JOEL KITCHENS
STATE REPRESENTATIVE • 1ST ASSEMBLY DISTRICT

Testimony for the Senate Committee on Health and Human Services
Senate Bill 286
Wednesday, Nov. 20, 2019

Thank you Chairman Testin and committee members for holding a public hearing and giving me the opportunity to testify on Senate Bill 286, which will authorize pharmacists to prescribe certain birth control.

Under current state law, women can only obtain most birth control through a prescription from a physician or advanced practice nurse who has met the required qualifications.

Senate Bill 286 would, under specific circumstances, allow a woman to obtain hormonal contraceptive patches and self-administered oral hormonal contraceptives, including common birth control pills, through a prescription from a pharmacist.

The rules to establish the standard procedures for pharmacists prescribing contraceptives will be promulgated by the Pharmacy Examining Board, after consulting with the Medical Examining Board, Board of Nursing and Department of Health Services.

In order to acquire a prescription for birth control from a pharmacist, the person must complete a self-assessment questionnaire and undergo a blood pressure screening. The questionnaire must be developed in consideration of the guidelines established by the American College of Obstetricians and Gynecologists.

If there are any red flags, the pharmacist is not required to prescribe and dispense birth control and can instead refer patients to their primary health care practitioners. If the woman is deemed a match, the pharmacist must dispense the contraceptive as soon as practicable and report the prescription to that individual's primary health care practitioner. Participation by Pharmacists is voluntary.

This bill only applies to women who are at least 18 years of age.

One of the reasons we introduced SB 286 is because of the high costs associated with unplanned pregnancies.

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According to the latest available statistics, nearly half of pregnancies in both Wisconsin and across the nation are unplanned, with the highest rates reported by women in their 20s and those who live in poverty. We know that 42 percent of those pregnancies will end in abortion.

For those children carried to term, a study from the Guttmacher Institute found that state and federal taxpayers spend about $21 billion annually on unplanned pregnancy-related care, with public insurance programs such as Medicaid financing 68 percent of unintended births. This figure does not include additional costs that stem from an unplanned pregnancy's impact on educational attainment, family economics and a child's health and well-being.

In Wisconsin, 63 percent of unplanned births are publically-funded. The total public cost for unintended pregnancies in Wisconsin is $286 annually for every woman in the state, which is considerably higher than the national average of $201 per woman.

Significant intergenerational health effects also exist with unplanned pregnancies. According to the Institute of Medicine, women with unintended pregnancies are more likely to smoke or drink alcohol during pregnancy, have depression and experience domestic violence. They are also less likely to obtain prenatal care or breastfeed.

Furthermore, short interpregnancy intervals have been associated with adverse neonatal outcomes, including low birth weight and prematurity, which increase the chances of children having health and developmental problems throughout their lives. Plus, these youth are more likely to score worse on behavioral and developmental measures than children who were born as a result of a planned pregnancy.

An unintended pregnancy can also severely disrupt a woman's educational goals, which in turn has a tremendous influence on future earning potential and family financial well-being. Community colleges are typically the place first generation college students begin their post-secondary education. Nationally, unplanned births are the reason 10 percent of women drop out of community college and most never obtain their degree. This perpetuates the intergenerational cycle of poverty.

Knowing all of these sobering facts, we should not be putting up artificial barriers that deny women more choices when it comes to their reproductive healthcare.

When the common birth control pill became available in the United States in the 1960s, you could only obtain the oral contraceptives through a prescription from a doctor. That made sense at the time, particularly since the pills had incredibly high hormone levels and experts were not sure how the medication would affect women physiologically.

Fast-forward almost 60 years and things have definitely changed. Decades of research have shown us that formulations for oral contraceptives have become much more benign. While all drugs come with the potential for harmful side effects – even Aspirin can cause bleeding disorders – the consensus of the medical community is that birth control pills are no more dangerous than ibuprofen.

More than 100 countries across the world allow access to birth control without a prescription. Yet, women in the United States still need a prescription from their doctor or nurse practitioner to be able to obtain birth control pills. Even the morning-after pill, which is seven times more potent than your average oral contraceptive, is available over-the-counter and doesn't require a prescription.

To understand why we need to update our laws in Wisconsin, I would like to explain that there are only two factors that are supposed to be used to determine whether a medication should be prescribed by a physician. Drugs are made prescription-only because they either have high abuse potential or they have a low margin of safety which requires a doctor's oversight.

There is no documentation that birth control pills have ever been abused and every single reputable medical organization of which I am aware says that birth control is safe enough to be available with no prescription at all. The American Medical Association, the Wisconsin Medical Association, the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians, the Wisconsin Nursing Association and the Pharmacy Society of Wisconsin all believe it is safe enough to be available without a prescription. None of our offices received a single contact from a physician with concerns about the safety of contraceptives, with the exception of representatives from the Catholic Physicians Association.

While making birth control over-the-counter may be their preferred direction these groups would like to go, only the Federal Food and Drug Administration can grant that status.

Dr. Eliza Bennett, from the UW School of Medicine and Public Health's Department of Obstetrics and Gynecology, said that the "risks associated with pregnancy are infinitely greater than those associated with birth control."

The primary health risk that comes with taking birth control is the potential for developing blood clots. The blood pressure screening performed by the pharmacist will prevent most of these problems. According to ACOG, this problem is easily managed and there are now multiple brands of pills with ultra-low levels of estrogen that avoid this problem. The risk of blood clots is also far greater in pregnancies than birth control.

I have also heard concerns that because birth control pills use hormones to block pregnancy, they may overstimulate breast cells, which can increase the risk of breast cancer. While there is a slight increased risk, especially in older women, a study published by *Cancer Research* shows that using birth control pills with a low dose of estrogen has not been linked to a higher probability of being diagnosed with breast cancer. While saying that birth control pills are a Class I carcinogen for breast cancer sounds ominous, it only means that a link has been shown. It does not indicate the severity of the risk. It is worth noting that alcoholic beverages, air pollution, sunshine and working the late shift are also listed as Class I carcinogens. Pregnancy itself increases the risk of breast cancer.

Research also has also found that birth control pills can lower the risk of uterine and ovarian cancer by 50 percent. In fact, women with family histories of these two types of cancer are frequently put on birth control as a preventive measure.

I trust the medical community which overwhelmingly believes it is much safer than many current over-the-counter drugs and should be dispensed with no screenings at all.

I would like to shift gears now and address a couple of the criticisms you will hear from the opponents of this bill. First, one of the arguments is that birth control is not effective and gives women a false sense of security. There is always room for some human error, but when used consistently and correctly, oral contraceptives are 99.9 percent effective.

In the Assembly hearing, the opponents told us about a study from the Guttmacher Institute, which uses data from 2001, which found that 48 percent of unplanned pregnancies occurred in women using birth control. They neglected to tell us that most of the women in the study used condoms or withdrawal rather than hormonal birth control as their form of birth control, which accounted for the high failure rate. When we restrict access to hormonal birth control, these are the methods that women turn to, and the results are abysmal. It is worth noting that the Guttmacher Institute supports the pharmacy access model for birth control.

The primary cause of failure of hormonal birth control is a lack of access. I think it is ironic that the people who oppose increased access to birth control are citing ineffectiveness when that lack of access is the major contributor to failure. Many OBGYNs have told me that women will frequently run out of oral contraceptives and cannot get an appointment with their doctors in a timely fashion. A large number of women also forget to bring their pills with them when they go on vacation. This bill will help alleviate that.

Some opponents are also claiming that birth control pills are an abortifacient that works by blocking the implantation of a viable embryo. That claim is purely hypothetical – there is absolutely no scientific evidence that oral contraceptives work this way.

Birth control pills stop pregnancies from happening by blocking ovulation and thickening cervical mucus, which prevent sperm from entering the uterus. The UW Department of Obstetrics and Gynecology says that if oral contraceptives worked by blocking the implantation of a viable embryo, we would expect to see large numbers of ectopic pregnancies with women on the pill, because a percentage of these fertilized ova would end up implanting in the Fallopian Tube. That is simply not happening.

ACOG says unequivocally that none of the current forms of the pill that are available are abortifacients. The current label on birth control pills says that it may prevent implantation of a viable embryo. ACOG says that this label was written in 1999 and does not reflect current research nor the opinion of the medical community.

I am also hearing from critics of SB 286 that birth control actually increases the number of unplanned pregnancies and abortions in our state and country.

According to a 2018 report from the Center for Disease Control, unintended pregnancy is the major contributor to induced abortion. "Increasing access to and use of effective contraception can reduce unintended pregnancies and further reduce the number of abortions performed in the United States," the report states.

Data from the Guttmacher Institute shows that from 2008 to 2014, the steep drop in unintended pregnancies — including births and abortions— was likely driven by improved contraceptive use. The U.S. abortion rate decreased 25 percent between 2008 and 2014, while the rate of abortion, about 42 percent of unplanned pregnancies, has remained unchanged. The evidence clearly suggests that contraception and fewer unintended pregnancies played a larger role than new abortion restrictions.

I would also like to point out that making birth control available with a prescription from a pharmacist is gaining popularity across the country.

Twelve states currently allow women to get their birth control prescriptions from a pharmacy. Several other states are currently considering similar legislative proposals. This is not a Republican or Democratic issue. Blue states like California and Oregon, as well as red states like Utah and Tennessee, have passed similar legislation. Recently, Sen. Ted Cruz asked Rep. Alexandria Ocasio-Cortez to co-author a bill with him asking the FDA to consider adopting full over-the-counter status for birth control.

Oregon was the first state to pass the pharmacist/birth control law and the results so far have been very encouraging. According to research conducted by Oregon State University, Oregon prevented more than 50 unintended pregnancies and saved an estimated $1.6 million in associated taxpayer costs in the first two years the law went into effect. Think about those 50 pregnancies. According to national percentages, 20 of those babies would have been aborted. Of the 30 that were born, 20 would have been born into welfare and covered by Medicaid. That is 20 women who would have likely been trapped in poverty and government dependence. Instead, they have an opportunity to complete their education and break the cycle of generational poverty.

As you can see, we are proposing SB 286 to give women more choices with their reproductive healthcare, decrease the number of unplanned pregnancies and abortions in our state, save taxpayer dollars and reduce generational poverty.

I respect the position of those who morally oppose birth control, but it is not the role of government to impose our morality onto others. We should not be putting up artificial barriers that prevent increased access to birth control – especially when there is no medical basis to do so.

I want to thank you for taking the time to listen to my testimony, and I hope you consider supporting SB 286. I am also extremely appreciate of all the work that my co-authors, Rep, Felzkowski and Sen. Bernier, and their staff put into this bill. I am now happy to answer any questions if you have them.

MARY FELZKOWSKI
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Testimony on Senate Bill 286

Senate Committee on Health and Human Services
Representative Mary Felzkowski
35th Assembly District
November 20, 2019

Good morning Chairman Testin and Committee Members,

Thank you for taking the time to hear testimony on Senate Bill 286, which would allow pharmacists to prescribe oral birth control in Wisconsin.

As you just heard from my co-author, Representative Kitchens, this bill will expand access to a safe and commonly used method of birth control that many women across our state use and benefit from.

