The Pharmacist Activist

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"A truthful witness gives honest testimony." Proverbs 12:17a

Editorial

Four Executive Orders Regarding Drug Pricing:
Two are Needed and Two Should be Rescinded!

The cost of many drugs is far too high!

Pharmaceutical companies, pharmacy benefit "managers" (PBMs), and health insurance companies have been engaged in a "blame game" for many years in faulting the others for the high cost of drugs. While they do this, drug costs continue to increase! These companies will not identify an equitable strategy and solution that will serve society well.

Elected officials and government agencies are engaged in partisan politics to such an extent that they have failed to effectively address the issue of excessive drug costs. This political impasse is not likely to be resolved anytime soon. The victims of these failures are patients and society, and the prescribers, pharmacists, and other health professionals who have the responsibility for assuring the most appropriate and effective use of medications with the least risk possible.

President Trump has issued four executive orders (EOs) regarding drug prices. I give him credit for recognizing the importance of taking action and his boldness in acting at a time when others who should be effectively addressing these matters have failed to do so. We can't expect anyone who does not have expertise in the areas of health care and medication use and costs to be in a position to identify the best strategies and actions. Indeed, many of the "experts" in health care, including health professionals do not agree on a course of needed action. However, the added challenges for the President are that many of those who have the greatest access to him and the opportunity to contribute to and influence decisions, have vested interests and/or political agendas. The consequence is actions that include some that are flawed. Let's consider the EOs on an individual basis.

Access to affordable life-saving medications

This EO is applicable to insulin and epinephrine (e.g., EpiPen) products. Federally qualified health centers (FQHCs) and hospitals that serve eligible patients (e.g., those with low income who do not have health insurance) participate in the 340B program and are able to obtain medications at large discounts from pharmaceutical companies. The EO directs FQHCs to pass along discounts for insulins and epinephrine ("life-saving" drugs) to patients.

This is a needed and important action BUT, it must be viewed as a small first step in eliminating the widespread abuses in the 340B program. The EO is only applicable to FQHCs and not the hospitals and PBMs involved in the program, it only includes the drugs considered life-saving, and the policies for

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implementation and monitoring compliance with the order have not yet been identified.

Increasing drug importation to lower prices for American patients

This is a seriously flawed concept and order, and should be rescinded! This EO would permit individual states to develop programs that would enable safe importation of certain drugs, and would enable personal importation waivers at authorized pharmacies. Such a system would be a great disservice for patients and place them at increased risk of drug-related problems. It would enable even more fragmentation of health care and drug therapy for patients, create additional questions about the quality and potency of imported medications, have a disruptive impact on the supplies of drugs in the countries from which they are imported, have a harmful economic impact on many pharmacies and other healthcare entities in the U.S., and require inefficient and costly regulations and procedures that would erode much of the anticipated cost savings.

The problem of excessive prices for many drugs has occurred and been enabled and exploited in the U.S., and must be resolved within this country!

Lowering prices for patients by eliminating kickbacks to middlemen

This EO is needed and extremely important BUT, it must be viewed as an essential first step in restoring the integrity of drug prices and the drug distribution system. Although there are some relatively small PBM middlemen who are committed to providing transparent and financially responsible services, the marketplace is dominated by three huge PBMs – CVS Caremark, Express Scripts, and Optum – that engage in secretive, deceptive, and highly profitable (for themselves) practices. If government officials and the public were specifically aware of the high percentage (often well above 50%) of the price of some drugs that is extracted as kickbacks/rebates by PBMs, there would be outrage and refusal to tolerate the continuation of these self-serving practices that are at the expense of patients, society, and health professionals. The terms of their secret deals are so fiercely hidden and protected that even government officials are not able to obtain the details of the financial arrangements. Government regulators in Ohio, West Virginia, Pennsylvania, and some other states have made progress in identifying the deception and fraud in certain government-funded programs, but even they are stonewalled and mislead by these PBMs.

Eliminating kickbacks from pharmaceutical companies to PBMs is a positive first step. However, this action must be accompanied by strong regulation of PBM practices in both government-funded and other prescription benefit programs, prohibiting direct and indirect remuneration (DIR) clawback fees from pharmacies, very close regulatory monitoring of their operations, and strong criminal and/or civil actions when harm from and fraud in their operations and programs are identified. Even if rebates from companies to PBMs are eliminated, if these other reforms and actions are not also taken, these PBMs will identify other secretive strategies to recoup their losses and continue their costly programs to the great disadvantage of patients, health professionals, and the healthcare system. More whistleblowers who are current or former employees of these PBMs are needed!

