2019 HOUSE HUMAN SERVICES COMMITTEE

HB 1336

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Union Room, State Capitol

HB 1336
1/21/2019
31111

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Elaine Stromme by Nicole Klaman

Explanation or reason for introduction of bill/resolution: Relating to printed information by Dept. of Health relating to informed consent requirements before an abortion

Minutes: 11

Vice Chairperson Rohr: Opened the Hearing on HB 1336

Representative Daniel Johnson: Introduced HB 1336 Read supporting testimony, **See attachment 1**
(0:01:00-0:05:54)

Representative Greg Westlind: What is the length of time it takes to abort a baby after taking this drug? If so, what is the length of time to intervene with another drug? If so, is there any physical damage recorded damage or chance of damaging the babies' health after both of these drugs have been administered?

Rep. Johnson: It varies. The first chemical administered is Mifepristone and progesterone will reverse. The length of time a baby has been save has been immediate to 70 hours. Survivability rate after reversal is 2/3 of the cases. If both chemicals are administered, the abortion will occur within a week's timeframe.

Discussion regarding need of additional testimony copies

Representative Mary Schneider: Do you plan on providing medical testimony? I'm trying to determine who to direct medical questions to.
(0:07:59)

Rep. Johnson: I do have some legal minds that will be testifying. Regretfully, I do not have a doctor present. I was in contact with Dr. Gary Obrich, OB GYN of the Bismarck area, and he could not attend today. He did state he would definitely make the Senate hearing when we get this through.

Rep. Schneider: Are you basing the medical statements that we've heard in your testimony on the case study?

Rep. Johnson: In part, yes.

Representative Mary Schneider: Are there any other pieces of research your comments were based on?
Rep. Johnson: There are, however limited. I included this case study as it was the most recent.

Rep. Schneider: Are there any case studies out of medical journals?

Rep. Johnson: Not that I know of.

Representative Gretchen Dobervich: I am concerned about the lack of evidence of impact on the developing fetus when a combination of these medications has been administered. There is no longitudinal research done on long term impact? There is just the one case study?

Rep. Johnson: I think there has been more than 1 study.

Rep. Dobervich: Is that information that can be provided?

Rep. Johnson: I can. Per my conversation with Dr. Obervich, he stated progesterone and it's been used for 50 years. In any cases of abortion reversal, none of the babies born demonstrated any side effects that is known.
(0:10:53)

Rep. Dobervich: Even if you could provide links to scientific research that has been done, it would be appreciated. Thank you.

Rep Johnson: Absolutely

Representative Karen Skroch: The focus has been on the damage to the fetus if the reversal occurs. Can you explain the damage to the fetus if the reversal is not allowed?

Rep. Johnson: The fetus starves to death, it dies.

Vice Chairperson Rohr: Any further questions? Seeing none. Further Supporting testimony?

Senator Janne Myrdal, District 10, Co-sponsor of bill: Oral support testimony given, written testimony not provided.
Why are we dealing with abortion any different than any other medical procedure? As a woman, I want all the information surrounding my options. The abortion industry, unable to testify today, stated, "This is an undue burden on women". I would say full medical disclosure of any medication I take is not an undue burden! This bill would give women an opportunity

to reverse, within 24 hours, the decision of a medical abortion. This not only affects the life of the woman but also the life of an unborn child.
(0:12:01-0:14:41)

Representative Schneider: Would you agree when information is given that it be credible, tested, accurate and appropriate.

Senator Myrdal: Yes. The problem, as with any medical issue, medical personnel is very loathed to testify due to HIPPA rules. This issue is also difficult because it is private and personal. With this said, any women I've talked to refuse to come forward. We are in the stage of discovering and trying to give the women a choice of reversal. In 2-4 years I believe there will be further medical evidence surrounding this.

Vice Chairperson Rohr: Further Testimony in support?

(0:16:02)

Nadia Smetana, Registered Nurse and Director of Dakota Hope Clinic: Oral supporting testimony given, information pamphlet provided, **see attachment 2**
Simple request for you to think about relating to any area of your life. Refer to a time you immediately regretted something you did and wanted a do-over.
A lot of women do regret, at some point, the decision of abortion. Surgical abortions are done in minutes, there's no going back on this decision. Medical abortions are done over a period of days, there is a chance to reverse within a certain timeframe. This bill would simply insure women know of this option.
2 reasons I support this bill. 1.) Good evidence, scientific evidence, the use of progesterone for reversal is safe and effective. 2.) It is reasonable and appropriate to respect a woman's right to choose reversal of a medical abortion.
A chemical/medical abortion is a 2 step process. A pregnant woman must be 9 weeks' gestation to be eligible.
1.) She will be administered the medication mifepristone in office. Over a period of 2-3 days it acts to deprive fetus of blood and oxygen, gradually.
2.) 2-3 days after the initial drug, the 2nd drug is taken. This drug starts uterine contraction to expel the dead fetus. The completion of the process takes an additional day or 2. The criteria for reversal: The 2nd drug cannot have been taken. Must be within 0-72 hours after ingestion of 1st drug. An ultrasound must be administered within 72 hours of the reversal process to confirm viability. This can be done before or after reversal, after if time is a concern. If not viable, stop progesterone. The reversal procedure involves a prescribing physician provides supplemental progesterone, the anecdote to the mifepristone. If the pregnancy is viable progesterone will be taken through first trimester. The success rates are 68% with oral progesterone and 64% with progesterone injections. If only the first drug, mifepristone, is administered and the reversal process is withheld, the fetus survival rate is 25%. The risk of progesterone and mifepristone causing birth defects to the fetus is 3%, which is the same percentage of birth defect risk of the general population.
Our clinic has addressed the issue of uninsured who may not be able to pay for the reversal process. We have partnered with 2 pharmacies and will provide funds to cover the progesterone.

Vice Chairperson Rohr: What is the cost for the reversal medication?

Nadia Smetana: An average of $500.00, depending upon length of time needed through the first trimester.

Representative Greg Westlind: Are the 3% birth defects caused by this drug?

Nadia Smetana: The 3% rate is the same as the general population. There is no increased risk of birth defect.

Rep. Westlind: When a fetus is denied up to 72 hours of oxygen or blood do you think there is a good chance that there will be some sort of defects?

Nadia Smetana: The observational studies do not show this.

Representative Gretchen Dobervich: You've discussed the safety of this however the American Medical Association (AMA) and American Congress of Obstetrics and Gynecology do not support this. Why?

Nadia Smetana: I've never understood this. I've read that the concern being the mind change. As though it wasn't thoroughly thought through from the beginning by the pregnant woman. However, all women have the right to change their minds. I have not read any real medical reason why they do not support it.

Vice Chairperson Rohr: Any further questions? Seeing none. Further supporting testimony?

Christopher Dodson, ND Catholic Conference: Read supporting testimony, **See attachment 3**
(0:38:05-0:45:12)

Rep. Dobervich: You stated in your testimony that the FDA has a approved a protocol for the use of mifepristone and the other medication. Is there an FDA approved protocol for the use of progesterone in conjunction with mifepristone?

Christopher Dodson: I do not know.

Representative Mary Schneider: Is any of the information you've provided from a medical journal?

Christopher Dodson: The information sighted in the fact sheet are peer review, publication to scientific studies.

Rep. Schneider: Which one's are peer reviewed?

Christopher Dodson: I do not know.

Rep. Schneider: I agree that women should be informed and have as much information as they need to make solid decisions. When the government is dictating what that information is, would you agree it needs to be creditable and accurate.

Christopher Dodson: The facts are undisputed. The question of medical certainty that you seek is rarely available and the Supreme Court has recognized that. The informed consent requirements can be factual but not certain. That would be an impossible burden upon the legislatures'. This fits within our informed consent requirements the type of things the legislature determines a woman should know.

Rep. Schneider: I'm concerned because we don't have medical studies. On something of this importance we should. I think these are observational, which differs from a peer reviewed study. One of them includes 6 people and one is a fact sheet. I'm concerned about the lack of medical community support for this, except in the limited groups described.

Christopher Dodson: It is a struggle to get physicians here on time. But we have physicians, in ND, whom are familiar with this process and the medications. We will try to get that information to you. More important, there is no peer reviewed study showing this doesn't work, that it is dangerous to the woman or the child. There is plenty of evidence that shows it works and is safe. The question is; Should women be deprived of the knowledge of the availability of reversal?

Vice Chairperson Rohr: Further questions? Any further support testimony?

Mark Jorritsma, Executive Director of Family Policy Alliance of ND: Read supporting testimony, **See attachment 4**
(0:51:06-0:56:55)

Vice Chairperson Rohr: Anyone who has further testimony in support, please hand out your testimony.

Medora Nagel, Executive Director ND right to life and board member on National Right to life committee: Oral supporting testimony given, written testimony not provided.
In support and recommends a Do Pass.

Donna Henderson, requested to read testimony on behalf of Linda Thorsen.

Vice Chairperson Rohr: I apologize, but we do not allow reading testimony in behalf of an individual.

Donna Henderson: I will just pass it out then. **See attachment 5**, handed out written supporting testimony by Linda Thorsen.

Donna Henderson, Citizen: Gave oral testimony, written not received.
As a citizen, I would like to say I'm in support of this bill as well. 2 points came up during testimony I'd like to address. Rep. Westlind was concerned about lack of blood and nourishment causing birth defects. I have a personal experience involving my pregnancy with my twins. During the pregnancy, my placenta favored one twin vs the other, they were

born half a pound weight difference. We were thankful for 2 healthy baby boys. My point is, the gradual nourishment deprivation didn't cause any birth defects. Comment to Rep. Schneider; I would be so upset if I was facing a decision like abortion and was not provided all of the information regarding reversal. We have to have all the information to be able to make the right choice.

Vice Chairperson Rohr: Questions? Further Support?

McKenzie McCoy, Citizen from Watford City, Representing the local right to life chapter: Gave oral support testimony, written testimony not provided.
I am a statistic that was not fully informed. I made a decision to have a medical abortion. I was informed about the discomfort, pain, cramping and issues that could happen. I was not informed that I could reverse the decision I had made. If I would have been informed that I had a 2nd chance to give my child a 2nd chance, I would have taken it.

Vice Chairperson Rohr: Thank you for your testimony. Any questions? Seeing none. Further support? Seeing none. Anyone here in opposition to HB 1336?

Opposition

Tammi Kromenaker, Director of Red River Women's Clinic: Read opposed testimony, **See attachment 6**

Vice Chairperson Rohr: Questions?

Representative Karen Skroch: Do You advise women about the medical abortion reversal?

Tammi Kromenaker: No we do not.

Rep. Skroch: If a woman starts the process and then comes back to you and says I don't think I want to complete this. Does your facility refer them to someone else to get help with that situation?

Tammi Kromenaker: No, I've never had a patient request a "reversal". If they did, I'd be honest and say based on scientific research there is nothing reliable that will reverse the abortion.

Representative Bill Tveit: In the 3rd paragraph of your testimony it reads, "HB 1336 would undermine our ability to have honest conversations with patients about their decision." Please explain what you mean by honest conversations.

Tammi Kromenaker: I think when we are asked to give information that our physicians and national organizations have told us is not true we are undermining our relationship with our patients.

Rep. Schneider: What is missing? We have heard a lot of testimony saying it's ok to give progesterone and there were percentages that were successful, with successful births. What

do we really look for to show the information given or received is scientifically accurate or appropriate?

Tammi Kromenaker: When mandating medical information, we can look to Physicians and ACOG for guidance on this. We need to use those physicians to provide us with the credible information to be passed to patients.

Rep. Schneider: What should be in a study? Is an observational study ok to rely on? If not, why and what do we need?

Tammi Kromenaker: Basic things I know a study should have: controls, should be published in a peer review journal, placebo and medication, varying regimens.

Rep. Skroch: Do you realize the difficulty of a blind study asking for a placebo in these cases?

Tammi Kromenaker: I am not a researcher and do not know how to put together a study.

Vice Chairperson Rohr: Additional questions? Seeing none, Thank you. Further opposed testimony?

Heidi Seltzler-Echola, Nurse Practitioner in ND: Provided opposed testimony, **See attachment 7.**
(1:16:08-1:19:46)

Rep Skroch: I'm aware of the application of progesterone therapy injectable or oral to stabilize pregnancies. I'm also aware this is probably well documented. If this is the case, why doesn't that documentation apply in the medical abortion reversal scenario?

Heidi Seltzler-Echola: You are correct, progesterone is used to prevent miscarriages and helps infertility. It is FDA protocol for this. However, we don't have studies showing possible complications or interactions with medications. There are also variations between the types of progesterone administered; injectable, suppository and oral. We do not know the safe levels or dosage of this. There is no FDA protocol right now. No medical basis for it.

Rep. Skroch: I would venture to say the doctors performing the reversals are not inexperienced nor do I believe they are using random dosing or inexperienced dosage. This is not experimental procedure but instead is backed up by medical practices.

Heidi Seltzler-Echola: Yes, providing progesterone for miscarriage is well established. I can't speak for what doctors are prescribing.

Vice Chairperson Rohr: Further opposing testimony?

Kristie Wolff, Executive Director of ND women's network: Read opposing Testimony, **see attachment 8**
(1:23:39-1:25:15)

Vice Chairperson Rohr: Neutral testimony?

Andrew Alexis Varvel, citizen of Bismarck district 46: Provided oral and written neutral Testimony, **See attachment 9**.
Also provided;
Attachment 10, opposed information- Oral testimony not provided
Attachment 11, support information- Oral testimony not provided

Vice Chairperson Rohr: Further Neutral testimony? Seeing none.

Vice Chairperson Rohr closes meeting

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Union Room, State Capitol

HB 1336
1/22/2019
31239

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Elaine Stromme by Donna Whetham

Explanation or reason for introduction of bill/resolution:

Relating to printed information by Dept. of Health relating to informed consent requirements before an abortion.

Minutes:

Chairman Weisz: Opened hearing on HB 1336. Are there any suggested amendments?

Representative Dobervich: I would like to propose amendment that this usage of progesterone, that the procedure would be approved by the FDA , it would put a trigger in the bill that it would go into place only after it received FDA approval.

Representative Schneider: Seconded.

Representative Rohr: When you are doing evidence based practice there is a hierarchy of approval and it is always great if you can have peer review in Articles that support that but it is not always the case. It is many times in evidence based practice that guidelines are written even though there aren't peer review journals.

Representative Skroch: There are procedures that are used every day that don't necessarily have the highest recommendation and there is evidence that they are successful. I think this is one of those cases. When you look at 68% of the reversals that have been attempted have succeeded. If you say there isn't approval until enough of these reversals occur. That might not happen until 10 years from now. How many choices for women and babies that will be lost because they don't even know this procedure exists? We are looking at a possible cost of $500 to reverse a chemical abortion. I don't see that as a terrible burden and I think the burden on us is to allow that information to be shared prior to that choice.

Representative Porter: Inside of medicine there are all sorts of off label uses for medications that physicians have the ability to do. It does not make them illegal. To tie something back to the FDA isn't a prudent way to do it. There is a medication we used to carry on the ambulance for asthma and somewhere along the line someone found one of the side effects of that drug was to stop contractions in women that had premature labor issues. Suddenly it was started being used for pregnant women. It was an off label use that was

perfectly legal for the physicians to use. I would oppose this kind of amendment. I do think there are circumstances that exist where off label uses are acceptable inside of the practice of medicine.

Representative Schneider: In response to that there is some medicines that had catastrophic birth defects when they are used for nausea in pregnant women. We don't always know what will happen. Sometimes using off label medicines in ways they weren't intended can have positive consequences but they can also have disastrous consequences. In this case the study that is being relied on here has been attacked a lot. It is not a simplistic thing to say we cannot always have peer controlled evaluations. We really don't know how progesterone could affect a developing fetus. I don't want to be responsible for birth defects in the future because we rushed into this. This is not a reliable scientific study we are seeing here. (9:21-10:51)

Representative Damschen: We have to pay attention to the actual results that we have observed here. We had some positive testimony about the results of the reversal process.

Representative Kiefert: I would resist the amendment too because it would just keep the bill from going anyplace. I think the fact the babies are being born alive without any birth defects should be enough to give these women the information that could possibly save the life of their baby. We don't know how many women would have changed their mind after taken the first pill.

Representative Dobervich: My Intention was not to amend this bill so it doesn't go anywhere. I think about medications and the terrible affects we can have both emotionally and financially. If we are putting off label use of medication out there as the state do we have any sort of legal responsibility the should down the road we end up in a bad situation. Are we released of responsibility for having put off label use out there?

Representative Rohr: There is an organization by the name of the American Association of Pro-life Obstetricians and Gynecologists that does support this procedure. They did have a public statement that said Progesterone has been safely used during pregnancy for decades without undesired effects. For those infants that survived there was no evidence of birth defects associated with the medication. The efficacy of reversal which is 55 % on average is higher than sitting and waiting alone to see if a pregnancy continues. I would oppose the amendment.

Chairman Weisz: Any further discussion? Seeing none. I will take a voice vote on the amendment.

Voice Vote on the amendment to HB1336**. Motion failed.**

Chairman Weisz: Who is providing the materials and who is in charge of the data base or information for the medical professionals? Are we requiring the Health Department to take care of the information and to maintain a database, because the language doesn't say. The bill says "information and assistance in locating a medical professional who can aid in the reversal" on page 3. Somewhere you have to have a list of those professionals? Did this come up in the hearing?

Representative Schneider: Do we have a fiscal note on this for the cost of preparing the booklets and providing a database?

Chairman Weisz: I am assuming the Health Department will be doing this. There is a cost but how will they know who the medical professional is that can aid in a reversal?

Representative Rohr: There is a booklet that they distribute now called Information about Pregnancy and Abortion and there would be an addendum to page 16 which says it may be possible to reverse the effects of a chemical abortion utilizing the if the second pill has not been taken. They also list a website.

Chairman Weisz: So website would list the medical professionals? Because we are mandating that they have to provide assistance in locating a medical professional. I am curious how that will happen. It is fairly simple to add it to the booklet there.

Representative Rohr: I think we would need additional information then.

Representative Schneider: If we are waiting on this could we get a fiscal note on what it costs the Health Department to redo their books.

Chairman Weisz: I assume the cost of redoing the book would be minimal depending on how you determine who is supposed the medical professionals. That might be more costly than the change in the book. If we pass this we are mandating the Health Department to refer them to professionals and somehow they have to determine who they are.

Representative M. Ruby: I am going through testimony and there is a network, so we could try to see if they have something and I can check to see if there is an existing database.

Chairman Weisz: If we can't resolve the questions we can wait on this. Hearing closed.

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Union Room, State Capitol

HB 1336
1/23/2019
31350

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature Elaine Stromme by Nicole Klaman

Explanation or reason for introduction of bill/resolution:

Relating to printed information by Dept. of Health relating to informed consent requirements before an abortion

Minutes: Attachment 1

Chairman Robin Weisz: Opened meeting on HB 1336

Chairman Weisz: I expressed a concern which nobody else seemed to have. Page 2 line 29- page 3, line 1 and 2. The language should end after line 31 where it says "directing the patient where to obtain further information" The reason as I have indicated it says assistance in locating a medical professional. This states that if someone calls in the department has to find them a doctor. Provide information, would support giving a website, contact your physician, etc. any suggested amendments.

Representative Mary Schneider: Off topic here but I sent a copy of an article which is Peer reviewed and a controlled study on reversal information from the New England Journal of Medicine. If we are going to give out information, but if it's not creditable I have a problem with the state being the provider of that information. (See Attachment 1)

Representative Dwight Kiefert: I was told there was a 24-hour hotline women can call which will get them in touch with a doctor that will do the reversal. We have doctors in our state available to do this reversal.

Chairman Weisz: Is it your desire the Health Department reference the hotline?

Rep. Kiefert: An email went around yesterday she referenced a Grand Forks woman who sought an abortion in Fargo. If the hotline number would be provided, it's better than no alternative at all.

Chairman Weisz: Rep Schneider's issue is; Should the state be promoting something that some consider risky or not established. My concern, I don't want to be asking the health

department for something or to do something that is not within their ability to carry out reasonably.

Representative Chuck Damschen: I'm led to believe a patient in this situation can contact their local physician. (7:00)

Chairman Weisz: I agree it would say contact your local physician as well as list other possible sources. My concern is "the department has to provide the assistance". How do they know who does or does not do this? To me it implies they would have to contact every doctor in the state of ND and then have that list available. Does anyone else have a concern about the language in the bill? Language stays.

Rep. Dobervich: Can you provide more information on the hotline?

Rep. Kiefert: That is listed in the testimony

Rep Schneider: There are many drugs used in the medical profession that are off label. It wasn't designed for the purpose but it works. Progesterone in a sense being this as it's not tied back to FDA protocol. Progesterone is a natural hormone used to retain pregnancy. The only side effect is a child lives.

Rep. Tveit: I move a DO PASS on HB 1336.

Representative Ruby: Seconded.

Chairman Weisz: Any further Discussion?

Rep. Keifert: Page 2 line 14 and line 29. It says "maybe" possible to reverse the effects of an abortion. It's not saying it's 100% successful. In medicine what is 100%?

Rep. Schneider: The case study I referenced is very informative. The scientific journal is saying it's almost the same and being claimed as the same as a reversal action if the 2nd drug is not administered and the progesterone is administered. When the state gets involved I strongly feel that we need to provide accurate credible information. We have a higher level of responsibility to the women of our state.

Rep. Keifert: I put my faith in the doctors providing the reversal services.

Chairman Weisz: There is a Motion on the floor, Clerk call the roll call
Motion Carried, Do Pass on HB 1336.
8 Yes, 3 No, 3 Absent

Rep. Skroch: Carrier. Hearing closed.

Date: 1-22-19
Roll Call Vote #: 1

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. HB 1336

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: only "after FDA Approval"

Recommendation: ☒ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Rep. Dobervich Seconded By Rep. Schneider

Representatives	Yes	No	Representatives	Yes	No
Robin Weisz - Chairman			Gretchen Dobervich		
Karen M. Rohr – Vice Chairman			Mary Schneider		
Dick Anderson					
Chuck Damschen					
Bill Devlin					
Clayton Fegley					
Dwight Kiefert					
Todd Porter					
Matthew Ruby					
Bill Tveit					
Greg Westlind					
Kathy Skroch					

Voice Vote

Total (Yes) _____ No _____

Absent _____

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Motion failed

Date: 1/23/19
Roll Call Vote #: 1

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. HB 1336

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Rep Tveit Seconded By Rep. M. Ruby

Representatives	Yes	No	Representatives	Yes	No
Robin Weisz - Chairman		✓	Gretchen Dobervich		✓
Karen M. Rohr – Vice Chairman	A		Mary Schneider		✓
Dick Anderson	A				
Chuck Damschen	✓				
Bill Devlin	✓				
Clayton Fegley	✓				
Dwight Kiefert	✓				
Todd Porter	A				
Matthew Ruby	✓				
Bill Tveit	✓				
Greg Westlind	✓				
Kathy Skroch	✓				

Total (Yes) 8 No 3

Absent 3

Floor Assignment Rep. Skroch

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1336: Human Services Committee (Rep. Weisz, Chairman) recommends **DO PASS** (8 YEAS, 3 NAYS, 3 ABSENT AND NOT VOTING). HB 1336 was placed on the Eleventh order on the calendar.

2019 SENATE JUDICIARY

HB 1336

2019 SENATE STANDING COMMITTEE MINUTES

Judiciary Committee
Brynhild Haugland, State Capitol

HB 1336
3/4/2019
#33168 (1:41:01)

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Meghan Pegel

Explanation or reason for introduction of bill/resolution:

A BILL for an Act to create and enact a new subdivision to subsection 1 of section 14-02.1-02.1 of the North Dakota Century Code, relating to printed information by state department of health; and to amend and reenact subsection 11 of section 14-02.1-02 of the North Dakota Century Code, relating to informed consent requirements before an abortion.

Minutes: 14 Attachments

Chair Larson opens the hearing on HB 1336. Senator Osland was absent.

Daniel Johnston, District 24 Representative, testifies in favor (see attachment #1)

(6:45) Senator Bakke: You quote trials in your testimony. Are these FDA clinical trials? To my knowledge there have been no clinical trials of these two medications by the FDA.

Representative Johnston: I don't believe they are FDA approved trials; they are observational case studies done by doctors. I included the packet for your reference.

Senator Bakke: There haven't been any clinical trials, so do you know what the effect of this medication will be on the fetus or mother if they are to be used?

Representative Johnston: Progesterone has been prescribed and used successfully for over 50 years now. In any case studies that have been done concerning progesterone and abortion reversal we've found that a mother who goes onto deliver the baby has no other side effects as the national norm. There's no discernable difference between a woman who was treated with progesterone and one that was not.

Senator Bakke: Were they given this pill to start the abortion before they were given the reversal in the cases you're referring to?

Representative Johnston: No. A woman first takes the Mifepristone, and up to 3 days they're supposed to take the second phase of that which is the misoprostol, but if in between those time frames you take progesterone, there is a 65-70% chance it is reversed.

Senator Bakke: but we don't know the long-term effect on the mother or fetus because there hasn't been a case study or any clinical trials.

Representative Johnston: Long-term, no I don't think so.

Senator Myrdal: It's been safe for 50 years. The drug for the reversal is not new; it is just a hormone to make the uterine wall hold the baby.
Representative Johnston: That is correct.

Senator Myrdal: This drug has been used for many years and proven that it works with no side effects.

Representative Johnston: Correct. While we may not know what the exact effects are for an APR pregnancy, we do know that if progesterone is not used, then the baby will die. Are we worried about a baby being born with disabilities or worried about a baby dying?

Senator Bakke: There's no fiscal note. You're requesting that there be printed material to be provided to women; who's paying for all this material?

Representative Johnston: We have an informed consent statute that already exists. The Department of Health requires that to be updated every 2 years and distributed to health facilities around the state. As far as the cost, it will be very minimal. It could amount to just a piece of paper being mailed to those facilities and added to the current pamphlet that they have until they get a new, updated one.

Senator Bakke: I would want in that information the side effects and long-term effects of these drugs on the fetus and mother. We don't have clinical trials to provide that information.

Representative Johnston: That would be between the woman and her doctor.

(13:10) Rick Becker, District 7 Representative, testifies in favor

Representative Becker: I testify in favor as a physician and one who has had elective training in medical statistics beyond what's required. A lot of what's been circulating around with this bill is the allegation that it's based on pseudoscience; that it's not proven. The wording says it "may" be possible to reverse the effects. To counter that, the argument would be that it cannot reverse the effects. In the House we received some materials from those that are opposed to the bill. In those materials there was something from a respected journal that had the indication as though it were a study when in fact it was an opinion piece, but because it comes from a respected journal, one assumes that it's a study. The opinion piece conducted by two authors looked at some of the initial reports of this. In their review of the study, it identified that after the first medicine, if a woman stops and does not go through the second, that there's a 20% chance of that pregnancy continuing, but with the advent of adding this abortion reversal, the progesterone, that the likelihood increases to 38%. In the opinion

of those two people, they say that's not significant. Now of course statistically, you and I know better; that's a 90% increase in the likelihood of the pregnancy continuing. No one is making the claim that it will save the pregnancy. It's stating something that we know to be true- that it may save the pregnancy. It also says nothing about any side effects and of course we can use scare tactics, but progesterone has been used without any significant known side effects. There are very few to no other procedures that occur in two parts separated by a couple of days because for any procedure that existed that had that character, I would say absolutely, certainly for something that's potentially life-altering for both the mother and the baby that they be told that they can change their mind after the first part. How can a woman exercise her prerogative to change her mind if she's not made aware that that possibility even exists? That choice has to be given to the mother; this is commonsense to me. I'll remind you to be cautious and look closely at any statistics you're given on this topic.

Senator Bakke: Are you comfortable as a physician to advise your patients to take medication that has had no clinical trials or FDA approval?

Representative Becker: Absolutely. FDA approval is not what you might think it is. FDA approval indicates that there's no known bad effects. Physicians routinely do procedures and make recommendations for medicines that are not formally FDA approved.

Senator Bakke: Do you inform your patients when you do these procedures that you're doing something that does not have FDA approval, no clinical trials and is totally experimental on your part?

Representative Becker: There have been clinical trials. We can discuss what evidentiary level those trials have been. There are 5 levels and some of them have been as low as a level 4. Level 1 is a prospective, double-blind, randomized study. We're not anywhere near that; this is not hardcore evidence, but what we do have thus far certainly indicates that there is the potential for a dramatic increase in the likelihood of saving that pregnancy if one takes it.

(19:40) Kathy Skroch, District 26 Representative, testifies in favor (see attachment #2)

Senator Bakke: My heart breaks for you. I understand completely because I held two of my children and a grandchild, and it's devastating. I want to know your comfort level with allowing this to happen with no FDA approval or clinical trials. This is an unknown science and by putting this into our Century Code, we're saying this is safe. Are you comfortable with that?

Representative Skroch: I am. This is a hormone. Progesterone has been prescribed for years by doctors to treat women who cannot retain their pregnancies for lack of the hormone progesterone. It can be taken orally, with creams or injected. We have volumes of information on the effectiveness of that. It's a natural formed chemical that we have in our bodies, not some fabricated chemical. All it simply does is reverse the effect of the first abortion-causing medication which deprives the baby of progesterone causing it to starve out. Intervening with the progesterone in a timely manner allows that baby to potentially live.

Senator Bakke: I'm not debating the value of the drug. I'm saying in combination with the first drug, we have no clinical trials to say what the long term effect of that is.

Representative Skroch: We do have sufficient information to know that there has been no change in the numbers of defects in babies that have been provided progesterone than any babies that are out there in the general population. This has been going on for several years, so we do have data established at this point to show that there has been no unusual increase in defects of children that have lived. We have before us the option of choosing a dead child or a living child. Would you take the risk of maybe there being a side effect for your child versus a dead child? I will opt for the living child.

(29:35) Dr. Jerry Obritsch, Gynecologist, testifies in favor (see attachment #3)

Chair Larson: I'm trying to imagine how there could be a clinical study. I can't imagine a pregnant woman submitting herself to this to test it out. Has there been any study on animals to this regard?

Dr. Obritsch: Correct, what patient would be randomized to either clinical arms of the trial to prove the efficacy of this drug or not? Animal models are not the same as human models. Progesterone is used for many different applications. It's been proven safe just by it's use since the early 50s, so I have no concerns about the abortion reversal pill as it's called; it's simply progesterone which we use in clinical practice all the time to prolong patients that have a luteal phase deficiency we call it in the medical terminology.

Senator Luick: I don't understand why anybody would think this is a bad thing to do. Why would anyone think getting more information and/or the reconsideration of an idea would be something detrimental?

Dr. Obritsch: When you look at the process for informed consent in caring for patients, it's my strong belief that the more a patient is given in terms of knowledge, the more empowered they are to make that decision.

Senator Myrdal: Progesterone is not damaging to the mother. Has it ever shown in treatment since the 50's to do damage to an unborn child?

Dr. Obritsch: You're referring to teratogenicity. Progesterone is not a known teratogen, but instead is a crucial element of the progression of pregnancy.

Senator Myrdal: The damaging part is the RU486 and the second pill, not the progesterone.
Dr. Obritsch: Correct.

Vice Chairman Dwyer: Senator Bakke has referenced the FDA component. Please speak to that.

Dr. Obritsch: We practice medicine without a lot of FDA approval in all aspects of medicine. There are many examples of drugs we use as off-label that haven't had FDA studies but have a multitude of other studies as Representative Becker spoke to earlier. These studies, although not sponsored by the FDA, are sponsored by various institutions with various grants, published in well-respected journals but aren't a part of the FDA clearance and approval setting.

Senator Myrdal: The current abortion facility in North Dakota actually used an off-label abortion drug for years, sued the state of ND and eventually lost.

(45:30) Christopher Dodson, Executive Director for the ND Catholic Conference, testifies in favor (see attachment #4)

Senator Myrdal: Please speak to the off-label lawsuit from the abortion industry that I mentioned earlier.

Dodson: They didn't use it, but sought the right to use it off-label which because of the unique nature of the abortion inducing drug, the law required that they follow the FDA protocol, and they lost.

(50:55) Oley Larsen, District 3 Senator, testifies in favor

Senator O. Larsen: I believe knowledge is the key for many things, not just this piece of legislation; knowledge is what breaks the shackles of poverty. There was a fight about having sonograms brought forward to these women; I think that has been a positive thing. The literature at the clinic that they are allowed to have is monumental. As I was listening to the testimony, there was quite a bit of questions about FDA approval. Interestingly enough there has been a lot of medications that are FDA approved, but they pull them off because they're very dangerous to people taking them. One that I was looking at is called "DES". It's a synthetic estrogen that from 1940-1971 they were giving women to try to stop premature labor and pregnancy complications. They found that it caused all kinds of horrible things, and the women who took it in the 40s that had children, there was a residual effect on their children's children causing more problems to generations beyond. There's ADHD, depression and other medicine that were FDA approved that is shown later to not be the best. I support the bill.

