From: Michael D. Cohen <michael@mdcpc.com>
Sent: Monday, June 5, 2017 7:13 AM
To: Jimenez, Joe
Subject: Re: Drug Pricing Initiatives

Received and I will forward to you their suggestions.

Yours,
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Sent from my iPhone

On Jun 5, 2017, at 4:31 AM, Jimenez, Joe <joe.jimenez@novartis.com> wrote:

> Michael,
> Based on our conversation last week, I am forwarding you some ideas to lower drug costs in the US.
> Best regards,
> Joe
>
> <Drug Pricing Initiatives.docx>

Drug Pricing Cost Initiatives

The US has created the strongest, most innovative bio-pharmaceutical industry in the world. These companies spend over USD 70 billion per year in the US on Research and Development, and support 4.5 million high paying jobs. The following initiatives are designed to lower the cost of healthcare in the US, while protecting this crown jewel industry and maintaining US leadership. Drug discovery and development is a high risk proposition. It is critical that initiatives to lower total costs be market-based, in order to preserve the continued flow of innovation and the US lead in this industry.

1. Foster value-based contracting to allow more innovative payment models.
Promoting value-driven health care by removing existing regulatory barriers will enable value-based contracts. This will control drug costs by linking payment to patient outcomes and will help ensure our health care system is paying for value over volume. Today, current regulations make it challenging to expand value-based contracting for medicines. Some policies to address this issue include updating off-label promotion laws, exempting value-based arrangements from Medicaid Best Price and modernizing rules related to manufacturer communications with payers and providers.

By modernizing outdated regulations, we can lower the cost of drugs to patients. Using the power of market competition to achieve better negotiation will control costs by getting the right treatment to the right patient at the right time. Better bidding and better contracts can help ensure prescription drugs are being used effectively to reduce other health care costs and better patient access to medicines.

2. Ensuring patients pay less for prescription drugs when their insurers and PBMs negotiate savings.
Health plans and pharmacy benefit managers (PBMs) negotiate with drug manufacturers to secure discounts and rebates that lower the cost of prescription drugs. However, in some cases when a patient pays for a medicine (*e.g.,* within their deductible or when they pay coinsurance), they are charged based on the list price, not the discounted, negotiated price. This is unfair for patients. It is time to begin delivering savings to patients at the pharmacy counter by requiring insurance companies to pass along at least some of the savings they negotiate with drug companies.

Discounts on brand medicines in particular can be significant. In Medicare Part D rebates have grown considerably, yet patients face rising out-of-pocket costs. Using authority that already exists, the Administration could call upon Part D plan sponsors to pass along a greater share of the savings they negotiate on prescription drugs to reduce beneficiaries' spending at the pharmacy counter. If implemented this summer, potential savings for Part D beneficiaries could be visible on the Medicare plan finder web site this year.

3. Lowering out of pocket costs at point of sale for Medicare Part D beneficiaries

It is important that Medicare beneficiaries have continued access to the medicines prescribed by their physicians. Today, Medicare beneficiaries currently have no limit on their out-of-pocket (OOP) costs in the Medicare Part D program and would need to exceed $8,000 out-of-pocket spending before they are eligible for catastrophic drug coverage. Current policies prohibit biopharmaceutical manufacturers to provide direct financial assistance to patients to reduce their total out of pocket (OOP) costs for these medicines. Allowing a policy change to permit biopharmaceutical manufacturers to offer financial assistance will ensure that Medicare Part D patients can better afford their prescription drugs. This would be an extremely popular move, appreciated by millions of patients in the US.

Reduction in OOP costs could improve public health. Improvements in medication adherence/persistence in turn can lead to lower total healthcare costs as even noted by the Congressional Budget Office.

4. Eliminating or updating outdated regulations that prevent efficiency in the private market.
Today's health care system is filled with outdated regulations and regulatory barriers. For example, the FDA has significantly increased regulation that extends the time and cost associated with developing a new drug. Finding regulatory relief that ensures the United States is still the world leader in innovation and delivering safe treatments to patients is critical. Reducing the time and cost it takes to develop a medicine and get it approved will enhance the competitive market for biopharmaceuticals, driving greater efficiency in drug development and discovery and holding down costs for payers and consumers.

5. Boosting competition and deterring future bad actors by accelerating government approval of generic medicines.
We need to speed U.S. Food and Drug Administration (FDA) approval of generic medicines so 'bad actors' cannot game the system by significantly increasing prices of older, off-patent medicines that lack competition. This can be done through a range of new regulatory and economic incentives to increase competition and lower costs of bringing products into the market, in circumstances where no patent or regulatory barriers stand in the way. Ways to speed new low cost generics to market include tax credits, waiving application fees, creating priority review vouchers for future applications, creating new exclusivity periods for first generic competitors and providing FDA technical assistance.

These policies will increase competition in areas of unmet patient need and prevent bad actors from acquiring off-patent drugs that have been widely used for decades and dramatically increasing prices. Together, these policies can increase competition, patient access to affordable medicines and reduce the overall cost of health care in the United States.

6. Negotiating stronger trade agreements and ensuring better enforcement.
Foreign governments often discriminate against innovation and the development of new medicines, to the detriment of American consumers and industry. Today, U.S. trade policy has not adequately addressed this imbalance in policies, including those that artificially undervalue innovative biopharmaceutical products through their pricing and reimbursement (P&R) systems. Inadequate intellectual property protection and lax enforcement in other countries also undermines innovation. Effectively addressing such practices and ensuring due process to innovators in foreign P&R regimes would spur the creation of U.S. jobs, innovation and the development of new medicines for patients.

The Administration can enforce and improve trade agreements to support American jobs, innovation and patients through the following steps:

- The U.S Government must enforce existing trade deals with Korea and Australia, and other developed economies under GATT and WTO rules, to ensure that their systems are valuing innovation and they are not getting a free ride on the back of US funding the innovation.
- Negotiate new trade deals that contain strong pricing and reimbursement language that requires our trading partners to value innovation, as required under the President's Trade Promotion Authority. Strong IP provisions, a closely-linked cornerstone for industry, will also be essential.
- The U.S. Government must identify and address the worst practices abroad, including through updating the 2004 Commerce Report and developing a strategy to address this important issue. Existing tools, including Section 301 and Special 301, are sufficient to ensure a strong U.S. Government approach and send a strong enforcement message from the Administration.