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Part 2 of 2 - Dr. Matt Harrison Answers Critics of Groundbreaking Abortion Pill Reversal Treatment

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Abortion pill reversal, or APR, has been catapulted into the abortion conversation over the last few years, drawing strong support from some and scathing criticism from others. We invited Dr. Matt Harrison, Associate Medical Director of Culture of Life Family Services and one of the pioneers of the APR treatment, to respond directly to the criticisms.

This article is the second in a series of two in which we share our conversation with Dr. Harrison. Part 1 addressed criticisms related to women's experiences and concerns about their health and choices. Click here to read Part 1. Part 2, below, addresses criticisms regarding the science of APR and the potential of this treatment from a physician's perspective.

The Critics

The main criticisms of APR treatment focus on the recency of the science, questions about safety and efficacy, and the treatment's impact on women's choice and options. Here are some examples:

- A Media Matters article that claims APR treatment encourages abortion stigma
- An RHRC article in which NARAL claims that APR is insulting to women
- The American Congress of Obstetrics and Gynecology's (ACOG's) official response, which cites lack of scientific evidence to support APR treatment

- An article in *The Atlantic* in which ACOG and pro-choice providers raise questions on efficacy and safety
- An RHRC article by pro-choice physician Dr. David Grimes that refutes the science behind APR treatment

Part 2: The Science

Part 2 of our conversation addresses efficacy, safety, and challenges to the scientific evidence behind APR.

SpeakLife: The abortion pill reversal treatment is obviously a new science, and like all other medical advances, it begins in the research and trial phase. That's where you are right now. But critics are actually calling it "quackery." How you respond to that?

Dr. Harrison: A lot of people are nervous and scared when they come across new ideas or new ways of looking at things, especially in science. But they need to realize that a lot of this is actually very old science that is well-documented and well-founded. The progesterone treatments that we use have been used for over 20 years with complete safety in women for fertility treatments and for women who have what's called short luteal-phase cycles, when they do not have enough progesterone of their own. So we supplement progesterone and support their pregnancies. The medications that we're using have been proven safe and effective. They have been approved by the FDA. They have just not been specifically approved by the FDA for the reversal of RU-486.

So the science is solid, and whenever you are thinking about a new medical procedure in the way of treating things, you have to first look at the medical science and say, "Does it make sense?" You have RU-486, which blocks the progesterone receptor. We know that it binds with about a four times the affinity that natural progesterone does. We know though, that once that it's bound, it's always going to stay in flux. RU-486, or Mifepristone, is coming on the receptor, engaging it, and breaking off the receptor. So we are adding more progesterone to the system, so that there's a higher likelihood that the progesterone will be available and around when RU-486 comes off of the receptor. The progesterone will be there at a higher percentage so that it can bind to the receptor preferentially. There are studies from Japan that demonstrate that the effects of RU-486 are nullified in mice when those mice are also given progesterone. So, that logically makes sense.

Then you have to decide, OK, if we're going to do this, then how are we going to go about it? We've heard from some of the people in ACOG and the research facilities who are saying this is junk science. They're saying this is not done with controlled studies, and this is not done with ethical review boards. Well, it's kind of hard to imagine how you could ethically take 1,000 pregnant women, give all of them RU-486, give half of them progesterone, and the other half nothing. That's not ethical. But that seems like what they are [suggesting]. That's the only thing that's going to satisfy their scientific criteria. We could consider a prospective trial using different forms of progesterone, but a placebo arm to that study would be unethical.

SpeakLife: An interesting point.

Dr. Harrison: Also, we have a standard protocol that we ideally like to use, but we're not going to force any women into a specific protocol. There are some women who don't want shots, or maybe they are willing to take one shot, but then they want to take progesterone suppositories or some other form of progesterone. So we work with each woman, because these women have been through some trauma already, and they're in crisis pregnancies. They have a lot of pressures on them, and the last thing we want to do is to put more pressure on them. So we say, "What are you comfortable with? What do you feel like you would like to do to try to help save your baby?" Some of the women have received shots. Some of the women have shots and progesterone suppositories. Some of them have used creams; some of them have used pills. We do feel like, if we could standardize this and get more retrospective case studies, then eventually, we would have enough data to understand which one works best.

When we understand which one works the best, then we could possibly think about prospective trials, but that would always be very, very difficult in this situation, because of the ethical concerns.

Of course, it is hard for me to want to bend to the ethical considerations of boards who think it is ethical to abort babies. The other thing that's interesting is that they say, "These doctors are flooding women with progesterone, and progesterone is known to have side effects such as clots and DVTs." But they have no problem giving Depo-Provera or oral contraceptive pills that, in many cases, are much higher doses than what we are using. For the most part, we're using bio-identical, physiologically identical levels of progesterone. They really shouldn't have a problem with, essentially, replacing the biologically identical amount of progesterone that should be in a woman in the first place.

