April 15, 2011

Connie Jung
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Determination of System Attributes for the Tracking and Tracing of Prescription Drugs; Public Workshop. FDA-2010-N-0633

Dear Connie:

Thank you for the opportunity to submit our comments following the above referenced FDA Workshop regarding the determination of system attributes for the tracking and tracing of prescription drugs. The National Community Pharmacists Association (NCPA) represents America’s community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises and chains. Together, these small business entities employ over 300,000 full-time employees and dispense nearly half of the nation’s retail prescription medicines.

NCPA feels strongly that “track and trace” technologies still remain unproven and ultimately burdensome and economically infeasible for the independent community pharmacy industry at this time. In addition, operational processes to allow for a track and trace system are currently still under development. As FDA continues to work on developing additional standards for securing the drug supply chain, the agency must carefully consider the impact of any potential track and trace system on a variety of supply chain partners. NCPA applauds the FDA for hosting a public workshop on February 15 and 16, 2011, to obtain input from those partners and appreciates the opportunity to attend the workshop, representing the viewpoints of independent community pharmacies.

**FDA Role and Product Scope**
The FDA needs to play a leadership role in determining any potential standardized track and trace system that could then be adopted and supported by supply chain stakeholders. The FDA should clearly define the functional requirements needed in the track and trace system as well as clearly determine the specific data that needs to be captured and a clear definition of authentication. Industry stakeholders would also look to FDA to determine the ultimate scope of any track and trace program, with appropriate input. NCPA recommends that FDA may wish to consider utilizing a risk-based approach to determine the scope of products to be included in any track and trace system, at least at the outset of any program.
Public Policy Case for Track and Trace/FDA Role in Data Collection
NCPA recommends that if a track and trace system were to be required for U.S. supply chain participants it would be imperative that FDA establish measures or metrics to evaluate the success or efficacy of any track and trace system. At this point it is unclear as to whether or not the FDA would monitor a track and trace system and perhaps evaluate such a system’s sustainability and value through regular and consistent audits. Without this type of oversight or assistance that would presumably result in the aggregation of critical data, a track and trace system may offer a greater perception of supply chain security, but in reality offer little more protection than those system integrity systems that are already in place.

Incentivize Adoption
In order to incentivize the voluntary adoption of track and trace technology, and if such a system were to be mandated, NCPA contends that federal grants must be made available to smaller supply chain participants—like independent pharmacies—so that these small businesses are able to implement and maintain track and trace systems.

Some of the participants in the FDA workshop cited the fact that a number of supply chain participants should be able to realize several value added features of a track and trace system in terms of “financial and brand protection benefit” or in terms of “potential theft reduction and inventory optimization.” It should be noted that any operational benefits from track and trace systems may not be evenly distributed among larger multi-unit corporations and small businesses. Larger corporate entities involved in the supply chain—namely manufacturers, wholesalers and chain pharmacies—would likely realize value added “benefits” that a track and trace system could bring to their overall business practices. However, for the majority of independent pharmacy owners, the cost of implementing a track and trace system would likely exceed any possible ancillary benefits like inventory management theft reduction. Until track and trace systems are configured or modified specifically to be applicable and advantageous to individual small pharmacies—voluntary adoption of such programs may be sluggish.

NCPA strongly opposes the suggestions offered by some workshop participants that would impose penalties on those supply chain participants who are non-compliant or to link reimbursement or payment from Medicaid/Medicare with authentication of packages. NCPA members would struggle with the financial aspects of compliance with track and trace measures and to place further penalties on these small businesses may drive them out of the market altogether. In addition, a direct link between authentication and Medicaid or Medicare reimbursement would most likely devolve into a logistical nightmare with severe financial consequences to pharmacies who would be caught “holding the bag” anytime the track and trace system malfunctioned or went down.

Interoperability
Ensuring interoperability between the systems used by all participants in the supply chain is essential to the success of any track and trace program. Use of the standardized numerical identifier should avert some of the problems or inevitable snags that may occur when attempting to connect or ensure communication between varying manufacturers and distributors. Although the creation of a standardized numerical identifier should assist in paving the way for interoperability, much work remains to be done.
NCPA has concerns that at the beginning or advent of any track and trace program, pharmacies may be forced to use more than one set of technologies (hardware/software) in order to comply. This would inevitably add to the financial burden with which many independent pharmacies will be dealing. Some workshop participants pointed out that in other industries, interoperability has only been realized when dealt with through government regulation—and NCPA feels that there may be some validity to considering this option in this instance.

