



JOEL KITCHENS

STATE REPRESENTATIVE • 1ST ASSEMBLY DISTRICT

**Testimony for the Assembly Committee on Health
Assembly Bill 304
Wednesday, August 14, 2019**

Thank you Chairman Sanfelippo and committee members for holding a public hearing and giving me the opportunity to testify on Assembly Bill 304, 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 nurses who have met the required qualifications.

Assembly Bill 304 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 the patient to their primary health care practitioner. 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 practitioners. Participation by pharmacists is voluntary and they will not be required to take part in this program if they have moral objections to birth control.

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

One of the reasons we introduced AB 304 is because of the high costs associated with unplanned pregnancies.

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.

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, compared to 38 percent of planned 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.

Almost 63 percent of unplanned births are publically-funded in Wisconsin, with the federal and state governments spending \$313.5 million each year on this care. Of that total, \$221.4 million is paid for by federal tax dollars and \$92.1 million by state tax dollars. 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 has 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 the American College of Obstetricians and Gynecologists, American Academy of Family Physicians and the American Medical Association all agree that birth control pills are so safe they should be available over-the-counter and with no prescription. While that may be their preferred direction, only the Federal Food and Drug Administration can make a medication over-the-counter.

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 the College of OB/Gyn's, 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 is worth noting that alcoholic beverages and working the late shift are also listed as Class I carcinogens for breast cancer.

Research also has 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 I have heard coming from the opponents of this bill. While these critics may not agree with many of the things I'm about to say, if you have any questions regarding the validity of the forthcoming information, please contact my office and we will be happy to provide you with science-based documentation.

First, one of the arguments I keep hearing 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 any given year, the two-thirds of American women at risk of unintended pregnancy who use contraceptives regularly throughout the year account for only 5 percent of all unplanned pregnancies. Meanwhile, 95 percent of unintended pregnancies are attributed to the one-third of women who do not use contraceptives or who use them inconsistently.

The primary cause of irregular use 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. However, that claim is purely hypothetical – there is no scientific evidence that oral contraceptives work this way.

Birth control pills stop pregnancies from happening by blocking ovulation and thickening the cervical mucus, which prevents sperm from entering the uterus. OGBYNs tell me that if oral contraceptives did block the implementation of a viable embryo, we would expect to see large numbers of ectopic pregnancies with women on the pill – and that is simply not happening.

A report from the Committee on Health Care for Underserved Women that was provided to my office by the American College of Obstetricians and Gynecologists says clearly 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. The College of Obstetricians and Gynecologists 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 AB 304 that birth control actually increases the number of unplanned pregnancies and abortions in our state and country.

According to a 2018 report from the Centers 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 also 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 40 percent of unplanned pregnancies, has remained unchanged. The evidence 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.

As you can see, we are proposing AB 304 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 AB 304. 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.

STATE SENATOR KATHY BERNIER
TWENTY-THIRD SENATE DISTRICT



State Capitol • P.O. Box 7882 • Madison, WI 53707
Office: (608) 266-7511 • Toll Free: (888) 437-9436
Sen.Bernier@legis.wi.gov • www.SenatorBernier.com

From: Senator Kathy Bernier

To: Assembly Committee on Health

Re: Testimony on Assembly Bill 304
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

Date: August 14, 2019

Thank you Chairman Sanfelippo and committee members for allowing me to testify on Assembly Bill 304 today. I am grateful for the opportunity to work with Representatives Kitchens and Felzkowski on this important piece of legislation.

Easy access to prescription medication is essential for everyone. However, for many Wisconsin women, getting and maintaining a prescription for birth control can be a major challenge.

To get a prescription for birth control, Wisconsin women must start by making an appointment with a physician or advanced practice nurse. As you all know from experience, seeing a doctor is not only expensive, but just getting an appointment requires waiting weeks for an opening. These challenges are magnified for women in rural areas, who not only wait weeks for an appointment, but often must travel long distances to reach a doctor. Unfortunately, most insurance and health care provider procedures make getting a prescription renewed or starting medication again after a break just as difficult.

At a time when the US is suffering from a nationwide doctor shortage, the American Medical Association reports that 30% of Wisconsin counties do not have an OB/GYN. This limited access to physicians can result in women going without their birth control medication for a period of time, which can increase the risk of unplanned pregnancy.

However, according to a Pew Research study, 93% of all Americans live within five miles of a pharmacy. AB 304 takes advantage of the widespread availability of pharmacies by allowing women who are 18 or older to receive a prescription for hormonal birth control directly from a pharmacist. AB 304 is modeled after laws in 12 other states and would require the pharmacy examining board, after consultation with the Medical Examining Board, the Board of Nursing and the Department of Health Services to establish standard procedures for pharmacists to prescribe birth control for those 18 and older. The bill requires a self-assessment questionnaire, modeled after guidelines established by the American Congress of Gynecologists and a blood

pressure screening to ensure that the medication is safe for the patient. The pharmacist would also be required to send a report to the patient's primary care provider.

This legislation is supported by both the Pharmacy Society of Wisconsin and the Wisconsin Nurses Association.

It is also important to note that unintended pregnancy is the number one reason women seek an induced abortion. Allowing easier access to contraceptives can reduce the number of unplanned pregnancies and thereby reduce the number of abortions in Wisconsin.

Assembly Bill 304 is an opportunity to remove obstacles that keep Wisconsin women from having access to reliable birth control. Please vote to recommend passage of Assembly Bill 304 and help make the lives of women across Wisconsin a little easier. Thank you again for allowing me to testify. I would be happy to take any questions.



MARY FELZKOWSKI (CZAJA)

Office: (608) 266-7694
Toll Free: (888) 534-0035
Rep.Felzkowski@legis.wi.gov

STATE REPRESENTATIVE • 35th ASSEMBLY DISTRICT

P.O. Box 8952
Madison, WI 53708-8952

Testimony on Assembly Bill 304

Assembly Committee on Health
Representative Mary Felzkowski
35th Assembly District
August 14, 2019

Good morning Chairman Sanfelippo and fellow Health Committee Members,

Thank you for hearing testimony on Assembly Bill 304 allowing for 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.



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It's time for the feds to stop micromanaging birth control in the US

BY CAROLINE KITCHENS, OPINION CONTRIBUTOR - 08/20/17 10:00 AM EDT

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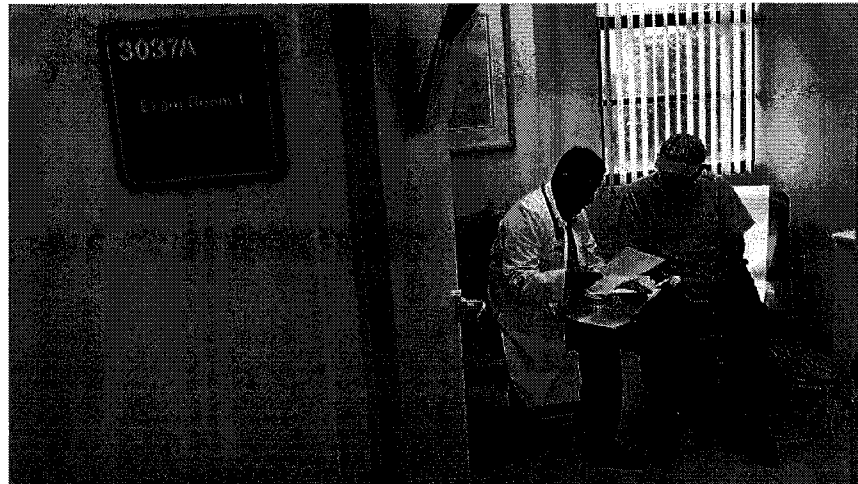
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It might surprise American women to learn the process most of them have to undergo to access hormonal birth control — which requires an annual screening and a prescription from an obstetrician-gynecologist — is fairly unusual in most countries around the globe.

