



DC FEDERAL LEGISLATIVE INITIATIVE

AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS

PRESERVING PATIENT ACCESS TO COMPOUNDED MEDICATIONS H.R. 1959

BACKGROUND:

Compounded medications are used to treat patients with unique medical conditions that make them resistant to standard medications. For example, using active ingredients without preservatives or allergenic substances, or putting an active ingredient in substances to be used topically or intravenously instead of orally for patients with digestive issues. Many nutritional and herbal remedies are also only available through compounding pharmacies, because large pharmaceutical manufacturers do not make small batches of these products.

These compounded products are used to treat a variety of conditions, including digestive disorders, chronic viral infections, anemia and vitamin deficiencies; migraine, colitis, asthma, hepatitis, diabetes, Parkinson's, chronic fatigue and other autoimmune disorders, or supportive therapies to mitigate side-effects of chemotherapy. They are essential for millions.

Historically, naturopathic doctors, along with Dermatologists, Ophthalmologists and many other provider types, maintain a supply of compounded medications to administer to a patient in the physician's office for the immediate treatment of a problem, a practice governed by state law and referred to as "office-use." This supply is obtained by the physician, without requiring an advance prescription for each individual patient.

The Drug Quality & Security Act (DQSA, P.L. 113-54) was enacted in response to a meningitis outbreak from contaminated sterile drugs compounded that tragically resulted in dozens of deaths. The DQSA gives the FDA new oversight over some compounding facilities to address these safety concerns. Neither office use nor the rejection of dietary supplement monographs have anything to do with the meningitis outbreak, and in passing the DQSA, Congress made clear statements noting the importance of maintaining patient access to office-use drugs and ensuring that compounding regulations should not interfere with the practice of medicine.

Since passage of the DQSA, the FDA has interpreted certain provisions of the law in a manner inconsistent with legislative intent to expand its oversight over physicians and compounding pharmacies, and the medications compounded by these pharmacies.

ISSUE #1: OFFICE-USE

FDA has issued non-binding guidance for industry (GFI) documents that do not have the force of law or administrative rule to restrict office-use of compounded medications. FDA guidance now requires that physicians may not use compounded medications for office-use to treat patients in real time. Instead, a physician must write a patient-specific prescription.

What formerly could be treated in the same visit now requires: 1) a trip to the physician office for evaluation and diagnosis, 2) a trip to the pharmacy to obtain the prescription, and 3) a follow-up visit to the physician office to administer the treatment. This causes a number of problems:

- Delays in patient care
- Increased patient cost of care through additional co-pays
- Increased risk of patients not adhering to a treatment protocol
- Increased risk to patients if the prescriptions - many of which require refrigeration or degrade easily - are not handled or stored safely by the patient
- Decreased supply of drugs, some pharmacies have stopped providing some compounded drugs
- Increased cost of prescriptions since each prescription is made specific for the patient instead of available in bulk through the physician

ISSUE #2: DRUG INGREDIENTS

FDA has also started a process to take long-used safe ingredients that are compounded for patients off the market. They have required that any substance that does not have a **Drug Monograph** in the US Pharmacopeia or National Formulary must be nominated for approval to compound. Of the 300+ ingredients that were nominated for the FDA's Pharmacy Compounding Advisory Committee (PCAC) to review, over 95% have been denied either after a review, or will be denied without a review at all, despite a long history of safe use and patient need. Yet many of these ingredients have U.S. Pharmacopeia **Dietary Supplement** monographs, which Congress intended to also be available for compounding but which FDA has refused to accept. If these monographs are not accepted, this will have the effect of **restricting patient access to over 300 compounded drugs** currently being used by hundreds of thousands of patients.

LEGISLATIVE ASK:

Representative Morgan Griffith (R-VA) and Henry Cuellar (D-TX) have introduced the "Preserving Patient Access to Compounded Medications Act (H.R. 1959)," which would clarify congressional intent regarding key provisions of the Food, Drug and Cosmetic Act (FDCA) as amended by the DQSA. H.R. 1959 would allow traditional compounding pharmacies to distribute compounded drugs for office-use without a patient-specific prescription in all states that allow office-use compounding, and would clarify acceptance of ingredients for compounding with dietary supplement as well as drug monographs.

HOUSE:

- Cosponsor the "Preserving Patient Access to Compounded Medications Act" (H.R. 1959) introduced by Representatives Morgan Griffith (R-VA) and Henry Cuellar (D-TX)
- Request a hearing for H.R. 1959

SENATE:

- Sponsor or cosponsor a Senate companion bill, and support H.R. 1959