The Pharmacist Activist

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"Enter into His gates with thanksgiving, and into His courts with praise. Be thankful to Him, and bless His name." Psalm 100:4

Editorial

If I was the Secretary of Health and Human Services (HHS)…"

As President-elect Trump has nominated individuals for Cabinet and other federal government leadership positions, there is often an immediate media/public response that supports or opposes the individual (s) nominated. Such is the case with the nomination of Robert F. Kennedy, Jr. to lead the HHS. Some healthcare professionals and their organizations have been highly critical of him and his being nominated for this important position.

The healthcare system, including the appropriate use of medications, is broken and requires major changes. No individual can be expected to have extensive expertise in all of the areas for which HHS has authority. Therefore, the best decisions and actions also require the participation of leaders and staff within HHS, as well as those in the public sector who have expertise and experience in one or more of the numerous and diverse areas of the healthcare system. Let's view the upcoming transition in leadership as an opportunity to provide information and recommendations to revise/construct a system that is safer and more effective and efficient than exists now.

My personal experience in pharmacy and advocacy for the most appropriate use of medications motivates me to identify the following areas as those to which I would give the highest priority if I had the authority of the Secretary of HHS.

1. Request recommendations from stakeholders

With respect to the development and most appropriate use of medications, I consider pharmaceutical companies, physicians, physician assistants, pharmacists, and nurses to be the primary stakeholders. Although each of these five groups has the prerogative to provide recommendations from its individual group, I would request that the five groups collaborate in developing a report with recommendations that all five groups would support. To emphasize the importance and urgency to make needed changes, I would request that the report be provided within 6 months. Each of the five groups would identify its participants in this collaborative process, and they collectively would determine the process, schedule, and other factors to be observed in developing the report/recommendations. Although the five groups collectively would have complete autonomy for its decisions and report, one approach would be to have each of the groups identify four of its leaders/visionaries to be its participants in the collaborative process.

Although the stakeholders do not have decision-making authority, this initiative provides the opportunity to provide substantial recommendations that have interdisciplinary support. If a stakeholder declines to participate, it not only misses an opportunity but could also risk losing "a seat at the table" in future discussions.

2. Healthcare system/programs

The coverage, eligibility, policies, costs, and restrictions of health insurance and prescription plans are excessively complex, and confusing for many. These programs should be re-designed and greatly simplified to facilitate understanding and use.

3. Compensation for health professionals

Compensation for pharmacists and prescribers in federal and other health/prescription programs is insufficient to provide comprehensive, high-quality services for patients and to financially sustain the operations of a professional practice. Many pharmacies have closed and the increased number of pharmacy "deserts" has resulted in inconvenience and hardship for many patients. When compensation is inadequate, some prescribers find it necessary to limit the number of patients in such plans for whom they can provide appropriate care.

Levels of compensation must be provided that enable financially

viable professional practices, increase the time available for personal communication with patients, and achieve optimum therapeutic outcomes.

4. Drug costs

The cost of new and most other single-source prescription medications is far too high. The advertising of prescription medications directly to the public should be prohibited, as should manufacturer coupons that may substantially reduce the cost for initial treatment for a limited period of time, following which the costs for patients and their prescription coverage plans markedly increase. Pharmaceutical companies spend millions of dollars for advertising to promote their most profitable products. Because of economic and insurance coverage pressures, prescribers do not typically have time to discuss other less costly treatment options with patients who are already encouraged by an advertisement that suggests a drug is "right" for them. The alleged educational value of increasing awareness of patients about treatment options for their conditions is negated by the biased and costly promotions of high-cost drugs.

Pharmacy benefit managers (PBMs) have assumed a large, but unnecessary, role in the prescribing, distribution, use, and cost of prescription medications. Their involvement is not only responsible for increasing the cost of medications, but also compromises the quality and timeliness of treatment. HHS should prohibit the involvement of PBMs in government-sponsored prescription programs, and utilize a prescription claims administration process that is much less costly. The complexity, confusion, and costs of prescription plans associated with the involvement of PBMs are described in a recent report, "Medicare Payouts Vary Widely for Same Drug" (*Wall Street Journal*; page A1; Jared Hopkins and Josh Ulick). The report notes:

> "The price for a single medicine can range by thousands of dollars depending on the drug plan.
>
> Medicare is paying wildly different prices for the same drug, even for people insured under the same plan."