A [2012 survey](#) conducted by researchers at Ibis Reproductive Health and published in the journal *Contraception* looked at rules in 147 countries and found that only 31 percent of them required a doctor's prescription to obtain oral contraceptives. For the rest — in countries like Brazil, Russia, India, China and South Africa, not to mention Greece, Turkey, Portugal, Mexico, New Zealand and South Korea — oral contraceptives can be obtained either over the counter or following a minor screening by a health professional.

If it seems strange that a communist country like China has a more open market in this area than the United States, at least there are efforts afoot to change U.S. practice in ways that would bring it more in line with global norms. Some states, for instance, now allow women to skip their doctor's visit and access birth control with a prescription from a pharmacist. California and Oregon last year became the first states to pass these "pharmacy access laws," but six more have since joined them, with Maryland set to become the ninth state in 2018.

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These regimes are not fully "over the counter," since they require a consultation with a pharmacist, who has authority to prescribe and dispense birth control. During these consultations, pharmacists check patients' blood pressure and screen for common side effects and potential drug interactions. Some states also require these results to be sent to primary care physicians. While not a perfect solution, the gradual proliferation of these rules marks a major step in the right direction.

But why has it taken this long for the issue to catch on? Usually, when libertarians see paternalistic regulations—and especially, protectionist licensing regimes—they are quick to suspect some lobbying group of rent-seeking. But that may not be the case here. The American College of Obstetricians and Gynecologists, which represents 58,000 ob-gyns across the country, has been on record as supporting over-the-counter birth control since 2012. In fact, the group's criticism of the California and Oregon laws are that they don't go far enough, noting in a January [2016 statement](#) that "we know from evidence and experience that oral contraceptives are safe enough for over-the-counter access, and do not require any prescription at all."

Indeed, the American Academy of Pediatrics also supports over-the-counter birth control, as do 76 percent of physicians, according to a [2015 survey](#) conducted by the University of California San Diego and University of California San Francisco.

While not completely risk-free, birth control is extremely safe, effective and easy to use. By making hormonal birth control available over the counter, we could give women greater control over their reproductive health while also experimenting with new, consumer-driven ways to deliver better health care to Americans. This would be a win for reproductive rights advocates and for deregulation advocates alike.

The issue is starting to gain attention, even among conservatives in Congress. Rep. Mia Love (R-Utah) and Sen. Joni Ernst (R-Iowa) have introduced [federal legislation](#) that seeks to enact a regime similar to the "pharmacy access" states nationwide. This is smart policy for a number of reasons. First, it has potential to increase access to contraception greatly and reduce the public health burden of unplanned pregnancies. Even with free coverage of birth control, the added step of having to make a doctor's appointment can serve as a high barrier to access—especially for disenfranchised women who have difficulty taking time off work. Women should be able to determine for themselves which form of birth control is best for them, and they shouldn't be forced to pay what Cato Institute scholar Jeffrey Singer has [called](#) a paternalistic "toll" — a doctor's office visit — for contraception.

For conservative champions like Rep. Love and Sen. Ernst, OTC birth control is seen as a free-market solution that could drive down health-care costs and increase consumer choice. It's also a politically advantageous counteroffensive to the claim that Republicans want to control women's bodies and restrict their reproductive freedom. And, many conservatives hope, it may be a useful tool for absolving insurance companies of the contraceptive mandate.

While Republicans and Democrats tend to favor OTC birth control for different reasons and are likely to continue to disagree on whether or not insurance should be required to cover the cost, that's a separate issue from the impact it could have on licensing reform. There's no reason why

pharmacists — who complete eight years of education and are trained experts in administering drugs — shouldn't have the authority to prescribe all forms of self-administered birth control that do not require insertion from a doctor, including hormonal pills as well as the birth control injection, patch and vaginal ring.

But more importantly, if the experiment with allowing pharmacists to prescribe birth control and provide clinical advice proves successful, it's easy to imagine pharmacists doing so for a host of other low-risk, commonly prescribed drugs. By allowing pharmacists to act as health-care providers, pharmacist-prescribed birth control could pave the way for much broader licensing reform across the medical profession.

Conservatives should embrace over-the-counter birth control—not only as a market-friendly, consumer-driven solution or as political ammo against the left's "war on women" rhetoric—but also as a useful experiment in finding innovative ways to deliver convenient and affordable health care to all Americans.

Caroline Kitchens (@cl_kitchens) is the outreach manager for the R Street Institute, a nonprofit group aimed at promoting limited government in Washington, D.C.

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TAGS CAROLINE KITCHENS HEALTHCARE OVER-THE-COUNTER DRUG WOMEN'S HEALTH HORMONAL CONTRACEPTION MEDICAL PRESCRIPTION

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To: Members, Assembly Committee on Health
From: Michelle Farrell, PharmD
Owner, Boscobel Pharmacy
Date: August 14, 2019
Subject: AB 304

Thank you very much for allowing me to testify in favor of Assembly Bill 304. 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. Assembly Bill 304 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.

There are two areas of the bill that could be strengthened to increase access.

First, the types of contraception that can be prescribed by a pharmacist should also include vaginal rings, which can be self-administered, and injectable contraception. Pharmacists are already able to administer injectable contraception under their existing scope of practice, so also allowing these products to also be prescribed by the pharmacist would further expand access to patients for these medications – they can both be prescribed and administered at the same location and the same pharmacy visit.

Additionally, this bill does not require 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, we 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. We 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.

Again, I appreciate the opportunity to offer this testimony today.



WISCONSIN FAMILY ACTION
Marriage|Family|Life|Liberty

PO Box 7486 • Madison WI 53707-7486
608-268-5074 (Madison) • 866-849-2536 (toll-free) • 608-256-3370 (fax)
info@wifamilyaction.org • www.wifamilyaction.org

TESTIMONY IN OPPOSITION TO ASSEMBLY BILL 304
ASSEMBLY COMMITTEE ON HEALTH
WEDNESDAY, AUGUST 14, 2019
JULAIN K. APPLING, PRESIDENT

Thank you, Chairman Sanfelippo and committee members, for holding this hearing on Assembly Bill 304. Wisconsin Family Action opposes this bill. While we understand the stated intent of the authors, 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.

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 or unknown 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.

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.

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

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



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

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:

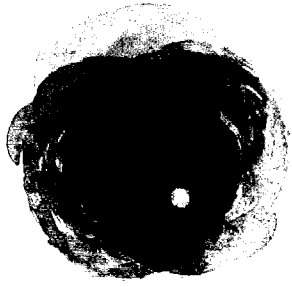
Condition	Sub-condition	Combined pill patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Stroke	a) Age < 35					Yes
	b) Age ≥ 35 < 15 cigarettes/day					Yes
	c) Age ≥ 35, ≥ 15 cigarettes/day (Not Eligible for contraception)					Yes
Postpartum Breastfeeding	a) < 21 days					Yes
	b) 21 days to 42 days: (I) with other risk factors for VTE (II) without other risk factors for VTE					Yes
Breastfeeding (see also Postpartum)	a) < 42 days					Yes
	b) 1 month or more postpartum					Yes
Diabetes mellitus (DM)	a) History of gestational DM only					Yes
	b) Non-vascular disease					Yes
	c) Non-insulin dependent (I) non-vascular disease (II) insulin dependent					Yes
	d) Nephropathy/retinopathy/neuropathy					Yes
Headaches	a) Non-migrainous (I) without aura, age < 35 (II) with aura, any age					Yes
	b) Migraine: (I) without aura, age ≥ 35 (II) with aura, any age					Yes
	c) Adequately controlled hypertension					Yes
	d) Elevated blood pressure levels (properly taken measurements): (I) systolic 140-159 or diastolic 90-99 (II) systolic ≥ 160 or diastolic ≥ 100					Yes
History of High Blood Pressure during pregnancy	a) Vascular disease					Yes
	b) Normal or mildly impaired cardiac function: (I) < 6 months (II) ≥ 6 months					Yes
	c) Vascular disease					Yes

