will.'" (verse 39). And again, in verse 42: "He went away a second time and prayed, 'My Father, if it is not possible for this cup to be taken away unless I drink it, may Your will be done.'" Jesus was not defying His Father's will when He requested that the cup of suffering and temporary separation be removed. It was just the opposite: He reiterated His earnest need and desire to do His Father's will by stating, *"Yet not as I will, but as You will."* Jesus' prayer discloses to us His horrible physical and emotional anguish. By being separated from God His Father, His suffering was actually worse than death. On the cross, God the Father treated Jesus as though HE had committed every sin of every person on the entire planet for all time. The sinless Son of God took our sins upon Himself so that anyone who believes in Him will be saved from an eternity of torment and separation from the Father. When John the Baptist saw Jesus he proclaimed and foretold Jesus' death in John 1:29b (ESV): "Behold, the Lamb of God, who takes away the sin of the world!" Jesus took away the sin of all mankind by His selfless act on the cross.

At any time, Jesus could have asked His Father to take Him away as He did when the Jewish Leaders tried to seize and stone Him for blasphemy in John chapter 10, NIV: *"We are not stoning you for any good work," they replied, "but for blasphemy, because you, a mere man, claim to be God"* (verse 33) *and "again they tried to seize him, but he escaped their grasp"* (verse 39). Since Satan knows Scripture, he quoted from Psalm 91 when he tested Jesus in the desert: *"For it is written: 'He will command his angels concerning you to guard you carefully; they will lift you up in their hands, so that you will not strike your foot against a stone.'* (Luke 4:10-11, NIV). Jesus decided the timing of His death according to His Father's will: *"And when Jesus had cried out again in a loud voice, he gave up his spirit."* (Matthew 27:50, NIV) and *"Jesus called out with a loud voice, 'Father, into your hands I commit my spirit.' When he had said this, he breathed his last."* (Luke 23:46, NIV). No one killed Jesus; He willingly gave His life so that we would not experience eternal damnation and separation from Him, but instead we would have everlasting life with Him. The purple robe that was intended to humiliate Jesus, ultimately exalted him as one more piece of evidence that He truly is the Son of Man and the Son of God.

I'm glad that my dentist questioned me further on my purple passion. I now can give a more articulate answer for my certainty that I will one day stand with my Lord and Savior (with no broken teeth or swollen, painful mouth). Since purple is also the color of royalty, it's perfectly appropriate for me to wear it often, since I AM royalty! I am the daughter of the King of Kings and Lord of Lords. I have professed with my mouth that Jesus is Lord and I believe in my heart that God raised Him from the dead (Romans 10:9); and by grace alone through faith alone in Jesus alone, I have been adopted into the royal family of God… *"For those who are led by the Spirit of God are the children of God."* (Romans 8:14, NIV). If you're a believer and follower of Jesus, then YOU are royalty, too… so go right ahead, be theologically correct and join me in proudly wearing purple.

Abortion, Mifepristone, The FDA, and Pharmacists: Life, Death, Conscience, and Silence By Daniel A. Hussar

"You have made known to me the path of life; you will fill me with joy in your presence, with eternal pleasures at your right hand." Psalm 16:11 (NIV)

Abortion is one of the most polarizing topics in today's society. It is with that recognition that I identify my following primary purposes in writing this commentary:

1. To recognize strong differences of opinion that exist, and to voice my own in a manner that is respectful of the rights of others to hold and voice different opinions;
2. To identify what I consider to be the responsibility of the FDA to protect the growth and development of the "products of conception" (which I choose to identify as an "unborn baby"), as well as the health of the mother;
3. To support what I consider to be the rights of pharmacists and other health professionals to exercise conscientious refusal in declining to participate in actions that are contrary to their ethical, moral, and/or religious beliefs.

Within the last 75 years in the U.S., abortion has moved from an infrequent occurrence that was seldom discussed

to a frequent occurrence that is supported by many, and even celebrated by some, yet for many is strongly opposed. The topic is a continuing cause for opinion, debate, anger, and hate. In the last two decades, pro-choice advocacy has gone from "Keep abortion safe, legal, and rare." to "Shout your abortion!"

