



**International Academy
of Compounding Pharmacists**

P.O. Box 1365

Sugar Land, Texas 77487

281/933-8400 voice

281/495-0602 fax

1-800-927-4227

www.iacprx.org

iacpinfo@iacprx.org

August 15, 2005

BY FACSIMILE/CONFIRMATION COPY BY U.S. MAIL

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

RE: Docket No. 2005P-0116 – Comments in Opposition to CHASM Citizen Petition re Labeling and Advertisements for Compounded, Aqueous-Based Drugs for Inhalation.

Dear Sir or Madam:

On March 24, 2005, the Consumer Alliance for Safe Medication (“CHASM”), filed the above-referenced citizen petition asking the Food and Drug Administration (“FDA” or “agency”) to take extensive regulatory action regarding labeling and advertisements for compounded, aqueous-based drugs for inhalation. The analysis that CHASM provides to support its request is flawed. The citizen petition offers nothing more than anecdotal evidence to support its request for sweeping regulations.

In addition, in the course of its attack on compounding pharmacies, it misstates the views of the International Academy for Compounding Pharmacists (“IACP”), a non-profit association of more than 1,800 compounding pharmacists. Contrary to the impression created by CHASM, IACP is devoted the professional integrity and advancement of pharmacy compounding. IACP, like CHASM, supports measures to improve compounding. IACP, and the broader pharmacy community, have taken many steps to further enhance the practice of compounding. Examples of these initiatives, which predate the citizen petition, include the implementation of a Potency Task Force to enhance standards and practices for pharmacies to ensure their medications are effective,

2005P-0116

C2

participation with a consortium of eight national pharmacy organizations to establish a rigorous accreditation program for compounding pharmacies, providing education to compounding pharmacists on preparation testing and safety protocols, and dissemination of numerous related publications, for example, a Hazard Alert guidance on preparing hazardous and potent medications.

Millions of Americans have unique health needs that off-the-shelf, prescription medicines cannot meet. For them, customized medications – prescribed or ordered by licensed physicians and prepared safely by trained, licensed compounding pharmacists – are the only way to better health. The Food and Drug Administration, the U.S. Supreme Court, Congress, and virtually every major association of healthcare professionals recognize the importance of pharmacy compounding. Patients with unique needs rely more heavily on compounded medications than the general population – including home healthcare patients, hospice care patients, cancer patients, women undergoing hormone treatment, hospital patients on intravenous medicines, pain management patients, dental patients, dermatological patients, and others. Similarly, many patients with respiratory illnesses whose unique needs are not served by pharmaceutical manufacturers also rely on compounded, aqueous-based drugs for inhalation.

CHASM's petition ignores both the benefits of compounding and all of the IACP quality initiatives, as well as any other information demonstrating the continuous improvements being implemented by pharmacists. Therefore, IACP takes this opportunity to correct CHASM's misstatements, to comment on the errors in the CHASM citizen petition, and to urge FDA to deny the petition.¹

I. The Analysis Provided by the CHASM Citizen Petition Is Flawed

The CHASM citizen petition alleges that pharmacies that compound aqueous-based inhalation drugs engage in misleading promotional practices, thereby causing the substitution of compounded inhalation medications for commercially available manufactured drugs without the knowledge of prescribers or patients. The citizen petition

¹ IACP does not seek in this response to address all of the issues raised in the CHASM's multi-prong citizen petition. The fact that IACP does not address a specific issue or assertion should not be construed as meaning that IACP agrees with CHASM's analysis of that particular issue or CHASM's allegations.

also claims that these substituted compounded drugs pose safety risks to patients because compounding pharmacies do not adhere to FDA's current good manufacturing procedures ("cGMPs") and the sterility requirements for manufactured aqueous-based inhalation drugs.

The petition bases its requests upon a series of unsubstantiated assertions and conclusions. At best, CHASM's assertions are supported only by anecdotal evidence, without providing any context. The petition, for example, relies heavily on statements contained in Warning Letters issued by FDA to just three compounding pharmacies.²

The citizen petition also asserts that "[c]ompounded inhalation drugs are not prescribed based on determinations by health care professionals that their patients' individual needs [require the compounding of a commercially unavailable medication]," but rather that "[t]hese drugs are prescribed based on promotional activities by compounding pharmacies."³ While CHASM offers examples of promotional materials from a handful of compounding pharmacies that it claims are misleading, nowhere in the citizen petition does CHASM offer evidence to establish that the dissemination of misleading promotional materials is widespread, or that health care practitioners routinely prescribe compounded, aqueous-based inhalation drugs for any reason other than they believe it to be in the patient's best interests. Indeed, even if a few pharmacies have improperly promoted their compounded drugs, it does not mean doctors prescribed compounded drugs for their patients "based" on the promotional information. CHASM presents no evidence to establish the supposed causal relationship between improper promotion and actual prescribing patterns.