Condition	Sub-condition	Combined pill patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
History of High Blood Pressure during pregnancy	a) Undiagnosed mass					Yes
	b) Benign breast disease					Yes
	c) Family history of cancer					Yes
History of bariatric surgery†	d) Breast cancer:† (I) current (II) past and no evidence of current disease for 5 years					Yes
	a) Restrictive procedures					Yes
	b) Malabsorptive procedures					Yes
	c) Major surgery (I) with prolonged immobilization (II) without prolonged immobilization (III) minor surgery without immobilization					Yes
History of DVT/PE	a) Higher risk for recurrent DVT/PE					Yes
	b) Lower risk for recurrent DVT/PE					Yes
	c) DVT/PE and established on anticoagulant therapy for at least 3 months					Yes
	d) Family history (first-degree relatives)					Yes
History of DVT/PE	e) Acute DVT/PE					Yes
	f) Complicated history of cerebrovascular accident					Yes
	g) Uncomplicated history of cerebrovascular accident					Yes
History of DVT/PE	h) History of DVT/PE, not on anticoagulant therapy					Yes
	i) Higher risk for recurrent DVT/PE					Yes
	j) Lower risk for recurrent DVT/PE					Yes

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)

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					Yes
	b) Carrier/Chronic					Yes
	c) Severe† (decompensated)					Yes
Cirrhosis	a) Mild (compensated)					Yes
	b) Severe† (decompensated)					Yes
	c) Severe† (decompensated)					Yes
Liver tumors	a) Benign:					Yes
	i) Focal nodular hyperplasia					Yes
	ii) Hepatocellular adenoma‡					Yes
	b) Malignant‡					Yes
Gallbladder disease	a) Symptomatic:					Yes
	(i) treated by cholecystectomy					Yes
	(ii) medically treated					Yes
	(iii) current					Yes
History of Cholelithiasis	b) Asymptomatic					Yes
	a) Pregnancy-related					Yes
Systemic lupus erythematosus‡	b) Past COC-related					Yes
	a) Positive (or unknown) antiphospholipid antibodies					Yes
	b) Severe thrombocytopenia					Yes
	c) Immunosuppressive treatment					Yes
	d) None of the above					Yes
Rheumatoid arthritis	a) On immunosuppressive therapy					Yes
	b) Not on immunosuppressive therapy					Yes
Blood Conditions?						
Epilepsy‡	(see also Drug Interactions)					Yes
	a) Non-pelvic					Yes
Tuberculosis‡ (see also Drug Interactions)	b) Pelvic					Yes
						Yes
HIV	High risk					Yes
	HIV infected (see also Drug Interactions) ‡					Yes
	AIDS (see also Drug Interactions) ‡					Yes
	Clinically well on therapy					Yes
Antiretroviral therapy	a) Nucleoside reverse transcriptase inhibitors					Yes
	b) Non-nucleoside reverse transcriptase inhibitors					Yes
	c) Ritonavir-boosted protease inhibitors					Yes
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)					Yes
	b) Lamotrigine					Yes
Antimicrobial therapy	a) Broad spectrum antibiotics					Yes
	b) Antifungals					Yes
	c) Antiparasitics					Yes
	d) Rifampicin or rifabutin therapy					Yes

If on treatment, see Drug Interactions.



ProLife
LOVE. FOR LIFE. WI.

Testimony in Opposition to Assembly Bill 304: permitting pharmacists to prescribe certain contraceptives
Assembly Committee on Health
By Matt Sande, Director of Legislation

August 14, 2019

Good morning Chairman Sanfelippo 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 Assembly Bill (AB) 304, 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." Accordingly, 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) 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 AB 304 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 AB 304 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.

To: Representative Joe Sanfelippo, Chair, Assembly Committee on Health
Members, Assembly Committee on Health

From: **Kassandra Bartelme, Pharm.D., BCACP**
Associate Professor of Pharmacy Practice
Ambulatory Care Pharmacist

Date: August 14, 2019

Subject: Testimony in Support of Assembly Bill 304

Representative Sanfelippo and members of the Committee, thank you very much for allowing me to testify in favor of Assembly Bill 304. 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. I also teach contraception to physician assistant students.

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.

AB 304 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.

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.^{4,5} 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.^{4,5} 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, 2016.⁶

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.⁷ 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.⁷ 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.⁸ Many Wisconsin residents drive 60 minutes or more to see an OB-GYN.⁸ 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.⁹ 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 and 73.8% of those 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. 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.¹⁰ 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.

Thank you again for the opportunity to provide testimony in favor of AB 304.

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WISCONSIN CATHOLIC CONFERENCE

**TESTIMONY REGARDING ASSEMBLY BILL 304:
PHARMACIST CONTRACEPTIVE PRESCRIBING
Presented by Kim Vercauteren, Executive Director
August 14, 2019**

The Wisconsin Catholic Conference (WCC), the public policy voice of the Catholic bishops of Wisconsin, urges you to oppose Assembly Bill 304, 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 AB 304, 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 AB 304 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.

(over)

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 AB 304, 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 AB 304'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 AB 304 become law, commercial pharmacy chains will likely make corporate policies instituting mandatory prescribing for their pharmacists, negating the permissive choice for pharmacists highlighted by AB 304'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 AB 304.

Thank you.



WISCONSIN CATHOLIC MEDICAL GUILDS

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

August 14, 2019

To: Members, Assembly Health Committee

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

RE: Assembly Bill 304 – permitting pharmacists to prescribe certain contraceptives

Good morning Chairman Sanfelippo 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 Assembly Bill (AB) 304 and strongly urges you to not pass this bill out of committee.

As you know, AB 304 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

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. 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 abortifacient effect. One of the 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 and getting the necessary nutrients to grow and develop.

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 AB 304 and encourages you to do likewise.

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



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

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/USMECh.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	a) Age < 35					Yes
	b) Age ≥ 35, < 15 cigarettes/day					Yes
	c) Age ≥ 35, ≥ 15 cigarettes/day (Not eligible for contraception)					Yes
Postpartum (see also Breastfeeding)	a) < 21 days					Yes
	b) 21 days to 42 days					Yes
Breastfeeding (see also Postpartum)	a) < 1 month postpartum					Yes
	b) 1 month or more postpartum					Yes
Diabetes mellitus (DM)	a) History of gestational DM only					Yes
	b) Non-vascular disease					Yes
	c) Non-insulin dependent					Yes
	d) Other abnormality					Yes
Headaches	a) Non-migrainous					Yes
	b) Migraine:					Yes
	i) without aura, age < 35					Yes
	ii) with aura, any age					Yes
Hypertension	a) Adequately controlled					Yes
	b) Elevated blood pressure levels (properly taken measurements):					Yes
	c) Systolic ≥ 160 or diastolic ≥ 100					Yes
History of stroke	a) Normal or mildly impaired cardiac function:					Yes
	b) < 6 months					Yes
History of stroke	a) Normal or mildly impaired cardiac function:					Yes
	b) ≥ 6 months					Yes

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)

