

AN EDUCATIONAL UPDATE FROM THE SOUTHEAST LAW INSTITUTE™, INC.

To: Interested Persons
Date: July 2024
From: A. Eric Johnston
RE: The FDA, States Rights and Abortifacients

You may have seen the US Supreme Court's opinion in the *FDA v. Alliance of Hippocratic Medicine*, handed down on June 13, 2024. The case questioned the Federal Food and Drug Administration's determination that abortion producing drugs could be mailed to women in all fifty states without consulting a physician. The court determined the plaintiffs in the case, an association of prolife physicians, did not have standing to bring the lawsuit and the merits were not reached.

STANDING IN POLITICIZED CASES

From a lawyer's standpoint, the opinion is very good. For decades we have suffered at the hands of activist courts who permit all sources of lawsuits to proceed on politicized issues. The ACLU is known for filing such lawsuits and the courts have given them quite a bit of leeway to complain about cultural issues which those courts went on to decide in their favor. However, the present Supreme Court is making its mark by returning to the words of the constitution to decide whether to get involved on "politicized issues." The worst example of political judging was of course the infamous *Roe v. Wade* (1973) case which legalized abortion.

Bad Medicine

This FDA case was, however, a medically valid challenge to policy positions of the FDA which are not good medicine. However, writing for a unanimous court, Justice Brett Kavanaugh reviewed the facts and history of the case. The drug mifepristone causes abortions. In earlier years, this drug, along with misoprostol, were prescribed by physicians to cause an abortion. Good medicine was for the woman to visit her physician who would then determine whether administration of this drug regimen would be appropriate. Alabama has had a law since 2013 that required an in-person physician visit before the drugs could be prescribed. See §26-23E-7, 1975 Code of Alabama.

However, under pressure from the drug manufacturers and the abortion lobby, culminating with orders from the Biden Administration, the FDA determined that physician participation was not necessary, the drugs are safe, and could be sent to a woman in the mail. The plaintiff physicians disagreed and raised many significant medical objections.

The court ruled those physicians did not have an actual "injury" that would give the basis for making a legal claim. "Standing" is a very important legal concept which means a person cannot bring a legal claim against another person without proving that he has been caused some injury. Otherwise, lawsuits could be filed randomly without consequences. Therefore, the decision in this case is very important to protecting the rule of law.

On the other hand, the effort to protect women from bad medicine did not succeed. Those issues will need to be addressed again in separate litigation. The issue of FDA providing unregulated drugs is yet to be determined. There are two other cases pending which question the FDA regulations. One is in North Carolina and the other West Virginia. Both of these cases are in the Fourth Judicial Circuit Court of Appeals. There have been no rulings except in the lower courts.

FEDERAL PREEMPTION

The questions there are whether the state laws regulating administration of these abortifacients are preempted by the federal law of the FDA. Traditionally, states have been responsible for how medicine is practiced and what health care laws and regulations are passed. The FDA takes the position that these laws are preempted by federal law under the U.S. Constitution Supremacy Clause and on the basis that the FDA knows best and must be uniform in its administration of this medicine. Normally, the FDA approves a drug and leaves the practice of medicine to the states. In this case, the Biden Administration is attempting to overrule the ability of states to regulate medicine and require the abortifacients to be made available basically without regulation.

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It is obvious this is an effort to promote abortion. At this time, it is generally accepted that about two-thirds of abortions are now being caused by drugs. Women are not visiting physician's offices. They are purchasing the drugs through the mail and self-administering.

As we have explained in earlier educational updates, the prolife community in Alabama is concerned with these unregulated abortifacients coming into the state. Under the Alabama Human Life Protection Act, women are exempt from prosecution. The prolife community is generally agreed that women are also victims and should be ministered to rather than prosecuted. Consequently, it is necessary to regulate and, in this case, prevent abortion producing drugs being available to them.

Many of those drugs come from China and India. Alabama laws have no authority over those jurisdictions. Additionally, a recent development is that states like California, who have abortifacient providers who ship to Alabama, have passed "shield" laws. These laws say that they will not honor extradition requirements for states like Alabama who would indict abortifacient providers in California or other such states. This raises significant legal issues for enforcing the law.

ALABAMA REGULATION

The legislation which we have developed would regulate purchase of abortifacients over the internet. This is done by regulating the internet itself and the pay mechanisms for purchasing the drugs. We expect there will be opposition from internet providers and special interest groups. However, we continue to hope the Alabama Legislature will appreciate its prolife history and continue to protect unborn life.

This still leaves unresolved at this time the question of whether the FDA would preempt such an Alabama law. Our hope is that circumstances will be right to introduce a bill in the 2025 Regular Session of the Alabama Legislature to pass such a law. That may set up an attack of the FDA position.

Our position is that the *Dobbs v Jackson Women's Health Organization* case which overruled *Roe v Wade* and returned abortion regulation to the states, will control. In other words, the issue is not only about whether FDA protocols are good medicine. Also, the issue is simply that abortifacients are not permitted in the state of Alabama. We have a significant degree of confidence this is the correct position that the Supreme Court must ultimately order.

The Alabama Prolife Coalition had intended to introduce a legislative bill for that purpose in the past session. However, the legislature's fascination with and its concentration on gambling, and the IVF diversion, were obstacles to a reasonable chance to pass the bill.

At the same time, we are hopeful of the other lawsuits attacking FDA's politicized medicine. We are all very dependent on the FDA for protecting us with good medicines and medical protocols. We are saddened by the political shenanigans taking place in the interest of those who promote abortion.

Just like the issue surrounding attempted gender change of minors through medicines and surgeries, we have come to a place in American medical history that we must question those upon whom we have faithfully relied on to provide us good medicine. We know they still have that ability and hopefully our efforts to oppose this harmful politicalization will result in better medicine for us all.