PATIENTS FOR AFFORDABLE DRUGS™

Patients For Affordable Drugs response to the Department of Health and Human Services' Request For Information on the American Patients First Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

July 13, 2018

IMPROVING COMPETITION

Distribution restrictions

Are there terms that could be included in REMS, or provided in addition to REMS, that could expand access to products necessary for generic development?

The Administration should lend its full support to passage of the Senate CREATES Act as introduced by Senators Grassley and Leahy. To be effective, there must be an incentive strong enough for the brand company to sell samples to generic developers. Absent a meaningful consequence, the brand companies who are making billions by blocking competition won't make samples available.

HHS and FDA should ensure that the requirement for a single shared REMS is flexible enough to allow a separate REMS by generic companies when the brand company refuses to cooperate on a single shared REMS.

Are there other steps that could be taken to facilitate access to products that are under distribution limitations imposed by the manufacturer?

The Administration should ensure that restricted distribution systems are not used to deny samples to generic developers. Brand companies must not be allowed to enter into contracts with distributors that disallow sales of samples to legitimate generic developers.

The FDA currently lacks statutory ability to hold pharmaceutical companies accountable when they refuse to give generics samples on the basis of REMS. We suggest that the administration require that the FDA makes a condition of approval of a drug with REMS a contract signed by the brand company that would require the company to provide samples to any generic company that meets FDA safety requirements and the generic company is willing to pay a fair market price.

Improving the Purple Book

How could the Purple Book be more useful to patients?

The Purple Book is hard for patients to maneuver through and understand. It often feels like it was written for a scientific community not the general public. It would be more useful to patients if the language was translated for a lay audience. Some patients get intimidated by the language and stop reading; others must read it multiple times to get a sense of what it means. If the technical language is important in the purple book for the provider community, we suggest that an additional resource is created for patients that is accessible to the lay community.

BETTER NEGOTIATION

Medicare formularies: We are supportive of changes that allow faster mid-year substitution of generic drugs onto formularies. We are generally supportive of changing Part D formulary standards to require a minimum of one preferred drug per category but ONLY if there is an effective and timely exceptions and appeals process for beneficiaries who require a non-preferred alternative based on the medical recommendation of a qualified health professional.

Medicaid demonstration: We are supportive of the President's proposal for five states to be granted Medicaid waivers to run demonstration projects to use more effective negotiating tools to reduce prices for beneficiaries. But we believe states should not be forced to forgo all rebates in order to enter into those negotiations. There is long-standing support in the US for states to serve as laboratories and much can be learned by allowing states to use their creativity and purchasing power to develop approaches that work better for individual states and the citizens they serve.

Value-based Arrangements and Price Reporting

We are supportive of finding creative approaches to pricing. Analyses to determine the value of a drug to patients can serve as an important input for negotiations by plans or by the Secretary directly. However, it is important to note that many existing drugs are overpriced. So efforts to determine the value of a new drug compared to an existing drug can fall short if the existing drug is not currently valued correctly.

How and by whom should value be determined?

The most rigorous and broadly accepted value analysis in the US is practiced by the Institute for Clinical and Economic Review (ICER). We support the use of ICER value analysis as one input to determine the appropriate price for a drug—especially for new drugs coming to market.

It is important to distinguish value analysis and outcomes based contracting. We support the former and oppose the latter as outcomes pricing leaves the price entirely in the hands of the drug company.

First, outcomes pricing doesn't lower drug prices. It allows the drug company to continue to set high prices. Drug companies know from clinical trials how many patients will fail on a given drug. And they'll set the price to cover that failure rate. So outcomes purchasing can could drive UP prices, not lower them.

Second, outcomes based purchasing has been tried in Italy, and it didn't work. They pay more for drugs (because they give up rebates). Reimbursements from drug companies represented on average less than 1% of the Italian regulator's total spending on drugs between 2013 and 2016, according to public filings.

Finally, most outcomes contracts deliver no value to patients. If a patient is on a drug to prevent heart attacks, and they have a heart attack, giving their insurance company a refund does patients no good.

