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The Peptide Playbook

A Practical Guide for Clinicians

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Some Light Housekeeping

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Why Are Peptides Gaining Attention?

- GLP-1s
- Social Media
- Shifts in federal policy

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The Federal Framework and FDA Authority

- Peptides are chiefly regulated under:
  - The Food, Drug, and Cosmetic Act (FDCA) for drugs, devices, cosmetics, food, and dietary supplements; or
  - The Public Health Service Act (PHSA) for biologics
- A “disease” claim, and most “structure/function” claims, pull the product into drug regulation.
  - Most therapeutic peptides are drugs or biologics requiring FDA approval.
  - Few legitimately sit in the supplement or cosmetic lanes.

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Chemistry vs. Regulatory Status

- A peptide is a chain of amino acids.
  - A chemistry, not a regulatory, classification.
- The same molecule can be a prescription drug, a biologic, an unapproved new drug, or, sometimes, a marketed supplement.
- What determines the category is ***the objective intended use*** of the peptide.

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The Four Categories That Matter

- **Drugs**
  - Intended to diagnose, cure, mitigate, treat, or prevent disease, or to affect the body's structure/function
  - A broad, claims-driven catch-all
- **Biologics**
  - A "protein" (and analogous products) applicable to treating a human disease or condition
- **Dietary Supplements**
  - A product bearing a listed dietary ingredient (vitamin, mineral, herb, amino acid) for ingestion, labeled as a supplement
- **Cosmetics**
  - A product applied to the body for cleansing, beautifying, or altering appearance

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Off-Label Prescribing

- Physicians may prescribe **FDA-approved** products off-label.
  - The FDCA regulates products/manufacturers, not the practice of medicine.
- **Crucial limitation:** The protection presupposes a lawfully marketed product.
  - It does **not** legalize administering an unapproved peptide (e.g., BPC-157 or TB-500).
- State duties persist.
  - Off-label use can be evidence of a standard-of-care breach.

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Off-Label Prescribing: Knowing the Boundaries

- <u>Lawful</u>
  - Off-label prescription of FDA-approved drugs (e.g., semaglutide for non-approved indication)
  - Compounded medicines from 503A/503B facilities using lawful bulk substances
- <u>Not “Off-Label”/Prohibited</u>
  - Prescribing a substance never approved for any indication (i.e., an unapproved drug)
  - Prescribing Category 2/3 substances through compounding pharmacies.

Many peptides marketed to physicians are not approved drugs being used off-label; they are unapproved substances.

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FDA's Category System

- CATEGORY 1
  - Under evaluation
    - Does not equate to "FDA-Approved"
  - Enforcement discretion; compounding permitted if certain conditions in FDA guidance are met
- CATEGORY 2
  - Significant safety risks
  - Compounding **PROHIBITED** (no enforcement discretion)
- CATEGORY 3
  - Further evaluation is needed
  - Compounding **PROHIBITED** (no enforcement discretion)

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What Does “Research Use Only” Mean?

- Many vendors market peptides as RUO.
  - RUO labeling does not authorize human administration.
  - This label does not immunize sellers or prescribers.
- FDA and DOJ have consistently taken the position that where evidence shows a product is intended for human use, the RUO label is merely a pretext, and the product is an unapproved new drug.
  - Multiple warning letters and enforcement actions in 2024-2026 have targeted RUO peptide vendors on this basis.

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Section 503A Pharmacies

- Traditional compounding pharmacies.
  - Patient-specific prescription **required** (no mass manufacturing)
  - Must be on 503A Bulks List or component of an approved drug
  - Cannot be “essentially a copy” of a commercially available drug
  - Regulated and inspected by State Boards of Pharmacy (no FDA registration required)

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Section 503B Outsourcing Facilities

- May compound in bulk (for office use)
  - Patient-specific prescriptions not required
- Regulated by the FDA
  - Requires registration
  - Subject to inspection
  - Mandatory adverse event reporting
- Must adhere to Current Good Manufacturing Practices (CGMP)
- May only compound:
  - Copies of FDA-approved drugs **in shortage**
  - Active pharmaceutical ingredient (API) listed on the 503B Bulks List

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Compounding Timeline: 2023-2026

September 2023	**FDA places 19 peptides in Category 2 (BPC-157, TB-500, MOTS-c, GHK-Cu, Semax, Epitalon, KPV, others)**
December 2024	PCAC votes against ipamorelin, MK-677, CJC-1295
Late 2024	Tirzepatide removed from Drug Shortage List
February 2025	**Semaglutide removed from Shortage List; compounding exception ends**
February 2026	HHS Sec. Kennedy announces ~14 peptides to move from Category 2 to Category 1
April 22, 2026	**12 peptides formally removed from Category 2**
July 23-24, 2026	PCAC reviews 7 peptides — recommends 6 of 7
By February 2027	5 more peptides to go to PCAC

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What Happened This Year and What It Really Means

- April: Removal of 12 Peptides from Category 2.
  - Move to Category 1 is **NOT** automatic.
  - Removal from Category 2 does **NOT** equal authorization to compound.
  - Formal rulemaking takes 12-24 months.
- July: Recommendation to add 6 Peptides to Bulks List
  - PCAC recommendations are ADVISORY ONLY.
    - FDA Has final authority.
  - This does **NOT** presently allow legal compounding.

