

The Unintended Consequences of Mifepristone: Evidence from the Clinical Trials

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Last September (2000), following years of political and social controversy, abortions using a combination of mifepristone (better known as RU-486) and misoprostal were approved for use in the United States. The common wisdom among abortion providers and opponents alike was that the new procedure, known as "medical abortion" to distinguish it from surgical methods, will encourage abortions in this country by increasing their privacy, ease and availability. Based on this prediction the pro-choice Democrat presidential candidate promptly hailed, and the pro-life Republican presidential candidate promptly condemned, this new development.

Much of the speculation on the social effect of the new procedure focused on its ease and simplicity. In medical abortion a woman takes two pills two days apart, after which her body expels the fetus in a manner similar to a miscarriage. This suggests that the procedure will make abortion more available by increasing the number of doctors willing and qualified to provide one and allowing both the woman and the provider to remain anonymous. Instead of running a gauntlet of protestors at a specialized surgical abortion clinic, a woman may make an anonymous visit to her obstetrician or family physician to receive a prescription and induce an abortion in the privacy of her home or the doctor's office.

Like all new drugs in the United States, prior to its approval the efficacy of mifepristone was tested in an extensive series of experiments, called "clinical trials". In the most comprehensive set of trials, its use and characteristics were carefully observed in 2121 women in abortion clinics across the country.¹ Because of the controversy surrounding this new drug regimen the trials were attended by an unusual number of studies of its acceptability to women and their social and emotional experience using it. Before the trials even began, the Population Council, the abortion rights group that holds the U.S. license to market mifepristone, held focus groups of abortion patients to learn their perceptions and possible reactions to medical abortion.² During the trials they administered extensive before and after questionnaires inviting participants to share their perceptions and experience using the drugs.³ These were buttressed by extensive interviews with a nationally representative sample of trial participants to probe their thoughts and feelings more deeply.⁴ In addition, workers at the clinics in the trials were interviewed for their observations of participants' experiences.⁵ Not only the general findings, but many open-ended comments and cases from these studies were reported in the medical literature.

To many who already oppose on religious or cultural grounds the prevalence of abortions in America the new method's convenience represents but a further trivialization of unborn life. In prospect at least, mifepristone appears to reduce the awesome responsibility of bearing human life to the level of an inconvenient, even minor, malady. Got a headache? Take aspirin. Pregnant? Take mifepristone. That something profound and irreplaceable is lost by the latter action becomes less than apparent, perhaps forgotten. As one prospective medical abortion user explained her understanding of how the drug worked, "If you miss your period and you think that you're pregnant, you can take a pill in your medicine cabinet and your period will come."⁶

But you don't have to be conscientiously opposed to abortion to believe that abortion by pill may make ending pregnancy a little too convenient. France, certainly no pro-life bastion and where medical abortion was approved in 1989, mandates a 7-day waiting period to allow the mother time to reflect before ingesting mifepristone. And many abortion patients in the pre-trials focus groups "were concerned that mifepristone would make the abortion procedure too "easy" and would allow . . . women to take too lightly the decision to have an abortion."⁷

Such concerns are meritorious, and no doubt valuable to the larger cultural debate over abortion, but I suggest that they rest on a premise that is at least highly overstated. As I will argue below, evidence from the clinical trials shows clearly that both the delight of abortion advocates and the dismay of abortion opponents are rooted in a rosy misunderstanding of the ease of medical abortion. The extensive body of information on women's experience with mifepristone in the trials suggests, in fact, that its use is fraught with consequences for the abortion experience that must be at odds with the intentions of its purveyors. Not only is it more difficult than surgery, but medical abortion as used in the trials has the effect of making clear, to some women quite forcefully, the horrible, grisly character of abortion. Furthermore, it requires by medical necessity some features of the abortion experience that abortion opponents have been advocating for years. These unintended consequences are so great, in fact, that if a pro-life advocate were somehow perversely forced to design an abortion regimen, he or she would no doubt include some of the features of abortion by mifepristone.

Time to reflect

Take, for instance, a waiting period. Numerous initiatives have tried and failed to legislate waiting periods for abortion, but the mifepristone/misoprostal regimen enforces a 48-hour waiting period by medical necessity. The pre-trials focus group study noted (under "Disadvantages") that "the prolonged wait could heighten the psychological trauma of having an abortion for some women." As the women thinking ahead to the experience reflected:

That will be a long two days. You get a lot of questions in your head—oh my God, maybe I shouldn't be doing this.

Can I change my mind between the first and second pill as to whether to have an abortion?

