FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

July 16, 2018

Secretary Alex M. Azar II
Department of Health and Human Services
200 Independence Ave. SW, Room 600E
Washington, DC 20201

Re: Request for Information (RFI) on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint), RIN 0991–ZA49

Dear Secretary Azar:

Thank you for the opportunity to provide HHS with information about policies to lower unconscionably high prescription drug prices. We appreciate that the administration has articulated a commitment to reducing prices that impose an enormous and growing burden on both individual consumers and the overall health care system. We encourage you to move forward on many ideas discussed in the RFI and associated Blueprint, which offer the opportunity for progress that helps families in America. However, as we make clear in the final section below, some of the most important problems affecting the country's broken prescription drug system are largely untouched by the specific proposals itemized in the RFI and Blueprint. We urge the administration to take two major steps to broaden its focus beyond the current proposals: (1) Directly limiting manufacturer prices through negotiation or the kind of administered pricing that Medicare uses for most other services, then making those same prices available to other payers; and (2) Reforming the drug innovation process so that significant progress improving people's health becomes the focus of drug development, rather than maximizing short-term profits through steps that leave critical public health priorities unmet.

This letter addresses, in turn, the five areas highlighted in Part III of the RFI: increasing competition; better negotiations; incentives to lower list prices; reducing patient out-of-pocket spending; and additional feedback. Within each area, we highlight particular issues of special interest rather than attempt a comprehensive response to each and every question.

Increasing competition

The RFI asks about the extent to which federal programs and policies, including taxes and required rebates, affect manufacturer prices. These federal rules have an impact, but they are not the main cost drivers. By far the most important causes of unconscionably high and rising prescription drug prices involve manufacturer leverage, the inherent limits to price competition in patent-protected markets, and consequent opportunities for enormous manufacturer profits.

In 2015, the 25 largest manufacturers achieved profit margins three times the average level secured by the world's 500 largest companies.[1] Patent-protected monopoly prices and marketing exclusivities give manufacturers powerful incentives to exploit every available opportunity to delay the introduction of generic and biosimilar competition.

The federal government has the inherent negotiating power to force lower prices. But an extraordinary statute—unique in the developed world—forbids Medicare from using its leverage to obtain reasonable and fair drug prices. The prospects of major price reductions are likely to remain dim so long as we ask

FamiliesUSA.org
1225 New York Avenue, NW, Suite 800
Washington, DC 20005
main 202-628-3030 / fax 202-347-2417

each insurer, employer, state, and even consumer to seek their own concessions from economically powerful manufacturers shielded from competition by federal law. Until this basic imbalance is remedied, drug companies are likely to continue amassing extraordinary profits by charging exorbitant prices.

As detailed below, Medicare's approach to drug pricing in 2018 looks a lot like the 1983 version of Medicare hospital pricing. We hope that the Trump administration will lower taxpayer costs by moving towards a more rational payment system with pharmaceuticals, adding a new and important chapter to the story begun during the Reagan administration.

Moving to a second topic in this section of the RFI, the questions involving reference pricing samples touch on a promising area of work. Manufacturers of brand-name drugs often use Risk Evaluation and Mitigation Strategy (REMS) requirements as an excuse to deny generic manufacturers the samples they need to develop competitive alternatives that, in today's system, are the single strongest force to lower drug prices. We urge the administration to support the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act), legislation that enjoys bipartisan, bicameral support.

Of course, REMS abuses are far from the only maneuver that brand-name drug manufacturers use to extend their government-conferred monopoly rights far beyond the period needed to incentivize drug development. Other tactics include filing of unfounded citizen petitions urging the Food and Drug Administration to delay or deny authorization for competitors to sell generics or biosimilars; "evergreening" patents that extend marketing exclusivities by making tiny changes to drugs with patents that are nearing their end; and collusive "pay for delay" agreements between brand-name and generic manufacturers. We urge the administration to broaden its focus and go after all of these abuses. In our view, the most effective strategy would both outlaw specific anti-competitive behaviors and articulate a general standard that holds manufacturers of name-brand drugs accountable with meaningful penalties for any actions that, without a compelling public health justification, delay the introduction of competing products beyond the end of the initial patent period.

The RFI also asks about methods to expedite the development of biosimilars and interchangeables and to promote their use. There are inherent challenges in trying to replicate with biologics the generic competition model that is the country's basic tool to lower the price of small-molecule drugs. For public policy to keep pace with scientific advances, including growing complexities affecting the manufacture of gene-based therapies, new strategies will likely be needed to keep biologic prices even remotely affordable. These could take the form of price limitations that, after the initial patent has expired, replicate the estimated impact of effective generic competition on the price of small-molecule drugs. As another example, patent owners could be required to make enough detailed information publicly available to enable the rapid and efficient development of truly interchangeable, competitive alternatives immediately after expiration of initial biologic patents.

