

# AFF

**Abby and I affirm Resolved: The United States federal government should impose price controls on the pharmaceutical industry.**

## **Our Sole Contention is Eliminating Price Gouging.**

**Currently, companies are able to charge as much as they would like for drugs, especially in situations where one company has a monopoly. For example,**

Jared **Bernstein**, *Senior fellow at the Center on Budget and Policy Priorities, was the chief economist and economic adviser to Vice President Joe Biden and executive director of the White House Task Force on the Middle Class*, 6-29-2016, "Drug Price Controls Are Vital in a Market That's Not Free," **New York Times**,

<https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-are-vital-in-a-market-thats-not-free> //AM

If Charles Dickens were writing today and seeking a life model for one of his villains, he'd be pleased to find **Martin Shkreli**, the former hedge fund manager who, **upon acquiring the rights to a critical drug for patients with life-threatening infections, raised its price to \$750 from \$13.50 per tablet.** But the problem we face is less this particular individual than the fact that we're imposing a market structure on something that should be a public good. We wouldn't squirm watching this guy try to explain himself if he were selling yachts or high-end real estate. The challenge is finding the public policies that will take pharmaceuticals from what any objective person would view as a highly distorted market — **prices don't rise 5,500 percent overnight in a functioning market** — to a more rational one.

### **This is not an isolated incident.**

Meg **Tirrell**, (Meg Tirrell joined CNBC in April 2014 as a general assignment reporter focusing on biotechnology and pharmaceuticals. She holds a master's degree in journalism from Northwestern University and a bachelor's degree in English and music from Wellesley College.), 6-27-17, "FDA aims to curb price gouging with list of off-patent medicines without generic competition," **CNBC**,

<https://www.cnb.com/2017/06/27/fda-aims-to-curb-price-gouging-with-list-of-off-patent-medicines.html> //AM

Bottom line is that generic drugs shouldn't have massive price increases: They should be near commodity products if the markets are even close to efficient. **Many other spec pharma companies have exploited similar artificial, regulatory-enabled monopolies around age-old drugs.** For sake of simplicity, I'll call these folks the Exploiters. **They've exploited the opaque, multi-layered and dysfunctional value chain around pharmaceutical pricing to their advantage, leveraging the FDA's suboptimal regulatory approach to generics to create artificial, unwarranted and inappropriate monopolies.** What's disappointing in all this is the damage done to real innovation. The whole industry is tarred and feathered in explosive PR crises like this one, as with Turing.

Norman R. **Augustine**, 2018, “Making Medicines Affordable A National Imperative,” **National Academies of Sciences, Engineering, and Medicine**, <https://www.nap.edu/read/24946/chapter/1#ii> //AM

As but one example, the price of Lipitor, a widely used anti-cholesterol drug, dropped from \$3.29 per unit to 11 cents when its patent protection expired. Historically, the greatest pricing concerns have focused on on-patent drugs; **however, major price increases for generic drugs have become increasingly common as more than half of existing generics are now produced by a single supplier.** An implicit trade-off exists when setting drug prices—investments in research and development can increase the cost of current drugs, but failure to make investments in research and development will ultimately limit the number of new, improved drugs with which to treat future patients. Biopharmaceutical manufacturers often point to the need to fund research and development as the principal justification for what many see as high prices.

Michael Alkire, 3-21-2016, "Unpacking Drug Price Spikes: Generics," Health Affairs, <https://www.healthaffairs.org/doi/10.1377/hblog20160321.054028/full/> (NK)

It should be noted that one of the first things some generics manufacturers do when they find themselves in a monopoly or duopoly position is steer clear of the competitive friction inherent in the group purchasing organization (GPO) contracting process, which leverages the combined purchasing power of hospitals and health systems to advocate for lower pricing on high-quality products. Instead, these manufacturers thrive on cornering the market and then holding it hostage. Case in point: According to a Premier analysis, **price increases for the top 20 non-GPO contracted generic drugs (in terms of money spent annually) increased on average by 413 percent over the three-year period 2013 through 2015, with some price spikes into the thousands of percent.** Moreover, only one or two manufacturers existed in all but one instance. In contrast, the price of the top 20 Premier GPO-contracted generics with the highest member spend *decreased* on average by 8 percent during this period.