In order to get a prescription for birth control now, women must go and make an appointment with a physician or an advanced practice nurse. Those of us in rural areas know that these appointments are not easy to make. The shortage we are facing with rural healthcare providers extends to OB/GYNs and in fact, the American Medical Association estimates that 30% of Wisconsin counties do not have a practicing OB/GYN. To see any physician and obtain a prescription, a woman in rural Wisconsin is faced with transportation costs and time constraints. This is an artificial barrier that we need to remove. The government should not play the role of gatekeeper in preventing women from accessing this medical tool.

One of the ways we can move forward on addressing the issue of access is to follow in the footsteps of the 11 states that have already passed this and allow pharmacists the authority to prescribe birth control. The Pew Research Center says that 93% of Americans live within 5 miles of a pharmacy. I can tell you that that reality is certainly reflected in my district and throughout the Northwoods.

As Representative Kitchens made clear, there is no medical reason that oral contraceptives need to be prescribed by a physician and OB/GYNs support making birth control available without a prescription at all. The government needs to remove the artificial red tape we have in place and allow women to access this medication without jumping through hoops.

Thank you for your time and consideration and I look forward to your questions.

Testimony from:
Courtney Joslin, Commercial Freedom Fellow, R Street Institute

Regarding SB 286, AN ACT ***to amend*** 450.095 (title) and 450.095 (3); and ***to create*** 450.01 (16) (L), 450.095 (1) (ag) and (ar) and 450.095 (2m) of the statutes; **relating to:** permitting pharmacists to prescribe certain contraceptives, extending the time limit for emergency rule procedures, providing an exemption from emergency rule procedures, granting rule-making authority, and providing a penalty.

November 20, 2019

Senate Committee on Health and Human Services

Chair Testin, Vice Chair Kooyenga, and members of the Senate Committee on Health and Human Services:

Thank you for considering my testimony today. My name is Courtney Joslin, and I am a Commercial Freedom Fellow for the R Street Institute. R Street is a nonprofit, nonpartisan public policy research organization. Our mission is to engage in policy research and outreach to promote free markets and limited, effective government in many areas. This includes working to reduce overly burdensome regulations that restrict both consumer freedom and professionals' ability to work in their highest capacities. This is why SB 286 is of particular interest to us.

Birth control access is hampered by state regulations that only permit doctors and some advanced-practice clinicians to prescribe hormonal birth control. In Wisconsin, as well as the majority of states, women are still required to go through the process of a doctor's visit just to maintain their birth control routine. A typical visit for a birth control prescription consists of a patient filling out her medical history, a blood pressure check and discussing which contraceptive methods she prefers. Only then is she given a prescription, which she can take to the pharmacy to have filled. But this restrictive barrier is unnecessary, as some states are proving with the "pharmacy access" model that SB 286 would allow.

In the last few years, both Republicans and Democrats in 11 states and Washington, D.C., have passed bills allowing pharmacists to undergo contraception-specific training and subsequently prescribe birth control directly to patients.[1] This pharmacy access model is proving successful—and beneficial—for women, their families, taxpayers and the medical community.

First, leading medical organizations, such as the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians and the American Medical

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[1] Courtney Joslin and Steven Greenhut, "Birth control in the states: A review of efforts to expand access." The R Street Institute. November 21, 2018. https://www.rstreet.org/2018/11/21/birth-control-in-the-states-a-review-of-efforts-to-expand-access/

Association all advocate for lowering the barriers to birth control due to its time-tested track record of safety and effectiveness.[2] The birth control pill gained FDA approval 60 years ago and since then has helped millions of women plan for their families and alleviate other reproductive health issues. In fact, the aforementioned medical organizations go so far as to advocate for complete over-the-counter access to birth control.[3]

However, over-the-counter access is a federal issue, so states like Tennessee, Utah, West Virginia and New Hampshire have all reduced barriers to birth control by enacting pharmacy access laws that allow women to go directly to a pharmacist for their birth control prescription.

Pharmacists are experts in medication, and allowing them to prescribe birth control after undergoing additional training frees them to practice well within their abilities. Oregon, which was the first state to implement pharmacy access, has already seen positive results within just two years of implementation. In those two years, Oregon pharmacists wrote 10 percent of new birth control prescriptions for Medicaid patients, none of whom had been on a birth control method previously.[4] Additionally, patients enjoy and are comfortable seeing a pharmacist for birth control. In a pilot study in Washington, virtually all patients who saw a pharmacist for birth control said they would continue to do so.[5]

Finally, it is important to consider just how pharmacy access ultimately benefits women and Wisconsinites. Pharmacy access can be especially beneficial for those in rural areas, the uninsured, or those who simply cannot afford the time and expense of regularly seeing a doctor to maintain their prescription. Additionally, it helps women plan for their families and futures. As the Wisconsin chapter of the American Academy of Pediatrics has highlighted, 46 percent of pregnancies in Wisconsin were unintended in 2010.[6] Unintended pregnancies impose costs on both individuals and taxpayers. For example, in Wisconsin that same year, taxpayers spent over $313 million on the medical costs associated with unintended pregnancies.[7] Additionally, 40

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[2] The Committee on Healthcare for Underserved Women, "Opinion: Access to Contraceptives," The American College of Obstetricians and Gynecologists, issued January 2015, reaffirmed 2017 https://acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Over-the-Counter-Access-to-Oral-Contraceptives?IsMobileSet=false; "Over-the-Counter Oral Contraceptives," The American Academy of Family Physicians. March 2019. https://www.aafp.org/about/policies/all/otc-oral-contraceptives.html; Gerald E. Harmon, MD, "Over-the-Counter Contraceptive Drug Access (Resolution 110-A-17)," The American Medical Association. http://ocsotc.org/wp-content/uploads/2018/06/2018-AMA-OCs-OTC-resolution-110-A-17.pdf.

[3] Ibid.

[4] Tracy Brawley, "Pharmacist-prescribed birth control reaches new users, saves Oregon $1.6M," Oregon Health & Science University. May 9, 2019. https://news.ohsu.edu/2019/05/09/pharmacists-prescribed-birth-control-reaches-new-contraceptive-users-saves-oregon-1-6-million-in-public-costs

[5] JS Gardner, et al., "Pharmacist prescribing of hormonal contraceptives: results of the Direct Access study." Journal of the American Pharmacists Association, 2008 48:2. https://www.ncbi.nlm.nih.gov/pubmed/18359734

[6] "WI State Facts About Unintended Pregnancy," https://www.wiaap.org/download/state-facts-about-unintended-pregnancy/

percent of unintended pregnancies end in abortion each year, but better access to birth control in recent years has led to fewer unintended pregnancies and, in turn, fewer abortions.[8] In fact, in Oregon, the pharmacy access model reduced unintended pregnancies and publicly funded medical costs in just two years after implementation.

Wisconsin should allow resident pharmacists to join the hundreds of pharmacists across the country who are successfully prescribing birth control to women. This is not only a safe and reasonable reform that the medical community supports—it directly lowers the costs imposed on both taxpayers and families due to unintended pregnancies. For all of these reasons, I urge the committee to pass SB 286.

My genuine thanks for your time,

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[7] Adam Sonfield and Kathryn Kost, "Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010." Guttmacher Institute. February 2015. https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy

[8] "Unintended Pregnancy in the United States," Guttmacher Institute. January 2019. https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states

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TESTIMONY IN OPPOSITION TO SENATE BILL 286
SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES
WEDNESDAY, NOVEMBER 20, 2019
JULAINE K. APPLING, PRESIDENT

Thank you, Chairman Testin and committee members, for the opportunity to testify on Senate Bill 286. Wisconsin Family Action opposes this bill. We acknowledge the stated intent of the authors, but we believe the problems that come with this proposal far outweigh the good intentions.

First, let me clarify our organizational position on contraceptives in general. We do not take a position on whether or not a married couple should use contraception, unless a contraceptive method can result in the destruction of the fertilized egg, which generally happens because a contraceptive drug or device prevents a fertilized egg from implanting in the uterine wall. We have never promoted contraception for unmarried persons because that position is inconsistent with our belief that what is in the best interest of unmarried individuals is to remain sexually abstinent until marriage and faithful to their spouse when they do marry.

Allowing pharmacists to prescribe and dispense contraception, at least to some degree, promotes unmarried individuals engaging in sexual activity. The argument that these individuals will get contraceptives somewhere, and it may as well be from a pharmacist who can't perform an abortion, rings hollow. Pharmacies often are much more convenient in location and hours than are other places where contraceptives might be obtained, increasing the likelihood that more people will turn to pharmacists for their prescriptions. Should the contraception fail, and studies show it surely does, and a woman becomes pregnant, that the woman received the contraception from a pharmacist rather than from an organization that performs abortions will not deter the woman from having an abortion if that is what she is determined to do.

I think it is also important to note that this proposed change in the scope of practice for pharmacists is not about health-care. Contraception is not health care. Contraception is about the personal choices and decisions of individual women, typically made under the advice and guidance of a doctor because of the potency of the pharmaceuticals involved. To talk in terms of this being about women's health care is, at a minimum, disingenuous.

In addition, some contraceptives are known to cause a pre-implantation chemical abortion. Scientifically, we know life begins at conception. Contraceptives that make it impossible for this newly conceived human being to implant in the uterine wall destroy the human being in the earliest stages of development.

Further, we are concerned about the well-being of the individual seeking the contraception. The bill provides that the person must complete "a self-assessment questionnaire and undergo a blood pressure screening." Based on this very limited information, most of which is self-reporting, the pharmacist must determine whether it is safe to prescribe a contraceptive for a given individual. The presumption is, of course, that the individual is accurately reporting his/her medical situation historically and currently. Inaccurate medical information could be dangerous, even in some instances fatal.

This same law is in effect in Colorado, and the self-assessment questionnaire that state uses is available online, as is the Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use (copy attached). That chart makes it clear a significant number of medical conditions pose a "theoretical or proven risk" or even an "unacceptable health risk" for contraceptives. If the individual has an undisclosed condition that dictates that contraceptives should not be used and the pharmacist, in good faith, prescribes and dispenses some form of contraception, the individual's health is at a minimum compromised.

(over)

Should this burden rest on a pharmacist who is severely limited in what he or she can learn about the real health of the individual seeking the contraception? Blood pressure is only one measure of one's health; it is certainly not something physicians typically rely on in isolation (or even in conjunction with a self-administered assessment) to determine one's overall health or the appropriateness of a certain prescription. Pharmacists cannot do further diagnostic testing or assessments.

Further, what is to prevent a person who has a severe reaction to the prescribed and dispensed contraception from suing the pharmacist and/or the pharmacy? The language of the bill does not address the liability of the pharmacist or the pharmacy, which presumably would have some culpability since the pharmacist is acting in his/her official capacity as an employee of the pharmacy. In the Assembly hearing on this bill, when asked by a committee member about liability, a pharmacist speaking in support of the bill, replied that "we don't know about liability." When I followed up with my testimony and addressed this issue, a committee member responded to me by saying, "You know we frequently pass bills where we don't know who is liable." I suggested that perhaps this was not the wisest course of action, particularly in this instance and especially in the ultra-litigious society in which we live.