(55) Mark Jorritsma, Executive Director of Family Policy Alliance of ND, testifies in favor (see attachment #5)

Senator Bakke: I agree that women have to have every piece of information, but it needs to be scientifically based and medically accurate. We don't have that on these medications.

Jorritsma: Most of us are parents. Let's say that medical professionals tell us that your child is going to die, 100% chance, because of something you did. However, the medical professional comes to you and says, "I have a pill that will give your child a 70% chance of living". You're going to ask question like what are the side effects, background and history. I can tell you what you're not going to ask. You're not going to ask if this has been done in a double blind study, put in peer reviewed journals, and if the American medical association has their stamp of approval on it. I'm not going to ask that; I'm going to take the pill, give it to my child and let my child live.

Senator Bakke: Are you going to take a chance with something that could kill your wife because it's unproven and nothing to prove that it's medically sound?

Jorritsma: I think previous testimony has proven that it will not kill the wife.

Senator Bakke: I have a problem putting something on paper that says this is medically and scientifically safe when we don't know that.

Jorritsma: I will again refer to the other people who testified who covered it very well.

Senator Myrdal: From earlier testimony we gathered that the RU486 is the one that's dangerous certainly to the child and potentially to the woman as well because it's an unnatural breaking down of the uterine wall while the reversal drug used since the 50s, has had no side effects and potentially may save the child.

Jorritsma: That is my understanding, yes.

(1:05:10) Linda Thorson, State Director for Concerned Women for America of ND, testifies is favor (see attachment #6)

Thorson: I am one of those women who now has a son and grandchildren thanks to the fact that I was given 6 months' bedrest and progesterone treatments that included two ambulance trips to get it. It didn't hurt me or my son.

Senator Myrdal: When you were given progesterone, did the doctors tell you that you could die from it?

Thorson: I don't recall that, but when Senator Oley Larsen talked about FDA medication and how they change their mind, I remember when I was given pregnant mare urine, PKU, to help with my estrogen level. There are times when they change their mind, and that's the reason you're supposed to go to the doctor for your yearly physical.

(1:09:00) Medora Nagle, Executive Director for North Dakota Right of Life, testifies in favor (see attachment #7)

Senator Bakke: Where did you get your information about over 500 babies saved from abortion?
Nagle: There are several sources that I can forward to you this evening.

(1:10:45) Emma Stehr, Collegians for Life at the University of Mary, testifies in favor (see attachment #8)

(1:14:25) Angela Wambach, Executive Director of the FirstChoice Clinic in Bismarck, Devils Lake, and Fargo, neutral party (see attachment #9)

Vice Chairman Dwyer: How many women do you see in your three clinics?

Wamback: For all of our different services, we see about 800 per year.

(1:18:45) Nadia Smetana, Director of Dakota Hope Clinic, testifies in favor (see attachments #10-11)

(1:30:20) Mary Graner, Mandan citizen, testifies in favor

Graner: In college I had a friend who was pregnant. A lot of times it's young girls who don't know what to do. She was 18 or 19 at the time and chose to have a suction-type abortion. Almost immediately after, she says it was her and her boyfriend's biggest regret that they ever had, and it still haunts her to this day. With this pill abortion, she would have had the option for reversal.

(1:31:50) Alexis Warner, University of Mary student, testifies in favor

Warner: It has been noted that the abortion reversal pill is not FDA approved, and I would like to speak to that. Since mid-July of 2015, I have suffered constant, undiagnosable cranial pain, sometimes simply written off as a migraine sufferer. On an average day, I have 8-9.5 out of 10 pain all of the time every day. I have seen 7 different neurologists, a cardiologist and an otologist not only at my local Sanford in Fargo but Mayo as well as several private practices. After trying nine different families of FDA approved medications unsuccessfully, I found that the most effective way to combat my daily pain is not currently FDA approved. If my doctors would not have suggested this non-FDA approved medication, I would not be able to have the current management of my pain that I do now. My current medication is currently only approved in Belgium which is mindboggling to me considering how it has changed my life. When you live everyday life in pain, one will eventually seek out any possible opportunity to find a way to bring greater health to oneself. I strongly encourage a do pass.

(1:35:35) Kristie Wolff, Executive Director of the North Dakota Women's Network, testifies in opposition (see attachment #12)

(1:38:40) Destini Spaeth, Fargo citizen, testifies in opposition

Spaeth: I work in medical research, and this is not a medically accurate bill. Before medication or a medical procedure is made available to the general public, it first needs to undergo extensive research to prove efficacy. Policy should only be developed based on evidence-based research with respect for the physician and patient relationship. Requiring a physician to disseminate information that has not been scientifically proven is negligent. Personally this bill insinuates that women are unsure about their decision to have an abortion. Women already experience several hurdles when accessing abortion care, especially in this state. This causes logistical, financial and time related barriers. When a woman decides to have an abortion, her visit to the clinic is the completion of that process that she's already started. Women don't have abortions on a whim or without thought, and I feel this bill suggests that women have not invested care in their decisions. Every person in this room loves someone who has had an abortion; I can say that without a shadow of doubt. These women should be trusted with their decisions and trusted with their relationship and dialogue that they have with their physicians.

Chair Larson closes the hearing on HB 1336.

Further testimony in opposition was provided to committee (see attachments #13-14).

2019 SENATE STANDING COMMITTEE MINUTES

Judiciary Committee
Fort Lincoln Room, State Capitol

HB 1336
3/13/2019
#33661 (26:26)

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Meghan Pegel

Explanation or reason for introduction of bill/resolution:

A BILL for an Act to create and enact a new subdivision to subsection 1 of section 14-02.1-02.1 of the North Dakota Century Code, relating to printed information by state department of health; and to amend and reenact subsection 11 of section 14-02.1-02 of the North Dakota Century Code, relating to informed consent requirements before an abortion.

Minutes: 1 Attachment

Chair Larson begins discussion on HB 1336. Senator Osland was absent.

(see attachment #1)

Senator Bakke: Moves to adopt amendment 19.0517.02001.
Vice Chairman Dwyer: Seconds.

Senator Bakke: I want them to know the risks and side effects of taking the second pill. If there are none, then put that there are none, but there's always a risk with every medication you take of some potential side effects or dangers.

Senator Myrdal: I understand the intent, but I'm against it. It's ironic that we're talking about the risk to the unborn child. The risk for the unborn child that we found out medically is in the first abortion pill. There lies the risk and death of the child.

Chair Larson: When they give the first abortion pills, do you know if they give all of the information for the risks and side effects? Do you know if they give all of that information out at that time?

Senator Myrdal: There's a section in the code where it talks about the information that they have to give out.

Chair Larson: so that is given.

Senator Myrdal: Not in detail I don't believe, but as far as abortion goes, there's a whole section on that.

Chair Larson: and if there's any risk to future pregnancies and unborn child?

Senator Myrdal: I don't know directly, but this is what would be added to what we have now, which is the part that has to do with the consent form. I think from the testimony we heard, it is clear that the first pill is the risk for the child. If you don't go through with the rest, there may be a chance that you don't self-abort the child at home already. However, if you take the reversal, there is no evidence that it's ever been destructive. Women have used it for over 50 years. I don't know how you will get scientifically based information on this particular procedure because no woman will be part of the study during her pregnancy to see if it works or not. This is not a study that anyone will volunteer for. I think this takes all the meat out of the bill. The bill says it "may" not shall or will.

Chair Larson: The part that will be amended says, "materials including information it may be possible to reverse the effects of an abortion-inducing drug, but time is of the essence. The materials must include information directing the patient where to obtain further information and assistance in locating a medical professional who can aid in the reversal drugs". Any time I've ever gotten drugs of any kind for anything, all of the known side effects are labeled. I would think this would be redundant; it seems like this would already be what a doctor and a pharmacist would give a person. It doesn't seem needed.

Senator Bakke: I feel that if you're going to make the assertion that if you take this particular pill, it could or may reverse the abortion, you have to be able to say it's safe by letting them know the side effects and what might occur. A pharmacy should provide that information, but when we provide information of the abortion so we need to provide the same information if we're telling them we're going to reverse that abortion.

Chair Larson: I think that is already standard practice for medical professionals and pharmacist to give information regarding medicines that they proscribe.

Senator Bakke: I think you're right, that is natural practice. This material is being provided to them at the place of the abortion. I want to make sure that what they're getting is something that gives them all the information so they know what to do with their health. A woman needs to have all the information if we're going to give her this second pill with this idea that it's going to do something it may or may not do.

(10:20) Senator Myrdal: She will get that information by the physician that tries to reverse it. It's their responsibility to give her that information for that drug and the pharmacist afterwards, not the abortion facility who has no interest in her reversing this.

Senator Bakke: The bill says it has to be provided with the information that explains the abortion procedure.

Senator Myrdal: You go into an abortion facility, take the first pill and they send you the other pills to go home and finish it. This is a notification added to this whole section of code that

says, “the materials must include information directing the patient where to obtain further information” which would be a physician that would assist her. When I go to a doctor and they send me to another one, the first doctor doesn’t tell me the consequences of the drug that I will get from the second doctor. All we’re asking for is for this to be added to a consent form to be presented to the woman that she can have that choice to call, and the second doctors will do what this says.

Vice Chairman Dwyer: Is it medical physicians that perform these abortions?

Senator Myrdal: There are currently four physicians that fly into the state that perform these abortions in Fargo.

Vice Chairman Dwyer: If it’s licensed medical physicians, they will have information.

Senator Bakke: They wanted added to the information that is given to these women that if you change your mind, you can reverse it. If I were in that position, I would go back to the person who gave me the first pill because I would want someone who knew what I’d already done.

Chair Larson: I’m picturing how this would work. When I get prescribed medicine, I almost never read through the information. If this is done, I think there are a lot of people that would take the pill and the doctor would haphazardly give them this information. On the other side of that, if they change their mind, then they have that information. I feel like this is not real onerous to give this information out.

Senator Myrdal: The doctors that come fly in from out of state on Wednesdays when this is performed in Fargo.

Chair Larson: Is this also for the pills?

Senator Myrdal: No, they can also give the pills, but you have to consult with a doctor on it. Generally, even the pills are done on that particular day. In common practice There’s never been one known case that if you call that particular doctor back, number one they aren’t available for you. Secondly, they’re not going to help you. Reality is, no one in that clinic is going to help you get a reversal. There are doctors that will help you with that reversal, and that’s all this is saying. This is a prochoice, prolife bill, and I think the language is equivalent to protecting all women’s rights to know.

Senator Bakke: I don’t think we can blankly say that any physician who provides medical care doesn’t care about their patient. Just because someone worked with a woman to secure an abortion for her doesn’t mean that this person is uncaring. That’s unfair, and we can’t make those generalizations. If we really feel that women need to have accurate information provided at the time they make this decision to have an abortion, they need to have all the information presented in a way that’s nonbiased and scientific. I don’t want it to be in such a way that they think it’s skewed one way or another. By putting this in here, we’re saying that all information they give them has to be scientifically based and medically accurate. It has to tell them the pros and cons of both sides of all the pills. They have every right to know what’s

going to happen with each of those pills. If we can't tell them what the side effects are, why are we giving it to them? To me, that's medically irresponsible.

Senator Myrdal: The abortion facility isn't giving them it. The secondary doctor will give it because the abortion facility and those doctors don't give reversal pills. The secondary doctor that they get referred to will give them all the information. That's already in the bill, and that's where they get that information.

Senator Bakke: Am I to understand the only person who has to give the woman information is the first place she goes? The people that give her the reversal pill aren't required to give her any information in writing?

Senator Myrdal: They are required by being a doctor already

Senator Bakke: So would the doctor at the other clinic.

Senator Myrdal: Yes, but they're not going to engage in the reversal.

(20:20) Chair Larson: We have different viewpoints on the truth behind it. Senator Bakke I agree with you in some aspects and that is that a person making this decision is not making it lightly; that the people providing the abortion are feeling like they are medically doing something on her behalf. However, I also believe that since the effect of what this pill does is to actually end of life, then some of those realities of what that pill does needs to be spelled out like it already is on that first page. Where it says a reversal may be possible, it isn't talking about ending a life. It's saying you may be able to save a life and so any medical risks along with that would just be part of what a medical doctor would have to do saying any treatment they give a person; they have to tell them what the risks are.

Senator Bakke: I agree, but I think when they perform this procedure on them, they tell them all the side effects and what to expect. I don't want to change any of that, but I think they also have to have the information that goes along with taking the reversal pill, and if that has to be in writing, then the second part has to be in writing.

Chair Larson: The problem that I have with that is the specific writing that you say has to be in there. I think it is pretty well understood that the medical professional is going to give that information to their patient because what we're talking about is saving a life and protecting the woman. That would be the responsibility of the medical doctor giving this information to her whereas it would not necessarily be the responsibility of a doctor that is taking a life. I worked with a girl on my caseload whose mother made her have an abortion. She really went into it blindly and did not know the full effect of what was happening until later when she learned more about. That's why I think that somebody that goes in may be under pressures, so it's especially important for that type of a decision to be given all of that information. Then if you change your mind, go see a doctor. It seems to me that it's clear.

Senator Bakke: I'm under the impression that both times they're seeing a doctor, and both doctors have the obligation to give the information. If we're going to spell out word for word what one doctor has to do, then we need to spell out word for word what the other doctor's going to do.

Chair Larson: I don't think that this is word for word.

Senator Bakke: It's just saying what are the potential side effects, and what can this person expect when they go home so they aren't blindsided if they still lose the baby. I was home when I had one of my miscarriages, and I had no idea what was going on. I'm saying they need to have the information of what to expect if this reversal pill doesn't work. I knew what was going to happen because the doctor had told me that I'd be having a miscarriage, but some of these kids aren't going to know.

A Roll Call Vote Was Taken: 1 yea, 4 nays, 1 absent. Amendment fails.

Senator Myrdal: Motions for a Do Pass.
Vice Chairman Dwyer: Seconds.

A Roll Call Vote Was Taken: 5 yeas, 0 nays, 1 absent. Motion carries.

Senator Myrdal will carry the bill.

Prepared by the Legislative Council staff for
Senator Bakke
March 4, 2019

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1336

Page 2, line 30, after "include" insert "scientifically based and medically accurate"

Page 2, line 31, after the first "information" insert "that provides all the repercussions that could occur to the unborn child and the mother if these additional medications are administered as well as information"

Page 3, line 2, after the underscored period insert "Information on all potential side effects, risks for future pregnancies, and risks to the unborn child must be given as a part of this written information."

Renumber accordingly

Date:3/13/2019
Roll Call Vote: 1

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1336

Senate **Judiciary** Committee

☐ Subcommittee

Amendment LC# or Description: 19.0517.02001

Recommendation: ☒ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Senator Bakke Seconded By Vice Chairman Dwyer

Senators	Yes	No	Senators	Yes	No
Chair Larson		X	Senator Bakke	X	
Vice Chair Dwyer		X			
Senator Luick		X			
Senator Myrdal		X			
Senator Osland	AB				

Total (Yes) 1 No 4

Absent 1

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Date:3/13/2019
Roll Call Vote: 2

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1336

Senate **Judiciary** Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Senator Myrdal Seconded By Vice Chairman Dwyer

Senators	Yes	No	Senators	Yes	No
Chair Larson	X		Senator Bakke	X	
Vice Chair Dwyer	X				
Senator Luick	X				
Senator Myrdal	X				
Senator Osland	AB				

Total (Yes) 5 No 0

Absent 1

Floor Assignment Senator Myrdal

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1336: Judiciary Committee (Sen. D. Larson, Chairman) recommends **DO PASS** (5 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). HB 1336 was placed on the Fourteenth order on the calendar.

2019 TESTIMONY

HB 1336

#1
HB 1336
1/21/2019
pg. 1

Rep. Daniel Johnston
January 21, 2019
House Human Services Committee
Testimony for HB 1336

Mr. Chairman and Members of the Committee, my name is Daniel Johnston and I represent District 24 in the North Dakota House. Thank you for allowing me to be here today and testify on HB 1336.

HB 1336 is a bill that seeks to update North Dakota's informed consent law by requiring an abortion provider to give abortion pill reversal information to a patient before a chemical abortion procedure begins. From time to time, the North Dakota Legislature has revisited and updated the informed consent statute so, what this bill seeks to do is not unusual.

At its core, HB 1336 addresses a question. Should a woman receive all information available before undergoing a potential life-altering procedure?

With any medical procedure, the patient is given all the information necessary to make an informed decision. They are told what the risks are, what kind of side effects to expect, and possible recovery time. Full disclosure exists. However, this is not the case for a woman that is considering a chemical abortion. Currently, an abortion provider does not give a woman all the information available, so that an educated decision can be made? This bill is about choice. A woman may choose to start the chemical abortion process, but she may also choose to change her mind.

What is a chemical abortion and is it reversible? Chemical abortion is most commonly in reference to RU486 (Mifepristone). Mifepristone blocks the hormone progesterone from allowing the womb to nourish the unborn child and causes the uterine lining to shed. Basically, this amounts to death by starvation. Later another chemical is taken, Misoprostol, which causes a miscarriage. Common side effects of chemical abortion include Cramping, nausea, vomiting/diarrhea, heavy bleeding, stomach pain, and mild fever and chills. Of course, the heavy emotional toll associated with abortion is often overlooked.

Mifepristone is REVERSIBLE and can be stopped by adding large amounts of natural Progesterone. The abortion pill reversal protocol increases the chances that a baby will survive after the mother ingests mifepristone. If the mother receives the APR rescue, then 65-70% of the babies will survive. I included an observational case study with my testimony that examined the results of 754 cases of abortion pill reversal. The study was published in 2018.

What this legislation does not do. HB 1336 does not adversely affect or hamper a woman's access, right, or choice to seek an abortion. It aligns with a ND Supreme Court opinion concerning Roe v. Wade (MKB Mgmt. Corp. v. Burdick, 2014 ND 197, P15, 855 N.W.2d 31, 36, 2014 N.D. LEXIS 202, *16, 2014 WL 5450069 (N.D. October 28, 2014), that stated the following, "For the stage subsequent to approximately the end of the first trimester, the State, in promoting its interest in the health of the mother, may, if it chooses, regulate the abortion procedure in ways that are reasonably related to

maternal health. . . A provision of law is only invalid, if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability"

This unequivocally means that the State has the constitutional right to regulate abortion procedures if it is reasonably related to maternal health and does not place a substantial obstacle in the path of a women to seek an abortion in the early stages of pregnancy.

Currently, 46 states and 17 countries have reported successful abortion reversal procedures. 430 medical practices and 84 pregnancy help centers prescribe abortion pill reversal. Five states have recently enacted legislation which requires informed consent for the abortion reversal procedure, and I expect that number to continue to rise as more abortion reversals take place.

Women have a right to know that they can choose to change their mind.

This legislation is Pro woman, pro-life, and it is pro-choice. A woman deserves to know.

Members of the House Human Services Committee, please give HB 1336 a **Do Pass** recommendation.

Thank you. I stand for questions.

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1/21/2019
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Abortion "Reversal" — Legislating without Evidence

Daniel Grossman, M.D., and Kari White, Ph.D., M.P.H.

Women up to 10 weeks pregnant who are having a medication abortion generally take one dose of mifepristone, which blocks the progesterone receptor, followed within 48 hours by a dose of misoprostol, a prostaglandin that causes cervical dilation and uterine contractions, leading to expulsion of the pregnancy tissue. Four states (Arkansas, Idaho, South Dakota, and Utah) require abortion providers to tell their patients about treatment that may reverse the effect of mifepristone if they change their mind after starting a medication abortion. So-called abortion reversal involves administering repeated doses of progesterone. Since 2017, other states have proposed similar bills and the California Board of Registered Nursing approved a course on medication-abortion reversal for continuing-education credit. This trend is troubling because of the lack of medical evidence demonstrating the safety and efficacy of the treatment; laws promoting it essentially encourage women to participate in an unmonitored research experiment.

When states began passing laws on abortion reversal, the only published report on this treatment was a case series involving seven patients. A systematic review we coauthored in 2015 found no evidence that pregnancy continuation was more likely after treatment with progesterone as compared with expectant management among women who had taken mifepristone.[1] Our review found that the proportion of continuing pregnancies after mifepristone alone varied from 8% to 46% in published studies.

Recently, Delgado et al. published a case series involving 754 patients who underwent reversal treatment in the United States and several unnamed countries.[2] After excluding 27% of patients for various reasons, they report that 47% had a live birth. The authors conclude that reversal treatment is effective, citing the higher proportion of continuing pregnancies in their study as compared with a historical control rate of 25% of women who had continuing pregnancies after taking mifepristone alone. This estimate comes from Maria et al., the only published report that examined rates of pregnancy continuation after a single 200-mg dose of mifepristone,[3] which is the dose most commonly used in current medication-abortion regimens. This study, which included 30 women who were up to 7 weeks pregnant, 25 of whom were no more than 6 weeks pregnant, found that 23% had continuing pregnancies 7 days later.

It is difficult to compare the results from Delgado et al. with data on mifepristone alone for several reasons. In the Delgado study, some providers performed ultrasonography in patients presenting for reversal and excluded those found to have embryonic death. These patients were removed from the denominator of the proportion of women with continuing pregnancies, which could have contributed to the higher success rate for reversal treatment — especially at gestational ages of more than 6 weeks, when cardiac activity is more apparent. In addition, the authors excluded patients who were lost to follow-up before 20 weeks, which probably exaggerated the treatment's reported success.

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Percentage of Women with Continuing Pregnancies after Taking 200 mg Mifepristone with or without Progesterone.*

Treatment	Total No. of Pregnancies	Continuing Pregnancies	Percentage of Continuing Pregnancies (95% CI)	P Value
Gestational age ≤6 wk				
Mifepristone followed by progesterone	189	71	38 (31–45)	0.119
Mifepristone alone	25	5	20 (9–39)	
Gestational age ≤7 wk				
Mifepristone followed by progesterone	291	121	42 (36–47)	0.076
Mifepristone alone	30	7	23 (21–41)	

* Data are from Delgado et al.[2] and Maria et al.[3] Maria et al. report a total of seven continuing pregnancies in the sample of 30 women who were 7 weeks pregnant or less. There were two abortion failures among the five women who were between 6 and 7 weeks pregnant, but whether these were continuing pregnancies is unclear. We therefore made the conservative assumption that five of the seven continuing pregnancies occurred among the 25 women who received mifepristone at 6 weeks' gestation or less and that the two failures that occurred among those who were between 6 and 7 weeks pregnant were both continuing pregnancies.

Gestational ages in Delgado et al. (up to 9 weeks) also differed from those in Maria et al. As Delgado et al. note, pregnancy continuation is more common with advanced gestation; therefore, it is important to compare groups of similar gestational age. We analyzed the effectiveness of reversal treatment by comparing rates of continuing pregnancy among women who were up to 6 or 7 weeks pregnant in the two studies.

Among women who were up to 6 weeks pregnant, 38% (95% confidence interval [CI], 31 to 45) of those who received reversal therapy had a continuing pregnancy.[2] This proportion was not significantly different from the 20% (95% CI, 9 to 39) of women who had a continuing pregnancy after taking mifepristone alone (P=0.119) (see table).[3] The rates of pregnancy continuation were also not significantly different when we included women who were up to 7 weeks pregnant, despite the fact that the reported success rate for reversal therapy was most likely an overestimate at 7 weeks because some patients were excluded from treatment after ultrasound screening for embryonic viability. Because there are no published data on rates of pregnancy continuation after a 200-mg dose of mifepristone alone at more than 7 weeks' gestation, we cannot evaluate the effectiveness of reversal treatment beyond this gestational age.

The safety data presented by Delgado et al. are minimal. No adverse events were reported among pregnant women, but it is unclear whether such data were routinely collected. The reported data on birth defects and preterm birth are generally reassuring; given the range of progesterone regimens used and the lack of reporting by regimen, however, it is difficult to draw conclusions about the treatment's safety. Data from a registry in France suggest that exposure to mifepristone alone does not increase the risk of birth defects.[4]

Equally unclear is the demand for reversal treatment. Since participants in the study by Delgado et al. were recruited from several unnamed countries over a period of 4 years, it is impossible to estimate what proportion of patients undergoing medication abortion is represented by this sample. According to data obtained from Danco Laboratories, the U.S. manufacturer of mifepristone, less than 0.004% of patients who took mifepristone between 2000 and 2012 ended up deciding to continue their pregnancies.[1] Other research indicates that decisional certainty among women having an abortion is high — and higher than it is among patients making other decisions about medical treatment.[5]

Still, efforts should be made at the time of preabortion counseling to identify women who may be conflicted and to provide additional support to help them make an informed decision. Allowing patients to take mifepristone at home, which has been permitted since the drug's label was updated in 2016, may reduce the already small number of women who change their mind by giving patients more control over where and when they take the medication. But for patients who do change their mind after taking mifepristone, what is the best course of action? If a woman changes her mind within an hour after taking the drug, vomiting should be induced. Beyond that time frame, we believe the pregnancy should be carefully followed.

One could argue that the demand for abortion reversal treatment is so low that additional research is not justified. But if

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researchers do perform additional studies, it is critical that such studies be rigorously designed and conducted in an ethical manner. Clinical equipoise exists for this question, since there is no evidence that treatment is superior to doing nothing. In such cases, a randomized, placebo-controlled trial is the most appropriate study design. For now, any use of reversal treatment should be considered experimental and offered only in the context of clinical research supervised by an institutional review board (IRB). Delgado et al. obtained IRB approval for their retrospective data analysis, but it is not clear that approval was obtained in advance for their experimental treatment protocol. In fact, the study was retracted temporarily because of concerns raised about what the authors initially described as an IRB "waiver."

We believe that states' mandating that health care providers give patients information about an unproven and experimental therapy is a disturbing intrusion into the relationship between physicians and their patients. Additional states will undoubtedly consider such legislation, despite the lack of evidence for abortion reversal treatment. We should all be concerned when politicians recommend treatment options over the advice of medical professionals.

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CHAPTER 14-02.1
ABORTION CONTROL ACT

14-02.1-01. Purpose.

The purpose of this chapter is to protect unborn human life and maternal health within present constitutional limits. It reaffirms the tradition of the state of North Dakota to protect every human life whether unborn or aged, healthy or sick.

14-02.1-02. Definitions.

As used in this chapter:

1. "Abortion" means the act of using or prescribing any instrument, medicine, drug, or any other substance, device, or means with the intent to terminate the clinically diagnosable intrauterine pregnancy of a woman, including the elimination of one or more unborn children in a multifetal pregnancy, with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child. Such use, prescription, or means is not an abortion if done with the intent to:
   a. Save the life or preserve the health of the unborn child;
   b. Remove a dead unborn child caused by spontaneous abortion; or
   c. Treat a woman for an ectopic pregnancy.
2. "Abortion facility" means a clinic, ambulatory surgical center, physician's office, or any other place or facility in which abortions are performed or prescribed, other than a hospital.
3. "Abortion-inducing drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of causing an abortion.
4. "Down syndrome" refers to a chromosome disorder associated with an extra chromosome twenty-one, in whole or in part, or an effective trisomy for chromosome twenty-one.
5. "Drug label" means the pamphlet accompanying an abortion-inducing drug which outlines the protocol tested and authorized by the federal food and drug administration and agreed upon by the drug company applying for the federal food and drug administration authorization of that drug. Also known as "final printing labeling instructions", drug label is the federal food and drug administration document that delineates how a drug is to be used according to the federal food and drug administration approval.
6. "Fertilization" means the fusion of a human spermatozoon with a human ovum.
7. "Genetic abnormality" means any defect, disease, or disorder that is inherited genetically. The term includes any physical disfigurement, scoliosis, dwarfism, Down syndrome, albinism, amelia, or any other type of physical or mental disability, abnormality, or disease.
8. "Hospital" means an institution licensed by the state department of health under chapter 23-16 and any hospital operated by the United States or this state.
9. "Human being" means an individual living member of the species of homo sapiens, including the unborn human being during the entire embryonic and fetal ages from fertilization to full gestation.
10. "Infant born alive" means a born child which exhibits either heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles or pulsation of the umbilical cord if still attached to the child.
11. "Informed consent" means voluntary consent to abortion by the woman upon whom the abortion is to be performed or induced provided that:
    a. The woman is told the following by the physician who is to perform the abortion, by the referring physician, or by the physician's agent, at least twenty-four hours before the abortion:
       (1) The name of the physician who will perform the abortion;
       (2) The abortion will terminate the life of a whole, separate, unique, living human being;

(3) The particular medical risks associated with the particular abortion procedure to be employed including, when medically accurate, the risks of infection, hemorrhage, danger to subsequent pregnancies, and infertility;
(4) The probable gestational age of the unborn child at the time the abortion is to be performed; and
(5) The medical risks associated with carrying her child to term.

b. The woman is informed, by the physician or the physician's agent, at least twenty-four hours before the abortion:
(1) That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care and that more detailed information on the availability of that assistance is contained in the printed materials given to her as described in section 14-02.1-02.1;
(2) That the printed materials given to her and described in section 14-02.1-02.1 describe the unborn child and list agencies that offer alternatives to abortion;
(3) That the father is liable to assist in the support of her child, even in instances in which the father has offered to pay for the abortion; and
(4) That she is free to withhold or withdraw her consent to the abortion at any time without affecting her right to future care or treatment and without the loss of any state or federally funded benefits to which she might otherwise be entitled.

c. The woman certifies in writing, prior to the abortion, that the information described in subdivisions a and b has been furnished to her.

d. Before the performance of the abortion, the physician who is to perform or induce the abortion or the physician's agent receives a copy of the written certification prescribed by subdivision c.

e. The physician has not received or obtained payment for a service provided to a patient who has inquired about an abortion or has scheduled an abortion before the twenty-four-hour period required by this section.

12. "Medical emergency" means a condition that, in reasonable medical judgment, so complicates the medical condition of the pregnant woman that it necessitates an immediate abortion of her pregnancy without first determining postfertilization age to avert her death or for which the delay necessary to determine postfertilization age will create serious risk of substantial and irreversible physical impairment of a major bodily function, not including psychological or emotional conditions. A condition may not be deemed a medical emergency if based on a claim or diagnosis that the woman will engage in conduct that she intends to result in her death or in substantial and irreversible physical impairment of a major bodily function.
13. "Physician" means an individual who is licensed to practice medicine or osteopathy under chapter 43-17 or a physician who practices in the armed services of the United States or in the employ of the United States.
14. "Postfertilization age" means the age of the unborn child as calculated from fertilization.
15. "Probable gestational age of the unborn child" means what, in reasonable medical judgment, will with reasonable probability be the gestational age of the unborn child at the time the abortion is planned to be performed.
16. "Probable postfertilization age of the unborn child" means what, in reasonable medical judgment, will with reasonable probability be the postfertilization age of the unborn child at the time the abortion is planned to be performed or induced.
17. "Reasonable medical judgment" means a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.
18. "Unborn child" means the offspring of human beings from conception until birth.
19. "Viable" means the ability of an unborn child to live outside the mother's womb, albeit with artificial aid.

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14-02.1-02.1. Printed information - Referral service.

1. The state department of health shall publish in English, and in every other language that the department determines is the primary language of a significant number of state residents, the following easily comprehensible printed materials:
   a. Geographically indexed materials designed to inform the woman of public and private agencies and services available to assist a woman through pregnancy, upon childbirth, and while the child is dependent, including adoption agencies. The materials must include a comprehensive list of the agencies available, a description of the services they offer and a description of the manner, including telephone numbers, in which they might be contacted, or, at the option of the department, printed materials, including a toll-free, twenty-four-hour-a-day telephone number that may be called to obtain, orally, such a list and description of agencies in the locality of the caller and of the services they offer. The materials must state that it is unlawful for any individual to coerce a woman to undergo an abortion and that if a minor is denied financial support by the minor's parent, guardian, or custodian due to the minor's refusal to have an abortion performed, the minor is deemed to be emancipated for the purposes of eligibility for public assistance benefits, except that those benefits may not be used to obtain an abortion. The materials also must state that any physician who performs an abortion upon a woman without her informed consent may be liable to her for damages in a civil action and that the law permits adoptive parents to pay costs of prenatal care, childbirth, and neonatal care. The materials must include the following statement: There are many public and private agencies willing and able to help you to carry your child to term and to assist you and your child after your child is born, whether you choose to keep your child or to place your child for adoption. The state of North Dakota strongly urges you to contact one or more of these agencies before making a final decision about abortion. The law requires that your physician or your physician's agent give you the opportunity to call agencies like these before you undergo an abortion.
   b. Materials, published in a booklet format, designed to inform the woman of the probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from the time when a woman can be known to be pregnant to full term, including any relevant information on the possibility of the survival of the unborn child and color photographs of the development of an unborn child at two-week gestational increments. The descriptions must include information about brain and heart function, the presence of external members and internal organs during the applicable states of development, and any relevant information on the possibility of the unborn child's survival. The materials must be objective, nonjudgmental, and designed to convey only accurate scientific information about the unborn child at the various gestational ages. The materials required under this subsection must be reviewed, updated, and reprinted as needed.
   c. Materials that include information on the support obligations of the father of a child who is born alive, including the father's legal duty to support his child, which may include child support payments and health insurance, and the fact that paternity may be established by the father's signature on an acknowledgment of paternity or by court action. The printed material must also state that more information concerning paternity establishment and child support services and enforcement may be obtained by calling state or county public assistance agencies.
   d. Materials that contain objective information describing the various surgical and drug-induced methods of abortion as well as the immediate and long-term medical risks commonly associated with each abortion method, including the risks of infection, hemorrhage, cervical or uterine perforation or rupture, danger to subsequent pregnancies, the possible increased risk of breast cancer, the

possible adverse psychological effects associated with an abortion, and the medical risks associated with carrying a child to term.

