care models) and health insurance services they value most. Empowered to control the spending on their behalf, insurers and providers will be incentivized to

directly serve patients, not third-party intermediaries. The result will be higher quality and lower cost healthcare services. Health insurance services, as distinct from healthcare services, could then focus on their core function of managing the financial risks of requiring high-cost medical services. Included with these reforms, policies will need to encourage the development of an efficient reinsurance market to improve insurers' ability to manage the tail-end costly risks.

The second set of reforms should establish an effective healthcare safety net to ensure people have access to both healthcare and health insurance. Often advocates confuse the issue of access with the need to create an efficient healthcare system. Their calls for Medicare for All or other socialized healthcare schemes would worsen healthcare outcomes and any monetary savings would only be achieved by reducing access to care.

Alternatively, combining health savings accounts with a cash-based income support system can ensure that families have sufficient resources to purchase the insurance and healthcare services they value. Further, such income support ensures that the healthcare system incorporates the values and needs of lower-income patients and provides greater consistency of care.

Providing a detailed analysis of these reforms would require a series of papers. With respect to compounding, these reforms will create a more efficient market for innovative medicines that more effectively manages the affordability and financial risks patients face should they require an expensive medication. Importantly, these reforms do not trade off greater short-term affordability for reduced affordability and innovation in the long-term.

"Combining health savings accounts with a cash-based income support system can ensure that families have sufficient resources to purchase the insurance and healthcare services they value.

Conclusion

A strong and predictable innovation framework is indispensable for improving "the quality and delivery of medical care."[55] Because the U.S. combines a robust regulatory framework, deep capital markets, scientific leadership and a traditional stance against price controls, the U.S. has become the undisputed leader of the biopharmaceutical revolution. Patients benefit from unprecedented access to cutting-edge medicines that improve our longevity and quality of life.

Unauthorized compounding is a threat to these gains and raise troubling safety and supply chain vulnerabilities for patients. These dangers, as expressed by the FDA, could arise from improper storage that compromises the quality of the compounded drug, dosing errors, the use of poor-quality APIs, and outright fraudulent or counterfeited compounded products. These quality issues can have severe health consequences for patients and there are numerous documented cases of patients experiencing significant health complications.

"Unauthorized compounding is a threat to these gains and raise troubling safety and supply chain vulnerabilities for patients.

By weakening the market exclusivity and regulatory certainty that support pharmaceutical innovation, unauthorized compounding also diverts revenues away from future research and development investments. Based on the current size of the unauthorized compounded GLP-1 market, these activities alone could directly cause the loss of 4 to 5 new innovative medicines. More broadly, when regulatory boundaries surrounding FDA-approved medicines become blurred, uncertainty increases and incentives to invest in the next generation of therapies weaken.

Due to these high costs, regulators should clearly state that compounding is for individualized care only and protect innovative manufacturers' patent rights and market exclusivity. The existence of a temporary drug shortage is not an excuse for compounders to engage in scaled manufacturing. Compounders who violate this rule, or misleadingly label mass production efforts as personalization, need to be held accountable. Enforcing these standards will promote a safer, more secure drug market while maintaining the beneficial incentives to develop the next generation of cures for diseases such as Alzheimer's, pancreatic cancer and muscular dystrophy.

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