*What happens if somebody takes the pill the first day and they chicken out and don't go through with it? What would happen to your body then?*⁸

The two-day waiting period between the doses of mifepristone and misoprostal enables the expression, and perhaps the enactment, of the ambivalence of many women regarding their abortion choice. It is not clear how often the effects of the mifepristone (the first pill) would be reversible if a woman changed her mind before taking the misoprostal (the second pill), but they clearly would be in some cases. Recall as well that the mother would be asking a recision, not from a clinic founded on abortion-rights principles, but from her local general practitioner who may be more willing to accommodate her with remedial medication. Unless suppressed, it is certain that some women will “chicken out” at the misoprostal stage and bring children to term who otherwise would have been aborted. Medical abortion’s enforced waiting period introduces the possibility that women can choose to abort their abortions.

Pain and bleeding

Then there is pain and bleeding. While these have never been desired objects of pro-life legislation, it is surely worth noting, while we’re considering the ease of medical abortion, that women using mifepristone experience all of these at much higher levels than with surgical abortion. In the trials participants were asked to list the worst features of the experience following their medical abortion. Pain and bleeding were at the top of the list. Nearly all (98%) of the participants experienced abdominal pain, a third (29%) so severe they were administered opiates. Bleeding was profuse and prolonged. Over 60 percent of the trial participants reported excessive or heavy bleeding the day following the abortion; for a fifth of these the bleeding required medication, surgery, intravenous fluids or transfusion. Most were still bleeding “normally”, that is, an amount comparable to normal menstrual bleeding, ten days after the procedure. Nine percent were still bleeding after 30 days.⁹

Her body, her choice

Medical abortion, further, forces a mother to recognize more clearly that the abortion is her choice and act. Surgical abortion enables denial on this point in a way that medical abortion does not. Most surgical abortions are performed under anesthesia; the mother goes to sleep, and wakes up no longer a mother. What happens in the interim occurs without her knowledge, and at the hand of another. By contrast, as an experienced French abortion nurse reflected, “When she has had a chemical abortion, a patient knows what she has been through.”¹⁰ In medical abortion the mother’s agency in taking her

child's life is clear, direct, and done with full alertness. She becomes, undeniably, her own abortionist.

To many abortion advocates this is an attraction of the procedure, because it takes control from the doctor and puts it in the hands of the woman. A woman's own body becomes the instrument of abortion, fulfilling the feminist ideal. Clinic nurses in the trials observed with approval that "mifepristone/misoprostal enabled a . . . more "empowering" abortion than a surgical procedure," producing "a heightened sense of responsibility [that] could be positive, could help a woman to experience her abortion as a affirmative act." But the stronger sense of agency bestowed by medical abortion is just as likely to give women pause. Indeed, "some providers emphasized that women who chose mifepristone had to be able to "commit themselves" to the abortion process" to a greater extent than with surgical abortion.¹¹ A physician's assistant at a Midwest abortion clinic poignantly describes the struggle brought home by the act of ingesting the abortion pill:

Nora: I'm primarily the person who gave people the mifepristone, which was what they saw as starting the process. And so the number of people who sat and looked at those pills—and you could see them deciding whether they were going to take that step or not—was amazing. It was not just, "Okay. Here take this pill." It was—people made that decision and they did this themselves and that's a big difference between medical abortion and surgical abortion.¹²

Encountering fetuses

The idea that medical abortion conveniently papers over the tragedy or difficulty of abortion more than surgery does, it should be clear by now, is simply false. But medical abortion goes even further. For, by medical necessity, mifepristone/misoprostal requires an aborting mother to encounter the one person who can most powerfully affect her understanding of the act: her unborn child.

Since about 5% of the time the mifepristone/misoprostal regimen alone fails to cause the fetus to be expelled, a condition which could be dangerous, women are encouraged to examine their discharge and identify the fetus when it is expelled. Much of the time, to the relief of some women, the fetus does not yet bear an obvious human shape. But in later medical abortions, and when the fetus becomes separated from the placental sac, arms, legs and optical buds may be visible, exposing a clearly identifiable human form. "For some women," reports the pretrials focus group study, "this aspect of a medical abortion procedure was particularly disturbing."¹³

Clinic workers from the trials described participants' reactions in greater detail:

Belle: Some of the women were not emotionally prepared for getting up from the toilet and going to throw their toilet paper away and seeing the fetus waiting in the little bucket. In the little collection bucket. We had a couple of real strong emotional responses to that. . . . Sometimes the fetus would pass and the sac would not and then they would see an obvious fetus lying in a little pool of blood in the toilet.