5. Generic drugs

For multiple reasons, the FDA has not been able to assure the quality, potency, and safety of generic drug products made in other countries, particularly India and China. To assure effective and consistent regulatory quality controls, incentives should be provided for pharmaceutical companies to manufacture generic drug products in the U.S. The source/manufacturer of active pharmaceutical ingredients (APIs) and generic drug products that are imported into the U.S. should be identified on the labels of the containers. A company/agency that is located and registered in the U.S. should have the responsibility (and accountability) for assuring that imported pharmaceutical products comply with regulatory requirements.

6. Potential therapies not having research/profit incentives

Pharmaceutical companies and advocacy groups they support are very unlikely to conduct costly research for potential therapies that are unlikely to generate substantial profits. An important example is the possible role of microorganisms and the use of generically-available and inexpensive antibiotics in patients with cognitive decline/Alzheimer's disease (please see my commentary in the September issue). This disease is devastating for millions of patients, families, and caregivers, approved medications are of limited effectiveness, and it is a huge cost burden for society including the federal government. The HHS and its agencies (e.g., National Institutes of Health) should assume the responsibility for conducting research of credible theories and therapies of potential value. For Alzheimer's disease, the need for greater HHS research involvement is urgent, and there are also other conditions for which corporate/private research sponsorship is not available or adequate, and HHS research would be of value.

The cannabis/marijuana debacle is a textbook case of Federal government mismanagement. As a consequence of failed policies and inaction at the federal level, many individual states have passed legislation regarding the availability and use of cannabis. There are far more differences in the laws/strategies of individual states than there are similarities, and chaos persists. HHS and its agencies should give high priority to rescheduling cannabis/marijuana (I recommend to Schedule II and, as justified, a subsequent transition to Schedule III) and to assume responsibility for conducting research regarding the therapeutic benefits and risks of its components. Individual components of cannabis have been studied and approved for selected disorders (e.g., cannabidiol for certain seizure disorders) but potential exists for therapeutic benefit to be demonstrated in a larger number and diversity of disorders. At the same time, the risks of cannabis/marijuana must be identified and quantified. What is already known about the risks should prohibit its availability for recreational use, although such use has been approved in some states. In states that have already legalized the products for recreational use, the laws should preferably be rescinded. Cannabis/marijuana should be viewed as a drug, and research and approval should be pursued in the already established manner. Pharmaceutical products containing it should be available in pharmacies. There is not a need for a separate and inefficient distribution system in dispensaries.

A very different example involves natural products/dietary supplements. These products are not patentable and many of these products contain multiple potentially active ingredients which would make research programs even more costly. Pharmaceutical companies do not anticipate these products to have sufficient profit potential to warrant research investment. However, billions of dollars are spent out-of-pocket each year based on suggested but unproven benefits. The disclaimers required on the labels for these products would be comical if the health implications were not as serious as they are for some of these products. HHS and its agencies should assume the responsibility for conducting research on these products, starting with those that are most commonly used and/or already have identified risks (e.g., drug interactions with St. John's Wort).

7. Drug efficacy

Some have known for several decades that phenylephrine is not effective as a nasal decongestant when it is administered orally. It has only been recently that the FDA has initiated steps to have this agent removed from orally-administered products in which it is included, attempting to justify the long delay by indicating that the agent is safe and that the question is a lack of effectiveness. However, its continued inclusion in products is confusing and adds unnecessary cost. Contrary to FDA's assertion that there is not a safety issue with oral phenylephrine, it is NOT safe for everyone. It should be removed from products that include it without further delay.

8. Drug safety

The concerns regarding the potency, quality, and contamination of

generic products made in certain other countries have already been identified. Health professionals and consumers are encouraged to report adverse experiences to programs such as the FDA Adverse Event Reporting System (FAERS) and Vaccine Adverse Event Reporting System (VAERS). However, verification, review, and analysis of these reports is limited and sometimes ignored. The recent experience with COVID-19 vaccines has resulted in thousands of reports to VAERS. With the possible exception of the risk of myocarditis in young men, the response of federal agencies gives the appearance of dismissing validity of the reports because they are anecdotal and unverified. The perceived unwillingness of health agencies to address or respond to concerns on a timely basis is an important reason for the loss of confidence in these agencies and the reluctance to trust their recommendations.

