The Pharmacist Activist

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**"Oh, the depth and riches of the wisdom and knowledge of God!
How unsearchable his judgments, and his paths beyond tracing out!"** Romans 11:33

Editorial

Is Radical Reform of the Healthcare System Possible?

Will Pharmacy Have a Role?

Without even starting to respond to those questions, a pharmacist friend of mine would challenge the title of this commentary: "We do not have a 'healthcare' system; we have a 'sickcare' system." I agree with him, but with the opinion that substantive reform needed to establish an "ideal" healthcare system may not be possible to accomplish. But do society and the health professions even have a concept of what services/products an "ideal" healthcare system should provide, how it would be administered, and how it would be financed? Is it realistic to even think that an ideal system could be identified and developed, or should the goal be to identify a system that would be considered "ideal" or "acceptable" to a large majority of stakeholders? Is it possible that our present very complex healthcare system that has evolved over decades has never had defined goals to be achieved? If there are such goals and measurable outcomes, as we consider important for so many other initiatives, please inform me where I can access them. If such a document, or even concept, does not exist, should it not be developed, and who should provide the leadership in developing it?

The availability and affordability of health care services are among the most important concerns for the public and legislators. Indeed, the primarily partisan and bitter division of opinion regarding the soon to expire subsidies of the Affordable Care Act (ObamaCare) was most responsible for the damaging and costly shutdown of many federal government operations for 43 days. Although the shutdown is now resolved, the underlying issue of the subsidies is not. This challenge must be considered an opportunity to establish an initial substantive reform of the healthcare system.

Whether one likes or dislikes President Trump, or supports or opposes his recommendations, he is the individual who will have the most influence for the next several years on decisions regarding healthcare programs. President Trump has recently emphatically recommended that the funds currently provided to health insurance companies as subsidies provided by ObamaCare be provided instead directly to the eligible individuals for the purpose of enabling them to select and purchase healthcare coverage they consider best for their individual circumstances.

ObamaCare is but one component of a very large and complex health insurance/benefits system. However, the decision whether the subsidies for ObamaCare will conclude at the end of the year, or whether they will be extended, is imminent and the legislative battle continues. In my opinion, President Trump's recommendation that consumers have the authority to select the coverage they consider most important, rather than choosing from pre-defined benefits offered by insurance programs, would provide a very important first step in assessing better alternatives to our current broken healthcare system. Reforming the use of the ObamaCare subsidies could be viewed as a pilot program, the anticipated suc-

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cess of which could be subsequently extended to the entire healthcare benefits system.

The experience with health savings accounts (HSA) could be used as a starting point in identifying the structure and components of a health benefits system in which consumers/employees/retirees would have the responsibility for choosing the health services, the extent of coverage (e.g., deductibles), and the utilization of funding available from government and employer programs, as well as from personal resources.

The primary goal of the model health benefits program to be constructed should be to transfer the authority for as many of the specific coverage and funding decisions as possible from the government, health insurance companies, and employers to individual consumers. In developing the model program, priority should be given to clarity and ease of understanding and use. It is essential that the model program be developed in a manner that it will be clearly recognized that it is superior to the present system. Potential issues, questions, and limitations should be anticipated to the extent possible.

The subsidies for the ObamaCare program are scheduled to conclude very soon in a timeframe that will not be sufficient to develop and implement a model "consumer-centered" program. I have been opposed to continuing the subsidies for what I have considered to be a flawed program. However, I would support a one-year extension of the subsidies with the condition that it be for the purpose of developing a model program that would be implemented on January 1, 2027.

Pharmacy's role

With the President and a number of legislators voicing support for a reformed health benefits program that would provide more authority for consumers, there has not been a better opportunity to achieve substantive reform in the current system. Numerous health professions, government officials/agencies, health insurance companies, and others will be stakeholders in the new program. I am not aware of any focused effort of stakeholders to identify the structure and components of a model health benefits program. Who should provide the leadership in responding to this opportunity? Why not PHARMACY? I recommend that the American Pharmacists Association quickly convene a group of individuals with expertise and experience with health benefits programs that would include pharmacists and representatives from other primary stakeholders. This group should be requested to propose a structure and *general* concepts for a Model Consumer-Centered Health Benefits Program, and identify *specific and detailed* recommendations for the roles to be assumed by pharmacists, the provision of medications, counseling, and other professional services, and the value/compensation to be provided for fulfilling these responsibilities.

If the profession of pharmacy does not act quickly to propose concepts and recommendations for a model program, we may not have a significant role later when we would have to respond, probably from a defensive position, to the roles (or lack thereof) proposed for pharmacists by those outside the profession. The disastrous influence of PBMs and health insurance companies on the practice of pharmacy and our entire profession is a hard-learned lesson of the importance of credible and authoritative early participation in the development, policies, and implementation of a new model program.

