



We Care About Patient Care

2633 5 JUL 22 A10 :01

VIA Hand Delivery

July 21, 2005

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, Maryland 20852

Re: Docket # 2005P-0116/CP1

Dear Sir or Madam:

We write to respond to Citizen Petition 2005P-0116/CP1 submitted on behalf of members of the Consumer Health Alliance for Safe Medication ("CHASM") on March 24, 2005. The Citizen Petition requests that the Food and Drug Administration ("FDA") impose labeling and advertising requirements on compounded aqueous-based inhalation drugs. Specifically, the Petition states that health care professionals and patients lack basic information regarding compounded inhalation drugs. It suggests that new, FDA-imposed labeling regulations are the only way to ensure that health care professionals and patients have access to this information. This suggestion is not accurate. As discussed in more detail below, pharmacists must dispense compounded medications in the context of the physician-patient-pharmacist relationship. This tripartite relationship ensures informed medical decision-making and ready access to detailed information regarding a medication's risks and benefits for the individual patient, without the need for burdensome product labeling. The petition further argues that new labeling regulations are necessary because some pharmacies are exceeding the scope of pharmacy compounding and operating in ways that are more like a drug manufacturer. However, new labeling regulations will not curtail potential violations of the existing pharmacy compounding laws and regulations. Because the requested labeling and advertising requirements would impose an unnecessary regulatory burden without compensatory benefits, the Petition should be denied.

Compounding is a longstanding component of the professional practice of pharmacy. Through compounding, pharmacists provide patients and their physicians access to otherwise unavailable medications to meet the patients' individual medical needs. As the United States Supreme Court has recognized, drug compounding is a traditional function of pharmaceutical practice and:

2005P-0116

C1

is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product. It is a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools . . . Many states specifically regulate compounding practices as part of their regulation of pharmacies.¹

The practice of compounding is regulated by the state boards of pharmacy pursuant to state pharmacy laws. These state laws permit a pharmacist to compound a medication for an individual patient in response to a physician's determination that there is no suitable, FDA-approved manufactured product available.² As a result, it is a pharmacist's professional obligation to dispense compounded medications only in consultation with the physician. A physician's decision to prescribe a compounded medication is based on his or her assessment of the patient's medical need and professional determination of how best to meet those needs. This determination encompasses an evaluation of all of the pharmaceutical options, including those that are not available commercially, but that are described in the technical literature or based on the physician and pharmacist's professional training, experience and judgment. The pharmacist's role in providing the physician with up-to-date technical literature and other information regarding the various pharmaceutical options is essential to this dialogue.³ Thus, communications between the physician and the patient, and the physician and the pharmacist are critical for appropriate compounding practice. As the Supreme Court has recognized, "compounding in response to individual medical needs may have important health benefits. It allows physicians and pharmacists to *work together* to develop customized therapies for patients for whom commercially manufactured drugs are not suitable for various medical reasons . . . the physician and pharmacist can *work together* to create a compounded product that addresses the patient's particularized needs."⁴ In other words, physician-pharmacist dialogue is essential in compounding, and a pharmacist may not compound a medication for an individual patient without physician participation. Because of the physician's role in prescribing specific

¹ *Thompson v. W. States Med. Ctr., et. al.*, 535 U.S. 357, 361 (2002).

² *See, e.g.*, ALA. ADMIN. CODE § 34-23-150, *et seq.*; ARK. REG. 07-02-0001; ARIZ. ADMIN. CODE R4-23-670; CAL. BUS. & PROF. CODE § 4127-4127.6; GA. COMP. R & REGS. r. 480-11.05, 11.09; IOWA ADMIN. CODE r. 657-20.1, *et seq.*; KAN. ADMIN. REGS. 68-13-1; KY. ADMIN. REGS. 2:076; MO. CODE REGS. ANN. tit. 4 §§ 220-2.200, 2.400; N.J. ADMIN. CODE tit. § 13:39-11.1, *et seq.*; S.C. Pharmacy Board Policy & Procedure 132, 133, 137; 18 VA. ADMIN. CODE § 110-20-416.

³ In *Western States*, the Supreme Court recognized a pharmacist's First Amendment right to advertise the availability of a compounded medication, holding that unless misleading or false, "Congress may not prohibit pharmacists from soliciting prescription orders or advertising or promoting, the compounding of any particular drug, class of drug or type of drug." 535 U.S. at 377.

⁴ *Id.* at 362 (emphasis added).

medications, the petitioner's proposed labeling is unnecessary and does not add appreciably to the exchange of information between the physician and pharmacist.

