The Pharmacist Activist

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"For you created my inmost being; you knit me together in my mother's womb. I praise you because I am fearfully and wonderfully made;" Psalm 139: 13-14a

Editorial

Abortion and Mifepristone
The FDA's Error

I am opposed to abortion with very few exceptions for religious and moral reasons. However, this commentary provides my perspective that I have not seen discussed elsewhere regarding the FDA's approval of mifepristone, "the abortion pill."

The FDA approved mifepristone (Mifeprex) in 2000 for oral use in a regimen with misoprostol for the medical termination of intrauterine pregnancy during the first seven weeks of pregnancy (since changed to "through 70 days gestation"). With respect to medications, primary responsibilities of the FDA are to evaluate their effectiveness and safety based on results of clinical trials, and to approve for marketing the medications it concludes to be effective and safe. The approval of mifepristone was based entirely on the FDA's decision that it is effective and safe for the pregnant women for whom it is prescribed. There is no disagreement with the decision that mifepristone is "effective" in terminating an intrauterine pregnancy. Although there is ongoing debate and review of the safety of mifepristone, many have considered it safe enough for pregnant women to justify its approval. The product labeling for mifepristone notes that serious adverse reactions were reported in less than 0.5% of women in the clinical studies. However, a recent, and largest, study on mifepristone abortion (based on insurance claims from 2017 to 2023) found that 10.9% of women experienced a serious adverse event (e.g., sepsis, infection, hemorrhaging) within 45 days following abortion, a rate approximately 22 times higher than that identified in the product labeling (Hall JB, Ryan RT, Ethics and Public Policy Center; 2025: https://eppc.org/publication/frequently-asked-questions-about-the-largest-study-on-chemical-abortion/).

FDA's responsibilities

The FDA's responsibility in evaluating the safety of a medication for women who are pregnant also includes a responsibility to evaluate its safety in their unborn babies. That the occurrence of pregnancy is associated with a new and separate life that is of value is reflected by the FDA-approved strong warnings against use during pregnancy that are included in the product labeling for many medications. The section on Pregnancy in the approved labeling for medications includes available data, a risk summary, and, if known, clinical considerations. Because women who are pregnant are not included in clinical trials of almost all medications, most, if not all, of the risk/safety data are from studies in animals. Although some information in the product labeling may pertain to adverse maternal outcomes (e.g., miscarriages), most of the section on Pregnancy pertains to the risk of birth defects and other adverse developmental outcomes in an unborn baby. There is no question that the outcome for an unborn baby is death when mifepristone is taken by a pregnant woman.

The FDA's responsibilities did not change when it was evaluating the effectiveness and safety of mifepristone. Its decision

Contents

The GLPs (continued): Recommendations for Lilly .....Page 3

to ignore the consequences for living and growing unborn babies can not be justified. I voiced my concerns when the FDA first approved mifepristone (*The Annals of Pharmacotherapy* 2001;35:373-5), and I regret my lack of boldness and persistence in continuing to communicate these concerns.

The use of mifepristone is now the most common method of abortion and has resulted in the deaths of hundreds of thousands of unborn babies. Initial restrictions on its availability have been eliminated. In my opinion, the FDA made a tragic error in approving the drug.

The changes in leadership of the FDA and the announcement that the FDA is initiating another study of the safety of mifepristone (*The Wall Street Journal*, June 4, 2026, Liz Essley Whyte) make this the appropriate time to correct the error the FDA made 26 years ago. I urge that the decision be rescinded, and that mifepristone be withdrawn from the market.

I recognize that abortion is legal (often with restrictions) in the U.S. I am also sympathetic to the concerns and fears of women who experience unplanned pregnancies. They do have alternatives including providing a gift of continuing life to the baby, and providing her/him as a gift to adopting parents who will provide love and nurturing.

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The GLPs (continued): Recommendations for Lilly

The GLPs Should be Switched to Nonprescription Status From a Pharmacist

The June issue of *The Pharmacist Activist* addresses the use and cost of the GLP-1s and my opinion that many individuals and our country can't afford the very widespread use of these very costly drugs. Many millions of patients quickly add up to many billions in revenue for Lilly and Novo Nordisk. I received many responses, all of which voiced concerns about the costs but without ideas/recommendations as to how this challenge can be managed. One of the responses is provided below:

"I appreciated your assessment and history of the GLPs. It has been a long time since a drug revolutionized not just the treatment of a medical condition (i.e., diabetes), but also has a pop-culture aspect that everyone knows the term "GLP". Your statement, "THE U.S. CAN'T AFFORD THE GLP-1s," is not just opinion, but if we prescribed GLPs for every American adult who experiences the FDA-approved indications, I have no idea what that looks like from a financial perspective.