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Semaglutide: The Most Watched Peptide Shift

- When supply shortages of branded products created gaps in patient access, the FDA allowed compounding pharmacies to produce semaglutide under shortage-based exemptions.
- Compounded semaglutide became heavily restricted after the FDA resolved its shortage designation in early 2025.
- By 2026, most compounding pharmacies cannot legally produce it.

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What Can (and Cannot) Be Said About Peptides

- **FDA-Approved Drugs/Biologics**: Must market per approved labeling; misbranding if false or misleading.
- **Dietary Supplements**: structure/function claims allowed only with substantiation, the mandatory disclaimer, and 30-day FDA notification; NO disease claims.
- **Cosmetics**: Appearance claims only; no structure/function or disease claims
- **Compounded Drugs**: Cannot claim "generic" or equivalent; must state "not FDA-approved"

- Don't forget about the Federal Trade Commission (FTC)!
  - All advertising must be truthful, non-misleading, and substantiated.

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Communicating About Non-FDA-Approved Peptides

- **Prohibited/High Risk**
  - Drug efficacy claims for non-approved peptides ("BPC-157 heals tendons"; "treats disease"); renders product an unapproved new drug (FDCA §502)
  - Claiming compounded products are "generic," "equivalent," or "same as" FDA-approved drugs; per se false/misleading (Sept 2025 FDA letters)
  - Claims of FDA approval or endorsement for non-approved peptides; false and misleading
  - "Research Use Only" disclaimers as a shield; FDA evaluates net impression (dosing info, injection supplies, patient communications)
  - Before/after photos implying efficacy for unapproved therapies; FTC treats as testimonials requiring substantiation
  - Social media therapeutic claims (practice or influencer); FTC holds both liable (2023 Endorsement Guides)
  - Implying Category 2 removal equals FDA approval; reclassification is compounding eligibility, not safety/efficacy endorsement

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Communicating About Non-FDA-Approved Peptides

- **Permitted (with conditions)**
  - Factual, educational information about peptide mechanisms, conditions under study (framed as informational, not promotional)
  - State the practice offers compounded peptide therapies (must identify products as compounded and not FDA-approved)
  - Reference published peer-reviewed research with qualifying language ("early research suggests..."; "animal studies have shown...")
  - Describe the prescribing process (physician evaluation, valid Rx, licensed compounding pharmacy)
  - Patient testimonials (genuine, typical experiences only; FTC Endorsement Guides (2023); disclaimer re: atypical results)
  - State which peptides are FDA-approved and their approved indications (e.g., semaglutide for T2D/weight management)

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Required Disclaimers and Best Practices

- **Required disclosure**: "This is a compounded medication. It is not FDA-approved and has not been evaluated by the FDA for safety, efficacy, or quality."
- **Informational vs. promotional framing**: describe what the practice offers, not why patients should choose peptide therapy
- **FTC substantiation**: all health claims must be truthful and backed by competent, reliable scientific evidence before publication
- **Review all channels regularly**: website, social media, brochures, Google/Meta ads, email; FDA/FTC evaluate the "net impression" of all materials collectively
- Have all marketing materials reviewed by health care regulatory counsel before publication

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What Patient Documentation is Important?

- Patient records should include:
  - Medical Necessity
  - Patient Evaluation
  - Treatment Rationale
  - Informed Consent
- Product Source Documentation
  - Verify pharmacy credentials

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The Importance of Informed Consent

- Essential that patients understand:
  - The FDA approval status of the peptide
  - Available evidence of efficacy, or lack thereof
  - The potential risks of treatment
  - Any alternatives to treatment
  - Response monitoring expectations and follow-up care
- Informed consent documentation should be tailored for the specific peptide therapy that is occurring.
  - One generic “catch-all” consent form is not enough

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Federal Enforcement Surge: 2025-26 Peptide Actions

50+	200+	$50M+	12+
Warning Letters (Sept 2025 wave)	Warning Letters (FY 2025 total)	Seizures & Forfeitures	Federal Criminal Prosecutions

Key Enforcement Agencies:

