

THE PEPTIDES REPORT: **PART 1**

Your Weekly Newsletter

by Dr. Nick Sieveking

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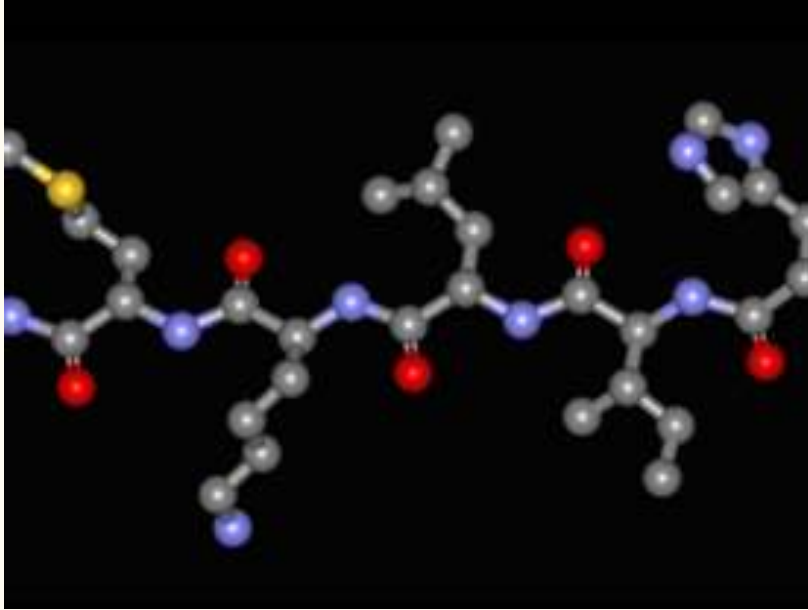
The Peptides Report - Part 1

Before we dive into the benefits, risks, and regulatory realities of peptide therapy, I want to share Part 2 of "The Facelift Journey - A Patient's Perspective", which focuses on the surgery phase. This video documentary aims to demystify the facelift experience and ease concerns about discomfort and recovery, helping patients understand that the process is often far more manageable than they anticipate with amazing, natural, and dreamed about results just weeks away. Click below to view the video:



What is a peptide?

In simple terms, a peptide is a short chain of amino acids—typically between 2 and 50—linked together by peptide bonds. As that chain length increases beyond ~50 amino acids, the molecule is more accurately referred to as a protein. In practice, however, the line is not rigid, and many biologically active “peptides” fall just above that threshold.



Examples of naturally occurring peptides:

- Insulin – 51 amino acids (technically a small protein), regulates blood glucose
- Vasopressin (ADH) – 9 amino acids, regulates water balance
- Glucagon – 29 amino acids, raises blood glucose
- Adrenocorticotrophic Hormone – 39 amino acids, stimulates cortisol production

These are not fringe molecules—they are core regulators of human physiology, underscoring how powerful peptide signaling can be when properly understood and applied.

Why the sudden surge in interest?

Over the past several years, peptides have moved from niche research tools to one of the most active areas in drug development and longevity medicine. Their ability to target specific receptors with precision, often with fewer systemic side effects than traditional small molecules, pharmaceuticals, and nutraceuticals, has made them highly attractive therapeutically.

By 2026, there are over 2,000 peptide-based compounds across the global development pipeline (from the discovery phase through late-stage clinical trials), according to GlobalData:

- ~624 in discovery
- ~1,069 in preclinical development
- 300+ in active clinical trials

Even more telling is the acceleration:

- 18 Phase I trials in 2023
- 72 in 2024
- 137 in 2025
- 300+ in 2026



That kind of growth doesn't happen by accident. It reflects a fundamental shift in how we approach disease treatment, recovery, and even optimization of human performance.

Bottom line:

Peptides are not new—but our ability to harness them clinically is advancing rapidly. As with any powerful tool, the opportunity is significant—but so are the risks, especially in an evolving regulatory landscape.

