

Brianna Jones, MPP, Sarah Kaminer Bourland, RN MPH

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OVERVIEW

The first case of COVID-19 in the United States was reported on <u>January 20</u>. The pandemic has killed more than 100,000 Americans, devastated our communities, tested our health care systems, and led to untold financial distress for millions of people. The Kaiser Family Foundation recently <u>found</u> that over 30 percent of respondents have had difficulty affording expenses like food, rent, and medical bills due to the pandemic. Despite the national crisis, drug companies have conducted business as usual where pricing is concerned. According to our analysis, pharmaceutical corporations hiked the prices of 245 drugs between January 20 and June 20 — on par with the same time periods in 2018 and 2019.

More than 75 percent of the 245 price hikes directly pertain to COVID-19. This report examines how drug companies raised prices on three key categories of drugs during the COVID-19 pandemic:





PATIENT PERSPECTIVE

Jacquie Persson

The pandemic has put Americans living with chronic and acute health conditions at higher risk for severe illness or death.

Jacquie, from Waterloo, Iowa, is at high risk for COVID-19 as she lives with Crohn's disease. She says COVID-19 has made managing her chronic illness challenging.

"It's been difficult to stay vigilant and take precautions to maintain my health. I've had to postpone appointments with a specialist because the hospital has active COVID-19 cases."

Additionally, Jacquie is anxious about her job security. She affords her expensive drug, Stelara, through her employer's health insurance plan. She doesn't know whether she would be able to afford it if she were to lose her job and therefore her insurance. Furthermore, Stelara's price increased by 5 percent in late January.



DRUGS IN USE FOR TREATMENT OF COVID-19

Mild COVID-19 Cases

Common medications like Tylenol, Ibuprofen, and Reglan can be used to treat routine COVID-19 symptoms such as fever, aches, and nausea. Since 70 percent of COVID-19 cases do not require hospitalization, more than 1 million sick Americans may be relying on these medications to manage their illness at home — an opportunity the pharmaceutical industry has sought to exploit by hiking the prices of more than 40 of these medications.



Severe COVID-19 Cases

Other medications are being used to manage more severe COVID-19 cases, like those that require hospitalization. Hospitals in 48 states, D.C., and Puerto Rico are at 50 percent capacity, and 11 states report 70 percent of all intensive care (ICU) beds are full. These soaring hospitalizations have led to increased demand for many vital medications used to fight COVID-19, with some drugs even entering into shortage.



Certain blood thinners and antibiotics allow health care providers to prevent and manage severe adverse effects of COVID-19 like <u>blood clots</u> and <u>pneumonia</u>. Due to the pandemic, the sharp increase in patients requiring ventilators — and therefore ICU beds — has led to an uptick in demand for certain IV medications that are critical for treating the most severe cases.

Although some price hikes may be attributable to interruptions in global manufacturing supply chains, others can be attributed to opportunistic hikes in the face of steep increases in demand. Demand for the drugs used to sedate ventilated patients <u>rose</u> by as much as 67 percent by the end of March — leading to FDA-declared <u>shortages</u> of sedatives like morphine, fentanyl, and ketamine — all drugs with price hikes in this report.

As demand for inpatient medicines rose over the course of the COVID-19 crisis, so did prices. Over the past six months, pharma raised the price of 44 inpatient drugs — including 20 essential ICU drugs.



Inpatient and ICU Drugs at a Glance

Sedatives: These medications are <u>necessary</u> for keeping patients pain-free and comfortable so that mechanical ventilation can support their lungs.

Morphine: IV morphine, which is under <u>shortage</u>, is a common pain and sedation drug in critical care. In March, Hikma Pharmaceuticals increased the price of its Duramorph product by 59 percent.

Ketamine: Ketamine, another sedative in <u>shortage</u>, was subject to a 9.9 percent change by Hikma in March. Ketamine is also being <u>studied</u> for its anti-inflammatory effects against COVID-19.

Chlorpromazine: Due to sedation shortages, the antipsychotic drug chlorpromazine is suggested as an alternative in the ICU. Hikma's 9.9 percent hike could add \$125 a day to the bill for an ICU patient. This drug is also in clinical trials for COVID-19 due to its antiviral activity.

Steroids: These medications are indicated in the <u>most severe</u> cases of acute respiratory distress syndrome (ARDS) and are emerging as a <u>promising</u> frontrunner in clinical trials.

