**Hillary's Plan to Respond to Unjustified Price Hikes for Long-Available Drugs**

Today, Hillary Clinton is offering a plan to protect Americans from unjustified price hikes in lifesaving treatments that have long been on the market. Over the last year, we've seen far too many examples of drug companies raising prices excessively for treatments that have been available for years – from Turing raising the price of pyrimethamine for AIDS patients by over 5,000 percent, to Mylan raising the price of the EpiPen by more than 400 percent. This is not an isolated problem: Between 2008 and 2015, drug makers increased the prices of almost 400 generic drugs by over 1,000 percent. Many of these companies are an example of a troubling trend—manufacturers that do not even develop the drug themselves, but acquire it and raise the price.

Our pharmaceutical and biotech industries are an incredible source of American innovation and revolutionary treatments for debilitating diseases. But it's wrong when drug companies put profits ahead of patients, with unjustified price increases not for new innovations, but for long-available and generic treatments – and we need rules of the road so fair competition keeps them in check. That's why, over the course of this year, Hillary Clinton has called out drug companies for outrageous and unjustified pricing practices.

Hillary believes we need to move beyond talking about these price hikes to acting to address them. Today she is calling for action to protect consumers from unjustified prescription drug price increases by companies that are marketing long-standing, life-saving treatments and face little or no competition. Her plan will establish dedicated consumer oversight at our public health and competition agencies. They will determine an unjustified, outlier price increase based on specific criteria including: 1) the trajectory of the price increase; 2) the cost of production; and 3) the relative value to patients, among other factors that pose a threat to public health.

Should an excessive, outlier price increase be determined for a long-standing treatment, Hillary's plan would make new enforcement tools available, including:

- **Making alternatives available and increasing competition:** Directly intervening to make treatments available, and supporting alternative manufacturers that enter the market and increase competition, to bring down prices and spur innovation in new treatments.
- **Emergency importation of safe treatments:** Broadening access to safe, high-quality alternatives through emergency importation from developed countries with strong safety standards.
- **Penalties for unjustified price increases to hold drug companies accountable and fund expanded access:** Holding drug makers accountable for unjustified price increases with new penalties, such as fines – and using the funds or savings to expand access and competition.

In combination with her broader, previously announced prescription drug plan – which addresses the costs facing consumers from both long-standing and patented drugs – these new tools to address price spikes for treatments available for many years will lower the burden of prescription drug costs for all Americans.

**Hillary Clinton's Plan to Immediately Respond to Outlier, Unjustified Drug Price Increases:**

Today, Hillary is offering an aggressive, immediate response plan to provide relief from unjustified drug price spikes for treatments, like EpiPens or pyrimethamine, that have long been on the market, where there has been little or no innovation or additional research and development. In combination with her broader agenda to lower prescription drug costs, which she is reiterating today, these strong new tools will ensure Americans can afford prescription drugs, and make sure that drug companies get ahead through innovation and research, rather than unjustified price increases.

***Dedicated oversight to protect consumers.*** Hillary's plan will ensure consumers have dedicated oversight and protection with new, aggressive enforcement tools to take on unjustified, outlier price increases. Hillary will convene representatives of Federal agencies charged with ensuring health and safety, as well as fair competition, to create a dedicated group charged with protecting consumers from outlier price increases. They would work closely with and be advised by patient advocates, independent non-government experts on drug pricing and comparative effectiveness, and state and local regulators to investigate and respond to situations like the recent price increases in EpiPens and pyrimethamine.