At-a-Glance Reference Table

Peptide	Class / Target	Regulatory Tier	Human Evidence	Primary Use
Tesamorelin	GHRH analog	FDA approved	Strong (RCTs)	HIV lipodystrophy; off-label visceral fat / GH support
PT-141 (Bremelanotide)	MC4R agonist	FDA approved	Strong (RCTs)	Premenopausal HSDD; off-label libido/ED
Afamelanotide (Scenesse)	MC1R agonist	FDA approved	Strong (RCTs)	Erythropoietic protoporphyria
Thymosin α -1 (Zadaxin)	TLR9 / T-cell modulator	FDA orphan-approved + Cat 2 (compounded)	Strong (RCTs, meta-analyses)	Chronic HBV, sepsis, immune reconstitution
Sermorelin	GHRH analog	Compoundable (formerly approved)	Moderate (pediatric)	Adult GH support, sleep
CJC-1295 ($\pm$ DAC)	GHRH analog, albumin-bound	Cat 2 (no July review)	Limited human PK data	Sustained GH/IGF-1 elevation
Ipamorelin	Selective GHS-R1a agonist	Cat 2 (no July review)	Limited (Phase I only)	GH support; pairs with CJC-1295
AOD-9604	hGH 176–191 fragment, β 3-AR pathway	Cat 2 (no July review)	Safety strong; efficacy mixed	Adipose-targeted fat loss
GHK-Cu (topical)	Copper tripeptide	Cat 1 path / under re-review	Strong topical / hair	Skin, hair, wound healing
GHK-Cu (injectable)	Copper tripeptide	Cat 2	Limited	Generally avoid
Kisspeptin	KISS1R, upstream of GnRH	Cat 2 / investigational	Limited (HA studies)	Hypothalamic amenorrhea
BPC-157	Multi-target tissue repair	Cat 2 (July 2026 review); WADA banned	Animal-dominant	Tendon/ligament/gut anecdotal
TB-500 (T β 4)	Actin-binding, angiogenic	Cat 2 (July 2026 review); WADA banned	Animal-dominant	Systemic recovery anecdotal
MOTS-c	Mitochondrial AMPK activator	Cat 2 (July 2026 review)	Limited	Metabolic, GLP-1 stacks
Epitalon	Pineal tetrapeptide / hTERT	Cat 2 (July 2026 review)	Mostly preclinical	Sleep, longevity research
KPV	α -MSH C-terminal, NF- κ B suppression	Cat 2 (July 2026 review)	Animal-dominant	IBD, gut & skin inflammation
Semax	ACTH(4-7) analog, BDNF/NGF	Cat 2 (July 2026 review)	Russian clinical data	Stroke recovery, cognition
LL-37 (Cathelicidin)	AMP, anti-biofilm, wound healing	Cat 2 (Feb 2027 review)	Mostly preclinical	Topical chronic wounds
Melanotan II	α -MSH (non-selective)	Cat 2	Harms documented	Avoid

Regulatory Update: Where Things Stand with the FDA (2026)

Peptide therapy is evolving quickly—but so is the regulatory landscape. In September 2023, the U.S. Food and Drug Administration reclassified approximately 17–19 commonly used peptides from Category 1 to Category 2 on the 503A compounding “bulks list,” effectively restricting their use in routine pharmacy compounding.

As of April 2026, the FDA announced that its Pharmacy Compounding Advisory Committee (PCAC) will reconvene July 23–24, 2026 to re-evaluate a subset of these peptides—including:

- Body Protection Compound
- TB-500
- MOTS-c
- Epitalon
- KPV
- Semax

- DSIP (Emideltide)

An additional group—GHK-Cu, Melanotan II, LL-37, Dihexa, and PEG-MGF—is expected to be reviewed before February 2027.

This ongoing review process—often informally referred to in clinical circles as a “reclassification”—will determine whether certain peptides may return to Category 1 status.

What Category 1 actually means

Category 1 designation does not equal FDA approval.

It simply means a 503A compounding pharmacy may prepare the peptide when prescribed by a licensed clinician, under federal and state compounding regulations.

How it compares

- Category 1: May be compounded (pending final evaluation)
- Category 2: Should not be compounded (safety/regulatory concerns)
- Category 3: Nominated but insufficient information (rarely used in practice)

Bottom line:

The regulatory environment for peptides is evolving. Access to many compounds is under active review, and future availability will depend on upcoming FDA determinations.

So how are these peptides currently accessed?

There is a regulatory gray zone centered around the “research use only” market:

- Labeled “not for human consumption”
- Sold by chemical suppliers rather than licensed pharmacies
- Intended legally for laboratory research—not patient care
- This structure allows vendors to avoid regulation as drug manufacturers

[Our Approach at The Clinic of Ageless Solutions:](#)

Given this landscape, safety and sourcing matter.