If CMS decides to use outcomes contracting, it should actually put the drugmaker at risk of lower payment. It should use expected outcomes based on clinical trials not merely endpoints selected by drug companies.

Are there unintended consequences of current low-cost drugs increasing in price due to their identification as high value?

If an older low-cost drug is suddenly found to produce positive outcomes in a new condition, then it is possible that value could be considered by CMS for that new indication only. But if it is an old drug with a low price, there should be generic competition to help hold the price in check.

Indication-based payments

Should Medicare or Medicaid pay the same price for the a drug regardless of the diagnosis for which it is being used?

We are supportive of indication based payment programs. Indication specific pricing can be important. If a drug produces a certain good result in one condition but a less valuable result in another condition, it could be priced differently for each based on value.

Long-term Financing Models

Should the state, insurer, drug manufacturer, or other entity bear the risk of receiving future payments?

Medicare may need to look at long-term financing models for some extremely high-priced drugs, but those financing schemes must not burden beneficiaries. Rather the government should develop long-term payment programs in which government payments are spread over a period of time, and payments are only made based on success in key milestones over the full payment period. In other words, if the patient fails on the drug at three years in a payment term of five years, payment should stop.

Part B Competitive Acquisition Program

We are supportive of a Competitive Acquisition Program for Part B drugs, but only if it results in lower prices than can be achieved using the current ASP+6 formulation. We suggest using an approach that reduces the percentage mark-up and moves to a fixed payment for the health professional administering the drug.

Part B to D

CMS must not simply merge Part B drugs into a Part D benefit structure -- to do so could impose huge new out-of-pocket costs on millions of beneficiaries. In 2005, the Bush Administration recommended against transitioning drugs from Part B to Part D citing concerns about increasing costs for patients and the Federal Government. Currently beneficiaries can buy reasonably priced Part B supplements that cover all out of pocket costs for Part B drugs. A Part D structure for Part B drugs will impose huge new out of pocket costs on many beneficiaries and can range as high as $12,000-15,000.

Should Part B drugs sold by manufacturers offering lower prices to OECD nations be subject to negotiation by Part D plans?

CMS should demand prices from drug companies that are no more than the average of six other OECD countries. CMS can clearly do this under Part B. Here is Senator Grassley's floor statement on non-interference under Part D. It specifically states:

"That language doesn't prohibit Medicare from negotiating with drug makers. It prohibits the government from *interfering in the negotiations that are actually happening."*

Since PBMs don't negotiate for Part B drugs, CMS could take this step right now. The goal must be to gain price concessions from the manufacturers—not from the patients abroad by trying to force higher prices in other nations.

Fixing Global Freeloading

We strongly oppose any policies that aim to raise drug prices abroad. There is no evidence that making trade deals meant to increase the prices of drugs abroad will in fact lower prices in the United States. This is the most wrongheaded element of the President's blueprint. The entities that are making prices high in the United States are pharmaceutical companies. Patients abroad must not be penalized because their governments negotiate effectively on their behalf—something we wish our US government would do for us. This is why we support plans to allow Medicare Part D to negotiate directly with drug companies. As patients, we never could advocate for a policy that would make drugs less accessible to some patients abroad.

CREATING INCENTIVES FOR PHARMACEUTICAL COMPANIES TO LOWER LIST PRICES

Direct to consumer advertising: We support disclosing price of drugs on DTC ads but do not think it will lower prices. Instead, we support the recommendation of the National Academies of Science, Energy, and Medicine to eliminate the tax deduction on DTC ads. This will likely reduce use of the ads, lower prices by reducing overhead and lower demand for unnecessary drugs, and thereby reduce costs to the government, employers, taxpayers, patients and consumers overall.

Capping Medicare Part D catastrophic phase: We believe Part D out of pocket should be capped at the catastrophic level. We hear from patients everyday who struggle to afford their medications under Medicare Part D. This is especially true for people taking very high cost drugs who enter the catastrophic phase early in the year. This would directly help about a million Medicare beneficiaries who take the most expensive Part D drugs and have the highest out-of-pocket costs. Drug manufacturers could contribute to such a restructuring of the program to cap out-of-pocket costs.