***Strong new enforcement measures to respond when there are unjustified, outlier price increases that threaten public health.*** This group dedicated to consumer protection would establish criteria for determining an unjustified price increase for a long-available treatment – which would enable a forceful response with the new set of enforcement measures outlined below. The group would investigate and consider enforcement in situations involving a life-saving or critically needed treatment that has long been available; with no meaningful change or improvement in the product (such as when a new acquirer rapidly raises the price); where there is limited or no competition among manufacturers of the treatment; and where there is an unjustified, outlier price increase. An unjustified price increase would be determined by a review of criteria including: 1) the trajectory and scope of the increase in price; 2) changes in the cost of production; and 3) the treatment's relative value to patients, among other factors that give rise to threatening public health. After a careful investigation and review of the evidence, this group would have an aggressive new set of enforcement tools to respond if it determined that a drug experienced an unjustified price increase. These measures will offer carrots

and sticks: they will immediately expand availability of treatments during a price spike, and potentially respond to and deter unjustified price increases with penalties including fines - which would be used to fund increased competition and access:

- **Directly intervening to make treatments available, and supporting generic and alternative manufacturers that enter the market and increase competition to bring down prices.** In cases where there is insufficient competition and an unjustified price spike, Hillary's plan would enable emergency purchases of alternative versions of longstanding, life-saving treatments to make them available to consumers in need, and encourage competition from additional suppliers. Leading experts have suggested direct purchases to respond to price increases and a lack of competition for generic drugs. And there is a precedent for this approach: the Vaccines for Children program, which Hillary Clinton championed in the 1990s, directly purchases and distributes life-saving vaccines to ensure their availability and supply. This will incentivize new generic manufacturers to enter the market and put downward price pressure on all manufacturers, so that American families can afford the life-saving drugs they depend on. And it will make our supply chain for drugs more resilient, so we prevent life-threatening shortages from happening in the first place.

- **Broadening access to safe, high-quality generic and alternative competitors through emergency importation.** Already during this campaign, Hillary has called for legislation to safely and securely import drugs for personal use from foreign nations whose safety standards are as strong as those in the U.S., with careful review by the FDA and other regulatory agencies. In the past, the FDA has allowed for temporary importation of drugs that are a substitute of a treatment in shortage in the U.S., after careful inspection of facilities and confirmation that that the imported drugs meet safety standards. Under Hillary's plan, temporary importation of alternative products with strong safety standards could be triggered as a tool to expand access and lower costs, in careful consultation with the FDA.

- **Holding drug makers accountable for unjustified price increases with new penalties - and using the funds to expand access and competition.** In cases where there is a price spike and a lack of competition for a life-saving treatment that has long been on the market, Hillary's plan will enable the ability to fine or increase rebates from drug companies who are excessively raising prices. Revenue or savings from these penalties could be used to support the aforementioned new programs to make lower-cost, effective alternatives available, and speed up approvals that will lead to greater competition. This will both deter companies from raising prices without justification, and support competition from alternative suppliers to bring down the price. There is a precedent for versions of this approach in certain Federal programs, which provide larger rebates from drug companies to respond to price

increases. As part of Medicaid's Drug Rebate Program, drug makers in some circumstances are required to pay additional rebates if their prices increase beyond inflation.

In combination, these measures will immediately protect Americans from unjustified and excessive price increases from drugs long on the market.

**Hillary Clinton's Broader Plan to Lower Prescription Drug Costs for All Americans**

In addition to these immediate protections, today, Hillary is reaffirming her commitment to her broader plan to lower drug prices for all Americans, introduced last year in September, by holding drug companies accountable, letting Medicare negotiate prices, capping monthly drug costs, and ensuring drug companies invest in research and innovation rather than marketing.

*Lower costs for Americans by limiting out-of-pocket spending, increasing competition, and demanding value for their purchases:*

- **Cap monthly and annual out-of-pocket costs for prescription drugs to save patients with chronic or serious health conditions hundreds or thousands of dollars.** Americans should be able to afford prescriptions for their conditions throughout the year, and not have to stop taking a needed medication. Following the example of states like California and Maine, Clinton's plan will require health insurance plans to place a monthly limit of $250 on covered out-of-pocket prescription drug costs for individuals to provide financial relief for patients with chronic or serious health conditions, ensuring Americans can get the care their doctors prescribe. The cap would apply to prescriptions covered by insurance that are specifically approved by FDA for the treated condition. Up to a million Americans could benefit from this proposal every year.