**This is really bad, as**

Norman R. **Augustine**, (Augustine currently serves as a member of the President’s Council of Advisors on Science and Technology and the Department of Homeland Security’s Advisory Council), 2018, “Making Medicines Affordable A National Imperative,” **National Academies of Sciences, Engineering, and Medicine**, <https://www.nap.edu/read/24946/chapter/1#ii> //AM

When the period of patent exclusivity for a drug expires, companies other than the developer are free to introduce copies—known as **generics**—into the market. These products **represent 89 percent of all prescriptions written** and 24 percent of the total cost of all prescription drugs. When generics enter the market, experience shows that the price of the original patented product frequently drops precipitously as the developer seeks to compete with the new, lower-cost entrants—or forfeits some or all of the market.

**Generics are supposed to be cheap alternatives to brand name drugs. But at the point where all drugs, including generics, are increasing in price a ton,**

Dr. Ezekiel **Emanuel**, *Vice Provost for Global Initiatives and chair of the Department of Medical Ethics and Health Policy at the University of Pennsylvania. From January 2009 to January 2011, he served as special advisor for health policy to the director of the White House Office of Management and Budget. Since 1997 he was chair of the Department of Bioethics at The Clinical Center of the National Institutes of Health*, 8-30-16, “Drugmakers exploit government-granted monopolies: Ex-Obama health advisor,”

**CNBC**,

<https://www.cnb.com/2016/08/30/drugmakers-exploit-government-granted-monopolies-ex-obama-health-advisor.html> //AM

**The only way to stop drug companies** — such as Mylan in the case of the EpiPen — **from jacking up the costs of live-saving treatments is through price controls.** Dr. Ezekiel Emanuel told CNBC on Tuesday. “If we had a market that would be great. I think prices would come down,” said Emanuel, one of the architects of Obamacare. “But let’s face it,” he continued, “in the drug

business there's a monopoly granted by the government ... through patents, through FDA marketing exclusivity and FDA regulation, which takes a long time to approve a line to produce drugs." Emanuel told "Squawk Box" it's no surprise that big pharmaceuticals "exploit the monopolies to raise prices." He added: "The only way in a monopoly situation to keep the prices reasonable is government regulation, unfortunately." The latest outcry over drug prices surrounds Mylan's decision to hike the cost of EpiPens about 400 percent in recent years.

## **There are two impacts. First, a decrease in non-adherence.**

Aaron S. Kesselheim, M.D., J.D., M.P.H., Associate Professor of Medicine at Harvard Medical School and faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital, 8-30-2016, "The High Cost of Prescription Drugs in the United States," **American Medical Association**,

<https://jamanetwork.com/journals/jama/article-abstract/2545691> //AM

In addition to their contribution to health care spending, **increasing drug costs have important clinical implications.**

Because cost-containment efforts require patients to pay higher copayments for their medications, such **increases can reduce the affordability of prescribed regimens and thus patient adherence, leading to negative health**

**outcomes.**<sup>12</sup> However, some costly drugs may offer reasonable value. For example, sofosbuvir (Sovaldi) was found to be a cost-effective treatment of hepatitis C infection even at its 2013 launch price of \$84 000 per 12-week course in certain patient populations when viewed from a patient's lifetime horizon and a societal perspective.<sup>13</sup> Payers must pay for this treatment upfront, though, with health care benefits often accruing decades later to a different payer. In 2014, state Medicaid programs spent an estimated \$1.1 billion (after discounts) on sofosbuvir, 14 usually with no additions to their budgets.

Norman R. Augustine, 2018, "Making Medicines Affordable A National Imperative," **National Academies of Sciences, Engineering, and Medicine**, <https://www.nap.edu/read/24946/chapter/1#ii> //AM

The burden of high-priced drugs often falls disproportionately on vulnerable elements of the population, in spite of government, industry, and charitable efforts to alleviate its impact. For example, the Kaiser Family Foundation reports that **in 2015, about 20 percent of Americans did not fill at least one prescription due to affordability considerations**, while others rationed the drugs that they did acquire. Two-thirds of personal bankruptcies in the United States have been attributed entirely or in part to the cost of medical care as a whole.

## **Reducing drug costs is imperative, as**

Jane E. Brody (B.S. in biochemistry from the New York State College, personal health columnist at NYT), 4-17-2017, "The Cost of Not Taking Your Medicine," **The New York Times**,

<https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html> //EH

People who do take prescription medications — whether it's for a simple infection or a life-threatening condition — typically take only about half the prescribed doses. **This lack of adherence**, the Annals authors wrote, **is estimated to cause approximately 125,000 deaths and at least 10 percent of hospitalizations, and to cost the American health care system between \$100 billion and \$289 billion a year.** Former Surgeon General C. Everett Koop put it bluntly: "Drugs don't work in patients who don't take them."