Fiduciary duty for Pharmacy Benefit Managers

Should PBMs be obligated to act solely in the interest of the entity for whom they are managing pharmaceutical benefits?

PBMs should have a fiduciary duty to work for the benefit for the ultimate consumer: patients. Currently, nobody in the drug pricing pipeline is held accountable for ensuring that patients are receiving the best deal—instead they are all seeking to maximize profits for shareholders. Secretary Azar has made this point twice in testimony to Congress. PBMs may actually stand in the way of lower prices in order to protect high rebates that are based on high list prices. Imposing fiduciary duty on PBMs on behalf of patients would truly put American patients first.

Should PBMs be forbidden from receiving any payment or remuneration from manufacturers and should PBM contracts be forbidden from including rebates or fees calculated as a percentage of list prices?

Payments and remuneration from manufacturers to PBMs discourages PBMs from fighting for the best price for patients. PBMs and distributors should be forbidden from receiving any payment, renumeration, or other incentives from manufacturers that are inconsistent with the goals of lower drug prices. This would include, but is not limited to, rebates and fees calculated as a percentage of list prices.

Reducing the impact of rebates

We believe the US should move away from a system of rebates to simple negotiated discount prices that are fully transparent in the same way other reimbursement levels are clearly set and articulated for doctors, hospitals, labs, and other services. Rebates create perverse incentives to raise drug prices, and secret rebates are an invitation to abuse of the system. Market forces cannot work without transparency, and all government programs should be transparent.

Copay discount cards

Does the use of manufacturer copay cards help lower consumer cost or actually drive increases in manufacturer list price?

Manufacturer copay cards are a device to sell more drugs, to allow manufacturers to raise prices, and to help keep prices high. A financial report from Citi found that for every $1 million drug companies spend on copay support, they gain $21 million in revenue. Copay cards are designed to:

- Hide the true cost of drugs from patients and consumers who pay the cost in higher premiums and taxes
- Encourage the use of more expensive drugs over less expensive alternatives
- Diminish the outrage of high prices and political pressure for elected officials to act to lower prices
- Ensure the drugmaker keeps full control of who gets the drug at reduced price and under what circumstances. Such decisions in the case of life saving medications should be made through the public sector and not leave patients at the mercy of private companies whose job is to maximize profits.

REDUCE PATIENT OUT-OF-POCKET SPENDING

Eliminating cost-sharing: We support eliminating cost-sharing on generic drugs for low-income beneficiaries. Eliminating cost-sharing on generic drugs encourages the use of generic drugs which will increase competition and drive down prices and spending to the benefit of beneficiaries and Medicare overall.

Federal preemption of contracted pharmacy gag clause laws

Should pharmacists be required to ask patients in Federal programs if they'd like information about lower-cost alternatives?

We support a prohibition on PBM contracts that include gag clauses and favor contracts that require pharmacists to offer information on lower cost alternatives. Contracts that prohibit pharmacists from disclosing the lowest cost payment options for prescription drugs are anti-competitive and anti-consumer and must be outlawed.

We believe that such contracts should also be banned in private insurance plans. We are supportive of the bipartisan legislation, Patient Right to Know Drug Prices Act, which would eliminate gag clauses for patients outside of federal programs. Patients should be able to depend on their pharmacists, and gag clauses prevent them from having a transparent relationship.

ADDITIONAL FEEDBACK

What other policies or legislative proposals should HHS consider to lower drug prices while encouraging innovation?

The administration has the power to make some of the recommended changes unilaterally, but we believe if the administration is serious about drug pricing, it must support and help pass legislation that would lower drug prices. In particular, pharmaceutical companies are gaming the patent system. Many of the solutions to this gaming require Congressional action. We encourage the administration to endorse bipartisan legislation that address patent abuses and allow the Hatch-Waxman framework to work as intended, increase competition, and decrease drug prices. Below are some bipartisan bills that we think are vital to preventing gaming of the patent system and other tactics that keep drug prices high.

