



Affordable Medicine for All: A Plan to Slash Drug Prices and Boost Pharmaceutical Innovation

We are living in a golden age of medicine development. A decade ago, a hepatitis C diagnosis meant a life sentence that could culminate in liver disease, cirrhosis, and death. Today, hundreds of thousands of lives have been cured of the infection by a breakthrough treatment. Medicines have vastly extended life expectancy for people with Hodgkin's lymphoma and cystic fibrosis, protected us from many viruses and certain cancers, and put us within reach of ending the AIDS epidemic for good.¹

Yet far too many of us are denied access to the benefits of these potentially life-saving medicines.² Drugs in the United States are more expensive than drugs anywhere else in the world.³ Americans pay an average of \$600 a year more for prescription drugs than residents of most other developed countries.⁴ This is despite the fact that American taxpayers contribute to virtually all drugs approved by the U.S. Food and Drug Administration (FDA) in some capacity and spent over \$100 billion from 2010-2016 for the basic research that undergirds miraculous drugs for both Americans and the rest of the world.⁵ At the same time that millions of Americans struggle to pay for drugs, pharmaceutical companies are enjoying record profits and remain the most profitable companies in the entire health industry.⁶

Time and time again, Washington has proven that it's either uninterested in or incapable of addressing this problem. Instead of siding with Americans, politicians have stood with corporate health care, as they did when Congress barred the federal government from negotiating with pharmaceutical companies on drug prices for seniors. That prohibition remains in place today. We are the largest purchaser of drugs in the world.⁷ Applying Walmart logic to the pharmaceutical industry, we should be paying the lowest prices, not the highest, for prescription drugs.

Washington's inaction impacts our lives in very real ways. Nearly one in four Americans struggle to pay for our medications.⁸ Three in ten skip doses or forgo filling prescriptions due to costs.⁹ Families across the country face difficult choices: medicine or child care for my two-year-old? Medicine or making rent on time? A medicine to treat my diabetes or control my cholesterol?

The high cost of medicine can have deadly consequences. In June 2019, Jesmiya David Scherer-Radcliff, a 21-year-old from Minnesota who lived with diabetes, died while rationing his insulin. He could not afford this life-saving drug despite working two jobs.¹⁰ At least five others have died under similar

¹ Cystic Fibrosis Foundation, "[2017 Cystic Fibrosis Foundation Patient Registry Highlights](#)," 2018.

² National Academy of Sciences, "[Making Medicines Affordable: A National Imperative](#)," 2017.

³ Langreth, Robert. "[Quick Take: Drug Prices](#)," Bloomberg, February 5, 2019.

⁴ Organization for Economic Cooperation and Development, "[Pharmaceutical spending](#)."

⁵ Cleary, Ekaterina G. et al. "[Contribution of NIH funding to new drug approvals 2010-2016](#)," PNAS, March 16, 2018.

⁶ Herman, Bob. "[Axios analysis: Drugmakers are getting richer](#)," Axios, May 13, 2019.

⁷ Dana O. Sarnak, David Squires, and Shawn Bishop. "[Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?](#)" The Commonwealth Fund, October 5, 2017.

⁸ Garber, Adam, Kilpatrick, Lance, Matthew, Reuben. "[The real price of medications: a survey of variations in prescription drug prices](#)," U.S. PIRG, 2019.

⁹ Kirzinger, Alex. "[KFF Health Tracking Poll - February 2019: Prescription Drugs](#)," Kaiser Family Foundation, March 1, 2019.

¹⁰ Right Care Alliance. "[High insulin costs are killing Americans](#)," 2019.



circumstances. These young people are dying from lack of access to insulin that is too expensive to manage their diabetes, a disease they didn't cause and a daily treatment they can't live without. This is a uniquely American tragedy; a vial of insulin that costs us up to \$300 can be bought for \$30 in Canada and is free to patients in Italy.^{11,12}

It's time for a new era of leadership in Washington ready and eager to make drugs affordable and take on pharmaceutical companies. Pete has the courage to break with the status quo by focusing on real solutions that will lower costs and make needed—even life-saving—prescription drugs available to all Americans.

Pete's Affordable Medicine for All plan dramatically reduces prescription drug costs, forces pharmaceutical companies to price responsibly and pay their fair share, and encourages innovation in new medicine manufacturing, financing, and delivery.

