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Signature Wellness
DR. ARNOLD'S OFFICE

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THE SIGNATURE WELLNESS WEEKLY

Compounding, Safety and Perimenopause

Where you get a medication matters.

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FROM THE PRACTICE

Compounded Hormones and How They Are Regulated

You may have heard that if you're considering hormone therapy, you should only use a Health Canada-approved medication. A commercially available product can be an excellent choice. But what happens when the dose that helps you isn't available, or when the formulation that's available causes side effects you can't tolerate?

I saw this early in my practice. Some women felt better on hormone therapy but had side effects at the doses I could prescribe commercially. Others needed a strength that simply wasn't available. A compounding pharmacist could prepare a prescription at the strength I wanted the patient to try. Over the years, I've seen how much that flexibility can matter for both women and men.

Two claims come up repeatedly in this discussion. The first is that compounding pharmacies are unregulated. The second is that compounded medications aren't Health Canada approved. They raise two different questions, and both deserve a closer look.

1. Who regulates compounding pharmacies in Ontario?

The Ontario College of Pharmacists accredits pharmacies and assesses how they operate. Ontario pharmacies that compound medications must follow the compounding standards adopted by the College. So what does the College actually look for when a pharmacy makes you a hormone cream or capsule?

Ontario College of Pharmacists accreditation requirements · Non-sterile compounding assessment criteria

For a **non-sterile preparation**, such as a hormone cream or capsule, the pharmacy must assess the risks of the ingredients and the work involved. That assessment determines what space, equipment and protective measures are needed. The College even uses a progesterone suppository as an example of how to document that assessment. The pharmacy must have a written formula and keep a record of what went into the preparation, including the ingredient lot numbers, the amounts weighed and who checked it. It must also assign a date after which the preparation should no longer be used.

Ontario College of Pharmacists risk assessment guidance · Non-sterile compounding assessment criteria

For a **sterile preparation**, such as an injection, the requirements are more extensive. The pharmacy needs a controlled environment, and staff must demonstrate that they can prepare the medication using techniques that prevent contamination. The College's sterile assessment criteria call for staff competency reassessments at least annually for low- and medium-risk preparations and at least twice a year for high-risk preparations. The College's own routine pharmacy assessments follow a separate, risk-based schedule.

Sterile compounding assessment criteria · Ontario College of Pharmacists assessment schedule

When someone suggests that a compounded prescription could be made in anyone's kitchen, this is the part of the story they're leaving out. An Ontario pharmacy needs accreditation to operate, and the College can assess the facility, the people doing the work and the records they keep.

Ontario College of Pharmacists accreditation requirements

2. What does "Health Canada approved" actually mean?

When Health Canada authorizes a manufactured medication for sale, the authorization applies to the **finished drug product**. A custom prescription prepared by a pharmacist doesn't receive its own Health Canada authorization. Health Canada addresses that kind of prescription in its policy on manufacturing and compounding, known as **POL-0051**. The policy recognizes a role for compounding when a patient has a therapeutic need or a suitable product is unavailable. It also says compounding should provide a customized solution and should generally avoid duplicating an approved product.

Health Canada's compounding policy

There are rules about ingredients, too. Health Canada's policy says the starting point should be an authorized drug or an active ingredient that is either used in a drug authorized in Canada or listed in a recognized pharmacopoeia, a reference that sets pharmaceutical quality standards. That's one reason the word *compounded* tells you very little about a peptide sold online. Health Canada has warned that activities involving unauthorized peptide ingredients can fall outside legitimate compounding and be subject to federal enforcement.

Health Canada's compounding policy · Health Canada's peptide regulations and enforcement

DHEA is a useful example. Health Canada identifies DHEA, also called prasterone, as a controlled substance and has warned about its sale as an unauthorized over-the-counter supplement. Canada has also authorized a specific prescription prasterone product, a 6.5 mg vaginal insert. A pharmacist can compound DHEA for an individual patient when there is a therapeutic need for a custom preparation and the prescription, sourcing and controlled-substance requirements are met. A custom DHEA prescription is prepared under the compounding framework.

Health Canada's DHEA advisory · Health Canada's controlled-substance rules

When I discuss a compounded hormone prescription with a patient, I start with one question.