We also oppose this bill because it puts pharmacists who may have religious or conscience objections to prescribing contraception in general and in particular contraception that is known to be abortifacient, in a difficult position. We currently have no specific statutory protection for the religious or conscience rights of pharmacists. While the bill does not force any pharmacy to take part in this prescription-writing authority, it's safe to say many will. Imagine a pharmacist working for a pharmacy that decides to do this and thereby requires its pharmacists to either write prescriptions for contraception or face disciplinary action which could even involve dismissal.

For these reasons, we urge this committee to oppose this bill that is not in the best interest of those seeking contraception or in the best interest of the pharmacists.

Thank you for your attention and thoughtful consideration of our position on this proposal.

To: Members, Senate Committee on Health & Human Services

From: Maren Rasmussen, PharmD
Pharmacist, Neuhauser Pharmacy

Date: November 20, 2019

Subject: Support for Senate Bill 286

Thank you for giving me the opportunity to testify in favor of Senate Bill 286. My name is Maren Rasmussen and I am a staff pharmacist at Neuhauser Pharmacy.

This bill would allow a pharmacist to prescribe and dispense self-administered oral hormonal contraceptives and hormonal contraceptive patches. By allowing pharmacists to perform this task, pharmacists will be able to bridge gaps in patient access to health care. Health care access issues are seen throughout the state by provider shortages, long distances to clinics, long wait times for appointments, and limited hours during the work day. Legislation that allows for pharmacist-prescribed contraception will increase patient access to these services; for example, patients who are unable to go to their clinic during the work day due to taking time off or finding child care during their appointment time would greatly benefit from increased access to medications in community pharmacies.

This bill helps to protect patients by putting certain processes in place to ensure that patients are appropriately screened and approved for these medications. In the ten other states that allow pharmacists to independently prescribe birth control, there is a requirement to give a patient a self-screening questionnaire, which asks the patient about blood pressure measurement, medical and medication history, pregnancy history and current status, and smoking history. After completing the screening process, the pharmacist will use their expertise to determine whether or not to prescribe and dispense medication for contraception. Additionally, if a pharmacist does prescribe and dispense birth control, the pharmacist must inform the patient's primary care provider. Senate Bill 286 follows the above stated safety requirements and follows other jurisdictions' precedents.

Concerns have been raised by others that it is not safe for a pharmacist to prescribe contraceptive products. I would disagree by citing that overwhelmingly, major medical groups -- including the American College of Obstetricians and Gynecology, the American Medical Association, and the American Academy of Family Physicians-- support over-the-counter access to contraceptives and believe they are safe enough for patients to purchase without any prescription whatsoever. An article from the American College of Obstetricians and Gynecology states:

> *"Despite the safety of OC use, one frequently cited concern regarding over-the-counter provision of OCs is the potential harm that could result if women with contraindications use them. However, several studies have shown that women can self-screen for contraindications. In one study that compared current family planning clients' self-assessment of contraindications with clinical assessment, 392 of the 399 participant (females aged 15–45 years) and health care provider pairs obtained agreement on medical eligibility criteria (greater than 90%) ... A study conducted in the United Kingdom replicated the findings that women take a more conservative approach compared with clinicians and also demonstrated that none of the 328 women studied would have*

incorrectly used OCs based on self-screening. Another study found that women obtaining OCs from pharmacies were no more likely to have contraindications than those who got OCs from a clinic."[1]

Additionally, a study from Oregon Health & Sciences University found that women obtaining oral contraceptives online without a physical exam were no more likely to have contraindications than those who got a prescription from their physician[2]. A study from the University of Washington concluded that "pharmacists can efficiently screen women for safe use of hormonal contraceptives and select appropriate products."[3] Lastly, a study published in the Journal of Family Planning and Reproductive Health Care concluded that "A self-completed history questionnaire is acceptable to women and can potentially replace traditional routine medical history taking for continuing hormonal contraception. Women completed the questionnaire with a high degree of reliability." and "Overall, clients reported more risk factors than clinicians, which increases the safety of the questionnaire."[4]

Pharmacists in the community have an important role to provide increased access to care in the midst of a primary care shortage. Because pharmacies tend to have longer hours than clinics, are open on weekends, and don't usually require an appointment to see a pharmacist, patients have more opportunities for care compared to the limited hours of a clinic. Pharmacists are highly trained in pharmacotherapy and truly are the medication experts on the healthcare team. Pharmacists are able to ease the burden on physicians and provider counterparts while also improving access to contraceptives.

Thank you for taking the time to consider my testimony. I am happy to answer any questions from the committee.

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[1] "Committee Opinion No. 544." *Obstetrics & Gynecology* 120, no. 6 (2012): 1527–31. http://ocsotc.org/wp-content/uploads/2012/12/ACOG-2012_OTC-Access-to-Oral-Contraceptives.pdf.

[2]Kaskowitz, Alexa P., Nichole Carlson, Mark Nichols, Alison Edelman, and Jeffrey Jensen. "Online Availability of Hormonal Contraceptives without a Health Care Examination: Effect of Knowledge and Health Care Screening." *Contraception* 76, no. 4 (2007): 273–77. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2706829/.

[3]Gardner, Jacqueline S., Donald F. Downing, David Blough, Leslie Miller, Stephanie Le, and Solmaz Shotorbani. "Pharmacist Prescribing of Hormonal Contraceptives: Results of the Direct Access Study." *Journal of the American Pharmacists Association* 48, no. 2 (2008): 212–26. https://www.ncbi.nlm.nih.gov/pubmed/18359734.

[4] Doshi, J. S., R. S. French, H. E. R. Evans, and C. L. Wilkinson. "Feasibility of a Self-Completed History Questionnaire in Women Requesting Repeat Combined Hormonal Contraception." *Journal of Family Planning and Reproductive Health Care* 34, no. 1 (January 2008): 51–54. https://www.ncbi.nlm.nih.gov/pubmed/18201408.

To: Members, Senate Committee on Health & Human Services
From: Dimmy Sokhal, PharmD
Chief Clinical Officer, Hayat Pharmacy
Date: November 20, 2019
Subject: Support for Senate Bill 286

Thank you very much for allowing me to submit comments in favor of Senate Bill 286. My name is Dimmy Sokhal and I am the chief clinical officer at Hayat Pharmacy in Milwaukee. I am a community pharmacist and have been working to improve access to medications for patients. I work with a wide demographic of patients and one of our biggest challenge is patient's engagement in their health. I visit patients in their homes to provide medication management and education; and as I perform my visits, I encounter several barriers they face to have access to health.

I work with younger adults on medication adherence and compliance, the biggest barrier is the lack of flexibility to be able to see a prescriber besides inability to keep up with other challenges in their lives. As a community pharmacist, I am accessible to the community and do not need an appointment to be consulted. It is a significant proportion of young adults who do not have primary care prescriber. Although these young adults want to consider an oral contraceptive, they are tied up because of the requirement to establish a primary prescriber. I have noticed an alarming high rate of young females coming in to purchase emergency contraceptive pills, and majority of these young females are the ones who are unable to keep up with follow up doctor visits to be able to get a refill for their oral contraceptive. These incidents can be prevented if a community pharmacist can assess the patient and recommend an oral contraceptive. I am trained to offer cognitive services involving making appropriate recommendation for oral contraceptive for a patient based on safety and efficacy profile. I have worked in collaboration with many prescribers in order to improve patient's health outcomes and access to care.

As this service involves utilization of clinical tools and to ensure that appropriate recommendation is made, this service should not be considered as a dispensing service. I support the adoption of Assembly Amendment 1, which requires Medicaid to reimburse pharmacists for the time spent screening a patient for a possible prescription order. As the pharmacists are not considered medical providers under Medicaid regulations for reimbursement purposes, pharmacists would not be reimbursed for the time spent with patients for this service. More pharmacists will be on-board with offering this service to their patient if Medicaid reimburses for the service. Therefore, I would strongly encourage the authors to include Medicaid reimbursement for pharmacists for this patient-care service, outside of the reimbursement for dispensing the drug should one be prescribed.

The bill will certainly be able to improve access to care, however there are certain measure need to be taken to ensure that appropriate recommendations are made. Each state that has passed legislation requires patients to complete a questionnaire as a means of screening for appropriate candidates, including screening for blood pressure, medical, and medication history, pregnancy history and status, and smoking history. The safety requirements are well laid out in Senate Bill 286.

I am confident that this bill will contribute in better quality of life for young females who want to successfully plan their future and be able to step into motherhood when they feel prepared.

Thank you.

Testimony in Opposition to Senate Bill 286: permitting pharmacists to prescribe certain contraceptives
Senate Committee on Health and Human Services
By Matt Sande, Director of Legislation

November 20, 2019

Good morning Chairman Testin and Committee members. My name is Matt Sande and I serve as director of legislation for Pro-Life Wisconsin. Thank you for this opportunity to express our opposition to Senate Bill (SB) 286, legislation permitting pharmacists to prescribe and dispense hormonal contraceptive patches and self-administered oral hormonal contraceptives to persons who are at least 18 years of age.

Studies demonstrate that the bill authors' means to achieving lower unplanned pregnancies (easy contraceptive access and use) is unworkable. A significant percentage of unintended pregnancies are in women using contraceptives, generally over 40% and in some studies up to 68%.

According to a March 2017 Guttmacher Institute study*, "A substantial proportion of unintended pregnancies occur despite women's and their partners' use of contraceptives. In 2001, some 48% of women experiencing an unintended pregnancy had been using a method in the month of conception." In the same study Guttmacher also reported that "about half of pregnancies terminated by induced abortions in 2008 occurred during use of contraceptives." Clearly, contraceptive use is not preventing unplanned pregnancies.

*(Perspectives on Sexual and Reproductive Health, Guttmacher Institute, Volume 49, Issue 1, March 2017, Pages 7-16, *Contraceptive Failure in the United States: Estimates from the 2006-2010 National Survey of Family Growth*)

A December 2015 study** out of Canada noted that "Imperfect contraceptive adherence was estimated to account for 124,024 of the 180,733 UPs [unplanned pregnancies] that occur annually in women age 18–44 years (Table 5)." That equates to over 68% of all unplanned pregnancies (18-44 years) in the study being due to imperfect contraceptive use. So you can give them the pills, but faulty or incorrect use makes them ineffective in reducing unplanned pregnancies.

**(Journal of Obstetrics and Gynaecology Canada, December 2015, Volume 37, Issue 12, Pages 1086–1097, *The Cost of Unintended Pregnancies in Canada: Estimating Direct Cost, Role of Imperfect Adherence, and the Potential Impact of Increased Use of Long-Acting Reversible Contraceptives*)

At the core of our opposition to SB 286 is the abortifacient effect of hormonal contraceptives. It is a medical fact that the morning-after pill (a high dosage of the birth control pill) and most if not all hormonal birth control drugs and devices including the intrauterine device (IUD), Depo Provera, the Patch, and the Pill can act to terminate a pregnancy by chemically

altering the lining of the uterus (endometrium) so that a newly conceived child (human embryo) is unable to implant in the womb, thus starving and dying. This mechanism of action is termed a pre-implantation chemical abortion.