2. The materials required under subsection 1 must be available at no cost from the state department of health upon request and in appropriate number to any person, facility, or hospital, and, except for copyrighted material, must be available on the department's internet website. The department may make the copyrighted material available on its internet website if the department pays the copyright royalties.

14-02.1-02.2. Abortion report form.

The state department of health shall prepare an abortion compliance report form and an abortion data report form to be used by the physician for each abortion performed, as required by section 14-02.1-07. The abortion compliance report form must include a checklist designed to confirm compliance with all provisions of this chapter, chapter 14-02.3, chapter 14-02.6, and section 23-16-14. The abortion data report form must include the data called for in the United States standard report of induced termination of pregnancy as recommended by the national center for health statistics.

14-02.1-03. Consent to abortion - Notification requirements.

1. No physician shall perform an abortion unless prior to such performance the physician certified in writing that the woman gave her informed consent as defined and provided in section 14-02.1-02 and shall certify in writing the pregnant woman's marital status and age based upon proof of age offered by her. Before the period of pregnancy when the unborn child may reasonably be expected to have reached viability, an abortion may not be performed upon an unemancipated minor unless the attending physician certifies in writing that each of the parents of the minor requesting the abortion has been provided by the physician in person with the information provided for in section 14-02.1-02 at least twenty-four hours before the minor's consent to the performance of abortion or unless the attending physician certifies in writing that the physician has caused materials of section 14-02.1-02 to be posted by certified mail to each of the parents of the minor separately to the last-known addresses at least forty-eight hours prior to the minor's consent to the performance of abortion. If a parent of the minor has died or rights and interests of that parent have been legally terminated, this subsection applies to the sole remaining parent. When both parents have died or the rights and interests of both parents have been legally terminated, this subsection applies to the guardian or other person standing in loco parentis. Notification by the attending physician is not required if the minor elects not to allow the notification of one or both parents or her guardian and the abortion is authorized by the juvenile court in accordance with section 14-02.1-03.1. None of the requirements of this subsection apply in the case of a medical emergency, except that when a medical emergency compels the performance of an abortion, the physician shall inform the woman, before the abortion if possible, of the medical indications supporting the physician's judgment that an abortion is necessary to avert her death or for which a twenty-four-hour delay will create grave peril of immediate and irreversible loss of major bodily function, and shall certify those indications in writing.
2. Subsequent to the period of pregnancy when the unborn child may reasonably be expected to have reached viability, no abortion, other than an abortion necessary to preserve her life, or because the continuation of her pregnancy will impose on her a substantial risk of grave impairment of her physical or mental health, may be performed upon any woman in the absence of:
   a. The written consent of her husband unless her husband is voluntarily separated from her; or
   b. The written consent of a parent, if living, or the custodian or legal guardian of the woman, if the woman is unmarried and under eighteen years of age.
3. No executive officer, administrative agency, or public employee of the state of North Dakota or any local governmental body has power to issue any order requiring an

abortion, nor shall any such officer or entity coerce any woman to have an abortion, nor shall any other person coerce any woman to have an abortion.

14-02.1-03.1. Parental consent or judicial authorization for abortion of unmarried minor - Statement of intent.

The legislative assembly intends to encourage unmarried pregnant minors to seek the advice and counsel of their parents when faced with the difficult decision of whether or not to bear a child, to foster parental involvement in the making of that decision when parental involvement is in the best interests of the minor and to do so in a manner that does not unduly burden the right to seek an abortion.

1. No person may knowingly perform an abortion upon a pregnant woman under the age of eighteen years unless:
   a. The attending physician has secured the written consent of the minor woman and both parents, if living, or the surviving parent if one parent is deceased, or the custodial parent if the parents are separated or divorced, or the legal guardian or guardians if the minor is subject to guardianship;
   b. The minor woman is married and the attending physician has secured her informed written consent; or
   c. The abortion has been authorized by the juvenile court in accordance with the provisions of this section.
2. Any pregnant woman under the age of eighteen or next friend is entitled to apply to the juvenile court for authorization to obtain an abortion without parental consent. All proceedings on such application must be conducted in the juvenile court of the county of the minor's residence before a juvenile judge or referee, if authorized by the juvenile court judge in accordance with the provisions of chapter 27-05, except that the parental notification requirements of chapter 27-20 are not applicable to proceedings under this section. A court may change the venue of proceedings under this section to another county only upon finding that a transfer is required in the best interests of the minor. All applications in accordance with this section must be heard by a juvenile judge or referee within forty-eight hours, excluding Saturdays and Sundays, of receipt of the application. The juvenile judge or referee shall find by clear and convincing evidence:
   a. Whether or not the minor is sufficiently mature and well informed with regard to the nature, effects, and possible consequences of both having an abortion and bearing her child to be able to choose intelligently among the alternatives.
   b. If the minor is not sufficiently mature and well informed to choose intelligently among the alternatives without the advice and counsel of her parents or guardian, whether or not it would be in the best interests of the minor to notify her parents or guardian of the proceedings and call in the parents or guardian to advise and counsel the minor and aid the court in making its determination and to assist the minor in making her decision.
   c. If the minor is not sufficiently mature and well informed to choose intelligently among the alternatives and it is found not to be in the best interests of the minor to notify and call in her parents or guardian for advice and counsel, whether an abortion or some other alternative would be in the best interests of the minor.
3. All proceedings in connection with this section must be kept confidential and the identity of the minor must be protected in accordance with provisions relating to all juvenile court proceedings. This section does not limit the release, upon request, of statistical information regarding applications made under this section and their disposition.
4. The court shall keep a stenographic or mechanically recorded record of the proceedings which must be maintained on record for forty-eight hours following the proceedings. If no appeal is taken from an order of the court pursuant to the proceedings, the record of the proceedings must be sealed as soon as practicable following such forty-eight-hour period.

5. Following the hearing and the court's inquiry of the minor, the court shall issue one of the following orders:
   a. If the minor is sufficiently mature and well informed concerning the alternatives and without the need for further information, advice, or counseling, the court shall issue an order authorizing a competent physician to perform the abortion procedure on the minor.
   b. If the minor is not sufficiently mature and well informed, the court may:
      (1) Issue an order to provide the minor with any necessary information to assist her in her decision if the minor is mature enough to make the decision but not well informed enough to do so.
      (2) Issue an order to notify the minor's parents or guardian of the pendency of the proceedings and calling for their attendance at a reconvening of the hearing in order to advise and counsel the minor and assist the court in making its determination if the court finds that to do so would be in the best interests of the minor.
      (3) Issue an order authorizing an abortion by a competent physician if the court has determined that it would not be in the best interests of the minor to call in her parents or guardian but has found that it would be in the minor's best interests to authorize the abortion.
6. The minor or next friend may appeal the determination of the juvenile court directly to the state supreme court. In the event of such an appeal, any and all orders of the juvenile court must be automatically stayed pending determination of the issues on appeal. Any appeal taken pursuant to this section by anyone other than the minor or next friend must be taken within forty-eight hours of the determination of the juvenile court by the filing of written notice with the juvenile court and a written application in the supreme court. Failure to file notice and application within the prescribed time results in a forfeiture of the right to appeal and render the juvenile court order or orders effective for all intents and purposes.
7. Upon receipt of written notice of appeal, the juvenile court shall immediately cause to be transmitted to the supreme court the record of proceedings had in the juvenile court.
8. An application for appeal pursuant to this section must be treated as an expedited appeal by the supreme court and must be set down for hearing within four days of receipt of the application, excluding Saturdays and Sundays.
9. The hearing, inquiry, and determination of the supreme court must be limited to a determination of the sufficiency of the inquiry and information considered by the juvenile court and whether or not the order or orders of the juvenile court accord with the information considered with respect to the maturity and information available to the minor and the best interests of the minor as determined by the juvenile court. The determination of the juvenile court may not be overturned unless found to be clearly erroneous.
10. After hearing the matter the supreme court shall issue its decision within twenty-four hours.
11. Within forty-eight hours of the hearing by the supreme court, the record of the juvenile court must be returned to the juvenile court and the juvenile court shall seal it at the earliest practicable time.
12. Nothing in this section may be construed to prevent the immediate performance of an abortion on an unmarried minor woman in an emergency where such action is necessary to preserve her life and no physician may be prevented from acting in good faith in such circumstances or made to suffer any sanction thereby other than those applicable in the normal course of events to the general review of emergency and nonemergency medical procedures.
13. Nothing in this section may be construed to alter the effects of any other section of this chapter or to expand the rights of any minor to obtain an abortion beyond the limits to such rights recognized under the Constitution of the United States or under other provisions of this code.

14-02.1-03.2. Civil damages for performance of abortions without informed consent.

Any person upon whom an abortion has been performed without informed consent as required by sections 14-02.1-02, 14-02.1-02.1, subsection 1 of section 14-02.1-03, 14-02.1-03.2, and 14-02.1-03.3 may maintain an action against the person who performed the abortion for ten thousand dollars in punitive damages and treble whatever actual damages the plaintiff may have sustained. Any person upon whom an abortion has been attempted without complying with sections 14-02.1-02, 14-02.1-02.1, subsection 1 of section 14-02.1-03, 14-02.1-03.2, and 14-02.1-03.3 may maintain an action against the person who attempted to perform the abortion for five thousand dollars in punitive damages and treble whatever actual damages the plaintiff may have sustained.

14-02.1-03.3. Privacy of woman upon whom an abortion is performed or attempted.

In every proceeding or action brought under section 14-02.1-03.2, the court shall rule whether the anonymity of any woman upon whom an abortion is performed or attempted should be preserved from public disclosure if she does not give her consent to such disclosure. The court, upon motion or sua sponte, shall make such a ruling and, upon determining that her anonymity should be preserved, shall issue orders to the parties, witnesses, and counsel, and shall direct the sealing of the record and exclusion of individuals from courtrooms or hearing rooms, to the extent necessary to safeguard her identity from public disclosure. Each such order must be accompanied by specific written findings explaining why the anonymity of the woman should be preserved from public disclosure, why the order is essential to that end, how the order is narrowly tailored to serve that interest, and why no reasonable less restrictive alternative exists. This section may not be construed to conceal the identity of the plaintiff or of witnesses from the defendant.

14-02.1-03.4. Required notice at abortion facility.

1. Any abortion facility that performs abortions shall display signs that contain exclusively the following words: "NOTICE: No one can force you to have an abortion. It is against the law for a spouse, a boyfriend, a parent, a friend, a medical care provider, or any other person to in any way force you to have an abortion."
2. The signs must be located so that the signs can be read easily and in areas that ensure maximum visibility to women at the time a woman gives consent to an abortion.
3. The display of signs pursuant to this section does not discharge any other legal duty of an abortion facility or physician.
4. The state department of health shall make the signs required by this section available for download in a printable format on its internet website.

14-02.1-03.5. Abortion-inducing drugs.

1. For purposes of this chapter, an abortion accomplished by the use of an abortion-inducing drug is deemed to occur when the drug is prescribed, in the case of a prescription, or when the drug is administered directly to the woman by the physician.
2. It is unlawful to knowingly give, sell, dispense, administer, otherwise provide, or prescribe any abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in that pregnant woman, or enabling another person to induce an abortion in a pregnant woman, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug is a physician, and the provision or prescription of the abortion-inducing drug satisfies the protocol tested and authorized by the federal food and drug administration and as outlined in the label for the abortion-inducing drug.
3. Every pregnant woman to whom a physician gives, sells, dispenses, administers, otherwise provides, or prescribes any abortion-inducing drug must be provided with a copy of the drug's label.
4. Any physician who gives, sells, dispenses, administers, prescribes, or otherwise provides an abortion-inducing drug shall enter a signed contract with another physician

who agrees to handle emergencies associated with the use or ingestion of the abortion-inducing drug. The physician shall produce the signed contract on demand by the patient, the state department of health, or a criminal justice agency. Every pregnant woman to whom a physician gives, sells, dispenses, administers, prescribes, or otherwise provides any abortion-inducing drug must be provided the name and telephone number of the physician who will be handling emergencies and the hospital at which any emergencies will be handled. The physician who contracts to handle emergencies must have active admitting privileges and gynecological and surgical privileges at the hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug.

5. When an abortion-inducing drug or chemical is used for the purpose of inducing an abortion, the drug or chemical must be administered by or in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug or chemical to the patient.

14-02.1-04. Limitations on the performance of abortions - Penalty.

1. An abortion may not be performed by any person other than a physician who is using applicable medical standards and who is licensed to practice in this state. All physicians performing abortion procedures must have admitting privileges at a hospital located within thirty miles [42.28 kilometers] of the abortion facility and staff privileges to replace hospital on-staff physicians at that hospital. These privileges must include the abortion procedures the physician will be performing at abortion facilities. An abortion facility must have a staff member trained in cardiopulmonary resuscitation present at all times when the abortion facility is open and abortions are scheduled to be performed.
2. After the first twelve weeks of pregnancy but prior to the time at which the unborn child may reasonably be expected to have reached viability, no abortion may be performed in any facility other than a licensed hospital.
3. After the point in pregnancy when the unborn child may reasonably be expected to have reached viability, no abortion may be performed except in a hospital, and then only if in the medical judgment of the physician the abortion is necessary to preserve the life of the woman or if in the physician's medical judgment the continuation of her pregnancy will impose on her a substantial risk of grave impairment of her physical or mental health.

   An abortion under this subsection may only be performed if the above-mentioned medical judgment of the physician who is to perform the abortion is first certified by the physician in writing, setting forth in detail the facts upon which the physician relies in making this judgment and if this judgment has been concurred in by two other licensed physicians who have examined the patient. The foregoing certification and concurrence is not required in the case of an emergency when the abortion is necessary to preserve the life of the patient.
4. An abortion facility may not perform an abortion on a woman without first offering the woman an opportunity to receive and view at the abortion facility or another facility an active ultrasound of her unborn child. The offer and opportunity to receive and view an ultrasound must occur at least twenty-four hours before the abortion is scheduled to be performed. The active ultrasound image must be of a quality consistent with standard medical practice in the community, contain the dimensions of the unborn child, and accurately portray the presence of external members and internal organs, including the heartbeat, if present or viewable, of the unborn child. The auscultation of the fetal heart tone must be of a quality consistent with standard medical practice in the community. The abortion facility shall document the woman's response to the offer, including the date and time of the offer and the woman's signature attesting to her informed decision.
5. Any physician who performs an abortion without complying with the provisions of this section is guilty of a class A misdemeanor.

6. It is a class B felony for any person, other than a physician licensed under chapter 43-17, to perform an abortion in this state.

14-02.1-04.1. Prohibition - Sex-selective abortion - Abortion for genetic abnormality - Penalty.

1. Notwithstanding any other provision of law, a physician may not intentionally perform or attempt to perform an abortion with knowledge that the pregnant woman is seeking the abortion solely:
   a. On account of the sex of the unborn child; or
   b. Because the unborn child has been diagnosed with either a genetic abnormality or a potential for a genetic abnormality.
2. Any physician who performs an abortion in violation of this section is guilty of a class A misdemeanor.

14-02.1-05. Preserving life of a viable child - Penalty.

An abortion of a viable child may be performed only when there is in attendance a physician other than the physician performing the abortion who shall take control and provide immediate medical care for the viable child born as a result of the abortion. The physician performing it, and subsequent to the abortion, the physician required by this section to be in attendance, shall take all reasonable steps in keeping with good medical practice, consistent with the procedure used, to preserve the life and health of the unborn child. Failure to do so is a class C felony.

14-02.1-05.1. Determination of detectable heartbeat in unborn child before abortion - Exception.

1. Except when a medical emergency exists that prevents compliance with this subsection, an individual may not perform an abortion on a pregnant woman before determining, in accordance with standard medical practice, if the unborn child the pregnant woman is carrying has a detectable heartbeat. Any individual who performs an abortion on a pregnant woman based on the exception in this subsection shall note in the pregnant woman's medical records that a medical emergency necessitating the abortion existed.
2. If a physician performs an abortion on a pregnant woman before determining if the unborn child the pregnant woman is carrying has a detectable heartbeat, that physician is subject to disciplinary action under section 43-17-31.

14-02.1-05.2. Abortion after detectable heartbeat in unborn child prohibited - Exception - Penalty.

1. Notwithstanding any other provision of law, an individual may not knowingly perform an abortion on a pregnant woman with the specific intent of causing or abetting the termination of the life of the unborn child the pregnant woman is carrying and whose heartbeat has been detected according to the requirements of section 14-02.1-05.1.
2. a. An individual is not in violation of subsection 1 if that individual performs a medical procedure designed to or intended, in that individual's reasonable medical judgment, to prevent the death of a pregnant woman, to prevent a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman, or to save the life of an unborn child.
   b. Any individual who performs a medical procedure as described in subsection 1 shall declare in writing, under penalty of perjury, that the medical procedure is necessary, to the best of that individual's reasonable medical judgment, to prevent the death of the pregnant woman or to prevent a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman. That individual also shall provide in that written document, under penalty of perjury, the medical condition of that pregnant woman that the medical procedure performed as described in subdivision a assertedly will address, and the medical rationale for the conclusion that the medical procedure is necessary

to prevent the death of the pregnant woman or to prevent a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman.

c. The individual who performs a medical procedure as described in subdivision a shall place the written documentation required under subdivision b in the pregnant woman's medical records and shall maintain a copy of the written documentation in the individual's own records for at least seven years.

3. An individual is not in violation of subsection 1 if that individual has performed an examination for the presence of a heartbeat in the unborn child utilizing standard medical practice and that examination does not reveal a heartbeat in the unborn child or the individual has been informed by a physician who has performed the examination for the unborn child's heartbeat that the examination did not reveal a heartbeat in the unborn child.
4. It is a class C felony for an individual to willingly perform an abortion in violation of subsection 1. The pregnant woman upon whom the abortion is performed in violation of subsection 1 may not be prosecuted for a violation of subsection 1 or for conspiracy to violate subsection 1.
5. This section does not prohibit the sale, use, prescription, or administration of a measure, drug, or chemical designed for contraceptive purposes.

14-02.1-05.3. Determination of postfertilization age - Abortion of unborn child of twenty or more weeks postfertilization age prohibited.

1. The purpose of this section is to protect the state's compelling interest in the unborn human life from the time the unborn child is capable of feeling pain.
2. Except in the case of a medical emergency, an abortion may not be performed or induced or be attempted to be performed or induced unless the physician performing or inducing the abortion has first made a determination of the probable postfertilization age of the unborn child or relied upon such a determination made by another physician. In making the determination, the physician shall make those inquiries of the woman and perform or cause to be performed the medical examinations and tests as a reasonably prudent physician, knowledgeable about the case and the medical conditions involved, would consider necessary to perform in making an accurate diagnosis with respect to postfertilization age.
3. Except in the case of a medical emergency, a person may not perform or induce or attempt to perform or induce an abortion upon a woman when it has been determined, by the physician performing or inducing or attempting to perform or induce the abortion or by another physician upon whose determination that physician relies, that the probable postfertilization age of the woman's unborn child is twenty or more weeks.

14-02.1-06. Soliciting abortions.

Repealed by S.L. 1999, ch. 50, § 79.

14-02.1-07. Records required - Reporting of practice of abortion.

1. Records:
   a. All abortion facilities and hospitals in which abortions are performed shall keep records, including admission and discharge notes, histories, results of tests and examinations, nurses' worksheets, social service records, and progress notes, and shall further keep a copy of all written certifications provided for in this chapter as well as a copy of the constructive notice forms, consent forms, court orders, abortion data reports, adverse event reports, abortion compliance reports, and complication reports. All abortion facilities shall keep the following records:
      (1) The number of women who availed themselves of the opportunity to receive and view an ultrasound image of their unborn children pursuant to section 14-02.1-04, and the number who did not; and of each of those numbers, the

number who, to the best of the reporting abortion facility's information and belief, went on to obtain the abortion.

(2) Postfertilization age:

(a) If a determination of probable postfertilization age was not made, the basis of the determination that a medical emergency existed.

(b) If the probable postfertilization age was determined to be twenty or more weeks and an abortion was performed, the basis of the determination that a medical emergency existed.

b. The medical records of abortion facilities and hospitals in which abortions are performed and all information contained therein must remain confidential and may be used by the state department of health only for gathering statistical data and ensuring compliance with the provisions of this chapter.

c. Records must be maintained in the permanent files of the hospital or abortion facility for a period of not less than seven years.

2. Reporting:

a. An individual abortion compliance report and an individual abortion data report for each abortion performed upon a woman must be completed by her attending physician. The abortion data report must be confidential and may not contain the name of the woman. The abortion data report must include the data called for in the United States standard report of induced termination of pregnancy as recommended by the national center for health statistics.

b. All abortion compliance reports must be signed by the attending physician within twenty-four hours and submitted to the state department of health within ten business days from the date of the abortion. All abortion data and complication reports must be signed by the attending physician and submitted to the state department of health within thirty days from the date of the abortion. If a physician provides an abortion-inducing drug to another for the purpose of inducing an abortion and the physician knows that the individual experiences during or after the use an adverse event, the physician shall provide a written report of the adverse event within thirty days of the event to the state department of health and the federal food and drug administration via the medwatch reporting system. For purposes of this section, "adverse event" is defined based upon the federal food and drug administration criteria given in the medwatch reporting system. If a determination of probable postfertilization age was not made, the abortion compliance report must state the basis of the determination that a medical emergency existed. If the probable postfertilization age was determined to be twenty or more weeks and an abortion was performed, the abortion compliance report must state the basis of the determination that a medical emergency existed.

c. A copy of the abortion report, any complication report, and any adverse event report must be made a part of the medical record of the patient at the facility or hospital in which the abortion was performed. In cases when post-abortion complications are discovered, diagnosed, or treated by physicians not associated with the facility or hospital where the abortion was performed, the state department of health shall forward a copy of the report to that facility or hospital to be made a part of the patient's permanent record.

d. The state department of health is responsible for collecting all abortion compliance reports, abortion data reports, complication reports, and adverse event reports and collating and evaluating all data gathered from these reports and shall annually publish a statistical report based on data from abortions performed in the previous calendar year. All abortion compliance reports received by the state department of health are public records. Except for disclosure to a law enforcement officer or state agency, the department may not disclose an abortion compliance report without first removing any individually identifiable health information and any other demographic information, including race, marital

status, number of previous live births, and education regarding the woman upon whom the abortion was performed.

e. The state department of health shall report to the attorney general any apparent violation of this chapter.

14-02.1-07.1. Forms.

The state department of health shall make available to physicians, hospitals, and all abortion facilities the forms required by this chapter.

14-02.1-08. Protection of infant born alive - Penalty.

1. A person is guilty of a class C felony if the person knowingly, or negligently, causes the death of an infant born alive.
2. Whenever an unborn child who is the subject of abortion is born alive and is viable, it becomes an abandoned and deprived child, unless:
   a. The termination of the pregnancy is necessary to preserve the life of the mother; or
   b. The mother and her spouse, or either of them, have agreed in writing in advance of the abortion, or within seventy-two hours thereafter, to accept the parental rights and responsibilities for the unborn child if it survives the abortion procedure.

14-02.1-09. Humane disposal of nonviable unborn child.

The physician performing the abortion, if performed outside of a hospital, must see to it that the unborn child is disposed of in a humane fashion under regulations established by the state department of health. A licensed hospital in which an abortion is performed must dispose of a dead unborn child in a humane fashion in compliance with regulations promulgated by the state department of health.

14-02.1-10. Concealing stillbirth or death of infant - Penalty.

It is a class A misdemeanor for a person to conceal the stillbirth of a fetus or to fail to report to a physician or to the county coroner the death of an infant under two years of age.

14-02.1-11. General penalty.

A person violating any provision of this chapter for which another penalty is not specifically prescribed is guilty of a class A misdemeanor. Any person willfully violating a rule or regulation promulgated under this chapter is guilty of an infraction.

14-02.1-12. Short title.

This chapter may be cited as the North Dakota Abortion Control Act.

Addendum to page 16:

The It may be possible to avoid, cease, or even to reverse the effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Further information about abortion pill reversal and help locating a medical professional that can aide in the reversal of an abortion see http://www.abortionpillreversal.com/ or call (877) 558-0333.

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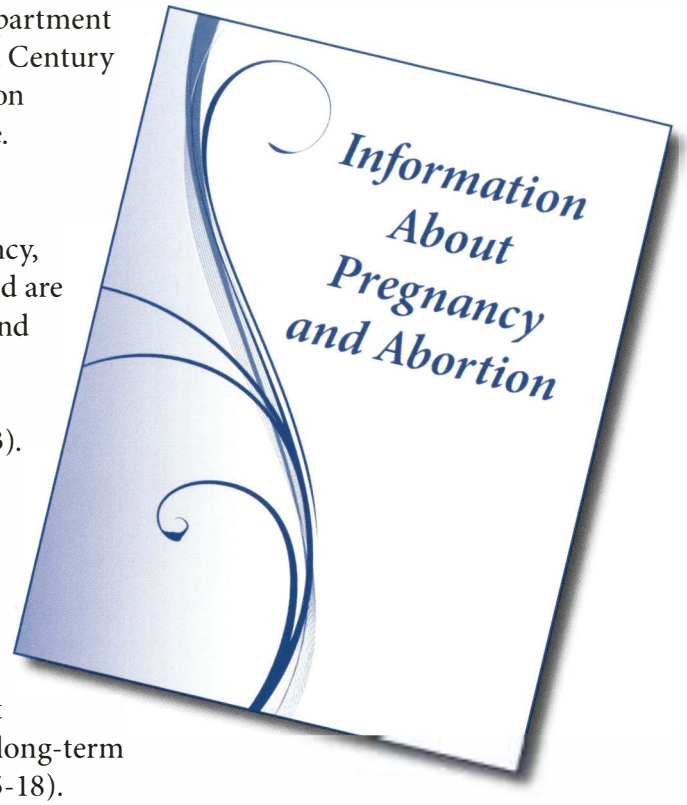
Table of Contents

Introduction

This booklet was produced by the North Dakota Department of Health to meet the requirements of North Dakota Century Code Chapter 14-02.1, Abortion Control Act, Section 14-02.1-02.1, Printed Information – Referral Service.



This booklet provides basic information regarding pregnancy. For every two weeks throughout pregnancy, color pictures of the development of the unborn child are shown, along with information about body organs and the chances of the unborn child living outside of the woman's body (page 4-10). The medical risk of pregnancy and childbirth also are discussed (pages 11-13).

Support obligations of the father and information about a resource that includes a list of agencies and services to assist women through, during and after pregnancy are discussed as well (page 14).

In addition, this booklet provides information about the various methods of abortion and the short- and long-term medical risks associated with each method (pages 15-18).

This booklet is meant to be informative and is not a replacement for professional medical advice or care.

Information about references used to develop this booklet can be found on the North Dakota Department of Health's website at **www.ndhealth.gov/familyhealth**.

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Pregnancy and Childbirth

For most women, pregnancy represents a normal part of life. Pregnancy can be one of the happiest times in a woman's life, but sometimes it may leave a woman feeling scared, anxious and unsure of what to expect. Throughout pregnancy, a woman's body goes through many physical and emotional changes which can be very frightening at times. Although these feelings can be overwhelming, pregnancy and the birth of a child can be one of the most fulfilling and life changing experiences of a woman's life.

Pregnancy can allow women to bond with their spouse, significant other, family and friends to develop a strong support system. For many men, pregnancy is a time of intense learning and preparation for the responsibility of fatherhood. The connections that are established are important for the well-being of the expectant mother to have during pregnancy and after the birth of her child. If a pregnant woman lacks a support system, she should not feel alone. There are several agencies in North Dakota that are available to support women throughout their pregnancies and following the birth of their babies. The North Dakota Department of Health and North Dakota Department of Human Services have published *A Connections Directory for Family and Agencies*. This directory includes a list of agencies, websites and contact information for services to women, children and families in North Dakota (see page 14 for information about how to access this publication).

It is the policy of the state of North Dakota that childbirth is given preference, encouragement and support as it is in the best interests of the well-being and common good of North Dakota citizens.

Growth and Development

Approximately two weeks after the first day of a menstrual period (in a 28-day cycle) a woman ovulates, or releases an egg from the ovary. Over the course of about a week, the egg will travel through the fallopian tube to the uterus. If a sperm cell fertilizes the egg and successfully implants in the uterine lining, the woman is pregnant.

Pregnancy can be measured in two ways: fertilization age and gestational age. Fertilization age refers to how long the unborn child has been developing since the egg was fertilized, and is calculated from the estimated day of ovulation. Ovulation can vary each month and there are no obvious signs that tell a woman exactly when she ovulates, so the date of fertilization can only be an estimate.

Gestational age is measured from the first day of the last menstrual period. A menstrual period provides a known date from which to measure the pregnancy. Gestational age is more accurate and more commonly used when discussing pregnancy. About nine calendar months, 10 lunar months, 40 weeks, or 280 days go by between the first day of the last menstrual period and the birth of the child.

The development of the unborn child depends on many factors and will vary somewhat for each pregnancy. This booklet will describe normal, approximate growth and development at gestational ages. The pictures in the Growth and Development Section of this booklet do not represent the actual size of the developing child. Approximate sizes are provided in the text for most weeks.

During the first 10 week of pregnancy, human growth and development is most sensitive to:

- Nicotine in cigarette smoke or other tobacco products.
- Alcohol.
- Some prescription medicines and over-the-counter drugs.
- Illegal drugs.
- Viruses (like German measles).
- X-rays, radiation therapy or accidental radiation exposure.
- Vitamin deficiencies (such as folic acid).

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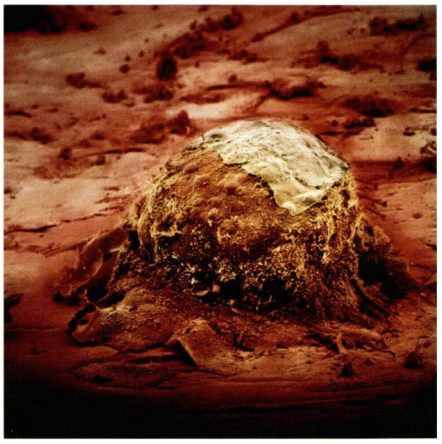
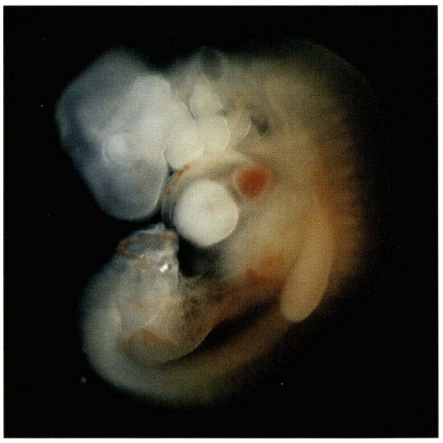
First Trimester

4 Weeks Gestation



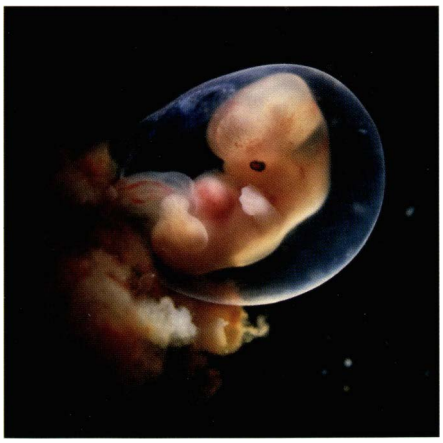
- The fertilized egg, now called an embryo, has traveled through the fallopian tube and may implant in the uterus.
- The heart and nervous system will soon begin to form.
- By the end of week four or during week five, most women notice a missed menstrual period.
- The embryo is about the size of a poppy seed.

6 Weeks Gestation



- The neural tube forms, which will become the spinal cord and brain.
- The heart, now a system of two tubes, continues to develop and has started to beat.
- Branches of the respiratory system are growing.
- The body is C-shaped with the head curved toward the tail (legs).
- Structures that will become arms and legs begin to appear as buds.
- Structures that will become the eyes and ears are beginning to form.
- The embryo is about the size of a pea.

8 Weeks Gestation



- The heart now has four chambers, but it is still too early to hear the heartbeat from the outside.
- The brain is growing rapidly.
- Tubes that will become the digestive tract are forming.
- Limbs (arm and legs) continue developing.
- Lungs and eyelids are beginning to form.
- The skeleton is soft and made of cartilage.
- The embryo is about the size of a kidney bean.

