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May 2023

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D'Youville School of Pharmacy



E-Board Members (From Left to Right): Elizabeth Bradley (Vice President), Benjamin Cresanti (President), Nicholas Steele (President Elect), Nicholas Rapini (Treasurer/Event Organizer), Emily Ganeshan (Secretary)

D'Youville School of Pharmacy: ACCP Chapter Synopsis

The goal of our chapter has always been to increase and foster interest in the field of clinical pharmacy. We have provided our members with information and resources regarding residencies and research. We have offered the opportunity to participate in clinical research competitions and collaborated with other organizations within our School. As the profession of pharmacy is ever changing and ever adapting, so is the atmosphere in which we learn. Through the adoption of an online pharmacy program through D'Youville University and our desire to do more, we are moving to merge with the School's SSHP chapter. This will allow us to work toward larger goals for the benefit of our students and our community. With the addition of the online program, we are also working to encourage online student involvement in the organization. This change is being brought about with the hope of improving our club's interest and impact within the School of Pharmacy. Our chapter will continue to promote the core values of ACCP as we move forward. Working with our current and new members to learn more about clinical pharmacy, research, residency, and publications is our goal for the future. We look forward to seeing what the future holds for this chapter and the School of Pharmacy at D'Youville University.

Benjamin Cresanti, PharmD Candidate Class of 2024 Nicholas Steele, PharmD Candidate Class of 2025

A Brief History of Contraception

Contraception has been used in various forms throughout history, dating back to ancient times. Methods included the use of herbs, animal bladders as condoms, spermicides and barrier devices. Historically, spermicides were made of honey, rock salt, acacia or crocodile dung. Sponges were made of moss, bamboo, or grass. Vaginal douches or sponges soaked in lemon juice, vinegar or cedar oil were used.1 These substances were utilized because they were believed to slow or weaken sperm. There were also oral contraceptives, including Queen Anne's lace seeds, lead and other toxic metals, pomegranate seeds, silphium, unripe papaya, and blue cohosh.¹ Herbs were problematic because many were toxic and lead to poisoning. It wasn't until the 20th century that the modern era of contraception began.

In 1930, the first oral contraceptive was developed by Dr. Gregory Pincus and Margaret Sanger, which contained synthetic estrogen and progestin.1 It was not until the 1960s that the U.S. Food and Drug Administration (FDA) approved Enovid, the first birth control pill for use as a contraceptive.² This medication contained higher doses of hormones than today's contraceptives, which increased the likelihood and severity of side-effects. In 1962, The Lippes Loop enters the market as the first IUD available in the United States.³

In 1965, the Supreme Court decision in Griswold v. Connecticut struck down state laws banning contraception, paving the way for greater access to birth control for all women.⁴ In the 1970s, safer medical procedures became available allowing for shorter recovery times as well. This led many women to consider tubal ligation as a permanent form of birth control.

In 1976, the FDA approved the first vaginal contraceptive ring, which released hormones to prevent pregnancy. In 1983, the first progestin-only pill, also known as the mini-pill, was approved. In 1990, the FDA approved the first hormonal implant, which provided long-term contraception. Then, in 1999, Plan B, the widely known emergency contraceptive pill, was approved by the FDA.

In 2000, the FDA approved the first intrauterine device (IUD) containing hormones. In 2001, a silicone ring called NuvaRing was approved for insertion into the vagina. In 2002, Ortho Evra was the first birth control patch approved by the FDA.⁵ In 2006, the FDA approved Implanon, a single, thin, plastic, etonogestrel-releasing rod.⁶ Following the advances in smartphones, a contraceptive app was approved by the FDA in 2018.⁷

Throughout history, access to contraception has been closely tied to political and social changes. Today, contraception is widely available and considered a basic healthcare necessity for women. However, access to contraception is still a contentious issue in many parts of the world, and legislative changes can have a significant impact on access to and affordability of different methods.

In the US, there are two main barriers to the accessibility to birth control: the need for a prescription and the out-of-pocket cost, since insurance coverage of birth control is not guaranteed in all states.⁸ We hope that this brief overview has provided some insight into the long and complex history of contraception.