Pete will ensure that everyone has access to health insurance with an affordable prescription drug benefit package through his public plan, Medicare for All Who Want It. To bring down drug costs across our health system, Pete will empower the federal government to negotiate drug prices for Medicare and his public plan. To ensure that Americans benefit from the cost savings from more affordable prices, the negotiated rates will be available to other public and private insurance programs to voluntarily adopt. Pete's plan also caps monthly out-of-pocket drug costs at \$200 a month for seniors on Medicare. Pete's plan expands American investment in the development and manufacturing of new medicines and modernizes the oversight of the pharmaceutical industry and our current system of financing drugs. Through higher taxes, inflation penalties, and pricing negotiation, it compels pharmaceutical companies to price responsibly and work for—not against—the American people.

These policies will:

- Cut out-of-pocket drug spending for seniors on Medicare by at least 50% by the end of Pete's first term, including an out-of-pocket cap on prescription drug costs of \$200 per month.
- Cap out-of-pocket spending on prescription drugs under \$250 per month for everyone choosing public coverage under Pete's Medicare for All Who Want It plan.
- Institute a \$0 co-pay for high-quality generic medicines for low-income people on Medicare, Medicaid, and Pete's Medicare for All Who Want It plan.
- Reduce median annual out-of-pocket drug spending for middle class Americans on Medicare Part D living with cancer by at least \$5,100¹³ and by at least \$2,000 for those living with certain immune disorders, such as rheumatoid arthritis and multiple sclerosis.¹⁴
- Guarantee that no one living with diabetes dies from rationing insulin due to cost.
- Help end the opioid epidemic by dramatically reducing the cost of naloxone, a drug used to reverse opioid overdoses, and other medicines used to treat substance abuse.

¹¹ ["Access to Insulin and Supplies Survey."](#) T1International. March 2016.

¹² Choi, Tyler. ["American caravan arrives in birthplace of insulin for cheaper medicine."](#) Reuters. June 29, 2019.

¹³ Cubanski, Juliette, Koma, Wyatt, Neuman, Tricia. ["The out-of-pocket cost burden for specialty drugs in Medicare Part D."](#) Kaiser Family Foundation. February 1, 2019. See Figure 2.

¹⁴ Cubanski, Juliette, Koma, Wyatt, Neuman, Tricia. ["The out-of-pocket cost burden for specialty drugs in Medicare Part D."](#) Kaiser Family Foundation. February 1, 2019. See Figure 2.

PEOPLE OVER PROFIT

Guarantee everyone has access to affordable prescription drugs through Medicare for All Who Want It, which will have a monthly out-of-pocket drug spending cap under \$250.

Pete’s Medicare for All Who Want It plan gives everyone the option of getting insurance coverage through an affordable and comprehensive new public insurance plan. This public plan will force private insurers to compete and lower their prices and produce better outcomes. If private insurers are not able to compete, the public plan creates a natural glide-path to Medicare for All.

To ensure affordable medicines, the federal government will be able to negotiate lower drug prices with pharmaceutical companies on behalf of the public plan, among other policy changes (see section on drug pricing negotiations below). It will also offer an affordable prescription drug benefit package that caps monthly out-of-pocket drug spending under \$250.

Bring down the cost of prescription drugs for seniors by capping Part D monthly out-of-pocket costs at \$200.

Today, the number of people covered under Medicare’s pharmacy benefit (Part D) who are paying high out-of-pocket costs above the catastrophic coverage threshold is over a million, twice what it was in 2007.¹⁵ Even when a beneficiary reaches the catastrophic coverage threshold, they are still required to pay five percent of drug costs. This means that there’s actually no limit on what a beneficiary can pay for prescription drugs. As a result, many people spend thousands of dollars on prescription drug treatment a year. For example, people living with rheumatoid arthritis pay a median of over \$5,000 out-of-pocket for a single medicine.¹⁶ Those living with certain types of cancers often pay upwards of \$10,000 out-of-pocket for a single medicine.¹⁷ This helps explain why over 40 percent of cancer patients deplete their entire life savings after two years of treatment, and one in four are forced to skip a prescription.^{18,19}

Pete will work with Congress to place a monthly cap on Part D out-of-pocket costs of \$200 and a maximum cap on annual Part D out-of-pocket spending of \$2,400. Seniors with lower incomes will have lower caps, as they are eligible for subsidies.