LO/OVRAL-28 is a standard birth control pill manufactured by Wyeth Laboratories. The Physicians' Desk Reference indicates that it can work to prevent a fertilized egg (a human embryo) from implanting in the uterine wall:

LO/OVRAL®-28, a standard birth control pill. Combination oral contraceptives act by suppression of gonadotropins. Although the primary mechanism of this action is inhibition of ovulation, other alterations include ***changes in the*** *cervical mucus (which increase the difficulty of sperm entry into the uterus) and the* ***endometrium (which reduce the likelihood of implantation)*** *(Physicians' Desk Reference (PDR). 56 ed. Montvale, NJ: Thompson PDR; 2002. 3533).*

WebMD also describes the pharmacological action of LO/OVRAL-28:

This combination hormone medication is used to prevent pregnancy. It contains 2 hormones: a progestin and an estrogen. It works mainly by preventing the release of an egg (ovulation) during your menstrual cycle. It also makes vaginal fluid thicker to help prevent sperm from reaching an egg (fertilization) and ***changes the lining of the uterus (womb) to prevent attachment of a fertilized egg. If a fertilized egg does not attach to the uterus, it passes out of the body.***

The United Kingdom's National Health Service (NHS) website describes the contraceptive patch's mechanism of action:

The patch releases a daily dose of hormones through the skin into the bloodstream to prevent pregnancy. It contains the same hormones as the combined pill – oestrogen and progestogen – and works in the same way by preventing the release of an egg each month (ovulation). It also thickens cervical mucus, which makes it more difficult for sperm to move through the cervix, ***and thins the womb lining so a fertilised egg is less likely to be able to implant itself.***

WebMD also describes the pharmacological action of the transdermal patch:

The patch blocks conception by delivering the hormones estrogen and progestin through the skin into your bloodstream. The hormones keep your ovaries from releasing an egg, thicken the cervical mucus to deter the swimming sperm, and ***make it harder for any fertilized egg to implant inside your womb.***

In the January 2019 Linacre Quarterly, a peer-reviewed publication of the Catholic Medical Association, medical researchers published a study*** entitled "Systematic Review of Ovarian Activity and Potential for Embryo Formation and Loss during the Use of Hormonal Contraception." The abstract of the study states, "...follicular ruptures and egg release with

subsequent low progesterone output have been documented in women using hormonal contraception...(this) suboptimal luteal progesterone production may be more likely than previously acknowledged, which may contribute to embryo loss. This information should be included in informed consent for women who are considering the use of hormonal contraception." In other words, the abnormally low progesterone production while taking hormonal contraceptives can lead to early embryo loss and women should be informed of this possibility.

***(The Linacre Quarterly, January 3, 2019, *Systematic Review of Ovarian Activity and Potential for Embryo Formation and Loss during the Use of Hormonal Contraception*)

While admitting that hormonal birth control can inhibit the implantation of a fertilized egg, the makers of these drugs claim that they do not cause an abortion. For example, they argue that hormonal contraceptives "prevent pregnancy" or "will not affect an existing pregnancy." However, they intentionally define the term "pregnancy" as implantation of a fertilized egg in the lining of a woman's uterus, as opposed to "pregnancy" beginning at fertilization.

Whether one understands "pregnancy" as beginning at implantation or fertilization, the heart of the matter is when human life begins. Embryological science has clearly determined that human life begins at fertilization - the fusion of an egg and sperm immediately resulting in a new, genetically distinct human being. This is not a subjective opinion, but an irrefutable, objective scientific fact. Accordingly, any artificial action that works to destroy a human embryo is abortifacient in nature.

The authors contend that hormonal contraceptives have no "potentially harmful side effects that require a physician's oversight." We strongly disagree. **Hormonal contraceptives have been proven dangerous to women's health.** The World Health Organization has classified combined hormonal contraceptives as Group 1 carcinogens (carcinogenic to humans.) The United Nation's International Agency on Research of Cancer (IARC) reported in their Monograph 91 that estrogen-progestin combination drugs (the Pill) were a Group 1 carcinogen for breast, cervical and liver cancers. Users of the Pill have an increased risk of blood clotting and ectopic pregnancy, both of which can be fatal. Lawsuits have been filed blaming the Patch for a number of deaths due to blood clots, heart attacks and strokes. The Food and Drug Administration has cautioned that the Patch carries a higher risk of blood clots than the birth control pill.

For the above reasons, we oppose legislation in whatever form that makes hormonal contraceptives more easily accessible or widely available. We urge you to NOT recommend SB 286 for passage.

Thank you for your consideration, and I am happy to answer any questions committee members may have for me. I am also happy to email any of the studies referenced in my testimony to committee members.

WISCONSIN CATHOLIC MEDICAL GUILDS

Upholding the Principles of the Catholic Faith in the Science and Practice of Medicine

November 20, 2019

To: Members, Senate Health Committee

FROM: Elizabeth Anderson, MD, Assistant State Director – Wisconsin Catholic Medical Guilds; President - Madison Catholic Medical Guild

RE: Senate Bill 286 – permitting pharmacists to prescribe certain contraceptives

Good morning Chairman Testin and Committee members. My name is Elizabeth Anderson. I am an emergency medicine physician here in Madison. I graduated from the Medical College of Wisconsin in 2005 and completed my residency at Froedtert Hospital in Milwaukee in 2008. I have been an ER physician here in Madison since then. I am also the current president of the Catholic Medical Guild of the Diocese of Madison and the Assistant Director of the Wisconsin Catholic Medical Guilds. I am here today on behalf of the Wisconsin Catholic Medical Guilds which represents the six guilds of the Catholic Medical Association throughout Wisconsin, with more than 100 physician and healthcare provider members.

The Wisconsin Catholic Medical Guilds (WCMG) is opposed to Senate Bill (SB) 286 and strongly urges you to not pass this bill out of committee.

As you know, SB 286 would allow pharmacists to prescribe either contraceptive patches or oral contraceptives to patients without the input of a medical doctor. WCMG is opposed to this practice for several reasons.

First, the patient-physician relationship is of utmost importance in providing safe, quality healthcare to individuals. This bill would eliminate that relationship, undermining the ongoing necessary healthcare that a patient should have with any prescription medication and any health condition. Primary care physicians have a unique relationship with their patients in which they can provide individualized counseling and recommendations, as well as discuss risks of prescription medications unique to each individual patient. This relationship and individualized care is eliminated if this bill moves forward.

Second, any prescription medication carries risks, which is why they require a prescription. A primary medical doctor has the ability to not only discuss these risks at the time of initial prescription but to monitor for signs/symptoms of these risks. Making contraceptives available, essentially as over-the-counter medications, ignores the significant risks associated with them. The CDC has produced a chart as reference for medical conditions that are affected by contraceptives. As you can see, it is extensive. A pharmacist does not have access to a patient's medical records and so is relying on a questionnaire that may or may not be answered correctly by the patient. I can assure you, that patients frequently do not remember or

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understand their medical diagnoses or medications they are taking. Thus, a pharmacist very likely will not get accurate information and therefore cannot adequately assess a patient's risk.

Contraceptives by themselves are medications with significant medical risk. The World Health organization has categorized contraceptives as class 1 carcinogens, meaning they have been proven to cause cancer in humans, including breast, cervical, and liver cancer. Some proponents of this bill quote a study out of Canada claiming a small increase in breast cancer (6.3%) and a "possible" prevention of 57% of endometrial and 29% of ovarian cancer. Use of this study to encourage pharmacist prescribing of contraceptives is faulty for a couple reasons. First, this study estimates the association of oral contraceptives based on a survey of women answering whether or not they used hormonal contraceptives and whether they developed cancer. Clearly this is not the highest level of evidence available. Second, giving a percentage reduction does not account for the incidence of these cancers. The National Cancer Institute lists the incidence of ovarian cancer at 11 per 100,000 whereas the incidence of breast cancer is 127 per 100,000. So, a reduction of 29% of ovarian cancer means 3 less cases per 100,000 whereas an increase in 6% of breast cancer means an increase of 8 cases per 100,000. I would like to point out an alternative, higher level of evidence study done as a meta-analysis that compiled 76 recent studies (from 2000 to 2013) on this topic. That meta-analysis found a significant increase risk in both breast and cervical cancer. They point out that given the high incidence of breast cancer, this means a substantial increase in the number of cases.

Contraceptives have been proven to increase the risk of blood clots, which can be fatal. They also have increased risk of causing heart disease, especially in smokers. These medications should not be prescribed by anyone except a medical doctor who has access to accurate medical records and the necessary medical tests.

Third, as Catholic medical physicians, we are opposed to contraceptives which have been proven to have an abortifacient effect. One of the proven mechanisms by which these drugs work is by impairing implantation of the developing embryo in the uterus. Essentially, they prevent the living embryo from implanting in the uterus and getting the necessary nutrients to grow and develop. During the Assembly hearing for the companion bill, it was argued that oral contraceptives are not abortifacients. If they were, we would see an increase in ectopic pregnancies. This, anatomically, does not make sense. An egg is released from the ovary and travels down the fallopian tubes and into the uterus. If it is fertilized, it attempts to implant in the lining of the uterus. This is where the action of contraceptives act as an abortifacient. They have been shown to prevent implantation in the uterus. The vast majority of ectopic pregnancies, however, occur before this when the developing embryo implants in the fallopian tube. In other words, the embryo is already past the location of ectopic pregnancy when the oral contraceptives act to prevent implantation in the uterus. So, of course we do not see a rise in ectopic pregnancies. Furthermore, newer hormonal contraceptives have a lower dose of estrogen, resulting in more women actually ovulating and more fertilized embryos ending in

"silent abortions" when the embryo cannot implant due to the progesterone component of contraceptives altering the uterine lining.

Finally, the proposed legislation is reportedly to improve access to "healthcare" and birth control, with the anticipated effect of reducing unintended pregnancies. However, studies have shown this is not the case. A study from the Guttmacher Institute published March, 2017 found that almost half of unintended pregnancies occurred while the woman was using birth control. The same study also reported about half of pregnancies terminated by abortion had occurred while using contraceptives.

A second study done in Canada looked at the cost of unintended pregnancies and the role of imperfect adherence. They found that 68% of all unplanned pregnancies occurred while the woman had access to contraceptives, but had imperfect use. In other words, you can provide the contraceptives, but that does not solve the problem of unintended pregnancies.

In summary, the proposed bill allowing pharmacist prescription of contraceptives diminishes the value of the patient-physician relationship, ignores the significant medical risks of contraceptives and their abortifacient effect, and does not solve the problem of unintended pregnancies. As such, the WCMG opposes SB 286 and encourages you to do likewise.

Thank you for hearing my testimony, and I would be pleased to answer any questions from committee members.

References:

Oral contraceptive use and risk of breast, cervical, colorectal, and endometrial cancers: a systematic review. Gierisch JM, et al. Cancer Epidemiol Biomarkers Prev. 2013 Nov;22(11): 1931-43.