Better negotiation

Many ideas in this area of the RFI would extend private insurance options to health plans that operate within Medicare and Medicaid. These ideas are worth exploring, but they leave intact a fundamentally flawed structure where individual insurers, sponsors, providers, and even consumers are asked to negotiate separate arrangements with manufacturers. Giving publicly-funded plans and programs the ability to strike better deals makes sense as a general proposition, but such measures are unlikely to

achieve adequate cost savings. Only if we consolidate the country's negotiating power will negotiation bring down unaffordable prices by significant margins.

Long-term purchasing models, mentioned in this section of the RFI, offer real promise in fixing drug innovation gaps that result from limited sales potential. For example, new antibiotics that treat drug-resistant infections are not being developed, because such medications are likely to be deployed only as the final line of defense after other antibiotics have failed. The resulting limited demand has discouraged investment in product development.[2] If the federal government guaranteed the purchase of a defined supply of medications meeting specifications for treating drug-resistant infections, manufacturers would have new incentives to develop these essential medications. Such purchasing agreements could also be structured to guard against potential shortages and to keep prices at reasonable levels.

Another positive option mentioned in the RFI would restructure and revive the Part B Competitive Acquisition Program. We encourage the administration to make use of MedPAC's recommendations in devising an approach that avoids past mistakes while leveraging new opportunities to negotiate for lower-price drugs.[3] Along similar lines, the RFI's suggestions for reclassifying drugs between Parts B and D offer opportunities for savings. One particularly promising idea noted in the RFI would single out medications for which other OECD countries pay much lower prices than Part B and authorize Part D plans to negotiate for the same prices that other countries obtain. One concern about the latter policy is that pharmaceutical manufacturers could pit Part D plans against one another within geographic markets. A plan that differed from its competitors in failing to meet a manufacturer's price demands could become an outlier that loses market share because it limits coverage of that manufacturer's medications. To prevent such tactics from undermining competition, strong regulatory or sub-regulatory action by the Center for Medicare and Medicaid Services will be needed to establish clear ground rules for negotiation and manufacturer obligation that protect plans' ability to achieve savings without compromising patients' access to essential medication.

Finally, we support the RFI's proposals for site-neutral reimbursement levels, including by equalizing payments in inpatient and outpatient settings. Varying reimbursement for the same product or service based on the site where the service is provided invites gaming and incentivizes providers to make clinical decisions based on factors that have nothing to do with patient health and welfare.

These and other ideas in this section of the RFI have merit, but we strongly object to the notion of "fixing global freeloading." When other countries are more effective than the U.S. in limiting prices, we should study their successful strategies for potential adaption and replication here, rather than ask these other countries to be less successful. Forcing other nations to increase their payments would swell the already ample coffers of drug companies without lowering prices paid by people in America. Such steps would choke off avenues through which U.S. residents now obtain less costly drugs from other developed nations. More fundamentally, corporate pricing decisions are based on assessments of what the market will bear. It seems implausible that corporations will forego available revenue merely because, thanks to unexpectedly high payments from abroad, they have already hit internally-defined aggregate revenue targets. We are not aware of any evidence that forcing other countries to pay more will let the U.S. pay less.

Incentives to lower list prices

We applaud the ideas in the RFI involving fiduciary duties for Pharmacy Benefit Managers (PBMs). Today, conflicts of interest are a foundation of PBMs' business model. Funded by plan sponsors that seek cost savings, PBMs also receive revenue from manufacturers that want to see their products receive favorable coverage, regardless of price. Moreover, basing PBM payments on percentage discounts from list prices can create incentives for high list prices. We strongly support the ideas suggested in the RFI that would refocus PBM incentives by (1) creating clear and enforceable duties for PBMs to act as fiduciaries; (2) prohibiting PBMs from receiving any financial consideration from manufacturers, instead limiting them to a single source of payment that ensures clear and unambiguous accountability; and (3) shifting from percentage-based payments to administrative fees. In addition, transparency and disclosure requirements could be helpful limiting PBMs ability to maximize profits without adding significant value. Arguments about the inherent sanctity of trade secrets would be groundless if mandated disclosure of all PBM costs and revenues applies equally to all firms, allowing fair competition under ground rules that incentivize positive behavior.

Within this same category of RFI questions, an important idea that merits strong support involves conditioning favorable treatment of Part B and C drugs on manufacturers' commitment to limiting price increases beyond the point of product launch. Over the past three years, prices for the most commonly used drugs to treat diabetes, cancer, HIV, multiple sclerosis, COPD, and autoimmune disease have risen between 25 and 40 percent—more than four times the rate of general inflation.[4] Using Medicare's leverage to incentivize efficiency and safeguard taxpayer resources makes tremendous sense. We encourage the administration to extend these strategies in two directions: first, to apply them to initial prices, not just price escalation, where charges at product launch clearly exceed those required to incentivize the development of new drugs that add significant clinical value; and second, to give private purchasers the right to access drugs at the price paid by federal health care programs.