## **The second is Hepatitis C in prisoners.**

Hepatitis, 9-29-2017, "Hepatitis C Information," **Centers for Disease Control and Prevention**,

<https://www.cdc.gov/hepatitis/hcv/index.htm> //AM

**Hepatitis C is a liver infection caused by the Hepatitis C virus (HCV). Hepatitis C is a blood-borne virus. Today, most people become infected with the Hepatitis C virus by sharing needles or other equipment to inject drugs.** For some people, hepatitis C is a short-term illness but **for 70%–85% of people who become infected**

**with Hepatitis C, it becomes a long-term, chronic infection. Chronic Hepatitis C is a serious disease than can result in long-term health problems, even death.**

The majority of infected persons might not be aware of their infection because they are not clinically ill. There is no vaccine for Hepatitis C. The best way to prevent Hepatitis C is by avoiding behaviors that can spread the disease, especially injecting drugs.

**Once a death sentence, the disease has recently become treatable.**

Ted Alcorn, [TED ALCORN is a lecturer at Columbia University's Mailman School of Public Health and New York University, he also contributes public health reporting to the New York Times, The Lancet, and other publications. He previously served as a policy analyst in the Office of the Mayor of New York City. He earned graduate degrees Johns Hopkins.], 3-15-2018, "Hepatitis C Drugs Save Lives, but Sick Prisoners Aren't Getting Them," **New York Times**,

<https://www.nytimes.com/2018/03/15/us/hepatitis-c-drugs-prisons.html> //AM

A leading cause of cirrhosis and end-stage liver disease, hepatitis C wreaks irreversible but invisible damage for years; when symptoms become apparent, it is too late to treat. The disease is blood-borne and usually acquired from unsafe transfusions or injection drug use, but perhaps only half of those infected know they have it. It can also be transmitted through tattooing using nonsterile equipment. Early therapies for hepatitis C induced fatigue and depression in many patients and cleared the infection in less than half of them. But **four years ago drugmakers began to introduce new medicines that** do not have the same debilitating side effects and **cure nearly all patients, revolutionizing treatment. In return, the companies demanded high prices** — Gilead Science debuted the first of the new class of hepatitis C drugs, Sovaldi, at **\$84,000 per course of therapy** — and private insurers proved willing to pay. **Competitors have driven down the price. The latest entrant, AbbVie's Mavyret, was introduced in August 2017 at \$26,400.** But the treatments remain highly profitable. Manufactured for just dollars per course of treatment, Gilead's hepatitis C drugs have brought in more than \$55 billion in revenue since 2014. Drugmakers have long defended their high prices, arguing that their business model for developing new drugs depends on being able to reap a profit from existing ones. **In the case of hepatitis C, this system has yielded drugs that the most affected populations have no way to afford. "We are harming millions of people because of allegiance to a model of innovation that constrains delivering that innovation,"** said Peter Bach, a drug pricing expert who directs the Center for Health Policy and Outcomes at the Memorial Sloan Kettering Cancer Center. "That model — the central dogma of pharmaceutical development — is broken." As people with private insurance gained access to hepatitis C treatment, it became less defensible to withhold it from prisoners.

**Prisoners with Hep C don't get treated because of cost**

Ted Alcorn, (graduate school at the Johns Hopkins Bloomberg School of Public Health and their School for Advanced International Studies (SAIS)), 3-15-2018, "Hepatitis C Drugs Save Lives, but Sick Prisoners Aren't Getting Them," **New York Times**,

<https://www.nytimes.com/2018/03/15/us/hepatitis-c-drugs-prisons.html> //AM

Any national campaign to eliminate hepatitis C, an insidious virus that kills tens of thousands of Americans a year, would almost certainly involve prisons. **One in seven state inmates are believed to be infected**, and the regimented environment of a prison has its advantages when it comes to screening and treatment. **The problem is, the drugs that effectively cure the disease are priced in the tens of thousands of dollars — far more than prisons can pay. In 2015, state corrections departments were treating less than 1 percent of those inmates known to be infected**, a survey found. Now courts have begun ordering states to provide the drugs regardless of cost, prompting an unusual showdown over how pharmaceutical companies set prices for the treatments. In at least nine states, prisoners have filed lawsuits arguing that withholding drugs constitutes deliberate indifference to their dire medical needs, violating a constitutional ban on cruel and unusual punishment.

**If price controls were enacted and the price for the cure for Hepatitis C was reduced, the lives of nearly 750,000 people could be saved.**

**Thus, we proudly affirm.**