Jody: . . .It [medical abortion] could just magnify their feelings of guilt because it gave them more time to think about this and what is meant to see the fetus sac. That could create havoc sometimes.

Carol: They [clinic patients] were very upset and it was totally intact. . . It had those big eyes. It was sitting on the pad and she didn't want to see that. [One woman] was very shaken up, very upset. I think I remember we followed up with her.¹⁴

In the follow-up interviews the experience of one participant is reported in chilling terms:

Gwen: I saw the fetus. And that really freaked me out. I mean, I started crying, and, you know, I never realized that it was going to have eyes. It was going to have the beginning of hands. You know what I'm saying?. . .I still dream about it.

Researcher: What do you think was so upsetting about it to you?

Gwen: The fact that I may not have another chance. The fact of what it could have been, you know. . . .The fact that it was *my baby*.¹⁵

Clearly the recognition of their own aborted babies can powerfully undermine the denial of the fetus' humanity that makes abortion possible for many mothers. Studies from the clinical trials did not report how often such experiences occurred, but to prevent them medical abortions in France are prohibited beyond the fifth week of pregnancy, lest women risk "seeing a fetus with tiny but discernible arms and legs."¹⁶ In the United States, however, the procedure has been approved through the ninth week, and it is expected that in the vast majority of cases it will be used well past the fifth week. In the trials over half (56%) of the medical abortions were performed in the eighth or ninth week.¹⁷ Thus in medical abortions performed in America encounters with fetuses as recognizable babies are likely to occur with some frequency.

Not surprisingly, purveyors of mifepristone see this possibility as a "major disadvantage" of the procedure.¹⁸ In order to address the problem the Guttmacher Institute study offers the following revealing proposal: "A simple and reassuring way to alleviate this anxiety [about seeing the fetus] could be to offer women the option of seeing a picture of the products of conception at the sixth week of pregnancy. Alternatively, . . .women could view a bottle containing the blood clots and tissue of a six-week pregnancy."¹⁹ In an environment where depictions of the fetus have typically been dismissed as graphic pro-life sensationalism, a development (i.e., medical abortion) that motivates abortion providers to show prospects a fetus cannot be an entirely bad thing.

More importantly, while such a presentation may alleviate anxiety for some women, it is just as likely to dissuade others from having a medical abortion at all. This, at least, was the experience of one clinic that, after observing the severe reactions of some of the first patients in the trials, began counseling "to prepare potential users for the possibility that they might have a dramatic response to seeing the embryo:

Trisha: On the phone. . .we would say, “You need to realize that there is the potential that you will see the fetus when you pass it.” For some people they would be like, “No, I can’t do that.” And others would be like, “Oh, Hmmm.” And they’d ask for more conversation about that. . . .”²⁰

Clearly this counseling is also a screening. Mifepristone, supposedly the easier alternative, is rejected by some women as more difficult when they learn what it entails. To the clinic who is screening them out, that risk is preferable to the “dramatic response” they might have if not warned off, a response that might make them likely to say to abortion altogether, “No, I can’t do that.”

Conclusion

America’s experiment with medical abortion is just beginning, and it would be premature to form settled conclusions about where that experiment may lead. Surely the legalization of mifepristone cannot be conceived as a positive development for the cause of unborn life in America. Regardless of its effect on the experience or incidence of abortion, it will almost certainly present new challenges to pro-life advocates. But in these challenges there is also cause for hope, for at the same time that mifepristone makes it harder for advocates of life to get their message to women, it provides intriguing new possibilities for giving pause to the users of abortion.

Those who succeed in social innovation must deal with the law of unintended consequences; or as the folk saying warns, “Be careful what you wish for, because you may get it.” What abortion supporters successfully fought to institute as a means of making abortion easier and more available entails, it turns out, restrictions that make it manifestly less easy and available than current methods, and that, moreover, enable a woman more easily to form and act on reservations about the act she is committing. Just because it is more simple and direct, mifepristone makes it harder to hide or deny the reality of what happens when a mother slays her unborn child. And if an easier, more pleasant experience is thought to encourage women to have abortions, then medical abortion will be a boon to the pro-life cause. Compared to surgical abortion, mifepristone gives a woman time to think about what she is doing; produces bleeding and pain that correspond to the gravity of her decision; makes clear that she is the actor in the abortion; and forces her to face—and potentially recognize as her own—the human being whose life she is ending. For those who support unborn life, these unintended consequences of mifepristone are hopeful signs, and provide much material for advancing their cause. For they potentially affect not only a woman’s choice of means but also go to the heart of her decision to abort altogether.

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