There is an increasing number of online and other remote suppliers of medications. This situation increases the risk of counterfeit and/or other products of unknown quality in the medication distribution system. Concerns exist regarding the extent to which the identity of the ownership and staffing of these manufacturers/suppliers is known, and whether they are inspected and approved as complying with requirements. Without even considering the smuggling of drugs into the country, questions continue regarding the quality and safety of some drug products that are available within the "legal" distribution system.

9. Medication errors

The number of harmful and fatal medication errors that continue to occur is an embarrassment for health professionals and unacceptable. Some errors are unavoidable but most are preventable. It has been 25 years since the National Institute of Medicine published its report, "To Err is Human," that sounded an alarm about the frequency and harm of medication errors. In spite of the efforts of some dedicated professionals who have established programs and systems to reduce the occurrence of these incidents, there has not been significant progress. Horrible consequences of preventable errors continue to be reported. Stronger and more effective reporting, educational, and remedial/disciplinary initiatives need to be established, and understaffing and workplace environment factors that increase the risk of errors must be corrected.

10. Drug misuse/abuse

Although the misuse of drugs may result from misunderstanding with respect to their appropriate use, it is often intentional as a well-meaning effort to achieve a better response from a medication, or as "recreational" use for the purpose of experiencing euphoria and other "pleasurable" responses. The latter use of medications, particularly controlled substances, results in dependence, irresistible craving for the drug(s), addiction, and consequences of overdosage and death. The pandemic of drug overdosage deaths and alcoholism is a great failure of our society, notwithstanding the dedicated efforts of many to prevent and manage addictions, and to provide rehabilitation programs.

The efforts of some regulatory agencies to prevent inappropriate access and use of addictive agents have also had unfortunate results that need to be promptly resolved. There are many individuals with medical problems (e.g., cancer, back problems) that are characterized by continuing, unrelenting severe pain. Opioids such as morphine are unsurpassed in their ability to provide pain relief, and effective pain management for some individuals REQUIRES their use in high and increasing dosages. Overzealous efforts (e.g., by the Drug Enforcement Administration [DEA]) to prevent the inappropriate use of opioids and other controlled substances have had an intimidating effect on prescribers and pharmacists with respect to their prescribing and dispensing opioids. For fear of being suspected or alleged and even penalized for being engaged in inappropriate practice activities, some have significantly restricted the extent and quantities of opioids they prescribe and dispense. However, inflexible adherence to "guidelines" and/or quantity restrictions (e.g., dosages not exceeding 90 morphine milligram equivalents [MME] a day) has resulted in patients who have legitimate need for higher dosages having difficulty obtaining their medication in quantities they require for adequate pain relief. Some patients, in desperation, resort to obtaining "street" or other illicit products

A small number of health professionals have engaged in criminal activities with respect to the inappropriate provision and use of opioids, and they should be identified and prosecuted. However, these situations represent only a small fraction of the huge opioid addiction/overdosage problems, most of which result from illegal products in which fentanyl or one of its analogs has been added. The DEA and other regulators should give priority attention to the illegal distribution and use of opioids, even if it results in less monitoring of licensed prescribers and pharmacists. Regulatory/enforcement actions that have resulted in some patients with a need for high-dosage opioid analgesia experiencing additional hardship and suffering because of denied or restricted accessibility must be avoided.

11. Drug shortages

In recent years there have been shortages of varying duration of hundreds of medications, some of which are standards of treatment for certain cancers. Although some shortages result from unexpected circumstances, others could be anticipated and either prevented or minimized by effective planning. Progress has been made in identifying and sharing information about drugs for which shortages exist, but strategies and actions to avoid shortages of "essential" drugs must be developed.

12. Drug fraud and waste

There have been recent reports of the extent of fraud at a cost of billions of dollars in the Medicare and other federal health programs. Actions must be taken to greatly reduce fraud and to prosecute those who are responsible for it. The waste of medications resulting from the current "broken" medication distribution and use system must also be effectively addressed. The DEA conducted its latest in a series of National Prescription Drug Take Back Days on October 26, with 630,000 pounds of unneeded medications being collected. The huge quantities of medications turned in at these events were initially shocking but is now almost expected and accepted. I recommend that an analysis (with appropriate protection of confidential information) of a large sampling of the returned medications be conducted to identify patterns and specific information that would be of value in identifying strategies and actions that would greatly reduce the waste and cost of the current system.