Contraceptive Failure in the United States: Estimates from the 2006-2010 National Survey of Family Growth. Sundaram A, et al. Perspectives on Sexual and Reproductive Health. 2017 Mar;49(1): 7-16.

The Cost of Unintended Pregnancies in Canada: Estimating Direct Cost, Role of Imperfect Adherence, and the Potential Impact of Increased Use of Long-Acting Reversible Contraceptives. Block et al. J. Oebstet Gynaecol Can. 2015 Dec;37(12):1086-97.

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Pages 1,2 .....Color coded in the left column to match the corresponding question of the Oregon Hormonal Contraception Self-Screening Tool Questionnaire.
Pages 3,4 ..... Arranged alphabetically by disease state

Key:	
1	No restriction (method can be used)
2	Advantages generally outweigh theoretical or proven risks
3	Theoretical or proven risks usually outweigh the advantages
4	Unacceptable health risk (method not to be used)

Updated November 2016. This summary sheet only contains a subset of the recommendations from the US MEC. For complete guidance, see: http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm

Corresponding to the order of the Colorado Hormonal Contraception Self Screening Tool Questionnaire:

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Age		Menarche to <40=1		Menarche to <18=1		Yes
		≥40=2		18-45=1		Yes
				>45=1		Yes
Smoking	a) Age < 35	2		1		Yes
	b) Age ≥ 35, < 15 cigarettes/day	3		1		Yes
	c) Age ≥ 35, ≥15 cigarettes/day	4		1		Yes
Pregnancy	(Not Eligible for contraception)	NA*		NA*		NA*
Postpartum (see also Breastfeeding)	a) < 21 days	4		1		Yes
	b) 21 days to 42 days:					
	(i) with other risk factors for VTE	3*		1		Yes
	(ii) without other risk factors for VTE	2		1		Yes
	c) > 42 days	1		1		Yes
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*		2*		Yes
	b) 1 month or more postpartum	2*		1*		Yes
Diabetes mellitus (DM)	a) History of gestational DM only	1		1		Yes
	b) Non-vascular disease					
	b) Other abnormalities:					
	(i) non-insulin dependent	2		2		Yes
	(ii) insulin dependent‡	2		2		Yes
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*		2		Yes
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*		2		Yes
Headaches	a) Non-migrainous	1*	2*	1*	1*	Yes
	b) Migraine:					
	i) without aura, age <35	2*	3*	1*	2*	Yes
	ii) without aura, age ≥35	3*	4*	1*	2*	Yes
	iii) with aura, any age	4*	4*	2*	3*	Yes
Hypertension	a) Adequately controlled hypertension	3*		1*		Yes
	b) Elevated blood pressure levels (properly taken measurements):					
	(i) systolic 140-159 or diastolic 90-99	3		1		Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4		2		Yes
	c) Vascular disease	4		2		Yes
History of high blood pressure during pregnancy		2		1		Yes
Hyperlipidemias		2/3*		2*		Yes
Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function:					
	(i) < 6 months	4		1		Yes
	(ii) ≥ 6 months	3		1		Yes

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
	b) Moderately or severely impaired cardiac function	4		2		Yes
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)	3/4*		2*		Yes
Ischemic heart disease‡	Current and history of	4		2	3	Yes
Valvular heart disease	a) Uncomplicated	2		1		Yes
	b) Complicated‡	4		1		Yes
Stroke‡	History of cerebrovascular accident	4		2	3	Yes
Thrombogenic mutations‡		4*		2*		Yes
Deep venous thrombosis (DVT) /Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy					
	i) higher risk for recurrent DVT/PE	4		2		Yes
	ii) lower risk for recurrent DVT/PE	3		2		Yes
	b) Acute DVT/PE	4		2		Yes
	c) DVT/PE and established on anticoagulant therapy for at least 3 months					
	i) higher risk for recurrent DVT/PE	4*		2		Yes
	ii) lower risk for recurrent DVT/PE	3*		2		Yes
	d) Family history (first-degree relatives)	2		1		Yes
	e) Major surgery					
	(i) with prolonged immobilization	4		2		Yes
	(ii) without prolonged immobilization	2		1		Yes
	f) Minor surgery without immobilization	1		1		Yes
History of bariatric surgery‡	a) Restrictive procedures	1		1		Yes
	b) Malabsorptive procedures	COCs: 3		3		Yes
Breast disease/ Breast Cancer	a) Undiagnosed mass	2*		2*		Yes
	b) Benign breast disease	1		1		Yes
	c) Family history of cancer	1		1		Yes
	d) Breast cancer:‡					
	i) current	4		4		Yes
	ii) past and no evidence of current disease for 5 years	3		3		Yes

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Viral hepatitis	a) Acute or flare	3/4*	2	1		Yes
	b) Carrier/Chronic	1	1	1		Yes
Cirrhosis	a) Mild (compensated)	1		1		Yes
	b) Severe‡ (decompensated)	4		3		Yes
Liver tumors	a) Benign:					
	i) Focal nodular hyperplasia	2		2		Yes
	ii) Hepatocellular adenoma‡	4		3		Yes
	b) Malignant‡	4		3		Yes
Gallbladder disease	a) Symptomatic:					
	(i) treated by cholecystectomy	2		2		Yes
	(ii) medically treated	3		2		Yes
	(iii) current	3		2		Yes
	b) Asymptomatic	2		2		Yes
History of Cholestasis	a) Pregnancy-related	2		1		Yes
	b) Past COC-related	3		2		Yes
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4		3		Yes
	b) Severe thrombocytopenia	2		2		Yes
	c) Immunosuppressive treatment	2		2		Yes
	d) None of the above	2		2		Yes
Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		Yes
	b) Not on immunosuppressive therapy	2		1		Yes
Blood Conditions?						
Epilepsy‡	(see also Drug Interactions)	1*		1*		Yes
Tuberculosis‡ (see also Drug Interactions)	a) Non-pelvic	1*		1*		Yes
	b) Pelvic	1*		1*		Yes
HIV	High risk	1		1		Yes
	HIV infected (see also Drug Interactions)‡	1*		1*		Yes
	AIDS (see also Drug Interactions) ‡	1*		1*		Yes
	Clinically well on therapy	If on treatment, see Drug Interactions.				
Antiretroviral therapy	a) Nucleoside reverse transcriptase inhibitors	1*		1		Yes
	b) Non-nucleoside reverse transcriptase inhibitors	2*		2*		Yes
	c) Ritonavir-boosted protease inhibitors	3*		3*		Yes
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		Yes
	b) Lamotrigine	3*		1		Yes
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		Yes
	b) Antifungals	1		1		Yes
	c) Antiparasitics	1		1		Yes
	d) Rifampicin or rifabutin therapy	3*		3*		Yes

Alphabetical Listing of USMEC Contraceptive Eligibility By Disease State

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Breast disease/ Breast Cancer	a) Undiagnosed mass	2*		2*		Yes
	b) Benign breast disease	1		1		Yes
	c) Family history of cancer	1		1		Yes
	d) Breast cancer‡					
	i) current	4		4		Yes
	ii) past and no evidence of current disease for 5 years	3		3		Yes
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*		2*		Yes
	b) 1 month or more postpartum	2*		1*		Yes
Cervical cancer	Awaiting treatment	2		1		Yes
Cervical ectropion		1		1		Yes
Cervical intraepithelial neoplasia		2		1		Yes
Cirrhosis	a) Mild (compensated)	1		1		Yes
	b) Severe‡ (decompensated)	4		3		Yes
Cystic Fibrosis		1*		1*		Yes
Deep venous thrombosis (DVT) /Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy					
	i) higher risk for recurrent DVT/PE	4		2		Yes
	ii) lower risk for recurrent DVT/PE	3		2		Yes
	b) Acute DVT/PE	4		2		Yes
	c) DVT/PE and established on anticoagulant therapy for at least 3 months					
	i) higher risk for recurrent DVT/PE	4*		2		Yes
	ii) lower risk for recurrent DVT/PE	3*		2		Yes
	d) Family history (first-degree relatives)	2		1		Yes
	e) Major surgery					
	(i) with prolonged immobilization	4		2		Yes
	(ii) without prolonged immobilization	2		1		Yes
	f) Minor surgery without immobilization	1		1		Yes
Depressive disorders		1*		1*		Yes
Diabetes mellitus (DM)	a) History of gestational DM only	1		1		Yes
	b) Non-vascular disease					
Diabetes mellitus (cont.)	(i) non-insulin dependent	2		2		Yes
	(ii) insulin dependent‡	2		2		Yes
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*		2		Yes
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*		2		Yes
Endometrial cancer‡		1		1		Yes
Endometrial hyperplasia		1		1		Yes
Endometriosis		1		1		Yes
Epilepsy‡	(see also Drug Interactions)	1*		1*		Yes
Gallbladder disease	a) Symptomatic					
	(i) treated by cholecystectomy	2		2		Yes
	(ii) medically treated	3		2		Yes
	(iii) current	3		2		Yes
	b) Asymptomatic	2		2		Yes

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Gestational trophoblastic disease	a) Decreasing or undetectable ß-hCG levels	1		1		Yes
	b) Persistently elevated ß-hCG levels or malignant disease‡	1		1		Yes
Headaches	a) Non-migrainous	1*	2*	1*	1*	Yes
	b) Migraine					
	i) without aura, age <35	2*	3*	1*	2*	Yes
	ii) without aura, age ≥35	3*	4*	1*	2*	Yes
	iii) with aura, any age	4*	4*	2*	3*	Yes
History of bariatric surgery‡	a) Restrictive procedures	1		1		Yes
	b) Malabsorptive procedures	COCs: 3 P/R: 1		3		Yes
History of cholestasis	a) Pregnancy-related	2		1		Yes
	b) Past COC-related	3		2		Yes
History of high blood pressure during pregnancy		2		1		Yes
History of pelvic surgery		1		1		Yes
HIV	High risk	1		1		Yes
	HIV infected (see also Drug Interactions)‡	1*		1*		Yes
	AIDS (see also Drug Interactions) ‡	1*		1*		Yes
	Clinically well on therapy	If on treatment, see Drug Interactions.				
Hyperlipidemias		2/3*		2*		Yes
Hypertension	a) Adequately controlled hypertension	3*		1*		Yes
	b) Elevated blood pressure levels (properly taken measurements)					
	(i) systolic 140-159 or diastolic 90-99	3		1		Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4		2		Yes
	c) Vascular disease	4		2		Yes
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	2/3*		2		Yes
Ischemic heart disease‡	Current and history of	4		2	3	Yes
Liver tumors	a) Benign					
	i) Focal nodular hyperplasia	2		2		Yes
	ii) Hepatocellular adenoma‡	4		3		Yes
	b) Malignant‡	4		3		Yes
Malaria		1		1		Yes
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)	3/4*		2*		Yes
Obesity	a) ≥30 kg/m² body mass index (BMI)	2		1		Yes
	b) Menarche to < 18 years and ≥ 30 kg/m² BMI	2		1		Yes
Ovarian cancer‡		1		1		Yes
Parity	a) Nulliparous	1		1		Yes
	b) Parous	1		1		Yes
Past ectopic pregnancy		1		2		Yes