- **Clear out the FDA generic backlog.** Clinton's plan will fully fund the FDA's Office of Generic Drugs to clear out their multi-year generic drug approval backlog, which has kept competitors off the market, and can help lower overall prescription drug prices.

- **Prohibit "pay for delay" arrangements that keep generic competition off the market.** Hillary Clinton would prohibit "pay for delay" agreements that allow drug manufacturers to keep generic competition off of the market – lowering prices for Americans, and saving the government up to $10 billion.

- **Ensure American consumers are getting value for their drugs.** Clinton's plan will ensure that new drugs coming on the market provide value and high quality to

consumers, rather than adding to cost without improving treatments and outcomes. Clinton recognizes that new drugs can constitute incredible breakthroughs in treating diseases from Hepatitis C to cancer to heart disease – and we need to ensure that there are proper incentives for real innovations that bring effective products to market. Clinton believes that Americans should not face extreme costs, or pay too much for drugs that do not in actuality improve available treatments. She has a long and strong record of supporting the evaluation of the value, quality, and comparative effectiveness of new drugs. That's why she'll build on provisions in the Affordable Care Act that invest in private research, and other private efforts, to use the results of private-sector analyses to hold drug companies accountable for justifying their costs and ensure Americans pay drug prices that reflect the improved value new treatments provide.

*Encourage innovation and new treatments from drug companies - rather than marketing and unjustified prices:*

- **Stop direct-to-consumer drug company advertising subsidies, and reinvest funds in research.** Almost every country in the industrialized world bans or severely restricts direct-to-consumer advertising because it increases prescription drug costs, and can include confusing, misleading or incomplete information or exaggerated claims if not regulated effectively. Clinton's plan would eliminate corporate write-offs for direct-to-consumer advertising, saving the government billions of dollars over the next decade. She would use the proceeds to help invest in research and making new treatments available. And going forward, Clinton's plan would establish a mandatory FDA pre-clearance procedure for these ads, funded through user-fees paid for by pharmaceutical manufacturers in order to be sure that the ads provide clear and understandable information to consumers.

- **Require drug companies that benefit from taxpayers' support to invest in research, not marketing or profits.** For years, Hillary Clinton has made the case that Americans should get the value they deserve for the billions of dollars in support they provide through federal investment in basic research and incentives for R&D. Drug companies should not be allowed to reap excessive profits or spend unreasonable amounts on marketing if they want to receive support that is designed to encourage life-saving and health-improving treatments. Clinton's proposal would require pharmaceutical companies that benefit from federal support to invest a sufficient amount of their revenue in R&D, and if they do not meet targets, boost their investment or pay rebates to support basic research. If elected President, she will convene business leaders, experts on drug pricing, and consumer advocates to set new parameters for federal support in order to ensure this requirement. The basic principle is based on a provision of the Affordable Care Act that required insurance companies

to pay rebates to consumers if their profits and administrative costs were an excessive share of benefits actually paid out to consumers.

*Leverage America's negotiating power as a backstop:*

- **Allow Medicare to negotiate drug and biologic prices and demand higher rebates for prescription drugs in Medicare.** Hillary Clinton has long believed that Medicare should use its leverage with more than 40 million enrollees to negotiate and drive down drug and biologic prices for seniors and others in the program. Today, drug prices in Medicare are negotiated by a disparate set of benefit managers, rather than using the full bargaining power of the program. Clinton believes that we should drive the best bargain for Americans, especially for senior citizens, by allowing Medicare to negotiate drug prices, notably for high-cost drugs with limited competition. Hillary Clinton would also require pharmaceutical companies to provide higher rebates in the Medicare low-income subsidy program, ensuring that rebates are at Medicaid levels. This would save more than $100 billion in Medicare costs.