¹⁵ Cubanski, Juliette, Neuman, Tricia, Damico, Anthony. “[How many Medicare Part D enrollees had high out-of-pocket costs in 2017?](#)” Kaiser Family Foundation. June 21, 2019.

¹⁶ Cubanski, Juliette, Koma, Wyatt, Neuman, Tricia. “[The out-of-pocket cost burden for specialty drugs in Medicare Part D.](#)” Kaiser Family Foundation. February 1, 2019.

¹⁷ Cubanski, Juliette, Neuman, Tricia, Damico, Anthony. “[How many Medicare Part D enrollees had high out-of-pocket costs in 2017?](#)” Kaiser Family Foundation. June 21, 2019.

¹⁸ Haefner, Morgan. “[Cancer forces 42 percent of patients to exhaust life savings in two years, study finds.](#)” Becker’s Hospital Review. October 24, 2018.

¹⁹ Szabo, Liz. “[As drug costs soar, cancer patients skip or delay treatment.](#)” NPR. March 15, 2017.



Pete will also support modernizing Medicare’s Part D pharmacy benefit to make insurance plans and pharmaceutical companies pay their fair share in the catastrophic phase of the benefit.

Make co-payments for generic drugs \$0 for people with low incomes insured by Medicare, the public plan, and Medicaid.

Generic drugs comprise 90 percent of the total prescription drug volume sold in the United States.²⁰ Many patients insured by Medicare and Medicaid have to make an out-of-pocket payment for access to these drugs.^{21,22} These out-of-pocket expenses can deter patients from getting the care they need.

Pete supports eliminating co-payments on all generic and biosimilar drugs covered under Medicaid, and for low-income people in the public plan and Medicare. These patients will pay \$0 out-of-pocket for generics and biosimilars. Pete also supports Medicare Part D plans and the public plan covering generics and biosimilars in their lowest formulary tier and identifying additional incentives to encourage clinicians, hospitals, and pharmacies to use generic drugs and biosimilars whenever clinically appropriate and available.^{23,24}

Bring down the cost of prescription drugs—starting with drugs to manage diabetes such as insulin—for all payers by allowing the federal government to negotiate drug prices with pharmaceutical companies.

Corporate health care has prioritized profits over people, and so have politicians in Washington. Congress has actually barred the federal government from negotiating with pharmaceutical companies to make drugs more affordable for seniors. That prohibition remains in place today. We are the largest purchaser of drugs in the world. Applying Walmart logic to this business, we should be paying the lowest prices, not the highest.

Pete will work for American families and employers by empowering the federal government to negotiate down the price of drugs with pharmaceutical companies. The federal government will negotiate on behalf of people covered by Medicare and the public plan.²⁵ The negotiated rates will be available to other public plans, including Medicaid, and private plans.

²⁰ IQVIA. [“Medicine use and spending in the U.S.”](#) May 9 2019.

²¹ DiGrande, Samantha. [“Insurance Guidelines Lead to Greater Out-of-Pocket Costs for Patients With MS.”](#) American Journal of Managed Care. February 9, 2019.

²² Recent Medicaid Prescription Drug Laws and Strategies. [“National Conference of State Legislatures.”](#) August 8, 2018.

²³ Dusetzina, Stacie, Shelly Jazowski, Ashley Cole, Joehl Nguyen. [“Sending the wrong price signal: why do some brand name drugs cost Medicare beneficiaries less than generics?”](#) Health Affairs. July 2019.

²⁴ Avalre. [“Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs.”](#) February 2019.

²⁵ Cubanski, Juliette, et al. [“What’s the latest on Medicare drug pricing negotiations?”](#) Kaiser Family Foundation. July 23, 2019. This is a proposal with multi-stakeholder support.

The criteria for negotiating prices will include: (1) the therapeutic gain offered by the drug, (2) the cost of bringing the therapeutic class of drugs to market, (3) the current costs of treating the indicated disease, and (4) international prices charged for these drugs.²⁶ The Secretary of Health and Human Services will be empowered to negotiate the prices of as many drugs as needed each year.