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Editor's note: *Jeffrey A. Tucker, founder and president of the Brownstone Institute (tucker@brownstone.org), has written an excellent commentary, "Reform Health Insurance Now." (11/13/20225). It includes a more extensive analysis of the problems of the current system and more recommendations than I am able to provide in this editorial.*

Drug Prices, Advertisements, and Distribution

Few would disagree that the prices of single-source trade-name drugs in the U.S. are too high. The mutually-enriching increases in list prices and rebates of the recurring blame game between pharmaceutical companies and PBMs are well known, but little has been done to address them. The initiatives of government officials/agencies to lower drug prices have been well intentioned but, with few exceptions, have been of limited effectiveness. Indeed, the government initiatives may have increased the intensity of the competition between the pharmaceutical companies and PBMs to maintain and increase their profits while they both attempt to exploit loopholes or otherwise circumvent governmental efforts to lower drug prices.

The pharmaceutical companies establish the list prices for drugs and are primarily responsible for the extravagant prices. The PBMs claim that they serve the public interest by containing/reducing drug prices, but drug prices continue to increase. However, the largest PBMs have manipulated the drug distribution and use system to such an extent that they have more control than anyone else over the selection/prescribing, cost, and distribution of medications, including the pharmacy from which the medication is provided. The prior authorization component of PBM-administered prescription benefit programs is NOT for the purpose of assuring optimal treatment of patients, but rather as a barrier to prevent/delay the provision of a high-cost medication and/or to use a lower-cost alternative. Some prescribers will not pursue the prior authorization process because it is cumbersome and time-consuming, and may not be successful. Thus, the prior authorization process is

an incentive for PBMs to reduce their own costs and increase their profits in a manner in which many patients are denied the medication that was initially prescribed and may be most appropriate for their treatment.

Drug advertisements

The U.S. is one of only two countries, New Zealand being the other, that permits pharmaceutical companies to advertise prescription drugs directly to consumers. In 2024, pharmaceutical companies spent almost $11 billion in consumer-directed advertising for their drugs. The highest advertising spend was for Skyrizi ($647 million; featuring the theme, "nothing is everything" for patients with psoriasis), followed by Rinvoq, Dupixent, Wegovy, Rexulti, Tremfya, Jardiance, Ozempic, Vraylar, and Otezla. Many of the ads conclude with the statement, "Ask your doctor if (drug name) is right for you."

The amount of time that physicians spend with individual patients is already significantly limited by health insurance companies and other payors. When patients ask a question about a drug they saw advertised for a medical condition they experience, physicians will often prescribe the drug rather than engaging in what could be a prolonged discussion about other available medications that may be equally effective and safe, and less costly. Most patients and physicians have no idea of the cost of the advertised drug, and may even be deceived into thinking it is inexpensive by the concluding statement in many ads such as, "Your co-pay may be as little as $0,' which is likely to be applicable to only the first prescription and maybe one refill. The advertised drug is likely to be clinically effective and, when benefit is experienced, the use of the high-cost medication will be continued for maintenance therapy.

It can be assumed that the revenues generated by the advertising and increased number of prescriptions for the drugs far exceed the billions of dollars the companies have spent for the ads. Otherwise, they would not be continuing and increasing the number of ads.

In September, the FDA issued a press release, "FDA Launches Crackdown on Deceptive Drug Advertising," in which it noted that it was "sending thousands of letters warning pharmaceutical companies to remove misleading ads and issuing approximately 100 cease-and-desist letters to companies with deceptive ads." The following statements are excerpts from the FDA press release:

> "In addition to enforcing existing law, the FDA is initiating rulemaking to close the 'adequate provision' loophole created in 1997, which drug companies have used to conceal critical safety risks in broadcast and digital ads, fueling inappropriate drug use and eroding public trust."
>
> "The FDA is concerned patients are not seeing a fair balance of information about drug products. This concern is magnified when serious risks ae not clearly presented, or the information is too difficult for seniors to read or hear."
>
> "For far too long, the FDA has permitted misleading drug advertisements, distorting the doctor-patient relationship and creating increased demand for medications regardless of clinical appropriateness."
>
> "The FDA will no longer tolerate such deceptive practices."

In my opinion, the advertising of prescription medications directly to the public should not be permitted at all. However, action to rescind the opportunity to do so would result in strong legal challenges from pharmaceutical companies, media organizations which receive substantial revenue from the ads, and others who would claim that such an action would violate protections of freedom of speech. Therefore, the best course of action is for the FDA to amend the existing law to eliminate loopholes and ambiguities, and then monitor and enforce the provision of a fair balance of information regarding the benefits and the most serious and most common adverse events of the drug.