Prednisone: Rayos, Horizon Pharmaceuticals' branded version of prednisone, increased in price by 4.6 percent to \$2,762 in early February. This oral steroid tablet is <u>being tested</u> against COVID-19-related pneumonia in clinical trials.

Cardiovascular medications: Since severe infections can lead to dangerous fluctuations in blood pressure, these medications are critical for the most severe cases.

Vasopressin: Vasopressin is currently <u>recommended</u> for COVID-19 patients with unstable blood pressure. The price for one vial of Vasostrict, Par Pharmaceutical's monopoly version of vasopressin, was increased by \$197 in February.

Blood thinners: Since severe blood clots, including strokes, have been <u>cited</u> as a dangerous outcome from COVID-19, these medications are important tools used to prevent clotting.

Many blood thinners have been subject to price increases since January, including warfarin, heparin, and dipyridamole. **Xarelto**, Janssen's blockbuster product, increased in price by 4.9 percent, bringing the price of a 30-tablet bottle to \$470.



DRUGS IN COVID-19 CLINICAL TRIALS

Researchers worldwide are racing to find potential treatments and vaccines for COVID-19, with more than 1,500 clinical trials currently in process. The majority of clinical trials are repurposing existing medications to test their potential against the virus. Since January 20, 30 drugs in clinical trials for COVID-19 have increased in price. Pharmaceutical companies may be increasing prices in anticipation of the uptick in demand if their drug shows promise in clinical trials.

Pricing on Prospects: 30 drugs that are currently in clinical trials for COVID-19 have increased in price since January.

+110%

Ascor, or IV vitamin C, is also being tested against COVID-19 in multiple clinical trials. The sole manufacturer of the medication, McGuff Pharmaceuticals, hiked the price by 110 percent on May 5 — just eight days after a new trial was announced.

+57%

Oxytocin, a drug typically used to induce labor, is in Phase II <u>clinical trials</u> for COVID-19. One maker of the drug, **Fresenius Kabi**, hiked the price by 57 percent in late March

Olumiant (baricitinib), which is commonly used to treat rheumatoid arthritis, has recently shown <u>promise</u> in COVID-19-related respiratory disease. The drug's only manufacturer, **Eli Lilly**, hiked its price by \$127 on January 31 — just five days before The Lancet <u>published an article</u> suggesting its use.

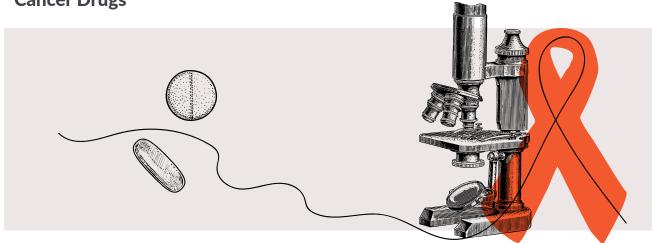
The new price is \$2,265 for a 30-tablet bottle.

DRUGS USED TO MANAGE CHRONIC CONDITIONS

Even before the pandemic, nearly 1 in 3 Americans did not take their medications as prescribed because of high costs. But during this crisis, the decision to forego a prescription due to cost is even riskier. Over 90 million Americans with chronic conditions are at higher risk for severe illness from COVID-19. A June study from the Centers for Disease Control and Prevention (CDC) found that people with heart disease, diabetes, chronic lung disease, or other underlying conditions were far more likely to be hospitalized or die from COVID-19.



Cancer Drugs



Cancer drugs at a glance

Cancer patients are at <u>higher</u> risk of severe illness or death if they contract COVID-19, so treatment that helps them stay healthy is critical. Pharmaceutical companies have hiked the price of 25 cancer medications during this pandemic.

Here are some examples of price hikes on monopoly products:

| Drug Name | Amount of Price Hike | New Price |
|----------------------------|----------------------|-------------|
| Farydak (multiple myeloma) | + \$927.20 | \$10,687.18 |
| Provenge (prostate cancer) | + \$3,487.77 | \$62,602.52 |
| Casodex (prostate cancer) | + \$285.97 | \$3,296.13 |
| Nerlynx (breast cancer) | + \$1,368.00 | \$15,191.00 |
| Arimidex (breast cancer) | + \$129.93 | \$1,497.59 |
| Verzenio (breast cancer) | + \$161.28 | \$3,094.28 |

PATIENT PERSPECTIVE

Denise Whipkey

Denise Whipkey is one of many Americans at risk for COVID-19 complications.