Mifepristone

In 2000, the FDA approved mifepristone (Mifeprex; also known as RU-486 and the "abortion pill") 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"). Mifepristone is a progestin antagonist and the consequences of its use are the termination and expulsion of the so-called "products of conception."

In response to the FDA approval, I wrote an editorial with the title, "Mifepristone: Controversy, Beliefs, and Politics – Issues for Everyone." The pharmacy organization that I anticipated would publish the editorial declined to do so for political reasons. Thanks to the beliefs and courage of the late pharmacist/publisher, Harvey Whitney, Jr., my editorial/opinion was published in *The Annals of Pharmacotherapy* (2001;35:373-5). Excerpts are included below:

> "In considering the application for approval of a new drug, the FDA thoroughly evaluates the studies of its effectiveness and safety. There is no question that mifepristone is highly effective for the indication for which it has been approved: the termination of intrauterine pregnancy."
>
> "Vaginal bleeding and uterine cramping occur in almost all women treated with mifepristone, and some women have experienced serious bleeding. However, the drug has been used safely in the vast majority of women, and news reports include observations such as 'The drug has been used by more than 500,000 women in Europe over the last decade with only one known death – a French woman in poor health.'
>
> "For many, the FDA decision to approve mifepristone is justified by the above information. However, its consideration of safety addresses just the safety of the woman. One respondent to the information about 'only one known death' notes 'That figure is wrong. At least 500,000 unborn babies died.'
>
> "That the occurrence of pregnancy is associated with a new life that is of value is reflected by the FDA's establishment of pregnancy categories, as well as the strong warnings against use during pregnancy that are included in the product labeling for many therapeutic agents." (Note: In 2015 the FDA discontinued using pregnancy categories to identify the extent of risk. The section on Pregnancy in the approved labeling for medications includes data [most if not all from studies in animals], a risk summary, and, if known, clinical considerations. Although some information pertains to adverse maternal outcomes [e.g., miscarriage], most of the section pertains to the risk of birth defects and other adverse developmental outcomes in the unborn baby).
>
> "The FDA clearly has a responsibility to protect unborn babies. However, it has ignored this responsibility in approving mifepristone and, in my opinion, it made the wrong decision."
>
> "Mifepristone will be supplied only to physicians who meet certain qualifications and who enter into an agreement that they will follow the guidelines for the use of the drug. It will not be made available through pharmacies."
>
> "Very specific guidelines (e.g., three visits to the healthcare provider's office) are provided for the use of mifepristone and misoprostol to terminate pregnancy, and patients and physicians must sign agreements regarding the use of the drugs and observance of the guidelines."
>
> "The guidelines for using mifepristone in the U.S. are less restrictive than the guidelines in other countries in which its use is approved (e.g., France). However, some contend that the guidelines are too restrictive."
>
> "As I write this, a story that was shared by a friend keeps recurring in my thoughts. As a teenager she became pregnant but did not marry the father. Abortion was an option but she chose to have the baby, a girl, for whom immediate adoption arrangements were made. When her daughter was in her late teens, she sought out the identity of her birth mother. They met and embraced and one of the first things the young woman said to her mother was 'Thank you for giving me life.'"

Personal beliefs and opinions regarding abortion and mifepristone vary greatly within society and among pharmacists. However, the vast majority of individuals (if not all of them) would agree with the following statements:

1. Regardless of the term used (e.g., products of conception, collection of cells, embryo, fetus, unborn baby), the "products of conception" are growing and developing during pregnancy. Many call it "life." Many in the scientific community agree that life begins at conception; if there is not growth and development at every stage of pregnancy, there would not be a cause for termination with mifepristone.
2. The administration of mifepristone during pregnancy terminates growth and development.
3. Any other drug with any other purpose for use that

can, like mifepristone, terminate a pregnancy, would be contraindicated during pregnancy.