- We work exclusively with high-quality compounding pharmacies
- Every product is vetted for sterility, purity, and ingredient integrity
- We prioritize compounds that align with current regulatory guidance (FDA “green-lit” ingredients)

Patient safety matters

Peptides obtained from unregulated online sources carry real risks:

- Unknown purity
- Contamination
- Inaccurate dosing

Bottom line: where these compounds come from is just as important as the compounds themselves.

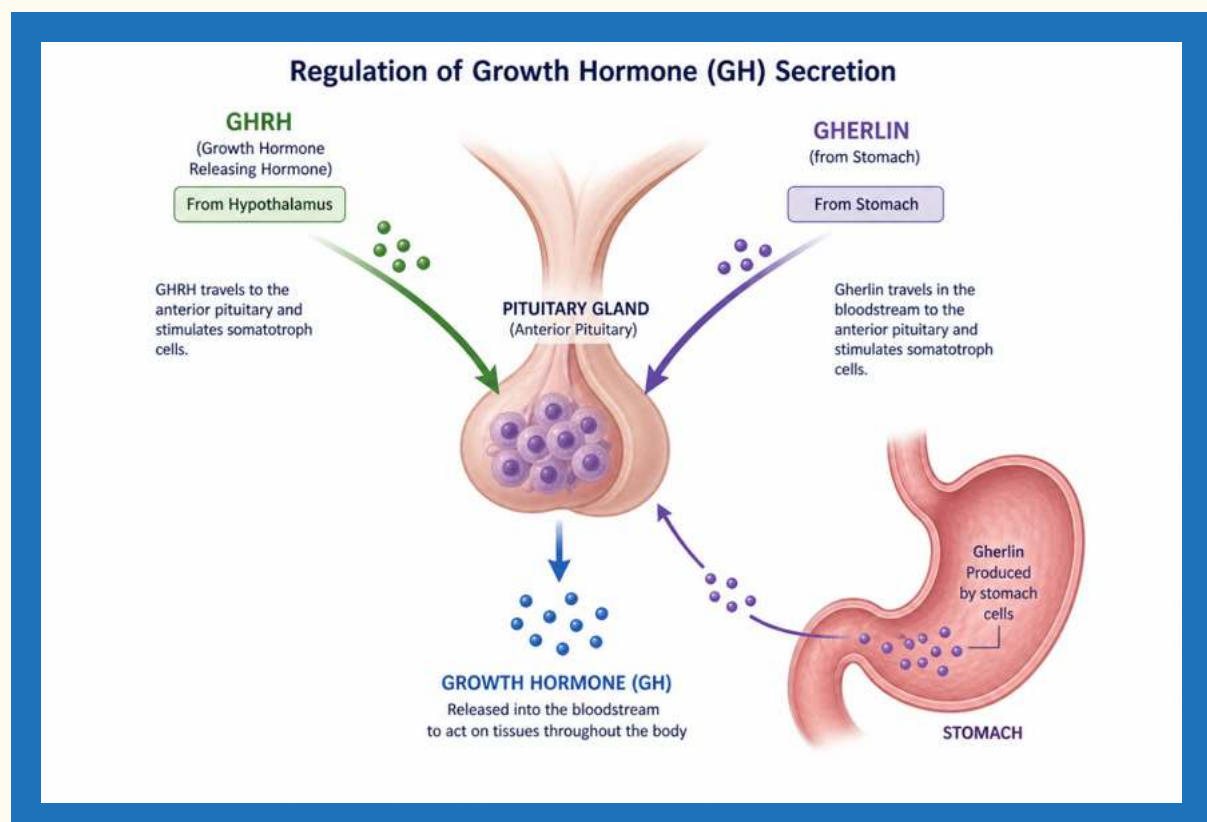
In the next 2 issues, we will review the most common Health and Longevity peptides that we prescribe at [*The Clinic of Ageless Solutions*](#):

1. “Growth Hormone Secretagogues” peptides (this issue)
2. Regenerative and healing peptides (this issue)
3. Weight loss and metabolic control peptides (next week)
4. Neurological and immune support peptides (next week)
5. Sexual dysfunction peptides (next week)

“Growth Hormone Secretagogues” Peptides

Advantages of increasing indigenous growth, hormone production:

- Increases lean muscle mass
- Promotes fat loss (especially visceral fat)
- Improves bone density
- Enhances tendon and ligament strength
- Accelerates tissue repair and wound healing
- Supports collagen production (skin, joints, fascia)
- Improves exercise capacity and recovery
- Aids metabolic function (lipid profile, energy utilization)
- Supports immune function
- Contributes to cardiovascular health
- Enhances sleep quality (linked to deep sleep cycles)
- May improve cognitive function and mood (indirect via IGF-1)



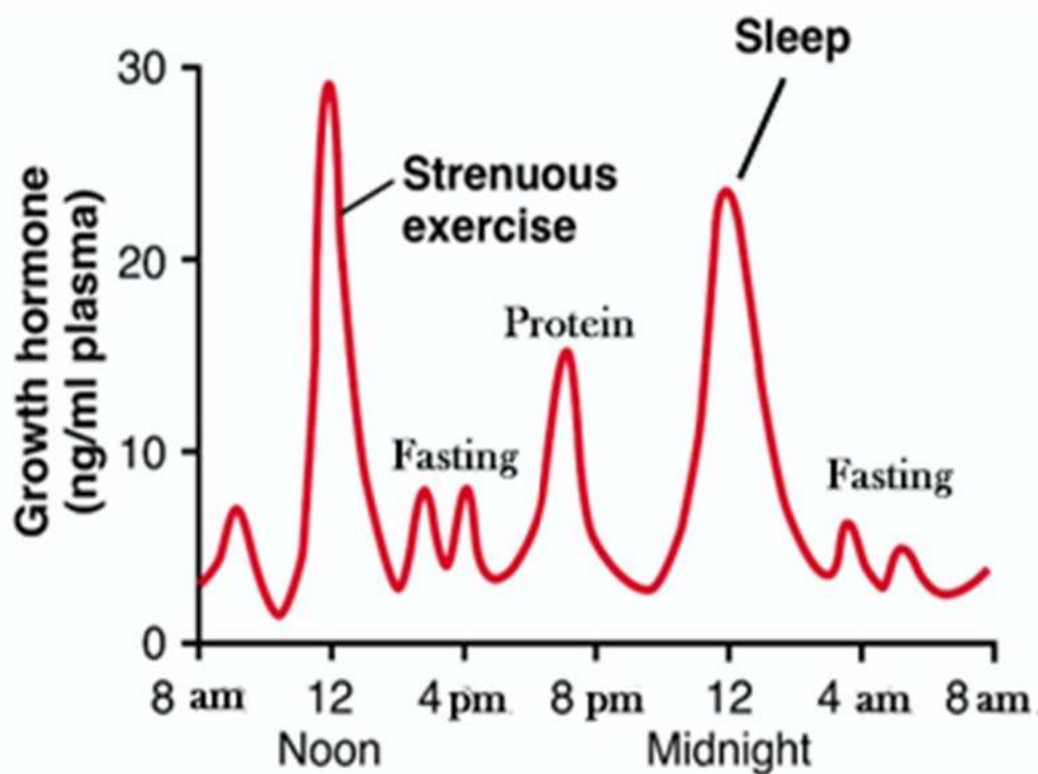
GHRH (Growth Hormone–Releasing Hormone) is a natural peptide hormone.

- What it is: A peptide produced in the hypothalamus (main active form is 44 amino acids)

- Role: Primary “on switch” for growth hormone release
- Mechanism: Travels to the anterior pituitary and binds GHRH receptors on somatotroph cells → triggers pulsatile GH secretion
- Physiology: Works in balance with somatostatin (the “off switch”) and synergistically with ghrelin

Ghrelin is a natural peptide hormone.

- What it is: A 28–amino acid peptide produced primarily in the stomach
- Physiologic role: Signals hunger (“hunger hormone”) and stimulates growth hormone (GH) release
- Mechanism: Binds to the growth hormone secretagogue receptor (GHS-R1a) in the pituitary and hypothalamus
- Function in GH axis: Works synergistically with GHRH to promote pulsatile GH secretion
- Other effects: Increases appetite, influences energy balance, and may affect glucose metabolism



Sleep & Strenuous Exercise are the two biggest drivers of GH pulses. Protein (Arginine) intake and Fasting cause modest pulses

Physiological GH release => “Pulsatile” dosing => brief, daily spikes of GH



Growth hormone levels decline after puberty...but they don't have to!