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Christiana Vazquez Rivera, PharmD Candidate Class of 2025

Overview of Different Oral Contraceptives

Contraceptives can be used to help females who are sexually active plan when they wish to conceive.¹ Other uses of contraceptives include acne alleviation and menstrual and hormonal regulation. There are various forms of contraceptives available, such as pills, patches, injections, and intrauterine devices (IUDs). Oral forms of contraceptives typically utilize hormones to achieve their desired effects. The two major hormones involved are estrogen and progesterone. Progestin is the synthetic form of progesterone, which is naturally found in the female body to regulate menstruation and pregnancy.

Progestin-only pills and estrogen-progesterone combination products work by thickening the cervical mucus, which makes it more difficult for sperm to penetrate the egg.^{2,3} Contraceptives that contain only progestin allow for changes of the endometrial lining, which reduces the chances of fertilized egg implantation into the uterus.³ Combination contraceptives work by inhibiting ovulation through suppression of luteinizing hormone (LH) release from the pituitary gland.⁴ A study found that progestin-only contraceptives had a success rate of 91% within the first year of use, while combination contraceptives had a success rate of 99%.⁵ Estrogen-containing products have been associated with more side effects, such as breakthrough bleeding, changes in menstrual cycles, and dermatological reactions.⁶ Some major adverse reactions to estrogen include breast tenderness, nausea, vomiting, stomach pain, headaches, weight gain, hyperpigmentation oft eh skin, hair loss, vaginal itching and bleeding and sometimes anaphylactic reactions can occur.⁷ When choosing a method of contraception, it is important to note the efficacy and hormone composition of the varying options.⁴ Even though progestin-only forms of contraception are less efficacious than combination products, they are considered to be safe and effective

during breastfeeding, whereas estrogen-containing products are not recommended. In addition, the side effect profile tends to be less, and there are less drug interactions with progestin-only contraceptives. In certain patient populations, such as individuals with a history of blood clots, stroke, liver disease, or certain types of migraines, estrogen-containing products are not recommended.⁴ In addition to oral medications, there are other dosage forms used for contraception. A few examples include vaginal rings, transdermal patches, and depo injections. These have all shown varying degrees of efficacy (vaginal rings: 96%, transdermal patch: 99%, depo injections: 98%).6 Ultimately, when considering contraception, it is important for the patient to contact their primary care provider, gynecologist, dermatologist, etc. in order to assess the risks and benefits of all options available.

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Kara Mendola, PharmD Candidate Class of 2026 Stefan Seroul, PharmD Candidate Class of 2026

Overview of Different Contraceptive Methods

Many elements need to be considered when choosing the most appropriate contraceptive method, such as safety, effectiveness, availability (including accessibility and affordability), and acceptability. Reversible methods of birth control fall into 3 categories: intrauterine devices (IUDs), hormonal methods, and barrier methods. Intrauterine contraception includes the levonorgestrel IUD system (LNG IUD) and the copper T IUD device. Hormonal methods include implants, injections, combination oral pills or progestin-only pills, a patch, and a vaginal ring. Barrier methods include a diaphragm or cervical cap, a male condom, and a female condom. Each contraceptive device has its own benefits and drawbacks.¹