4. The FDA has a responsibility to assess, describe, and communicate the maternal and "fetal" risks of adverse developmental effects and/or other harm with every drug when used during pregnancy, reflecting its duty to both the mother and the unborn baby.

Hormonal Contraceptives

Long before the FDA approval of mifepristone in 2000, there were medications and situations that resulted in ethical, moral, and/or religious concerns for some pharmacists and others. Estrogens and/or progestins included in hormonal contraceptive products have several mechanisms of action identified in their product labeling including the possibility that the hormones could interfere with the implantation of a fertilized egg in the womb. Some viewed this action as equivalent to an abortifacient effect, even though there was general agreement that this was not the most prominent contraceptive action and might be a factor in only a small percentage of women. However, there is no way of identifying the individual women in whom it would be a factor.

Situations that resulted in the strongest responses, both supporting and opposing, included the increased use of hormonal products as emergency contraceptives to reduce the possibility of pregnancy after unprotected sex (if other birth control failed or was not used). Some pharmacists declined to dispense products for this purpose because of the potential for them to cause what they considered to be an abortifacient action. The fact that the doses of hormones used for emergency contraception were substantially higher than the doses that are used on a daily basis as contraceptives added to the uncertainties and concerns. The discussions/debates escalated and were often argumentative and antagonistic. To address the increasing concerns, the delegates of the 1998 House of Delegates of the American Pharmacists Association (APhA), following extensive discussion, adopted the following policy ("conscience clause"):

"APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal."

As a delegate who participated in discussing and composing this policy, it is my opinion, both then and now, that it provides the appropriate balance and rights for those with opposing positions, and has served patients, pharmacists, and the APhA well.

Emergency Contraception

Levonorgestrel (Plan B) was the first product the FDA approved for use as an emergency contraceptive and it was used in a two-dose regimen with a high dose of 0.75 mg of the drug in each tablet to be taken 12 hours apart. Initially the product was only available on prescription, but the FDA subsequently approved nonprescription availability for women 18 years of age and older and by prescription for women 17 years of age and younger, with a later revision to reduce the ages by one year to 17 years and 16 years, respectively. In 2009, the FDA approved Plan B One-Step that contains 1.5 mg of levonorgestrel in a tablet for single-dose use as an emergency contraceptive and, in 2013, it approved nonprescription availability without any age restrictions.

The FDA has recently approved revisions in the Drug Facts label and Consumer Information leaflet for Plan B One-Step to remove wording about fertilization and implantation from discussions of the mechanism of action. The FDA explains the changes by stating that "the current science supports a conclusion that Plan B One-Step works by inhibiting or delaying ovulation and the midcycle hormonal changes" and that "the evidence also supports the conclusion that there is no direct effect on fertilization or implantation." To my knowledge, there have not been recent studies or enhanced science and evidence that justifies the changes that the FDA has approved in labeling that has been in place for many years. Indeed, the FDA statements include wording that appears to circumvent definitive language that would be expected from terms such as "science" and "evidence." As examples, the suggestion that science and evidence "supports" conclusions falls short of words like "demonstrates;" the statement that "there is no 'direct' effect on fertilization or implantation" ignores the question as to whether there are "indirect" effects; and the vague reference to "midcycle hormonal changes."

It is noteworthy that the labeling for ulipristal (Ella), a progesterone agonist/antagonist approved for prescription use as an emergency contraceptive includes the following statement in section 12.1 Mechanism of Action: "The likely primary mechanism of action of ulipristal acetate for emergency contraception is therefore inhibition of delay of ovulation; however, alterations to the endometrium that may affect implantation may also contribute to efficacy." In addition, the labeling for the prescription hormonal contraceptives that I reviewed continues to identify multiple possible mechanisms of action, in contrast to the abbreviated information for Plan B One-Step that does not mention fertilization or implantation. The revised labeling for this product gives the appearance of being politically motivated, rather than being based on new but undisclosed studies, science, and/or evidence. The illusion perpetrated by FDA damages its credibility, as well as the confidence that used to be accorded to "science" and "evidence."

