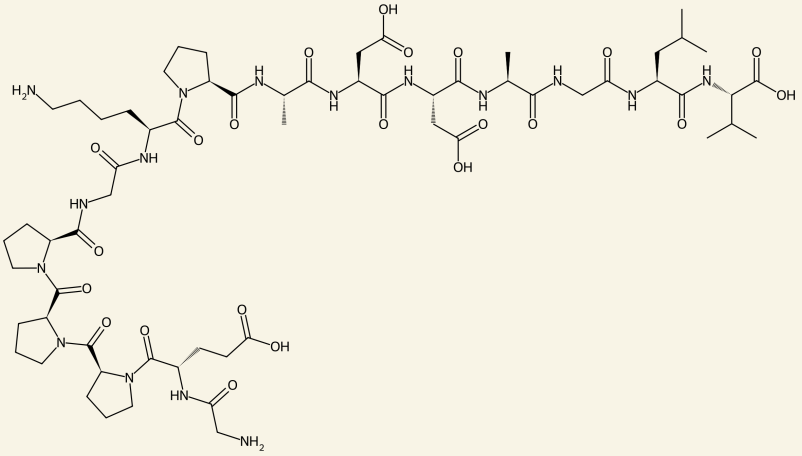
HORMONALY PRESS · 2026 A POCKET REFERENCE

VOLUME ONE · MEDICOLEGAL PRACTICE

The Expert Witness Pocket Guide

A field reference for the clinician who testifies in *peptide*, *hormone*, *and longevity* medicine — or who is called to answer for it.



FADY HANNAH-SHMOUNI, MD FRCPC

Clinical Endocrinologist & Geneticist
University of British Columbia
Founder & CEO, Hormonaly.ai

2026 EDITION

The Expert Witness Pocket Guide

Peptide, hormone, and longevity medicine in the courtroom, before the board, and under cross-examination.

A companion to The Peptide Pocket Guide, which rates the evidence behind seventy peptide therapeutics. This volume addresses what happens when that evidence — or its absence — is examined by a court, a licensing board, or a regulator. One issue per spread: the governing rule, what the expert may and may not say about it, how the other side will argue it, and the authorities that control.

FADY HANNAH-SHMOUNI, MD FRCPC

Clinical Endocrinologist & Geneticist
University of British Columbia
Founder & CEO, Hormonaly.ai

2026 EDITION

How to use this guide

A reference for two readers: the clinician who has been retained, and the lawyer who retained them.

This guide covers the medicolegal terrain of peptide, hormone, and longevity practice in the United States. It is written for the physician, nurse practitioner, or physician assistant who has been asked to serve as an expert witness; for the clinician who has received a board complaint or a summons; and for the attorney who must decide what an expert in this field can credibly say.

Each entry occupies a two-page spread and follows a consistent template. The body type is one size throughout, and wording is compressed so that a single issue — a rule, a doctrine, an injury pattern — fits within a single spread without carrying into the next entry.

READING AN ENTRY

The header carries two things: a colored pill at the top-left reading SETTLED, MAJORITY, EVOLVING, or NOVEL, describing how settled the governing law is; and a subject label at the top-right locating the entry in its field. Note that this rates the law, not the evidence — it is a different scale from the GRADE letters in The Peptide Pocket Guide.

The rule	The black-letter statement of governing law.
The expert's role	What you opine on — and the questions that belong to the court, not to you.
Elements · factors	The test, as a court applies it.
The other side	How opposing counsel argues the same issue.
Discovery targets	Documents to demand, or to expect a demand for.
Cross-examination	The attack you should expect, and the preparation that answers it.
Practice pointer	One concrete step, in a shaded box.
Unsettled	What remains open as of 2026, where anything does.
Status-dated	On time-sensitive regulatory pages, replaces Unsettled and carries the date the status was checked.
Authorities	The two to four citations that control the page.

WHAT THE CITATIONS MEAN

Citations print in the form a reader can pull. Every authority marked verified was read in a primary or official source during preparation, and the note beside it states what that source establishes. Ten state provisions are marked read at one remove. Material that could not be confirmed against a source was cut rather than printed: nothing in this guide is cited as authority on the strength of recollection alone. That is a statement about preparation, not a substitute for reading — pull the source before it enters a report.

Jurisdiction. This guide states federal law and majority state rules. Practice regulation, informed consent, damages caps, and expert prerequisites are state law and vary materially. Every entry that turns on state law says so. Confirm the rule in your forum before relying on it.

How settled is the law?

The colored pill at the top of every entry rates the authority, not the case.

The Peptide Pocket Guide rates each peptide A–D by GRADE, reflecting the strength of the clinical evidence. This volume rates a different quantity — how settled the governing authority is — and names it in words rather than letters, so that a reader who owns both books never has to ask which scale a letter belongs to. A reader who knows how firm the ground is can judge how much weight an argument will bear.

SETTLED
Binding and settled. A statute, a rule of evidence or procedure, a controlling Supreme Court holding, or a rule adopted uniformly across jurisdictions. The rule is not seriously in dispute; only its application is.

MAJORITY
Settled in the majority, with variation at the margins. A doctrine adopted by most jurisdictions, or a federal rule applied consistently by most circuits, where a minority position survives and matters if you are in it.

EVOLVING
Split, evolving, or thin. Courts disagree; the authority is sparse, recent, or drawn from analogous contexts rather than this one. Expect the issue to be litigated rather than assumed.