Denise typically manages her diabetes with the medication Trulicity. "It really makes a difference in how I feel."

But her Medicare plan doesn't cover the drug, and it would cost her nearly \$1,000 out of pocket for a three-month supply.

She is reliant on drug samples she receives from her doctor. But when the pandemic hit, the manufacturer stopped shipping samples to her doctor, and the price of Trulicity raised by five percent. It has meant Denise has gone without.

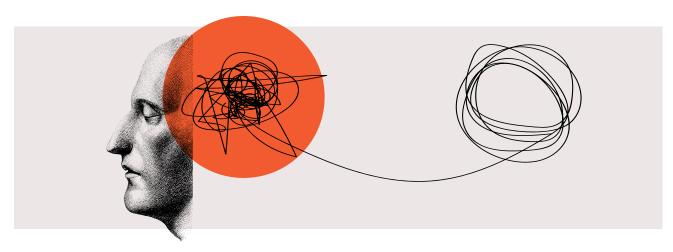
"I have not been able to use Trulicity for a few months. I've been taking Novolin, but it doesn't control my blood sugar levels as well as Trulicity."

Skipping or rationing medications can lead to a disease exacerbation — making patients with chronic conditions more susceptible to serious illness from the virus or even landing them in the emergency room, where they are more likely to be exposed to COVID-19.

At the start of the outbreak, the CDC and health experts <u>recommended</u> chronically ill patients stock up on a 90-day supply of necessary medications, leading to a sudden increase in demand for many drugs. Some pharmaceutical companies appear to have timed price hikes right before that increase in demand.



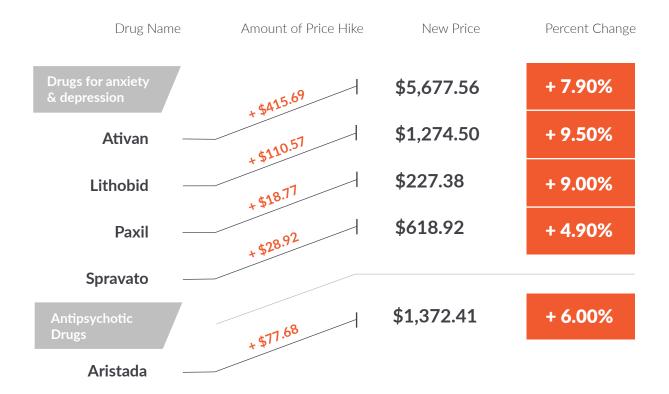
Mental Health Drugs



Taking advantage of the emotional toll

Almost 40 percent of Americans say their mental health has been negatively impacted by the COVID-19 pandemic and its effects. This impact was evident early in the pandemic. By mid-April, there was a 21 percent increase in demand for antidepressants, anti-anxiety drugs, and anti-insomnia drugs. Pharmaceutical companies seized this opportunity to hike the price of 22 mental health drugs.

Here are some examples of price hikes on monopoly products:



Additionally, due to widespread <u>unemployment</u> and <u>insurance loss</u>, price hikes are now even more devastating to patients. Many newly uninsured patients — who are already suffering from loss of income — will now be required to pay high list prices for necessary medications. At a time when chronically ill patients are especially reliant on their medications to stay healthy, price hikes are devastating. Yet, 118 drugs for chronic conditions have seen a price hike. This includes 25 cancer drugs, 23 cardiovascular medications, nine autoimmune treatments, and nine HIV drugs.

PATIENT PERSPECTIVE

Nicole Wells

Nicole Wells is from Richmond, Kentucky and was diagnosed with cirrhosis and two rare autoimmune diseases when she was 15. She had been on medications to manage the diseases for a decade. Last year, she received a liver transplant from her sister and is responding well.

In order to remain healthy and continue to thrive on her liver transplant, she is required to take anti-rejection medications every 12 hours for the rest of her life. If she doesn't, she could land in the hospital, where she's susceptible to COVID-19 infection and severe illness.

But due to COVID-19, Nicole's husband lost his job, and with it, she lost the insurance that helps pay for one of her expensive anti-rejection medications, Tacrolimus.