Dobbs Supreme Court Decision
The 2022 Dobbs v. Jackson decision by the Supreme Court (SCOTUS) has been a lightning rod that has escalated the anger, arguments, and even violence regarding abortion. The decision has the effect of overturning the Roe v. Wade decision made by SCOTUS in 1973 that provided a national constitutional right to abortion. The Dobbs decision does not ban, restrict, or enable abortion, but rather provides the authority for individual states, instead of the federal government, to make pertinent decisions and laws.

The arguments regarding abortion have become much more intensive, bitter, and divisive. Some states have acted to ban or greatly restrict the circumstances in which abortion is permitted, whereas several states have legalized abortion even after "delivery," an action designated by critics as "infanticide."

Mifepristone Again
The availability of mifepristone has required an in-person visit with and dispensing by a certified prescriber. However, as a consequence of restrictions associated with the COVID pandemic, the FDA modified the Mifepristone Risk Evaluation and Mitigation Strategy (REMS) to permit the abortifacient to be dispensed by mail by certified prescribers or pharmacies. Most recently, on January 3, 2023, the FDA announced additional modifications to the REMS for mifepristone that will enable certified pharmacies to dispense the product to patients who provide a prescription from a certified prescriber. In addition, the "in-person" requirement (that patients see healthcare professionals in physical locations) which was temporarily removed during the COVID pandemic, is now permanently removed. To my knowledge, there have not been new studies, science, or evidence that justify a reduction of availability restrictions. Indeed, the removal of restrictions increases the risk of situations in which a woman with an ectopic pregnancy who takes mifepristone/misoprostol being unrecognized before the health of the woman is at serious risk. Is this another politically motivated decision by the FDA that may be, at least in part, a response to the SCOTUS decision?

Shortly prior to the FDA announcement, the Department of Justice provided its opinion that the U.S. Postal Service (USPS) could continue delivering mifepristone by mail, including in states that have passed restrictions on abortion subsequent to the SCOTUS decision. This opinion may also protect the USPS from being sued for delivering mifepristone.

Danco, the company that manufactures and distributes mifepristone, issued a press release following the FDA announcement on January 3. It notes that more than 4 million women in the U.S. have used the agent in the 20+ years since it was first approved. It also notes that it "is 97% effective in terminating early pregnancy" but that "approximately 3% of women will require surgical prevention for ongoing pregnancy, heavy bleeding, incomplete expulsion or other reasons such as patient request."

CVS and Walgreens announced that they will pursue certification of their pharmacies to dispense prescriptions for mifepristone, and it is anticipated that some other chain and independent pharmacies will also do so. The APhA announced on January 4 that it "advocated on your behalf urging FDA to level the playing field by permitting any pharmacy that chooses to dispense this product to become certified under the REMS."

Lawsuits
Lawsuits representing almost the entire spectrum of opinion regarding abortion, the FDA approval of mifepristone and enabling increased availability, and state laws have been initiated. In several states which have abortion restrictions, lawsuits have been filed to challenge the validity of restrictions to the availability of an agent that has been approved by FDA as the federal authority. The FDA has been sued by groups seeking to reverse the FDA's 2000 approval of mifepristone. The FDA has responded, in part, by stating that overturning of the approval "would cause harm by depriving patients of a safe and effective drug," and that it would "upend the status quo and the reliance interests of patients and doctors who depend on mifepristone, as well as businesses involved with mifepristone distribution" (my emphasis). When did it become part of FDA's responsibility to protect the interests of businesses involved with the development and marketing of products? It does not have that responsibility and its disingenuous response raises serious additional questions regarding its relationships with pharmaceutical companies and the drug approval process.

Conscience
Although many pharmacists will legally dispense mifepristone, there will be others who will exercise conscientious refusal and decline to dispense it while working in a certified pharmacy. The rights of both groups of pharmacists must be respected, and their actions based on their beliefs and opinions must be protected! But will that be done?