1. Sermorelin

- Class: 29-aa GHRH analog— the shortest fully active GHRH sequence (Wikipedia).
- Mechanism: GHRH receptor agonist → endogenous pulsatile GH release. Preserves negative feedback => Does NOT shut off endogenous GH production
- FDA history: Originally approved as **Geref** for pediatric idiopathic GH deficiency; discontinued commercially in 2008 for business reasons, not safety. Now compounded only.

• **Benefits:**

- Stimulates natural GH production
- Preserves normal hormone feedback
- Improves deep sleep
- Supports fat loss + lean muscle
- Enhances recovery and healing
- Pulsatile (physiologic) GH release

2. Tesamorelin (Egrifta)

- Class: GHRH analog (44 amino acids)
- Mechanism: Binds pituitary GHRH receptors → pulsatile GH release → IGF-1 elevation.
- FDA approval: HIV-associated lipodystrophy (excess visceral abdominal fat).
- Human evidence: Selectively reduces visceral adipose tissue ~15% over 26 weeks and ~18% over 52 weeks, modest reduction in liver fat as well

• **Benefits:**

- Potent stimulator of natural GH → ↑ IGF-1
- Reduces visceral (abdominal) fat (best clinical evidence)
- May decrease liver fat
- Improves body composition (fat ↓, lean mass ↑)

- Supports recovery and tissue repair
- Maintains pulsatile GH release (via pituitary)

3. Ipamorelin

- Class: Ghrelin receptor agonist (5 amino acids)
- Mechanism: Stimulates pituitary via Ghrelin receptors → increases pulsatile GH release → downstream IGF-1 elevation
- FDA approval: None (research/compounded use only; not approved for clinical indications)
- **Benefits:**
 - Stimulates natural GH release (ghrelin pathway)
 - Works synergistically with GHRH analogs (stronger pulses)
 - Selective → minimal cortisol & prolactin increase
 - Supports sleep, recovery, and repair
 - Aids fat loss and lean muscle support
 - More physiologic, pulsatile GH release
 - Generally well tolerated with fewer side effects

4. CJC-1295 (with or without DAC)

- Class: Modified GHRH with 29 amino acids
- DAC vs no-DAC: (“DAC” = Drug Affinity Complex)
 - No-DAC: Half-life ~30 minutes → preserves pulsatile GH physiology.
 - With DAC: binds to albumin → half-life 6–8 days, sustained GH/IGF-1 elevation => viewed as “non-physiologic and not recommended at [Ageless Solutions](#). Chronic, non-pulsatile GH stimulation is the main concern. Does it “burn out” the pituitary and downregulate GH receptors
- Regulatory: Moved to Category 2 in Sept 2023; not on the July 2026 PCAC review list
- **Benefits:**
 - Stimulates natural GH release (GHRH pathway)
 - Increases IGF-1 levels
 - Supports fat loss and lean muscle
 - Enhances recovery and tissue repair
 - Improves sleep quality (when dosed appropriately)
 - Can be short-acting (physiologic pulses) or long-acting (DAC)
 - Works synergistically with ipamorelin for stronger GH pulses

5. “Stacks” for GH production

1. Tesamorelin/Ipamorelin combo- Stronger visceral fat targeting;
2. Ipamorelin/CJC 1295 combo – two different physiologic pathways working together to amplify a natural GH pulse--improves sleep, recovery, energy, and body composition.



Rare, potential side effects of GH-promoting Peptides

- Fluid retention / edema
- Joint pain or stiffness
- Numbness/tingling (carpal tunnel–type)
- Increased appetite
- Injection site irritation
- Elevated blood sugar / insulin resistance
- Increased IGF-1 levels
- Mild prolactin or cortisol elevation (more with GHRPs)
- Headaches or fatigue
- Nausea

Regenerative and healing peptides

1. Body Protection Compound

- Class: 15-aa fragment derived from a sequence in human gastric juice. Not FDA approved
- Mechanism (preclinical): Promotes angiogenesis (VEGFR2/eNOS pathway), modulates nitric oxide signaling, activates fibroblasts, reduces inflammation; oral form thought to act on gut barrier and gut-brain axis.
- Evidence reality check: Predominantly rodent and in-vitro data.
- Regulatory:
 - WADA (World Anti-doping Agency) Prohibited List, Class S0 (non-approved substances) — banned at all times for athletes. USADA (U.S. Anti-doping Agency) mirrors WADA. Dept. of Defense prohibits service members from using Body Protection Compound.
 - FDA Category 2 since 2023; scheduled for PCAC review July 23–24, 2026 for potential 503A bulks list inclusion.