> ***What would this custom prescription allow us to do that the available products can't?***

If you're offered a compounded prescription, ask what specific issue it's meant to solve, what evidence supports that use and how you and your prescriber will tell whether it's helping. If you'd like to check the pharmacy's accreditation, you can look it up in the College's public register.

Ontario College of Pharmacists public register guide

HEALTH CANADA ADVISORY

Health Canada Found Bacteria in Unauthorized Injectable Peptides

Earlier in this issue, I walked through what an Ontario pharmacy must do to prepare a sterile prescription. Two recent Health Canada advisories show why those requirements matter.

On **November 6**, Health Canada reported that laboratory testing found bacteria in unauthorized injectable products sold online. The agency seized more than 11,400 vials from a supplier and two Canadian online retailers. The advisory lists products labelled as retatrutide, tirzepatide and hCG, among others. On **November 12**, Health Canada issued a second advisory after finding bacteria in an injectable peptide product seized from an Ottawa wellness retailer that had been selling unauthorized peptides in-store and online.

What can a label really tell you?

I've written before about retatrutide being sold online and the confidence people place in a seller's "certificate of analysis." The name on the vial is the seller's claim about what's inside. A certificate posted on a website should never be taken as proof that the vial in your hands contains the stated ingredient at the stated strength or that it's sterile. Some of the products Health Canada seized carried a "For Research Purposes Only" label. That phrase signals that the product is intended for laboratory use.

Injecting a contaminated product can cause a serious infection, require hospitalization and, in severe cases, lead to life-threatening sepsis. Health Canada also warns that unauthorized products can contain the wrong amount of an ingredient or contain substances missing from the label.

Where you get a medication matters

When I prescribe a sterile compounded medication for a patient, an accredited pharmacy prepares it under standards that cover the facility, staff training and preparation records. The pharmacist is accountable for how it is prepared and dispensed, and I'm responsible for deciding whether it's appropriate for the patient and following up. For the products identified in these advisories, Health Canada found unauthorized sales and confirmed contamination through laboratory testing.

> **What should you do?** Health Canada advises against buying or using unauthorized peptide products. If you've injected one and feel unwell or develop fever, chills, redness, pain or swelling at the injection site, **seek immediate medical attention**. Obtain prescription medications through a licensed pharmacy under the care of a qualified prescriber.

Want to know more? Read Health Canada's November 6 advisory on products sold online and its November 12 advisory on products sold by the Ottawa retailer.

That brings me to perimenopause. A recent CNN article describes why so many women struggle to get help, and a patient I saw this fall illustrates where individualized care and a regulated compounding pharmacy can fit.

WOMEN'S HEALTH

Perimenopause Is Finally Getting Attention. Are Women Getting the Help They Need?

I was glad to see CNN give perimenopause some attention this week. For years, I've listened to women describe changes in their sleep, periods, mood and concentration, only to tell me they'd already asked for help and come away feeling dismissed. By the time they sit down with me, many are wondering whether anyone will take the time to put the pieces together.

In her November 16 article, CNN's Amanda Schupak tells the story of Tamsen Fadal, an experienced news anchor who suddenly felt overheated and faint during a live broadcast. In the months leading up to that evening, she had been sleeping poorly, struggling with scripts she once would have handled easily, and dealing with unusually heavy periods. It took several appointments before someone identified the menopause transition. CNN also notes that nearly three in four women aged 45 to 54 in a Gallup survey reported symptoms of menopause or perimenopause, and only a little over half of those with symptoms reported receiving a diagnosis.

How much menopause training does a gynaecologist get?

It takes five years of specialty training in Canada to become an obstetrician-gynaecologist. How much of that time would you expect us to spend learning to care for women through the menopause transition and the decades that follow?

Training varies by program. A 2023 survey of U.S. obstetrics and gynaecology residency program directors found that only about one in three respondents reported having a menopause curriculum. My own training, many years ago, gave me a simple framework. If a woman was still having periods and needed hormonal treatment, consider the birth control pill. If she was menopausal, consider hormone replacement therapy.