<u>Contraceptive</u> Device ^{1, 2, 3}	Description	Pros	Cons
Copper T intrauterine device (IUD)	Placed inside the uterus by a doctor; it slowly releases copper into the uterus	 non-hormonal, so no hormonal side effects contraceptive effects begin immediately after placement may stay in uterus for up to 10 years can be taken out at any time by a doctor and fertility returns immediately safe to use while breastfeeding failure rate is only 0.8% 	 menstrual cycle can be heavier, longer, or more painful for 3-6 months after placement does not protect against sexually transmitted infections (STIs)
Levonorgestrel intrauterine device (LNG IUD)	Placed inside the uterus by a doctor; it releases the hormone progestin	 may stay in uterus for up to 3-8 years, depending on device can be taken out at any time by a doctor and fertility returns immediately may make menstrual cycle lighter, shorter, or even stop safe to use while breastfeeding failure rate is only 0.1-0.4% 	 hormonal side effects, such as mood swings, acne, and breast tenderness, are possible can take up to 7 days for contraceptive effects to begin does not protect against STIs
Implant	Placed under the skin in the upper arm by a doctor; it releases the hormone progestin	 effective for up to 3 years can be taken out at any time by a doctor and fertility returns immediately safe to use while breastfeeding failure rate is only 0.1% 	 hormonal side effects, such as mood swings, acne, and breast tenderness, are possible initial localized bruising, swelling, or tenderness after implantation can take up to 7 days for contraceptive effects to begin menstrual cycle can be irregular, lighter, heavier, longer, or even stop drug interactions may decrease its efficacy does not protect against STIs
Injection	Injected into the muscle in the upper arm or buttocks; it releases the hormone progestin	 effective for up to 12 weeks safe to use while breastfeeding failure rate is only 4% 	 hormonal side effects, such as mood swings, acne, and breast tenderness, are possible weight gain is a common adverse effect can take up to 7 days for contraceptive effects to begin menstrual cycle can be irregular, lighter, heavier, longer, or even stop can take up to 1 year for fertility to return after your last injection, as well as for any side effects to subside does not protect against STIs
Oral Pill	Taken by mouth; may contain progestin alone or a combination of estrogen and progestin	 ease of administration (non-invasive) may help with heavy or painful menstrual cycles may reduce risk of cancer of the ovaries, uterus, and colon may protect against pelvic inflammatory disease (PID) safe to use while breastfeeding 	 the combined pill is not suitable for individuals 35 years and older who also smoke adherence (daily administration) hormonal side effects, such as mood swings, acne, and breast tenderness, are possible can take up to 7 days for contraceptive effects to begin drug interactions may decrease its efficacy failure rate can be up to 7% does not protect against STIs



Patch	Placed on the upper body (but not the breasts), lower abdomen, or buttocks; it releases the hormones estrogen and progestin	 ease of administration (non-invasive) replaced once weekly may make menstrual cycle more regular, lighter, and less painful may reduce risk of cancer of the ovaries, uterus, and colon safe to use while breastfeeding 	 not suitable for individuals 35 years and older who also smoke or those who weigh 90 kg or more hormonal side effects, such as mood swings, acne, and breast tenderness, are possible skin irritation at the site of placement is common can take up to 7 days for contraceptive effects to begin drug interactions may decrease its efficacy failure rate can be up to 7% does not protect against STIs
Vaginal Ring	Self-inserted into the vagina; it releases the hormones estrogen and progestin	 less invasive than an IUD, implant, or injection replaced monthly usually makes menstrual cycle more regular, lighter, and less painful 	 hormonal side effects, such as mood swings, acne, and breast tenderness, are possible can take up to 7 days for contraceptive effects to begin can take up to a few months for fertility to return after removal drug interactions may decrease its efficacy failure rate can be up to 7% does not protect against STIs
Diaphragm	Self-inserted into the vagina; used with spermicide before intercourse to cover the cervix	 ease of use (can be inserted at any convenient time before sex but within 3 hours preferably) no serious health risks or hormonal side effects 	 must be sized correctly for it to be effective must be left in place for 6 hours after intercourse[Text Wrapping Break]-spermicide must be reapplied if it's been in place for 3 hours or more before intercourse may have a higher risk of bladder infections failure rate can be up to 17% does not protect against STIs
Male/Female Condom	Worn by a man/woman; it prevents sperm from getting into the body	 available over-the-counter (OTC) at most drug stores, so you don't need a prescription ease of use (only used during sex; female version can be inserted up to 8 hours before sex for convenience) latex and synthetic versions available (male version) helps protect against STIs low risk of side effects associated with their use 	 may "interrupt" intercourse or alter the perceived pleasure may slip or tear if not used properly, causing failure of the contraceptive method may cause allergic reaction due to latex component (for certain male products) not as widely available as male condoms and may be more expensive (female version) failure rate can be up to 13% for male version and 21% for female version

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Nicholas Steele, PharmD Candidate Class of 2025 Elizabeth Bradley, PharmD Candidate Class of 2025

Nextstellis[®]: A New Contraceptive on the Market

Labeled Indications:

Nextstellis[®] (drospirenone/estetrol) is a combination oral contraceptive product that was FDA approved in April 2021 for use by females of reproductive age.¹ The product contains drospirenone, which is a progestin, and estetrol (E4), which is an estrogen and a synthetic analog of the naturally hormone produced by the human fetal liver.²