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Cardiac function	a) Moderate or severely impaired cardiac function (such as older age, smoking, diabetes and hypertension)					Yes
	b) History of DVT/PE and established on anticoagulant therapy for at least 3 months					Yes
History of cerebrovascular accident	a) Uncomplicated					Yes
	b) Complicated					Yes
History of DVT/PE	a) Higher risk for recurrent DVT/PE					Yes
	b) Lower risk for recurrent DVT/PE					Yes
Major surgery	a) Major surgery (i) with prolonged immobilization					Yes
	b) Minor surgery without immobilization					Yes
Restrictive procedures	a) Restrictive procedures					Yes
	b) Malabsorptive procedures					Yes
Undiagnosed mass	a) Undiagnosed mass					Yes
	b) Benign breast disease					Yes
Family history of cancer	a) Family history of cancer					Yes
	b) Breast cancer					Yes
Past and no evidence of current disease for 5 years	a) Past and no evidence of current disease for 5 years					Yes
	b) Current					Yes

Condition	Sub-condition	Combined pill, patch, ring		Progesteron-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Viral hepatitis	a) Acute or flare					Yes
	b) Carrier/Chronic					Yes
	c) Mild (compensated)					Yes
Cirrhosis	a) Mild (decompensated)					Yes
	b) Severe† (decompensated)					Yes
Liver tumors	a) Benign:					Yes
	i) Focal nodular hyperplasia					Yes
	ii) Hepatocellular adenoma‡					Yes
Gallbladder disease	b) Malignant‡					Yes
	a) Symptomatic:					Yes
	i) treated by cholecystectomy					Yes
History of Cholelithiasis	ii) medically treated					Yes
	iii) current					Yes
	b) Asymptomatic					Yes
Systemic lupus erythematosus‡	a) Pregnancy-related					Yes
	b) Past COC-related					Yes
Rheumatoid arthritis	a) Positive (or unknown) antiphospholipid antibodies					Yes
	b) Severe thrombocytopenia					Yes
	c) Immunosuppressive treatment					Yes
Blood Conditions?	a) None of the above					Yes
	a) On immunosuppressive therapy					Yes
Epilepsy‡	b) Not on immunosuppressive therapy					Yes
	(see also Drug Interactions)					Yes
Tuberculosis‡ (see also Drug Interactions)	a) Non-pulvic					Yes
	b) Pulvic					Yes
HIV	High risk					Yes
	HIV infected (see also Drug Interactions) ‡					Yes
Androtretinone therapy	(see also Drug Interactions) ‡					Yes
	AIDS					Yes
Androtretinone therapy	Clinically well on therapy					Yes
	a) Nucleoside reverse transcriptase inhibitors					Yes
	b) Non-nucleoside reverse transcriptase inhibitors					Yes
Anticonvulsant therapy	c) Ribonavir-boosted protease inhibitors					Yes
	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)					Yes
	b) Lamotrigine					Yes
Antimicrobial therapy	a) Broad spectrum antibiotics					Yes
	b) Antifungals					Yes
	c) Antiparasitics					Yes
	d) Rifampicin or rifabutin therapy					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					Yes
	b) Benign breast disease					Yes
	c) Family history of cancer					Yes
	d) Breast cancer†					Yes
Breastfeeding (see also Postpartum)	i) past and no evidence of current disease for 5 years					Yes
	ii) past and no evidence of current disease for 5 years					Yes
Cervical cancer	a) < 1 month postpartum					Yes
	b) 1 month or more postpartum					Yes
Cervical ectropion	Awaiting treatment					Yes
						Yes
Cervical Intraepithelial Neoplasia						Yes
						Yes
Cystic Fibrosis	a) Mild (compensated)					Yes
	b) Severe† (decompensated)					Yes
Deep venous thrombosis (DVT) /Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy					Yes
	i) higher risk for recurrent DVT/PE					Yes
	ii) lower risk for recurrent DVT/PE					Yes
	iii) higher risk for recurrent DVT/PE and established on anticoagulant therapy for at least 3 months					Yes
Depressive disorders	i) higher risk for recurrent DVT/PE					Yes
	ii) lower risk for recurrent DVT/PE					Yes
	d) Family history (first-degree relatives)					Yes
	e) Major surgery					Yes
	f) with prolonged immobilization					Yes
	g) without prolonged immobilization					Yes
Diabetes mellitus (cont)	i) Minor surgery without immobilization					Yes
	ii) Minor surgery without immobilization					Yes
Diabetes mellitus (cont)	a) History of gestational DM only (DM)					Yes
	b) Non-vascular disease					Yes
Diabetes mellitus (cont)	i) non-insulin dependent					Yes
	ii) insulin dependent†					Yes
	c) Nephropathy/retinopathy/neuropathy†					Yes
	d) Other vascular disease or diabetes of >20 years' duration†					Yes
Endometrial cancer†						Yes
						Yes
Endometrial hyperplasia						Yes
						Yes
Endometriosis						Yes
						Yes
Epilepsy†	(see also Drug Interactions)					Yes
	a) Symptomatic					Yes
Gallbladder disease	i) treated by cholecystectomy					Yes
	ii) medically treated					Yes
	iii) current					Yes
						Yes
Gestational trophoblastic disease	a) Decreasing or undetectable β-hCG levels					Yes
	b) Persistently elevated β-hCG levels or malignant disease†					Yes
Headaches	a) Non-migrainous					Yes
	b) Migraine					Yes
History of high blood pressure during pregnancy	i) without aura, age <35					Yes
	ii) without aura, age ≥35					Yes
	iii) with aura, any age					Yes
History of bariatric/bariatric surgery†	a) Restrictive procedures					Yes
	b) Malabsorptive procedures					Yes
History of cholelithiasis	a) Pregnancy-related					Yes
	b) Past COC-related					Yes
History of pelvic surgery						Yes
						Yes
HIV	High risk					Yes
	HIV infected (see also Drug Interactions)† AIDS (see also Drug Interactions) ‡					Yes
Hypertension	a) Adequately controlled					Yes
	b) Elevated blood pressure levels (properly taken measurements)					Yes
Hypertension	i) systolic 140-159 or diastolic 90-99					Yes
	ii) systolic ≥160 or diastolic ≥100†					Yes
Hypertension	c) Vascular disease					Yes
	d) Vascular disease (Ulcerative colitis, Crohn's disease)					Yes
Hypertension	Current and history of					Yes
						Yes
Liver tumors	i) Focal nodular hyperplasia					Yes
	ii) Hepatocellular adenoma†					Yes
Liver tumors	a) Benign					Yes
	b) Malignant†					Yes
Malena						Yes
						Yes
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)					Yes
						Yes
Obesity	a) ≥30 kg/m ² body mass index (BMI)					Yes
	b) Menarche to < 18 years and ≥ 30 kg/m ² BMI					Yes
Ovarian cancer†						Yes
						Yes
Parity	a) Nulliparous					Yes
	b) Parous					Yes
Past ectopic pregnancy						Yes
						Yes