In my practice as the Director of Pharmacy at a psychiatric hospital. I closely monitor my drug budget. This year it was much higher than in previous years, and for the first time ever, our spending for a different drug class (Diabetes Management) will be the number one drug class in pure drug acquisition cost. In the past it has always been antipsychotics. With the prices of clozapine, olanzapine, quetiapine, risperidone, etc. coming down since 2010 to 2016 or so, my drug expense budget looks a lot different.

Our P&T Committees are struggling with this issue. This month I will be presenting our year-long MUE of GLPs to our Executive Clinical Leadership along with our P&T Committee. The reality is that our usage is in line with good clinical practice per the FDA labeling. I am not sure how we will continue to pay for it, and also importantly, whether there will be payment coverage when our long-term psychiatric patients for whom treatment during their hospitalization has been successful are discharged after 1 to 5 years.

There is an additional discussion in my patient population that we have **caused** the BMI problem with clozapine, olanzapine, and/or quetiapine. One of our initiatives after the GLP assessment was to reassess how are we doing with our metformin usage to prevent/mitigate/treat antipsychotic-induced weight gain. So the GLP MUE has created a second MUE to evaluate metformin. I am not complaining about the extra work as I like this type of pharmacy responsibility. Coaching/inspiring the clinical pharmacists here to investigate and educate is something I enjoy as the Director."

Continuing chaos

The GLP-1 chaos continues with intense competition between Lilly and Novo Nordisk, increased promotion and advertising of happy users of the medications, employers and other payors discontinuing or restricting use in their prescription plans, discount/

rebate games, increased availability of "equivalent?" and counterfeit products from online sources, difficulties in accessing/navigating the Medicare GLP-1 Bridge program, millions of individuals who are unable to afford the medications, little to no attention to identifying, documenting, and avoiding adverse events, drug interactions, and other risks, company treasuries overflowing faster than they can count the revenue, and Lilly suing six companies for illegally distributing an agent alleged to be the same as an investigational drug (retatrutide) that Lilly is evaluating. There is a single underlying factor for all of these issues that cause the GLP-1 chaos, and that is the unconsciable cost of medications that are used by tens of millions of individuals.

The last factor identified above involving retatrutide illustrates the extent to which the drug approval, distribution, and use system is out of control. The effectiveness and safety of retatrutide are currently being evaluated by Lilly, and it is not approved for medical use in the U.S. or any other country. Although comparative studies have not been conducted, it is anticipated by many that it will be even more effective than semaglutide (Ozempic, Wegovy), tirzepatide (Mounjaro, Zepbound), or orforglipron (Foundayo). The primary reason for this expectation is that retatrutide acts as an agonist at three different receptor types (i.e., a triple agonist) -- glucagon-like peptide-1 (GLP-1), glucose-dependent insulinotropic polypeptide (GIP), and glucagon receptors, whereas tirzepatide is a dual agonist (GLP-1 and GIP), and semaglutide and orforglipron are agonists at GLP-1 receptors. A huge black market for retatrutide has developed using the chemical from suppliers in containers with labels with designations such as "for research-use only," and preparing formulations for subcutaneous administration. This is all occurring many months and even years before retatrutide is likely to be approved for medicinal use in the U.S. or any other country.

Lilly has initiated lawsuits against six online suppliers, medical spas, and compounding pharmacies accusing them of selling illegal versions of retatrutide. In addition, it has reported this illegal activity of more than 200 companies to the FDA, the Department of Justice, state attorneys general, law enforcement agencies, and professional licensing boards. It has also identified more than 14,000 websites, advertisements, and media postings regarding the sale of retatrutide in more than 100 countries.

The sale of retatrutide for the stated or disguised intention of medicinal use is ILLEGAL, and those involved should be prosecuted and severely penalized. Lilly has valid reasons for filing the lawsuits and urging enforcement by regulatory agencies. However, it is hard to be sympathetic for a company that states one of the reasons for its concerns as the unknown quality, safety, and risk for consumers from illegal products. Although these are valid concerns, the primary but unstated reason for Lilly's legal actions is to protect the anticipated future billions of dollars in revenues it will receive when retatrutide is approved for marketing. In addition, Lilly itself has caused significant disruption of the drug distribution system through its rebates/kickbacks to PBMs and others, as well as its direct-to-consumer program for selected drugs that bypasses the involvement of local pharmacists who provide quality and safety services and advice that optimize the use of medications.