Dosing:

Nextstellis[®] is available as a blister card, which contains 24 pink-colored active tablets (each containing 2 mg of drospirenone and 14.2 mg of estetrol) and 4 white-colored inactive tablets. The recommended dose of Nextstellis is 1 tablet daily for 28 consecutive days. The first 24 days should consist of the active tablets, and the final 4 days consist of the inactive tablets.¹

Warnings, Precautions, and Drug Interactions:

Nextstellis[®] is not recommended for use in patients with thromboembolic disorders. Patients with cardiovascular risk factors should be evaluated before the initiation of this medication.¹ As stated in the FDA boxed warning, females over 35 years old who smoke cigarettes are at significantly higher risk for serious cardiovascular events. It is not to be used in patients with hyperkalemia. A baseline basic metabolic panel should be conducted during the first treatment cycle for patients at risk of hyperkalemia. This medication may increase the patient's blood pressure, so this should be monitored periodically. Patients with hormone-sensitive malignancies, cholestasis or, liver disease should not be on this medication. Concomitant use of CYP3A inducers increase the risk of contraceptive failure and breakthrough bleeding. If concomitant use is unavoidable, patients should use a backup method of contraception during co-administration and for 28 days after discontinuation of the CYP3A inducer.¹

Uses in Specific Populations:

<u>Obesity:</u> Nextstellis has been proven to be less effective in obese females (Body Mass Index [BMI] >30 kg/m^2).¹

<u>Lactation</u>: Mothers should use an alternative contraceptive while nursing, as Nextstellis[®] can cause a decrease in total milk production.¹

Pregnancy: Discontinue Nextstellis®1

Clinical Trials:

Pooled results of Phase 2 clinical trials comparing Nextrellis[®] to two common birth control products, Yaz[®] and Nordette[®], in 681 participants concluded that Nextstellis[®] was 98% effective in preventing pregnancy and had slightly less efficacy in those with a BMI of 30 or greater.¹ The trial also depicted that bleeding patterns were similar to a natural, predictable menstrual cycle and that unscheduled spotting or bleeding was minimal. The safety and tolerability of Nextrellis[®] was studied in a pooled analysis of data from two multi-center, phase 3 clinical trials.² This study analyzed data from a total of 3725 premenopausal participants 16-50 years old with a BMI of \leq 35 kg/m² and other relevant inclusion criteria. The most common treatment related adverse events observed was bleeding complaints (9.5%), breast pain or tenderness (4%), acne (3.3%), and mood disorders (3.2%). The most common adverse event leading to discontinuation of the medication was bleeding complaints (2.8%).² The investigators concluded that Nextstellis[®] had a favorable safety profile.

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Nicholas Rapini, PharmD Candidate Class of 2025 Emily Ganeshan, PharmD Candidate Class of 2025

New Legislation in NYS Regarding Contraceptives

Healthcare disparities have affected communities throughout the United States for as long as healthcare has existed. These underserved patients have historically experienced difficulties in obtaining self-administered hormonal contraceptives. In New York State (NYS), several legislative updates have impacted the availability of hormonal contraceptives, including pills, intrauterine devices (IUDs), and many other available forms.

A new Bill, S10143A, which is endorsed by Governor Kathy Hochul, grants the ability for pharmacists to prescribe contraceptives under a non-patient specific order written by a licensed physician, certified nurse practitioner, or the New York State Commissioner of Health, which will significantly increase access to contraceptives across the state.¹

The new Bill is currently moving through the legislative process and is now awaiting the Governor's signature.¹ Under this law (currently, Bill S1043A), pharmacists will be allowed to prescribe and dispense oral contraceptives, patches, and rings to patients 18 years or older, with a few stipulations. Before providing a contraceptive to a patient, and at a minimum of every 12 months for each returning patient, the pharmacist shall provide the patient with a self-screening questionnaire developed by the Commissioner of Health. In addition, the pharmacist must provide the patient with a fact sheet developed by the Commissioner of Health, which must include clinical considerations and recommendations. Lastly, the pharmacist must notify the patient's primary care provider (PCP), unless the patient opts out of such

notification within seventy-two hours or does not have a PCP.¹ States may require pharmacists to undergo additional training as well, but no such protocols have been released at this time.

