Statement of National Community Pharmacists Association (NCPA)

Food and Drug Administration Compounding Listening Session
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Good morning and thank you for allowing us this opportunity to share community pharmacy’s perspective regarding drug compounding and FDA’s efforts to implement the compounding provisions of the Drug Quality and Security Act (DQSA). I am Ronna Hauser, VP of Pharmacy Affairs for NCPA and I am joined by Kristen Riddle, Chair of the NCPA Compounding Committee and President of US Compounding Pharmacy.

NCPA represents America’s community pharmacists, including the owners of nearly 23,000 independent community pharmacies, and as the vast majority of our members do not plan to register as a 503B outsourcing facility they will be held to the laws and regulations of section 503A of the Food, Drug, and Cosmetic Act (FD&C).

We would like to focus our remarks on four areas today:

1. Compounded Medications Intended for Office-Use

   Although the issue of office-use has not been formally addressed in draft guidance format, NCPA understands from FDA statements that the Agency intends for 503A pharmacies to have prescriptions for individual patients and that prescriptions are not required for 503B pharmacies, therefore office-use compounding would be restricted to 503B pharmacies. NCPA has serious concerns with this situation, as not all needs for extemporaneous office-use compounds can be met by 503B pharmacies such as Dr. Riddle’s.

   As H.R. 3204 was debated, numerous Congressional members expressed their understanding and expectation that compounding for office-use would remain under the purview of the State Boards of Pharmacy. Section 503A of the FD&C is silent as to when an individual patient prescription is required and it also allows anticipatory compounding based on a history between the pharmacist and physician and is silent as to how this compounded medication leaves the pharmacy. Therefore, State pharmacy practice laws should govern whether office-use is allowed and under what circumstances it is allowed.
2. **Bulk Drug Substances That May Be Used To Compound Drug Products in Accordance With Section 503A of the FD&C**

Since the Pharmacy Compounding Advisory Committee only recently had their inaugural meeting to discuss proposed criteria for developing the 503A positive list, NCPA believes that it was premature for the FDA to have solicited nominations for the list as well as selected six products to consider before the Committee ever met. As a nominating organization, it was difficult to substantiate the nominations without completely understanding the criteria and process that will be used to develop the list.

NCPA recommends that all bulk drug substances that were nominated via the Federal Register Revised Request for Nominations be considered formally by the Committee. NCPA also urges the FDA to institute a formal process by which the list is updated and communicated to the compounding community.

It has taken 18 months to review only 6 nominated bulk substances, and the impact of FDA prohibiting the use of bulk substances that are not components of drugs approved under section 505, or the subject of USP or NF monographs is the abrupt termination of effective compounded drug therapies. To prohibit use of these substances is disruptive for the patients who have relied upon these medications for years, and for the doctors who prescribe them. FDA should exercise enforcement discretion pending the final publication of the positive list.

3. **Memorandum of Understanding between the FDA and the States**

Regarding the draft MOU addressing certain distributions of compounded human drug products between states and FDA, NCPA believes that assigning a specific percentage limit that is applicable to all states is not in the best interest of patients, given varying degrees of compounding activity in each state. Applying this type of approach to the provision of “patient specific” compounded medications that are dispensed pursuant to a prescription is not practical and will likely result in gaps in patient care and diminished access.

Ideally, each individual Board of Pharmacy should determine what constitutes an “inordinate amount.” Each Board would make this decision based on their knowledge of the number of compounding pharmacies and the makeup of the overall compounding marketplace located in their state.

Many pharmacies specialize in specific treatment areas. Because of their expertise, these pharmacies have relationships with doctors and patients in wide geographic areas, are registered in multiple states, and ship their medications. Under the draft MOU, most would involuntarily be deemed an outsourcing facility by FDA. In some cases these pharmacies may not compound sterile products, and therefore would not be eligible to become an outsourcing facility.

NCPA is also concerned that the draft MOU released in February does not include any provisions related to pharmacies that are located near a border with other states as was provided for in the FDA’s previous draft version.
4. Long Term Care Pharmacy Concerns Related to Draft Guidance on Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

NCPA has concerns that FDA, via this Draft Guidance, is trying to limit the amount of product that a pharmacy can repackage at one time. NCPA has many members who service long-term care facilities. For these LTC pharmacies this draft guidance could have great operational consequences. For example, our members provide the homes they service with medication cabinets or automated dispensing systems in addition to emergency kits or crash carts that could drastically be affected by a 14 day supply limit.

Similar to hospitals, LTC pharmacies utilize a variety of remote dispensing and first dose technologies that are essential to minimize waste and decrease wait time for urgently needed medications. These machines are loaded in advance of a patient order arriving at the pharmacy and the draft guidance would sharply hinder their use.

Our members and the facilities who currently utilize these technologies do so under the complete authority and oversight granted by their respective boards of pharmacy and they always follow the expiration date as stated by the manufacturer.

NCPA believes the impact on LTC pharmacies and the facilities they serve is an unintended consequence of the draft guidance and we ask that FDA fully take into consideration the LTC community when finalizing this guidance.

Conclusion

In conclusion, NCPA is committed to working with the FDA, the Pharmacy Compounding Advisory Committee and other stakeholders regarding these important matters. We appreciate your consideration of our remarks today. Thank you.