FDA Public Hearing on “Using Innovative Technologies and Other Conditions of Safe Use to Expand which Drug Products Can be Considered Nonprescription”
Docket No. FDA-2012-N-0171

Introduction
Good morning. Thank you for the opportunity to present the views of the nation’s pharmacists. I am Tom Menighan, a pharmacist and Executive Vice President and CEO of the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, is the oldest and largest professional society for pharmacist. APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. Our members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA supports the proposed revisions to the drug paradigm that FDA is considering. We agree with continuing the two-class drug system of prescription and nonprescription (or over-the-counter (OTC)) products, with the added flexibility of OTCs being dispensed with “conditions of safe use.”

APhA sees this as a significant and important opportunity for pharmacists to improve public health, and increase access, much as we’ve done with immunizations. APhA applauds FDA for stimulating discussion on this public health initiative and for taking advantage of the roles that pharmacists can play in improving public health.

APhA recognizes and accepts the fact that many logistics and details will be determined by product sponsors and the FDA. We are comfortable with the initial ambiguity and will work with FDA and other stakeholders on revised regulations and market-place solutions to achieve the stated public health goals.

APhA’s Comment Areas
APhA’s comments are based upon the following:
- Support for the concept of “conditions of safe use” for certain medications.
• The opportunity to expand patient access, improve public health, and provide another avenue to bring people who may have poorly treated chronic conditions back into the health care system.
• The opportunity to further communicate and collaborate with physicians and other providers.
• The success of pharmacist-administered immunizations and other patient care programs on improving public health. And,
• A recognition that there are several key focus areas to consider as the new paradigm concept evolves.

APhA’s General Support of Dispensing Medications with “Conditions of Safe Use”
Pharmacists are the most accessible health care provider to many patients. This is not a competitive statement, but rather an acknowledgement of the fact that there are more than 60,000 pharmacies in the U.S. where consumers can walk in during often extended hours and have access to a pharmacist. We view the new drug paradigm concept being considered by FDA as an exciting opportunity to utilize this open access to pharmacists to safely increase the availability of certain medications and to optimize the important role pharmacists can play in improving public health.

APhA greatly appreciates FDA referencing the use of a pharmacist intervention as a possible “condition of safe use,” in addition to the use of innovative technologies. We believe that more opportunities for pharmacist-patient interventions and communication will lead to improved medication use and improved health outcomes.

Importantly, we also see this as a great opportunity to reconnect and link patients back into the health care system. We see millions of patients who may have dropped out of therapy, may be non-compliant with therapy, or may be the "walking well" but may have an undertreated chronic condition. It is widely known in pharmacy, but often not well documented, that pharmacists routinely refer patients to an appropriate provider, and improve care coordination, everyday.

We also see this proposed new paradigm as a way to ensure that patients have another avenue to access life-saving, emergency drugs such as antidotes and rescue medications through approved algorithms, documentation, standards of care, and other appropriate requirements for “conditions of safe use” for a specific product as pursued by the product sponsor.

Pharmacists are committed to a team-based approach to patient care. The new paradigm being considered should not segment or silo patient care activity in the pharmacy but rather provide for redirecting undertreated patients back into care to reduce morbidity and decrease costs.

While we do not know what the future holds in health care, innovations and technology will continue to challenge current delivery structures and processes. FDA needs the tools and flexibility to utilize and respond to innovative technologies, patient care strategies and needs, challenges, and other developments as they evolve.

When this meeting announcement was published we stimulated discussion in the pharmacy community with a blog and other social media. Pharmacists responded quite positively, and in essence said public health could improve with greater involvement of pharmacists.
APhA’s View of the New Drug Continuum Being Considered by FDA
APhA sees the new paradigm concept fitting into the overall drug safety continuum much like risk evaluation and mitigation strategies, or REMS, do by allowing access to certain prescription drugs. Focusing on less risk and the OTC side of the drug continuum (the gray column in Figure 1) we can visualize how the new drug paradigm would allow more flexible access to drugs that would remain prescription-only absent the “conditions of safe use” being considered by FDA.

Draft New Drug Paradigm Being Considered by FDA:
Creating more flexibility on the drug safety continuum to benefit patients and public health

- OTCs
- Draft New FDA Idea
- Prescription drugs
- REMS

Drugs that would not receive FDA approval or be allowed to remain on the market because the risk outweighs the benefit

Drugs that would remain prescription absent “conditions of safe use” being considered by FDA

Prescription drugs that would not be FDA approved or remain on the market without a REMS

Average Risk of Drug

Source: American Pharmacists Association

Figure 1.

Building on Pharmacy’s Successful Immunization Model
Over the last decade or so, all states enacted laws and regulations to empower pharmacists to immunize. As experience increased and opportunities to improve public health presented themselves, pharmacists sought out the training and the rest is history – today, more than 175,000 pharmacists completed certificate training programs. And, in the 2010-11 influenza season, it is estimated that pharmacists administered approximately 20 million influenza vaccinations, thus meeting a major public health need for improved immunization rates and access.

APhA believes that the new paradigm being considered can build on the successful immunization public health model. We would hope to implement new training processes, scale-up across pharmacy practice settings, and collaborate with the medical community to help fill the needs of our patients and improve public health.
APhA’s Key Focus Areas as “Conditions of Safe Use” are Considered
As FDA considers this new paradigm, we suggest the following 8 key focus areas:

1. **Evidence and Clinical Experience:** As currently described, we appreciate and understand that approval of any product in the new paradigm would need to be based on science, clinical evidence of efficacy and patient safety in actual use.