- **CREATES Act (S.974 and H.R.2212)**: The administration has been outspoken about addressing the abuse of Risk Evaluation and Mitigation Strategies (REMS) in which brand name companies refuse to provide drug samples to generic companies for testing to gain generic approval. We are encouraged by Secretary Azar's and FDA Commissioner Gottlieb's words on the abuse of the REMS program, but we know that the executive branch only has so much authority to address it. The CREATES Act is a bipartisan bill in the Senate and House sponsored by Senators Chuck Grassley (R-IA) and Patrick Leahy (D-VT). The bill aims to stop brand drug companies from abusing the Hatch-Waxman framework and blocking less expensive generics. This results in decreased competition and increased costs to consumers. CBO estimates the CREATES Act will save taxpayers over $3.8 billion. The Senate Judiciary Committee just

reported the legislation on a bipartisan vote to the full Senate. We hope the administration will actively support this bill and work for its passage.

- **Preserve Access to Affordable Generics Act (S.124)** is a bipartisan bill sponsored by Senators Chuck Grassley (R-IA) and Amy Klobuchar (D-MN). The bill would address a tactic used by pharmaceutical companies called "pay for delay" in which brand name pharmaceutical companies pay generic companies to delay bringing their generic to market. The FTC has made this one of its top priorities to address and oppose, yet additional action is needed. This is why legislation like S.124 is so important. We urge the administration to support this bill and push for its passage.
- **PACED Act (S.2514)** is a bipartisan bill sponsored by Senators Tom Cotton (R-AR) and Claire McCaskill (D-MO). It addresses a tactic taken recently by the pharmaceutical company, Allergan, to transfer the patent of their expensive drug, Restasis, to the Mohawk Indian Tribe in order to utilize their sovereign immunity to avoid inter partes review and prevent less expensive drugs from coming to market. This bill would prevent drug companies from "renting" sovereign immunity. This practice is a clear abuse of the system and must be stopped to increase generic competition and drive down prices. We urge the administration to support this bill and push for its passage.
- **The Patient Right to Know Drug Prices Act (S.2554) and the Know the Lowest Price Act (S.2553)** are bipartisan bills sponsored by Senators Susan Collins (R-ME) and Debbie Stabenow (D-MI). Both would prohibit PBM contracts that prevent local pharmacists from communicating with their patients about the best prices for their medications. S.2554 ensures this practice is prohibited in private insurers, which can only be accomplished through legislation. S.2553 bans it from contracts with federal programs. As the administration says it is unable to prohibit such contracts with private insurers unilaterally, we encourage the administration to support S.2554 and S.2553 and push for their passage.

To what extent do current regulations or government policies related to prescription drug pricing impose burden on providers, payers, or others?

According to proceedings of National Academy of Science, all of the 210 drugs approved by the FDA from 2010-2016 were based on science funded by taxpayers through the NIH. The head of the NIH Office of Technology Transfer, Mark L. Rohrbaugh, said in May of this year "The public sector now has a much more direct role in the applied-research phase of drug discovery."

The fact is that taxpayers are paying for basic science and drug development leading to IP for blockbuster drugs priced at over $100,000 per treatment. This system is unsustainable for our system. Taxpayers are paying twice for drugs, once for the research and again to take the lifesaving drug. Recently, three new drugs based on basic science funded through the NIH came to market with price tags of $373,000 (Yescarta), $475,000 (Kymriah), and $850,000 (Luxturna).

As patients, we value deeply the work of the NIH and innovation. Many of our patients are dependent on innovation to stay alive. But we also know that drugs don't work if people can't afford them. The NIH may have been able to stay out of drug pricing when drugs it helped develop were priced at $10, $100, or $1,000, but with drugs priced at more than half a million dollars, we think it is vital that there be a national dialogue about the connection between NIH investment and drug pricing.

We suggest that an entity such as the National Academy of Medicine convene a process to discuss the pricing of NIH funded drugs. Such a conference could answer questions about how public research expenditures affect prices and access to treatment. We encourage the administration to work with the NIH to participate in such a national review of policy.

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