CHASM clearly would prefer that pharmacists did not tell physicians that they can compound aqueous-based respiratory medications. CHASM's preferences notwithstanding, the Supreme Court has rejected that viewpoint, finding a constitutional

² See, e.g., CHASM Citizen Petition at 6, (Reference to Warning Letters issued by FDA to Lincare, Inc./Reliant Pharmacy Services, Respi Care Group of Puerto Rico, and Med-Mart Pulmonary Services). FDA has not pursued subsequent disciplinary measures through court proceedings against the three pharmacies, or any other pharmacy that compounds aqueous-based drugs for inhalation.

³ CHASM Citizen Petition at 18.

right for pharmacists to advertise their compounding services.⁴ Thus, CHASM's attack on the advertising of the ability to compound identified respiratory medications is foreclosed by the First Amendment.

CHASM further arrives at its conclusions by ignoring critical facts. The citizen petition, for example, asserts that "federal policies related to reimbursement under Medicare have enabled durable medical equipment suppliers to secure reimbursement for compounded inhalation drugs based on levels of reimbursement established for approved medications with the same active ingredient(s)," which has created "a considerable inducement to replace approved medications with compounded medications with the same active ingredient(s), which can be prepared by pharmacists at a far lower cost."⁵ The citizen petition neglects to mention, however, that Medicare's relevant reimbursement policies were revised under the Medicare Part B reforms in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),⁶ and that the economic inducements referred to in the citizen petition no longer exist. Prior to 2004, Medicare reimbursed for inhalation medications at 95% of Average Wholesale Price (AWP). Under the revised policies, implemented in 2005, compounded pharmacists are reimbursed based on Average Sales Price (ASP) plus 6%. This MMA revision is estimated to cut reimbursement payments for inhalation medications by as much as 58%⁷ and save Medicare over \$4.2 billion by the end of 2013.⁸ Thus, the economic incentives posited by CHASM as the source of drug substitution no longer exist.

⁴ Thompson v. Western States Med. Ctr., 535 U.S. 357 (2002).

⁵ CHASM Citizen Petition at 5.

⁶ Pub. L. No. 108-173, § 305, 117 Stat. 2006 (2003).

⁷ J. Gunderson, Drug bill deals AWP pricing a heavy blow, HME News, January 2004. Available at http://www.findarticles.com/p/articles/mi_qa4029/is_200401/ai_n9400530/print.

⁸ Letter from Congressional Budget Office to Senator Ted Stevens, Senate Appropriations Committee Chairman, (November 20, 2003) at 5. Available at <http://www.cbo.gov/ftpdocs/48xx/doc4853/11-20-MedicareLetter3.pdf>.

CHASM seeks FDA's involvement in the prevention of the alleged surreptitious inhalation drug substitution. Yet CHASM provides no evidence that this behavior occurs, and its speculative concerns do not warrant any FDA intervention. With the exception of the statutorily authorized substitution of lower-cost generic drugs for prescribed brand name drugs under specified circumstances, the substitution of drugs without the prescriber's prior consent is generally prohibited as a matter of state pharmacy law.⁹ This, like all aspects of the practice of pharmacy, is already pervasively regulated by state boards of pharmacy. A pharmacist who substitutes a compounded drug without complying with state law can be sanctioned. FDA should not be spending scarce resources to regulate conjectural conduct which, if it occurs, violates state law.

