IACP COMPOUNDERS ON CAPITOL HILL

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ADVANCE

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H.R. 1959: THE PRESERVING PATIENT ACCESS TO COMPOUNDED MEDICATIONS ACT

SECTION 1. OFFICE USE

a. FDA has taken the position in final Guidance to Industry that human office use compounding is not permitted by 503A pharmacies despite statements in the Congressional record that it was not supposed to affect office use.
b. The House Agriculture Appropriations Subcommittee has previously issued report language directing the agency to issue a guidance document allowing a pathway for medications to be compounded for office use consistent with 503A and Congressional intent.
c. Recent FDA draft Guidance limits 503B Outsourcing Facilities' ability to provide office use medications emphasizing the need for 503A traditional pharmacies to help fill this gap.
d. H.R. 1959 allows office use where permitted by state law.

SECTION 2. MEMORANDUM OF UNDERSTANDING (MOU) & DISPENSE VS DISTRIBUTE

a. Section 503A of the DQSA includes a provision limiting the out-of-state distribution of compounded drug products to 5% of total prescriptions dispensed or distributed, unless that state has entered into a Memorandum of Understanding ("MOU") with FDA.
b. The purpose of the MOU is to address the distribution of "inordinate amounts" of compounded medications.
c. FDA has chosen to conflate the words dispense and distribute as the same word despite them being two separate and distinct words as written in the law. This means patients are limited or prohibited from access to compounded medications prepared by pharmacists who specialize in certain therapies.
d. Access should not be determined by where you live. The House Agriculture Appropriations Subcommittee has approved report language directing the agency to treat them as separate activities for 4 years now.
e. H.R. 1959 correctly defines dispense and distribute so patients don't lose access to patient specific prescriptions.

SECTION 3. USP/NF MONOGRAPHS

a. In its finalized Policy on Bulk Substances, FDA indicates that it does not consider USP monographs in the dietary supplements section of USP to be "applicable" USP or NF monographs, and are limiting it to only those monographs in the section of USP talking discussing drugs. This is inconsistent with the plain language of the statute.
b. Patients can buy these meds without consulting a healthcare professional but cannot have them compounded.
c. H.R. 1959 clarifies that all USP monographs are applicable under the law.

SECTION 4. FDA INSPECTION OF PHARMACIES

a. Under 21 USC 374 and 21 USC 360, pharmacies are provided a records exemption and are not required to register with the FDA. Pharmacies have reported that upon inspection by FDA they have been asked to provide records, which are exempted by law.
b. H.R. 1959 would clarify that the current records exemptions applies to all pharmacies, including compounding pharmacies.

ASK

House: Please cosponsor H.R. 1959, Preserving Patient Access to Compounded Medications Act of 2019. Contact the office of Morgan Griffith or Henry Cuellar to register your support.

Senate: Please consider sponsoring companion legislation.