SpeakLife: Right now, you have around 300 physicians that are trained to offer the reversal protocol. What has to happen for a saturation to occur throughout the country? Are you looking towards FDA approval? Are you looking for support from ACOG? What is your threshold, if that makes sense?

Dr. Harrison: The simplest and most straight forward way would be if [the treatment] was available in emergency rooms, because emergency rooms are generally available to most people. You can get it onto protocols at different hospitals. I have heard some people complaining that we [prolife physicians] say we don't want unschooled providers performing abortions, but we think it's fine for anybody to give progesterone to a woman wanting to reverse their abortion. And I would say that those are two very, very different procedures. An abortion is quite different than giving someone a shot of progesterone. Emergency room physicians are skilled and intelligent. They can see a heartbeat and they know that the baby is in the womb and not an ectopic pregnancy, and they could very easily start the procedure.

[On FDA approval]

Also, there are lots of treatments and medications that are not FDA-approved. There are off-label uses of medications all the time in medicine. To get FDA approval is extremely time-consuming and expensive. So if we have a treatment that works and everyone knows it works, then it's not absolutely necessary. It's not something we are actively seeking.

[On APR versus doing nothing after taking Mifepristone]

The other issue that we have heard a lot about from the medical community is that if you don't do anything, [versus engaging in an abortion pill reversal] that you get just as good a result. That is probably the biggest complaint that we've had. But that statement is really supported by incorrect analysis of the literature. So, if you look at their own literature—the vast majority is through the Guttmacher Institute, which is kind of like going to Phillip Morris and asking for research on cigarettes—their own research shows, according to their statistics, an anywhere from 7% to 40% failure rate if RU-486 [Mifepristone – the first drug] is used alone.

But the problem is that they don't precisely define failure rate. So in a vast majority of their studies, a failure rate means that a dead embryo didn't come out of the mother. That's what they consider a failure. So even if the embryo has died, doesn't have a heartbeat anymore, if it doesn't come out, if it is not expelled, then they consider that an RU-486 failure. So if you really look closely at the data—and we'll be publishing something this coming spring with Mary Davenport and George Delgado—the number's going to be closer to a 7% to 20% failure rate [the embryo is still alive]. In other words, about 7% to 20% of embryos, if they are given RU-486 alone, will continue to have a heartbeat after they are given the medication. So our success rate is 55% and their failure rate is 7% to 20%. That's a very large difference.

So, the progesterone treatment certainly must be doing something.

SpeakLife: ACOG's claim is that 30% to 50% of women who only take the first drug can go on and do nothing and still have a baby. I'm wondering if abortion providers communicate that to their patients, that if change their mind, they can decide not to take the second drug and do nothing. Have you heard of that being offered to patients in terms of informed consent for chemical abortion?

Dr. Harrison: In news reports, I've heard doctors say that they say that. But in real life, I've never heard of a provider saying that. The mothers have told me that they were told nothing that can be done. If the baby doesn't come out, then they have to come in for a surgical abortion. I have never heard of a single case where the patient was told to just wait and hope for the best.

Another issue is: Are they giving them proper informed consent when they give them RU-486 in the first place? Are they telling these women, who are paying $300 to $500 for a chemical abortion, "Hey, this only has about a 50% chance of causing an abortion if used alone." I feel certain that they're not saying that. And that's not really what [critics] are telling us. They're saying 50% could go on and survive, if RU-486 is used alone, which is not supported by the research at all.

SpeakLife: Do you have any final comments or anything else you wanted to add to the discussion?

Dr. Harrison: This is an area where there are more and more prolife physicians; physicians that got into this business to save lives, not to do just procedures, not to just make a dollar, not just make productivity on abortion. There are people that got into this career to help mothers, help babies, to support lives. And I think there are more and more doctors who are coming up, and I

think the vast majority of physicians are prolife. They've kind of been thwarted by the medical community to think that the standard of care is to just have abortions. But as we can see, they're having a harder and harder time finding abortionists, people to do these procedures, because it is a nasty business. No one wants to do it. It's not pleasant. It's not like taking out a gallbladder.

SpeakLife: No, as evidence by the leaked videos from the NAF [National Abortion Federation] conferences. It was very interesting to watch and hear abortionists actually talk about the work they do. I think that there's actually a lot of common ground between what we are saying and what they are saying. We both believe the same things [about what abortion really is]. It's just that they're continuing on despite the truth.

Dr. Harrison: Yes.

Sarah Quale, President of SpeakLife

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NOTE: OUR CONVERSATIONS WITH DR. HARRISON WERE EDITED FOR CLARITY AND BREVITY AND REVIEWED FOR SCIENTIFIC ACCURACY PRIOR TO PUBLICATION. TO REQUEST A FULL TRANSCRIPT, PLEASE CONTACT US.
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