Physicians Must Uphold 'Do No Harm' with Compounded Medications

Written by The Life Science Feed Editorial Team · Published 21 June 2026 · Edited by Mara Voss

> The use of compounded medications presents a clinical dilemma: they address unique patient requirements, such as allergies to excipients or specific dosage forms, but operate outside the stringent regulatory oversight of commercially manufactured drugs. Physicians must therefore exercise heightened caution, ensuring that the potential benefits of a compounded preparation demonstrably outweigh the risks, and that the 'do no harm' principle remains paramount in their prescribing decisions.

KEY TAKEAWAYS

- The Pivot: Compounded medications lack the rigorous safety and efficacy data required for FDA-approved products.
- The Data: No specific quantitative data is available for this general topic, but the absence of efficacy and safety data is the key point.
- The Action: Prescribing clinicians should consider compounded medications only when no FDA-approved alternative exists and document the specific medical necessity.

Compounded medications are preparations tailored to individual patient needs by a pharmacist, often in response to a physician's prescription. These preparations are distinct from commercially available, FDA-approved drugs. The Food and Drug Administration (FDA) regulates commercially manufactured drugs through a comprehensive process that includes pre-market approval based on demonstrated safety and efficacy data from clinical trials. This regulatory pathway ensures consistent quality, potency, and purity across batches. Compounded medications, however, are generally exempt from this pre-market approval process. This exemption is predicated on the understanding that compounding is intended for individual patient needs when an FDA-approved drug is unsuitable or unavailable.

The primary rationale for compounding includes addressing patient allergies to inactive ingredients, providing specific dosage strengths not commercially available, creating alternative dosage forms (e.g., liquid formulations for patients unable to swallow pills), or preparing medications for rare diseases where commercial production is not viable. While these applications serve critical patient needs, the lack of FDA pre-market review for compounded products introduces inherent risks. These risks include variability in potency, sterility, and purity, as well as the absence of robust clinical data on efficacy and safety for the specific compounded formulation. Without standardized clinical trials, the therapeutic profile of a compounded medication cannot be established with the same certainty as an FDA-approved product.

The clinical background for considering compounded medications often arises in specialized patient populations. Pediatric patients, for example, frequently require liquid formulations or lower doses not available in commercial products. Geriatric patients may also benefit from customized dosages or alternative delivery methods due to

polypharmacy or swallowing difficulties. Patients with rare diseases, for whom commercial drug development is not economically viable, often rely on compounded preparations. In these scenarios, the physician must carefully weigh the benefits of a tailored medication against the inherent risks of a product without full FDA oversight. Understanding the specific physiological differences and vulnerabilities of these patient groups is paramount when making such prescribing decisions.

Physician Responsibility and Risk Mitigation

Physicians prescribing compounded medications bear a significant responsibility to mitigate potential patient harm. This responsibility extends beyond the initial decision to prescribe and encompasses ongoing patient monitoring. Before considering a compounded preparation, physicians should exhaust all available FDA-approved alternatives. If a compounded medication is deemed necessary, the specific medical rationale must be clearly documented in the patient's record. This documentation should detail why an FDA-approved product is inappropriate, unavailable, or unable to meet the patient's unique medical needs. For instance, a patient with a severe anaphylactic allergy to a common excipient in all commercially available formulations of a necessary drug may warrant a compounded alternative.

Furthermore, physicians should ensure that the compounding pharmacy selected adheres to appropriate quality standards. While the FDA does not approve individual compounded products, it does provide guidance for compounding pharmacies, particularly concerning good compounding practices. Physicians should inquire about the pharmacy's quality control measures, including sterility testing for sterile preparations and potency testing for all compounded products. The absence of such measures increases the risk of adverse events, including infections from non-sterile products or therapeutic failures due to incorrect potency. Patients receiving compounded medications should be informed of the differences in regulatory oversight compared to FDA-approved drugs and the potential for variability. Open communication regarding expected outcomes and potential adverse effects is essential for informed consent.

The mechanism by which compounded medications can pose risks often relates to the lack of stringent manufacturing controls. Unlike large-scale pharmaceutical manufacturers that operate under Good Manufacturing Practices (GMP) and undergo regular FDA inspections, compounding pharmacies, particularly those operating under Section 503A of the Federal Food, Drug, and Cosmetic Act, have different regulatory requirements. This can lead to inconsistencies in the active pharmaceutical ingredient (API) concentration, improper mixing, or contamination. For example, a compounded sterile product, if not prepared in an appropriate sterile environment, can introduce bacterial or fungal infections. Similarly, a compounded oral medication with an inconsistent API concentration can lead to sub-therapeutic dosing or toxicity, directly impacting patient safety and treatment efficacy. Physicians must understand these potential mechanistic failures to better assess the risks for their patients.