⁹ See, e.g., State of Alaska Statutes and Regulations, Appendix C: Good Compounding Practices, Feb. 2005 (available at <http://www.dced.state.ak.us/occ/pub/PharmacyStatutes.pdf>) ("When a compounded product is to be substituted for a commercially available product, both the patient and the prescribing practitioner must authorize the use of the compounded product. The pharmacist shall document these authorizations on the prescription order or in the computerized patient medication record."); Wash. Admin. Code 246-878-020 ("When a compounded product is to be substituted for a commercially available product, both the patient and also the prescriber must authorize the use of the compounded product. The pharmacist shall document these authorizations on the prescription or in the computerized patient medication record."); 201 Ky. Admin. Regs. 2:080 ("... whenever any registered pharmacist is requested to sell, furnish, or compound any drug, medicine, chemical or pharmaceutical preparation by means of a prescription and substitutes or causes to be substituted therefore, any other drug, medicine, chemical, or pharmaceutical preparation without specific or express permission, approval, or consent of the prescriber, the board may find such person guilty of engaging in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public, and may revoke or suspend his license as prescribed by law."); Okla. Stat. tit. 59 § 8-353.13.D ("No pharmacist being requested to sell, furnish or compound any drug, medicine, chemical or other pharmaceutical preparation, by prescription or otherwise, shall substitute or cause to be substituted therefore, without authority of the prescriber or purchaser, any like drug, medicine, chemical or pharmaceutical preparation."); W. Va. Code § 30-5-12 ("... the following acts shall be prohibited . . . (2) the substitution or the dispensing of a different drug in lieu of any drug prescribed in a prescription without the approval of the practitioner authorizing the original prescription . . .").

CHASM also attacks compounding pharmacies for not meeting drug cGMPs. Yet, the petition also notes that FDA's preamble to the sterility regulation, 21 C.F.R. 200.51, states that the agency anticipated that the regulation would apply to pharmacies that, in FDA's view, cross over the line from medication compounding to drug manufacturing, but that pharmacies whose operations remain within the ambit of pharmacy compounding must comply with the United States Pharmacopoeia's (USP) requirements for the compounding of sterile preparations (USP <797>).¹⁰ Since Section 503A of the Food, Drug and Cosmetic Act ("FDC Act") was intended only to distinguish between compounding and manufacturing practices and set no standards for pharmacy compounding, the subsequent Supreme Court decision had no bearing on the standards that should apply to compounded inhalation drugs and did not mean that cGMPs applied to compounding pharmacies instead of the USP standards. Therefore, by CHASM's own admission, there are two sterility standards for inhalation drugs, FDA's regulation, which applies to manufactured drugs, and the USP <797> sterility standards, which apply to compounded medications. Nevertheless, the citizen petition suggests that there is a single operative sterility standard – the one that applies to manufactured drugs – and incorrectly insinuates that compounding pharmacies are required to meet this standard.¹¹ Compounding pharmacies, however, are not required to conform to the sterility standard for manufactured drugs. Hence, CHASM's assertion that "compounding pharmacists have themselves generally acknowledged that they cannot or will not meet FDA's sterility requirement for their compounded medications" only reflects FDA's own position.¹²

II. The CHASM Citizen Petition Mischaracterizes IACP's Positions Regarding Pharmacy Compounding

The CHASM citizen petition is also flawed because it grossly misstates IACP's positions – and the position of the broader compounding community – on a number of critical issues. Therefore, we are compelled to correct these mischaracterizations.

¹⁰ CHASM Citizen Petition at 9.

¹¹ Id.

¹² Id.

A. Sterility of Compounded Aqueous-Based Drugs for Inhalation

Contrary to CHASM's assertions,¹³ IACP agrees that all compounded aqueous-based inhalation drugs must be sterile, and IACP does not oppose the USP's sterility standards for compounded preparations.¹⁴ In fact, IACP has long supported such standards. IACP believes that pharmacies engaged in the compounding of inhalation medications should incorporate all pharmacy-specific USP protocols regarding personnel training, environmental sampling, process, procedure and personnel validation, end-product testing, and equipment and facilities control and certification to assure sterility and proper endotoxin levels of inhalation medications.

The CHASM citizen petition also mischaracterizes IACP's position regarding compounded medication sterility standards that have been proposed in the past by state boards of pharmacy. The petition asserts that IACP "has opposed requirements related to validation of sterilization, aseptic processing, environmental quality controls, processing, and finished product release checks."¹⁵ This characterization, however, distorts the record. IACP's January 31, 2003 letter to the Missouri State Board of Pharmacy,¹⁶ for example,

¹³ See CHASM Citizen Petition at 8-9.

¹⁴ See, e.g., IACP, Aqueous-based Oral Inhalation Medications Must be Sterile, The Pharmacists' Link (July 2002) at 18 ("...all compounded aqueous-based medications for oral inhalation need to be prepared sterile"); IACP, USP Proposes New Requirements for Sterile Compounding, *Id.* ("IACP supports the efforts of USP to develop guidelines and standards for the preparation of sterile drug products to be administered to patients and believes the profession of pharmacy must expand its efforts to ensure that pharmacists are implementing proper standards when preparing sterile drug products."). (Available at <http://www.iacprx.org/pdf/July2002Link.pdf>). The criticisms of the USP sterility standards that IACP registered during the USP chapter revision process were driven by the fact that the chapter had been hastily revised and released for public comment prematurely, without regard for whether the draft provisions were capable of being implemented in the real world of pharmacy compounding or were capable of achieving their intended goals.