2. **Public Input:** There must be an opportunity for public input on any sponsor’s proposal for a product moving through an application process with “conditions of safe use.”

3. **Consistent Definitions and Processes:** The process for drug availability through “conditions of safe use” must be defined in a uniform and standardized process.
   - Any new paradigm must ensure that the patient care and drug dispensing processes are not disjointed, variable or confusing across different practice settings.

4. **Communication Technology:** Pharmacist-patient care activities could be communicated through phone calls and faxes but more efficiently and efficiently through the expanding use of health information technology (HIT) infrastructure and electronic health records (EHRs).
   - Pharmacy organizations, through the Pharmacy e-HIT Collaborative, are working together on HIT and privacy issues to promote the delivery, communication and documentation of and billing for pharmacist-provided services.

5. **Use of Practice Algorithms:** A pharmacist-patient intervention as part of a “conditions of safe use” to determine appropriate dispensing should be built upon consensus-based, best-practice algorithms for pharmacists to implement and communicate with other providers.
   - Such interventions could include screening, assessment and consultation, or referral of the individual to the physician or other appropriate health care provider. Further, these processes might rightly be developed in collaboration among professions involved.

6. **Ability to Bill for Services:** Pharmacists must be able to bill, via a standardized mechanism, and be compensated for the clinical services required to dispense products with “conditions for safe use”.
   - APhA appreciates that in the meeting notice FDA recognizes the payment challenges for any new drug paradigm. We understand that such payment solutions for “conditions of safe use” activities may be market-driven and not under the purview of FDA.
   - However, without a viable business model these services will not be sustained and the benefits would not be realized.
   - FDA’s initiatives should not preclude payment for pharmacists’ services by the patient, third-party payers, state programs, Medicare, the sponsor, or others.
   - In addition, consideration should be given to legislatively provide CMS with the option of creating a regulatory system where pharmacists could be compensated...
for providing these services to Medicare patients so that a viable self-sustaining business model can be created if CMS or other payers see value in such an option.

- We recognize that payers will need to determine payment policies for non-prescription medications that may require “conditions of safe use”.

7. Provider Education: Education about a new paradigm must focus on the availability of a product, the targeted patient population, processes and logistical requirements of the program, clinical nuances, and resource materials for the pharmacist.

- Pharmacists are the medication experts and are well qualified to provide clinical interventions on the safe use of a product, just as we already do with prescription and OTC products.
- Pharmacists train for a minimum of 6 years in clinically-oriented programs that lead to a doctor of pharmacy (PharmD) degree. Additional information about pharmacy education is provided in testimony from the Accreditation Council for Pharmacy Education (ACPE).
- We believe that through our extensive professional education programs we can help distribute appropriate information to pharmacists about requirements to dispense drugs that are available through “conditions of safe use.”

8. Use of PDUFA: APhA supports pursuing broad and general authority through the Prescription Drug User Fee Act (PDUFA) legislative vehicle currently working its way through Congress.

- We believe that general authority can be achieved through legislation that is prospectively looking at more flexible ways in which we may be accessing and dispensing drugs in the future.

Successful Pharmacist-Patient Care Models
Finally, I would like to close by highlighting just a few more examples of pharmacists’ success in current, scalable patient care activities that have improved patient health and collaboration with medicine. This is not new – pharmacists have been working to improve patient safety and public health for a long time.

As part of the U.S. Public Health Service, pharmacists have 49 years of successful collaboration with medicine to improve patient care. In the recent report to the Surgeon General, the Public Health Service, Office of the Chief Pharmacist, highlighted improved patient safety, enhanced cost-effectiveness, and care delivery through pharmacist-provided services. The report further includes 27 pages of studies that document the value of pharmacist services.

Additionally, community pharmacists are working with self-insured employers to improve patient outcomes as highlighted in the APhA Foundation’s work with the city of Asheville, North Carolina and through the Diabetes Ten City Challenge activities. Through these pharmacist-patient encounters, we’ve seen improved public health, positive clinical and economic outcomes, use of guideline-based care, improved patient education, collaboration among healthcare providers, and use of patient self-management strategies. And, such studies as the Asheville Project, have demonstrated that healthcare quality outcomes improve, and the number of referrals to physicians increase, as appropriate, when pharmacists are actively engaged in clinical intervention with the patients.
These studies further document that pharmacists assist patients in managing their medications, increase patient compliance, improve patient safety, and improve overall health outcomes. This is the type of information that further supports FDA’s consideration of dispensing with “conditions of safe use” that can include an interaction with the pharmacist.

Conclusion
In conclusion:

- APhA supports the overall concept of “conditions of safe use”.
- We recognize that a more flexible process for ensuring access to certain medications also requires appropriate communication and collaboration with the medical community.
  And,
- We support legislation that would provide FDA with general authority to utilize “conditions of safe use” – knowing that specifics related to logistics, payment, challenges and other uncertainties can be addressed in the future.

We offer our support and assistance to the Agency in future discussions and meetings about this important public health initiative. APhA led the efforts to coordinate communication among pharmacy organizations in advance of this meeting and we will continue to do so as we prepare complete written comments in the coming weeks.

While many details remain to be worked out, none of them are significant enough to stop this important initiative from being enacted. America's pharmacists view this proposal as "Yes... if" rather than "No... but" and look forward to working with FDA and other healthcare providers and stakeholders to answer the "if" questions and make this concept a reality.

Again, the pharmacy community is excited for our patients and for evolving opportunities to help improve public health and reduce overall health care costs.

Thank you.