It has been noted or suggested that some of the smaller supply chain participants may be able to rely on the systems or track and trace solutions of the larger participants. The most likely scenario may entail an independent pharmacy relying on the track and trace system and network capabilities of their wholesale distributor. It is important to note that the cost to the pharmacy could vary greatly based on such an arrangement. Also, questions related to ownership of a pharmacy’s data generated by the operation of the track and trace system would invariably arise. Additionally, this situation could become complicated in situations in which a pharmacy may need to switch their wholesaler for any reason. In order for this type of arrangement to be mutually beneficial to both wholesaler and pharmacy, more detailed discussions as to the roles and responsibilities of both parties would need to be discussed in greater detail.

**Authentication**

NCPA would request that the FDA provide a clear definition of authentication—and at which point in the supply chain such authentication should occur. Some workshop participants raised the issue of the inherent distinction between “track” and “trace”. In order to track—a supply chain participant would only need verification that the serialized number is indeed valid. In order to “trace”, a supply chain participant would need to be able to actually access and verify all of the prior transactions.

If the FDA were to determine that all supply chain participants must do both—track and trace—pharmacies, which serve as the last stop in the supply chain, would have a potentially greater burden than other supply chain participants if they were required to actually authenticate or trace the entire distribution history of each product. Several workshop participants raised the point that perhaps only certain products or classes of products with the greatest risk of being counterfeited should be subject to “trace”. Also, other participants suggested that FDA or regulators would be the only entities that would have an actual need for a full distribution history. If access to the entire distribution history were limited to FDA or other regulators, this may also alleviate some of the concern voiced by a number of entities who are understandably nervous about supply chain partners having access to their proprietary data.

Another issue that would need to be determined with regard to authentication would be standard operating procedures that would be employed in the event that a product could not be authenticated. Which participant (sender, recipient or system) would have to ultimately bear the cost of the product in the event a product could not be authenticated and then subsequently sold? Also, there needs to be clear protocol surrounding the reporting of such an event.
Identification and Validation of Authorized Participants
Another item that was discussed at the workshop was the issue of how supply chain participants would be able to accurately recognize and validate their trading partners. Some participants suggested that the FDA may wish to play a role in organizing or facilitating a centralized database by perhaps accessing those state records of licensed distributors and pharmacies that are currently established and maintained by the individual boards of pharmacy. This particular scenario may blur the lines that currently exist between federal and state jurisdiction and may also present some complicated privacy concerns. NCPA contends that the drug supply chain industry is currently structured around working relationships with trusted business partners and is in many ways self-policing. Ultimately, the creation of a separate FDA database in order to facilitate the validation of authorized trading partners may likely be unwarranted.

Inference
Inference is one facet of the track and trace process that would greatly ease the time and labor costs for distributors but would not be available for independent pharmacies. Inference allows distributors to “read” a case or pallet of product and then infer that a certain set of serial numbers exists within that case or pallet. Independent pharmacies do not purchase products at a case or pallet level and therefore would be forced to individually or manually “scan” each bottle or serial number as it arrives in the pharmacy. This would be extremely time consuming and would necessitate an increase in labor costs for independent pharmacy owners. NCPA recommends that as part of any discussions surrounding a proposed track and trace system, efforts to pilot inference at the tote level must be considered.

Pilot Perspectives
NCPA strongly recommends pilot projects be pursued for any track and trace system in order to adequately identify and work through the complexities and substantial costs surrounding such a system—and that all supply chain participants be involved in any proposed pilot program.

Conclusion
NCPA appreciates the opportunity to submit these comments following participation in the FDA workshop on system attributes of a track and trace system for prescription drugs. NCPA recognizes that all supply chain partners need to be engaged in the ongoing dialogue on this topic in the interest of maintaining the integrity of the U.S. pharmaceutical supply chain. Please do not hesitate to contact Susan Pilch, Director of Policy and Regulatory Affairs, by email at susan.pilch@ncpanet.org, or by telephone at (703) 683-8200, if you have any questions.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Policy & Regulatory Affairs