NOVEL
No controlling authority. The question has not been squarely decided for this subject matter, and the argument proceeds from first principles, regulatory inference, or analogy. Most peptide-specific questions sit here.

A low rating is not a weak position. Novel marks an unresolved question, not a losing one. Several of the most consequential issues in this field — whether a duty exists to disclose that a drug is compounded, whether sourcing verification is a standard-of-care duty — are Novel precisely because they are new. They are argued, not looked up.

Editorial standards

What this guide is, what it is not, and the disclosure it owes the reader.

This is a reference for professionals. It is not legal advice, and reading it creates no attorney-client or physician-patient relationship. It does not tell you what to conclude in a case, whether to accept a retention, or how to treat a patient.

NOT A BRIEF FOR EITHER SIDE

Entries state the rule and then set out how each side argues under it. The guide does not favor plaintiffs or defendants, claimants or licensees. An expert who understands the opposing theory is harder to surprise; the "other side" section exists for that reason and not as advocacy.

THE LIMITS OF A POCKET FORMAT

One issue per spread buys portability at the cost of nuance. Nothing here substitutes for reading the statute, the rule, or the opinion. Where an entry compresses a doctrine that fills a treatise chapter — informed consent, causation, corporate practice — the compression is deliberate and the citations are the way out of it.

WHY UNSETTLED LAW IS LABELLED, NOT SMOOTHED

Peptide medicine outpaces the law that governs it. Much of this field has no controlling authority, and a reference that concealed that would be worse than useless in a deposition. Where the law is open, the entry says so and says why. An expert who testifies that a question is settled when it is not has handed the cross-examiner the case.

CURRENCY

Prepared in 2026. Compounding eligibility, shortage-list status, telehealth prescribing rules, and pending litigation move quickly — the federal compounding entries in Part II are the most perishable pages in the book. Verify current status before relying on any of them.

Medical disclaimer. Clinical content in Part IV describes injury patterns and monitoring practice for medicolegal analysis. It is not treatment guidance and must not be used to direct the care of any patient. Clinical decisions belong to the treating clinician with the full patient record in front of them.

Classification: what the molecule is

Every peptide dispute begins with a classification question, because the regulatory pathway, the compounding rules, and the exclusivity all follow from it. The taxonomy below is the one used in The Peptide Pocket Guide, restated here for the courtroom.

THE BIOCHEMICAL DESCRIPTION

A peptide is a short chain of amino acids joined by peptide bonds. The conventional distinction from a protein is length: peptides run roughly two to fifty residues, while proteins are longer, fold into stable tertiary structure, and usually exceed 10 kDa. The boundary is genuinely fuzzy — insulin, at 51 residues in two disulfide-linked chains, is variously called a polypeptide or a small protein. That description is useful for explaining chemistry to a jury. It decides nothing legally.

THE REGULATORY LINE

The operative federal line is statutory and regulatory. The PHS Act includes protein within the biological-product definition at 42 U.S.C. 262(i)(1); FDA's implementing regulation, 21 C.F.R. 600.3(h)(6), defines a protein as an alpha amino acid polymer with a specific, defined sequence greater than 40 amino acids. Below that threshold the article is generally a drug under the Federal Food, Drug, and Cosmetic Act. Route of manufacture no longer decides the question: Congress struck the exception for a chemically synthesized polypeptide in December 2019, so a synthetic molecule above the threshold can be a biological product.

40 or fewer amino acids	Peptide for FDA classification purposes; generally regulated through the FD&C Act drug pathway unless it falls within another biological-product category.
Greater than 40	May meet FDA's definition of a protein, and so be a biological product. Chemical synthesis does not exclude that status: the exception for a chemically synthesized polypeptide was struck from the statute in 2019.
Modified or unusual	Classification may turn on which residues count as alpha amino acids, on associated chains, and on whether the article is analogous to a listed biological product.

CLASSIFICATION: WHAT THE MOLECULE IS · CONTINUED

WHY THE LINE DECIDES CASES

Classification is not a labeling formality. It fixes the approval pathway, the exclusivity term, whether a generic or a biosimilar can enter, the chemistry-and-manufacturing burden, and — most often litigated in this field — whether the article may be compounded at all. The compounding exemptions at 21 U.S.C. 353a and 353b are written for drugs, and a licensed biological product does not sit comfortably inside them.

> Establish which side of 40 the molecule falls on, and by what synthesis route, before forming any opinion on whether it could lawfully be compounded. The answer changes the governing statute.

THE CHANNELS A MOLECULE ARRIVES BY

Independent of what the molecule is, the same molecule reaches patients by different routes. In testimony these matter because each fixes what documentation should exist.

FDA-approved	Approved label, indications and dosing; cGMP manufacture; post-market surveillance.
503B outsourcing	Compounded under cGMP for office stock; FDA-registered and inspected. The manufacturing standard is regulated, not the formula.
503A compounding	State-licensed, patient-specific prescription. The bulk substance must be listed, monographed, or from an approved product.
Investigational	An IND clinical trial or FDA-authorized expanded access. The lawful investigational pathway for a drug that is not approved and does not qualify for a compounding exemption.
Research use only	Sold labeled for laboratory use. The disclaimer confers no authorization; intended use governs.
Gray market	No recognized approval, compounding, or investigational pathway — not an absence of enforcement. Independent testing has reported content well below and above the stated amount.

A classification opinion is within an expert's competence when it rests on sequence length, synthesis route, and the documents in the record. Whether a particular exemption applied to a particular transaction is a legal conclusion for the court.

Contents