March 14, 2013

Division of Dockets Management
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.

Re: FDA–2013–N–0124; Food and Drug Administration Drug Shortages Task Force and Strategic Plan; Request for Comments

Dear Sir or Madam:

Thank you for the opportunity to share community pharmacy’s perspective as the Food and Drug Administration (FDA) convenes a drug shortages task force to develop and execute a strategic plan for enhancing the Agency’s response to preventing and mitigating drug shortages. The National Community Pharmacists Association (NCPA) represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent an $88.5 billion health-care marketplace, have more than 300,000 employees including 62,000 pharmacists, and dispense over 40% of all retail prescriptions.

We applaud the significant steps the FDA has made to not only address the critical issue of drug shortages, but also implement solutions that will mitigate or prevent such events from happening. The cause behind drug shortages is multi-factorial and while most of the time the reasons are manufacturing-related, there are also economic incentives and pricing policies at play, which can affect drug supply which FDA needs to consider as well. In addition, compounding pharmacists have filled gaps in patient care during drug shortages in the past and should be allowed, through compounding and under existing rules and authorities, to continue to fill these gaps in these critical times of drug shortages to preserve access to medications. NCPA strongly encourages FDA to address effectively the issue of drug shortages and in doing so preserve the role of compounding pharmacies in providing critical patient access to these medications. NCPA is pleased to provide our perspectives in response to the questions on drug shortages FDA has sought public input.
In our work to prevent shortages of drugs and biological products, FDA regularly engages with other U.S. Government Agencies. Are there incentives these Agencies can provide, separately or in partnership with FDA, to prevent shortages?

While NCPA is not in a position to provide comments on incentives, we do support interagency coordinated activities. The issue of drug shortages is a complex issue that will require not only several departments within FDA working together, but also collaboration and communication across federal agencies as well. We believe the FDA should be working closely with agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Drug Enforcement Administration (DEA) to address issues such as pricing fluctuations and allocation quotas, respectively.

The current drug pricing and reimbursement dynamic in both the Medicaid and Medicare Parts D and B programs could cause major problems during a drug shortage involving critical access drugs which FDA should be aware of. In the context of the Medicaid program, States set their maximum allowable cost (MAC) reimbursement based on the federal upper limit (FUL) amount. The FUL standard, in turn, is calculated based on the average manufacturer price (AMP), which is a lagging standard that is several months old. Since the FUL and MAC reimbursement standards are based on the lagging AMP standard, the FULs and MAC reimbursements are also delayed in terms of how much they reflect real-time prices. When a drug becomes a critical access drug the acquisition cost may immediately skyrocket, but the FULs and MACs will not adjust for those changes until months later. Therefore, pharmacies end up purchasing critical access drugs at suddenly high prices, while the reimbursement remains the same and fails to adjust. We would encourage the task force to consider recommendations such as a suspension on limiting reimbursement in Medicaid to the FUL for any critical access drug and would require the Health and Human Services (HHS) Secretary to establish a new benchmark for reimbursement for those drugs, which reflects the changing costs of those drugs.

Similarly, under the Medicare Part D program, we would encourage the requirement of more frequent updates by Part D plans to their MAC reimbursement standards, along with government oversight over this process. Presently, contrary to law, Part D plans do not provide weekly updates to their MAC reimbursement standards, nor do they provide transparency regarding the methodology for how their MACs are set. As described in the Medicaid context, when acquisition prices for a Part D drug go up, it is generally observed that the Part D MAC reimbursement rate for that drug lags for weeks or months before it reflects the drug price increase. The lag in MAC reimbursement updates is particularly problematic in the case of critical access drugs subject to drug shortages because those drugs are subject to sudden significant price increases. In such situations, the MAC reimbursement may not be enough to cover the actual cost of the drug.
Our recommendation would be to require Part D plans to submit to CMS their MACs for critical access drugs on a regular basis, and require CMS to ensure that the MAC reimbursements reflect the actual current market prices of the critical access drugs. Regarding Medicare Part B reimbursement, the same lack of frequent updating exists due to use of a flawed government set price, ASP, which lags multiple months behind and doesn’t reflect the costs to community pharmacies of buying these drugs.

With regard to controlled substances, NCPA encourages a collaborative process between FDA’s Center for Drug Evaluation Divisions and the Attorney General that would apply some leniency to current regulations and expedite the increase in manufacturing and production quotas in the event of controlled substance shortages.

To manage communications to help alleviate potential or actual shortages, FDA uses a variety of tools, including posting information on our public shortages Web sites and sending targeted notifications to specialty groups. Are there other communication tools that FDA should use or additional information the Agency should share to help health care professionals, manufacturers, distributors, patients, and others manage shortages more effectively? Are there changes to our public shortage Web sites that would help enhance their utility for patients, prescribers, and others in managing shortages?

Depending on the nature of a drug shortage, community pharmacists may be able to provide valuable compounding services to their patients when appropriate. Until FDA adequately addresses drug shortages, it will be more difficult for states and the FDA to effectively address compounding issues. NCPA encourages FDA to take necessary steps to address the issue of drug shortages and in doing so to recognize the role that compounding plays in preserving access to vital medications during times of drug shortages.

A positive example of coordinated communications efforts was this past flu season with the increased demand for Tamiflu oral suspension. The FDA placed the product on its current drug shortages index and reminded all health care professionals of the FDA-approved instructions for the emergency compounding of an oral suspension from Tamiflu capsules. This information was very helpful to pharmacists, and NCPA would greatly encourage similar communications and notices to providers in the future.
What other actions or activities should FDA consider including in the strategic plan to help prevent or mitigate shortages?

Drug shortages can also lead to the emergence of grey markets and price gouging. When FDA is addressing drug shortage events and taking actions to mitigate the impact, the agency should be just as vigilant about speculators who are preying on desperate patients and providers who are seeking the product.

Conclusion

NCPA appreciates the opportunity to provide our comments and recommendations as the FDA evaluates its approach to medical product shortages and begins to prioritize its work. While drug shortages are multi-faceted and involve a number of factors, it is important to keep the safety of our patients as a top priority and work towards addressing drug shortage factors that can be controlled and predictable. We remain committed to working collaboratively with the FDA to develop solutions that will minimize product disruptions and ultimately strive for prevention of drug shortages in the future.

Sincerely,

Ronna B. Hauser, PharmD
VP Policy and Regulatory Affairs