Lilly has also taken actions to restrict licensed compounding pharmacies from preparing versions of certain of its approved medications. Local pharmacies were in operation in the U.S. long before Lilly and other long-established pharmaceutical companies were founded. The primary responsibility of the pharmacists of that time was to compound prescriptions. The founders of Lilly and many other pharmaceutical companies were pharmacists who recognized that many of the compounded prescription formulations could be prepared in bulk quantities more efficiently and of consistent quality, and had the vision and abilities to start their companies. Their valued "customers" were local pharmacies and hospitals which dispensed their products. There is a sad irony that Lilly and other companies which were founded by and had a mutually beneficial working relationship with pharmacies, are now engaged in restricting local pharmacies from compounding certain of their approved medications, and bypassing pharmacies by promoting and supplying their medications directly to patients. Lilly and other pharmaceutical companies are adversaries with PBMs in the drug distribution and use system. However, their antagonistic, but mutually-enriching, working relationship has had a very destructive financial impact on local pharmacies that has forced thousand of them to close.

I had the privilege of meeting Eli Lilly in the 1960s. He was the last member of the Lilly family to serve as CEO of the company. He was a pharmacist who respected and valued the pharmacy roots of his company, and was committed to continue the mutually beneficial relationship with practicing pharmacists, colleges of pharmacy, and pharmacy organizations. Unlike other pharmaceutical companies, almost all of the Lilly sales representatives of that era were pharmacists. Eli Lilly enjoyed the well-justified reputation of being a very ethical and capable gentleman, as well as a highly effective corporate leader, and most pharmacists viewed his company as the best and the leader in the pharmaceutical industry. Today, the Lilly company can claim the greatest financial "success" of the pharmaceutical companies, but certain of its strategies and operational practices betray and are destructive for the profession of pharmacy and the legacy of its founding family.

If it wishes to do so, Lilly management has the expertise, research programs, and financial and other resources to establish itself as the clear leader in the pharmaceutical industry, restore the values

and priorities of the Lilly family, and to re-establish a mutually respectful and effective working relationship with the profession of pharmacy that includes the protection and preservation of local pharmacies that provide the personalized services for the patients that use the company's medications. I urge the Lilly executives and board to consider the following actions:

- Reduce the list prices of its GLP-1s and related drugs by 75%.
- Terminate its working relationships with CVS Caremark, Express Scripts, and Optum.
- Discontinue its programs to supply its medications directly to consumers.
- Discontinue lay media advertising of specific drugs and limit its advertising to information which celebrates the accomplishments and commitments of the company.
- Participate in executive-level meetings with peers at the national pharmacy organizations for the purpose of establishing mutually-beneficial and synergistic working relationships and programs that will facilitate the provision of advice and services by pharmacists that will optimize therapeutic outcomes for patients.

Although I believe that these actions will be beneficial for Lilly, the profession of pharmacy, practicing pharmacists, and patients (i.e., win-win-win-win), I am realistic enough to anticipate that Lilly will not take these actions. However, there are alternatives.

Alternatives

In my editorial in the June issue, I identified the following options for consideration:

- **Price controls** (i.e., imposed by the federal government);
- **Benefit programs** (i.e., restrict coverage for weight management in prescription benefit programs to patients who have diabetes or another weight-related comorbid condition);
- **Exercise and diet** (i.e., restrict coverage in prescription benefit programs to patients who observe dietary modification and exercise recommendations);
- **Nonprescription status from a pharmacist** (i.e. would not be covered by prescription benefit programs).

Of the many responses I received regarding my previous editorial, none of them addressed these alternatives. Accordingly, I recommend the alternative which I consider the best direction in which to proceed. The GLP-1s and related drugs for weight management should be switched from prescription-only to nonprescription status with availability only from a pharmacist who provides counseling regarding their use. The effectiveness of these drugs is well documented. Although gastrointestinal adverse events are common, they can be prevented or managed by starting with a low dosage and gradually increasing it, and the use of OTC products for symptomatic management. Serious adverse events have been rarely reported.

Of the tens of millions of individuals now using these medications, millions of them have obtained them from sources without meeting with a physician or other prescriber, or a pharmacist, without serious previously unknown safety issues being identified. Nonprescription availability from a pharmacist provides the professional expertise that facilitates the appropriate and safe use of the medications. With nonprescription status, the products will not be covered in prescription benefit programs and the prices will have to be sharply reduced to be competitive in the nonprescription marketplace.

Lilly and Novo Nordisk will strongly oppose such an action and the FDA will not initiate it. Therefore, this change will have to be initiated at the state level. Ivermectin is a recent example of how some states have changed the regulations regarding its availability.

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