† If on treatment see Drug Interactions

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 or STIs)					Yes
	(i) with subsequent pregnancy (ii) without subsequent pregnancy					Yes
Peripartum cardiomyopathy†	b) Current					Yes
	a) Normal or mildly impaired cardiac function					Yes
	(i) < 6 months					Yes
	(ii) ≥ 6 months					Yes
Postabortion	b) Moderately or severely impaired cardiac function					Yes
	a) First trimester					Yes
	b) Second trimester					Yes
Postpartum (see also Breastfeeding)	c) Immediately post-septic abortion					Yes
	a) < 21 days					Yes
	b) 21 days to 42 days					Yes
Postpartum (in breastfeeding or non-breastfeeding women, including post-caesarean section)	(i) with other risk factors for VTE					Yes
	(ii) without other risk factors for VTE					Yes
	c) > 42 days					Yes
Pregnancy	a) < 10 minutes after delivery of the placenta					Yes
	b) 10 minutes after delivery of the placenta to < 4 weeks					Yes
Rheumatoid arthritis	c) ≥ 4 weeks					Yes
	d) Puerperal sepsis					Yes
Schistosomiasis	a) On immunosuppressive therapy					NA*
	b) Not on immunosuppressive therapy					NA*
Severe dysmenorrhea	a) Uncomplicated					Yes
	b) Fibrosis of the liver †					Yes
Sexually transmitted infections (STIs)	a) Current untreated cervicitis or chlamydial infection or gonorrhea					Yes
	b) Other STIs (excluding HIV and hepatitis)					Yes
Sexually transmitted infections (cont.)	c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)					Yes
	d) Increased risk of STIs					Yes
	a) Age < 35					Yes
	b) Age ≥ 35, < 15 cigarettes/day					Yes
Solid organ transplantation†	c) Age ≥ 35, ≥ 15 cigarettes/day					Yes
	a) Complicated					Yes
Stroke†	b) Uncomplicated					Yes
	History of cerebrovascular accident					Yes
Superficial venous thrombosis	a) Varicose veins					Yes
	b) Superficial thrombophlebitis					Yes
Systemic lupus erythematosus†	a) Positive (or unknown) antiphospholipid antibodies					Yes
	b) Severe thrombocytopenia					Yes
	c) Immunosuppressive treatment					Yes
	d) None of the above					Yes
Thrombogenic mutations†						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/hypothyroid/hypothyroid					Yes
	a) Non-pelvic (see also Drug Interactions)					Yes
Unexplained vaginal bleeding	b) Pelvic (suspicious for serious condition) before evaluation					Yes
	Uterine fibroids					Yes
Valvular heart disease	a) Uncomplicated					Yes
	b) Complicated†					Yes
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding					Yes
	b) Heavy or prolonged bleeding					Yes
Viral hepatitis	a) Acute or flare					Yes
	b) Carrier/Chronic					Yes
Antiestrogenal therapy (All other ARVs are 1 or 2 for all methods)	Estrogen-free (E-free)					Yes
	Estrogen-containing					Yes
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)					Yes
	b) Lamotrigine					Yes
	c) Broad spectrum antibiotics					Yes
	d) Antiparasitics					Yes
Antimicrobial therapy	a) Rifampin or rifabutin therapy					Yes
						Yes
SSRIs						Yes
						Yes
St. John's Wort						Yes

† = 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.



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Washington, D.C. 20005
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Testimony from:
Caroline Kitchens, Director of Federal Affairs, R Street Institute

Regarding AB304, "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. (FE)"

August 14, 2019

Assembly Committee on Health

Chairman Sanfelippo and Members of the Committee:

Thank you for the opportunity to testify today. My name is Caroline Kitchens and I am director of federal affairs at the R Street Institute. R Street is a nonprofit, nonpartisan public policy research organization based in Washington, D.C., whose mission is to engage in policy research and outreach to promote free markets and limited, effective government. I appreciate the opportunity to offer insight on birth control delivery in Wisconsin and the pharmacy access model.

In Wisconsin and most U.S. states, women are required to make routine visits to a doctor or advanced practice nurse to get a prescription for hormonal contraception. This is unnecessary from a medical standpoint and puts an undue burden on Wisconsin women, families and taxpayers. If enacted, Assembly Bill 304 would allow Wisconsin to join a growing number of states who have safely expanded access to birth control and given women more autonomy over their reproductive health.

At the R Street Institute, we have worked with a number of state legislatures who have adopted the pharmacy access model, which allows women to safely obtain a birth control prescription directly from pharmacists. To date, 12 states across the country and political spectrum have adopted this model.¹ In these states, preliminary evidence shows that the new model has been received favorably and is working effectively to reduce unintended pregnancies and associated public health care expenditures. Currently, there are ongoing legislative efforts to bring pharmacy access to many other states, including Iowa, Illinois, Minnesota, Texas, South Carolina, Missouri and more.

The impact of pharmacy access laws will become clearer over time as more states that have passed bills implement their programs. However, early evidence out of Oregon, the first state to implement the pharmacy access model in 2015, is promising. A recent study found that 10 percent of all new birth



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Suite 900
Washington, D.C. 20005
202-525-5717

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control prescriptions given to Oregon Medicaid enrollees were written by pharmacists. 74 percent of the women prescribed birth control by pharmacists had no history of birth control prescriptions in the past month.ⁱⁱ This suggests that the pharmacy access model has been able to reach women who otherwise would not be using hormonal birth control.

Oregon's pharmacy access program has also decreased unintended pregnancies and saved money for taxpayers. A study examining Oregon's program and Medicaid enrollees shows that, over just two years, pharmacists prescribing birth control reduced the publicly funded medical costs associated with unintended pregnancies by \$1.6 million and prevented more than 50 unplanned pregnancies.ⁱⁱⁱ Because 42 percent of unintended pregnancies end in abortion^{iv}, it is reasonable to conclude that the pharmacy access model reduced abortions in the state as well. These outcomes will likely become more pronounced as public awareness increases and the program is more fully implemented.

There is longstanding evidence showing that birth control access increases women's workforce participation, reduces public spending and drives down rates of unintended pregnancy and abortion. Unintended pregnancies are at an all-time low in the United States and in Wisconsin but still represent about 45 percent of all pregnancies. This rate has decreased substantially from 54 percent in 2008. An overall increase in birth control use and the use of more effective methods is credited as the primary reason for this decrease.

While the R Street Institute does not take a direct position on abortion, historical data clearly demonstrates that better access to contraception and declining abortion rates have gone hand-in-hand. As mentioned above, 42 percent of unintended pregnancies end in abortion at present, and that has remained constant since 2008. However, from 2008 to 2015, while the percentage of unintended pregnancies that end in abortion remained stable, the overall abortion rate declined by 25 percent. The declining abortion rate is attributable to fewer unintended pregnancies, largely made possible by birth control access.^v

There's no denying that hormonal birth control is effective. When taken properly, the pill has a failure rate of less than one percent. Meanwhile, couples who do not use any method of contraception have an 85 percent chance of getting pregnant within a year.^{vi} Unnecessary barriers like doctors' visits impede women's ability to access hormonal contraception and use it consistently without interruption. The pharmacy access model reduces these barriers.

Evidence from across the country and around the world has shown that birth control can safely be prescribed without the unnecessary intermediation of a doctor. The United States is outside the norm with its strict regulatory approach: In the vast majority of countries, birth control is available with no prescription at all.^{vii} Leading medical groups like the American College of Obstetricians and



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Gynecologists, the American Academy of Family Physicians and the American Medical Association all agree that birth control is appropriate for over-the-counter distribution.^{viii}

Improved birth control access is tied to many positive social outcomes, but the current regulatory environment in Wisconsin needlessly restricts access and limits women's choices. Allowing pharmacists to prescribe hormonal contraception is a proven strategy to expand birth control access while also reducing the public health and taxpayer burdens of unplanned pregnancies.

For these reasons, AB 304 is a significant step toward more sensible regulation and deserves serious consideration.

