JOHNS HOPKINS
UNIVERSITY

The Center for Hospital
Finance and
Management
624 North Broadway/Third Floor Baltimore
MD 21205
410-955-3241/Fax 410-955-2301

May 7, 2019

Congress of the United States
House of Representatives
Committee on Oversight and Reform
2157 Rayburn House Office Building
Washington, DC 20515

Dear Committee Members,

Below please find my response to your letter dated March 22, 2019 in reference to the hearing held on January 29, 2019, "Examining the Actions of Drug Companies in Raising Prescription Drug Prices." I will be very happy to answer any additional questions that you may have.

Sincerely,

Gerard F. Anderson, PhD
Professor

Questions from Ranking Member Jim Jordan

1) In 2018, FDA Commissioner Scott Gottlieb initiated the practice of publishing brand name drugs on the FDA website that have stymied the ability of competitor drug companies to develop affordable generic drugs. Is this public "name and shame" tactic effective in increasing the availability of generic drugs?

The name and shame approach is a good first step and something that the FDA commissioner should do.

However, I do not think the name and shame approach is sufficient to get some drug companies to comply. The Oversight Committee had Martin Shkreli testifying a few years ago. He had a drug that he put on a limited supply chain, and he said he would not sell the drug to any generic firms. I cannot imagine that posting his drug on the FDA website would be sufficient shame for Martin Shkreli to sell the drug to a generic drug company.

For this reason, I believe legislation like the CREATES Act is necessary to compel the branded drug companies to make the drugs available to generic companies at the appropriate time. It is the best way to get generic firms to access the drugs.

2) What additional steps can the FDA take to ensure brand name drugs are not abusing the Risk Evaluation and Mitigation Strategies (REMS) program to block generic competition?

I testified at the Oversight hearing with a few years ago on a panel with Janet Woodcock of the FDA, and she was very clear that the FDA was doing all it could to prevent abuses of the REMS program under current law.

Congress has not given the FDA the authority to compel drug companies to make the drug available. All the FDA can do is to say that having an REMS designation does not preclude the branded drug company from selling the drug to a generic company.

REMS does not prevent generic drug companies from obtaining access to the drugs, but some branded drug companies have asserted this. Perhaps the FDA could reissue a letter stating that having a REMS status does not preclude access to the branded drug if some courts have found the prior language unclear. The key is to pass something like the CREATES Act to make it clear that REMS is not a justification for not making the drug available to generic companies.

The key is to pass something like the CREATES Act to make it clear that REMS is not a justification for not making the drug available to generic companies.

Questions from Representative Clay Higgins

1) Is it accurate to say that manufacturers pay pharmacy benefit managers to ensure their drugs are prescribed ahead of competitors? How much in rebates and discounts do PBMs receive from the drug makers?

In general, it is correct to say that branded drug companies compensate pharmacy benefit managers to have their drugs placed on a favorable position in the formulary, or simply "pay-to-play". It occurs most commonly when the pharmacy benefit managers have alternative drugs to place on the formulary.

There are times when rebates may not be paid. In some cases, the PBM negotiates a rebate to be paid for a drug's greater overall market share. Because this rebate is related to overall sales, not sales that can be attributed to any one single plan, the PBM may not pass through this rebate to any insurer or patient. Also, when the drug does not have any competitors – no therapeutically equivalents- then the drug company may not pay a rebate. In that case, the drug needs to be on the formulary, and there is no justification for paying a rebate.

Another exception is drugs that are in Medicare protected classes. f the drug has to be on the formulary because it is in a protected class then why pay a rebate? In some cases, a rebate is paid to get a better placement – lower tier, more favorable prior authorization, etc.

In other cases, the PBM will not pass-through a rebate because it classifies the rebate as "administrative fees" or "health management fees" or "grants" received from drug manufacturers.

It is uncommon for generic drugs to pay a rebate. The reason is simple – if generic drugs compete on the basis of price then paying a rebate means that the generic drug company will earn a lower profit. However, the branded drug company might pay a rebate even when there are generic competitors. The branded company pays the rebate in order to be able to sell the drug. In many cases, the branded drug is given a more favorable placement on the formulary than the generic drug because of the rebates. This adds to Medicare's spending and the cost to the beneficiary.

We do not know how much in rebates and discounts the PBMs receive from the drug companies. We published a paper in the Annals of Internal Medicine showing the rapid growth of profits in PBMs over the last 10 years[1] However, we were unable to determine how much of the growth is attributable to rebates and discounts although we assume it is a significant proportion. This is why some of the requests to PBMs by the House Oversight Committee are so important.

[1] (Bai, Ge, Aditi P. Sen, and Gerard F. Anderson. "Pharmacy benefit managers, brand-name drug prices, and patient cost sharing." *Annals of internal medicine* 168.6 (2018): 436-437.)

2) Do PBMs pass along these payments in the form of savings for patients? Or are savings passed along to insurers, even when patients may have had the opportunity to purchase a lower priced alternative?

We do not know exactly who gets the savings when the PBM negotiates a discount with the drug company.

In some cases, the PBM keeps all of the savings. This is true especially for the smaller companies that do not have the time or the expertise to ask the correct questions.

In other cases, the company gets to keep some of the savings. However, the companies do not know what percentage of the savings they are receiving. This is why it is so important for the House Oversight Committee to make information available about the discounts the PBMs earn to employers so the employers can discern if they are getting a good deal.

In some cases, the rebates may be given to the patient. When this occurs it can cause a problem and distort the market. Rebates are typically larger on the more expensive drugs. If the patient gets the rebate, then the out of pocket cost to the patient is lower which means that the patient is more likely to purchase the drug. For expensive specialty drugs the rebate could be larger than the cost-sharing amount and therefore the expensive specialty drug could be free to the patient. However, no rebates are paid on generic drugs so the out of pocket cost for the generic would be less than the expensive specialty drug. This would severely distort the market.

3) Let's say the savings are passed through to insurers and they lower premiums for patients – is that not merely the sick subsidizing the healthy? Is the real cost then passed along to other patients?

Yes, it could be considered as the sick subsidizing the healthy.

However, the sick are still worse off under this scenario. This is the because premium savings for the sick patients is far less than their overspending due to their lower cost sharing. Cost-sharing due is based on an inflated list price. However, there are other and better ways to assess the issue instead of paying rebates to the patient.

Health insurers design benefit packages to provide the greatest value to patients. In the case of drugs, they are designed to push the patient in the direction of the drugs that are most effective and provide the greatest value. They do this by creating formularies and other utilization controls. Eliminating the cost-sharing provisions by having the rebates directly to the patient eliminates the cost-sharing for expensive drugs and makes patients insensitive to the high cost of those drugs. It also undermines these formulary designs.

It would be easier to limit the amount of cost sharing that any person has to pay for drugs. It is not necessary to impoverish a person because they have multiple chronic conditions that require them to take many different drugs or for someone that has a rare disease that can only be treated by a very expensive drug. Health insurers including Medicare should place a limit on the amount of out-of-pocket spending that any person should have to pay.