Pharmaceutical companies will be heavily penalized if they refuse to participate in negotiations or leave the negotiation before a fair price is agreed upon. The penalty will be a tax on the company's gross sales of the drug starting at 65 percent and increasing by 10 percentage points every quarter the company is out of compliance, to a maximum of 95 percent.

The first drugs for negotiation will be those with very high price tags and large price differences between what we pay and what other industrialized countries pay, including those to treat diabetes, asthma, arthritis, HIV, and cancer.

For “worst offender” pharmaceutical companies that continue to price egregiously, exercise the government’s “eminent domain” rights to tame high drug prices.

Patents are a privilege guaranteed by the American people to innovators. Pharmaceutical companies found to be abusing that privilege by harming consumers through irresponsible pricing should face real consequences.

The federal government has the power to acquire intellectual property rights from pharmaceutical companies under 28 United States Code § 1498 (known as Section 1498) and certain provisions in the Bayh-Dole Act. The provisions in the Bayh-Dole Act empower the federal government to exercise their rights over patents when American taxpayers helped fund the development of new drugs and biologics.²⁷

For “worst offender” pharmaceutical companies that continue to price in a way that harms patients due to unaffordability, when attempts at direct negotiation are rebuffed, and in cases of national emergency related to either a natural disaster or a public health emergency, Pete will judiciously exercise these rights. When and if these rights are asserted, the federal government will identify a willing supplier capable of making the drug at an affordable price.

Pete will appoint an Attorney General willing and able to defend these rights and a Secretary of Health and Human Services prepared to use them to ensure prescription drug access and affordability for all.

Increase taxes on pharmaceutical companies to ensure they pay their fair share and help make drugs more affordable for all.

²⁶ Frank, Richard and Nichols, Len. “[Medicare Drug Price Negotiation — Why Now... and How.](#)” New England Journal of Medicine. September 4, 2019.

²⁷ Thomas, John R. “[March-In Rights Under the Bayh-Dole Act.](#)” Congressional Research Service. August 22, 2016.



As millions of Americans struggle to pay for drugs, pharmaceutical companies are getting richer and richer. Today, pharmaceutical companies are among the most profitable companies in the entire health industry.²⁸ Pete will increase the annual Branded Prescription Drug Fee on drug manufacturers and importers that was established by the Affordable Care Act.²⁹ The revenue collected by this fee will be used to help fund Americans' access to affordable prescription drugs.

Rein in outrageous drug price increases by penalizing pharmaceutical companies that raise prices by more than inflation.

In the first six months of 2019, pharmaceutical companies increased prices for 3,400 drugs, and for those drugs, the average increase was 10.5 percent, five times the rate of inflation.³⁰ More than 40 drugs had price hikes greater than 100 percent, including a 879 percent increase for Prozac, a drug to treat depression; a 326 percent increase for Phenergan, which treats cold symptoms; and a 118 percent increase for the ADHD-drug Intuniv.³¹ These price increases are largely driven by shareholder pressure to increase profits.

Pete wants people to be protected against unexpected price inflation. Pete will implement pricing protections against outrageous drug price inflation in Medicare and the public plan, similar to Medicaid's current protections. Every quarter, branded pharmaceutical companies would be required to pay a rebate for drugs that increase faster than inflation. Pharmaceutical companies that fail to comply with the rebate requirement will not be paid until they do.

Make it easier for generics and biosimilars to enter the market by ending the egregious tactics used by pharmaceutical companies to prevent or obstruct competition.

Ensuring competition from generic drugs and biosimilars is critical to sustaining access, as well as ensuring low prices and high quality. And yet, pharmaceutical manufacturers of brand name drugs are increasingly using several legal tactics to stifle competition. For example, branded drug manufacturers use "pay-for-delay" tactics to essentially pay companies not to bring safe, effective, and low-cost generic drugs to market.³² This abusive maneuver alone costs the American people \$3.5 billion a year.³³

Pete will end the pay-for-delay deals. Pete also supports the Protecting Consumer Access to Generic Drugs Act, which would make clear that pay-for-delay settlements are illegal. In addition, Pete supports legislation that would modernize the FDA's public listings of prescription drugs, including patents on drug delivery devices and court decisions finding patents invalid. He will close regulatory loopholes

²⁸ Herman, Bob. "[Axios analysis: Drugmakers are getting richer.](#)" Axios. May 13, 2019.