- FDA (CDER/ORA): Warning letters, import alerts, injunctions, facility inspections
- DOJ (Consumer Protection Branch): Criminal prosecutions, seizure actions, consent decrees
- DEA: Controlled substance diversion investigations (tirzepatide, semaglutide)
- FTC: Deceptive advertising claims for weight-loss peptide products

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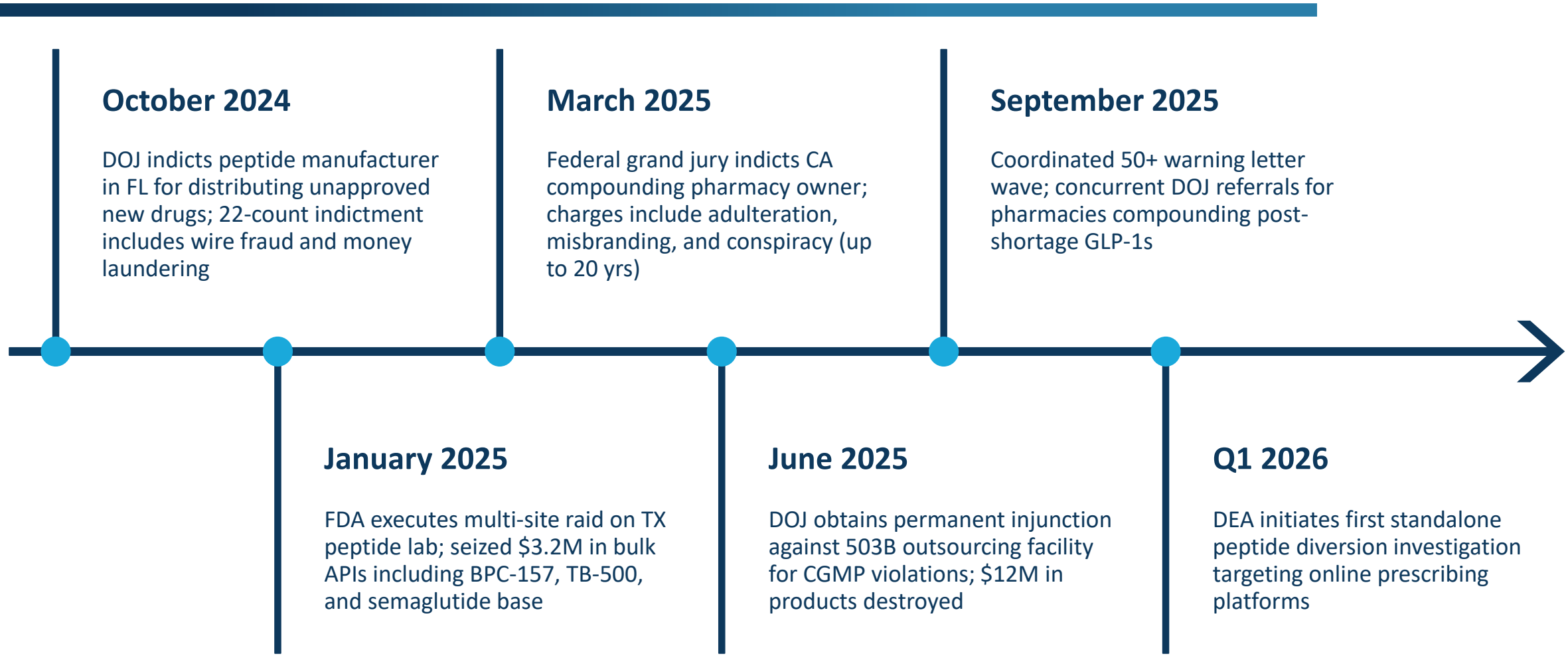
Criminal & Physical Enforcement Escalation



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State-Level Enforcement Landscape

Boards of Pharmacy

- **TX**: Emergency suspensions of 5 compounding licenses (2025)
- **FL**: New peptide-specific inspection protocols for 503A pharmacies
- **CA**: Board investigations into pharmacies compounding post-shortage
- **NY**: Cease-and-desist orders to online-only peptide vendors

Attorneys General

- Consumer protection actions against misleading peptide marketing
- Multi-state investigations into telehealth peptide prescribing mills
- State UDAP claims parallel to FTC actions
- Civil penalties ranging from $50K-$500K per violation in settled cases

Medical Boards

- License suspensions for prescribing unapproved peptides without adequate informed consent
- Investigations triggered by adverse event reports linked to compounded peptides
- Standard-of-care inquiries into "peptide clinics" offering non-evidence-based protocols
- Referrals from pharmacy board actions to medical boards for prescriber review

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Brand Manufacturer Litigation

