



State of Utah
Utah Board of Pharmacy
Compounding Task Force

January 8, 2015

The Honorable Orrin G. Hatch
104 Hart Building
United States Senate
Washington, D.C. 20510

Re: Maintaining Utah Patient Access to Compounded Drugs

Dear Senator Hatch:

The Utah Compounding Task Force on behalf of the Utah State Board of Pharmacy would like to bring an important issue to your attention that is affecting our health care here in Utah. This issue, associated with the Drug Quality and Security Act (DQSA) HR 3204 signed into law in November 2013, is impacting our medical and pharmacy communities as well as individual patients.

As a result of the tragic events from the aftermath of the New England Compounding Center (NECC), the regulation of prescription drug compounding has been undergoing drastic changes to ensure this does not happen again. The DQSA introduces increased oversight and tighter regulation, which we applaud. Our point of contention pertains to *non-sterile* compounded products provided by a pharmacy to a practitioner's office for "office use only." Specifically, DQSA HR 3204 prohibits "for office use" compounding and delineates that any compounded drug product prepared and dispensed without a prescription for an identified individual patient is adulterated and misbranded.

The practice of *non-sterile* compounding for "office use only" occurs when a practitioner orders non-sterile compounded medications that are not commercially available, to administer to their patients in the office. It has been a common practice among compounding pharmacies for decades. These products are utilized by all practices in the medical field, but dermatological, dental and critical care sites are finding the new regulations most restrictive to their daily practices.

Some examples of *non-sterile* "for office use only" compounds that are now prohibited are topical agents such as cantharidin plus, Dinitrochlorobenzene, and trichloroacetic acid solutions that dermatologists use every day; or numbing agents that contain tetracaine, lidocaine, and prilocaine used by that dentists on patients; or lidocaine, epinephrine, and tetracaine (LET) gels that critical care sites depend on for numbing and stitching wounds. These medications are often necessary to administer in critical emergency situations to better treat patients. In some cases, the prescribing practitioner may want to carefully monitor a patient after administration for potential side effects. Additionally, all too often, manufactured medications that need to be used in the office are in short supply and thus can only be compounded. To be clear, the *sterile*

products compounded by the NECC were extremely complex intrathecal corticosteroid *sterile* injections. Necessary actions to ensure appropriate safety measures were delayed until it was too late.

The *non-sterile* medications we are referring to are vastly different than the *sterile* medications produced at NECC. *Non-sterile* products such as topical creams and ointments pose minimal risk when compared to *sterile* products.

There are two main points that are problematic with this new regulation. First, as the events were unfolding with the DQSA, numerous times compounding stakeholders and several professional pharmacy organizations were told traditional compounding, which included “office use only” compounding, would not be affected and would remain under state regulation. Ultimately, this was not the case.

Second, the Utah State Board of Pharmacy and the Utah Department of Commerce, Division of Occupational and Professional Licensing (DOPL) drafted rules to address concerns regarding “office use only” compounding. After the Utah Legislature passed S.B. 77 in 2014 that allowed "office use only" compounding, Utah was prepared to implement these rules. Unfortunately, upon further inquiry of the FDA and the Utah Office of Attorney General, DOPL determined under the DQSA and the Federal Drug Cosmetic Act (FDCA), Utah compounding pharmacies are prohibited from “office use only” *sterile* and *non-sterile* compounding. As a result, DOPL proposed a rule that complied with the federal law.

Practitioners in Utah are frustrated that they are unable to obtain *non-sterile* medications that they previously could compound and have used safely for many years. DQSA has drastically changed their practice and the way they provide treatment to their patients. While the FDA does allow practitioners to obtain “for office use” medications from the 40 outsourcing facilities across the country which are regulated by the FDA, there is no such facility in Utah. Even if this were not the case, the practice of outsourcing has multiple issues which are of concern. These include outsourcing facilities that are relatively new and practitioners are not familiar with them or their standards of safety. In addition, practitioners are finding it very difficult to get necessary *non-sterile* products at outsourcing facilities, since outsourcing facilities primarily produce *sterile* products. Most importantly, there is no evidence to show improved safety with *non-sterile* medications obtained at outsourcing facilities compared to those compounded by traditional compounding pharmacies “for office use.”

Not allowing “for office use” compounding also denies commerce to Utah businesses. The DQSA is denying the practitioner the right to make the best medical decisions for their patients by preventing them access to the correct medications as well as access as to the best place to receive the medications.

We have two important objectives to accomplish. First, there will be new federal legislative initiatives forthcoming in 2015 to correct this issue within the DQSA. We want to express our

concerns at this time so you are aware and informed of the desires and concerns of your Utah stakeholders.

Second, we would like to entertain any questions you may have and would be happy to meet for further discussion at your convenience, to include all stakeholders you see fit, and within a forum that would best meets your needs. **You may contact Dr. Trip Hoffman, Chair of the Utah Compounding Task Force, with any questions. Dr. Hoffman can be reached at trip@universitypharmacy.com.**

We are truly concerned about the deleterious effects of this new regulation on our State. We would like to see *non-sterile* “for office use” compounding resume in Utah early this year. We strongly believe that not only is this a safe and effective practice in the State of Utah, but to continue to deny the practice will have a significant detrimental impact on patients. We would value your help and guidance in bringing this practice back in the realms of traditional compounders in Utah and allowing our practitioners to choose the appropriate medications to best treat their patients.

Sincerely,

Utah Compounding Task Force Committee

Utah Board of Pharmacy