Respectfully submitted,

Caroline Kitchens
Director of Federal Affairs
R Street Institute
ckitchens@rstreet.org

ⁱ Courtney M. Joslin and Steven Greenhut, "Birth Control in the States: A Review of efforts to Expand Acces," R Street Institute, November 2018. <https://www.rstreet.org/wp-content/uploads/2018/11/Final-159.pdf>

ⁱⁱ Maria Rodriguez et al., "Association of Pharmacist Prescription of Hormonal Contraception with Unintended Pregnancies and Medicaid Costs" *Obstetrics & Gynecology* 133:6, p. 1238-1246.

https://journals.lww.com/greenjournal/Abstract/2019/06000/Association_of_Pharmacist_Prescription_of_Hormonal.23.aspx

ⁱⁱⁱ Lorinda Anderson et al., "Pharmacist Provision of Hormonal Contraception in the Oregon Medicaid," *Obstetrics & Gynecology* 133:6, pp. 1231-1237.

https://journals.lww.com/greenjournal/Abstract/2019/06000/Pharmacist_Provision_of_Hormonal_Contraception_in.22.aspx

^{iv} "Fact Sheet: Contraceptive Use in the United States," Guttmacher Institute, July 2018.

<https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>

^v "Fact Sheet: Unintended Pregnancy in the United States," Guttmacher Institute, January 2019.

<https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states>

^{vi} ^{vi} "Fact Sheet: Contraceptive Use in the United States," Guttmacher Institute, July 2018.

<https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>

^{vii} Kate Grindlay, Bridgit Burns and Daniel Grossman, "Prescription Requirements and Over-the-Counter Access to Oral Contraceptives: A Global Review," *Contraception* 88:1, p. 91-96.

[https://www.contraceptionjournal.org/article/S0010-7824\(12\)01029-3/abstract](https://www.contraceptionjournal.org/article/S0010-7824(12)01029-3/abstract)

^{viii} See, e.g., "Committee Opinion: Over-the-Counter Access to Oral Contraceptives," The American College of Obstetricians and Gynecologists, No. 544, December 2012 (Reaffirmed 2018) <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Increasing-Access-to-Contraceptive-Implants-and-Intrauterine-Devices-to-Reduce-Unintended-Pregnancy>; Report of the Board of Trustees, "Over-the-Counter Contraceptive Drug Access," American Medical Association, Resolution 110-A-17, 2017. <http://ocotc.org/wp-content/uploads/2018/06/2018-AMA-OCs-OTC-resolution-110-A-17.Pdf>; "Policies, Over-the-Counter Oral Contraceptives," The American Academy of Family Physicians, 2014. <https://www.aafp.org/about/policies/all/otc-oral-contraceptives.html>.



The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

Number 615 • January 2015

Committee on Health Care for Underserved Women

This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Access to Contraception

ABSTRACT: Nearly all U.S. women who have ever had sexual intercourse have used some form of contraception at some point during their reproductive lives. However, multiple barriers prevent women from obtaining contraceptives or using them effectively and consistently. All women should have unhindered and affordable access to all U.S. Food and Drug Administration-approved contraceptives. This Committee Opinion reviews barriers to contraceptive access and offers strategies to improve access.

Recommendations

The American College of Obstetricians and Gynecologists (the College) supports access to comprehensive contraceptive care and contraceptive methods as an integral component of women's health care and is committed to encouraging and upholding policies and actions that ensure the availability of affordable and accessible contraceptive care and contraceptive methods. In order to accomplish this goal, the College recommends and supports the following:

- Full implementation of the Affordable Care Act (ACA) requirement that new and revised private health insurance plans cover all U.S. Food and Drug Administration (FDA)-approved contraceptives without cost sharing, including nonequivalent options from within one method category (eg, levonorgestrel as well as copper intrauterine devices [IUDs])
- Easily accessible alternative contraceptive coverage for women who receive health insurance through employers and plans exempted from the contraceptive coverage requirement
- Medicaid expansion in all states, an action critical to the ability of low-income women to obtain improved access to contraceptives
- Adequate funding for the federal Title X family planning program and Medicaid family planning services to ensure contraceptive availability for low-income women, including the use of public funds for contraceptive provision at the time of abortion
- Sufficient compensation for contraceptive services by public and private payers to ensure access, including appropriate payment for clinician services and acquisition-cost reimbursement for supplies
- Age-appropriate, medically accurate, comprehensive sexuality education that includes information on abstinence as well as the full range of FDA-approved contraceptives
- Confidential, comprehensive contraceptive care and access to contraceptive methods for adolescents without mandated parental notification or consent, including confidentiality in billing and insurance claims processing procedures
- The right of women to receive prescribed contraceptives or an immediate informed referral from all pharmacies
- Prompt referral to an appropriate health care provider by clinicians, religiously affiliated hospitals, and others who do not provide contraceptive services
- Evaluation of effects on contraceptive access in a community before hospital mergers and affiliations are considered or approved
- Efforts to increase access to emergency contraception, including removal of the age restriction for all levonorgestrel emergency contraception products, to create true over-the-counter access
- Over-the-counter access to oral contraceptives with accompanying full insurance coverage or cost supports

- Payment and practice policies that support provision of 3–13 month supplies of combined hormonal methods to improve contraceptive continuation
- Provision of medically accurate public and health care provider education regarding contraception
- Improved access to postpartum sterilization, including revision of federal consent requirements for women covered by Medicaid, the Indian Health Service, the U.S. military, or other government health insurance
- Institutional and payment policies that support immediate postpartum and postabortion provision of contraception, including reimbursement for long-acting reversible contraception (LARC) devices separate from the global fee for delivery, and coverage for contraceptive care and contraceptive methods provided on the same day as an abortion procedure
- Inclusion of all contraceptive methods, including LARC, on all payer and hospital formularies
- Funding for research to identify effective strategies to reduce health inequities in unintended pregnancy and access to contraception

Background

The benefits of contraception, named as one of the 10 great public health achievements of the 20th century by the Centers for Disease Control and Prevention, are widely recognized and include improved health and well-being, 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 (1). Ninety-nine percent of U.S. women who have been sexually active report having used some form of contraception, and 87.5% report use of a highly effective reversible method (2). Universal coverage of contraceptives is cost effective and reduces unintended pregnancy and abortion rates (3). Additionally, noncontraceptive 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.

Unintended Pregnancy in the United States and the Case for Contraceptive Access

The College supports women's right to decide whether to have children, to determine the number and spacing of their children, and to have the information, education, and access to health services to make those choices (4). Women must have access to reproductive health care, including the full range of contraceptive choices, to fulfill these rights.

Unintended pregnancy and abortion rates are higher in the United States than in most other developed countries, and low-income women have disproportionately high rates (5). Currently, 49% of pregnancies are unintended (5). Reducing this high rate is a national priority

reflected in the Healthy People 2020 goal to decrease the rate of unintended pregnancies from 49% to 44% (6). The human cost of unintended pregnancy is high: women must either carry an unplanned pregnancy to term and keep the baby or make a decision for adoption, or choose to undergo abortion. Women and their families may struggle with this challenge for medical, ethical, social, legal, and financial reasons. Additionally, U.S. births from unintended pregnancies resulted in approximately \$12.5 billion in government expenditures in 2008 (7). Facilitating affordable access to contraceptives would not only improve health but also would reduce health care costs, as each dollar spent on publicly funded contraceptive services saves the U.S. health care system nearly \$6 (8). The most effective way to reduce abortion rates is to prevent unintended pregnancy by improving access to consistent, effective, and affordable contraception.