¹⁵ See CHASM Citizen Petition at 8-9.

¹⁶ CHASM Citizen Petition at Tab 3.

was critical of the Board's proposed emphasis on end-product testing, which we believe is inadequate for assuring product quality and sterility. Instead, IACP recommended that the Board adopt a more reliable and robust regulatory regime consisting of systemic process controls, including (1) personnel, process, and procedure validation, monitoring and testing, (2) equipment validation, (3) environmental quality sampling, and (4) quantitative end-product testing performed on a sampling basis.¹⁷ The CHASM citizen petition itself emphasizes the limited value of the Missouri State Board of Pharmacy's reliance on end-product testing as the determinative indicator of product quality.¹⁸ IACP's criticism of the Missouri Board's focus on end-product testing in favor of a more comprehensive set of controls can in no way be construed as opposing regulation.

B. Commercially Available Medications

IACP acknowledges that it is generally unacceptable to compound exact duplicates of approved, commercially available drug products. Board of pharmacy regulations and USP standards preclude this practice.¹⁹ However, when a manufactured drug is not available – a situation that arises occasionally for a variety of reasons, e.g., the inability of the manufacturer to meet cGMPs or commercial factors – compounding pharmacists are essential for filling the void. Accordingly, we believe that compounding pharmacies should have procedures in place requiring pharmacy personnel to determine whether a prescription

¹⁷ Id.

¹⁸ See CHASM Citizen Petition at 8 (quoting preamble to FDA regulation 21 C.F.R. 2000.50, 62 Fed. Reg. 49,368, 49, 369 (1997)) (“End-product microbial limits tests performed prior to distribution may not be capable of detecting sufficiently low levels of contamination.”); CHASM Citizen Petition at 12 (quoting letter from The Hon. Tom Bliley, Chairman, The Committee on Energy and Commerce, United States House of Representatives, to Jane Henney, M.D., Commissioner, FDA (May 8, 2000)) (In the event counterfeit bulk drugs containing impurities are used in drug manufacture, “no amount of finished product testing can build quality into the product.”).

¹⁹ See, Good Compounding Practices Applicable to State Licensed Pharmacies, Subpart A. National Association of Boards of Pharmacy Model Practice Act (2003) (Available at <http://www.nabplaw.net>); <1075> Good Compounding Practices, USP Pharmacists' Pharmacopeia (2005) at 455.

August 15, 2005

Page 9

or order for a compounded medication is commercially available before filling the prescription or order. Further, pharmacy personnel should establish procedures to periodically confirm whether frequently compounded medications have become commercially available.

However, it is important to note that in enacting the FDA Modernization Act, Congress defined copies of commercially available drug products to exclude a compounded medication in which there is a change from the commercial product that produces a ‘significant difference’ for the patient, as determined by the prescribing practitioner.²⁰ According to Congress, “for example, the removal of a dye from a commercially available drug product for a particular patient who is allergic to such dye shall be presumed to be a ‘significant difference.’”²¹ During debate over this topic, Congress expressed its expectation that FDA and the courts would accord great deference to the health care prescriber’s judgment in determining whether the change produces a “significant difference.”

The need for individualized patient care requires an individualized determination by the physician. If the physician prescribes a compounded drug because he or she believes that there may be a therapeutically significant difference, the doctor’s evaluation of that patient should be determinative. Believing that manufactured respiratory medications almost always will suffice to meet patients’ needs, CHASM appears to want to subordinate the judgment of physicians to its opposition to compounded drugs. That is incorrect.

Compounded medications for inhalation provide vital medication therapy options that are frequently needed to treat vulnerable patient populations such as children and the elderly. Tens-of-thousands of elderly patients (those over the age of 65 years) suffer from respiratory illnesses – with the most prevalent being chronic obstructive pulmonary disease (COPD). A significant number of these patients also suffer from secondary illnesses including congestive heart failure (CHF), diabetes, and other chronic illness, which can complicate their treatment.

²⁰ FDC Act § 503A, 21 U.S.C. § 353a (Struck down by Thompson v. Western States Med. Ctr., 535 U.S. 357 (2002)).