The principle of 'do no harm' mandates that physicians prioritize patient safety. In the context of compounded medications, this means a judicious and evidence-informed approach. Prescribing decisions should be based on a clear medical necessity, a thorough understanding of the risks associated with compounding, and a commitment to monitoring patient outcomes. The convenience or lower cost of a compounded medication should not supersede the imperative for safety and efficacy, particularly when FDA-approved alternatives exist. Physicians must remain vigilant and advocate for their patients by ensuring that any compounded medication prescribed meets the highest possible standards of quality and safety, even in the absence of full FDA pre-market approval.

To further your understanding of essential clinical best practice and patient safety principles applicable to all prescribing decisions, refer to the Oxford Handbook of Clinical Medicine.

CLINICAL IMPLICATIONS

The ongoing reliance on compounded medications, while sometimes unavoidable, highlights a persistent gap in pharmaceutical oversight that places an undue burden on prescribing clinicians. It is not enough to simply acknowledge the necessity of these preparations; physicians must actively scrutinize the rationale for their use. The absence of rigorous Phase III trial data for compounded products means that every prescription is, in essence, an unmonitored experiment. This is a stark departure from the evidence-based practice we demand for FDA-approved therapies.

The pharmaceutical industry, for its part, has little incentive to develop niche formulations for small patient populations, leaving these gaps to be filled by compounding pharmacies. This economic reality does not, however, absolve physicians of their ethical obligations. When a physician opts for a compounded medication, they are implicitly vouching for its safety and efficacy without the backing of regulatory approval. This demands a level of due diligence that extends to understanding the compounding pharmacy's quality control processes, a task often outside the typical scope of clinical practice.

Patients, often unaware of the regulatory distinctions, place their trust implicitly in their physicians. It is incumbent upon clinicians to educate patients about the differences between FDA-approved and compounded medications, including the potential for variability and the absence of comprehensive safety data. The 'do no harm' principle is not merely a philosophical tenet; it is a practical directive that requires physicians to be vigilant gatekeepers, ensuring that the therapeutic benefits of a compounded medication genuinely outweigh the inherent, and often unquantified, risks.

EDITORIAL & AI STANDARDS

AI tools are used to structure and summarise evidence from peer-reviewed primary sources. Articles that carry a signed Editor's take have been read in full by William Lopes. The others are not individually read by an editor, so check the cited source before relying on a figure.

REFERENCES

1. 1. Gudeman J, Jozwiakowski M, Chollet J, Randell M. Potential risks of pharmacy compounding. Drugs R D. 2013;13(1):1-8. doi:10.1007/s40268-013-0005-9
2. 2. Randell M. Risk and liabilities of prescribing compounded medications. Postgrad Med. 2014;126(4):178-180. doi:10.3810/pgm.2014.07.2816
3. 3. Watson CJ, Whitledge JD, Siani AM, Burns MM. Pharmaceutical compounding: a history, regulatory overview, and systematic review of compounding errors. J Med Toxicol. 2021;17(2):197-217. doi:10.1007/s13181-020-00814-3
4. 4. Isles M. Patient safety issues associated with the use of compounded medicines as alternatives to approved pharmaceutical products in Europe and how best practice can improve outcomes. Int J Risk Saf Med. 2020;31(3):133-144. doi:10.3233/JRS-200002
5. 5. U.S. Food and Drug Administration. Understanding the Risks of Compounded Drugs. Available at: https://www.fda.gov/drugs/human-drug-compounding/understanding-risks-compounded-drugs

LICENCE & RIGHTS

© 2026 The Life Science Feed. All rights reserved. This content is produced for medical education purposes. It may not be reproduced, distributed, or transmitted without prior written permission from The Life Science Feed.

MEDICAL DISCLAIMER

This content is intended for healthcare professionals only and does not constitute medical advice. Clinical decisions must be made by qualified practitioners based on individual patient circumstances.

FOLLOW THE LIFE SCIENCE FEED

Instagram @lifesciencefeed **LinkedIn** linkedin.com/company/thelifesciencefeed

thelifesciencefeed.com