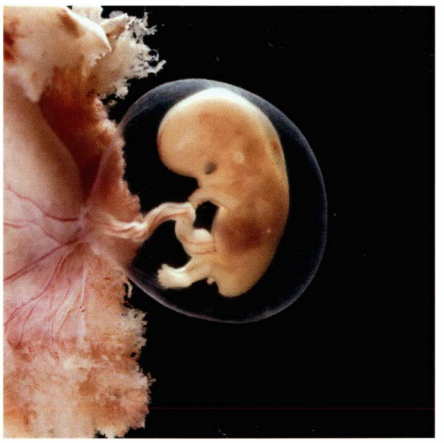
Note: Pictures do not represent the actual size of the developing child. Approximate sizes are provided in the text for most weeks.

10 Weeks Gestation

The term ***fetus*** is now used to describe the developing child.

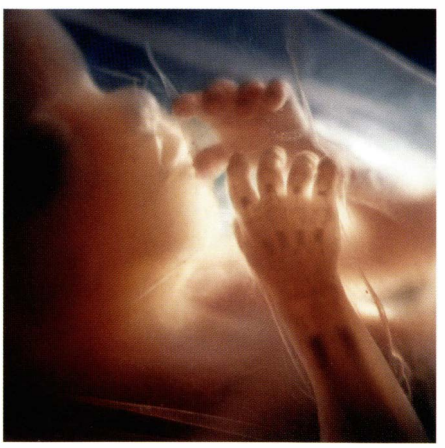
- The heartbeat can now be detected by ultrasound.
- Electrical activity from the brain can be recorded.
- Real bone starts to take the place of cartilage.
- The beginnings of all the key body parts and organs are present, although they are immature and not exactly positioned in their final locations.
- The fetus is about the size of a brussel sprout.

12 Weeks Gestation



- The heart is complete and will continue to mature.
- Small movements of the arms, legs and chest are being made, but are too slight to be felt.
- Skin is starting to cover the body and fingernails start to grow.
- The eyelids cover the eyes and the eyes remain closed until about week 26.
- The kidneys and digestive system are beginning to function.
- External genitalia are present, but still difficult to see by ultrasound.
- The fetus is about the size of a lime.

14 Weeks Gestation



- The heart is growing and pumping blood.
- The brain surface is smooth, without the grooves that will develop as it matures.
- Kidneys begin to make small amounts of urine.
- Fine hair, called lanugo, begins to cover the delicate skin.
- Ultrasound may possibly identify gender.
- The fetus is about the size of a lemon.

Note: Pictures do not represent the actual size of the developing child. Approximate sizes are provided in the text for most weeks.

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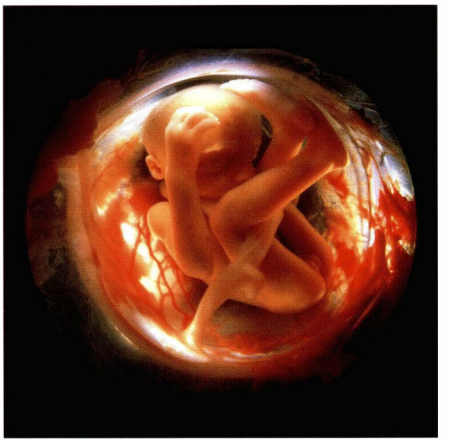
Second Trimester

16 Weeks Gestation

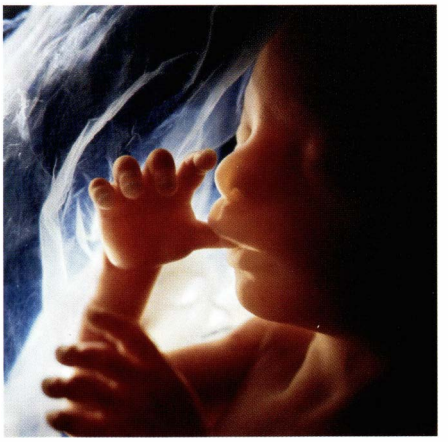
- The heart muscle is well developed.
- The lobes of the brain are taking shape.
- Developing muscles and bones make the body stronger.
- The skin is transparent and blood vessels are visible under the skin.
- The fetus is about the size of an avocado.

18 Weeks Gestation



- The heart is pumping blood to the lungs.
- Swallowing and sucking reflexes are present.
- Fingerprints are forming.
- Many women will start feeling movements soon.
- The fetus is about the size of a mango.

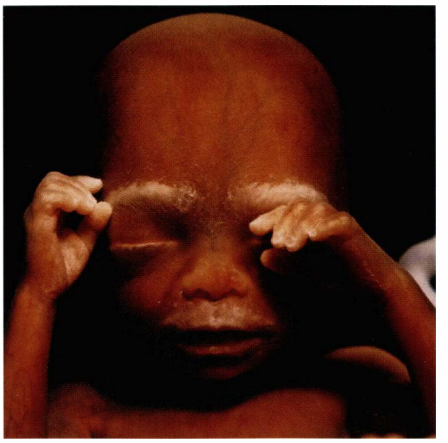
20 Weeks Gestation



- The heart continues to get stronger and pump more blood through the body.
- All organs and structures, including the brain, have been formed and continue to develop but are too immature for survival outside of the womb.
- The skin is thin, wrinkled and covered by vernix, a waxy white protective substance.
- Most women feel moving or fluttering sensations.
- Hair on the head is growing.
- The fetus is about the length of a banana.

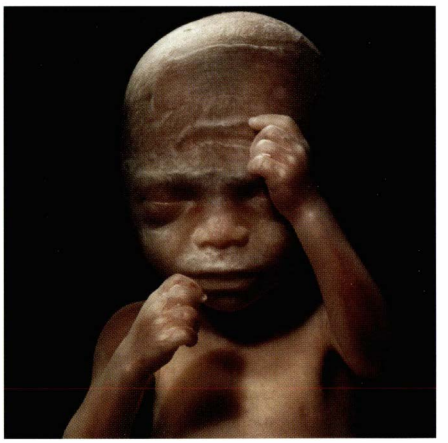
Note: Pictures do not represent the actual size of the developing child. Approximate sizes are provided in the text for most weeks.

22 Weeks Gestation



- The heart is beating strongly enough to hear with just a stethoscope.
- The nerves throughout the body are maturing.
- The hands can grasp and play with the umbilical cord.
- A child could potentially survive outside the womb, but survival rates are very low and the risk for permanent disability is high. Most babies born before this time have little chance of survival.
- The fetus is about the length of an ear of corn.

24 Weeks Gestation



- The heart will soon pump blood into the tiny developing capillaries.
- Another period of rapid brain maturation is beginning.
- The skin is still loose and wrinkled.
- The sense of sound is developing.
- The lungs are immature and survival rates outside of the womb are 50 to 60 percent with a high risk for permanent disability.

26 Weeks Gestation

- The heart and circulatory system are well developed.
- The brain and nervous system start taking control of some body functions.
- The body is thin due to the lack of body fat, but weight is being put on steadily.
- Fingerprints are developed.
- Eyes begin to open and close.
- The lungs are maturing, which makes survival rates outside of the womb better (approximately 80%), but there is still a risk for permanent disability.

Note: Pictures do not represent the actual size of the developing child. Approximate sizes are provided in the text for most weeks.

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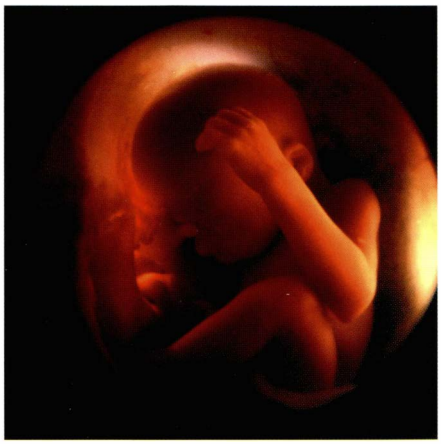
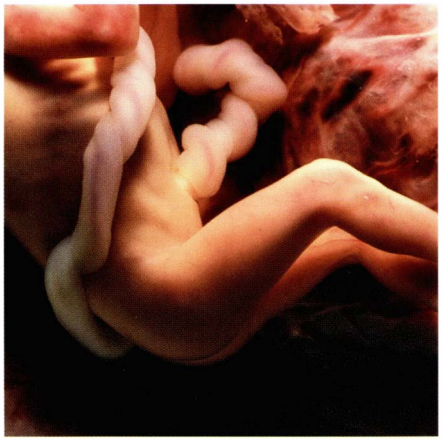
Third Trimester

28 Weeks Gestation



- The heart continues to get stronger.
- The brain and nerves can respond to light and sound.
- Eyelashes are present and eyes can blink.
- Many women may feel hiccup sensations and notice sleep-wake cycles.
- Survival rates outside of the womb are about 90 percent, but all body systems are still immature.

30 Weeks Gestation



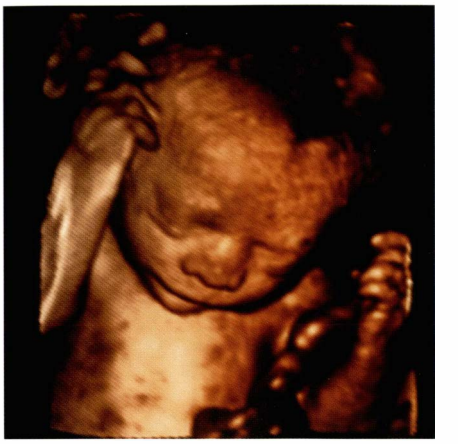
- The heart pumps more blood to the brain than anywhere else in order to help the brain grow.
- The brain continues maturing and can control breathing and body temperature.
- The lungs are almost ready to breathe air outside of the womb.
- The body starts to assume a head-down position.
- The fetus continues to put on weight and is about the size of a cabbage.

32 Weeks Gestation

- The heart continues to get nutrients and remove wastes through the placenta.
- Brain cells are interacting to prepare for learning, speaking and survival.
- The skin is pink and no longer so transparent.
- Toenails are now fully formed.
- Growth in length slows as weight gain increases.
- The possibility of survival outside of the womb continues to improve.

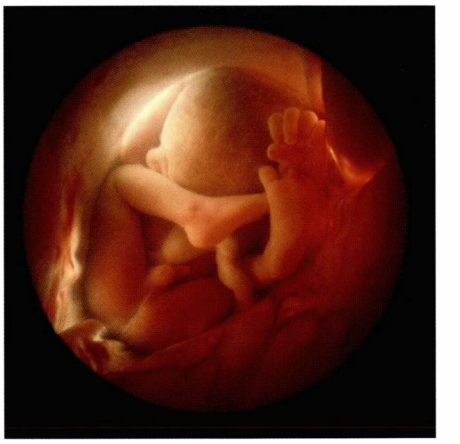
Note: Pictures do not represent the actual size of the developing child. Approximate sizes are provided in the text for most weeks.

34 Weeks Gestation



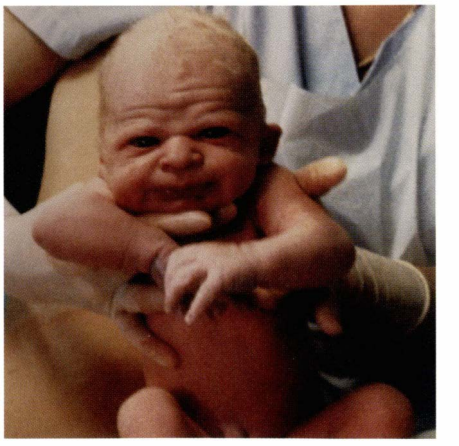
- The heart rate begins to slow down a little.
- The head is making room for the growing brain.
- The eyes close during sleep and open during alert times.
- The skin becomes more smooth, plump and pigmented.
- Survival rates outside of the womb are more than 95 percent and children born now may not need critical care.
- The fetus is almost his or her full length and continues gaining about a half a pound per week.

36 Weeks Gestation



- The heart wall has a hole called the foramen ovale that will naturally close after birth.
- The brain is very active.
- Muscle tone improves so the head can be turned and lifted.
- The hair on the head is getting longer.
- Meconium, the first bowel movement, is forming in the intestines.
- Chances for survival outside of the womb are very good.

38 to 42 Weeks Gestation



- Full term ranges from 38 to 42 weeks gestation.
- The heart rate is about 120 to 160 beats per minute.
- The bones over the brain have flexible spaces between them called fontanels that adjust to the birth canal during delivery.
- The grasp reflex is strong and more deliberate.
- Lungs are mature and capable of breathing.
- Sexual characteristics are mostly defined and if it's a boy, the testes will descend.
- Protective antibodies from the mother's immune system are being passed through the placenta and can be passed through breastmilk after delivery.
- The body systems are mature enough for survival outside of the womb.

Note: Pictures do not represent the actual size of the developing child. Approximate sizes are provided in the text for most weeks.

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Risks of Pregnancy and Childbirth

Pregnancy and childbirth are usually safe, healthy processes, but complications can occur. Early and ongoing prenatal care helps address potential problems before they become serious. Women who have certain chronic diseases have better chances of successful pregnancies if their illness is under control before pregnancy occurs. Listed below are the potential risks of pregnancy and childbirth.

Ectopic pregnancy – Ectopic pregnancy occurs when an embryo implants anywhere other than the uterus, most often the fallopian tube. The incidence is about 2 percent of all pregnancies. Ectopic pregnancy can be life-threatening and can cause internal damage and tubal rupture.

Pregnancy induced hypertension (high blood pressure) – About 6 to 8 percent of pregnant women will develop hypertension during pregnancy. It is a life-threatening condition for mother and child.

Gestational diabetes – About 6 to 7 percent of pregnant women will develop gestational diabetes, which increases the risk of hypertension during pregnancy as well as chances of a more difficult delivery.

Miscarriage – A miscarriage (sometimes referred to as a spontaneous abortion) happens when, for various reasons, a woman's body cannot support the pregnancy or there is a problem with growth and development that causes the pregnancy to end on its own. If the uterus does not empty itself completely, a medical or surgical procedure may be required to remove the tissues. Dilation and curettage (D&C) is a surgical procedure that can be used to remove remaining tissue. A local anesthetic will be used to numb the cervix. The procedure involves a cervical dilation after which the uterus will be scraped with a curved curette. A D&C procedure usually takes five to 10 minutes. Because most patients who undergo a D&C are given general anesthesia (medicine to put you to sleep), recovery time is about 24 hours.

Premature labor – About 12 percent of pregnancies will result in premature delivery (between 20 and 37 weeks gestation). It is a leading cause of infant disability and/or death.

Cesarean section (C-section) – C-sections are done both by necessity and by choice. They are major, invasive abdominal surgeries that carry the risks of hemorrhage, infection, blood clots, structural damage and death. About one-third of all deliveries are C-section.

Infection – Infection in the genital tract for any reason is associated with future fertility problems. It can cause internal damage if untreated. In some cases, antibiotics may be given during labor and delivery to prevent infection, or will be prescribed if symptoms develop after delivery. It is estimated to occur in 1 to 6 percent of vaginal deliveries and a considerably higher percentage of Cesarean deliveries.

Retained tissue – Occasionally, fragments of placenta remain in the uterus after delivery (.5% to 3% of deliveries). Heavy or irregular bleeding and infection may result. This may require an aspiration or dilation and curettage to empty the uterus.

Hemorrhage – Hemorrhage is heavy bleeding that can happen during or after labor. Some bleeding will be expected with all deliveries, but heavy bleeding is not normal and is not common. If it occurs, aspiration or medications may be used to treat it. It is estimated to occur in 4 to 5 percent of deliveries. Surgery or blood transfusion is rare.

Structural damage – Lacerations to the genital tract, or injury to the bladder or rectum can occur during delivery. Damage can range from a self-healing surface cut to a deep tear requiring stitches or surgery. Uterine rupture is a rare complication of pregnancy.

Adverse reaction to medication – Any medication carries a risk of an allergic or adverse reaction. There are many medications that may be requested or prescribed during childbirth. Depending on the medication, risks and side effects may include a change in blood pressure, a change in the mother's or unborn child's heartbeat, trouble breathing, trouble pushing during delivery, dizziness, drowsiness, nausea, hemorrhage, headache and back pain. Seizures, uterine rupture and serious allergic reactions are rare.

Mental health issues – Because every woman is different, each woman will experience childbirth differently. Feelings can range from intense joy to disappointment and sadness. It is common for women to experience a few days of the "baby blues" after delivery as the body and mind naturally adjust. Age, religion, financial situation, support network and past coping experiences can all affect how a woman adapts to motherhood. Women who feel they are having trouble functioning in their new role should know they are not alone and should contact their health-care provider for help, especially if the feelings last more than two or three weeks or are extreme. Postpartum depression can interfere with a woman's ability to care for herself and her child, and it is a fairly common and treatable disorder (occuring in 15% to 30% of new mothers).

Death – The risk of death during childbirth is about 12 per 100,000.

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Tobacco Use and Secondhand Smoke During and After Pregnancy

Smoking and exposure to secondhand smoke are harmful. Secondhand smoke is a mixture of gases and particles that come from the burning end of a cigarette, cigar or pipe, as well as the smoke breathed out by smokers. Tobacco smoke contains more than 7,000 chemicals – like tar, formaldehyde, carbon monoxide and cyanide. More than 70 of these chemicals can cause cancer. Chemicals in tobacco smoke reduce the blood supply and oxygen to the womb that is necessary for normal growth and development. They also can interfere with the body's ability to absorb nutrients that a woman and developing child need.

The 2006 Surgeon General's Report, "The Health Consequences of Involuntary Exposure to Tobacco Smoke," reports the following facts:

- During pregnancy, many of the compounds in tobacco smoke change the way an unborn child's brain develops.
- Smoking and exposure to secondhand smoke during pregnancy can lead to low birthweight and can reduce a child's lung function.
- Children who breathe secondhand smoke after they are born are more likely to die of sudden infant death syndrome (SIDS). SIDS is the leading cause of death in children between 1 month and 1 year of age. If anyone is smoking in the home where a child lives or is cared for, the child is inhaling the toxic chemicals from the smoke and is suffering the effects, which could include a higher risk of dying from SIDS.
- Children exposed to secondhand smoke are at an increased risk for acute respiratory infections, ear problems and more severe asthma. Smoking by parents causes respiratory symptoms and slows lung growth in their children. Their breathing problems can continue as they grow older and even when they become adults.

To protect children from the effects of secondhand smoke:

- Never smoke around your child. If you smoke, get help with quitting.
- Don't allow anyone else to smoke in your home or around your child either, including family members and babysitters. People moving to another room to smoke or opening a window does not protect children from secondhand smoke.
- Don't take your child to public places where people are smoking.

For help quitting smoking or other tobacco use, contact NDQuits by calling 1.800.QUIT.NOW (1.800.784.8669) or visiting **www.ndhealth.gov/ndquits**.

NDQuits is a free services to all North Dakotans who want to quit tobacco. Qualified enrollees receive:

- Counseling and advice from professional counselors.
- 24/7/365 online support from other quitters.
- Free nicotine patches, gum or lozenges.

NDQUITS
www.ndhealth.gov/ndquits
1.800.QUIT.NOW

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Help for You

Services Available To You

The North Dakota Department of Health and North Dakota Department of Human Services have published *A Connection Directory for Families and Agencies*. This 100-plus-page directory includes a list of agencies, websites and contact information for services offered to women, children and families in North Dakota.

Included in this publication is information about public and private agencies and services available to assist women during and after pregnancy, upon childbirth, and while the child is dependant, including adoption agencies. To access the directory online, visit the North Dakota Department of Health, Division of Family Health website at **www.ndhealth.gov/familyhealth**. To order a copy of the directory, call 701.328.4532 or 800.427.2286 and press 1.

A Father's Duty

The father of a child born alive has a legal duty to support his child, which may include child support payments and health insurance. The child also may have rights to Social Security, veteran's benefits, inheritances and other benefits.

Paternity may be established through a voluntarily paternity acknowledgement process or by court action. Paternity testing is available at no charge upon request by either parent. There is no fee to open a case with the Child Support Program. Some fees may be assessed after child support is established. Services are available to help locate the father of the child, establish court orders and enforce those orders.

In North Dakota there are offices in Bismarck, Dickinson, Grand Forks, Minot, Devils Lake, Fargo, Jamestown and Williston. You can call the Child Support offices toll-free at 800.231.4255 or send an e-mail to centralofficecse@nd.gov. More information concerning paternity establishment and child support services and enforcement is available at **www.childsupportnd.gov**.

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What is Abortion?

What is abortion?

Abortion is an early termination of a pregnancy. This can happen either by choice through surgery or medication (induced abortion) or it can happen naturally (spontaneous abortion – often called a miscarriage).

Induced abortion – a procedure done by choice to end a pregnancy either through surgery or medication. North Dakota Century Code (Law) Chapter 14-02.1, Section 14-02.1,02 (8)(a)(2) requires that a woman is told the [induced] abortion will terminate the life of a whole, separate, unique, living human being.

In addition, Section 14-02.1-02.1 (1)(a) states:

- It is unlawful for anyone to coerce you to undergo an abortion.
- If a minor is denied financial support by the minor's parent, guardian or custodian due to the minor's refusal to have an abortion, the minor is deemed to be emancipated for the purposes of eligibility for public assistance benefits.
- Any physician who performs an abortion without a woman's informed consent may be liable to her for damages in a civil action.
- Adoptive parents are allowed to pay costs of prenatal care, childbirth and neonatal care.

There are many public and private agencies willing and able to help you to carry your child to term and to assist you and your child after your child is born, whether you choose to keep your child or place your child for adoption. The state of North Dakota strongly encourages you to contact one or more of these agencies before making a final decision about abortion. The law requires that your physician or your physician's agent give you the opportunity to call agencies like these before you undergo an abortion. See page 14 in this booklet for information about a directory of services offered to women, children and families in North Dakota.

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Types of Abortion

Medical Abortion

Medical abortion purposely ends a pregnancy with medications:

- Mifepristone (Mifeprex) – blocks the hormone progesterone which is needed to maintain pregnancy.
- Misoprostol – causes contractions to empty the uterus.

Medical abortion only can be done early in the pregnancy (a woman must be no more than nine weeks pregnant). A medical abortion does not require surgery or anesthesia, but multiple visits to the doctor are needed. Generally, Mifepristone will be taken orally in the clinic on the first day and Misoprostol will be taken orally 48 hours later. Usually, the pregnancy will end within a few hours or days, but bleeding may continue for several weeks. Bleeding, passing of blood clots and cramping are expected. A follow-up visit to the doctor will be required after 14 days to determine if the pregnancy has ended.

Aspiration Abortion, also called Vacuum Aspiration

Vacuum aspiration is the most common method of early abortion (performed up to 16 weeks gestation). In preparation for the procedure, a local anesthetic will be used to numb the cervix and the cervix is usually dilated to a width of less than one centimeter. A cannula – a hollow tube – will be passed through the cervical opening and suctioning through the cannula will empty the uterus. Medications to reduce discomfort may be available during and after the procedure. The procedure takes approximately five to 10 minutes, in addition to preparation and about 30 minutes of recovery time. Some bleeding and cramping will be expected for a few days.

Dilation & Curettage (D&C)

Dilation and curettage is no longer a common method of abortion but may be required if spontaneous abortion (miscarriage) or other abortion methods fail to entirely empty the uterus. A local anesthetic will be used to numb the cervix. The procedure generally involves a wider cervical dilation after which the inside of the uterus will be scraped with a curved curette. A D&C procedure usually takes five to 10 minutes. Because most patients who undergo a D&C are given general anesthesia, recovery time is about 24 hours.

Dilation & Evacuation (D&E)

Dilation and evacuation can be performed after 14 weeks gestation. The cervix may be dilated by an absorbent material placed in the cervix for several hours or overnight. Medications may be given for several reasons – to ease discomfort, to prevent infection, to induce contractions and to limit bleeding. Vacuum aspiration will be used to empty the uterus, and if necessary a curette or forceps also may be used. The procedure usually takes 10 to 15 minutes followed by a couple hours of recovery time.

Labor induction

This procedure is generally used after 16 weeks of pregnancy. Medicines will be used to start labor. These medicines can be put in the vagina, injected in the uterus (womb) or given into the vein (intravenously or IV). The medicines used cause the uterus to contract and labor to begin. Sometimes more than one medicine will be used. This procedure may take from several hours to several days. Your doctor may use instruments to scrape the uterus and make sure that the fetus, placenta and other contents of the uterus have been completely removed.

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North Dakota Catholic Conference

Representing the Diocese of Fargo and the Diocese of Bismarck

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To: House Human Services Committee
From: Christopher T. Dodson, Executive Director
Subject: House Bill 1336 - Woman's Right to Know about Abortion Pill Reversal
Date: January 21, 2019

The North Dakota Catholic Conference supports House Bill 1336 to update our Woman's Right to Know law.

Women considering abortions deserve to have information about the abortion procedure, possible consequences of an abortion, the development of the unborn child, and services available as alternatives to abortion. This is why the state has a Woman's Right to Know law that requires informed consent and the publication of materials about pregnancy, abortion, and abortion alternatives.

From time to time the state must update this information to reflect current practices. For example, the law was substantially revised in 2011 to address, among other things, the use of abortion-inducing drugs. HB 1336 revisits and updates the law further by including information about the possibility of reversing the effect of the abortion drug regimen should the woman change her mind after taking the first drug in the process.

North Dakota law requires that abortion-inducing drugs be administered according to the protocol approved by the federal Food and Drug Administration (FDA). The FDA approved protocol consists of mifepristone, followed by misoprostol taken 24 to 48 hours later. The mifepristone blocks the production of progesterone, which is stabilizes the uterine lining, which in turn is necessary for the development of the unborn child. By blocking the production of progesterone, mifepristone cuts off blood and nourishment to the unborn child, usually causing he or she to die. The second drug, misoprostol, forces the body to expel the dead unborn child or in some cases a live child.[1]

Since physicians know exactly how mifepristone works (i.e., by blocking progesterone), they also know that treating a woman with progesterone can

"kick off" the mifepristone (i.e., displace mifepristone from the progesterone receptors). This allows the woman's body to respond naturally to the progesterone and to effectively fight the effects of the mifepristone-induced blockage.

Progesterone itself has been used safely in pregnancies for decades. Using progesterone to reverse the effects of mifepristone is a targeted medical response that is safe for the woman and the baby. We also know that use of mifepristone alone does not cause birth defects.[2]

The fact that the effects the abortion-inducing drug mifepristone can be reversed or blocked should not be disputed. Hundreds of babies among us attest to that fact. Those who oppose merely informing women about the possibility reversing the abortion drug process point to the absence of large-scale studies explaining how the process works. The number of women at issue, however, is so small that large-scale controlled studies are difficult to conduct. Nevertheless, even the opponents of informing women have noted that reversal makes "biological sense" and there is no evidence that abortion pill reversal does not work or is not safe.[3] Indeed, initial studies show that without abortion pill reversal, the chances that an unborn child will survive mifepristone are around 15%. However, if the mother receives the progesterone-based rescue, then 65-70% of the unborn children will survive.

The state's right to ensure that woman receive information about abortion as part of the informed consent process is well-established. *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 882–83 (1992). While the state cannot compel an individual to simply to speak the state's ideological message — which HB 1336 does not do — it can use its regulatory authority to require a physician to provide truthful, non-misleading information that the legislature concludes could be relevant to a patient's decision to have an abortion, even if that information might also encourage the patient to choose childbirth over abortion. *Planned Parenthood Minn., N.D., S.D. v. Rounds,* 686 F.3d 889 (8th Cir. 2012). Mere claims of scientific uncertainty by opponents of informed consent do make the requirements unconstitutional. *Rounds*, 686 F.3d at 899; *Gonzales v. Carhart*, 550 U.S. 124, 163-64 (2007).

Working within this constitutional framework and our existing statutory structure, HB 1336 does two things. First, it directs the Department of Health to update its printed materials on abortion and pregnancy to include information about the possibility of abortion pill reversal. (HB 1336,

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page 2, line 27 through page 3, line 2.) These printed materials are required by Chapter 14-02.1-02.1 of the Century Code and include information on abortion, abortion alternatives, fetal development, services available, and a pregnant woman's legal rights. They are periodically updated and must be provided to all women seeking an abortion.

Second, HB 1336 adds to the informed consent requirements assurance that the woman is told (1) that it may be possible to reverse the effects of the abortion-inducing drug if she changes her mind and (2) that further information is available in the printed materials. (HB 1336, page 2, lines 14-18.) This information must be provided at least twenty-four hours before the abortion, which in this case is the taking of the mifepristone. It requires nothing more from the physician or the physician's agent.

In summary, HB 1336 is a simple, but important update to North Dakota's Woman's Right to Know law. Some women change their minds after taking the first drug of the abortion pill regimen, but without HB 1366 these women may not know about the possibility of abortion pill reversal. Women deserve better. Women deserve HB 1366.

We urge a **Do Pass** recommendation on House Bill 1336.

[1] We know this because some women who do not take misoprostol have their pregnancies continue. For purposes of North Dakota law, however, the "abortion-inducing drug" is the mifepristone.

[2] The scientific facts concerning abortion pill reversal are summarized in the attached fact sheet from the American Association of Pro-life Obstetricians and Gynecologists.

[3] https://www.washingtonpost.com/news/to-your-health/wp/2018/04/03/as-controversial-abortion-reversal-laws-multiply-researcher-says-new-data-shows-it-can-work-critics-are-still-skeptical/

ProLife OB|GYNS
AAPLOG American Association of Pro-life Obstetricians & Gynecologists

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AAPLOG FACT SHEET Abortion Pill Reversal

The American Association of Pro-Life Obstetricians and Gynecologists strongly supports a woman's right to choose to keep her pregnancy, and to attempt to reverse the effects of a medical abortion which she no longer desires. The Abortion Pill Reversal process is safe for both the mother and for her unborn child, and offers a real chance for the woman to rescue her unborn child when she has changed her mind about abortion. The following facts about APR are important to understand:

- Progesterone is the hormone produced by the mother's ovaries, which allows the mother's womb to carry an unborn child. ("Pro"=for, "gest"=pregnancy, "erone" = hormone). When progesterone is too low, the unborn child cannot receive nutrients, and dies. ASRM FACT SHEET (Ref 1)

- Mifepristone(RU486/Mifeprex) is a progesterone blocker. (Ref 2) Mifepristone blocks progesterone from allowing the womb to nourish the unborn child. But Mifepristone is a REVERSIBLE (Ref 2) blocker- which means that the effects of Mifepristone can be stopped by adding large amounts of natural progesterone. The natural progesterone competes for the binding sites on the progesterone receptors, and kicks the mifepristone off of these binding sites.

- Natural progesterone has been used for over 50 years in the treatment of early pregnancies who are threatening to miscarry because the mother's progesterone level is too low. Progesterone has also been used for over 3 decades in women who have conceived with IVF. In the extensive medical literature on the use of progesterone in early pregnancy, there are no increased risks of any birth defects with natural progesterone. (Ref 1)

- The use of natural progesterone to reverse the effects of mifepristone poisoning is a simple application of common sense in the treatment of poisonings in situations where the mechanism of poisoning is well understood. Mifepristone poisoning is well studied and well understood. Using natural progesterone to reverse mifepristone effects is a logical extension of understanding the biochemical mechanism of action of mifepristone. (Similar application is used in chemotherapy with methotrexate followed by leukovorin rescue.) (Ref 3)

- In children who survive mifepristone poisoning and continue to birth, mifepristone alone has not been found to be associated with birth defects. In those children who have survived after the mother has ingested mifepristone alone, there have been no increased risks of birth defects noted. (Ref 4)

- The APR protocol involves giving natural progesterone to women who have taken mifepristone alone- who have not yet taken the second abortion drug misoprostol. (Ref 3)

- The APR protocol increases the chances that a baby will survive after the mother ingests mifepristone. Without APR, the chances that an unborn child will survive mifepristone poisoning are around 15%. However, if the mother receives the APR rescue, then 65-70% of the babies will survive. There are currently 200 babies born nationwide after using the APR protocol, and another 100 coming soon. (Ref 6)

- The babies born after using the APR protocol are not at increased risk for birth defects. (Ref 4)

- See AAPLOG FACT SHEET REFERENCES Abortion Pill Reversal

Life. It's why we are here.