²¹ Conf. Rep. on S. 830, Food and Drug Administration Modernization Act of 1997, 105th Cong. (1997) (enacted) (November 9, 1997).

Pharmacists report that as many as 150 different oral inhalant drug combinations have been ordered for compounding by physicians for their older patients who suffer from COPD, with and without active, secondary disease. Recurring reasons that physicians request compounded medications include:

- Larger dose required.
Patients may be, or become over time, refractory to the drug concentration in commercially available, off-the-shelf preparations and require a higher drug concentration per dose than is available in the marketplace.
- Smaller dose required.
Patients may be unable to tolerate the drug concentration in commercially available, off-the-shelf preparations and require a reduced drug concentration per dose or smaller dose sizes than are available in the marketplace. This requirement commonly occurs in COPD patients with CHF and with children.
- Intolerance to additives.
Some patients can not tolerate the excipients and preservatives that are sometimes added to commercially manufactured medications in order to assure the lengthy (2 to 3 year) shelf life required in order to maintain the integrity of the millions of doses in the commercial distribution chain.
- Multiple drugs combined into a single dose.
As the citizen petition points out, many of the inhalation medications currently compounded by pharmacies contain combinations of two or more active ingredients which are not manufactured in that combination. Pharmacies compound these combination inhalation medications upon receipt of a prescription or order from health care practitioners who have determined that the combinations are medically necessary, for example, because they facilitate ease of administration for their patients or improve patient compliance. This condition is common among older patients who often require several different types of drugs to treat their condition – such as a combination of two or three bronchodilators (such as albuterol, ipratropium bromide, or metaproterenol); a glucocorticoid (such as dexamethasone, triamcinolone, or flunisolide); and anti-inflammatory agents (such as cromolyn sodium). These drugs may not be commercially available in suitable dose sizes or, more frequently, the number of nebulizer administrations per day becomes so numerous and time consuming with single doses of each medication that, in the judgment of prescribing physicians,

patient compliance can only be assured by combining several drugs into a single dose and a single administration. Further, older patients may have great difficulty in managing the measurement, mixing, and multiple administrations of oral inhalant medications when they are provided in single- or multi-dose packages. There are very few commercially available two- or three-drug combinations because of the relatively small size of the potential user-group and the difficulty of maintaining long-term stability sufficient to assure a 2- or 3-year shelf life.

IACP does believe that pharmacists should make efforts to ensure that combinations of active pharmaceutical ingredients prescribed by physicians are compatible and do not result in accelerated chemical degradation or inactivation. Because preservatives, stabilizing agents, solvents, alcohols, and other additives may cause adverse events in some patients, compounded medications for inhalation should be free from such ingredients when appropriate. Prescribing health care providers should be informed of the important characteristics of the compounded medications, including the presence of preservatives or excipients that may affect their patients. IACP has taken steps to educate pharmacists about these considerations. However, rather than identifying constructive measures to further improve compounding so that respiratory patients and their physicians have more therapeutic options to meet individualized needs, CHASM indulges in a blanket condemnation of compounding.

C. Quality and Safety of Compounded Medications

Contrary to the misimpression created by CHASM, IACP has actively advocated many measures designed to improve the quality of compounded drugs through activities such as continuing education sessions, member alerts and publications, interaction with state boards of pharmacy, and contributions to accreditation standards. For example, IACP supports the standard outlined in USP <1075>²² that compounding pharmacies should purchase pharmaceutical ingredients from FDA-registered facilities that are subject to FDA inspections and the agency's cGMP requirements for manufacturing and/or repackaging. Such requirements include appropriate labeling of pharmaceutical ingredients and assuring the accuracy of the certificates of analysis. Certificates of analysis should accompany all pharmaceutical ingredients obtained by a pharmacy for use in preparing compounded

²² See, <1075> Good Compounding Practices, USP Pharmacists' Pharmacopeia (2005) at 457.

medications. Pharmaceutical ingredients used for purposes of pharmacy compounding also should meet official compendia requirements (USP/NF) whenever possible.

In addition, IACP supports USP standards that compounded medications – whether for inhalation or other indications – should be dispensed in packaging with quality and labeling characteristics comparable to commercially available medications.²³ Further, pharmacists should avoid using paper labels applied directly to the primary container of the medication because the label may contain components with the potential to leach and enter the drug product.