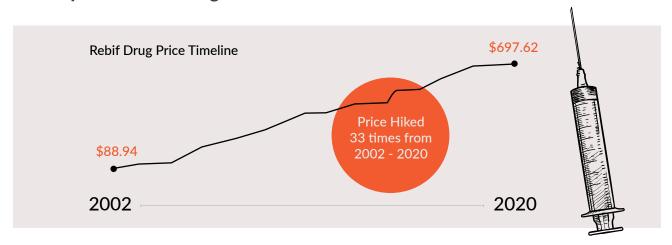
"I am worried that I will not be able to afford my anti-rejection medications and my transplant will be rejected."

Meanwhile, AmerisourceBergen's generic subsidiary raised the price of Tacrolimus by 15 percent — in the midst of the pandemic.



Price hikes on drugs for chronic conditions also disproportionately impact Black and Hispanic Americans, who are more likely to live with chronic illnesses and face higher risk of COVID-19. The intersection of chronic disease and COVID-19 in the Black community reflects systemic inequalities that stem from historically discriminatory housing, employment, and health care policies. It is a clear example of how the current system for pricing drugs disproportionately impacts many minority communities.

Multiple Sclerosis Drugs



Patients suffering from MS are accustomed to high prices; treatments for the autoimmune disease <u>have increased</u> at 5-7 times the rate of inflation, with some even surpassing a price tag of \$60,000 a year. The price of a four-tablet package of **Mavenclad**, an MS treatment made by **EMD Serono**, rose by \$1,800 to \$32,545 on April 3. **EMD Serono** also increased the price for a single syringe of MS treatment, **Rebif** (interferon beta-1A), to \$697. The drug company hiked this price on April 3, just weeks after <u>the end of a clinical trial</u> testing the drug against COVID-19.



POLICY SOLUTIONS

In our recent <u>blog series</u>, we examined how pharmaceutical corporations could reap excessive profits from forthcoming COVID-19 vaccines and cures. This analysis demonstrates how the drug industry is already exploiting our current crisis by hiking the prices of existing drugs related to COVID-19. *Congress can enact numerous reforms to stop the pharmaceutical industry from profiteering on the pandemic:*

1

Penalize Brand Price Hikes

Two bills in Congress (H.R. 3 and S. 2543) would penalize drug manufacturers for increasing their prices faster than the rate of inflation — a sanction that would have applied to most price hikes in this analysis.

2

Price Negotiation

In our current system, pharma has the ability to set and hike prices at will. The federal government should be empowered to negotiate drug prices on behalf of U.S. taxpayers and federal health programs. H.R. 3 would grant the Secretary of Health and Human Services authority to negotiate the cost of high-priced drugs to no more than 120 percent of the cost in other wealthy nations. Nearly 9 in 10 Americans support direct negotiations by the federal government with drug manufacturers on the price of a treatment for COVID-19.

3

Transparency into Generic Pricing

S. 2543 would also require the HHS Secretary to conduct a survey of National Average Drug Acquisition Costs (NADAC), introducing much needed transparency into the generic pricing system.

4

Fairly Priced Publicly Funded Drugs

Almost \$10 billion in taxpayer funds have been allocated for drug manufacturers to develop and manufacture drugs for COVID-19. Instead of permitting drug companies to profit off taxpayer-funded inventions, public investment should be accounted for in the final price. The Make Medications Affordable by Preventing Pandemic
Pricegouging Act prohibits exclusive licensing of new, taxpayer-funded drugs that are used to mitigate, prevent, or treat COVID-19 in order to ensure universal access. It also requires the federal government to enter into reasonable pricing agreements for drugs invented with taxpayer funds.



CONCLUSION

Jacquie, Denise, Nicole, and patients across the country should not live at the mercy of pharmaceutical corporations' pricing abuse, especially while in the midst of a global pandemic. It is imperative that Congress take action to ensure patients are protected from high prices for COVID-19 treatments and vaccines, and that all patients have access to affordable drugs.

METHODOLOGY

We used the drug price database AnalySource by First Databank¹ to find the number of unique national drug codes (NDCs) that experienced increases in Wholesale Acquisition Cost (WAC) between January 20 and June 20. We found that 1,458 NDCs had increases during this period. Since multiple NDCs exist for variations of the same drug (i.e. different doses or routes), and each drug's price hike was identical for all associated NDCs, we only included one NDC for each drug. We determined which NDC to include based on average doses, routes, and relevance to COVID-19. Using this method, we found price hikes on 245 drugs. This report uses AnalySource's variable definitions, which can be found below.