Alphabetical Listing of USMEC Contraceptive Eligibility By Disease State

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Pelvic inflammatory disease	a) Past, (assuming no current risk factors of STIs)					
	(i) with subsequent pregnancy	1		1		Yes
	(ii) without subsequent pregnancy	1		1		Yes
	b) Current	1		1		Yes
Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function					
	(i) < 6 months	4		1		Yes
	(ii) ≥ 6 months	3		1		Yes
	b) Moderately or severely impaired cardiac function	4		2		Yes
Postabortion	a) First trimester	1*		1*		Yes
	b) Second trimester	1*		1*		Yes
	c) Immediately post-septic abortion	1*		1*		Yes
Postpartum (see also Breastfeeding)	a) < 21 days	4		1		Yes
	b) 21 days to 42 days					
	(i) with other risk factors for VTE	3*		1		Yes
	(ii) without other risk factors for VTE	2		1		Yes
	c) > 42 days	1		1		Yes
Postpartum (in breastfeeding or non-breastfeeding women, including post-cesarean section)	a) < 10 minutes after delivery of the placenta					
	b) 10 minutes after delivery of the placenta to < 4 weeks					
	c) ≥ 4 weeks					
	d) Puerperal sepsis					
Pregnancy		NA*		NA*		NA*
Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		Yes
	b) Not on immunosuppressive therapy	2		1		Yes
Schistosomiasis	a) Uncomplicated	1		1		Yes
	b) Fibrosis of the liver‡	1		1		Yes
Severe dysmenorrhea		1		1		Yes
Sexually transmitted infections (STIs)	a) Current purulent cervicitis or chlamydial infection or gonorrhea	1		1		Yes
	b) Other STIs (excluding HIV and hepatitis)	1		1		Yes
Sexually transmitted infections (cont.)	c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1		1		Yes
	d) Increased risk of STIs	1		1		Yes
Smoking	a) Age < 35	2		1		Yes
	b) Age ≥ 35, < 15 cigarettes/day	3		1		Yes
	c) Age ≥ 35, ≥15 cigarettes/day	4		1		Yes
Solid organ transplantation‡	a) Complicated	4		2		Yes
	b) Uncomplicated	2*		2		Yes
Stroke‡	History of cerebrovascular accident	4		2	3	Yes
Superficial venous thrombosis	a) Varicose veins	1		1		Yes
	b) Superficial thrombophlebitis	2		1		Yes
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4		3		Yes
	b) Severe thrombocytopenia	2		2		Yes
	c) Immunosuppressive treatment	2		2		Yes
	d) None of the above	2		2		Yes
Thrombogenic mutations‡		4*		2*		Yes

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid.	1		1		Yes
Tuberculosis‡ (see also Drug Interactions)	a) Non-pelvic	1*		1*		Yes
	b) Pelvic	1*		1*		Yes
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	2*		2*		Yes
Uterine fibroids		1		1		Yes
Valvular heart disease	a) Uncomplicated	2		1		Yes
	b) Complicated‡	4		1		Yes
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		2		Yes
	b) Heavy or prolonged bleeding	1*		2*		Yes
Viral hepatitis	a) Acute or flare	3/4*	2	1		Yes
	b) Carrier/Chronic	1	1	1		Yes
Antiretroviral therapy (All other ARVs are 1 or 2 for all methods)	Fosamprenavir (FPV)	3*		2*		Yes
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		Yes
	b) Lamotrigine	3*		1		Yes
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		Yes
	b) Antifungals	1		1		Yes
	c) Antiparasitics	1		1		Yes
	d) Rifampicin or rifabutin therapy	3*		3*		Yes
SSRIs		1		1		Yes
St. John's Wort		2		2		Yes

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable

* Please see the complete guidance for a clarification to this classification: www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm

‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

ACOG
The American College of Obstetricians and Gynecologists
Wisconsin Section

To: Senate Committee on Health and Human Services
From: Kristin Lyerly, MD, MPH, FACOG
Date: November 20, 2019
Re: Senate Bill 286

Chairman Testin and members of the Committee, I am here today to testify in support of Senate Bill 286.

I am a specialist in general obstetrics and gynecology, practicing in Green Bay. I am also a Fellow of the American College of Obstetricians and Gynecologists (ACOG), which represents over 58,000 OB/GYNs throughout the U.S. and internationally. I am a Wisconsinite by birth and a proud graduate of the University of Wisconsin School of Medicine and Public Health. On a personal note, I am the mom of four sons, ages 11 to 20, and I have a special interest in rural medicine, mentoring and supporting our young physicians, and the advocacy work that binds our communities together.

Nearly all U.S. women who have ever had sexual intercourse have used some form of contraception at some point during their reproductive lives. ACOG has long supported over-the-counter access to oral contraceptives with no age restrictions. In September of this year ACOG expanded its recommendation on over-the-counter access to contraception to include vaginal rings, the contraceptive patch, and depot medroxyprogesterone acetate injections, also known as DMPA, or "the depo shot". Only the U.S. Food and Drug Administration can confer over-the-counter status for these medications. Recognizing that women want more options to manage their reproductive health, ACOG's updated recommendation now includes support for pharmacist provided contraception, identifying it as a necessary intermediate step to increase access to hormonal contraception.

Facts are important when discussing healthcare. Lack of knowledge, misperceptions, and exaggerated concerns about the safety of contraceptive methods are major barriers to contraceptive use. So let's examine the facts.

Blood clots, or venous thromboembolism (VTE) are one of the most commonly cited safety concerns. The risk of VTE with the typical "combined" estrogen/progestin pill is half the risk of VTE in pregnancy and only 1/10 of the risk during the postpartum period. The risk for progestin-only methods, including pills and shots, is considered minimal to none. Numerous studies have demonstrated that women are capable of self-screening for risk factors, including VTE. With the use of a validated questionnaire and a blood pressure check, women who choose to get their contraception from a pharmacist will receive screening similar to what I would offer prior to writing a prescription during an office visit.

Concern has been raised that contraceptives are a Class I carcinogen and that they are associated with breast cancer. This is true - depending upon personal risk factors, some women who choose to use hormonal contraception do have a slightly higher risk of breast cancer. Class I carcinogens by definition can cause cancer in humans. Other Class I carcinogens include processed meat, air pollution, alcoholic beverages, and sunshine. For the general population, the risk of breast cancer related to the use of hormonal contraception is low. [1]

The efficacy of these methods has also been called into question. The data here is very clear: with *typical* use, these contraceptive methods are greater than 90% effective, and greater than 99% effective with *perfect* use. In contrast, one in four women who use natural family planning will experience an unintended pregnancy.

[1] https://www.nejm.org/doi/full/10.1056/NEJMoa1700732

The mechanism of action for these contraceptive methods has also been challenged. To be clear, no FDA-approved contraceptive methods are abortifacients. By definition, an abortifacient refers to the termination of a pregnancy. These contraceptives either prevent fertilization from occurring or implantation. Importantly, implantation failure is the natural fate of about 50% of fertilized eggs.

The benefits of contraception are widely recognized and include improved health and wellbeing, reduced global maternal mortality, health benefits of pregnancy spacing for maternal and child health, female engagement in the work force, and economic self-sufficiency for women. Additionally, non-contraceptive benefits may include decreased bleeding and pain with menstrual periods, and reduced risk of gynecologic disorders, including a decreased risk of endometrial and ovarian cancer. Universal coverage of contraceptives is cost effective. The most powerful way to reduce abortion rates is to prevent unintended pregnancy by improving access to consistent, efficacious, and affordable contraception.

Barriers prevent women from obtaining contraceptives, or using them effectively and consistently. Barriers to access are one reason for inconsistent or nonuse of contraception. The requirement for a prescription can be an obstacle for some contraceptive users. One national survey of 1,385 women reported that among the 68% of individuals who had ever tried to obtain a prescription for hormonal contraception, 29% had problems accessing the initial prescription or refills. Reported obstacles included cost barriers or lack of insurance (14%); challenges in obtaining an appointment or getting to a clinic (13%); the health care provider requiring a clinic visit, examination, or Pap test (13%); not having a regular physician or clinic (10%); difficulty accessing a pharmacy (4%); and other reasons (4%).[2]

All women should have unhindered and affordable access to all U.S. Food and Drug Administration approved contraceptives. Pharmacist provided contraception will improve availability, but it should not be at the expense of affordability, or limited by age restrictions. Insurance coverage and other financial support for contraception should still apply. It is important that access to pharmacist provided contraception includes access to all hormonal contraception including vaginal rings, the contraceptive patch, and the depo shot, and is not limited by age restrictions. Legislation should also protect women from new out-of-pocket costs and ensure that contraceptives dispensed by pharmacists are covered by insurance.

In closing, I want you to remember that these contraceptive methods are safe, efficacious, and cost-effective. They do not cause abortions. They do prevent cancer, treat pain, and help to lift women and families out of poverty. Chairman Testin and members, Senate Bill 286 is your opportunity to remove barriers for women who want to manage their own reproductive health with hormonal contraception. Thank you for your time and I am available for any questions.

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2 Landau SC, Tapias MP, McGhee BT. Birth control within reach: a national survey on women's attitudes toward and interest in pharmacy access to hormonal contraception. Contraception 2006;74:463-70; Grindlay K, Burns B, Grossman D. Prescription requirements and over-the-counter access to oral contraceptives: a global review. Contraception 2013;88:91-6; Frost JJ, Singh S, Finer LB. U.S. women's one-year contraceptive use patterns, 2004. Perspect Sex Reprod Health 2007;39:48-55; Grindlay K, Grossman D. Prescription birth control access among U.S. women at risk of unintended pregnancy. J Womens Health (Larchmt) 2016;25:249-54.

WISCONSIN CATHOLIC CONFERENCE

TESTIMONY REGARDING SENATE BILL 286:
PHARMACIST CONTRACEPTIVE PRESCRIBING
Presented by Kim Vercauteren, Executive Director
November 20, 2019

The Wisconsin Catholic Conference (WCC), the public policy voice of the Catholic bishops of Wisconsin, urges you to oppose Senate Bill 286, which allows pharmacists to prescribe certain hormonal contraceptives. This bill not only impacts women's health in Wisconsin, but also alters established medical standards and impacts the individual conscience rights of pharmacists.

The Catholic Church opposes the use of artificial contraception. However, the Church's objection to artificial contraception is not about trying to penalize or control individuals. It is about prizing the most creative power that we human beings possess. It is about protecting the human dignity of parents and their unborn children. It is about reminding society that women should not have to radically delay childbirth, artificially suppress their fertility, or ingest strong chemicals in order to get an education and participate in the workforce at every level.

The Church teaches that the use of artificial contraception restricts the total self-giving of spouses and introduces a "false note" in a marriage, sometimes causing one or both spouses to treat each other more like objects rather than people. In some cases, the failure of contraception may tempt couples to seek an abortion when an unwanted life is conceived. In other cases, hormonal contraception interferes with implantation, thus ending a new human life. Finally, scientists now recognize that the growing presence of hormonal contraceptives in our waterways is having an adverse effect on the environment and on aquatic species. For all these reasons, the Church encourages all to "go organic" and utilize Natural Family Planning rather than artificial hormonal contraception.