I welcome your comments about these concerns, as well as your recommendation of additional pertinent issues that I have not addressed.

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The PBMs (continued)

Matt Stoller is an authority on monopolies and writes the newsletter BIG and is the author of "Goliath: The 100-Year War Between Monopoly Power and Democracy." I have enjoyed and learned from his expertise and perspectives, particularly as they apply to healthcare issues. His recent (November 19) newsletter includes a commentary, "On the Democratic Party's Cult of Powerlessness," with the following observations about PBMs:

> "(In) September of this year, The Federal Trade Commission launched a highly publicized lawsuit against pharmacy benefit managers. PBMs have been killing local pharmacies for more than a decade, and hiking up the price of medicine. There is no reason for this industry to exist, it's just a series of spreadsheets with political power. The top three PBMs serve administrative functions, yet they have more revenue than France spends on its entire universal health care system. Anyway, well-trained FTC lawyers had spent years investigating the industry, and finally litigation started. After several more years, prices will come down and independent pharmacies will once again flourish.
>
> On one level, that's a story of success. But in 2020, we knew about PBMs, and pharmacists were desperate. It's been four years, and the situation on the ground has worsened. Instead of spending FTC resources and years of litigation, the Department of Health and Human Services could have fixed this problem with the stroke of a pen. But HHS Secretary Xavier Beccera doesn't know what a PBM is, and it's not clear that the Domestic Policy Council head Neera Tanden does either. Even worse, the Biden Pentagon renewed its contract with PBM goliath Express Scripts for major government contracts. Meanwhile, Senate Democratic leader Chuck Schumer didn't see any value in moving anything in Congress."

These remarks provide strong support for pharmacy's message about the need for PBM reform and our messages to our representatives in Congress to approve pending legislation.

A "new" voice?

In several recent issues of The Pharmacist Activist I have included excerpts from the battle of full-page advertisements from PBMs and PhRMA in major publications such as The Wall Street Journal (WSJ). On November 20 another full-page ad appeared in the WSJ (page A6A) with the following message:

> "PASS SENATE FINANCE PBM REFORMS.
>
> Pharmacy benefit managers are taking advantage of Medicare and American seniors.
>
> Rein in PBMs by requiring them to increase transparency, share discounts with seniors, and delink PBM profits from the cost of medicines in Medicare.
>
> Pass S. 2973 and S. 3430 today."

The ad was placed by the PBM Accountability Project, an organization with which I was not familiar. In looking at its website (pbmaccountability.org), I learned that it is comprised of 14 partners that include three pharmacy organizations – National Community Pharmacists Association, Pharmacists United for Truth and Transparency, and the National Alliance for State Pharmacy Associations.

On the following day Express Scripts continued its series of full-page ads (WSJ; Nov. 21; page A16) with the following message:

> "Keeping Medication Costs Under $250 per Year for Millions of Patients.
>
> That's Not a Middleman. That's an Advocate.
>
> In 2023, the median annual price of new drugs coming to market was $300,000. Four in five of our patients still spent less than $250 a year out-of-pocket for all of their medications."

Express Scripts attempts to impress readers by taking credit for "results" that they don't expect to be questioned. But their numbers are deceptive and need to be challenged. Identifying the median annual price of new drugs marketed in 2023 as $300,000 is a misleading scare tactic. Most of these drugs have been approved for the treatment of ultra-rare or rare diseases and/or types of cancer that only a miniscule (if any) fraction of individuals with an Express Scripts plan is experiencing. Express Scripts should identify the specific number/fraction of its "patients" who are receiving one of the new high-cost medications to which they make reference.

How was $250 a year out-of-pocket costs identified as an apparently "acceptable" goal? How many of the individuals in its plans would spend less than $250 a year out-of-pocket if they did not have a prescription plan? Might the number be more than 80% (i.e., "four in five")? Is Express Scripts unintentionally acknowledging that it reduces costs by restricting/preventing the use of more costly medications that prescribers consider to be the best treatment for their patients?

I strongly agree with Matt Stoller's opinion that "there is no need for this industry to exist," and am committed to be an advocate for his prediction that "independent pharmacies will once again flourish."

Have you contacted your legislators?

Express Scripts is spending millions of dollars for its advertisements and lobbying programs. How many pharmacists have contacted their legislators to urge their support for S. 2973, S. 3430, and other pertinent legislative proposals? If you haven't done so yet, it is important that you do so now!

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