- **Benefits:**

- Supports tendon, ligament, and muscle healing
- Promotes angiogenesis (new blood vessel formation)
- May accelerate wound healing (skin, soft tissue, GI tract)
- Helps reduce inflammation
- Supports gut health (protective effects on the intestinal lining)
- May aid in joint recovery and pain reduction
- Shows neuroprotective potential in early studies

- **Counseling points:** Tell athletes or military patients explicitly — testing methods exist. Sourcing risk is high (most Body Protection Compound online is research-grade, not pharmaceutical-grade).

2. TB-500 (Thymosin β 4 fragment)

- Class: 43 amino acid fragments of naturally occurring thymosin beta-4.
- Mechanism: Actin-sequestering signaling peptide → cell migration, angiogenesis, NF- κ B downregulation, anti-apoptotic effects, modulated inflammation.

- **Benefits:**

- Supports muscle, tendon, and ligament healing
- Promotes angiogenesis (improves blood flow to injured tissue)
- Enhances cell migration → faster tissue repair
- Helps reduce inflammation
- May improve flexibility and mobility during recovery
- Can aid in recovery from overuse or chronic injuries
- Potential systemic healing effects (not just at injection site)

3. The Wolverine Stack

- Body Protection Compound acts more locally (tissue-level repair signaling);
- TB-500 acts more systemically (recruits cells to where they're needed).

- Regulatory: WADA-prohibited (Thymosin- β 4 and derivatives explicitly listed, WADA Prohibited List). FDA Category 2 since 2023; on the July 2026 PCAC docket.

- Counseling: Same caution as Body Protection Compound — primarily animal data, no FDA-quality human safety profile.

- **Benefits:**

- Accelerated tissue healing (muscle, tendon, ligament)
- Enhanced blood flow (angiogenesis) to injured areas
- Reduced inflammation → faster recovery, less pain
- Improved mobility and flexibility during rehab
- Supports chronic injury repair (overuse, nagging issues)
- Systemic + localized healing effects (Body Protection Compound more localized, TB-500 more systemic)

- **Why they're paired**

- **Body Protection Compound: Strong for tendon/ligament + gut healing**

- **TB-500: Better for cell migration + whole-body recovery**

→ Together: **more complete repair signal**



4. GHK-Cu (The “Glow”)

- Naturally occurring tripeptide (Gly-His-Lys) bound to Cu^{2+} . Identified in human plasma in 1973 (Pickart). Plasma levels drop ~60% from age 20 to 60
- Upregulating tissue-repair and DNA-repair while downregulating inflammatory and several oncogenic pathways. Stimulates fibroblast proliferation, collagen/elastin synthesis
- Promotes angiogenesis => new blood vessel formation at the site of injury/repair

- **Clinical applications:**

- Skin: Increased dermal density, reduced fine lines, improved elasticity (effects compared to retinoids in mechanism, with better tolerability).
- Hair: Stimulates dermal papilla cells, improves perifollicular vascularity; clinical work pairing with microneedling shows ~26% regrowth.
- Wound healing: Accelerates closure, reduces scarring.

- **Benefits:**

- Stimulates collagen and elastin production → improves skin firmness and texture
- Supports wound healing and tissue repair
- Promotes hair growth and follicle health
- Reduces inflammation and oxidative stress
- Improves skin tone, fine lines, and wrinkles
- Enhances angiogenesis (blood flow to tissue)
- May support nerve repair in early research



Potential but rare side effects of Wolverine

- Injection site irritation
- Headache
- Nausea / GI upset
- Dizziness or fatigue
- Flushing

Watch-outs:

- Angiogenesis → theoretical tumor risk

SPECIAL PROMO

Receive 20% OFF your first vial of
Wolverine*.

Come experience this health-promoting peptide first hand.

**Patients must be deemed eligible following brief medical history questionnaire. Offer expires 5/21/26.*

Call to Schedule

STAY TUNED!

Be on the lookout for next week's newsletter, "*The Peptide Report - Part 2.*"

[Newsletter Archives](#)



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