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ProLife OB|GYNS
AAPLOG American Association of Pro-life Obstetricians & Gynecologists

AAPLOG FACT SHEET REFERENCES Abortion Pill Reversal

- ASRM FACT SHEET http://www.reprodsurgery.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Educational_Bulletins/Progesterone_supplementation.pdf
- Baulieu.E.E. (1985) RU 486: an antiprogestin steroid with contragestive activity in women. In Baulieu.E.E. and Segal,S.J. (eds), The Antiprogestin Steroid RU 486 and Human Fertility Control. Plenum Press, New York,
- Delgado G, Davenport M. Progesterone Use to Reverse the Effects of Mifepristone. Ann Pharmacother 2012;46. Published Online, 27 Nov 2012, theannals.com, doi: 10.1345/aph.1R252
- Bernard N, Elefant E, Carlier P, Tebacher M, Barjhoux C, Bos-Thompson M, Amar E, Descotes J, Vial T. Continuation of pregnancy after first-trimester exposure to mifepristone: an observational prospective study. BJOG 2013;120:568–575 http://onlinelibrary.wiley.com/doi/10.1111/1471-0528.12147/epdf
- http://abortionpillreversal.com/page/2-Abortion%20Pill%20Reversal/
- Davenport et. Al. publication pending.

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Family Policy ALLIANCE of North Dakota

Testimony in Favor of House Bill 1336

Mark Jorritsma, Executive Director
Family Policy Alliance of North Dakota
January 21, 2019

Good morning Chairman Weisz and honorable members of the House Human Services Committee. My name is Mark Jorritsma and I am the Executive Director of Family Policy Alliance of North Dakota. I am testifying in favor of House Bill 1336 and respectfully request that you render a "DO PASS" on this bill.

At its core, House Bill 1336 is about women having access to the highest quality and quantity of information possible prior to making an important health decision. Abortion procedures should not be an exception to quality standards of care. Every pregnancy is life-changing. Imagine a mom who chooses an abortion because her current circumstances are screaming at her, but then she has a change of heart. Something is speaking to her through her fear, through her circumstances…and it is brave, fierce, and deserves attention. If a pregnant mom revisits her choice, she has hope of possible success. But only if she knows of her medical options. Why would we want to deny her that?

HB 1336 is a necessary and logical enhancement to North Dakota's informed consent laws and aligns with standard practices in the medical field. Strengthening this law by allowing an expectant mother the knowledge of the potential to reverse a chemical abortion, simply increases the amount of relevant, helpful information available. This bill in no way impedes access to an abortion and places no additional burden on the abortion business.

HB 1336 will close this information gap in one of the fastest growing abortion methods – the abortion pill. One-third of all abortions in the United States are now performed as chemical abortions. This is a relatively new method that has increased in popularity over the 19 years since it was approved in the United States. The bill simply requires that when an abortionist prescribes the abortion pills to a woman, he must also inform her of an alternative, should she change her mind.

Doctors and other medical professionals provide women with incredible amounts of information to keep their baby well. In fact, women are typically overwhelmed with information. Yet, in this one instance, opponents of this type of notification law seek to ***limit*** the information women receive about their options. Why should a woman seeking an abortion be treated so differently from other pregnant women when it comes to medical choices and information?

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Twenty-nine states, including North Dakota, have abortion-specific informed consent laws that allow women to know about the risks and alternatives to abortion. HB 1336 will simply add information to pre-existing informed consent laws about this new method. With increasing numbers of women who are now choosing a chemical abortion, they deserve access to the full spectrum of information.

It is true that the abortion reversal method may not work on every single woman who changes her mind about an abortion, but every woman still deserves to know all her options. Abortion Pill Reversal is not a guarantee, but it IS an opportunity.

Pro-life opponents often decry that abortion is all about "choice". I ask you, how is a woman free to choose if she doesn't know there's a possibility her chemical abortion can be stopped/reversed? She effectively can't. The pro-abortion movement rallies around the phrase "it's a woman's right to choose". I say, that sentiment has to cut both ways. Withholding critical information about an abortion procedure takes away her choice. This needs to change.

I would like to close with a real story about a woman in Fargo who experienced the exact set of choices we have been discussing. The expectant mother had been conflicted over her decision to abort her child through medical means and began to have doubts after ingesting the first of three pills given to her by the Red River Women's Clinic, the abortion clinic in North Dakota that takes the lives of roughly 1,200 preborn children each year. Even though this young mother had taken the first of the pills, she now wanted her child to live.

She called the abortion facility but was told it was too late and that she should just consume the remaining pills and move forward with the abortion. She soon learned they had lied to her. Our partner FirstChoice Clinic told her the truth, that she could still stop the process, and by the next morning she had a prescription called into the pharmacy to undo the chemical abortion. Shortly thereafter she had the joy of witnessing the ultrasound image of her beautiful baby safely tucked in her womb. She carried her preborn child to full term and the baby was saved. The last two pages of this document we distributed tell her story in more detail and show the smiling mother and healthy baby boy!

Living with regret can be a cruel burden. But regret centered around our children can be suffocating.

Second chances are rare and HB 1336 extends the hand of support for a woman wanting to take that second chance. If the protocol is successful, a life is saved. But regardless, she will know she did all she could to undo a regrettable choice.

I respectfully request that you vote House Bill 1336 out of committee with a "DO PASS" recommendation.

- Please protect access to all medical information that serves as the foundation of true freedom of choice,
- Please help protect the lives of children, and
- Please protect young mothers from a potential lifetime of regret.

Thank you for the opportunity to testify and I stand for any questions you may have.

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Family Policy ALLIANCE of North Dakota

FirstChoice Clinic Helps Effect First Local Medical Abortion Reversal

Second chances are rare and HB 1336 extends the hand of support for a woman wanting to take that second chance. If the protocol is successful, a life is saved. Regardless, she will know she did all she could to undo a regrettable choice.

FirstChoice Clinic recently experienced a life-saving "first" when staff helped guide a client through a medical-abortion reversal, undoing the effects of the RU486 drug that would have ended the life of the client's baby.

It happened on a Wednesday, the day abortions take place at the local abortion facility downtown Fargo.

According to Denise Cota, Client Services Director, that morning staff had gathered to pray as always that hearts would be transformed and minds changed.

"There is a sense of urgency on Wednesdays, but also a sense of hope that these mothers and fathers will be heroes for their children and choose to carry these babies," she explains.

Though prayers continue well past Wednesday and after the staff goes home for the evening, the fruits of their prayers don't always become clear. However, this Wednesday was different.

A client who had been conflicted over her decision to abort her child through medical means began to have doubts after ingesting one of three pills given to her by the Red River Women's Clinic.

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As Denise notes, the client had sought out FirstChoice earlier for counseling regarding what seemed a truly impossible situation. Thankfully, cell phone numbers had been exchanged at that time, and the client sent a text to her that evening to ask whether it was too late to change her mind.

Earlier, she'd called the abortion facility, but was told it was too late, and that she should just consume all three pills and move forward with the abortion. But the client had done some online research indicating a reversal could be possible, and FirstChoice staff knew this as well, and that it was still early enough to try.

"We connected her with our medical director, Dr. Richard Vetter, who was able to counsel her on the reversal of the pill," Denise says. "By the next morning, we had her prescription called into the pharmacy, and an ultrasound scheduled at our clinic. And soon, we had the joy of witnessing the beautiful visual of a baby with a heartbeat safely tucked into his or her mother's womb."

Three weeks later, the mother went in for her first obstetrician visit at her hometown clinic. She asked Denise to travel and meet her at that appointment, which she gratefully did.

"The ultrasound image showed a healthy baby, which brought relief and happiness to our client," Denise says. "She's since expressed her conviction of the choice that she made and, and how aware she's become of the powerful instinct of motherly protection."

Angela Wambach, Executive Director, says the staff's coordination that helped bring about the reversal was a tremendous achievement, and that much gratitude goes to Dr. Vetter for his willingness to be called during evening hours, and respond with his professional advice to save a child's life.

She also notes that, despite the fact that the client wasn't from Fargo, because the abortion facility is, the Fargo location continues to be important, in that its staff is sometimes the "first responder" in such a crisis, and would never turn away a client regardless of their home base location. Currently, the client is continuing with prenatal and parenting education at a pregnancy center in her hometown.

"On that Wednesday night, we all learned a valuable lesson. Our client learned what a gift it is to be a mother, and what it's like to feel like a heroine," Denise says. "We, as a staff, learned that even when things seem hopeless, quickly that can change to hopeful."

UPDATE Baby boy has arrived! Both mom and baby are doing well.

http://www.teamfirstchoice.com/testimonials/

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CONCERNED
WOMEN for AMERICA
OF NORTH DAKOTA

January 21, 2019
House Human Services Committee
Testimony in Support of HB 1336

Madam Chairman and Members of the Committee, my name is Linda Thorson, and I am the State Director for Concerned Women for America (CWA) of North Dakota. We are the state's largest public policy women's organization and part of the country's largest public policy women's organization with over 500,000 members. We are here today on behalf of our North Dakota members in **support of HB 1336, the Abortion Pill Reversal Informed Consent Legislation.**
Women are strong, capable, and should have the right to know, if they change their mind after taking the first abortion pill, that they may be able to reverse the chemical abortion procedure. Women should have the right to complete information regarding their health decisions, especially one as important as this one.

The concept of "choice" and "rights" must go both ways. Those who support *a woman's right to an abortion*, should have no problem supporting *a woman's right to change her mind about an abortion.*

Women not only have the right to be informed; they want to know their options. The APR Hotline Medical Director, who has overseen thousands of calls, stated that when women are given the opportunity to reverse the effect of the abortion pill, they are extremely grateful.

Women are being told that there is no possibility of reversal. A number of women have told the APR Hotline nurses, that when they changed their minds and called the abortion clinic personnel asking about reversal, they were falsely told that "there is no possibility of reversal." We need an APR informed consent law to ensure that the patient receives accurate and complete information about the reversal protocol by abortion clinic personnel.

In closing, there are three things I respectfully ask this committee to consider. 1. A positive pregnancy test is one of the most life-changing moments for a woman, 2. We all sometimes make decisions that we wish we could take back, and 3. This is a historic opportunity for you to give hope to women desiring choices.

Concerned Women for America of North Dakota urges you support this pro-information, pro-woman bill that will change lives. We urge a "Do Pass" on HB 1336.

P.O. BOX 213 | PARK RIVER, ND 58270 | DIRECTOR@NORTHDAKOTA.CWFA.ORG | 701-331-9792
FACEBOOK: CONCERNED WOMEN FOR AMERICA OF NORTH DAKOTA

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Testimony of Tammi Kromenaker
Director of Red River Women's Clinic
In Opposition to House Bill 1336
January 21, 2019

Chairman Weisz, members of the House Human Services Committee, thank you for the opportunity to present testimony in opposition to HB 1336.

My name is Tammi Kromenaker and I am the Director of Red River Women's Clinic. Red River Women's Clinic is the only abortion provider in the state of North Dakota and has provided safe abortion care services to women in North Dakota for over 20 years. We are members in good standing of the National Abortion Federation and maintain the highest quality standards for our practice. Our mission is to not only provide medically safe reproductive healthcare services, but to also provide those services in an emotionally supportive environment.

Red River Women's Clinic provides abortion services to women from a broad range of backgrounds. Each year, approximately sixty percent of our patients are already mothers, with at least one child at home. These women have personal experiences and understandings of pregnancy and parenting and are making careful decisions about what is best for them and their families. In addition, most of our patients receive abortions very early in pregnancy. Twenty-eight percent of our patients received medication abortion in 2018.

At Red River Women's Clinic, we go to great lengths to ensure women are confident in their decision to have an abortion. Each woman has a one-on-one counseling session to discuss her feelings, her support system and to determine if she is confident in her decision to have an abortion. If a woman is ever uncertain in her decision, we encourage her to take more time to think about it and consider her options. Our clinic will not perform an abortion on a patient who indicates that she is uncertain of her decision. HB 1336 would undermine our ability to have honest conversations with our patients about their decisions. By mandating patients be given false information about medication abortion reversal, the state seems to be encouraging women to take the first medication even when they are not sure of their decision

HB 1336 would force physicians to lie to their patients by telling them that it may be possible to "reverse" a medication abortion. There is no credible, medically accepted evidence that a medication abortion can be "reversed." The idea that an abortion can somehow be reversed has not been rigorously tested and, as a result, it is impossible to know the relative effectiveness and safety of any of the treatments compared to not having any treatment at all.

Experts in reproductive health, including the American College of Obstetricians and Gynecologists (ACOG), recommend against this co-called "reversal" treatment and routinely oppose bills like HB 1336. ACOG is the nation's leading expert on women's health care. In 2017, ACOG released a document entitled "Facts Are Important: Medication Abortion 'Reversal' Is Not Supported by Science." According to that document, "The American College of Obstetricians and Gynecologists (ACOG) ranks its recommendations on the strength of the

evidence, and does not support prescribing progesterone to stop a medical abortion. . . Unfounded legislative mandates represent dangerous political interference and compromise patient care and safety."[i] I have included ACOG's official statement to this testimony.

An article published in *Issues in Law and Medicine* by anti-abortion physician George Delgado describes a series of women who took mifepristone and then underwent one of 10 different progesterone treatments. This was not a controlled study. The paper describes anecdotal experiences among women who received varying regimens of progesterone. The authors note that in some cases the treatment was provided to people who had evidence of a continuing pregnancy, but they were unable to present data on the proportion of women who in fact had a continuing pregnancy. This is critical because it means only a subset of patients who may have had a continuing pregnancy received the treatment, and the success rate is likely substantially inflated.

We should never mandate that healthcare providers give their patients inaccurate information about an unproven treatment.

Moreover, the Journal *Issues in Law and Medicine*, is co-sponsored by organizations connected to the anti-abortion movement and regularly publishes ideologically motivated research. The editor-in-chief, Barry A. Bostrom, has been active in the anti-abortion movement in Indiana, having served as the director and general counsel of the Indiana Right to Life. Women and their health care providers must be able to make decisions about the care that's right for them based on solid evidence and sound medical practice, not political agendas.

The National Abortion Federation (NAF), which includes Red River Women's Clinic as a member in good standing, is the professional association of abortion providers. NAF sets the medical standards for abortion providers in the US, Canada and Mexico. Each year, they publish their *Clinical Policy Guidelines for Abortion Care (CPG's).* The CPG's have been cited repeatedly and used to set standards in state health departments and have been referenced in litigation right here in North Dakota. NAF has provided Red River Women's Clinic with a letter, attached to my testimony, stating that "providing patients unverified information on an experimental treatment would be a violation of medical ethics and NAF's *Clinical Policy Guidelines."*

Many women choose medication abortion because they feel it is more natural and less invasive than a surgical procedure.[ii,iii] Access to this type of care can be especially important to women who may be survivors of sexual violence, for whom the insertion of medical instruments into their bodies may be especially unwanted and frightening. Women feel that medication abortion is more private and allows them to exert more control over their bodies. They like that this method does not require an anesthesia or sedation.[iv,v] Many women also prefer to have the procedure largely at home, rather than in a clinic. At home, they can have partners, relatives, or friends nearby.[vi]

Studies further demonstrate that women who, together with their medical provider, decide that a medication abortion is right for them, are satisfied with their decision.[viii,ix]

A vote for HB 1336 is a vote to lie to North Dakota women. It is a vote to undermine the best medical judgment of health care providers and force them to communicate false information they do not believe to be accurate, at the expense of the patients they serve.

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I urge you to vote no on House Bill 1336. I appreciate you giving me the opportunity to testify today and I would be happy to take any questions from the committee.

Sincerely,

Tammi Kromenaker

Tammi Kromenaker

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[i] American College of Obstetricians and Gynecologists, Facts are Important: Medication Abortion "Reversal" is Not Supported by Science, https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/FactsAreImportantMedicationAbortionReversal.pdf?dmc=1 (last visited January 16, 2019).

[ii] Batya Elul et al., *In-depth interviews with medical abortion clients: thoughts on the method and home administration of misoprostol*, 55 (Suppl) J Am Med Womens Assoc 169, 170 (2000).

[iii] Tara Shochet & James Trussel, *Determinants of demand: method selection and provider preference among US women seeking abortion services*, 77 Contraception 397, 400 (2008).

[iv] Beverly Winikoff, *Acceptability of medical abortion in early pregnancy*, 27 Fam Plann Perspectives 142, 144, 146 (1995).

[v] Christian Fiala & Kristina Gemzell-Danielsson, *Review of medical abortion using mifepristone in combination with a prostaglandin analogue*, 74 Contraception 66, 76 (2006).

[vi] Batya Elul et al., *In-depth interviews with medical abortion clients: thoughts on the method and home administration of misoprostol*, 55 (Suppl) J Am Med Womens Assoc 169, 171 (2000).

[viii] Beverly Winikoff, *Acceptability of medical abortion in early pregnancy*, 27 Fam Plann Perspectives 142, 148 (1995).

[ix] Christian Fiala & Kristina Gemzell-Danielsson, *Review of medical abortion using mifepristone in combination with a prostaglandin analogue*, 74 Contraception 66, 76 (2006).

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ACOG
The American College of Obstetricians and Gynecologists

August 2017

Facts Are Important:
Medication Abortion "Reversal" Is Not Supported by Science

Facts are important, especially when discussing the health of women and the American public. Claims regarding abortion "reversal" treatment are not based on science and do not meet clinical standards. The American College of Obstetricians and Gynecologists (ACOG) ranks its recommendations on the strength of the evidence,[i] and does not support prescribing progesterone to stop a medical abortion.

Yet, politicians are pushing legislation to require physicians to recite a script that a medication abortion can be "reversed" with doses of progesterone, and to steer women to this care. Unfounded legislative mandates represent dangerous political interference and compromise patient care and safety.

What is Medication Abortion?

- Medication abortion is the use of medications, rather than surgery, to end a pregnancy. This safe and effective evidence-based regimen includes a combination of two drugs—mifepristone, taken first, and misoprostol, taken at a later point.
- Mifepristone stops the pregnancy growth by blocking the hormone progesterone; misoprostol makes the uterus contract to complete the abortion.
- Medication abortion is more effective when both drugs are used, because mifepristone alone will not always cause abortion. In fact, as many as half of women who take only mifepristone continue their pregnancies.[ii]
- Mifepristone is not known to cause birth defects.

So-called abortion "reversal" procedures are unproven and unethical.

- A 2012 case series reported on six women who took mifepristone and were then administered varying progesterone doses. Four continued their pregnancies.[iii] This is not scientific evidence that progesterone resulted in the continuation of those pregnancies.
- This study was not supervised by an institutional review board (IRB) or an ethical review committee, required to protect human research subjects, raising serious questions regarding the ethics and scientific validity of the results.
- Case series with no control groups are among the weakest forms of medical evidence.[iv]

Legislative mandates based on unproven, unethical research are dangerous to women's health.

Politicians should never mandate treatments or require that physicians tell patients inaccurate information.

Additional ACOG Resources:

- ACOG Practice Bulletin 143 *Medical Management of First-Trimester Abortion* (March 2014)

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[i] Hal C. Lawrence, M.D., "The American College of Obstetricians and Gynecologists Supports Access to Women's Health Care," *Obstetrics & Gynecology* vol. 125 1282, 1283 (Jun. 2015) available at http://journals.lww.com/greenjournal/Fulltext/2015/06000/The_American_College_of_Obstetricians_and.2.aspx.

[ii] Grossman D et al. "Continuing Pregnancy After Mifepristone and 'Reversal' of First-Trimester Medical Abortion: A Systematic Review," *Contraception* 92 206–211 (Jun. 2015).

[iii] Delgado G and Davenport M, "Progesterone Use to Reverse the Effects of Mifepristone," *The Annals of Pharmacotherapy* vol. 46 (Dec. 2012).

[iv] ACOG, *Reading the Medical Literature*, available at http://www.acog.org/Resources-And-Publications/Department-Publications/Reading-the-Medical-Literature.

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January 20, 2019

Tammi Kromenaker
Clinic Director
Red River Women's Clinic
Fargo, ND 58102

Re: House Bill No. 1336

Dear Tammi,

Thanks so much for your request for information related to North Dakota's House Bill No. 1336, a bill that compels patients requesting abortion to hear about abortion reversal.

When giving information about abortion, National Abortion Federation (NAF) providers must give comprehensive, evidence-based information about the abortion procedure, its risks, benefits, and alternatives. Asking providers to give unverified information about an experimental treatment like abortion reversal violates principals of medical ethics and NAF's *Clinical Policy Guidelines*

NAF is the professional association of abortion providers. For more than 40 years, NAF has ensured the safety and high quality of abortion practice by providing standards of care, protocols, and accredited continuing medical education. NAF represents approximately 400 clinics, hospitals and physicians' offices in the United States, Canada, Mexico City, and Colombia. All NAF member facilities, including your clinic in North Dakota which would be affected by this legislation, must comply with our evidence-based *Clinical Policy Guidelines for Abortion Care* (CPGs), which set the standards for quality abortion care. Our mission is to ensure safe, legal, and accessible abortion care, which promotes health and justice for women.

Sincerely,

Alice Mark MD

Alice Mark, MD, MSc
Medical Director, National Abortion Federation

#7
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House Bill 1336
January 21st, 2019
Testimony of Heidi Selzler-Echola, Fargo, ND

Chairman Weisz and members of the House Human Services Committee, thank you for giving me the opportunity to provide testimony today.

My name is Heidi Selzler-Echola and I am a board-certified Women's Health Nurse Practitioner in North Dakota. I have worked in women's health for close to 7 years. I am also an adjunct instructor, teaching students who are just beginning their nursing career.

One of the first lessons new nursing students learn concerns the notion of evidence-based practice. According to the Academy of Medical Surgical Nurses (2019), Evidence Based Practice is the conscientious use of current best evidence in making decisions about patient care. This includes appraising medical evidence and using medical interventions and education that are based in peer reviewed scientific research.

All medical professionals strive for providing care based on evidence. Patients trust us to make the best decisions possible.

HB 1336 directly opposes the careful standards of the medical profession. The American Congress of Obstetricians and Gynecologists, which is the leading association in women's health care, released a position statement in 2017 stating that "abortion reversal" is not based on science, and does not meet clinical standards (ACOG. 2017). The so-called research conducted on abortion reversal was not supervised by an ethical review committee, was not randomized, and did not have control groups. In the scientific world, these are indicators of a low quality study—in short, the results of this study should not be used when providing medical care.

HB 1336 would require healthcare providers in the state of ND to defy best practice and ethical guidelines, by presenting false information to patients that is not evidence based. Essentially it would require healthcare providers, such as myself, to provide information and recommendations to my patients that has not been tested and not found to be safe.

The Women's Health Nurse Practitioner Association's practice guidelines state that Nurse Practitioner's practicing women's health MUST "provide education and counseling that is evidence-based and patient-centered" (NPWH, 2014). Furthermore, Provision 3 of the American Nurses Association's code of ethics states that "the nurse promotes, advocates for, and strives to protect the health, safety, and rights of the patient." Forcing speech on nurses, such as myself, to provide inaccurate information to patients who trust me, stands in contradiction to the

guidelines I must follow. This government mandate would force healthcare professionals to disregard these guidelines put forward by the governing associations of my profession.

For the past 16 years, nurses have been voted the most trusted profession in the United States because of our caring nature, high ethical standards and our use evidence-based practice. Nurses advocate for their patients, and provide the best care, education, and information possible. This mandate to provide untested information to patients is unethical. It demeans the nurses who choose to work in our state.

Because of this, I urge a 'Do Not Pass' recommendation on tHB 1336.

I appreciate you giving me the opportunity to testify today.

Sincerely,

Heidi Selzler-Echola

Academy of Medical Surgical Nurses. 2019. *Evidence Based Practice.* https://www.amsn.org/practice-resources/evidence-based-practice.

American Congress of Obstetricians and Gynecologists. 2017. *Facts are Important: Medication is not Supported by Science*. https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/FactsAreImportantMedicationAbortionReversal.pdf

NPWH. 2014. *Women's Health Nurse Practitioner: Guidelines for Practice and Education.*

#8
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North Dakota Women's Network

Kristie Wolff – Executive Director, North Dakota Women's Network
Opposition HB 1336
North Dakota House Human Services Committee

January 21, 2019

Chairman Weisz and members of the House Human Services Committee, my name is Kristie Wolff, I am the Executive Director of the North Dakota Women's Network.

Based on our mission to improve the lives of women, I am writing in opposition of HB 1336.

HB 1336 would force doctors to provide patients with information that is medically inaccurate and could be harmful to a woman's health.

There have been no clinical trials proving that reversing a medication abortion is possible. Moreover, the medical protocol that "reversal" proponents advocate has never been tested for safety, effectiveness, or the likelihood of side effects. It is equally unclear how increased exposure to high doses of progesterone, which is used as part of this protocol, may impact a developing fetus.

The American College of Obstetricians and Gynecologists, a professional membership organization dedicated to the improvement of women's health, does not support this protocol. They rank their recommendations on the strength of the evidence and state that "claims regarding this "reversal" treatment are not based on science and do not meet clinical standards."

Therefore, we ask that you give HB 1336 a Do Not Pass recommendation.

Thank you.

Kristie Wolff
kristie@ndwomen.org

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ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

FROM:	**The North Dakota Section of ACOG**
DATE:	**January 21, 2019**
RE:	**North Dakota House Bill 1336**

The North Dakota Section of the American College of Obstetricians and Gynecologists (ACOG) opposes **HB 1336 which would require ND physicians to inform patients that their medical abortion may be reversed if she acts quickly and where to seek treatment if they want to reverse the abortion.**

Claims regarding abortion "reversal" treatment are not based on science and do not meet clinical standards. The American College of Obstetricians and Gynecologists (ACOG) ranks its recommendations on the strength of the evidence and does not support prescribing progesterone to stop a medical abortion. Yet, politicians are pushing legislation to require physicians to recite a script that a medication abortion can be "reversed" with doses of progesterone, and to steer women to this care. Unfounded legislative mandates represent dangerous political interference and compromise patient care and safety.

ACOG firmly believes that science must be at the core of public health policies and medical decision-making. HB 1336 would insert the government into those personal medical decisions.

The American College of Obstetricians and Gynecologists (The College) is the nation's leading group of physicians providing health care for women. The College strongly advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. The American Congress of Obstetricians and Gynecologists is its companion organization (ACOG).

ACOG supports guaranteed access to the full array of clinical and reproductive services appropriate to each individual woman's needs throughout her life and recognizes that patients and families with input from their doctors should make decisions regarding each person's individual healthcare needs, not the government.

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The American College of Obstetricians and Gynecologists (The College), a 501(c)(3) organization, is the nation's leading group of physicians providing health care for women. As a private, voluntary, nonprofit membership organization of approximately 55,000 members, The College strongly advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. The American Congress of Obstetricians and Gynecologists (ACOG), a 501(c)(6) organization, is its companion organization. www.acog.org.

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House Human Services Committee
Testimony on HB 1336 and HB 1546
Andrew Alexis Varvel
January 21, 2019

Chairman Weisz and Members of the Committee:

My name is Andrew Alexis Varvel and I live in Bismarck, District 47.

I hope that each member of this committee already has a copy of the amending language for House Bill 1336 and House Bill 1546. In case you haven't, it is included as a coda to this testimony. Although my testimony is neutral about these bills as written, you will find that this amending language is germane to each bill. My neutrality on these bills comes not from any lack of opinion on my part, but rather because I regard mandating uterine anesthesia during abortions to be a morally paramount concern.

We can argue all day long over whether protecting a fetus is about human rights or about animal rights, but we should all agree as a matter of basic decency that a fetus should not get killed without anesthetic. Protecting a fetus from unnecessary pain is about protecting a fetus from unnecessary pain. The Supreme Court has decided that a mother has a constitutional right to kill her fetus up to the third trimester, but the Supreme Court has not decided that the process of killing the fetus must be painful.

As a former fetus, I have a stake in this matter. As a former fetus, I have a right to talk about this subject. My mother was in her fifth month of pregnancy with me when she attended a St. Louis Cardinals baseball game in early April of 1971. A loud drunk behind her would yell whenever he disagreed with the umpire's call. And whenever that loud drunk yelled, I kicked. Given that my mother remembers that this event happened during the first home game of the Cardinals' baseball season, we can reasonably narrow down that day to April 10, 1971. Given how I was born on July 30 of that same year, that would mean I would have been in my second trimester.

A few weeks later, my mother attempted to type something. Every time she typed, I kicked. When she stopped typing, I stopped kicking. When she typed again, I kicked again. It become obvious to her that I disliked the clickety-clack sound of a typewriter. In retrospect, this is completely believable, because I remember how much I intensely disliked the clickety-clack sound of a manual typewriter when I was a small child.

These episodes show that, when I was a fetus, I reacted to an outside stimulus. These episodes show that even when I was a fetus, I had my own opinions. And as you can tell, I have not stopped having opinions ever since. In my own rudimentary and infantile way, I was communicating. So, when we talk about fetuses, we should not think about them in abstract terms but rather as living beings who might just have their own opinions about loud drunks and noisy typewriters. I sometimes wonder if other families have their own stories about how fetuses express their own points of view.

Medical researchers disagree over exactly where the line is for when fetuses feel pain. I'm not quite sure how one would be able to find this out without resorting to unethical experimentation. In any case, rather than argue over when fetuses feel pain and when they don't, we should simply make sure they don't feel pain when they get killed.

I hope the following language makes it into one of these bills. I also hope that these bills' sponsors and co-sponsors will regard this language to be a friendly amendment to their proposed legislation. Regardless of whether you are pro-choice or pro-life, this amending language to mandate uterine anesthesia during abortions is something that we should all be able to support. Let's make painful abortions a thing of the past.

Thank you.

Andrew Alexis Varvel
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701-255-6639
mr.a.alexis.varvel@gmail.com

PROPOSED AMENDMENT LANGUAGE FOR HOUSE BILL 1336 AND/OR HOUSE BILL 1546

SECTION ?. Section 14-02.1-04.2 of the North Dakota Century Code is created and enacted as follows:

14-02.1-04.2. Uterine anesthesia mandatory for abortions – Penalty.

1. The attending physician shall perform all abortions with uterine anesthesia unless, in the opinion of the attending physician, general anesthesia is medically appropriate to ensure that the fetus does not suffer pain from the procedure.

2. Any physician who performs an abortion in violation of this section is guilty of a class A misdemeanor.

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ACLU
North Dakota

ACLU opposition testimony to House Bill 1336 (medication abortion reversal)

The ACLU of North Dakota opposes House Bill 1336.

Claims regarding abortion "reversal" treatment are not based on medical science and do not meet clinical standards, according to the American Congress of Obstetricians and Gynecologists. This bill would force doctors to provide women with medically inaccurate and misleading information that could be harmful to their health.

The decision to have an abortion is deeply personal and private and best left to a woman, her family and her doctor. It's a decision that is also protected under the U.S. Constitution.

ACLU opposition testimony to House Bill 1546 (method ban)

The ACLU of North Dakota opposes House Bill 1546, a bill that would ban the safest method of care for a woman at a certain stage of pregnancy.

A woman's health should drive important medical decisions, regardless of how we feel about abortion at different points in a pregnancy. With the exception of some, lawmakers are not medical experts and should not stand in the way of a woman having a range of effective, affordable, medically-proven methods of abortion care available to her as her pregnancy progresses.

Throughout her pregnancy, a woman must be able to make health decisions that are best for her circumstances, including whether to end a pregnancy.

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PHYSICIAN TESTIMONIES

"To be an agent of hope to a woman desperately seeking a second chance is a blessing, indeed. The 'second choice' we offer women who change their minds after taking mifepristone not only gives their unborn babies a fighting chance, it also provides an avenue for emotional and spiritual healing on the mothers' and sometimes the fathers' part."
– ***George Delgado, M.D., F.A.A.F.P., APR Medical Director***

"Abortion Pill Reversal is a process that I feel was presented to me as an answer to prayer when a scared young pregnant woman came to me in 2006 desiring reversal of her RU-486 chemical abortion. She heroically accepted the risks of this new treatment and supported her baby throughout her pregnancy with progesterone injections. She delivered a healthy baby girl who is still healthy and growing at 8 years of age. APR has been a real life giving force in my practice and my outlook on Pro-Life medicine. Dr. Delgado's vision of a global network to support women who regret their abortions has been a real inspiration to me in my everyday practice of medicine."
– ***Matt Harrison, M.D., Associate Medical Director***

"It has been my privilege to participate in the abortion pill reversal program since 2011 . To witness a vulnerable, frightened young women who has made hasty and imprudent decision, often under pressure or coercion, and see her transform into an expectant mother, committed to her unborn baby, is a true miracle."
– ***Mary Davenport, M.D., F.A.C.O.G, Research Director***

"It has been a privilege to have been able to participate in the APR program for the past three years. Clinically I can tell you it has been extremely successful. Even though not all pregnancies could be saved, I assure you that the emotional rescue that was provided for the mothers in knowing that they were doing all they could to reverse their decision was invaluable to them. This innovative initiative gives hope to a very difficult situation."
– ***Ronaldo De Leon, M.D., F.A.C.O.G.***

"Abortion Pill Reversal is truly a blessing. As a Pro-Life obstetrician, having something to offer patients in their moments of remorse leads to immeasurable healing and the possibility of saving a life. The nurses involved are always so kind and compassionate toward the patients, never treating them with anything but love. The healing begins with that interaction and the resources they offer. As a NaPro-trained physician, I have seen first-hand the benefits of progesterone in at risk-pregnancies, and I feel confident that with over 140 babies saved through APR many more are yet to be saved! God bless APR and those who utilize these services!"
– ***Monique Ruberu, M.D.***

https://abortionpillreversal.com/stories/physician-testimonies?fbclid=IwAR2d3PKTzCuJR4-eNuEmd6uF71yx3Vr1sVRSwYRUPD9SfIl9LRCU6ANHeKU

#1
#HB 1337
1-23-19
P1.