Restricting prices of the most costly Medicare Part B drugs to no more than the amounts charged in other economically comparable countries

This is the second seriously flawed concept and EO that should be rescinded! Suffice it to say that, if government regulators are not able to completely and accurately identify the amounts of kickbacks/rebates and other financial parameters of drug pricing in this country, there is no way of obtaining specific and accurate drug pricing information in other countries beyond knowing that their drug prices are lower.

Recommendations

Pharmaceutical companies, PBMs, and health insurance companies will continue their current drug pricing strategies and programs, and further increase drug prices, unless firm actions are taken to prevent them from doing so. The President, other elected officials, and appropriate government agencies must learn from and act on the counsel and recommendations of patients, pharmacists, and other health professionals who are victims of the destructive present healthcare system. They must give the highest priority to eliminating kickbacks from pharmaceutical companies to PBMs, and to eliminating the unnecessary and costly involvement of PBMs, or rigidly controlling their policies, operations, and programs. Organizations of pharmacists and other health professionals must work together with a united voice and strategy to lower drug prices and attain reforms in the health care system.

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New Drug Review

Romosozumab-aqqg
(Evenity – Amgen)

Agent for Osteoporosis

New Drug Comparison Rating (NDCR) = 4
(significant advantages)
in a scale of 1 to 5 with 5 being the highest rating

Indications:
Administered subcutaneously for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Comparable drugs:
Abaloparatide (Tymlos), teriparatide (Forteo).

Advantages:
- May be more effective in reducing the risk of vertebral fractures in some patients;
- Has a unique mechanism of action (sclerostin inhibitor);
- Has not been associated with the occurrence of osteosarcoma (risk is identified in boxed warnings in labeling of comparable drugs)
- Has not been associated with the occurrence of hypercalcemia;
- Is administered less frequently (once a month compared with once a day with comparable drugs).

Disadvantages:
- May be less effective in reducing the risk of nonvertebral fractures;
- Labeled indications are more limited (compared with teriparatide that is also indicated for increasing bone mass in men with primary or hypogonadal osteoporosis at high risk of fracture, and for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture);
- Has been associated with a risk of myocardial infarction, stroke, and cardiovascular death (boxed warning);
- May cause hypocalcemia;
- Treatment should not be continued for more than 12 months (because of a decline in effectiveness; comparable drugs are used for up to 24 months);
- Should be administered by a healthcare provider (whereas comparable drugs are self-administered).

Most important risks/adverse events:
Risk of myocardial infarction, stroke, and cardiovascular death (boxed warning; treatment should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year); contraindicated in patients with hypocalcemia (hypocalcemia should be corrected before initiating treatment; patients with severe renal impairment or receiving dialysis are at greater risk and serum calcium concentrations should be monitored; adequate supplementation with calcium and vitamin D should be provided); hypersensitivity reactions; osteonecrosis of the jaw; atypical femoral fracture (new or unusual thigh, hip, or groin pain should be evaluated).

Most common adverse events:
Arthralgia (13%), headache (7%), muscle spasms (5%).

Usual dosage:
210 mg once a month subcutaneously; should be administered by a healthcare provider; two separate syringes are needed to provide the dose of 210 mg and should be administered one after the other; duration of treatment should be limited to 12 months because of subsequent decline in effectiveness.

Products:
Injection in single-use prefilled syringes – 105 mg (should be stored in a refrigerator).

Comments:
Sclerostin is a glycoprotein that is a regulatory factor in bone metabolism which inhibits activation of osteoblast function and bone formation. Romosozumab is a monoclonal antibody that is the first sclerostin inhibitor. By inhibiting sclerostin, it stimulates osteoblastic activity and increases bone formation. In one clinical trial, either romosozumab or placebo was used for the first 12 months, and both groups were then treated with denosumab (Prolia) for the next 12 months. Romosozumab significantly reduced the occurrence of new vertebral fracture (0.5%), in the first 12 months, compared with 1.8% of those receiving placebo. At month 24, 0.6% of patients treated with romosozumab experienced a new vertebral fracture, compared with 2.5% of those receiving placebo followed by denosumab. In a second trial, romosozumab was compared with oral alendronate; 4.1% of patients treated with romosozumab followed by alendronate experienced a new vertebral fracture through month 24, compared with 8% of those who were treated with alendronate alone for 24 months.