The petitioner also argues that compounded inhalation medications pose specific risks for patients with respiratory diseases because the compounded formulations do not satisfy FDA regulatory requirements for drug manufacturing. Pharmacy compounding is not drug manufacturing and is not subject to the same FDA laws and regulations as drug manufacturing. Physicians prescribe compounded medications because they believe, based upon their knowledge of the patient and available medications, their professional training, judgment and experience, the scientific literature and consultation with the pharmacist, that the benefits of a particular medication, dosage, formulation or combination of medications will provide therapeutic benefits without unacceptable risk for a particular patient. Importantly, the alternative to a compound medication is not an FDA-approved and regulated pharmaceutical. Rather, the alternative is not providing the desired medication at all because, by definition, compounded medications are those that are not commercially available. The Supreme Court has acknowledged that compounded medications are not, and should not be, subject to the same requirements as manufactured drugs. Specifically, in *Western States*, the Court said "it would not make sense to require compounded drugs created to meet the unique needs of individual patients to undergo the testing required for the new drug approval process."⁵ Further, as the FDA recognizes, "pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner."⁶ As a result, the FDA typically defers to the states to regulate pharmacy compounding as a component of the practice of pharmacy.⁷

Importantly, although not subject to the pre-marking approval requirements and post marking controls applicable to new drugs under the Food, Drug and Cosmetic Act ("FDCA"), the practice of pharmacy compounding is subject to numerous state and federal laws, regulations and guidelines. Pharmacists who compound inhalation medicines are subject to state regulations and rigorous official compendia standards, which many states have adopted and enforce. State pharmacy laws regulate all aspects of a pharmacy's operations, including licensing, record-keeping, facility cleanliness, and prescription protocol. Many states also incorporate the rigorous requirements imposed pursuant to the United States Pharmacopoeia ("USP"). USP standards are authoritative and science-based.⁸ USP Chapter <797>, relating to the compounding of sterile preparations, is of particular import for a pharmacy that compounds inhalation preparations. USP <797> establishes requirements for assuring a preparation's

⁵ *Id.*

⁶ The Office of Regulatory Policy and the Office of Compliance in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. Compliance Policy Guides Manual, Section 460.200, Pharmacy Compounding (May 2002).

⁷ *Id.* at 2.

⁸ In addition to many chapters pertaining to medications generally, USP chapters that specifically address compounding practices include, Chapters <795> (nonsterile preparations), <797> (sterile preparations), <1075> (good compounding practices) and <1160> (pharmaceutical calculations in prescription compounding).

stability, sterility and potency and requires, among other things, sterility testing, beyond-use-dating, quality assurance programs, environmental monitoring, equipment maintenance and specific compounding methods. The requirements of USP <797> are intended to prevent patient harm or fatality that could result from nonsterility, excessive bacterial endotoxins, large content errors in strength of correct ingredients, and incorrect ingredients in compounded sterile preparations. The FDCA and the food and drug laws in many states provide that a drug product that fails to satisfy USP requirements of strength, purity, and quality is adulterated.

The FDA also has developed guidance on what it considers to be acceptable compounding practices. In May 2002, FDA issued a Compliance Policy Guide which outlines nine factors that FDA considers in evaluating pharmacy compounding practices.⁹ Among other considerations, this Compliance Policy Guide suggests that FDA will seek enforcement action against compounding pharmacies that engage in many of the activities the petitioners cite in their Petition as problematic and potentially harmful. In fact, the petitioners cite several examples of the FDA exercising its enforcement authority against compounding pharmacies for what it believes are specific violations of the Compounding Compliance Policy Guide. In light of this FDA oversight, the requirements of the USP, and state pharmacy laws and regulations, additional labeling requirements provide no additional protection for patients from the potential harms the petitioners seek to address.

For the reasons identified above, we do not believe that additional labeling and advertising regulations are necessary. We therefore request that Citizen Petition 2005P-0116/CP1 be denied. We appreciate this opportunity to provide our comments.

Respectfully Submitted,



Robin L. Menchen
Chief Compliance Officer

DC\773606.1

⁹ We note that the enforceability of the FDA's Compliance Policy Guide as it pertains to pharmacies is currently being challenged and we do not concede any rights, challenges or arguments with respect to FDA's alleged jurisdiction over pharmacies and pharmacy compounding. See *Medical Center Pharmacy, et. al., v. Ashcroft*, No. 7:04-cv-130 (W.D. Tex. Filed Sept. 2004).