Knowledge Deficits

Lack of knowledge, misperceptions, and exaggerated concerns about the safety of contraceptive methods are major barriers to contraceptive use. There has been a focus on abstinence-only sexuality education for young people in the United States despite research demonstrating its ineffectiveness in increasing age of sexual debut and decreasing number of partners and other risky behavior (9, 10). In contrast, data suggest the effectiveness of comprehensive sexuality education in achieving these outcomes (10). The emphasis on abstinence-only education may have in part led to widespread misperceptions of contraceptive effectiveness, mechanisms of action, and safety that can have an effect on contraceptive use and method selection (11). For example, many individuals have unfounded concerns that oral contraceptives are linked to major health problems or that IUDs carry a high risk of infection (12, 13). Many individuals also incorrectly believe certain types of contraception to be abortifacients (14). None of the FDA-approved contraceptive methods are abortifacients because they do not interfere with a pregnancy and are not effective after a fertilized egg has implanted successfully in the uterus (15).

Health care providers also may have knowledge deficits that can hamper their ability to offer appropriate contraceptive methods to their patients. For example, many clinicians are uncertain about the risks and benefits of IUDs and lack knowledge about correct patient selection and contraindications (16–18). Improving health care provider and patient knowledge about contraceptive methods would improve access and allow for safer use.

Restrictive Legal and Legislative Climate

Unfavorable legal rulings and restrictive legislative measures can impede access to contraceptives for minors and adults and interfere with the patient–physician relationship by impeding contraceptive counseling, coverage, and provision. With the U.S. Supreme Court's *Burwell v. Hobby Lobby* ruling that a closely held corporation can exclude contraceptive coverage from workers' insurance

benefits based on the company owner's religious beliefs, additional employers may now refuse to comply with federal birth control coverage requirements. Some corporations also may use the legal process to challenge laws in states that ensure equitable contraceptive coverage.

Additionally, state lawmakers may be emboldened to further restrict access to contraception. For example, in 2012, Arizona revisited its decade-old law that ensures equitable insurance coverage for birth control and authorized a much broader class of employers to exclude this coverage from employee health insurance plans. In 2013, bills designed to weaken existing contraceptive equity laws or to allow employers—secular and religious—to deny contraceptive coverage to their workers were introduced in more than a dozen states.

Measures that define life as beginning at fertilization and, thereby, conferring the legal status of "personhood" on fertilized eggs also pose a significant risk to contraceptive access. Supporters of "personhood" measures argue erroneously that most methods of contraception act as abortifacients because they may prevent a fertilized egg from implanting; if these "personhood" measures were to be implemented, contraception opponents may assert that hormonal contraceptive methods and IUDs are illegal.

Currently, 20 states restrict some minors' ability to consent to contraceptive services (19). Although the Title X family planning program and Medicaid require that minors receive confidential health services, state and federal legislation requiring parental notification, parental consent, or both for minors who receive contraceptive care has been increasingly proposed (20). Even though policies should encourage and facilitate communication between a minor and her parent or guardian when appropriate, legal barriers and deference to parental involvement should not stand in the way of needed contraceptive care for adolescents who request confidential services.

Cost and Insurance Coverage

More than one half of the 37 million U.S. women who needed contraceptive services in 2010 were in need of publicly funded services, either because they had an income below 250% of the federal poverty level or because they were younger than 20 years (8). One in four women in the United States who obtain contraceptive services seek these services at publicly funded family planning clinics (21). The number of women in need of publicly funded contraceptive services increased by 17%, or nearly three million women, from 2000 to 2010 (8). Expanding access to publicly funded family planning services produces cost savings by reducing unintended pregnancy. In 2010, federal and state governments saved an estimated \$7.6 billion because of contraceptive services provided at publicly funded centers (8). As the ACA goes into effect, obstetrician-gynecologists can be strong advocates for continued expansion of affordable contraceptive access, which has been shown to be cost neutral at worst and cost saving at best (22, 23).

High out-of-pocket costs, deductibles, and copayments for contraception also limit contraceptive access even for those with private health insurance. Most private health plans cover prescription contraception, but cost sharing and formularies vary (24). In 2000, the federal Equal Employment Opportunity Commission concluded that a company's failure to cover contraception is sex discrimination under Title VII of the Civil Rights Act as amended by the 1978 Pregnancy Discrimination Act (25). However, even when contraception is covered, women pay approximately 60% of the cost out of pocket compared with the typical out-of-pocket cost of only 33% for noncontraceptive drugs (26).

Under the ACA, all FDA-approved contraceptive methods, sterilization procedures, and patient contraceptive education and counseling are covered for women without cost sharing by all new and revised health plans and issuers as of the first full plan year beginning on or after August 1, 2012. This requirement also applies to those enrolled in Medicaid expansion programs. However, many employers are now exempt from these requirements because of regulatory and court decisions. Women covered through exempted employers, as well as women such as unauthorized immigrants who remain uninsured in spite of the ACA, will not benefit from coverage introduced by the ACA. For these women, cost barriers will persist and the most effective methods, such as IUDs and the contraceptive implant, likely will remain out of reach.

Other insurance barriers include limits on the number of contraceptive products dispensed. Data show that provision of a year's supply of contraceptives is cost effective and improves adherence and continuation rates (27). Insurance plan restrictions prevent 73% of women from receiving more than a single month's supply of contraception at a time, yet most women are unable to obtain contraceptive refills on a timely basis (26, 28, 29).

Some insurers, clinic systems, or pharmacy and therapeutics committees also require women to "fail" certain contraceptive methods before a more expensive method, such as an IUD or implant, will be covered. All FDA-approved contraceptive methods should be available to all insured women without cost sharing and without the need to "fail" certain methods first. In the absence of contraindications, patient choice and efficacy should be the principal factors in choosing one method of contraception over another.

Another strategy for improving access to contraception is to allow over-the-counter access to oral contraceptive pills (30). However, over-the-counter provision may improve access only if over-the-counter products also are covered by insurance or other cost supports in order to make them financially accessible to low-income women.

Objection to Contraception

Efforts to frame access as an issue of conscience or religious belief rather than as essential health care have grave

consequences for women and can create major obstacles to obtaining insurance coverage, receiving prescriptions from health care providers, obtaining medications from pharmacists, and receiving care at hospitals. Ten of the 25 largest health systems in the country are Catholic-sponsored facilities (31). Mergers between religious (predominantly Catholic) health care facilities and other hospitals are common and often result in decreased access to reproductive health services, including contraception (31). Advocacy by clinicians and community leaders has been effective in preserving access in some communities (32, 33).

Pharmacist refusals to fill contraceptive prescriptions or provide emergency contraception, as well as pharmacies that refuse to stock contraceptives, are considerable barriers. Although some women have access to an alternative pharmacy, women in areas where pharmacies and pharmacists are limited, such as rural areas, may find insurmountable obstacles to obtaining prescribed contraception. In eight states, laws specifically prohibit pharmacy or pharmacist refusal; seven states allow refusal but prohibit pharmacist obstruction of patients' receipt of medications; and six states specifically allow pharmacists to refuse to dispense legally prescribed medications without protections for patients, such as a referral requirement (34). The American Pharmacists Association supports the establishment of systems to ensure patient access to contraception when individual pharmacists refuse provision (35). The College supports unhindered access to contraception for all women and opposes health care provider and institutional refusals that create obstacles to contraceptive access.

Unnecessary Medical Practices

Common medical practices prevent easy initiation of contraception. There is no medical or safety benefit to requiring routine pelvic examination or cervical cytology before initiating hormonal contraception. The prospect of such an examination may deter a woman, especially an adolescent, from having a clinical visit that could facilitate her use of a more effective contraceptive method than those available over the counter (36).

Another common practice is requiring one medical appointment to discuss initiation of a LARC method and a second for placement of the device or requiring two visits to perform and obtain results from sexually transmitted infection testing. Clinicians are encouraged to initiate and place LARC in a single visit as long as pregnancy may be reasonably excluded. Sexually transmitted infection testing can occur on the same day as LARC placement, and women do not require cervical preparation for insertion (37, 38). Insurer payment policies should support same-day provision by providing appropriate payment and reimbursement for multiple services performed during a single visit. Similarly, health care providers should encourage patients initiating combined hormonal contraceptives to start on the day of the medical visit (38).