Abortion "Reversal" — Legislating without Evidence

Daniel Grossman, M.D., and Kari White, Ph.D., M.P.H.

Women up to 10 weeks pregnant who are having a medication abortion generally take one dose of mifepristone, which blocks the progesterone receptor, followed within 48 hours by a dose of misoprostol, a prostaglandin that causes cervical dilation and uterine contractions, leading to expulsion of the pregnancy tissue. Four states (Arkansas, Idaho, South Dakota, and Utah) require abortion providers to tell their patients about treatment that may reverse the effect of mifepristone if they change their mind after starting a medication abortion. So-called abortion reversal involves administering repeated doses of progesterone. Since 2017, other states have proposed similar bills and the California Board of Registered Nursing approved a course on medication-abortion reversal for continuing-education credit. This trend is troubling because of the lack of medical evidence demonstrating the safety and efficacy of the treatment; laws promoting it essentially encourage women to participate in an unmonitored research experiment.

When states began passing laws on abortion reversal, the only published report on this treatment was a case series involving seven patients. A systematic review we coauthored in 2015 found no evidence that pregnancy continuation was more likely after treatment with progesterone as compared with expectant management among women who had taken mifepristone.[1] Our review found that the proportion of continuing pregnancies after mifepristone alone varied from 8% to 46% in published studies.

Recently, Delgado et al. published a case series involving 754 patients who underwent reversal treatment in the United States and several unnamed countries.[2] After excluding 27% of patients for various reasons, they report that 47% had a live birth. The authors conclude that reversal treatment is effective, citing the higher proportion of continuing pregnancies in their study as compared with a historical control rate of 25% of women who had continuing pregnancies after taking mifepristone alone. This estimate comes from Maria et al., the only published report that examined rates of pregnancy continuation after a single 200-mg dose of mifepristone,[3] which is the dose most commonly used in current medication-abortion regimens. This study, which included 30 women who were up to 7 weeks pregnant, 25 of whom were no more than 6 weeks pregnant, found that 23% had continuing pregnancies 7 days later.

It is difficult to compare the results from Delgado et al. with data on mifepristone alone for several reasons. In the Delgado study, some providers performed ultrasonography in patients presenting for reversal and excluded those found to have embryonic death. These patients were removed from the denominator of the proportion of women with continuing pregnancies, which could have contributed to the higher success rate for reversal treatment — especially at gestational ages of more than 6 weeks, when cardiac activity is more apparent. In addition, the authors excluded patients who were lost to follow-up before 20 weeks, which probably exaggerated the treatment's reported success.

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Percentage of Women with Continuing Pregnancies after Taking 200 mg Mifepristone with or without Progesterone.*

Treatment	Total No. of Pregnancies	Continuing Pregnancies	Percentage of Continuing Pregnancies (95% CI)	P Value
Gestational age ≤6 wk				
Mifepristone followed by progesterone	189	71	38 (31–45)	0.119
Mifepristone alone	25	5	20 (9–39)	
Gestational age ≤7 wk				
Mifepristone followed by progesterone	291	121	42 (36–47)	0.076
Mifepristone alone	30	7	23 (21–41)	

* Data are from Delgado et al.[2] and Maria et al.[3] Maria et al. report a total of seven continuing pregnancies in the sample of 30 women who were 7 weeks pregnant or less. There were two abortion failures among the five women who were between 6 and 7 weeks pregnant, but whether these were continuing pregnancies is unclear. We therefore made the conservative assumption that five of the seven continuing pregnancies occurred among the 25 women who received mifepristone at 6 weeks' gestation or less and that the two failures that occurred among those who were between 6 and 7 weeks pregnant were both continuing pregnancies.

Gestational ages in Delgado et al. (up to 9 weeks) also differed from those in Maria et al. As Delgado et al. note, pregnancy continuation is more common with advanced gestation; therefore, it is important to compare groups of similar gestational age. We analyzed the effectiveness of reversal treatment by comparing rates of continuing pregnancy among women who were up to 6 or 7 weeks pregnant in the two studies.

Among women who were up to 6 weeks pregnant, 38% (95% confidence interval [CI], 31 to 45) of those who received reversal therapy had a continuing pregnancy.[2] This proportion was not significantly different from the 20% (95% CI, 9 to 39) of women who had a continuing pregnancy after taking mifepristone alone (P=0.119) (see table).[3] The rates of pregnancy continuation were also not significantly different when we included women who were up to 7 weeks pregnant, despite the fact that the reported success rate for reversal therapy was most likely an overestimate at 7 weeks because some patients were excluded from treatment after ultrasound screening for embryonic viability. Because there are no published data on rates of pregnancy continuation after a 200-mg dose of mifepristone alone at more than 7 weeks' gestation, we cannot evaluate the effectiveness of reversal treatment beyond this gestational age.

The safety data presented by Delgado et al. are minimal. No adverse events were reported among pregnant women, but it is unclear whether such data were routinely collected. The reported data on birth defects and preterm birth are generally reassuring; given the range of progesterone regimens used and the lack of reporting by regimen, however, it is difficult to draw conclusions about the treatment's safety. Data from a registry in France suggest that exposure to mifepristone alone does not increase the risk of birth defects.[4]

Equally unclear is the demand for reversal treatment. Since participants in the study by Delgado et al. were recruited from several unnamed countries over a period of 4 years, it is impossible to estimate what proportion of patients undergoing medication abortion is represented by this sample. According to data obtained from Danco Laboratories, the U.S. manufacturer of mifepristone, less than 0.004% of patients who took mifepristone between 2000 and 2012 ended up deciding to continue their pregnancies.[1] Other research indicates that decisional certainty among women having an abortion is high — and higher than it is among patients making other decisions about medical treatment.[5]

Still, efforts should be made at the time of preabortion counseling to identify women who may be conflicted and to provide additional support to help them make an informed decision. Allowing patients to take mifepristone at home, which has been permitted since the drug's label was updated in 2016, may reduce the already small number of women who change their mind by giving patients more control over where and when they take the medication. But for patients who do change their mind after taking mifepristone, what is the best course of action? If a woman changes her mind within an hour after taking the drug, vomiting should be induced. Beyond that time frame, we believe the pregnancy should be carefully followed.

One could argue that the demand for abortion reversal treatment is so low that additional research is not justified. But if

researchers do perform additional studies, it is critical that such studies be rigorously designed and conducted in an ethical manner. Clinical equipoise exists for this question, since there is no evidence that treatment is superior to doing nothing. In such cases, a randomized, placebo-controlled trial is the most appropriate study design. For now, any use of reversal treatment should be considered experimental and offered only in the context of clinical research supervised by an institutional review board (IRB). Delgado et al. obtained IRB approval for their retrospective data analysis, but it is not clear that approval was obtained in advance for their experimental treatment protocol. In fact, the study was retracted temporarily because of concerns raised about what the authors initially described as an IRB "waiver."

We believe that states' mandating that health care providers give patients information about an unproven and experimental therapy is a disturbing intrusion into the relationship between physicians and their patients. Additional states will undoubtedly consider such legislation, despite the lack of evidence for abortion reversal treatment. We should all be concerned when politicians recommend treatment options over the advice of medical professionals.

Disclosure forms provided by the authors are available at NEJM.org.

From Advancing New Standards in Reproductive Health, Bixby Center for Global Reproductive Health, and the Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco (D.G.); and the Department of Health Care Organization and Policy, School of Public Health, University of Alabama at Birmingham (K.W.).

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#1
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Rep. Daniel Johnston
February 4, 2019
Senate Judiciary Committee
Testimony for HB 1336

Mr. Chairman and Members of the Committee, my name is Daniel Johnston and I represent District 24 in the North Dakota House. Thank you for allowing me to be here today and testify on HB 1336.

HB 1336 is a bill that seeks to update North Dakota's informed consent law by requiring an abortion provider to give abortion pill reversal information to a patient before a chemical abortion procedure begins. From time to time, the North Dakota Legislature has revisited and updated the informed consent statute so, what this bill seeks to do is not unusual.

At its core, HB 1336 addresses a question. Should a woman receive all information available before undergoing a potential life-altering procedure?

With any medical procedure, the patient is given all the information necessary to make an informed decision. They are told what the risks are, what kind of side effects to expect, and possible recovery time. Full disclosure exists. However, this is not the case for a woman that is considering a chemical abortion. Currently, an abortion provider does not give a woman all the information available, so that an educated decision can be made? This bill is about choice. A woman may choose to start the chemical abortion process, but she may also choose to change her mind.

What is a chemical abortion and is it reversible? Chemical abortion is most commonly in reference to RU486 (Mifepristone). Mifepristone blocks the hormone progesterone from allowing the womb to nourish the unborn child and causes the uterine lining to shed. Basically, this amounts to death by starvation. Later another chemical is taken, Misoprostol, which causes a miscarriage. Common side effects of chemical abortion include Cramping, nausea, vomiting/diarrhea, heavy bleeding, stomach pain, and mild fever and chills. Of course, the heavy emotional toll associated with abortion is often overlooked.

Mifepristone is REVERSIBLE and can be stopped by adding large amounts of natural Progesterone. The abortion pill reversal protocol increases the chances that a baby will survive after the mother ingests mifepristone. If the mother receives the APR rescue, then 65-70% of the babies will survive. I included an observational

case study with my testimony that examined the results of 754 cases of abortion pill reversal. The study was published in 2018.

What this legislation does not do. HB 1336 does not adversely affect or hamper a woman's access, right, or choice to seek an abortion. It aligns with a ND Supreme Court opinion concerning Roe v. Wade (MKB Mgmt. Corp. v. Burdick, 2014 ND 197, P15, 855 N.W.2d 31, 36, 2014 N.D. LEXIS 202, *16, 2014 WL 5450069 (N.D. October 28, 2014), that stated the following, "For the stage subsequent to approximately the end of the first trimester, the State, in promoting its interest in the health of the mother, may, if it chooses, regulate the abortion procedure in ways that are reasonably related to maternal health. . . A provision of law is only invalid, if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability"

This unequivocally means that the State has the constitutional right to regulate abortion procedures if it is reasonably related to maternal health and does not place a substantial obstacle in the path of a women to seek an abortion in the early stages of pregnancy.

Currently, 46 states and 17 countries have reported successful abortion reversal procedures. 430 medical practices and 84 pregnancy help centers prescribe abortion pill reversal. Five states have recently enacted legislation which requires informed consent for the abortion reversal procedure, and I expect that number to continue to rise as more abortion reversals take place.

Women have a right to know that they can choose to change their mind.

This legislation is Pro woman, pro-life, and it is pro-choice. A woman deserves to know.

Members of the Senate Judiciary Committee, please give HB 1336 a **Do Pass** recommendation.

Thank you. I stand for questions.

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PHYSICIAN TESTIMONIES

"To be an agent of hope to a woman desperately seeking a second chance is a blessing, indeed. The 'second choice' we offer women who change their minds after taking mifepristone not only gives their unborn babies a fighting chance, it also provides an avenue for emotional and spiritual healing on the mothers' and sometimes the fathers' part."
– George Delgado, M.D., F.A.A.F.P., APR Medical Director

"Abortion Pill Reversal is a process that I feel was presented to me as an answer to prayer when a scared young pregnant woman came to me in 2006 desiring reversal of her RU-486 chemical abortion. She heroically accepted the risks of this new treatment and supported her baby throughout her pregnancy with progesterone injections. She delivered a healthy baby girl who is still healthy and growing at 8 years of age. APR has been a real life giving force in my practice and my outlook on Pro-Life medicine. Dr. Delgado's vision of a global network to support women who regret their abortions has been a real inspiration to me in my everyday practice of medicine."
– Matt Harrison, M.D., Associate Medical Director

"It has been my privilege to participate in the abortion pill reversal program since 2011. To witness a vulnerable, frightened young women who has made hasty and imprudent decision, often under pressure or coercion, and see her transform into an expectant mother, committed to her unborn baby, is a true miracle."
– Mary Davenport, M.D., F.A.C.O.G, Research Director

"It has been a privilege to have been able to participate in the APR program for the past three years. Clinically I can tell you it has been extremely successful. Even though not all pregnancies could be saved, I assure you that the emotional rescue that was provided for the mothers in knowing that they were doing all they could to reverse their decision was invaluable to them. This innovative initiative gives hope to a very difficult situation."
– Ronaldo De Leon, M.D., F.A.C.O.G.

"Abortion Pill Reversal is truly a blessing. As a Pro-Life obstetrician, having something to offer patients in their moments of remorse leads to immeasurable healing and the possibility of saving a life. The nurses involved are always so kind and compassionate toward the patients, never treating them with anything but love. The healing begins with that interaction and the resources they offer. As a NaPro-trained physician, I have seen first-hand the benefits of progesterone in at risk-pregnancies, and I feel confident that with over 140 babies saved through APR many more are yet to be saved! God bless APR and those who utilize these services!"
– Monique Ruberu, M.D.

https://abortionpillreversal.com/stories/physician-testimonies?fbclid=IwAR2d3PKTzCuJR4-eNuEmd6uF71yx3Vr1sVRSwYRUPD9SfIl9LRCU6ANHeKU

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ProLife OBGYNS
AAPLOG American Association of Pro-life Obstetricians & Gynecologists

AAPLOG FACT SHEET Abortion Pill Reversal

The American Association of Pro-Life Obstetricians and Gynecologists strongly supports a woman's right to choose to keep her pregnancy, and to attempt to reverse the effects of a medical abortion which she no longer desires. The Abortion Pill Reversal process is safe for both the mother and for her unborn child, and offers a real chance for the woman to rescue her unborn child when she has changed her mind about abortion. The following facts about APR are important to understand:

- Progesterone is the hormone produced by the mother's ovaries, which allows the mother's womb to carry an unborn child. ("Pro"=for, "gest"=pregnancy, "erone" = hormone). When progesterone is too low, the unborn child cannot receive nutrients, and dies. ASRM FACT SHEET (Ref 1)

- Mifepristone(RU486/Mifeprex) is a progesterone blocker. (Ref 2) Mifepristone blocks progesterone from allowing the womb to nourish the unborn child. But Mifepristone is a REVERSIBLE (Ref 2) blocker- which means that the effects of Mifepristone can be stopped by adding large amounts of natural progesterone. The natural progesterone competes for the binding sites on the progesterone receptors, and kicks the mifepristone off of these binding sites.

- Natural progesterone has been used for over 50 years in the treatment of early pregnancies who are threatening to miscarry because the mother's progesterone level is too low. Progesterone has also been used for over 3 decades in women who have conceived with IVF. In the extensive medical literature on the use of progesterone in early pregnancy, there are no increased risks of any birth defects with natural progesterone. (Ref 1)

- The use of natural progesterone to reverse the effects of mifepristone poisoning is a simple application of common sense in the treatment of poisonings in situations where the mechanism of poisoning is well understood. Mifepristone poisoning is well studied and well understood. Using natural progesterone to reverse mifepristone effects is a logical extension of understanding the biochemical mechanism of action of mifepristone. (Similar application is used in chemotherapy with methotrexate followed by leukovorin rescue.) (Ref 3)

- In children who survive mifepristone poisoning and continue to birth, mifepristone alone has not been found to be associated with birth defects. In those children who have survived after the mother has ingested mifepristone alone, there have been no increased risks of birth defects noted. (Ref 4)

- The APR protocol involves giving natural progesterone to women who have taken mifepristone alone- who have not yet taken the second abortion drug misoprostol. (Ref 3)

- The APR protocol increases the chances that a baby will survive after the mother ingests mifepristone. Without APR, the chances that an unborn child will survive mifepristone poisoning are around 15%. However, if the mother receives the APR rescue, then 65-70% of the babies will survive. There are currently 200 babies born nationwide after using the APR protocol, and another 100 coming soon. (Ref 6)

- The babies born after using the APR protocol are not at increased risk for birth defects. (Ref 4)

- See AAPLOG FACT SHEET REFERENCES Abortion Pill Reversal

Life. It's why we are here.

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ProLife OBGYNS
AAPLOG American Association of Pro-life Obstetricians & Gynecologists

AAPLOG FACT SHEET REFERENCES Abortion Pill Reversal

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- Davenport et. Al. publication pending.

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A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone

George Delgado, M.D.,* Steven J. Condly, Ph.D.,** Mary Davenport, M.D., M.S.,*** Thidarat Tinnakornsrisuphap Ph.D.,**** Jonathan Mack, Ph.D., NP, RN***** Veronica Khauv, B.S., and Paul S. Zhou

ABSTRACT:

Background: Some women who take mifepristone, a progesterone receptor antagonist, in order to terminate their pregnancies, change their minds and desire to stop the medical abortion process. There are only two articles in the medical literature documenting the reversal of the effects of mifepristone.

Objective: We present and analyze a series of women who attempted to reverse the effects of mifepristone by taking supplemental progesterone to determine if the reversal of the effects mifepristone with progesterone is possible and safe. Additionally, we compare different progesterone regimens to determine relative efficacies.

Methods: This is an observational case series of 754 patients who decided to attempt to reverse the medical abortion process after taking mifepristone but before taking the second drug in the protocol, misoprostol. We followed the patients, who were given progesterone in an effort to reverse the effects of

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mifepristone, and conducted statistical analyses to determine the efficacies of different protocols compared to a control mifepristone embryo survival rate, derived from the literature.
***Results*: Intramuscular progesterone and high dose oral progesterone were the most effective with reversal rates of 64% ($P < 0.001$) and 68% ($P < 0.001$), respectively. There was no apparent increased risk of birth defects.**
***Conclusions*: The reversal of the effects of mifepristone using progesterone is safe and effective.**

Introduction

Medical induced abortion utilizing mifepristone has been available in the United States since 2000. In 2014, 31% of non-hospital induced abortions were medical induced abortions.[1] Some women decide to attempt to reverse the medical abortion process after taking mifepristone but before taking misoprostol, and inquire about the possibility of reversing the effects of mifepristone.[2]

The new FDA protocol, approved for medical abortion in 2016, involves the administration of mifepristone 200 mg orally as a single dose, which leads to embryonic or fetal demise, followed 24-48 hours later by misoprostol 800 mcg buccally as a single dose, which stimulates myometrial contractions. The protocol is approved up to 70 days after the first day of the last menstrual period.[3] Misoprostol is part of the protocol because mifepristone alone has an incomplete abortion rate of 20-40%, as determined by the end point of complete expulsion.[4]

Pharmacology

Mifepristone is a competitive antagonist of progesterone at the progesterone receptor (PR). It binds to the PR twice as avidly as progesterone.[5] Mifepristone is an orally active compound with a nearly 70% absorption rate, but its bioavailability is reduced to approximately 40% because of the first-pass effect.[6]

Demethylation and hydroxylation are catalyzed by CYP3A4; three metabolites retain biologic activity. The half-life of mifepristone is approximately 18-25 hours. Mifepristone and its metabolites can be measured up to 72 hours after an ingested dose.[5] The half-life of progesterone is longer, approximately 25-55 hours.[6,7]

Effects of Mifepristone

By blocking progesterone receptors, mifepristone leads to the separation of the decidua basalis from the trophoblast. This separation diminishes the oxygen and nutrients that can be delivered to the embryo or fetus by the maternal circulation and is the primary embryocidal and feticidal effect of mifepristone.[4,8,9]

In addition to this primary effect, mifepristone causes softening and dilatation of the cervix.[4] It also leads to myometrial contractions, increased myometrial sensitivity to prostaglandins[4,10] and the disinhibition of prostaglandin synthesis by the myometrium.[11]

Progesterone has been shown to have an autoregulatory effect on progesterone synthesis by the corpus luteum. Blocking progesterone receptors with mifepristone decreases progesterone secretion by the corpus luteum.[12]

Logic of Using Progesterone to Reverse Mifepristone Effects

Mifepristone is a competitive inhibitor of the progesterone receptor. It is well known that receptor agonism and antagonism are parts of a dynamic process that can be influenced by changing concentrations of the agonist or antagonist. Therefore, it makes biologic sense that increasing the progesterone levels in a pregnant woman by giving supplemental progesterone would favor the agonist progesterone effects and blunt the abortifacient effects of mifepristone.

An Animal Model

A Japanese rat study provides basic-science evidence of the ability of progesterone to negate the effects of mifepristone. In this experiment, one group of pregnant rats was given mifepristone while a second was given mifepristone and progesterone. In the group that only received mifepristone, only 33% of the pups survived. In the group that received mifepristone and progesterone, 100% of the pups survived. Furthermore, the first group had characteristic changes in the myometrium and ovaries; the group that received the combination had no such changes.[13]

Early Mifepristone Studies Reporting Continuing Pregnancy

When mifepristone was first studied as an abortifacient, misoprostol was not part of the protocol. During the 1980's, researchers determined that even though mifepristone was effective as an abortifacient, they believed it was necessary to add a prostaglandin analog to achieve a satisfactory complete uterine evacuation rate.[4] We must emphasize that the definition of incomplete abortion is incomplete emptying of the uterus.[14] Embryo or fetus survival is not implied.

The earliest studies also revealed that some embryos survived mifepristone. Baulieu, the principal developer of the drug, stated that at 4-7 weeks the percentages of efficacy of the regimen were approximately 70% for complete abortions, 20% for incomplete abortions and 10% for ongoing pregnancies (i.e., presumed embryo survival). For gestations 8-10 weeks, the comparable rates were 50% for complete abortions, 35% for incomplete abortions and 15% for embryo survival.[15]

In 2015, Grossman et al. published a review of the first case series of progesterone reversal of mifepristone, as well as 13 studies from the 1980's, addressing continuing pregnancies after mifepristone. The authors concluded that there was insufficient evidence to show that progesterone therapy improved survival over expectant management, based on the reported high ongoing pregnancy rates in some of these older studies.[16] However, closer scrutiny of the studies cited for high ongoing pregnancy rates reveals inadequate criteria for the diagnosis of continuing pregnancies. Many early researchers focused on an efficacy end point of complete uterine evacuation, and did not distinguish missed or incomplete abortions from continuing pregnancies (embryo or fetus

survival).[17] Only eight studies cited by Grossman had criteria sufficient to determine embryo survival and showed continuing pregnancy rates of 8-25%.[17]

A recent review found that 18 of the 30 articles investigating mifepristone monotherapy had adequate criteria to determine embryo survival.[17] After eliminating duplicate publications, 12 studies were identified which utilized follow-up ultrasound to distinguish between incomplete or missed abortion and embryo survival at the end of the study period. The mean percentage of embryos surviving mifepristone among all studies was 12.6%.[17] A single dose of 600 mg in five studies of early gestations 42-49 days in 493 subjects showed survivals of 9.4-17.1%.[17,18,19,20,21] Three studies of 58 women with gestations <49 days, using the current predominant 200-300 mg doses, noted embryo survival rates of 10-23.3%.[19,22,23,24] Four studies of 83 women included gestations up to 70 days, daily doses of 100-200 mg, and total doses 400-800 mg.; in three of these four studies, embryo survival was <25%.[25,26,27,28,29,30,31,32]

Methods

This is an observational case series with data analysis that received an institutional review board waiver.[33] Subjects were pregnant women from across the United States and from several other countries who had taken mifepristone, but had not yet taken misoprostol, and were interested in reversing its effects. Subjects called an informational hotline linked to an informational website and staffed by nurses and a physician assistant. After receiving information about the reversal process, those who decided to proceed with reversal were referred to physicians and mid-level practitioners in their respective geographic areas for treatment. The women gave written informed consent for treatment to their respective treating medical professionals that included permission to track their data. Data were collected from the women themselves and from their treating healthcare professionals.

Data were collected for different variables including gestational age at the time of mifepristone ingestion, mode of delivery of progesterone given, amounts of progesterone received, birth defects and preterm delivery. Progesterone was given in a variety of regimens by the 325 different medical professionals who treated these women. The modes of delivery of progesterone were intramuscular injection of progesterone in oil, oral administration of micronized progesterone, vaginal use of oral micronized progesterone capsules, compounded micronized progesterone vaginal suppositories, progesterone vaginal gel and progesterone vaginal suppositories.

We selected a 25% embryo or fetus survival rate, if mifepristone alone is administered, as a control because it is at the upper range of mifepristone survival rates and close to the 23% survival rate of the one early study that used a single 200 mg dose, the dose currently favored for medical abortions.[17] This study is designed to ascertain which progesterone treatments clinicians have offered to women seeking mifepristone reversal that demonstrate efficacy beyond the 25% embryo survival rate, and compares the relative efficacies of different treatment protocols to the historic control.

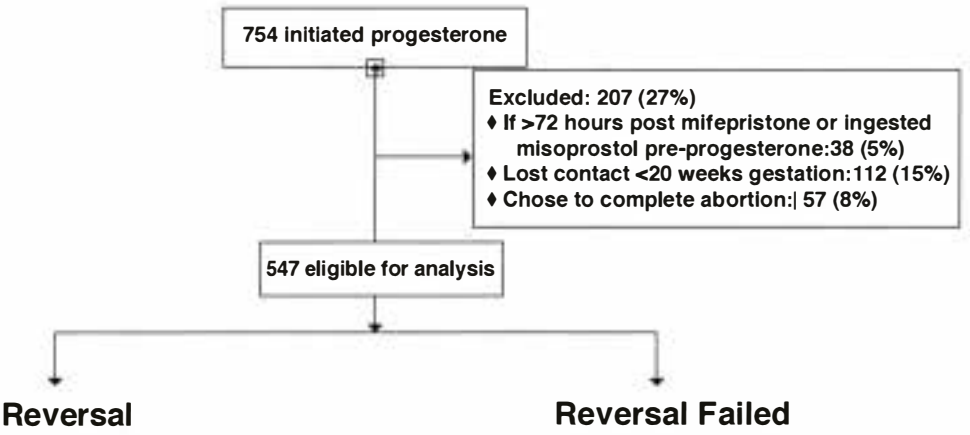
Results

From June 24, 2012 to June 21, 2016, 1,668 calls were received by the hotline from women who had taken mifepristone and were interested in reversal. Seven hundred fifty-four (45%) actually initiated progesterone therapy.

Subjects were included in the study if they were 72 hours or less post-mifepristone and had not taken misoprostol; 38 (5%) did not meet these criteria. Of the women who started progesterone therapy and met inclusion criteria, 116 (15.4%) were lost to follow-up at some point. Of those,112 (14.9%) were lost to follow-up prior to 20 weeks gestation and were excluded from the analysis. Four (0.5%) women remained pregnant with viable fetuses but were lost to follow-up after twenty weeks gestation and were included in the analysis as reversals.

Fifty-seven (7.6%) of the women, after starting progesterone therapy, changed their minds again and either took misoprostol to complete the medical abortion or procured surgical induced abortion. Of those 57, 39 (5.2%) chose to complete abortion medically with misoprostol, seven (0.9%) procured surgical abortions and 11 (1.5%) completed abortion by unspecified means. These were not included in the analysis as they chose to no longer attempt reversal. See Figure 1.

Figure 1



Women who delivered babies after progesterone therapy or who were lost to follow-up after 20-weeks gestation were considered to have reversed their medical abortions, since any pregnancy loss after 20 weeks would be unlikely to be attributable to the early mifepristone exposure. The data analysis was accomplished using the Statistical Hypothesis Test on a population proportion.

After exclusions, there were 547 patients with analyzable outcomes who underwent progesterone therapy. There were 257 births (47%). Another four were pregnant with viable fetuses but were lost to follow-up after 20 weeks gestation (0.7%). The overall rate of reversal of mifepristone was 48%.

Two subgroups had the highest reversal rates. Those who received progesterone intramuscularly (IM) initially or exclusively had a 64% reversal rate. One subject in this group had an undocumented number of injections. The high-dose oral subgroup received oral progesterone, 400 mg twice a day for three days, followed by 400 mg once a day until the end of the first trimester and had a reversal rate of 68%, similar to the IM group. These survival rates compare favorably with published embryo and fetal survival rate of 25%, if no treatment is attempted,[17] the rate used as a control. See Table 1.

The gestational age at the time of ingestion was directly related to reversal success. See Table 2. This is not surprising since mifepristone embryocidal and feticidal rates fall with advancing gestational age.[34]

There was no correlation between maternal age and rate of reversal. In the subset of records noting time intervals, the time between mifepristone ingestion and the first progesterone dose was not statistically significant in relation to the success rate for reversals attempted within 72 hours of mifepristone injection.

Birth Defects

There were seven reported birth defects in the women who had reversals and follow-up after their deliveries for a rate of 7/257 (2.7%). See Table 3. This is equal to the birth defect rate in the general population of approximately 3%[35] and suggests that there is no increased risk of birth defects in babies born after mifepristone reversal.

Preterm Delivery

There were seven deliveries at <37weeks for a preterm delivery rate of 2.7%. The United States average is 10%.[36]

Multiple Gestations

There were nine sets of twins (4.3% of the pregnancies). There were no higher order multiples.

Discussion

Progesterone Safety

Progesterone is a naturally occurring hormone produced by the corpus luteum and by the placenta, and is essential for maintenance of the maternal fetal interface of pregnancy. It has been used safely in pregnancy for over 50 years.[37] The American Society of Reproductive Medicine states that no long-term risks have been identified when progesterone is used in pregnancy.[38] The FDA has given progesterone a category B rating in pregnancy, in contrast to synthetic progestins.[39]

Table 1: Reversals Compared to Reported Control of 25% Survival if No Treatment Undertaken

Progesterone Group	Number	Reversals	Reversal Failures	Percent Reversals	P Value	95% Confidence Intervals
All Groups	547	261	286	48%	<0.001	0.44-0.52
High Dose Oral	31	21	10	68%	<0.001	0.51-0.84
Intramuscular, All groups	125	80	45	64%	<0.001	0.56-0.72
IM, 1 Injection	50	24	26	48%	<0.001	0.34-0.62
IM, 2-5 Injec.	36	21	15	58%	<0.001	0.42-0.74
IM, 6-8 Injec.	9	9	0	100%	<0.001	0.67-1
IM, 9-10 Injec.	10	9	1	90%	<0.001	0.77-1.0
IM, 11 or More Injec.	19	17	2	89%	<0.001	0.76-1.0
Oral, All Groups	119	64	55	54%	<0.001	0.45-0.63
Oral Caps Vaginally, All Doses	156	61	95	39%	<0.001	0.31-0.47
Vaginal Suppository	34	11	23	32%	0.161	0.17-0.48

A recent retrospective study of a Danish infertility cohort suggested a possible increased risk of acute lymphocytic leukemia and sympathetic neural tumors in children born to mothers who had taken progesterone during pregnancy and before pregnancy. The increased risk was greatest in women who had taken progesterone for three or more cycles.[40] However, the infertility population examined in the Danish study, exposed to

Table 2: Gestational Age Compared to Reversal Rate

Gestational Age	Total	Reversal	Reversal Failure	Reversal %	*P* value	95% Confidence Intervals
5 weeks	76	19	57	25%	0.5	0.15-0.35
6 weeks	113	52	61	46%	<0.001	0.37-0.55
7 weeks	102	50	52	49%	<0.001	0.39-0.59
8 weeks	88	54	34	61%	<0.001	0.51-0.72
9 weeks	30	23	7	77%	<0.001	0.62-0.92

Table 3: Birth Defects

Birth Defect	Instances
Port Wine Stain	1
Bilateral Absent Toe	1
Unilateral Two Absent Fingers	1
Choroid Plexus Cyst	1
Cystic Kidney	1
Unilateral Failed Hearing Test	1
Heart Murmur	1

many cycles of progesterone and other medications, differs significantly from our population of fertile women who had a single exposure to progesterone.

Mifepristone Teratogenicity

While previous human studies are not large in number, the available evidence suggests that mifepristone is not teratogenic.[4,41,42] The American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin March 2014 states that there is no evidence that mifepristone is associated with teratogenicity.[43] Our data set, the largest of babies exposed to mifepristone in utero, also indicates that the birth defect risk in women who have reversed mifepristone abortions is no higher than the risk in the general population.

Study Limitations

This study is limited in that it is not a randomized placebo-controlled trial. However, a placebo-controlled trial in the population of women who regret their abortion and

want to save the pregnancy would be unethical. Furthermore, although the number of women lost to follow-up was small, it could have affected the results. In addition, some data collection was incomplete.

One potential confounding variable is the use of ultrasound to select for living embryos prior to the first progesterone dose. It is possible that those embryos who were alive at the time of sonogram may have survived without progesterone therapy. However, our study also included some women who started progesterone therapy prior to sonographic documentation that the embryo was alive. Undoubtably, this group included women who already had an embryonic demise prior to initiation of progesterone therapy. Inclusion of these women would falsely lower the success rate of progesterone therapy. The numbers of women who received or did not receive ultrasound exams prior to initiating therapy were not available to our researchers. If ultrasound is readily available, sound practice would dictate that embryonic or fetal viability should be confirmed, or at least suggested, before treatment is started in order to avoid giving women progesterone unnecessarily and to exclude ectopic pregnancy before starting progesterone therapy.

