American Pharmacists Association

FDA Drug Compounding Annual Listening Session – Hospital and Health System Organizations
Representing the American Pharmacists Association:
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- Thank you for the opportunity to represent our nation's pharmacists at today's compounding listening session on hospital and health system organizations. Thank you for the opportunity to provide our perspective to the FDA. We hope FDA considers these points as it crafts future policy and contacts APhA as a resource to ensure patients have appropriate access to compounded medications.

Drug Shortages

- As discussed in previous comments, APhA acknowledges the FDA's risk-based approach to compounding as well as the role health system pharmacies play, especially in addressing drug shortages. It is crucial to clearly outline how compounding practices can comply and adapt during these shortages to ensure patients have access to vital medications without compromising safety or quality.

- The guidance provided by the FDA during the shortage of ibuprofen oral suspension serves as a positive example of collaborative efforts to meet patient needs.

- Drug shortages remain the primary challenge for our hospital and health system members, often requiring daily monitoring and intervention to uphold patient care standards.

- Here are examples illustrating the operational impacts, particularly related to compounding, experienced within hospitals and health systems.

    - When an FDA-regulated product becomes unavailable, hospital pharmacies must scramble to source alternative package sizes and manufacturers. Unfortunately, sometimes this leads to excessive orders, worsening supply and demand issues for other pharmacies. Even if an alternative is available from a 503B pharmacy, recent increases in 483 findings at these facilities mean this supply can also become suddenly unavailable, as seen recently with cardioplegic solutions.

    - If a formulary standard product must be substituted, additional operational efforts are required to update electronic medical records and communicate changes to providers and staff, ensuring safe ordering, dispensing, and administration of alternate medications.

    - Beyond the logistic challenges, these shortages significantly impact hospital pharmacy compounding volumes. For example, during the IV contrast shortage,

pharmacies had to compound, repackage, or prepare anticipatory batch preparations for products they typically did not handle, resulting in increased volumes and logistical challenges. Similarly, shortages of D50W syringes necessitated repackaging or compounding from available strengths, leading to increased compounding activities to maintain access to this critical medication.

- Ketamine vial shortages required repackaging of existing product sizes into smaller units to support neonatal and pediatric care needs and minimize waste. Other controlled substance shortages occur frequently, causing disruptions in the supply chain and operations.

- On better days, pharmacists, technicians, and leaders find solutions and implement workflows to ensure patients receive necessary medications. But on worse days, therapeutic or supply alternatives are scarce, leading to modified treatment plans, care rationing, or care delays, particularly for oncology medications such as fludarabine, fluorouracil, and methotrexate.

- Despite the FDA's efforts to mitigate drug shortages, hospitals and health systems must react and respond daily, investing significant time, labor, and financial resources to care for patients. Often these solutions counteract the goal of FDA's guidance – to reduce the need for compounded drug products and limit risks to patient safety and quality of the drug supply chain.

- As the FDA considers further guidance for 503A and 503B compounding pharmacies, we urge clarification and guidance on compounding practices during shortages to support healthcare facilities in safely and effectively meeting patient needs.

- APhA, along with every compounding pharmacist and technician, is dedicated to patient safety and continuity of care, especially during drug shortages. We appreciate the FDA's attention to these critical issues and look forward to continued collaboration to ensure that compounding guidelines effectively address the challenges posed by shortages.

- We also call on the FDA to enhance communication channels with healthcare providers and stakeholders regarding drug shortages, providing timely updates, guidance, and resources to support effective management strategies.

Syringe Stability

- Manufacturer shortages often require repackaging of available products, e.g., to the smallest dose and package size to avoid waste. However, there is a lack of syringe-specific stability information which limits the ability to repackage, which leads to more waste.

- APhA recommends that FDA identify ways to incentivize manufacturers to consider appropriate package sizes and stability testing in a variety of package types and sizes to allow for more appropriate unit-of-use packaging and reduce the need for compounding or repackaging.

Controlled substance shortages:

- Controlled substance shortages seem almost predictable e.g., 2nd quarter or 4th quarter, possibly related to maxing out on production quotas.
- APhA recommends that FDA work closely with the DEA and manufacturers to ensure quotas do not create shortage situations.

Concern regarding FDA oversight of hospital compounding:

- Some hospitals have experienced inspections requiring practices beyond USP <797> standards, especially related to competency assessment. This seems inconsistent with the guidance provided.

Lack of insurance reimbursement for compounded products:

- While this may not be an issue directly under the purview of the FDA, it could impact patient care when the demonstrably difficult to compound (DDC) draft guidance goes into effect. While the proposed list of drugs includes compounding methodologies, the rationale in the document is broad and could be interpreted in a variety of ways. That is, if certain compounded drugs are on the DDC list, payers may restrict reimbursement of compounded preparations, thereby limiting patient access to necessary medications.