Contrary to the aspersions cast by CHASM, compounded respiratory medications have an excellent safety record. This past performance, though, has not resulted in complacency by the pharmacy community. As noted above, IACP, pharmacy associations, state boards of pharmacy, schools of pharmacy, and accreditation bodies are all engaged in efforts to further improve compounding. Additional FDA regulatory actions are unwarranted.

D. Labeling

CHASM asks FDA to take extensive regulatory action, including the promulgation of regulations requiring specific language for labeling for all compounded, aqueous-based inhalation medications. The measures that CHASM advocates are unwarranted and potentially harmful. The specific language proposed by CHASM in some instances is misleading and therefore potentially violative of the FDC Act. As noted earlier, for example, FDA uses two sterility standards for aqueous-based inhalation drugs, the agency's regulation for manufactured drugs and the USP sterility standards for compounded drugs. Nevertheless, CHASM advocates labeling compounded inhalation medications with the statement "the product does/will not meet FDA standards for sterility," notwithstanding the fact that the statement will not be true if the drug has been compounded in conformance with USP sterility standards. CHASM's proposed labeling language also is unduly alarmist. The fact that a properly compounded medication "has not been demonstrated safe and effective" is entirely inappropriate because compounded drugs are not subject to the FDC Act's new drug requirements. Yet this language could well induce patients to avoid the use of medications that prescribing healthcare professionals have determined are

²³

Id.

medically necessary and for which there are no commercially available alternatives, to the detriment of the patients' health and well being. Indeed, because of the nocebo effect,²⁴ this kind of text could cause the patient to have a worse outcome.

IACP does agree that prescribers should always know when a prescription requires a medication to be compounded and dispensed to a patient. Patients should also always be informed through labeling and/or through counseling, that the medication they are receiving has been compounded by the pharmacy. Existing USP Chapters <795> and <1075> address counseling and labeling standards. IACP supports the USP standards for information that should be included on the prescription label for all pharmacy compounded medications, as follows:

- (1) patient's name,
- (2) prescriber's name,
- (3) name and address of compounder,
- (4) prescription number,
- (5) the medication's established or distinct common name,
- (6) strength,
- (7) statement of quantity,
- (8) directions for use,
- (9) date prescription is filled,
- (10) beyond-use date and storage instructions,
- (11) appropriate designation indicating the medication is compounded, and
- (12) any other state or federal requirements.²⁵

²⁴ A nocebo effect is defined as "a negative placebo effect as, for example, when patients taking medications experience adverse side effects unrelated to the specific pharmacological action of the drug. The nocebo effect is associated with the person's prior expectations of adverse effects from treatment as well as with conditioning in which the person learns from prior experiences to associate a medication with certain somatic symptoms. Anxiety and depression predispose to the nocebo effect.", MedicineNet.com, <http://www.medterms.com/script/main/art.asp?articlekey=31482>; see also Katharine Dunn, The Nocebo Effect, Harvard Magazine (May-June 2005). (Available at <http://www.harvard-magazine.com/on-line/050572.html>).

²⁵ See <1075> Good Compounding Practices, USP Pharmacists' Pharmacopeia (2005) at 458.

IACP advocates that compounded inhalation medication labeling contain this type of information because prescribers and patients must always have the opportunity for an informed dialogue with the pharmacist filling the prescription to ensure the most appropriate medication is used for the particular patient's needs. Similarly, upon request, pharmacists should be able to provide information to the prescriber related to the identity, ingredients, quality assurance, and other important characteristics of their compounded medications.

* * * * *

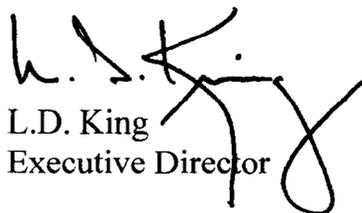
CHASM has broadly and aggressively attacked the compounding of inhalation medications. Yet, this practice is medically essential for a number of patients, including the pediatric and older patient populations previously referenced. CHASM's attack relies heavily on limited anecdotal reports. FDA regulations require a far stronger foundation.

Compounding, like all aspects of pharmacy practice, is already pervasively regulated by state boards of pharmacy and enhanced through professional organizations' quality initiatives. CHASM's concerns can be sufficiently addressed within these forums and without federal intervention.

Contrary to CHASM's attacks, IACP does support the continuous quality improvement programs underway by professional societies. We strongly believe that these initiatives along with existing USP standards and state regulations provide the best approach to achieving optimal therapeutic options for patients.

For all the aforementioned reasons, IACP respectfully requests that FDA deny the CHASM Citizen Petition.

Sincerely,


L.D. King
Executive Director