Conclusions

The use of progesterone to reverse the effects of the competitive progesterone receptor blocker, mifepristone, appears to be both safe and effective. Progesterone therapy makes biologic sense, has been previously published as effective in an animal model and is supported by this case series which demonstrates a statistically significant difference in survival between treatment groups and the historic control. Mifepristone is embryocidal and feticidal but not teratogenic; progesterone is not associated with birth defects.

Based on these new data, two reasonable protocols can be suggested for women who seek to reverse the effects of mifepristone:

1. Progesterone micronized 200 mg capsule two by mouth as soon as possible and continued at a dose of 200 mg capsule two by mouth twice a day for three days, followed by 200 mg capsule two by mouth at bedtime until the end of the first trimester; and

2. Progesterone 200 mg intramuscular as soon as possible and continued at a dose of 200 mg intramuscular once a day on days two and three, then every other day for a total of seven injections. Some clinicians may choose to continue intramuscular treatment longer since this recommendation is based on relatively small numbers.

Recommendations for Future Research

We propose that further research employing randomized controlled trials comparing progesterone doses and routes of administration are needed to confirm which mode of delivery, dose and duration of progesterone therapy is most efficacious and carries the least burden for the patient.

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Senate Judiciary Committee, March 4, 2019, HB1336
Testimony by Representative Kathy Skroch

Madam Chair Larson and members of the Senate Judiciary Committee,

For the record, I am Representative Kathy Skroch, representing District 26 which contains portions of Dickey, Ransom, Richland and all of Sargent counties of southeast North Dakota.

I come before you today to represent myself, women and little people. I am a mother of seven living children and a grandmother to 12 children.

Today I want to tell you about our 3rd child, Christina Marie. She was born on June 7, 1980. She was exceptionally healthy and had a robust giggle at the age of 7 weeks which is one of my favorite memories. On August 7, 1980, I found her unresponsive in her crib. I began CPR but after 20 minutes I stopped when I saw that her pupils had 'blown' and I knew I had lost her. I called for an ambulance because I didn't know what else to do. The nearest hospital was an hour away. I was beside myself with a flood of emotions. I just sat and rocked her in my arms until they came and took her from me, transported to the hospital where she was pronounced dead. The autopsy determined that she was a classic SIDS baby. That is Sudden Infant Death Syndrome.

Holding your own baby dead in your arms changes you. There is a piercing, wrenching knowing, that everything I hoped and dreamed for her, all her sparkle, all that she was, is gone. I received a profound and deep understanding of the preciousness of little people as I held Tina in my arms.

Our last baby was a miscarriage at 3 months gestation due to cancer. I held this tiny baby in the cup of my hand, so little, yet unmistakably our little baby, our little Isaac Joseph. There is something about holding ones own dead baby that changes you forever. I would have done nearly anything to have had the chance to see Tina and Isaac alive again; to have a second chance to hold them, cuddle them and see them live a full life.

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The Abortion Reversal Procedure gives women and their babies a second chance. That is why I am here in support of House Bill 1336. This bill ensures that information about the procedure be given to women contemplating a medical (chemical) abortion. Professionals will provide for you, as they did the House Human Services Committee, a wealth of credible information about this procedure.

The Abortion Reversal Procedure works. It has saved hundreds of babies, one was saved this past December in Grand Forks, North Dakota. We have documented proof of its success.

In closing, I ask the members of this committee to notice subsection (4) which precedes the new subsection (5) language in House Bill 1336. It states that, "she (the woman) is free to withhold or withdraw her consent to the abortion at any time". She needs to know her options.

I, as a woman, as every woman in this state, have the right:

- **to be fully informed before making my medical decisions**
- **to have access to all information related to any medical procedure and**
- **To know all of my options before making any medical decision**

Then, I am able to make an informed choice. I also have the right to change my mind and choose an alternate choice when I feel it is in my best interest.

This bill ensures that every woman is provided with a fully informed choice and for many women a second choice, a second chance. I urge the members of this Judiciary Committee to vote unanimously for a Do Pass recommendation on HB1336.

Thank you for allowing me to speak before you today.

Kathy Skroch

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Abortion Pill Reversal Testimony
Jerry M. Obritsch, MD, FACOG
March 4, 2019

My name is Dr. Jerry Obritsch. I am an Obstetrician and Gynecologist practicing at Mid Dakota Clinic Center for Women here in Bismarck. The views I am presenting today are my own and do not necessarily represent my clinic or my colleagues.

As an introduction to myself, I graduated with a Bachelor's degree in Biology and a Bachelor's degree in Chemistry from Dickinson State University, a Master's degree in Microbiology from the University of Nebraska-Lincoln, and my Medical Doctor degree from the University of North Dakota School of Medicine and Health Sciences. I completed my Graduate Medical Education consisting of an Internship and Residency in Obstetrics and Gynecology at the School of Medicine, University of Missouri – Columbia. I am in active clinical practice in Bismarck in Obstetrics and Gynecology and have been so, for the past 28 years having delivered approximately 6000 babies to the present time. I serve as Clinical Professor and Vice Chairman in the Department of Obstetrics and Gynecology at the University of North Dakota School of Medicine and Health Sciences. I am a registered sonographer of the American Registry of Diagnostic Medical Sonographers and serve as Director of Ultrasound Studies at the Center For Women at Mid Dakota Clinic.

I am here today to speak about House Bill 1336 which informs patients about the possibility of abortion pill reversal. I would like to speak on 3 points today concerning this bill. First, I would like to briefly explain how a medical abortion is carried out. I will not discuss surgical abortions performed through Suction Dilatation and Curettage in early pregnancy or Dilatation and Evacuation as the surgical approach is not germane to this discussion. Secondly, I would like to explain how abortion reversal works. Thirdly, I would like to cover the Science of Abortion reversal.

A medical abortion is generally carried out with 2 medications. These 2 medications are mifepristone, also known as Mifeprex or RU-486. It was first approved for use in the US in 2000 by the Federal Food and Drug Administration (FDA). The second medication is misoprostol, which is also known as Cytotec. Mifepristone is administered as the first medication in a single 600 mg pill. It acts as a progesterone antagonist. This means it prevents the crucial hormone, progesterone, from supporting the continuation of the pregnancy. After mifepristone has exerted its effect for 36 – 72 hrs., the second medication, misoprostol, is administered, either vaginally or orally. Misoprostol acts by inducing uterine cramping and contractions. The process of completing a medical abortion occurs at home. It may require several hours to

several days to complete, and involves associated vaginal bleeding, cramping, and pain, the amount and severity of which, varies from patient to patient. Approximately 5 -10% of the time, medical abortions are not completed successfully on their own. In these cases, the medical abortion is then completed surgically by a Physician performing a surgical procedure, which is called a Suction Dilatation and curettage.

Secondly, I would like to explain how Abortion reversal is carried out. The term, "Abortion reversal", is somewhat erroneous in that an Abortion is not reversed but rather, Abortion is prevented from occurring. Prevention of an abortion from occurring is performed mainly by preventing the antiprogesterone effect of mifepristone from exerting its effect upon the pregnancy. Giving the patient progesterone after the patient has taken mifepristone may successfully prevent Abortion occurring by saturating the progesterone receptor sites, preventing mifepristone from exerting it antiprogesterone effect. If you recall, I earlier stated progesterone is crucial to the continuation and health of a pregnancy. In fact, as an Obstetrician, I will administer Progesterone to a pregnant patient if their Corpus Luteum on their ovary produces insufficient quantities of progesterone until the placenta begins to produce adequate quantities, beginning usually at 10 weeks of gestation. I know this is a fair amount of medical science to understand, but this information is central to understanding how Abortion reversal or prevention occurs. Ideally, Progesterone needs to be given before the second pill, misoprostol, is administered because misoprostol initiates uterine cramping, expelling the pregnancy. Its effect is not negated by administration of Progesterone. It is also important that the patient understands not to take the second pill, misoprostol, if the Abortion is to be prevented.

Thirdly, I would like to go over the Science of Abortion reversal. There is a fair amount of discourse regarding Abortion reversal being unscientific or so called "junk science". Even my College that I am a member of, the American Congress of Obstetricians and Gynecologists, also known as "ACOG", has called Abortion reversal "junk science" or "inadequately studied". This opinion clearly has a political tone in its usage. I am a Scientist by training and practice, recalling that I have a Bachelor's degree in Biology, a Bachelor's degree in Chemistry, a Master's degree in Microbiology, and a Medical Doctor degree. Every day, in my medical practice, I am using and rely heavily on evidence based medicine to provide high quality care to my patients. Best practice principles are based on the latest research and scientific principals applied to the clinical practice of Medicine.

Abortion reversal began its use with a Family Physician, Dr. George Delgado, practicing in California. He has been studying reversing the effects of mifepristone since 2009. Dr. Delgado applied the scientific concept of Progesterone receptor saturation to prevent the efficacy or the

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ability of mifepristone to exert its antiprogesterone effect after a patient called him in desperation to reverse the effects of mifepristone after she had a change of heart and mind. In theory, this is good, sound Pharmacological practice. In clinical application, it is now being practiced such that the case studies are demonstrating its success. I do agree that are there limited studies regarding its use; however, this is because its practice is relatively new. The best research to conduct regarding the study of a clinical trial is called the randomized, prospective trial where the outcomes are double blinded, meaning both the researcher and patient do not know what medication or procedure is being done to them under study. All clinical studies require approval from an Investigation Review Board, assigned an IRB number, before being carried out. It is obvious that an IRB approval would be difficult, if not impossible, to achieve for this kind of study regarding Abortion reversal, secondary to legal, ethical, and moral issues. Therefore, we must make our best scientific observations based on the information, perhaps limited by reasons above, to provide the best care of our patients. In time, other studies with less power of statistical significance evolve, such as retrospective or case cohort studies. There are approximately 200 babies born nationwide after using the Abortion Pill Reversal (APR) protocol regarding the latest data. This may not seem like a high number . . . . unless you are one of those babies. One would naturally conclude that this number will only increase once patients are given information on abortion reversal as a possibility.

Finally, and I will conclude with this thought. This bill simply requires information be given to the patient regarding their options. It does not take away the patient's choice or limit their reproductive options. What it does do, is provide patients with information regarding potentially a chance to change their mind regarding a very important decision in their life. Who hasn't thought about past choices in their life regarding important decisions that, had they had a second chance to change their mind, may have done so? I strongly believe that knowledge is power and the more informed a patient is, the better decisions they are able to make regarding their health care. This has been one my most important practice tenets over the last 28 years practicing Obstetrics and Gynecology.

Thank you for your time.

1. Abortion Pill Reversal Helpline.

https://www.abortionpillreversal.com/

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4. AAPLOG Fact Sheet: Abortion Pill Reversal.

http://aaplog.org/wp-content/uploads/2017/02/AAPLOG-APR-Fact-Sheet.pdf

5. Bernard, N., Elefant, E., Carlier, P., Tebacher, M., Barjhoux, CE., Bos-Thompson, MA., Amar, E., Descotes, J., Vial, T. (2013). Continuation of pregnancy after first-trimester exposure to mifepristone: an observational prospective study. BJOG, 120(5), 568-575.

The study, examined 261 successful mifepristone reversals, that showed the success rates were 68% with the high-dose oral progesterone protocol and 64% with the injected progesterone protocol; both were significantly better rates than the 25% survival rate if no treatment is offered. There was no increased risk of birth defects or preterm births.

Based on these new data, two reasonable protocols can be suggested for women who seek to reverse the effects of mifepristone: 1. Progesterone micronized 200 mg capsule two by mouth as soon as possible and continued at a dose of 200 mg capsule two by mouth twice a day for three days, followed by 200 mg capsule two by mouth at bedtime until the end of the first trimester; and 2. Progesterone 200 mg intramuscular as soon as possible and continued at a dose of 200 mg intramuscular once a day on days two and three, then every other day for a total of seven injections. Some clinicians may choose to continue intramuscular treatment longer since this recommendation is based on relatively small numbers.

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North Dakota Catholic Conference

Representing the Diocese of Fargo and the Diocese of Bismarck

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To: Senate Judiciary Committee
From: Christopher T. Dodson, Executive Director
Subject: House Bill 1336 - Woman's Right to Know about Abortion Pill Reversal
Date: March 4, 2019

The North Dakota Catholic Conference supports House Bill 1336 to update our Woman's Right to Know law.

Women considering abortions deserve to have information about the abortion procedure, possible consequences of an abortion, the development of the unborn child, and services available as alternatives to abortion. This is why the state has a Woman's Right to Know law that requires informed consent and the publication of materials about pregnancy, abortion, and abortion alternatives.

From time to time the state must update this information to reflect current practices. For example, the law was substantially revised in 2011 to address, among other things, the use of abortion-inducing drugs. HB 1336 revisits and updates the law further by including information about the possibility of reversing the effect of the abortion drug regimen should the woman change her mind after taking the first drug in the process.

North Dakota law requires that abortion-inducing drugs be administered according to the protocol approved by the federal Food and Drug Administration (FDA). The FDA approved protocol consists of mifepristone, followed by misoprostol taken 24 to 48 hours later. The mifepristone blocks the production of progesterone, which is stabilizes the uterine lining, which in turn is necessary for the development of the unborn child. By blocking the production of progesterone, mifepristone cuts off blood and nourishment to the unborn child, usually causing he or she to die. The second drug, misoprostol, forces the body to expel the dead unborn child or in some cases a live child.[1]

Since physicians know exactly how mifepristone works (i.e., by blocking progesterone), they also know that treating a woman with progesterone can

"kick off" the mifepristone (i.e., displace mifepristone from the progesterone receptors). This allows the woman's body to respond naturally to the progesterone and to effectively fight the effects of the mifepristone-induced blockage.

Progesterone itself has been used safely in pregnancies for decades. Using progesterone to reverse the effects of mifepristone is a targeted medical response that is safe for the woman and the baby. We also know that use of mifepristone alone does not cause birth defects.[2]

The fact that the effects the abortion-inducing drug mifepristone can be reversed or blocked should not be disputed. Hundreds of babies among us attest to that fact. Those who oppose merely informing women about the possibility reversing the abortion drug process point to the absence of large-scale studies explaining how the process works. The number of women at issue, however, is so small that large-scale controlled studies are difficult to conduct. Nevertheless, even the opponents of informing women have noted that reversal makes "biological sense" and there is no evidence that abortion pill reversal does not work or is not safe.[3] Indeed, initial studies show that without abortion pill reversal, the chances that an unborn child will survive mifepristone are around 15%. However, if the mother receives the progesterone-based rescue, then 65-70% of the unborn children will survive.

The state's right to ensure that woman receive information about abortion as part of the informed consent process is well-established. *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 882–83 (1992). While the state cannot compel an individual to simply to speak the state's ideological message — which HB 1336 does not do — it can use its legitimate regulatory authority to require a physician to provide truthful, non-misleading information that the legislature concludes could be relevant to a patient's decision to have an abortion, even if that information might also encourage the patient to choose childbirth over abortion. *Planned Parenthood Minn., N.D., S.D. v. Rounds,* 686 F.3d 889 (8th Cir. 2012). Mere claims of scientific uncertainty by opponents of informed consent do make the requirements unconstitutional. *Rounds*, 686 F.3d at 899; *Gonzales v. Carhart*, 550 U.S. 124, 163-64 (2007).

Working within this constitutional framework and our existing statutory structure, HB 1336 does two things. First, it directs the Department of Health to update its printed materials on abortion and pregnancy to include information about the possibility of abortion pill reversal. (HB 1336,

page 2, line 27 through page 3, line 2.) These printed materials are required by Chapter 14-02.1-02.1 of the Century Code and include information on abortion, abortion alternatives, fetal development, services available, and a pregnant woman's legal rights. They are periodically updated and must be provided to all women seeking an abortion.

Second, HB 1336 adds to the informed consent requirements assurance that the woman is told (1) that it may be possible to reverse the effects of the abortion-inducing drug if she changes her mind and (2) that further information is available in the printed materials. (HB 1336, page 2, lines 14-18.) This information must be provided at least twenty-four hours before the abortion, which in this case is the taking of the mifepristone. It requires nothing more from the physician or the physician's agent.

In summary, HB 1336 is a simple, but important update to North Dakota's Woman's Right to Know law. Some women change their minds after taking the first drug of the abortion pill regimen, but without HB 1366 these women may not know about the possibility of abortion pill reversal. Women deserve better. Women deserve HB 1366.

We urge a **Do Pass** recommendation on House Bill 1336.

[1] We know this because some women who do not take misoprostol have their pregnancies continue. For purposes of North Dakota law, however, the "abortion-inducing drug" is the mifepristone.

[2] The scientific facts concerning abortion pill reversal are summarized in the attached fact sheet from the American Association of Pro-life Obstetricians and Gynecologists.

[3] https://www.washingtonpost.com/news/to-your-health/wp/2018/04/03/as-controversial-abortion-reversal-laws-multiply-researcher-says-new-data-shows-it-can-work-critics-are-still-skeptical/

ProLife OBIGYNS
AAPLOG American Association of Pro-life Obstetricians & Gynecologists

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AAPLOG FACT SHEET Abortion Pill Reversal

The American Association of Pro-Life Obstetricians and Gynecologists strongly supports a woman's right to choose to keep her pregnancy, and to attempt to reverse the effects of a medical abortion which she no longer desires. The Abortion Pill Reversal process is safe for both the mother and for her unborn child, and offers a real chance for the woman to rescue her unborn child when she has changed her mind about abortion. The following facts about APR are important to understand:

- Progesterone is the hormone produced by the mother's ovaries, which allows the mother's womb to carry an unborn child. ("Pro"=for, "gest"=pregnancy, "erone" = hormone). When progesterone is too low, the unborn child cannot receive nutrients, and dies. ASRM FACT SHEET (Ref 1)

- Mifepristone(RU486/Mifeprex) is a progesterone blocker. (Ref 2) Mifepristone blocks progesterone from allowing the womb to nourish the unborn child. But Mifepristone is a REVERSIBLE (Ref 2) blocker- which means that the effects of Mifepristone can be stopped by adding large amounts of natural progesterone. The natural progesterone competes for the binding sites on the progesterone receptors, and kicks the mifepristone off of these binding sites.

- Natural progesterone has been used for over 50 years in the treatment of early pregnancies who are threatening to miscarry because the mother's progesterone level is too low. Progesterone has also been used for over 3 decades in women who have conceived with IVF. In the extensive medical literature on the use of progesterone in early pregnancy, there are no increased risks of any birth defects with natural progesterone. (Ref 1)

- The use of natural progesterone to reverse the effects of mifepristone poisoning is a simple application of common sense in the treatment of poisonings in situations where the mechanism of poisoning is well understood. Mifepristone poisoning is well studied and well understood. Using natural progesterone to reverse mifepristone effects is a logical extension of understanding the biochemical mechanism of action of mifepristone. (Similar application is used in chemotherapy with methotrexate followed by leukovorin rescue.) (Ref 3)

- In children who survive mifepristone poisoning and continue to birth, mifepristone alone has not been found to be associated with birth defects. In those children who have survived after the mother has ingested mifepristone alone, there have been no increased risks of birth defects noted. (Ref 4)

- The APR protocol involves giving natural progesterone to women who have taken mifepristone alone- who have not yet taken the second abortion drug misoprostol. (Ref 3)

- The APR protocol increases the chances that a baby will survive after the mother ingests mifepristone. Without APR, the chances that an unborn child will survive mifepristone poisoning are around 15%. However, if the mother receives the APR rescue, then 65-70% of the babies will survive. There are currently 200 babies born nationwide after using the APR protocol, and another 100 coming soon. (Ref 6)

- The babies born after using the APR protocol are not at increased risk for birth defects. (Ref 4)

- See AAPLOG FACT SHEET REFERENCES Abortion Pill Reversal

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ProLife OB|GYNS
AAPLOG American Association of Pro-life Obstetricians & Gynecologists

AAPLOG FACT SHEET REFERENCES Abortion Pill Reversal

- ASRM FACT SHEET http://www.reprodsurgery.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Educational_Bulletins/Progesterone_supplementation.pdf
- Baulieu.E.E. (1985) RU 486: an antiprogestin steroid with contragestive activity in women. In Baulieu.E.E. and Segal,S.J. (eds), The Antiprogestin Steroid RU 486 and Human Fertility Control. Plenum Press, New York,
- Delgado G, Davenport M. Progesterone Use to Reverse the Effects of Mifepristone. Ann Pharmacother 2012;46. Published Online, 27 Nov 2012, theannals.com, doi: 10.1345/aph.1R252
- Bernard N, Elefant E, Carlier P, Tebacher M, Barjhoux C, Bos-Thompson M, Amar E, Descotes J, Vial T. Continuation of pregnancy after first-trimester exposure to mifepristone: an observational prospective study. BJOG 2013;120:568–575 http://onlinelibrary.wiley.com/doi/10.1111/1471-0528.12147/epdf
- http://abortionpillreversal.com/page/2-Abortion%20Pill%20Reversal/
- Davenport et. Al. publication pending.

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Family Policy ALLIANCE of North Dakota

Testimony in Favor of House Bill 1336

Mark Jorritsma, Executive Director
Family Policy Alliance of North Dakota
March 4, 2019

Good morning Madam Chair Larson and honorable members of the Senate Judiciary Committee. My name is Mark Jorritsma and I am the Executive Director of Family Policy Alliance of North Dakota. I am testifying in favor of House Bill 1336 and respectfully request that you render a "DO PASS" on this bill.

At its core, House Bill 1336 is about women having access to the highest quality and quantity of information possible prior to making an important health decision. Abortion procedures should not be an exception to quality standards of care. Every pregnancy is life-changing. Imagine a mom who chooses an abortion because her current circumstances are screaming at her, but then she has a change of heart. Something is speaking to her through her fear, through her circumstances...and it is brave, fierce, and deserves attention. If a pregnant mom revisits her choice, she has hope of possible success. But only if she knows of her medical options. Why would we want to deny her that?

HB 1336 is a necessary and logical enhancement to North Dakota's informed consent laws and aligns with standard practices in the medical field. Strengthening this law by allowing an expectant mother the knowledge of the potential to reverse a chemical abortion, simply increases the amount of relevant, helpful information available. This bill in no way impedes access to an abortion and places no additional burden on the abortion business.

HB 1336 will close this information gap in one of the fastest growing abortion methods – the abortion pill. One-third of all abortions in the United States are now performed as chemical abortions. This is a relatively new method that has increased in popularity over the 19 years since it was approved in the United States. The bill simply requires that when an abortionist prescribes the abortion pills to a woman, he must also inform her of an alternative, should she change her mind.

Doctors and other medical professionals provide women with incredible amounts of information to keep their baby well. In fact, women are often overwhelmed with information. Yet, in this one instance, opponents of this type of notification law seek to ***limit*** the information women receive about their options. Why should a woman seeking an abortion be treated so differently from other pregnant women when it comes to medical choices and information?

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Twenty-nine states, including North Dakota, have abortion-specific informed consent laws that allow women to know about the risks and alternatives to abortion. HB 1336 will simply add information to pre-existing informed consent laws about this new method. With increasing numbers of women who are now choosing a chemical abortion, they deserve access to the full spectrum of information.

It is true that the abortion reversal method may not work on every single woman who changes her mind about an abortion, but every woman still deserves to know all her options. Abortion Pill Reversal is not a guarantee, but it IS an opportunity.

Pro-life opponents often decry that abortion is all about "choice". I ask you, how is a woman free to choose if she doesn't know there's a possibility her chemical abortion can be stopped/reversed? She effectively can't. The pro-abortion movement rallies around the phrase "it's a woman's right to choose". I say, that sentiment has to cut both ways. Withholding critical information about an abortion procedure takes away her choice. This needs to change.

Some opponents of this bill would argue that not enough medical studies have been done confirming that this reversal procedure works. I would point to the 500+ babies who have been born using this procedure, which equates to roughly a 70 percent success rate! That may not constitute a peer reviewed study, but it is overwhelming evidence that it is successful. In fact, in terms of probability and statistical significance, if only 3 percent of completed RU486 abortions still result in a live birth (based on extensive peer-reviewed studies), but with reversal 70 percent do, then there is a 100% statistically significant difference between the two methods. Put quite simply, it's quantitatively undeniable that it works.

I would like to close with a real story about a woman in Fargo who experienced the exact set of choices we have been discussing. The expectant mother had been conflicted over her decision to abort her child through medical means and began to have doubts after ingesting the first of three pills given to her by the Red River Women's Clinic, the abortion clinic in North Dakota that takes the lives of roughly 1,200 preborn children each year. Even though this young mother had taken the first of the pills, she now wanted her child to live.

She called the abortion facility, but was told it was too late and that she should just consume the remaining pills and move forward with the abortion. She soon learned they had lied to her. Our partner, FirstChoice Clinic, told her the truth; she could still stop the process, and by the next morning she had a prescription called into the pharmacy to undo the chemical abortion. Shortly thereafter, she had the joy of witnessing the ultrasound image of her beautiful baby safely tucked in her womb. She carried her preborn child to full term and the baby was saved. The last two pages of this testimony document tell her story in more detail and show the smiling mother and healthy baby boy!

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Living with regret can be a cruel burden. But regret centered around our children can be suffocating.

Second chances are rare and HB 1336 extends the hand of support for a woman wanting to take that second chance. If the protocol is successful, a life is saved. But regardless, she will know she did all she could to undo a regrettable choice.

Based upon all these considerations, I respectfully request that you vote House Bill 1336 out of committee with a "DO PASS" recommendation.

- Please protect access to all medical information that serves as the foundation of true freedom of choice,
- Please help protect the lives of children, and
- Please protect young mothers from a potential lifetime of regret.

Thank you for the opportunity to testify and I stand for any questions you may have.

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FirstChoice Clinic Helps Effect First Local Medical Abortion Reversal

Second chances are rare and HB 1336 extends the hand of support for a woman wanting to take that second chance. If the protocol is successful, a life is saved. Regardless, she will know she did all she could to undo a regrettable choice.

FirstChoice Clinic recently experienced a life-saving "first" when staff helped guide a client through a medical-abortion reversal, undoing the effects of the RU486 drug that would have ended the life of the client's baby.

It happened on a Wednesday, the day abortions take place at the local abortion facility downtown Fargo.

According to Denise Cota, Client Services Director, that morning staff had gathered to pray as always that hearts would be transformed and minds changed.

"There is a sense of urgency on Wednesdays, but also a sense of hope that these mothers and fathers will be heroes for their children and choose to carry these babies," she explains.

Though prayers continue well past Wednesday and after the staff goes home for the evening, the fruits of their prayers don't always become clear. However, this Wednesday was different.

A client who had been conflicted over her decision to abort her child through medical means began to have doubts after ingesting one of three pills given to her by the Red River Women's Clinic.

Family Policy ALLIANCE of North Dakota

As Denise notes, the client had sought out FirstChoice earlier for counseling regarding what seemed a truly impossible situation. Thankfully, cell phone numbers had been exchanged at that time, and the client sent a text to her that evening to ask whether it was too late to change her mind.

Earlier, she'd called the abortion facility, but was told it was too late, and that she should just consume all three pills and move forward with the abortion. But the client had done some online research indicating a reversal could be possible, and FirstChoice staff knew this as well, and that it was still early enough to try.

"We connected her with our medical director, Dr. Richard Vetter, who was able to counsel her on the reversal of the pill," Denise says. "By the next morning, we had her prescription called into the pharmacy, and an ultrasound scheduled at our clinic. And soon, we had the joy of witnessing the beautiful visual of a baby with a heartbeat safely tucked into his or her mother's womb."

Three weeks later, the mother went in for her first obstetrician visit at her hometown clinic. She asked Denise to travel and meet her at that appointment, which she gratefully did.

"The ultrasound image showed a healthy baby, which brought relief and happiness to our client," Denise says. "She's since expressed her conviction of the choice that she made and, and how aware she's become of the powerful instinct of motherly protection."

Angela Wambach, Executive Director, says the staff's coordination that helped bring about the reversal was a tremendous achievement, and that much gratitude goes to Dr. Vetter for his willingness to be called during evening hours, and respond with his professional advice to save a child's life.

She also notes that, despite the fact that the client wasn't from Fargo, because the abortion facility is, the Fargo location continues to be important, in that its staff is sometimes the "first responder" in such a crisis, and would never turn away a client regardless of their home base location. Currently, the client is continuing with prenatal and parenting education at a pregnancy center in her hometown.

"On that Wednesday night, we all learned a valuable lesson. Our client learned what a gift it is to be a mother, and what it's like to feel like a heroine," Denise says. "We, as a staff, learned that even when things seem hopeless, quickly that can change to hopeful."

UPDATE Baby boy has arrived! Both mom and baby are doing well.

http://www.teamfirstchoice.com/testimonials/

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CONCERNED
WOMEN for AMERICA
OF NORTH DAKOTA

March 4, 2019
Senate Judiciary Committee
Testimony in Support of HB 1336

Madam Chairman and Members of the Committee, my name is Linda Thorson, and I am the State Director for Concerned Women for America (CWA) of North Dakota. We are the state's largest public policy women's organization and part of the country's largest public policy women's organization with over 500,000 members. We are here today on behalf of our North Dakota members in **support of HB 1336, the Abortion Pill Reversal Informed Consent Legislation.**

Because you will be hearing from, or have already heard from, those in the medical field in support of this bill, I will confine my comments to the issue of a woman's right to be informed of this legal procedure.

Women are strong, capable, and should have the right to know, if they change their mind after taking the first abortion pill, that they may be able to reverse the chemical abortion procedure. Women should have the right to complete information regarding their health decisions, especially one as important as this one.

The concept of "choice" and "rights" must go both ways. Those who support *a woman's right to an abortion*, should have no problem supporting *a woman's right to change her mind about an abortion.*

Women not only have the right to be informed; they want to know their options. The APR Hotline Medical Director, who has overseen thousands of calls, stated that when women are given the opportunity to reverse the effect of the abortion pill, they are extremely grateful.

Women are being told that there is no possibility of reversal. A number of women have told the APR Hotline nurses, that when they changed their minds and called the abortion clinic personnel asking about reversal, they were falsely told that "there is no possibility of reversal." We need an APR informed consent law to ensure that the patient receives accurate and complete information about the reversal protocol by abortion clinic personnel.

In closing, there are three things I respectfully ask this committee to consider. 1. A positive pregnancy test is one of the most life-changing moments for a woman, 2. We all sometimes make decisions that we wish we could take back, and 3. This is a historic opportunity for you to give hope to women desiring choices.

Concerned Women for America of North Dakota urges you support this pro-information, pro-woman bill that will change lives. We urge a "Do Pass" on HB 1336.

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FACEBOOK: CONCERNED WOMEN FOR AMERICA OF NORTH DAKOTA

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North Dakota Right to LIFE

The North Dakota Abortion Pill Reversal

Medora Nagle Testimony

March 4, 2019

Madam Chair Larson, Members of the Senate Judiciary Committee, thank you for the opportunity to ask for your support on HB 1336, regarding the Abortion Pill Reversal.

My name is Medora Nagle and I am the Executive Director for North Dakota Right to Life. I am also a board member on the National Right to Life Committee. I have been in these positions for almost three years.

If enacted, HB 1336 would require abortion providers in North Dakota to give the mother information on how she could possibly save her baby if she changes her mind after taking the first set of medication.

Regret is a common feeling among women who have had an abortion. We now know that the abortion can be reversed if action is taken in a timely manner.

We know that there have been over 500 babies saved from abortion because the mother sought help after beginning the chemical abortion procedure. As a representative of the largest and oldest pro-life organization in North Dakota, we are in favor of this life-saving legislation.

I recommend a "do pass" on HB 1336.

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Testimony in Support of HOUSE BILL NO. 1336

Emma Stehr
Collegians for Life, University of Mary
March 4, 2019

Good afternoon Madam Chairman Larson and members of the Senate Judiciary committee. My name is Emma Stehr and I am part of the leadership team of Collegians for Life at the University of Mary. We are the local chapter of Students for Life of America, and we have over 300 members in our organization at the University of Mary. I am testifying on behalf of our organization and its students in support of HB 1336 on the Abortion Pill Reversal Informed Consent legislation.

I am here as a millennial, I am here as a Pro-Life woman, and I am here as a nursing student, to standup for the lives of the unborn and the rights of women to be informed on ALL procedures related to their reproductive health.

As a millennial, I am extremely blessed to have survived the ruling of Roe v Wade in 1973, which disastrously legalized abortion as a woman's reproductive right. In excluding the unborn from the U.S. Constitution's definition of "persons," over 60 million children have been aborted in the United States since Roe v Wade. I am saddened at the lives lost, lives that could have been my friends and my peers, lives that should have been protected and respected.

