



Compounding Legislation: It Hurts Everyone

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Draft legislation that has been circulated by Senators Edward Kennedy (D-Mass.), Richard Burr (R-N.C.) and Pat Roberts (R-Mo.) to significantly broaden the Food and Drug Administration's authority over pharmacy compounding will endanger patients who are prescribed compounded medicines and create onerous, new regulations for prescribers and pharmacists. This legislative approach is so problematic that it should be rejected in its entirety.

Millions of Americans have critical medical needs that are unmet by one-size-fits-all manufactured pharmaceuticals. For them, compounded medicines - prescribed by authorized medical practitioners and prepared by licensed, trained pharmacists - are often their best and only treatment option.

Federal legislation that restricts compounding will severely restrict patients' access to proper medicines and doctors' ability to prescribe these medicines. This proposal in particular would:

- Insert the FDA into the doctor-patient relationship in an unprecedented way by giving the agency the authority to determine when compounded medicines are needed. Allowing FDA to regulate compounded medicines in this way is one short step away from requiring doctors to document medical need for prescribing medications for off-label use.
- Prematurely establish a new regulatory structure before it is resolved in a live federal case. In August 2006 a federal district judge ruled that compounded drugs for humans are not new, unapproved drugs subject to FDCA and that pharmacies in compliance with all state regulations are exempt from FDA inspections. This decision is currently under appeal.
- Give FDA wider authority over compounded medicines because FDA has proven itself to be an overly aggressive regulator of compounding and unresponsive to Congress on compounding related matters. For example:
 - For the past 20 years, the FDA has maintained the position that all compounded medicines are illegal.
 - In 1997, when legislation passed that gave FDA some authority over compounded medicines - legislation that the Supreme Court later ruled unconstitutional - FDA regularly misinterpreted and misapplied the law. For example:
 - Rather than restrict compounding of certain "drug products" as Congress intended, FDA instead restricted compounding of entire drug classes, unnecessarily limiting patients' access to many compounded medicines.
 - By regularly publishing guidelines and meeting notices late, the FDA gave compounding pharmacists little time to respond to key issues that affected their practice.
 - The FDA restricted interstate distribution of compounded medicines in a way that was contrary to what Congress intended.

- FDA has yet to revise poorly written compliance policy guides despite the requests of hundreds of members of Congress.
- Dilute the FDA's already strained resources. Compounding pharmacies are already well regulated by their state board of pharmacy. Federalizing the practice of pharmacy will only add to FDA's work load and will be duplicative of current state structures. FDA's resources could be better used to help FDA get through the overwhelming backlog of manufactured drugs they have pending approval.
- Prohibit well-established community and hospital pharmacy practices that state laws explicitly allow. To the extent pharmacy practice should be improved, broadening FDA authority should be a last step, not a first step. Rather, we should continue working with state boards of pharmacy, the U.S. Pharmacopeia and the Pharmacy Compounding Accreditation Board to improve pharmacy practice.
- Create onerous regulations that do little to improve patient safety while significantly raising costs to patients and impeding the ability of small, community pharmacies to survive; and
- Open the door for outside interests - particularly pharmaceutical manufacturers - to unduly influence the regulation of compounded medicines.
- Override long established laws in most states allowing for office use of compounded products by physicians to meet patient need.
- Restrict the ability of prescribers to prescribe and distribute compounded medications for office use, a critical function that allows prescribers to prescribe certain compounded medicines that patients cannot administer themselves, such as injectables.
- Call for FDA to write regulations for sterile compounding when stringent USP standards are already in place for the practice and also requires the alarmist statement on the label, "This drug was not prepared using FDA's manufacturing standards for sterile drugs."
- Would broadly eliminate the availability of critical, commonly compounded sterile preparations, particularly those commonly prescribed by physicians in hospitals.
- Severely restricts interstate distribution of compounded medicines, a move that will endanger hundreds of thousands of patients served by pharmacies operating near state borders, "snowbird" patients whose hometown pharmacies continue to serve them during winter months, and patients living in rural communities who may be hundreds of miles away from the nearest compounding pharmacy.
- Would resurrect many poorly implemented and troublesome aspects of FDAMA Section 503 (A).

Ultimately, this bill, or any like it, will be extremely damaging to the medical community and patient health. It will eliminate an important treatment option that doctors currently prescribe and patients benefit from and will place unneeded burdens on the FDA, as well as prescribers and pharmacists.

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