²⁹ Internal Revenue Service. "[Annual fee on branded prescription drug manufacturers and importers.](#)" 2015.

³⁰ Picchi, Aimee. "[Drug prices in 2019 are surging with hikes at five times inflation.](#)" CBS News. July 1, 2019.

³¹ *ibid.*

³² Federal Trade Commission. "[Pay for delay.](#)" No date.

³³ *ibid.*

being exploited by some brand manufacturers to deny access to reference materials needed for research and development and procedural abuse by brand manufacturers delaying generic application review.³⁴

Pete will appoint a chair of the Federal Trade Commission who will enforce the rights of Americans to gain access to high-quality, low-cost generic drugs and biosimilars, and stop greedy pharmaceutical company tactics to forestall competition.

INVESTING IN NEW AND SAFE MEDICINE

Expand public investment in the development and manufacturing of medicines to address significant unmet needs, including medicines to protect against pandemics and antibiotics.

Pete will broaden current federal incentives that support research for drug development that prioritizes unmet needs.

These include expanding funding to support the work that the Biomedical Advanced Research and Development Authority Defense Authority is doing leading national medical countermeasures. Similarly, Pete will increase support for the work of the Army Futures Command that turns basic discoveries into tools to fight pandemics and other national threats to health and productivity, in concert with other federal agencies. As the threat of microbial resistance to existing therapies grows, Pete will further embolden American ingenuity by expanding funding for the Combating Antibiotic Resistance Bacteria program, which supports researchers and companies developing new antibiotics and diagnostics for this global threat.^{35,36}

As a matter of national security, Pete also supports investing in expanding American drug manufacturing capacity for essential drugs, especially those prone to shortages and quality problems. Currently, global medicine production is largely dependent on China.³⁷ This is a serious national security vulnerability that could be weaponized. If China were to “shut the door” on medicine exports and drug ingredients, drug costs could skyrocket, and hospitals and clinics could stop functioning within months, if not days.³⁸

The United States must remain a leader in the high-tech field of drug manufacturing. Pete supports expanding federal initiatives to invest in American manufacturing of prescription drugs, such as providing companies with tax incentives and grants to explore novel manufacturing like 3D printing technologies,

³⁴ Frank, Richard. “[Friction in the path to use of biosimilar drugs.](#)” New England Journal of Medicine. March 1, 2018.

³⁵ Biomedical Advanced Research and Development Authority. “[National Biodefense Strategy.](#)” 2018.

³⁶ For more information on the CARB-X program, please visit the program’s website [here](#).

³⁷ Gibson, Rosemary. “[Exploring the Growing U.S. Reliance on China’s Biotech and Pharmaceutical Products.](#)” Testimony Before the U.S.-China Economic and Security Review Commission. July 31, 2019.

³⁸ Ibid.

and encouraging public-private partnerships to invest in new domestic production.^{39,40} This prioritization will drive research and commercialization of new technologies to speed up the drug production process and provide alternatives in supply for the increasingly complex medicines of today and tomorrow.

Support state innovation to improve drug affordability and access, including by piloting subscription models and value-based contracting.

Many new medicines to prevent, treat, or even cure conditions—such as pediatric leukemia, hemophilia, and sickle cell anemia—are now or will soon be available to patients. Yet too many will be unable to access such therapies due to cost.

Pete will promote emerging collaborations between insurers, state governments, and pharmaceutical companies to expand access to preventative and curative drugs in new ways. For example, the state of Louisiana has implemented a new ‘subscription’ model, expanding access to hepatitis C treatments for all state Medicaid beneficiaries and incarcerated populations who need them.⁴¹ Other states, including Michigan and Florida, are experimenting with alternative approaches to increasing access and affordability.^{42,43}

Pete will encourage this type of experimentation by reducing regulatory and financing barriers to new contracting models. He will allow states to experiment with importing safe drugs from the very best, highest-quality manufacturers in the world. Lastly, Pete will equip these pilots with federal funding to rigorously evaluate and publicly report their results. All Americans should learn what really works to improve access and affordability to clinically effective prescription drugs.

Bring transparency to drug pricing.