Inclusion Criteria: We included both prescription and non-prescription medications, recognizing the important role of over-the-counter medications in managing COVID-19 symptoms. Nutritional supplements (i.e. formula), drugs primarily used for diagnostic tests, and drugs with pediatrics indications were removed. Duplicate drugs (i.e. generics) were included if made by different manufacturers.

Categorization: We classified the 245 drugs into subcategories based on the main indications of the medication, relevance to COVID-19, route of administration (IV, oral, etc.), and the other variable definitions below. Drugs that did not meet one of the variable definitions found below were classified as "not applicable." Multiple variables were applied to the same drug if applicable.



Variable Definitions

Treats COVID-19 Symptoms or Adverse Effects: Used if the primary indication of the drug is a symptom found on the COVID-19 CDC symptom list; this includes fever reducers, cough suppressants, sore throat remedies, and drugs that treat nausea and diarrhea. Antibiotics were only included if they were <u>indicated in treatment protocols</u> for the management of COVID-19-related pneumonia. All anticoagulants were included in this category due to the extensive <u>evidence of hypercoagulopathy</u> in COVID-19 patients. Other categorizations (i.e. sedatives) were made using treatment guidelines from top hospitals (<u>MGH, University of Pennsylvania, and University of Michigan</u>). Drugs found in COVID-19 clinical trials on <u>clinicaltrials.gov</u> were included because they are being used therapeutically against the virus.

Inpatient Drug: Drug routes commonly administered in an inpatient setting (intravenous, intramuscular, subcutaneous) were included in this classification. Inpatient medications were further categorized as common ICU drugs if they are commonly used for sedation (for ventilated patients) or inpatient procedures (anesthetics for central line placements, anticoagulants used for dialysis), if they were vasoactive (used to medically increase or decrease blood pressure), or if they were indicated in COVID-19 associated sepsis or ARDS (determined by national critical care guidelines). We excluded intravenous medications that are common Part B drugs since this indicates they can be administered in an outpatient setting (chemotherapies, other injectable chronic treatments).

Treats Chronic Condition: Drugs that are taken for a prolonged course or to manage a chronic medical condition; this includes medications to treat mental health conditions.

Treats Chronic Condition at Risk for Severe Illness or Worse Outcomes in COVID-19:

This label was applied to drugs whose primary indication is on the CDC's list of conditions at risk for serious COVID-19 illness; this category also included drugs to treat conditions that cause lower immunity (HIV/AIDS) and drugs that themselves suppress immunity (chemotherapeutic/oncologic agents, immunosuppressants for autoimmune disorders/transplant recipients).

Not Applicable: These drugs may be vital to the health outcomes of many patients, but were not deemed relevant to the analysis for various reasons. Drugs in this category included drugs for non-chronic conditions (e.g. most antibiotics); drugs taken for a short duration (e.g. acute pain medications); electrolytes or nutritional supplements; topical creams, gels, and ointments; and drugs used to treat chronic dermatologic conditions that do not affect organ systems.



AnalySource Definitions

WAC: Wholesale Acquisition Cost (WAC) as published by First Databank¹ represents the manufacturer's published catalog or list price for a drug product to wholesalers as reported to First Databank by the manufacturer. WAC does not represent actual transaction prices and does not include prompt pay or other discounts, rebates, or reductions in price.

Brand/Generic Indicator: Specifies whether a product is a brand-named product or a generically named product, using the product name as the criteria. When discussing drug products with respect to their manufacturers, generically named drug products are products without a proprietary (or "brand") name. Typically in the United States, these products are named consistent with the United States Adopted Names (USAN).

Labeler Name (Manufacturer): Used to uniquely identify the product labeler (a manufacturer, distributor, or repackager).

New WAC: Price after price change.

Unit of Measure: Shows the current WAC Package unit of measure (i.e. bottle or vial).

Strength: Strength of drug.

Dosage: Form of drug; tablet, capsule, ampule, etc.

Package Size: Number of units in the package.

Effective Date: Date the price increase was posted to the database.

Indication: Conditions the drug treats, as found on the manufacturer's website and on the CMS dashboard.

^{1.} AnalySource® as reprinted with permission by First DataBank Inc. All rights reserved. © (2020). Please refer to http://www.fdbhealth.com/policies/drug-pricing-policy/ for more information.