- Novo Nordisk (Ozempic / Wegovy)
  - Filed 15+ federal lawsuits against compounding pharmacies and telehealth platforms (2024-2026)
  - Trademark claims: "Ozempic," "Wegovy," and semaglutide trade dress
  - Patent infringement claims under delivery device patents
  - Lanham Act false advertising against "generic semaglutide" marketing
  - TROs obtained freezing compounder assets in 3 cases
  - Settlement terms include permanent manufacturing bans
- Eli Lilly (Mounjaro / Zepbound)
  - Filed 10+ lawsuits targeting compounders and distributors of tirzepatide
  - Unique argument: tirzepatide is NOT a single entity — compounders cannot replicate the molecule
  - Trade secret claims regarding manufacturing process
  - Sought and obtained emergency injunctions in multiple jurisdictions
  - Coordinated with FDA on shortage status updates to accelerate enforcement
  - Damages claims exceeding $100M across pending cases

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Key Takeaways for Prescribers

1. Always verify the current regulatory status before prescribing
2. Source only from licensed 503A/503B compounding pharmacies
3. Document clinical rationale and obtain informed consent for off-label/compounded use
4. Monitor state board guidance
5. Reclassification ≠ FDA approval
6. Off-label ≠ unapproved
7. Maintain physician independence (CPOM) in clinic/telehealth settings
8. GLP-1 compounding post-shortage carries significant regulatory and liability risk

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David Traskey, co-head of the Firm's Washington, DC Office, advises individuals and entities involved in government investigations, guides clients on corporate compliance and governance matters, and litigates civil and white-collar health care fraud cases. Prior to joining Garfunkel Wild, David served as Senior Counsel with the United States Department of Health and Human Services (HHS), Office of Inspector General (OIG). David's unique expertise in health care enforcement and compliance provides clients with specialized insight into federal investigations and enforcement actions based on his knowledge of the government's case identification strategies, its legal theories, and its interpretation of the applicable laws, rules, and regulations. His HHS-OIG experience also allows him to share critical information with clients about the government's corporate governance expectations and compliance best practices. David routinely provides advice to clients on fraud and abuse issues, including matters arising under the False Claims Act, the Anti-Kickback Statute, the physician self-referral law (Stark Law), federal health care reimbursement, and other regulations promulgated by the Centers for Medicare & Medicaid Services, the Food and Drug Administration, and HHS-OIG. He also counsels clients about risk mitigation strategies, implementing compliance safeguards, responding to investigations or audits, identifying and returning overpayments, and submitting OIG self-disclosures. In his role at HHS-OIG, David represented HHS-OIG in litigation and settlements under the Civil Monetary Penalties Law and False Claims Act, collaboratively recovering over $118 million. He litigated appeals of provider exclusions before HHS's Departmental Appeals Board and served as an advisor in subsequent appeals to U.S. District Court. He expanded OIG's use of data analytics and served as Litigation Hold Coordinator and the Affirmative Litigation Branch Component Liaison, where he provided related guidance and training to all OIG components on a variety of topics.

David's government service roles span nearly two decades including time served as an attorney with the United States Department of Veterans Affairs (VA), OIG. There, he represented VAOIG before the Merit Systems Protection Board and Equal Employment Opportunity Commission, advised management on employee relations and human resources issues, and prepared referrals to VA's suspension and debarment committee. David also served as an Acting Veterans Law Judge at VA's Board of Veterans' Appeals where he supervised a team of attorneys, conducted administrative hearings with veterans, and adjudicated veterans' benefits appeals. Upon law school graduation, David clerked for Hon. Cheryl Johnson of the Court of Criminal Appeals of Texas, the court of last resort for all criminal matters in the state. David is a Certified Fraud Examiner (CFE), certified by the Association of Certified Fraud Examiners (ACFE).

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Kathleen ("Kat") Brown advises clients on a broad spectrum of regulatory and compliance matters in the highly regulated health care sector. She assists health care providers, organizations, and stakeholders in navigating complex regulatory frameworks, including federal and state anti-referral laws, HIPAA compliance, and fee splitting and corporate practice of medicine (CPOM) rules. Kat also counsels clients on licensure and scope of practice issues, telehealth and remote patient monitoring, and regulatory concerns related to pharmaceuticals and medical devices, including 340B Program compliance. In addition to her regulatory work, Kat frequently performs health care diligence in large transactions, including mergers and acquisitions, helping clients address compliance and risk management issues throughout the process.

Before joining the firm, Kat gained extensive experience in private practice, New York State government, government relations, and health care consulting. This diverse background provides her with a deep understanding of the regulatory landscape and empowers her to advocate effectively for clients across both public and private sectors.

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Garfunkel Wild Health Care Conference

October 28, 2026 | Virtual | Complimentary

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