This Bill will benefit patients who live in underserved areas with limited access to healthcare, those who have difficulty scheduling and/or attending appointments, or those who have any other barriers to access. Pharmacists can provide these patients with quick and convenient access to contraceptives. There has already been an exponential success in states that have implemented similar bills. For example, Oregon, which became the first state to pass legislation allowing pharmacist to prescribe birth control in 2016, has experienced a 1.6-million-dollar reduction in public cost related to medical care associated with poor maternal and infant outcomes.² This example illustrates the significant benefits this bill will have in the NYS healthcare system.

At the time of writing, pharmacists have not yet been granted prescribing power, as the Bill still needs to be reviewed and signed into law by the Governor.

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Ricardo Gonzalez Ramirez, PharmD Candidate Class of 2025

Clinical Faculty Spotlight: Dr. Talisa Marchese, PharmD, BCPS, BCPP

Clinical Associate Professor at D'Youville School of Pharmacy & Psychiatric Pharmacist

Please describe the path that led you to where you are today.

"I completed my undergraduate degree in biology and psychology. I always had an interest in pursuing a health profession with special interest in psychology. It was in my undergraduate years that a professor of mine suggested pursuing a career in academia and clinical work at the same time. Taking this to heart, I attended Lake Erie College of Osteopathic Medicine (LECOM) for three years to obtain a Doctor of Pharmacy (PharmD) degree. Then, I completed a PGY1 residency in Tallahassee, FL. I began working at D'Youville University in 2015, and my clinical practice site is Erie County Medical Center (ECMC). This has been a rewarding job as there is a large psychiatric population at ECMC to work with and each patient case is unique."

What are your current roles and responsibilities?

"I am a Clinical Associate Professor at the D'Youville School of Pharmacy, and I am a Psychiatric Pharmacist at ECMC."



What advice do you have for current pharmacy students interested in pursuing a career in academia?

"Get involved early! It is important to get involved in every aspect of pharmacy while in school. Getting involved in local clubs, as well as regional organizations, can help benefit a student. It is also important to get involved in student positions on faculty committees to learn what the faculty does behind the scenes. As students, you cannot fully understand what tasks and responsibilities are performed by professors, and thus, it is important to get as much exposure as possible. I also recommended that students pursuing a career in academia find a faculty mentor to speak with that can help guide them toward their career goals."

How do you keep up with the latest findings and advancements in clinical pharmacy?

"If you stay active and go to CE events, it is easy to stay caught up. For example, I am a member of the Western New York Society of Health-System Pharmacists (WNYSHP), and I go to monthly events to keep up to date. In addition, I am required to complete CE hours as part of my board certifications. I treat this as an opportunity to learn rather than a requirement because it helps keep me up to date on current therapies. Being a psychiatric pharmacist, I attend a psychiatric conference every year through the *American Association of Psychiatric Pharmacy*. Through this conference, I have been able to remain current on updates in psychiatric medicine and practices."

What do you enjoy most about your role in pharmacy?

"I enjoy seeing students achieving learning outcomes. Being able to watch P1 students in the Self Care Therapeutics (Non-Prescription Medications) course who are just learning about clinical decision making progress to Advanced Pharmacy Practice Experiences (APPEs) where they put everything together is a wonderful experience as a faculty member. I also enjoy my role at ECMC, since the patient population I get to work with is vulnerable, and it is self-fulfilling to contribute to these patients that may otherwise fall through the cracks of the healthcare system. Working with students at ECMC is a worthwhile experience because psychiatric medicine is a continuously changing field of pharmacy."

What do you enjoy doing outside of pharmacy?

"Outside of pharmacy, I enjoy walking with my rescue Pitbull, named Faith, as well as spending time with family. As an avid Buffalo Bills fan, I choose to spend many fall days and nights attending football games."

Interviewed by Benjamin Cresanti, PharmD Candidate Class of 2024

A special thanks to: D'Youville School of Pharmacy—Student ACCP Chapter; Dr. Mario V. Beccari and Dr. Adinoyi O. Garba (ACCP Faculty Liaisons/Editors)