Reduce Patient Out-of-Pocket Spending

This section of the RFI includes positive proposals that would equip pharmacists to provide their patients with information about the costs and benefits of alternative medications, taking into account the details of each patient's insurance coverage. The American people would be outraged if they understood that, in many cases, their neighborhood pharmacist is contractually prohibited from giving patients information needed to make informed choices. We urge the administration to do everything in its power to forbid restrictions on pharmacist advice to patients, including information about the costs and benefits of alternative treatments. Imposing a duty on pharmacists to inform patients about the availability of treatment options with lower out-of-pocket costs would help patients receive the information they need to make sound choices. Without that information, competition cannot succeed in lowering prices and consumer costs.

Another idea in this general category would require PBMs and other intermediaries to share all rebates and discounts with beneficiaries at the point of service. Such a step would lower consumer costs without increasing pressure to raise list prices, since it would shift the point at which rebates and discounts are paid without increasing the amount of such list-price concessions.

Additional feedback

As indicated earlier, we urge the administration to build on the measures itemized in the RFI and Blueprint in several ways. First, we hope the Department will broaden its focus to support negotiated or administratively-set limits on Medicare's payment of manufacturer prices. Medicare's current approach to drug payment resembles Medicare's hospital reimbursement system before the Reagan Administration introduced prospective payment in 1983. Before then, Medicare paid hospitals' "usual and customary rates," which incentivized high and rising charges. The Reagan Administration's successful shift to prospective payment revolutionized hospital finance, in both public and private sectors, and it remains in place today, 35 years later. It is time for the Trump Administration to sponsor a second payment revolution, this time changing the broken incentives that have driven drug pricing through the roof. Considerable analytic work will be required to devise payment structures that incentivize patient-centered drug development and taxpayer-friendly pricing; but it is hard to think of other efforts that would provide a comparable pay-off in consumer well-being and lower costs for publicly-financed health programs. Offering private insurers the same favorable drug prices obtained by Medicare would promote private-sector growth across a variety of industries, as resources formerly used to pay extortionate drug prices could be rechanneled to far more productive uses.

Second, we ask the administration to pursue all available remedies to fix our country's broken system of drug innovation. An estimated 78 percent of drug patents granted between 2005 and 2015 were for variations on existing drugs, rather than new medicines.[5] Fewer than 7 percent of all drugs introduced between 2008 and 2017 added anything beyond minimal clinical value to existing treatments.[6] At the same time, crucial public health needs, such as for more universally effective flu vaccines and antibiotics that treat life-threatening drug-resistant infections, are going unmet.

We urge a multi-pronged approach to return drug innovation to its patient-centered roots. For example:

- Whether through changes to "orange book" listings or amending federal statutes, modifications to existing drugs should not qualify for new patents unless the owner of the relevant intellectual property demonstrates a clear and significant clinical advantage over existing treatments.
- When market failures prevent corporate drug development from addressing key public health problems, financing methods other than government-granted monopoly rights should incentivize the development of truly patient-centered treatments. Such financing mechanisms could include prizes, federal grants and research contracts, and the kind of guaranteed-purchase arrangements described earlier. To ensure an evidence-based identification of vital clinical needs that are going unmet by profit-driven drug development, and to insulate that identification from political pressures, the National Academy of Sciences could be tasked with identifying a multi-year agenda for patient-centered drug development that HHS would then pursue through public incentives.
- Both federal agencies and the beneficiaries of federal funding should be required to promptly make publicly available all relevant information about federal support for drug development, encompassing basic research and contracts with private parties. The receipt of public funding should trigger public duties, including reasonable pricing. Competitive development should be preferred over marketing exclusivities with drugs that benefit from significant taxpayer investment, unless compelling evidence proves that a government-conferred monopoly of a specified period is essential to develop products that produce major clinical advances.

Put simply, the RFI and Blueprint represent a promising start on a broader agenda of tremendous importance to our country. We look forward to working with you and your colleagues in the coming months to help the administration achieve the important goals it has articulated. It is time for better medicine at lower prices.

Sincerely,

Families USA

---

[1] https://www.gao.gov/assets/690/688472.pdf
[2] https://www.bloomberg.com/news/articles/2018-07-13/superbugs-win-another-round-as-big-pharma-leaves-antibiotics
[3] http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf
[4] https://www.bloomberg.com/graphics/2018-drug-price-index/
[5] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567
[6] http://www.prescrire.org/Fr/0D5B69F2A0474C37B4805595123B5C44/Download.aspx