I remember a conversation I had with an Ob/Gyn resident in their final year of training who was assisting me at a Cesarean section a couple of years ago. We got on to the topic of menopause care and he mentioned that he was doing an elective in Menopause care because throughout his almost 5 years of training, he had received about 2 weeks of education regarding menopause. 2 weeks! to learn about the time period women will spend almost half of their life in. 2 weeks out of 260 weeks of training, less than 1% of his time. And perimenopause? Even less. No wonder women are searching for care.

Almost all of my training in menopause and perimenopause came after my residency training, through additional education I sought out myself, along with years of looking after women in this stage of life.

Why the dose matters

Perimenopause can unfold over several years. Ovulation becomes less predictable, progesterone production varies, and estrogen can swing from high to low. A woman can still be having periods and experience night sweats, disrupted sleep or difficulty concentrating at work. For most women over 45 with a typical pattern, and some women in their 30's, the history and changes in their cycles are more informative than a single hormone measurement. Heavy bleeding, persistent fatigue or new mood symptoms may also need their own assessment.

Some women I see have already tried a birth control pill, an antidepressant or several supplements, with little relief or side effects they found hard to live with. I want to hear what changed first, what has already been tried and what is getting in the way of daily life. That conversation helps us decide whether hormonal treatment makes sense, what else may need attention and how we'll judge whether the plan is helping.

Some women in my practice have done well with very small doses. Too much of a hormone can cause symptoms of its own. When I prescribe one, I consider the woman's symptoms, her stage of the transition, her medical history and how she tolerates treatment. Sometimes a commercially available product fits those needs. Sometimes the dose or formulation I'm looking for is available only through a compounding pharmacy.

Three months later, Wendy was back at the gym

Wendy, a name I've changed for privacy, came to see me in August. She was raising children, managing a household and working in a demanding executive role. Her symptoms were affecting her quality of life, and she was finding it harder to function at the level she was used to at work.

After a full assessment, we started a very low dose of compounded progesterone cream, addressed vitamin deficiencies and put together a plan for her weight concerns. At her first follow-up three months later, she told me she was "feeling really good." She was back at the gym and felt a significant improvement in her day-to-day life.

We addressed several things together, so there's no way to know how much of her improvement came from each change. That's one reason I value the follow-up visit. I want to know how the woman is actually doing.

Why I started this issue with compounding pharmacies

Wendy's story illustrates why I wanted to talk about compounding this week. For women and men alike, there are times when a prescription needs a strength or formulation that commercially available products don't offer. An Ontario compounding pharmacy can prepare a medication for a patient under provincial pharmacy standards. That care involves a prescriber who knows the patient, a pharmacist accountable for preparing and dispensing the medication, and follow-up to see how the patient is doing.

Earlier in this issue, I shared Health Canada's warnings about unauthorized injectables. On November 6, Health Canada reported bacterial contamination in products sold online. On November 12, it issued a separate warning after finding contamination in an injectable product seized from an Ottawa retailer. The way a medication is prescribed, prepared and supplied matters. Both advisories tell consumers to avoid the products identified and to seek immediate medical attention if they feel unwell after injecting them or develop fever, pain or swelling at the injection site.

Women deserve better care

Many of you tell me you hope I never retire. I have no plans to retire, but I do want more women to have access to this kind of care. That's why I started **Signature Wellness Institute**, where I train physicians and nurse practitioners in individualized hormone care. Our first fellow, also an obstetrician-gynaecologist, is already well into her year of training. I want more clinicians to have the time and training to listen carefully, assess the whole picture and work through treatment options with their patients.

If changes in your sleep, cycle, mood or concentration are starting to affect your life, write down what changed, when it started and what you've already tried. Bring that to your next visit and ask whether perimenopause could be part of the picture. If you or someone you know is still looking for help putting those pieces together, tell them about **Signature Wellness**.

Want to know more? Read Amanda Schupak's CNN article on perimenopause.

A question for readers

As I put the finishing touches on my Breast Cancer book, I'd like to hear from those of you who have lived through it.

> ***If you've faced a breast cancer diagnosis, what's one question you wish someone had helped you answer when you were making decisions about your care or your life after treatment?***

If you'd like to share it, just reply to this newsletter. Your question alone is enough.

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