In addition to these concerns, pharmacist prescription of contraceptives could have adverse health impacts on both a woman and her unborn child. This is because under SB 286, there would be no requirements that a pharmacist test for pregnancy, order diagnostic exams that would provide a comprehensive assessment of a woman's current health status, or even have access to a woman's complete medical history and records, all of which normally inform the medical decision-making process. For example, hormonal contraception may be contraindicated if a woman has certain health conditions, such as hypertension, diabetes, certain types of migraines, or multiple risk factors for heart disease. A doctor would have access to the woman's full medical history, as well as diagnostic tests, but a pharmacist would not.

Furthermore, while SB 286 charges certain state entities with designing the standards and rules for implementing pharmacist prescribing, these requirements are limited by the bounds of state law regarding who may engage in the practice of medicine.

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Lastly, in an era when public health advocates and policy makers are trying to improve comprehensive and high-quality primary care through regular patient-provider interactions, it is difficult to understand the need for a law that discourages individuals from annually meeting with their primary provider.

In permitting pharmacists to prescribe contraceptives, the bill also significantly alters the current legal requirements for dispensing prescriptions. Currently under Wisconsin Statutes s. 450.095, the duty to dispense lies with a pharmacy, not the individual pharmacist. A pharmacy may forgo filling a prescription if it is incompatible with another drug or device prescribed for the patient, is prohibited by state or federal law, or is fraudulent, among other reasons.

Under SB 286, once a pharmacist opts to prescribe contraceptives, the bill directs the pharmacist to immediately dispense the contraception. However, what if a pharmacist were to learn, after writing the prescription, of new information that would trigger an option under current law to forgo dispensation, such as the customer committed fraud and lied about their age? It is uncertain, given the SB 286's mandate to dispense, whether the pharmacist must continue to dispense in these circumstances.

Also, the current pharmacy duty to dispense preserves an individual pharmacist's right of conscience. This aligns with Article I, Section 18 of our Wisconsin Constitution, which explicitly affirms, "nor shall any control of, or interference with, the rights of conscience be permitted." Should SB 286 become law, commercial pharmacy chains will likely make corporate policies instituting mandatory prescribing for their pharmacists, negating the permissive choice for pharmacists highlighted by SB 286's supporters. Facilitating a commercial market where pharmacists will be expected to prescribe contraception will drive pharmacists of conscience to other states, including those that surround Wisconsin, where no such pressure to prescribe contraceptives exists.

As a Church, we recognize an inherent and inalienable dignity in every human being. Our health care system should preserve this dignity by ensuring that best practice standards are observed when prescribing synthetic hormonal medications to women. Legislation that fails to promote and protect our humanity and coerces the conscience of medical professionals should not be supported. We urge you to oppose SB 286.

Thank you.

To: Members, Senate Committee on Health & Human Services

From: Kristin Weiler-Nytes, PharmD

Owner, Sniteman Pharmacy

Date: November 20, 2019

Subject: Support for Senate Bill 286

Good Afternoon and thank you for allowing me to testify in support of Senate Bill 286. My name is Kristin Weiler-Nytes, and I am a pharmacist and owner of Sniteman Pharmacy, an independent community pharmacy in central Wisconsin.

Senate Bill 286 would allow a pharmacist to both prescribe and dispense oral and topical hormonal contraceptives. Passing of this bill would add Wisconsin to the growing list of states that have passed legislation that allows for pharmacists to prescribe contraceptives without collaborative practice agreements. Wisconsin statutes allow for collaborative practice agreements which have expanded the practice of pharmacy throughout the state, allowing pharmacists to practice at the top of their license and education. However, collaborative practice agreements can be somewhat restrictive in the sense that pharmacists must enter into an agreement with each individual practitioner. Enacting legislation would only increase access to hormonal contraceptives in community pharmacy settings.

Lack of access to healthcare is a reality for the rural citizens that my community pharmacy serves. The principal benefit that health care providers hope to see by allowing pharmacists to prescribe contraceptives is bridging the gaps in patient access to health care. Lack of access has many root causes and social determinants: primary care provider shortages (especially in rural settings), long wait times for appointments, distance to provider facilities, exacerbated by no reliable transportation or funds to pay for gas, and scheduling issues- I.e. working mothers who cannot leave work between the clinic hours of 9-5 or arrange for childcare during appointment times.

Community pharmacist are well positioned to increase access as many pharmacies are open 7 days per week and have extended evening hours. Pharmacists are often referred to the most accessible member of the healthcare team. We answer and triage patient questions about their medications and their health every single day. Due to the nature of dispensing drug product every 30 or 90 days, based on insurance allowances, we are fortunate to have meaningful encounters with our patients at a minimum of 4-12 times per

year, which generally exceeds the amount of times that patients see their primary care physicians. This extensive contact with our patients puts pharmacists in the position to continually monitor drug therapy for safety and effectiveness. Afterall, pharmacists' expertise lies in pharmacology, drug action and delivery, medication monitoring and medication counseling.

Over-the-counter access to contraception is supported by most major medical groups including the American Medical Association, the American Academy of Family Physicians and the American College of Obstetricians and Gynecologists. These groups hold the position that birth control is safe enough and should be available over-the-counter. In order to assure patient safety, each state that has passed legislation requires patients to complete a questionnaire as a means of screening for appropriateness. These standardized questionnaires ask candidates about blood pressure, medical history, medication history, pregnancy history and status, smoking history and any potential contraindications to therapy. After reviewing the questionnaire with the patient and obtaining a current blood pressure reading, the pharmacist may decide to either issue a prescription for birth control or refer her to a physician. These states also require pharmacists to inform a patient's primary care provider if contraceptives have been prescribed. Senate Bill 286 follows this precedent in its safety requirements.

Access will only be increased for pharmacist prescribed birth control if pharmacists are reimbursed for the time associated with screening patients. At this time, pharmacists in Wisconsin are not considered medical providers under Medicaid regulations which would result in no reimbursement for this service. There likely would be reduced uptake by community pharmacies to provide this service if their time to do so is not reimbursed. Therefore, I encourage the committee consider adoption of Assembly Amendment 1, which ensures that Medicaid will reimburse pharmacists for contraception prescribing.

Pharmacists in community pharmacies are well-positioned and educated to provide this expanded service safely to Wisconsin women. I encourage the committee to support Senate Bill 286.

To: Members, Assembly Committee on Health
From: Michelle Farrell, PharmD
Owner, Boscobel Pharmacy
Date: November 20, 2019
Subject: Support for Senate Bill 286

Thank you very much for allowing me to submit written comments in favor of Senate Bill 286. My name is Michelle Farrell and I am the owner of Boscobel Pharmacy.

This bill would permit a pharmacist to prescribe and dispense hormonal contraceptive patches and self-administered oral hormonal contraceptives. Currently, there are 10 U.S. jurisdictions with statutes or regulations that allow pharmacists to prescribe contraceptives (without a collaborative practice agreement): California, Colorado, District of Columbia, Hawaii, Idaho, Maryland, New Mexico, Oregon, Utah, and West Virginia. The principal benefit that health care providers hope to see by allowing pharmacists to prescribe contraceptives is bridging the gaps in patient access to health care. Access issues can be caused or exacerbated by provider shortages, long waiting periods for appointments, patient distance to their healthcare providers, and scheduling issues – for example, patients who are unable or unwilling to go to their clinic between 9 and 5 on a weekday due to work or childcare needs.

In 2011, nearly 50% of pregnancies in the United States are unintended. These pregnancies are associated with a lack of prenatal care, poor behavior by the mother, low birth rates, and an increased rate of child abuse. There is a high public cost related to unintended pregnancy in Wisconsin.

Although this bill will improve access to care, certain steps must be taken to ensure that patients are appropriately assessed and approved for medication. Each state that has passed legislation requires patients to complete a questionnaire as a means of screening for appropriate candidates. Topics include blood pressure, medical, and medication history, pregnancy history and status, and smoking history. After completing the screening process, the pharmacist may decide to either issue the patient a prescription for birth control or refer her to a physician. Additionally, pharmacists are required to inform a patient's primary care provider if contraceptives have been prescribed. Senate Bill 286 follows this precedent in its safety requirements.

I have seen firsthand in my pharmacy successful expanded access to primary care through the use of collaborative practice agreements. We have employed various collaborative agreements since 2000. The agreements allow us to continue, change and even initiate therapy under an agreement with the physician and these collaboratives include refill protocols, immunization administration, smoking cessation therapy initiation, and therapeutic substitution. The key to the safe and successful deployment of care under these collaboratives lies in protocols that ensure a proper assessment and follow-up with pharmacist and physician. This bill outlines requirements for a patient assessment and follow up with physician.

I also encourage the adoption of Assembly Amendment 1, which requires Medicaid to reimburse pharmacists for the time spent screening a patient for a possible prescription

order. Because pharmacists are not considered medical providers under Medicaid regulations for reimbursement purposes, pharmacists would not be reimbursed for the time spent with patients for this service. Uptake of this service within pharmacies would be significantly diminished if reimbursement from Medicaid is not provided. Therefore, I would strongly encourage the authors to include Medicaid reimbursement for pharmacists for this patient-care service, outside of the reimbursement for dispensing the drug should one be prescribed.

Community pharmacists can provide a key health care access point in the midst of a primary care shortage. Pharmacists are well positioned to expand access to primary care, as more than 90% of Americans live within 5 miles of a pharmacy. Additionally, pharmacies are often open late, on weekends, and rarely require an appointment in order to receive a given service – all factors that can greatly increase access for patients. Pharmacists are highly trained in pharmacotherapy and can ease the burden on our physician counterparts while enhancing access. All of these factors can increase access to contraceptives, thereby decreasing unwanted pregnancies and associated costs.

Thank you.

To: Senator Patrick Testin

Members, Senate Committee on Health and Human Services

From: Kassandra Bartelme, Pharm.D., BCACP

Associate Professor of Pharmacy Practice

Ambulatory Care Pharmacist

Date: November 18, 2019

Subject: Testimony in Support of Senate Bill 286

Senator Patrick Testin and members of the Committee, thank you very much for allowing me to provide testimony in favor of Senate Bill 286. My name is Kassandra Bartelme and I am a pharmacy faculty member and ambulatory care pharmacist. I teach women's health pharmacotherapy topics to pharmacy students, including contraception (4 hours of instruction on contraception). I also teach contraception to physician assistant students (1.5 – 2 hours of instruction on contraception). I regret I am not able to address you in person during the hearing on November 20, 2019.

Pregnancy prevention is a public health concern as 45% of all pregnancies nationwide are unintentional, according to the Centers for Disease Control or Prevention (CDC).[1] In Wisconsin, 46% (42,000) of all pregnancies are unintended.[2] Of these unintended pregnancies in Wisconsin, 65% resulted in births, 21% in abortions, and 14% in miscarriages.[2]

Unintended pregnancies can have significant negative impact on women, their families, and society, including social and economic difficulties. It is worth noting that women who are economically disadvantaged are affected by unintended pregnancies and its consequences at a significantly higher rate than other women.[2] Specifically, in 2011, the pregnancy rate of women in the U.S. with incomes lower than the federal poverty level was 112 per 1,000 women compared to just 20 per 1,000 in women with incomes more than 200% the poverty level.[2]

Of the two-thirds of women in our country who are at risk of unintended pregnancy (that is, they are able to get pregnant), those who use contraceptives account for only 5% of all unintended pregnancies.[2] Therefore, the vast majority of unintended pregnancies are in women who are not using contraception or use them inconsistently. Women who have access to and use contraception are not the women getting pregnancy unintentionally.