Institutional and Payment Barriers

Appropriate compensation for contraceptive services enables health care providers to provide the full range of contraceptive options, which improves quality of care and optimizes health outcomes. Public and private payers can contribute to efforts to improve contraceptive access by working with health care providers to ensure appropriate payment for clinician services and to provide reimbursement for contraceptive devices at acquisition cost levels.

Twenty-seven percent of reproductive-aged women choose to undergo permanent sterilization once they have completed childbearing (39). Institutional and payment barriers often prevent women from receiving this desired procedure. Many sterilization procedures are planned immediately postpartum, which is an advantageous time because the woman is not pregnant, is within a medical facility, and often has insurance coverage. However, many women do not obtain their planned postpartum sterilization because of limited operating room availability, lack of motivation or coordination on the part of the health care team (obstetricians, nurses, and anesthesiologists), perceived increased risk because of the postpartum state, or misplaced or incomplete sterilization consent forms. In one study, almost 50% of women who did not receive a requested postpartum sterilization were pregnant again within 1 year (40). Federal regulations require a specific sterilization consent form to be signed 30 days before sterilization for women enrolled in Medicaid or covered by other government insurance (41). This requirement eliminates immediate postpartum sterilization as an option if the paperwork is not completed in advance and available at the time of delivery. This regulation, created to protect women from coerced sterilization, also can pose a barrier to a desired sterilization. Women with commercial or private insurance who desire sterilization are not mandated to follow the same consent rules. Revision of the federal consent mandate in order to create fair and equitable access to sterilization services for women enrolled in Medicaid or covered by other government insurance would improve access. These revisions can be balanced by educating patients and obtaining informed consent to address concerns of coercion (41).

Highly effective LARC methods are underutilized, and promoting affordable access to LARC methods for current low-use populations, including adolescents and nulliparous women, may help reduce unintended pregnancy (37). In addition to the high up-front costs associated with these methods, another common barrier is inadequate reimbursement for LARC devices in certain settings. Providing effective contraception postpartum and postabortion can be ideal because the patient is often highly motivated to avoid pregnancy, is within the health care system, and is not pregnant. Appropriate reimbursement for LARC methods immediately postpartum or postabortion can be difficult to obtain.

Health Care Inequities

Rates of adverse reproductive health outcomes are higher among low-income and minority women. Unintended pregnancy rates are highest among those least able to afford contraception and have increased substantially over the past decade (5). The unintended pregnancy rate for poor women is more than five times the rate for women in the highest income bracket (5). Low-income minority women have higher rates of nonuse of contraceptives and are more likely to use less effective reversible methods such as condoms (42). Additionally, low-income women face health system barriers to contraceptive access because they are more likely to be uninsured, a major risk factor for nonuse of prescription contraceptives (42). Publicly funded programs that support family planning services, including Title X and Medicaid, are increasingly underfunded and cannot bridge the gap in access for vulnerable women. To address these barriers, the ACA has encouraged states to expand Medicaid eligibility for family planning services to greater numbers of low-income women. Also, in states that choose to expand Medicaid under the ACA, fewer poor women will lose Medicaid eligibility postpartum.

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ACOG

The American College of
Obstetricians and Gynecologists
Wisconsin Section

To: Assembly Committee on Health
From: American College of Obstetricians and Gynecologists – Wisconsin Section
Sheldon A. Wasserman, MD, FACOG, Chair
Date: August 14, 2019
Re: Statement on Assembly Bill 304 - For Information

Sheldon Wasserman, MD, FACOG

Nearly all U.S. women who have ever had sexual intercourse have used some form of contraception at some point during their reproductive lives. However, multiple barriers prevent women from obtaining contraceptives, or using them effectively and consistently. All women should have unhindered and affordable access to all U.S. Food and Drug Administration-approved contraceptives. This is why the American College of Obstetricians and Gynecologists (ACOG) has long supported over-the-counter access to oral contraceptives. Only the U.S. Food and Drug Administration can confer over-the-counter status. Over-the-counter status would help more women benefit from the ability to control their own reproductive health, and decades of use have proven that oral contraceptives are safe for the vast majority of women.

Behind-the-counter access is different than over-the-counter access. Pharmacist prescribing replaces one barrier — a physician's prescription — with another. We know from evidence and experience that oral contraceptives are safe enough for over-the-counter access. We respectfully request the committee consider the following:

- Sunset the pharmacist gatekeeper role so it is in place if and when the FDA confers over-the-counter status for hormonal contraceptives;
- Require pharmacies to display signs in stores and on websites indicating on-site, behind-the-counter availability of contraceptives. Optimally this would be uniform and the Pharmacy Examining Board would establish the content. The Board should also track, monitor and report on availability of over-the-counter contraceptives.
- Eliminate age restrictions and required proof of a prior prescription or doctor visit;
- Add protections to avoid new out-of-pocket costs and to ensure that contraceptives dispensed by pharmacists are covered by insurance.

Facts are important when discussing healthcare. Understanding the difference between a contraceptive and an abortifacient requires an understanding of the biological processes leading to pregnancy and how various forms of contraception work to prevent pregnancy. Lack of knowledge, misperceptions, and exaggerated concerns about the safety of contraceptive methods are major barriers to contraceptive use. For example, many individuals have unfounded concerns that oral contraceptives are linked to major health problems or that IUDs carry a high risk of infection. Many individuals also incorrectly believe certain types of contraception to be abortifacients. Contrary to recent assertions made by some, no FDA-approved contraceptive methods are abortifacients because they do not interfere with a pregnancy and are not effective after a fertilized egg has implanted successfully in the uterus.

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. Universal coverage of contraceptives is cost effective and reduces unintended pregnancy and abortion rates. 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. The most effective way to reduce abortion rates is to prevent unintended pregnancy by improving access to consistent, effective, and affordable contraception.

Wisconsin Association of Health Plans

The Voice of Wisconsin's Community-Based Health Plans

From: Tim Lundquist, Wisconsin Association of Health Plans
To: Members, Assembly Committee on Health
Re: Assembly Bill 304
Date: August 14, 2019

Wisconsin's community-based health plans are committed to providing members access to high-quality health care, including access to FDA-approved contraceptive options.

Under federal law, health insurance providers are required to cover, without cost sharing, each of the FDA-approved methods of birth control. State law also requires health insurers provide coverage of contraceptives prescribed by a health care provider, defined under Wis. Stat. 146.81(1) to include pharmacists.

The Wisconsin Association of Health Plans appreciates the underlying goal of Assembly Bill 304, but the bill as drafted raises several questions:

1. Will pharmacists be required to complete any additional training related to the administration of the self-assessment and prescribing of the hormonal contraceptive patch or self-administered oral contraceptives?
2. What type of education will pharmacists provide to patients as they prescribe these birth control options? Will patients be encouraged to seek additional preventive health care services of the type often provided by their physician?
3. Coverage today for prescription contraceptives includes payment for the drug and dispensing fees. What are the authors expectations for insurance coverage of contraceptives prescribed by a pharmacist? Will coverage provisions be the same as coverage when prescribed by a physician or will be there new reimbursement requirements?
4. If a patient seeks contraceptives at an out-of-network pharmacy, will the pharmacist be required to refer the patient to an in-network pharmacy to ensure insurance coverage?

Wisconsin's community-based health plans appreciate the opportunity to learn more about these issues and look forward to working with the bill authors and Committee members to address any outstanding concerns.