

Yes to Appropriate Compounding, No to Illegal Compounding

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Dermatology is often described as a "visual" specialty. While it is true that many of our diagnoses can be made based on a relatively quick recognition of morphology, such a characterization of our profession overlooks the reality that dermatologists are "doers" in the clinic. From aesthetic injections to biopsies and cryosurgery, much of our patient care time is spent performing minor and major procedures. We are well known for our in-office efficiency and cost saving practices.

In order to perform those procedures, we rely on certain drugs that are not available to us in commercially marketed formulations. From hemostatic agents such as Monsell's solution to numbing creams to cantharidin for warts, dermatologists are arguably among the specialties most reliant on drug compounding. As such, we stand to be profoundly impacted by potential changes by the Drug Quality and Security Act (DQSA). Draft regulations are so strict that it will ban us from making simple dilutions in the clinic setting such as adding saline to neurotoxins or buffering Lidocaine.[1] If DQSA regulations fully enacted, we may find it difficult to render care to patients as needed which eventually may lead to the end of our efficient and cost saving practice model. To be sure, the deaths of 76 individuals in 2012 due to an outbreak of meningitis perpetuated by tainted products from the New England Compounding Center demonstrates the need for regulation of mass-compounding.[2] We all have a vested interest in ensuring the purity and quality of any drug products we use. However, we have not seen a patient injured by proper use of compounded Aluminium Chloride or Monsell's solution yet. Therefore, reaction to a few bad actors—who arguably were operating outside existing best practices—must not be allowed to interfere with appropriate care for millions of Americans.

Existing and proposed regulation of compounding is complex, but understanding context is important. Although the scope of new rules will impact even simple dilution of neurotoxins and buffering of Lidocaine as well as acquisition of small quantities of NOT readily available products, they will also be positively impacting another important aspect of dermatologic treatment which is crucial for patient safety. This important part of the equation is the necessity to control the illegal compounding of existing topical drugs that we use every day in our practices. The key word here is "existing". The whole purpose and spirit of compounding is to create commercially not available and not FDA approved drugs.[3] Not only is it absolutely unnecessary and illegal to create compounded products replacing existing drugs but also is dangerous for patient safety. It is important to remember and consider the breadth of the research to prove clinical efficacy and safety as well as the efforts to meet FDA requirements to bring a topical product to the market versus mixing a powder with a gelling agent in a blender. As dermatology providers, we all recognize the importance of vehicles and their impact on efficacy and tolerability of topical therapy. The short financial gain from such practices of illegal compounding is certainly outweighed by risks including malpractice and criminal prosecution. Actually, Federal Food, Drug, and Cosmetic Act (FDCA) prohibits physicians from regularly compounding prescriptions that are essentially copies of commercially available drugs. First violation is considered a criminal act with a penalty of up to one-year imprisonment or a fine up to $1000 or both. A second violation may carry a punishment of up to 3 years in prison and/or up to $10000 penalty as well as mandatory exclusion from Medicare and Medicaid.[4]

As specialists in the treatment of the skin, hair, and nails, we know what tools we need to accurately and efficiently diagnose and treat our patients. Therefore, we must take the time to understand the complexities of the new regulations for drug compounding, recognize the

differences between legal and illegal compounding so that we can fight to preserve the appropriate and safe patient care and stop the illegal compounding. If we do not fight the fight ourselves then someone else will do it for us, which will not be the best outcome as we have seen in the past. As importantly, we must then respond to regulatory concerns with a reasonable argument to protect our practices. We must advocate for ourselves and for our patients to protect access. No one else has a vested interest in protecting our access to compounding.

We can only save appropriate compounding by preventing inappropriate and illegal compounding!!

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