As a junior level nursing student at the University of Mary, I recognize that patient advocacy is crucial in health care. As a future nurse, I will have the duty of advocating for my patients. This means that in all situations, I will support the desires of my patients in medical care and ensure that informed consent has been obtained by the physician. If an abortion physician does not inform a woman of her options, a nurse cannot witness the informed consent, because it is NOT "informed" consent.

Those who support abortion as a woman's choice and reproductive right, should have NO issue with supporting a woman's choice to change her mind about an abortion. As a Pro-life woman, I believe that providing a woman with information about the available abortion reversal agents, empowers her to make decisions regarding her reproductive health, and this includes reversing her abortion if she so chooses.

Again, I reiterate that a woman's right to choose goes BOTH ways: If she has the right to choose to have an abortion, she also has the right to choose NOT to have an abortion. I recognize the duty of the physician to provide the woman with ALL the options, so she can make an informed decision.

For these reasons, I and the 300+ members of University of Mary Collegians for Life, urge a "DO PASS" on HB 1336.

I appreciate the opportunity to speak today in support of this bill and am willing to stand for any questions you may have. Thank you.

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Angela Wambach, BSN
Executive Director
FirstChoice Clinic
Fargo, ND
March 4, 2019

Good afternoon. My name is Angela Wambach. I am the Executive Director of the FirstChoice Clinics in Bismarck, Devils Lake, and Fargo.

FirstChoice Clinic does not have a political viewpoint regarding this bill. As such, I can neither speak in support of or opposition to the bill. I am simply here to relay the story of a client who could not be here herself. This young woman asked me to share her story, but not her name. Therefore, I will refer to her as "Ann" throughout this story.

Ann came to our center for a pregnancy test the summer before her senior year in college. She had big aspirations for her future, was no longer in a relationship with her boyfriend, and didn't have much local support since her family lived out of state. Ann did not feel this was the right time to bring a child into her life and she was feeling very uncertain about her possible circumstances.

The pregnancy test was positive, so we provided a limited ultrasound which confirmed a viable pregnancy. Ann spent a considerable amount of time with our nurse, talking about her current circumstances, how she was feeling, what her thoughts were, and the possible options she could consider. She was emotionally conflicted with her situation.

A couple of weeks later her father flew into town to visit her and help in anyway that he could. Ann and her dad came to FirstChoice to visit with our nurse and have another ultrasound. Again, the ultrasound confirmed a viable pregnancy. And again, they spent a considerable amount of time talking. Ann remained very conflicted. Her father was very supportive of her, no matter what her choice would be. His big

concern was that the baby would be born during the school year and Ann would be alone, so far away from her family. He offered to help her in any way that she needed. Ann left our center still very uncertain of what she would do.

Several days later, Ann called to talk with our nurse and said that she had decided to go through the medical abortion pill procedure. She had just been at a clinic and taken the first of three doses of the medications that were prescribed. Ann immediately regretted her decision.

She stated that she had been reading online to see what she could do and learned that there was a way to reverse what she had begun. Ann asked if we could help her. We quickly connected her with our medical director who prescribed medication to reverse the effects of the abortion pill Ann took.

Ann came back to our center a couple of days later for another ultrasound. A viable pregnancy was still noted. And a week later she had an appointment with an OB/GYN. An ultrasound confirmed a viable pregnancy and she was told that things were looking good.

In March of 2017 Ann gave birth to a healthy baby boy that she named Noah. All the while she continued to attend her college courses and graduated that May. Ann now has a full-time job and is living in the same community as her father. She is a proud and happy mom.

Thank you for your time.

Angela

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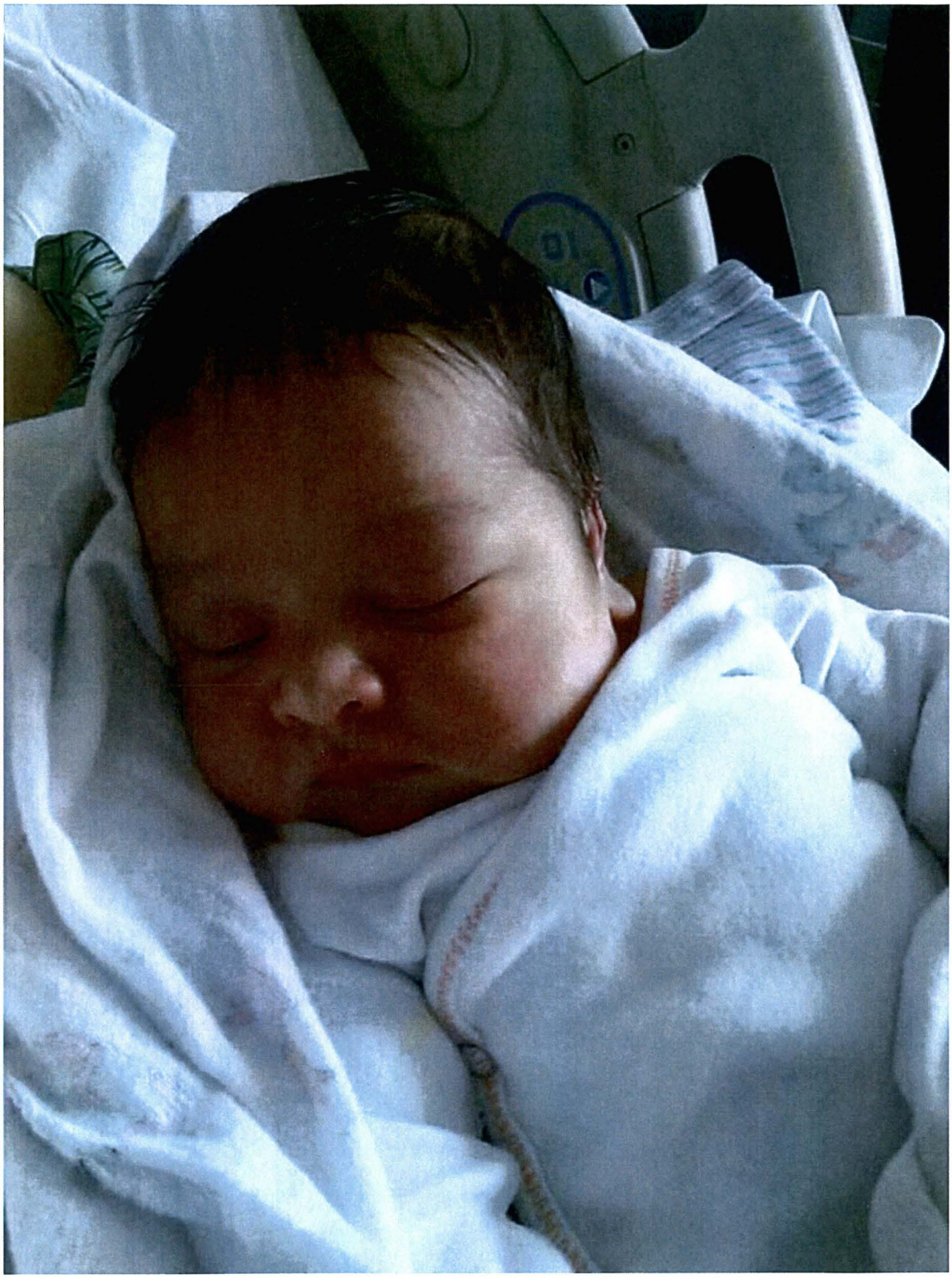
3.4.19

BABY NOAH



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HB 1336 Testimony in Favor

Nadia Smetana, RN, BSN
Clinic Director
Dakota Hope Clinic
Minot, ND
2/4/19

Madam Chairman, and members of the committee, my name is Nadia Smetana. My home is near Lansford, ND. I am an RN and the director of Dakota Hope Clinic, a pregnancy help center in Minot. Dakota Hope Clinic is one of several pregnancy help centers around the state that refer clients for the abortion pill reversal. My testimony will be in favor of HB 1336.

I have a simple request of each of you. Think with me for a moment of how you felt sometime in your life when you said or did something that you immediately regretted and wanted a chance for a do over.

One time I gave my credit card number to someone on the phone. As soon as I hung up, I realized that was not a wise decision. A quick google search confirmed that I had been scammed and I sure wished for a chance to reverse what I had done. I will tell you later that situation turned out.

Abortion is one of the most impactful decisions that a woman can ever make in her life. A significant number of women at some point regret that decision. Surgical abortions are completed in minutes and there is no chance for a do-over. However, because a medical abortion is a **process** that occurs over several days, there is a **chance for a woman to reverse the process**. House bill HB 1336 would simply ensure that she is informed about that option.

I am here to speak in favor of HB 1336 for 2 basic reasons.

1. There is good evidence that Abortion Pill Reversal using progesterone is safe and effective.
2. It is reasonable and appropriate to respect a woman's right to choose to reverse the process of a medical abortion.

Medical abortion is a 2 step process:

1. Mifepristone, also known as RU-486, the abortion pill, is taken at the abortion clinic. Over the next few days, this drug blocks the women's womb from being able to absorb the hormone progesterone. Gradually, the fetus is deprived of food and oxygen that it needs to survive.

2. A 2nd drug, misoprostol, also known as Cytotec, is sent home for the women to take by herself about two days later. This drug causes the womb to contract and typically within 24-48 hours the dead fetus is delivered. This completes the abortion.

How can this process be reversed?

1. If a woman regrets starting the process, she can reach out for help any time prior to the completion of the abortion. Time is of the essence and the sooner she gets treatment, the more likely it is to be successful in reversing the abortion.
2. By calling the Abortion Pill Rescue (APR) national hotline or the local pregnancy help center, she can be put in touch with a medical provider who can determine if she is a candidate for attempted reversal.
3. An ultrasound will be done as soon s possible to confirm that there is a heartbeat, placement, and dating of the pregnancy. As long as the fetus is determined by ultrasound to still be living, there is a chance for reversal.

4. After signing a consent which informs the woman that this is an off-label use of the medication, she would be given a prescription for supplemental progesterone, using national guidelines. This works by enabling the woman's womb to absorb enough progesterone for the fetus to survive.
5. The progesterone will usually be continued through the first trimester under supervision of the physician.

Does the reversal process work?

There have been two articles containing observational case studies published in medical journals documenting the safety and effectiveness of this reversal process. The latest article, published last year in the peer – reviewed journal, Issues in Law and Medicine, documented 547 cases. The results of this analysis showed a ***68% success rate with oral progesterone and a 64% survival rate for those given progesterone shots.*** This was a significant increase over the 25% survival rate documented in the historical literature if no supplemental progesterone was given.

What about the safety of the reversal process?

1. The case studies revealed no increase in birth defects. This shows that neither mifepristone (the first abortion drug) nor progesterone constitute an increased risk.
2. The American College of Obstetricians and Gynecologists states that there is no evidence that mifepristone causes birth defects.
3. The case studies also showed no increase in premature births.
4. Safe for pregnant women - Progesterone has been used safely in pregnancy for more than 40 years to prevent miscarriage, including routine use for women who have undergone in-vitro fertilization.
5. The American Society of Reproductive Medicine states that no long-term risks have been identified when progesterone is used in pregnancy.

What about Availability?

The abortion pill reversal process is becoming more widely available in ND. Across the country, there is a network of physicians that participate in giving women this option. So far, we know of 2 physicians in Minot who have agreed to be prescribing physicians. Dr. Billings, an OBGYN at Trinity Health in Minot is one of them and his letter is attached.

Is Additional Support available?

1. Long-term emotional, educational and material support is available from Pregnancy Help Centers. There are 7 pregnancy help centers in ND. The APR hotline can put the woman in touch with the closest center.
2. Financial support is available if she cannot afford the progesterone. In Minot, have arranged with a couple of pharmacies to charge the cost to pregnancy help center. Financial help is available through the APR Network also.

This bill upholds the Principles of INFORMED Consent for healthcare

1. Consent for medical procedures are required to include the nature of the procedure, the risks, benefits, **and alternatives**.
2. Medical consent is more than a signature on a form – it is an on-going process.
3. A patient has a right to know that **their initial and their continuing consent is optional**.
4. Healthcare consent is not like a contract where once you sign on the dotted line you have to go through with it. A patient has a right to withdraw consent at any time and choose an alternative option.
5. This process is the foundation of the ethical principle of respecting the autonomy of the individual.

Post-abortive woman who regret their abortion suffer emotional and psychological effects that can be serious and long-lasting. Some of this suffering can be avoided by passing this bill to simply inform women of all their options. I was very happy for a second chance when I gave my credit card number to a scammer. I called the bank and canceled my card before the charge was made.

In summary:

1. There is good evidence that Abortion Pill Reversal using progesterone is safe and effective.
2. It is reasonable and appropriate to respect a woman's right to choose to reverse the process of a medical abortion.

For these reasons, I urge a yes vote on HB 11336. We owe it to the women of ND to make sure they are fully informed of this option.

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Dakota Hope Clinic

Choices for a Bright Future

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Minot, ND 58701

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01/20/2019

ND State Legislature
Human Services Committee

Dear Chairperson and Committee Members:

As Medical Director for Dakota Hope Clinic in Minot, I have agreed to be a prescribing physician for the Abortion Pill Reversal Program. I have reviewed the medical literature and believe that it is safe and effective. In my practice at Trinity Health, I have prescribed progesterone in early pregnancy to prevent miscarriage and found it to be safe. I believe that all women who consent to a medical abortion should be informed of the possibility of a reversal if they change their mind.

Sincerely,

David Billings, MD, FACOG
Board Certified – Obstetrics and Gynecology

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Off-Label Drug Use and the Use of Progesterone for Abortion Pill Reversal

Information compiled by Nadia Smetana, RN, BSN

What Does it Mean?

1. The most common form of off-label drug use involves prescribing currently available and marketed medications for an indication (e.g. a disease or symptom) that has not received FDA approval. *Progesterone is an FDA approved drug but it has not been FDA approved for the indication of abortion pill reversal.*

Why Does Off-Label Drug Use Happen?

1. The FDA's role is to control which medications are available commercially. *Progesterone is available commercially.*
2. The FDA does not regulate the practice of medicine. *A physician does not need the approval of the FDA to use progesterone for abortion pill reversal. They also do not need the approval of large medical organizations such as the American Medical Association(AMA). or the American College of Obstetricians and Gynecologists (ACOG)*
3. From the FDA perspective, once the FDA approves a drug, healthcare providers may lawfully prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient. *Physicians may lawfully prescribe progesterone for other indications such as abortion pill reversal.*
4. Off-label prescribing of medicines is prevalent worldwide because it gives freedom to physicians to apply new therapeutic options. *Abortion Pill reversal is a new therapeutic option to a drug that has been approved to be safe and effective for related conditions.*
5. When drug companies develop a new drug, they limit the indications that they seek FDA approval for in order to save money and to reduce the time it takes to get through the regulatory process. *When progesterone was first approved by the FDA, the abortion pill was not in use. Approval for Abortion pill reversal has never been denied by the FDA, it has not been applied for.*
6. The cost of obtaining FDA approval for new uses of an old drug may exceed the benefit. *Progesterone is an old drug and It is unlikely that any drug company will ever seek FDA approval for the indication of abortion pill reversal.*

How Common is Off-Label Prescribing?

1. Very Common – estimated that at least 21% of prescriptions are off-label, and it is higher in certain populations. *Physicians, Nurse Practitioners, and Physician Assistants all do off-label prescribing.*
2. Exists in every specialty of medicine. Physicians are not required to disclose to their patients that the drug they are prescribing is off-label. *However, the consent form used by the abortion pill reversal network, does disclose this fact to the women who are seeking to reverse their medical abortion.*

3. More common in populations less likely to be included in clinical trials, such as pediatric, pregnant, or psychiatric patients. *It is not ethical to do a placebo controlled randomized clinical trial on women who seek abortion pill reversal because half of them would have to be given a placebo.*
4. If the features of 2 conditions are similar, a physician may use a medication approved for 1 of these conditions for both. *Progesterone is used by physicians to try to prevent a pregnant woman from having a miscarriage and for women who are pregnant by assisted reproductive technology. A pregnant woman who has taken the abortion pill is a similar condition.*
5. Off-label drug use can gradually become the standard of care for a given condition. *Dr. Delgato, at the end of his article documenting the case studies, recommends more research be done to confirm which mode of delivery, dose and duration of progesterone therapy is most effective.*

Scientific Evidence

1. Randomized controlled clinical trials have long been accepted as the best process to determine safety and effectiveness. However, the results might not always correspond to what is seen in real world practice, where physicians apply the treatments to a broader range of patients.
2. It is common for off-label prescriptions to have little or no scientific evidence of the risk-benefit ratio. Studies have shown that only about 30% of off-label prescribing is supported by adequate scientific data. *Giving progesterone for abortion pill reversal does have some scientific evidence (observational studies) and progesterone has been used and deemed safe for more than 40 years.*
3. There are many medically accepted off-label uses that do not ever become approved by the FDA due to cost and lack of feasibility of doing clinical trials.
4. For serious health conditions that have few if any satisfactory treatment options, decision makers are more willing to accept greater uncertainty in the evidence of promising treatments. *The observational studies done for abortion pill reversal may not provide a high degree of certainty but physicians across the United States and around the world are judging that the information they provide, along with previous research on the drugs involved, are the lack of other options, are evidence enough for them to use the abortion pill reversal protocol.*
5. Most clinical decisions can benefit from evidence (such as observational studies) that provide a lower level of certainty. *Other research has determined that progesterone at the recommended dosage for abortion pill reversal is not harmful to pregnant women or their babies during the first trimester. Previous research has shown that the abortion pill mifepristone does not cause birth defects and that the percentage of babies that survive mifepristone alone is significantly lower than if progesterone is taken.*
6. High quality observational studies have an important role in in scientific research because they can address issues that are otherwise difficult or impossible to study. *Pregnant women are difficult to study.*

7. Observational studies are often necessary to answer important questions about particular populations and conditions. *The case study published by Dr. Delgato and others provides valuable evidence for the safety and effectiveness of the successful reversal of a medical abortion for those women who choose to try it.*

Advantages

1. Because off-label prescribing is allowed, many new therapies and evidences of effectiveness are discovered and the knowledge spreads so more patients can benefit. *Dr. Delgato has established a network of abortion pill reversal providers. When a woman is found to be eligible and she signs consent, she also signs consent to be followed to see what the outcome is for herself and her baby. This information will be shared in further case studies.*
2. Patients can benefit from off-label prescribing if there are no approved drugs for a certain disease or medical condition. *There are no FDA approved drugs for abortion pill reversal*
3. Patients can benefit from off-label prescribing when all approved treatments have been tried without seeing any benefits.
4. Patients have earlier access to potentially valuable medications. *If physicians had to always wait for higher levels of certainty before prescribing, important treatments for heart failure, nerve pain, migraine headaches, psychiatric disorders, cancer, nausea from chemotherapy, and many other conditions would not be able to receive many safe and effective treatments.*
5. Some off-label uses give tremendous benefits to patients. *A woman who desires to reverse the process of medical abortion should be given the information that there is a chance of doing this in a way that is not harmful to her or her baby. Whether the attempt fails or is successful, either result is likely to result in a better emotional outcome for the woman.*

References

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Wittich, Chritopher M. et al, Ten Common (and Their Answers) About Off-Label Drug Use,Mayo Clinic Proceedings 2012 Oct. 87(10): 982-990

Gupta, Sandeep Kumar et al, Journal of Pharmacology and Pharmacotherapeutics, 2014 Apr-Jun; 5(2): 88-92

Understanding Unapproved Use of Approved Drugs "Off Label", FDA.Gov for Patients

Coomarasamy, Arri, et al, A Randomized Trial of Progeterone in Women with Recurrent Miscarriages

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North Dakota Women's Network

Opposition HB 1336
North Dakota Senate Judiciary Committee
March 4th, 2019

Chair Larson and members of the Senate Judiciary Committee, my name is Kristie Wolff, I am the Executive Director of the North Dakota Women's Network (NDWN). NDWN is a statewide advocacy organization with a mission to improve the lives of women through legislation, communication and increased public activism.

Based on our mission to improve the lives of women, I am here to stand in opposition to HB 1336.

HB 1336 would force doctors to provide patients with information that is medically inaccurate and could be harmful to a woman's health.

The American College of Obstetricians and Gynecologists (ACOG), a professional membership organization dedicated to the improvement of women's health, does not support this protocol. The North Dakota region of ACOG has submitted testimony in opposition to HB 1336 stating '*Claims regarding abortion "reversal" treatment are not based on science and do not meet clinical standards. ACOG ranks its recommendations on the strength of the evidence and does not support prescribing progesterone to stop a medical abortion*.'

The medical protocol that HB 1336 advocates has never been tested for safety, effectiveness, or the likelihood of side effects. There have been no clinical trials proving that reversing a medication abortion is possible. There is no FDA protocol.

Moreover, there is no recent medical research that tells us whether attempting to reverse a medication abortion would be safe or not safe – therefore we have no way of knowing how it could impact a woman's health or her future pregnancies.

One case study claiming to prove that abortions can be "reversed," which was co-authored by George Delgado, who runs a website promoting abortion reversals has been thoroughly discredited.

The study was not peer reviewed—a basic requirement for scientific article publication—nor did it undergo any form of approval process from an ethics board or institutional review board. In a deposition, one of the case study's authors agreed that the data for the report was not systematically collected, that it was missing facts, and that it is uncertain if the women discussed in the case study had even provided their consent to be included.

Therefore, we ask that you give HB 1336 a Do Not Pass recommendation. Thank you.

Kristie Wolff, Executive Director
North Dakota Women's Network
kristie@ndwomen.org

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ACLU
North Dakota

ACLU opposition testimony to House Bill 1336 (medication abortion reversal)

The ACLU of North Dakota opposes House Bill 1336.

Claims regarding abortion "reversal" treatment are not based on medical science and do not meet clinical standards, according to the American Congress of Obstetricians and Gynecologists. This bill would force doctors to provide women with medically inaccurate and misleading information that could be harmful to their health.

The decision to have an abortion is deeply personal and private and best left to a woman, her family and her doctor. It's a decision that is also protected under the U.S. Constitution.

ACLU opposition testimony to House Bill 1546 (method ban)

The ACLU of North Dakota opposes House Bill 1546, a bill that would ban the safest method of care for a woman at a certain stage of pregnancy.

A woman's health should drive important medical decisions, regardless of how we feel about abortion at different points in a pregnancy. With the exception of some, lawmakers are not medical experts and should not stand in the way of a woman having a range of effective, affordable, medically-proven methods of abortion care available to her as her pregnancy progresses.

Throughout her pregnancy, a woman must be able to make health decisions that are best for her circumstances, including whether to end a pregnancy.

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ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

FROM: **The North Dakota Section of ACOG**

DATE: **March 1, 2019**

RE: **North Dakota House Bill 1336**

The North Dakota Section of the American College of Obstetricians and Gynecologists (ACOG) opposes **HB 1336 which would require ND physicians to inform patients that their medical abortion may be reversed if she acts quickly and where to seek treatment if they want to reverse the abortion.**

Claims regarding abortion "reversal" treatment are not based on science and do not meet clinical standards. The American College of Obstetricians and Gynecologists (ACOG) ranks its recommendations on the strength of the evidence and does not support prescribing progesterone to stop a medical abortion. Politicians who push legislation to require physicians to recite a script that a medication abortion can be "reversed" with doses of progesterone, and to steer women to this care represents dangerous political interference in patient care and compromises patient safety.

ACOG firmly believes that science must be at the core of public health policies and medical decision-making. HB 1336 would insert the government into those personal medical decisions.

The American College of Obstetricians and Gynecologists is the nation's leading group of physicians providing health care for women. The College strongly advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. The American Congress of Obstetricians and Gynecologists is its companion organization.

ACOG supports guaranteed access to the full array of clinical and reproductive services appropriate to each individual woman's needs throughout her life and recognizes that patients and families with input from their doctors should make decisions regarding each person's unique healthcare needs, not the government.

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The American College of Obstetricians and Gynecologists (The College), a 501(c)(3) organization, is the nation's leading group of physicians providing health care for women. As a private, voluntary, nonprofit membership organization of approximately 55,000 members, The College strongly advocates for quality

health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. The American Congress of Obstetricians and Gynecologists (ACOG), a 501(c)(6) organization, is its companion organization. www.acog.org

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Testimony of Tammi Kromenaker
Director of Red River Women's Clinic
In Opposition to House Bill 1336
March 4, 2019

Senator Larson and Members of the Senate Judiciary Committee:

Chairwoman Larson, members of the Senate Judiciary Committee, thank you for the opportunity to provide this written testimony today regarding House Bill 1336.

My name is Tammi Kromenaker, and I am the Director of Red River Women's Clinic in Fargo. Red River Women's Clinic has provided safe abortion care services to women in North Dakota for over twenty years – we are, in fact, the state's *only* abortion provider. We are members in good standing of the National Abortion Federation and maintain the highest quality standards of practice. Our mission is to not only provide medically safe reproductive health care services, but also do to so in an emotionally supportive environment.

We know that women who choose abortion in the United States come from a wide range of backgrounds – about sixty percent are mothers, who already have at least one child at home; sixty-two percent are religious;[i] and no racial or ethnic group makes up the majority of abortion patients.[ii] Each year, Red River Women's Clinic sees a similarly diverse array of women. The reasons that these women choose abortion underscore their understanding of pregnancy and parenthood; they are making decisions about what is best for them and their families.

Most of our patients receive abortions very early in pregnancy. In fact, last year, twenty eight percent received medication abortions. Many women choose this option because they feel it is more natural and less invasive than a surgical procedure.[iii,iv] Access to this type of care can be especially important to women who may be survivors of sexual violence, for whom the insertion of medical instruments into their bodies may be especially unwanted and frightening. Some patients appreciate that this method of termination does not require anesthesia,[v] and many opt for medication abortion so that they can receive the support of partners, family, or friends in the comfort of their own homes.[vi]

With this, I am providing testimony in opposition to House Bill 1336. HB 1336 would force physicians to lie to their patients by telling them that it may be possible to "reverse" a medication abortion using progesterone. **Yet, there is no credible, medically accepted evidence to support these claims. Not one study has conducted proper scientific research into the idea that a medication abortion can somehow be reversed, or into the relative effectiveness and safety of the "reversal treatment" that HB 1336 would mandate providers to offer**.

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Indeed, the American College of Obstetricians and Gynecologists (ACOG), the nation's leading expert on women's health care, denounces this practice, stating that "claims regarding abortion 'reversal' treatment are not based on science and do not meet clinical standards…and ACOG does not support prescribing progesterone to stop a medical abortion."[vii] ACOG is not alone in their opinion – **no major public health organization or medical association has endorsed the practice of medication abortion "reversal," or lent any credence to the very limited, biased research that has been published on it**. Not only this, but the mandates in HB 1336 would suggest that patients often want to "reverse" their abortion procedures after they've already begun – a claim that is factually debased. Research shows that women have high decisional certainty around their abortion decisions – higher, in fact, than several other common medical procedures.[viii] Studies further demonstrate that women who, together with their doctor, decide that medication abortion is right for them, are satisfied with their decision.[ix,x] **Staff at Red River Women's Clinic are consistently working to ensure that we provide patients with the counseling, time, and support they need to make informed decisions about their pregnancies that they feel confident in**.

In the interest of women's health care and for the sake of medical integrity, **I urge you to vote no on House Bill 1336**. To legislate medical practice void of legitimate clinical research would be a complete deviation from ethical and medical standards. As ACOG states, "unfounded legislative mandates represent dangerous political interference and compromise patient care and safety."[xi] A vote for HB 1336 is a vote to lie to North Dakota women. It is a vote to undermine the best medical judgment of their doctors. Plain and simple, it is a vote to prioritize a misguided legislative agenda over the health and safety of women and their families.

Thank you, again, for the opportunity to provide this written testimony.

Tammi Kromenaker

Clinic Director
Red River Women's Clinic

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[i] Guttmacher Institute, U.S. Abortion Patients, https://www.guttmacher.org/infographic/2016/us-abortion-patients (last visited March 1, 2019).
[ii] Guttmacher Institute, Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008, https://www.guttmacher.org/report/characteristics-us-abortion-patients-2014 (last visited March 1, 2019).
[iii] Batya Elul et al., *In-depth interviews with medical abortion clients: thoughts on the method and home administration of misoprostol*, 55 (Suppl) J Am Med Women's Assoc 169, 170 (2000).
[iv] Tara Shochet & James Trussel, *Determinants of demand: method selection and provider preference among US women seeking abortion services*, 77 Contraception 397, 400 (2008).
[v] Beverly Winikoff, *Acceptability of medical abortion in early pregnancy*, 27 Fam Plann Perspectives 142, 144, 146 (1995).
[vi] Batya Elul et al., *In-depth interviews with medical abortion clients: thoughts on the method and home administration of misoprostol*, 55 (Suppl) J Am Med Women's Assoc 169, 171 (2000).
[vii] American College of Obstetricians and Gynecologists, Facts are Important: Medication Abortion "Reversal" is Not Supported by Science, https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/FactsAreImportantMedicationAbortionReversal.pdf?dmc=1 (last visited March 1, 2019)
[viii] Ralph LJ, Foster DG, Kimport K, Turok D, Roberts SCM. Measuring decisional certainty among women seeking abortion. Contraception 2017;95:269-78.
[ix] Beverly Winikoff, *Acceptability of medical abortion in early pregnancy*, 27 Fam Plann Perspectives 142, 148 (1995).

[x] Christian Fiala & Kristina Gemzell-Danielsson, *Review of medical abortion using mifepristone in combination with a prostaglandin analogue*, 74 Contraception 66, 76 (2006).

[xi] American College of Obstetricians and Gynecologists, Facts are Important: Medication Abortion "Reversal" is Not Supported by Science, https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/FactsAreImportantMedicationAbortionReversal.pdf?dmc=1 (last visited March 1, 2019).

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ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

August 2017

Facts Are Important:
Medication Abortion "Reversal" Is Not Supported by Science

Facts are important, especially when discussing the health of women and the American public. Claims regarding abortion "reversal" treatment are not based on science and do not meet clinical standards. The American College of Obstetricians and Gynecologists (ACOG) ranks its recommendations on the strength of the evidence,[i] and does not support prescribing progesterone to stop a medical abortion.

Yet, politicians are pushing legislation to require physicians to recite a script that a medication abortion can be "reversed" with doses of progesterone, and to steer women to this care. Unfounded legislative mandates represent dangerous political interference and compromise patient care and safety.

What is Medication Abortion?

- Medication abortion is the use of medications, rather than surgery, to end a pregnancy. This safe and effective evidence-based regimen includes a combination of two drugs—mifepristone, taken first, and misoprostol, taken at a later point.
- Mifepristone stops the pregnancy growth by blocking the hormone progesterone; misoprostol makes the uterus contract to complete the abortion.
- Medication abortion is more effective when both drugs are used, because mifepristone alone will not always cause abortion. In fact, as many as half of women who take only mifepristone continue their pregnancies.[ii]
- Mifepristone is not known to cause birth defects.

So-called abortion "reversal" procedures are unproven and unethical.

- A 2012 case series reported on six women who took mifepristone and were then administered varying progesterone doses. Four continued their pregnancies.[iii] This is not scientific evidence that progesterone resulted in the continuation of those pregnancies.
- This study was not supervised by an institutional review board (IRB) or an ethical review committee, required to protect human research subjects, raising serious questions regarding the ethics and scientific validity of the results.
- Case series with no control groups are among the weakest forms of medical evidence.[iv]

Legislative mandates based on unproven, unethical research are dangerous to women's health.

Politicians should never mandate treatments or require that physicians tell patients inaccurate information.

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Additional ACOG Resources:

- ACOG Practice Bulletin 143 *Medical Management of First-Trimester Abortion* (March 2014)

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[i] Hal C. Lawrence, M.D., "The American College of Obstetricians and Gynecologists Supports Access to Women's Health Care," *Obstetrics & Gynecology* vol. 125 1282, 1283 (Jun. 2015) available at http://journals.lww.com/greenjournal/Fulltext/2015/06000/The_American_College_of_Obstetricians_and.2.aspx.

[ii] Grossman D et al. "Continuing Pregnancy After Mifepristone and 'Reversal' of First-Trimester Medical Abortion: A Systematic Review," *Contraception* 92 206–211 (Jun. 2015).

[iii] Delgado G and Davenport M, "Progesterone Use to Reverse the Effects of Mifepristone," *The Annals of Pharmacotherapy* vol. 46 (Dec. 2012).

[iv] ACOG, *Reading the Medical Literature*, available at http://www.acog.org/Resources-And-Publications/Department-Publications/Reading-the-Medical-Literature.

#1
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3-13-19

19.0517.02001
Title.

Prepared by the Legislative Council staff for
Senator Bakke
March 4, 2019

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1336

Page 2, line 30, after "include" insert "scientifically based and medically accurate"

Page 2, line 31, after the first "information" insert "that provides all the repercussions that could occur to the unborn child and the mother if these additional medications are administered as well as information"

Page 3, line 2, after the underscored period insert "Information on all potential side effects, risks for future pregnancies, and risks to the unborn child must be given as a part of this written information."

Renumber accordingly