

August 28, 2017

The Honorable Mike DeWine
Attorney General of Ohio
30 E Broad Street, 14th Floor
Columbus, Ohio 43215

Dear Attorney General DeWine,

Recently, Greater Columbus Right to Life completed a review¹ of the reported complications from the use of RU-486 (also called Mifeprex or mifepristone) in Ohio. In March of 2016, the FDA approved a change to the drug label. Ohio is one of several states that requires the abortion-inducing drug, which carries a REMS black box warning, to be dispensed according to the FDA label. The label change effectively altered the dosing strength and extended the time in pregnancy that the abortion pill can be used from seven to ten weeks gestation. As part of that review, we were startled to learn that the rate of reported complications in Ohio has gone up by 400% since the FDA label change.

Our research was done by reviewing requested public records that are required to be filed by the dispensing physician each time any of a list of serious complications is reported or observed. This report, the “RU-486 Event Report” is required to be reported to the Ohio Medical Board under Ohio Revised Code 2919.123. Our office requested those public records for a time span that included January of 2012 through July of 2017. A compilation of the data revealed several surprises. The first was that we did not expect the increase to be as significant as it was: a five-fold increase in the fifteen months after the label change when compared to the fifteen months prior to the label change. The second was our observation that among the hundreds of public records which our office cataloged, there were no RU-486 Event Reports made by at least one network of for-profit abortion clinics operating in Ohio. There were no reports from either Capital Care Network of Toledo or Founder’s Women’s Health between 2012 and July of 2017, and there were no reports from the now closed Capital Care Network of Columbus (closed in 2012) or the now-closed Capital Care Network of Cuyahoga Falls (closed in 2013). The penalty for knowingly failing to file an RU-486 Event Report is a fourth degree felony on the first offense and a third degree felony for individuals who had previously been convicted of or plead guilty to one of several related offenses.

This is an incredible outlier, but we did not wish to jump to conclusions. After all, it is possible that the clinics did not provide RU-486 and it is theoretically possible that they did provide RU-486 but, unlike any other clinic in Ohio, did not have a single reported complication. Thus, we decided to investigate further prior to making any rushed claims against the businesses.

¹ See Attachment 1

However, we have identified statements from the current websites of both Capital Care Network² of Toledo and Founder's Women's Health³ that indicate the clinics have experienced a failure/complication rate of the abortion pill that is between five and seven percent. Previous versions of the websites for all of the clinics within the Capital Care Network and Founder's network, including those no longer in operation, state a five percent failure rate⁴ of the abortion pill. The FDA label⁵ is not consistent with either statistic, as it notes a failure rate of between five and eight percent. There is no reasonable conclusion except that the currently operating Founder's Women's Health and Capital Care Network of Columbus as well as the now-closed Capital Care Network clinics have systematically failed to report RU-486 complications to the Ohio Medical Board.

While someone defending the clinics might argue that neglect of the reporting law was unintentional, it is hard to defend that not a single administrator, physician, nurse, staff member, or volunteer at a multi-clinic network of Ohio abortion providers was unaware of this provision in the law. Indeed, that defense begins to grow quite thin when we look at the history and business practices of these clinics. At every level, this network of companies is engaged in business practices that are either completely mismanaged or that willfully ignore the standards that are expected of any entity wishing to do business in the State of Ohio and **especially** those engaged in the practice of medicine. If it is the former, their facilities are not safe, and if it is the latter, their facilities are not operating in a legal manner.

To further detail some of these claims, we would invite you to review the details relating to the closure of Capital Care Network of Cuyahoga Falls⁶ as well as the subsequent Ohio Medical Board⁷ sanctioning of one of the physicians who practiced there: David Burkons. Mr. Burkons' medical license was recently suspended for his prescribing practices, including prescriptions of controlled substances. As an aside, there do not appear to be any RU-486 Event Reports for Dr. Burkons when he was providing abortions at a Capital Care Network clinic (and there is no available information proving that he was or was not providing medical abortions and the abortion pill during his time at Capital Care), but after Capital Care Network of Cuyahoga Falls closed, Dr. Burkons opened a clinic in the same location and subsequently filed several RU-486 Event reports. Furthermore, we have recently sent a letter to the Ohio Secretary of State outlining the way in which Founder's and Capital Care Network have operated (or failed to operate) their business over the past decade. While the delinquencies, unpaid taxes, missed filings, expired licenses, and more appear to be minor at a micro level, at a macro level they show that the clinics have the same contempt for our laws and regulations that they have for the dignity of unborn life.

Furthermore, in our review of the abortion pill label change and the Ohio incidence of abortion pill complications, we encountered a research study conducted by the University of California San Francisco and co-authored by a physician at Planned Parenthood in Columbus. The study analyzed the data on abortion pill complications from four Ohio abortion clinics between 2010

² See Attachment 2 (pertinent pages supplied with our highlights)

³ See Attachment 3 (pertinent pages supplied with our highlights)

⁴ See Attachment 4 (pertinent pages supplied with our highlights)

⁵ See Attachment 5 (pertinent pages supplied with our highlights)

⁶ See Attachment 6 (pages 1-2 provided)

⁷ See Attachment 7 (pages 1-10 provided)

and 2014. Although the study was approved by a local ethics and research board, we noted several areas of concern. We are concerned that the clinics did not gain proper consent from patients before sending their private medical records to researchers. A recent scandal involving aborted fetal research practices outside of Ohio alleged that many (non-Ohio) Planned Parenthood affiliates failed to obtain the proper consent from clinic patients. A second concern is that the research notes indicate⁸ a high number of reported lost and incomplete reports that had to be excluded from the research: 352 and 17, respectively. The loss of these reports and subsequent inability to find them is very concerning, as is the failure to maintain complete and accurate patient reports, and should be investigated.

To further provide background for these concerns that we have raised, we have attached a number of documents and exhibits for your review, and we are enclosing a copy of a recent letter we sent to Ohio Secretary of State Jon Husted.

To be very clear: as an organization we believe abortion to be an act of absolute barbaric cruelty against an unborn human. We work every day to build a culture that protects innocent human life from the moment of conception until natural death. Were it not for the fact that these businesses exist for the primary purpose of intentionally destroying innocent, unborn, human life, these irregularities would not have come to our attention and we would not be petitioning you to provide investigation, oversight, and, if appropriate, prosecution.

We are not asking that you use your role as Attorney General to act on a bias for or against the subject of abortion or to mediate philosophical and moral arguments between pro-life organizations and abortion providers. Our work is particularly focused on creating change at the personal level, which is why our focus is working with individuals, families, churches, and communities to change hearts and minds. However, we believe that the scope and scale of what appears to be happening amounts to systematic mismanagement and reckless disregard for accepted business and medical standards that directly places patients in danger and harms communities. Because it is happening in a network that extends to multiple businesses located in several counties and related to laws and regulations overseen by multiple offices and agencies, we believe that it is appropriate to request review by Ohio's chief law officer.

Therefore, we would like to respectfully request that your office review the concerns that we have raised and take any reasonable legal or regulatory action appropriate. If it is your finding that Ohio law has no remedy for these egregious activities or that the complaints are best filed with other entities, we would appreciate that perspective as we continue our education work and policy recommendations.

Sincerely,

Beth Vanderkooi
Executive Director
Greater Columbus Right to Life

ENC: Attachments, Letter to Secretary Husted

⁸ See Attachment 8 (pages 1-5 attached, pertinent sections highlighted)