CVS and Walgreens have announced their plans to have their pharmacies certified to dispense mifepristone, at least in the states which have not banned or restricted its access. Will their policies accommodate the rights of their pharmacists who choose to exercise conscientious refusal? I am aware of two current situations in which nurse practitioners employed in CVS clinics have been terminated because they refused to prescribe mifepristone because of their religious beliefs. These nurses have filed lawsuits against CVS that allege religious discrimination. If

CVS terminates its nurse employees who exercise conscientious refusal, it should be anticipated that it will also terminate its pharmacists who do so.

The APhA has appropriately urged FDA to permit any pharmacy that chooses to dispense mifepristone to become certified. The APhA also issued a statement (July 25, 2022) in response to the SCOTUS Dobbs decision that includes support for pharmacists "providing FDA-regulated medications and evidence-based patient care services." However, in its statements on behalf of its members and the profession, APhA fails to identify its conscience clause policy and the right of pharmacists to exercise conscientious refusal.

In addition to its support for the rights of patients to obtain approved medications in pharmacies, as well as the professional role and responsibility of pharmacists in dispensing and providing medication administration services, APhA should also communicate support for the rights of pharmacists to exercise conscientious refusal, urge owners/employers of pharmacists to identify arrangements through which patients will have access to legal products that its pharmacist who exercises conscientious refusal declines to provide, and strongly oppose disciplinary or retaliatory action against a pharmacist who exercises conscientious refusal.

Silence

Most pharmacists will respect the right of their colleagues to have differing beliefs and opinions, and to decline to participate in certain activities. However, there are some who will strongly criticize and even vilify those with beliefs with which they do not agree. Some pharmacists will be sufficiently intimidated by what they anticipate will be strong criticism and possible disciplinary action and/or loss of employment, that they will not voice or act on their beliefs. This is a very unfortunate self-suppression of rights, but one which I fully understand and empathize with pharmacists in these situations.

I recognize that some readers may strongly criticize me for the opinions I have voiced in this commentary. However, my personal situation is one in which I do not fear criticism (and may learn from it), and am not vulnerable to retaliation or termination of employment. Therefore, I am better positioned than most others to voice my beliefs and concerns, and am encouraged by the supportive comments of those who share my views but are not in a position to otherwise share them. Although I have previously voiced my opposition to abortion with few exceptions based on my religious and moral beliefs, I regret that I have not done so more boldly, more often, and to more pharmacists and others.

Closing Perspectives

- "You shall not murder." Exodus 20:13 (The Ten Commandments)
- Abortion is a matter of life or death and there is no more important reason to exercise one's conscience than when a life is at risk.
- As a society, we need to sincerely ask the question: "What is different about the unborn child that deprives it of the rights awarded to other born members of civilization?"
- Critics should be challenged if they say that pharmacists who will not dispense every approved medication for reason of conscience should leave the profession. Our profession, our patients, and society need pharmacists who will act on their beliefs.
- Every one of the strongest advocates for the "right" to have an abortion was born to a mother who chose life.

Daniel A. Hussar is Dean Emeritus and Remington Professor of Pharmacy Emeritus at the Philadelphia College of Pharmacy. He has served as a member of the Board of Trustees and as Honorary President of the American Pharmacists Association (APhA) and is a Past President of the Drug Information Association and the Pennsylvania Pharmacists Association. He has served on the Board of Directors of World Vision and the Board of Directors of Christian Pharmacists Fellowship International. He is a recipient of the Remington Honor Medal of the APhA and the Distinguished Pharmacy Educator Award of the American Association of Colleges of Pharmacy.

Dr. Hussar's primary interests are in the areas of new drugs, drug interactions, patient safety, and issues facing the profession of pharmacy, and he has written and spoken extensively on these subjects. For many years he has published articles in several professional journals on the new medications that have been marketed in the United States. He serves as the Author/Editor of The Pharmacist Activist monthly newsletter.