I also urge that advertisements include the list price for a 30-day supply of the recommended usual maintenance dosage of the drug. We are familiar with the response that no one pays the list price for the drug. However, it provides a documented starting point established by the company that can be used for comparisons with other treatments before PBM rebates and other manipulations of the cost are made in a non-transparent manner.

Drug distribution

The ongoing battle between pharmaceutical companies and PBMs, the markedly increased direct-to-consumer advertising of prescription drugs, and President Trump's "flexible" tariff policies combine to facilitate what I consider complex and destructive changes to the drug distribution system. The lead editorial in the October 2 edition of *The Wall Street Journal* (page A14) carries the title "America's Pharmacist in Chief," that describes the deal between the President and the CEO of Pfizer that will presumably lower prices for selected Pfizer drugs in exchange for tariff breaks.

Facilitated by a new government website (TrumpRx), Pfizer would avoid using a PBM and sell selected medications directly to consumers at discount prices. However, one of the many questions that exists is whether the discount prices identified in the agreement might actually be higher than those which patients are paying out-of-pocket now under the terms of their existing benefits. From the very limited information that is available, it appears that President Trump and his advisors do not have a thorough awareness of the extent and ways in which the companies and PBMs can manipulate drug prices.

The effectiveness and demand for the glucagon-like peptide-1 receptor agonists (GLP-1s; semaglutide [Ozempic, Wegovy], tirzepatide [Mounjaro, Zepbound]) have resulted in great disruption in the availability and use of these agents. These drugs, at least initially, cost more than $1,000 for a one-month supply. Shockingly, even with such a high cost, the compensation for pharmacists was often markedly less than the amount pharmacists paid to purchase the drugs. The intense competition between the companies (Novo

Nordisk and Lilly) that market the drugs included programs in which the companies would sell the drugs directly to patients at lower prices. Most recently, President Trump has made agreements with Novo Nordisk and Lilly that will result in their semaglutide and tirzepatide products being available at much lower prices, and to many more patients because of reduced availability limitations in government-funded programs.

Information regarding the structure and implementation of the agreements between the President and the pharmaceutical companies is very limited, and many questions exist. Of greatest importance for the profession of pharmacy is the role of local pharmacists in programs in which pharmaceutical companies are providing selected widely-used medications directly to patients. Related questions include:

Are the companies establishing and obtaining licenses for their own mail-order pharmacies to dispense their medications directly to patients?

Will the companies use existing mail-order pharmacies (e.g., CVS Caremark, Express Scripts) to provide their medications to patients?

Will the companies be using local pharmacies at all or limiting the local dispensing of their medications to the largest chain pharmacies (e.g., CVS, Walgreens)?

To what extent are the national pharmacy associations participating in discussions with the companies that will be supplying their medications directly to patients?

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Continued Harassment and Corruption at CVS

In several recent issues of *The Pharmacist Activist* I have voiced concern about the recent suicides of CVS pharmacists and technicians. Investigation is continuing with respect to the suicides of two CVS pharmacists in the Lancaster, PA area, and CVS continues to refuse to respond to requests for information unless it feels it is to its advantage to do so. Tragically, there have been additional reports of deaths of young CVS pharmacists identified although specific information is not yet available.

The avalanche of millions of additional prescriptions from closed Rite Aid stores continues to overwhelm pharmacists in many already understaffed CVS stores, and pharmacists are being harassed by district leaders and upper management to aggressively promote immunizations.

Corruption and subsequent lawsuits against CVS persist with one example described in a recent press release, "U.S. Attorney Announces $37.76 Million Settlement With CVS For Over-Dispensing Insulin Pens To Patients." The lawsuit was initiated by the U.S. Attorney's Office in the Southern District of New York and includes allegations that, from 2010 through 2020, CVS violated the False Claims Act in connection with the billing and dispensing of insulin pens to patients enrolled in Government healthcare programs (GHPs) including Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Programs.

In most settlements of lawsuits, CVS or other defendants are able to reach a settlement for a monetary amount "without admitting any wrongdoing." It is noteworthy that as part of this settlement "CVS also admitted and accepted responsibility for certain conduct alleged by the Government in its complaint, including that GHPs paid CVS substantial amounts for insulin pen refills that were ineligible for reimbursement and CVS pharmacies dispensed more insulin to GHP beneficiaries than they needed." The circumstances of this situation strongly suggest that the fraud was intentional, and that the illegal actions were so egregious and evident over an extended period of time that CVS was not able to escape by claiming no wrongdoing.

CVS has sufficient resources that a settlement of $37.76 million will not deter it from continuing to participate in fraudulent actions. CVS should be suspended or barred from future participation in programs in which its fraud is documented!

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