Daniel A. Hussar

Hydroxychloroquine Hysteria

Some are obsessed with science. Some are obsessed with evidence from randomized clinical trials. Some are obsessed with the opinions of those whom they consider as "experts." Some are obsessed with politics. And some are obsessed with knowledge, experience, and reason. I applaud the benefits of science and evidence but I consider knowledge, experience, and reason to be even more important, particularly when there is no evidence.

Almost everyone in the above groups has an opinion, that is often adamant, regarding the effectiveness and safety of hydroxychloroquine (HCQ) in patients with COVID-19 infection. There are many topics about which I have no expertise. However, I am knowledgeable and have taught about malaria and lupus, and the properties, effective use, and safety of HCQ in these conditions. In the treatment of lupus, many patients have used it for decades.

I was surprised when I first heard the suggestion that HCQ might be of value in some patients with COVID-19 infection, and was skeptical when President Trump identified it as a possible treatment. I feel it was unwise for the President to voice his opinion regarding HCQ, but he did. As a consequence, the vast majority of claims, opinions, and media coverage with respect to HCQ are highly politicized, and obscure objective attention to science, studies, knowledge, experience, and reason.

There have been "studies," and more studies of HCQ, many of which have not been randomized, controlled, powered, or met other objective criteria. Some of the information from the studies supports the value and safety of HCQ in patients with COVID-19, whereas information from other studies refutes its value and safety. Several published papers with purported study results in thousands of patients and conclusions that HCQ is ineffective and dangerous, have been challenged and retracted because the authors were not able to provide documentation to support the data and claims provided. Strong opinions either supporting or opposing the use of HCQ have been voiced by some who have expertise regarding the drug, and even more often by individuals who have no or limited knowledge about HCQ and whose opinions are based on those of others. Many opinions are alarming and create fear regarding risks of HCQ, most often the potential of the drug to prolong the QT interval of the electrocardiogram that is associated with an increased risk of arrhythmias. These alarmist comments are often made in the absence of any context that recognizes the use of HCQ for more than 50 years, including safe use for decades in thousands of patients with lupus without the occurrence or suspicion of serious cardiovascular risks, the widespread use of other medications (e.g., moxifloxacin [e.g., Avelox]) that appear to cause greater prolongation of the QT interval than what has been suggested for HCQ, and the opportunity to assess and monitor the risk in patients in whom the anticipated benefit outweighs the risk.

At this time, there is NO EVIDENCE that permits definitive conclusions that HCQ is effective, or is not effective, in the treatment of patients with COVID-19 infection. Some of those who insist on the availability of evidence before any medication is used, strongly oppose the use of HCQ for these patients. However, when asked how these patients should be treated, their advice is to provide supportive care, use remdesivir (that appears to be of value, but for which data are still very limited and it has not yet been officially approved by the FDA), and the use of a ventilator if necessary. But tens of thousands of patients in the U.S., primarily the elderly with additional risk factors, who have received this care, have died as a consequence of complications of COVID-19 infection.

In the absence of evidence, I am most impressed by the individual anecdotal experiences of patients with COVID-19 infections who have been treated with HCQ and have recovered, the experiences of prescribers who have used HCQ in many patients with this infection and are of the opinion that it has been of value in their recovery without the occurrence of serious adverse events, and the experiences of rheumatologists and other prescribers and patients with lupus who have been safely treated with HCQ for many decades.

I have never taken HCQ. However, because of my age and medical issues, I am at high risk of experiencing serious infection if I am exposed to the virus. I take the recommended precautions but, if I tested positive for COVID-19 (and am confident that it is not a false-positive), and began to experience symptoms, I would immediately start to take HCQ, as I have recommended for family members and friends who have been diagnosed with this infection. Any risk of HCQ is much lower than the risk of serious consequences from COVID-19 infection in high-risk patients. To not use HCQ is a disservice for these patients that may have deadly consequences.

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