SB 286 proposes that pharmacists be allowed to prescribe and dispense hormonal contraceptive patches and self-administered oral hormonal contraceptives to a person who is at least 18 years of age. Pharmacists are highly educated professionals that have the potential to increase access to contraception, therefore decreasing unintentional pregnancies and saving an untold amount of money in our healthcare system. Pharmacist-prescribed hormonal contraception is evidence-based and has been studied to show feasibility and safety. For example, one study of 26 community pharmacists in Seattle who prescribed hormonal contraceptives to 195 patients found that 92.6% were still using the contraception at 1 month, 80.3% at 6 months, and 70% at 12 months.[3] Patients appreciated the convenience related to pharmacist accessibility. Additionally, 97.7% of patients were satisfied or very satisfied with their experience and reported it was convenient or very convenient to obtain hormonal contraception from a pharmacist compared to another provider. Upwards of 96.6% felt comfortable asking the pharmacist about their prescription or any other questions they have. This study shows patients were accepting and satisfied with obtaining a contraceptive prescription from a pharmacist.

The primary mechanism of action of the contraceptive pill and patch is to prevent ovulation.[4] These contraceptives are not abortifacients. They so reliably prevent ovulation that, when taken correctly, the

likelihood of fertilization is quite low.[4] A secondary mechanism by which these medications prevent pregnancy is by altering the cervical mucus resulting in an inhospitable environment for sperm and preventing sperm penetration.[4] Therefore, even if ovulation occurred, it is unlikely sperm would be able to reach the egg to fertilize it. Additionally, the pill and patch may affect the endometrial lining, such as making it thinner. This may result in a lighter period for some women. There is insufficient evidence to demonstrate that this change could or would actually prevent implantation.[4]

A hormonal contraceptive pill and patch can be prescribed without a physical exam or other tests, besides a blood pressure assessment, per the American College of Obstetricians and Gynecologists (ACOG) and the CDC's U.S. Selected Practice Recommendations for Contraceptive Use, 2016.[5,6] ACOG further states a blood pressure obtained in a non-clinical setting is acceptable. Any other tests or examinations, including a pelvic exam, do not contribute substantially to safe and effective use of these contraceptives. Additionally, ACOG and CDC state no routine follow-up is required after initiation of combined hormonal contraception.[5,6] Pharmacists are trained to educate patients on how and when to take medications and what to monitor for effectiveness and safety (eg, side effects). Pharmacists are easily accessible during many, if not all, hours of the day for questions or problems related to their medications. As the prescriber, the pharmacist would be able to easily adjust a patient's contraception prescription if side effects occur, such as switching to a pill with a different hormone balance. Pharmacists are qualified to use patients' responses to a questionnaire to determine their eligibility for contraception using the CDC's Medical Eligibility Criteria for Contraceptive Use, 2016.[7]

My position at my university includes practicing as a pharmacist one and one-half days per week. I am an ambulatory care pharmacist and I work in a primary care clinic alongside physicians, nurse practitioners, registered nurses, and other health care providers. I practice under a collaborative practice agreement that covers several diseases states, such as hypertension, hyperlipidemia, smoking cessation, asthma/COPD, and anticoagulation. I spend the majority of my time taking care of patients who take warfarin (Coumadin) which is a blood thinning medication taken to prevent clots and strokes. Patients make an appointment with me for an INR (International Normalized Ratio) which is a test that measures how thin their blood is. I perform the finger stick INR test and adjust their warfarin dose based on their result all without consulting a physician. The goal is to keep a patient's INR between 2-3 or 2.5-3.5 depending on the reason for the medication. This means the patient's blood is thinner than someone who is not taking warfarin (whose INR would be 1 or 1.1). Warfarin is a high-alert medication per the Institute for Safe Medication Practices.[8] This means it bears a heightened risk of causing significant patient harm when they are used in error. Consequences of errors with high-alert medications are more devastating to patients. Warfarin has a high risk of causing bleeding if the INR gets too high and the risk of clots or strokes is higher in these patients if the INR is too low. The INR goal range is the sweet spot between those two risks and it can be challenging to keep the INR within that goal range. There are many food and drug interactions with warfarin that can cause changes in a patient's INR. The contraceptive pill and patch are not listed as high-alert medications. If the physicians I work with are comfortable with me, a pharmacist, dosing warfarin and other high-alert medications such as insulin, there is no reason why a pharmacist couldn't manage and prescribe contraceptives. Pharmacists managing anticoagulation is quite common and a simple Google search will reveal there are many pharmacist-managed anticoagulation clinics nationwide.

Pharmacist-prescribed contraception may help fill a gap caused by a shortage of primary care physicians and OB-GYN physicians in Wisconsin. According to the Wisconsin Council on Medical Education and Workforce 2018 Healthcare Workforce Report, the majority (82.5%) of Wisconsin's total physicians are in metropolitan areas, yet only 71% of Wisconsin's population is located in those areas.[9] Less than 10% of physicians practice in rural areas, yet nearly 1/5th of the population lives in rural areas of the state. The primary care physician workforce is projected to increase by 3.8% but nearly 40% are expected to retire by 2035, causing a deficit of primary care physicians in the state.[9] The rural areas are likely to be hit the hardest. Additionally, there is a shortage of OB-GYN physicians in our state, and 26 of Wisconsin's 72

counties don't even have an OB-GYN.[10] Many Wisconsin residents drive 60 minutes or more to see an OB-GYN.[10] Many rural areas have a pharmacy at which pharmacists are more easily accessible than primary care physicians. In fact, about 90% of Americans live within five miles of a pharmacy.[11] This means patients who have trouble accessing a primary care physician or OB-GYN due to location or time to get an appointment would be able to obtain contraception at their local pharmacy, increasing access and potentially decreasing the number of unintentional pregnancies. A study in Oregon showed their pharmacists prescribed contraception to a total of 367 Medicaid patients. Of those, 73.8% had no history of contraception prescriptions in the previous 30 days and 61.5% had no history in the previous 180 days, indicating that these patients were initiating hormonal contraceptive care in the pharmacy.[12] Patients who have not used contraception in the recent past or ever are seeking contraception from a pharmacist.

Unintended pregnancies are also costly to state and federal governments. In 2010, $21 billion was spent by state and federal governments nationwide. In Wisconsin, 62% of unplanned births were publically funded and in 2010, $313.5 million of federal and state funds (42% of that coming from the state) were spent on unintended pregnancies. The public costs were $286 per woman aged 15 – 44 in Wisconsin.[2] In 2010, publicly funded family planning services provided by safety-net health centers in Wisconsin helped save the federal and state governments $171.5 million.[2] A research study in Oregon demonstrated their policy allowing pharmacists to prescribe contraception averted an estimated 51 unintended pregnancies among their Medicaid population and saved $1.6 million dollars.[13] Imagine what pharmacists could do in Wisconsin!

A pharmacist prescriber is the key to increasing patient access to contraception resulting in potentially decreased unintentional pregnancies and elective abortions and reduced costs for federal and state governments. It is my professional judgement that pharmacists are highly qualified to prescribe safe and effective medications like the oral contraceptive pill and patch (and other self-administered contraceptives).

Thank you again for the opportunity to provide testimony in favor of SB 286.

References:

1. Unintended Pregnancy Prevention. Center for Disease Control and Prevention. https://www.cdc.gov/reproductivehealth/contraception/unintendedpregnancy/index.htm. Page last reviewed: 20 December 2016. Accessed 11 August 2019.
2. State Facts About Unintended Pregnancy: Wisconsin. Guttmacher Institute. 2014. https://www.guttmacher.org/sites/default/files/factsheet/wi_5.pdf. Accessed 11 August 2019.
3. Gardner JS, Miller L, Downing DF, Le S, Blough D, Shotorbani S. Pharamacist prescribing of hormonal contraceptives: Results of the Direct Access Study. *J Am Pharm Assoc*. 2008;48:212–221.
4. Rivera R, Yacobson I, Grimes D. The mechanism of action of hormonal contraceptives and intrauterine contraceptive devices. *Am J Obstet Gynecol*. 1999;181:1263-9.
5. Lichtmacher A, Adams M, Berga SL, Davis AJ, Edelson MI, Jamshidi RM, Lehman RA, Peipert JF, Perlmutter JF, Richter HE, Walters MD, Witkop CT, eds. Guidelines for Women's Health Care: A Resource Manual. 4th Ed. Washington DC: American College of Obstetricians and Gynecologists; 2014.
6. Curtis KM, Jatlaoui TC, Tepper NK, Zapata LB, Horton LG, Jamieson DJ, Whiteman MK. U.S. Select Practice Recommendations for Contraceptive Use, 2016. MMWR Recomm Rep. 2016;65(4):1-66. https://www.cdc.gov/mmwr/volumes/65/rr/rr6504a1.htm?s_cid=rr6504a1_w.
7. Curtis KM, Tepper NK, Jatlaoui TC, Berry-Bibee E, Horton LG, Zapata LB, Simmons KB, Pagano HP, Jamieson DJ, Whiteman MK. U.S. Medical Eligibility Criteria for Contraceptive

Use, 2016. MMWR Recomm Rep. 2016;65(4):1-104. https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html.
8. High-alert Medications in Community/Ambulatory Settings. Institute for Safe Medication Practices. 31 Jan 2011. https://www.ismp.org/recommendations/high-alert-medications-community-ambulatory-list. Accessed 20 Aug 2019.
9. Mapping Our Way to Success: Wisconsin's Physician Workforce. 2018 WCMEW Healthcare Workforce Report. Wisconsin Council on Medical Education and Workforce. 2018. https://static1.squarespace.com/static/5a3ac16af14aa15aede6d0ed/t/5b48b65faa4a997984be0b1c/1531491941742/WCMEW+2018+Workforce+Report.pdf. Accessed 11 August 2019.
10. 2014 ACOG Workforce Fact Sheet: Wisconsin. American Congress of Obstetricians and Gynecologists. 2014. https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/WF2014WI.pdf?dmc=1&ts=20150408T0659294548. Accessed 11 August 2019.
11. Eder R, Dombach T., eds. By The Numbers: How community pharmacists measure up. *RxImpact*. 2015;4:8-9.
12. Anderson L, Hartung DM, Middleton L, Rodriguez MI. Pharmacist Provision of Hormonal Contraception in the Oregon Medicaid Population. *Obstet Gynecol.* 2019;133:1231-1237.
13. Rodriguez MI, Hersh A, Anderson LB, Hartung DM, Edelman AB. Association of Pharmacist Prescription of Hormonal Contraception With Unintended Pregnancies and Medicaid Costs. *Obstet Gynecol.* 2019;133:1238–46.