Pete will establish a national All-Payer Claims Database that will improve the quality of research around health care costs and quality and make it easier for patients, providers, and insurers to reward high quality and cost-effective care, including for prescription drugs.⁴⁴

Moreover, all pharmaceutical companies with an agreement to sell prescription drugs to Medicaid, the public plan, and Medicare will be required to report to the federal government important information regarding sales volume, price, discounts, rebates and free goods, promotion, costs of manufacturing drugs, and research and development spending. They will also be required to report the sources of their drugs’ base ingredients and final place of manufacturing on the drug’s label.

³⁹ Lee, Sau. “[Modernizing the way drugs are made: a transition to continuous manufacturing.](#)” U.S. Food and Drug Administration. May 17, 2017.

⁴⁰ Introcaso, David and Szlezinger, Zack. “[Presidential candidates aren’t talking about drug shortages. They should be.](#)” Stat News. August 9, 2019.

⁴¹ Alcorn, Ted. “[Louisiana’s deal for hepatitis C drugs may serve as model.](#)” The Wall Street Journal. September 13, 2019.

⁴² Eggert, David. “[Michigan Medicaid Approved for Drug Pricing Experiment.](#)” US News and World Report. November 14, 2018.

⁴³ Findlay, Steven. “[States Pass Record Number of Laws to Reel in Drug Prices.](#)” Kaiser Health News. September 9, 2019.

⁴⁴ Calsyn, Maura. “[Policy options to encourage all-payer claims databases.](#)” Center for American Progress. April 20, 2018.

Pharmacy benefit managers (PBMs) that help plans manage the prescription drug benefit for Medicaid, the public plan, and Medicare will be required to report to the federal government annual dollar sales, sales volume, pricing, spread pricing, and rebates received by drug and plan.^{45,46}

Support the development of complex generic medicines and increase competition to lower prices.

Competition is thriving for many generic drugs, but not all. Pete will streamline regulations to make it easier for generic drugs and biosimilars to enter the U.S. market to encourage greater competition and, consequently, lower prices and increase quality.

For some complex medicines—such as inhalers for asthma—competition is limited due to the higher costs of development and strategic decisions to renew patents.⁴⁷ To address this development gap, Pete supports boosting current funding for the FDA to \$100 million for bioequivalence research, a key area of applied science that can reduce the cost of generic drug development and improve regulatory reviews and approvals. Pete will also direct the federal government to streamline regulations and approval processes for complex generics and biosimilars.

Secure the quality and safety of drugs produced at home and abroad.

The FDA is tasked with inspecting all drugs on the American drug market. Yet, tainted drugs often make it into patients' hands, such as when an HIV drug had red silicone particles, blood pressure medicine had been tainted with a carcinogen, and a stool softener used by children had been contaminated with bacteria.⁴⁸ There were 8,000 drugs recalls in the last five years, and almost 3,500 were for drugs developed in manufacturing plants that had either passed FDA inspection or had not been inspected since 2008.⁴⁹ Quality control is a particularly acute problem for drugs manufactured overseas.⁵⁰

Pete will empower federal agencies to better secure the quality and safety of drugs destined for American consumption, including by improving systems that regulate medicines coming from abroad. This will include increasing staff for foreign inspections, instructing the federal government to evaluate the safety of imports, and bolstering transshipment and importation tracing initiatives as part of current “track-and-trace” laws and regulations.

⁴⁵ Dusetzina, Stacie, Bach, Peter. [“Prescription drugs- list price, net price, and the rebate caught in the middle.”](#) JAMA Network. March 6, 2019.

⁴⁶ Royce, Trevor, Kircher, Sheetal, Conti, Rena. [“Pharmacy benefit manager reform.”](#) JAMA Network. June 20, 2019.

⁴⁷ [“Evaluating Inhaled Steroids Used to Treat Asthma.”](#) Consumer Reports: Best Buy Drugs. November 2013.

⁴⁸ Lupkin, Syndey. [“How tainted drugs make patients sicker.”](#) Kaiser Health News. January 4, 2019.

⁴⁹ Lupkin, Syndey. [“How tainted drugs make patients sicker.”](#) Kaiser Health News. January 4, 2019.

⁵⁰ Eban, Katherine. [“Americans need generic drugs. But can they trust them?”](#) The New York Times. May 11, 2019.