May 7, 2012

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

[Submitted online at: http://www.regulations.gov]


Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the Food and Drug Administration (FDA) request for comments on FDA’s new paradigm under consideration Using Innovative Technologies and Other Conditions of Safe Use To Expand Which Drug Products Can Be Considered Nonprescription published February 28, 2012 (77 FR 12059). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA 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. Our comments reflect the views of pharmacists practicing across the spectrum of health and patient care settings.

APhA applauds FDA’s efforts to improve public health and increase patient access to certain medications. We support the proposed revisions to the drug paradigm that FDA is considering. Specifically, 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.” We also agree with FDA’s belief that pharmacists have a key role to play in this potential new drug paradigm.

Pharmacists, the medication experts on the health care team, are the most accessible health care provider to many patients. With more than 60,000 pharmacies in the U.S., APhA sees the new potential drug paradigm concept as an exciting opportunity to utilize such access to pharmacists to safely increase the availability of certain medications, to collaborate with other health care providers, and to optimize pharmacists’ role in improving public health.
Through our commitment to a team-based approach to patient care, we foresee the potential new drug paradigm concept as a great opportunity to reconnect and link patients back into the health care system. Throughout the nation, pharmacists encounter millions of patients who may have dropped out of drug therapy, may be non-compliant with their therapy, or may be the "walking well" but may have an undertreated chronic condition and need to be redirected and referred back into care.

In addition, APhA sees this proposed new paradigm as a way to ensure that those with conditions diagnosed by a medical provider maintain access to life-saving emergency drugs like antidotes and rescue medications through approved algorithms, documentation, standards of care, and other appropriate requirements for conditions of safe use for a specific product when petitioned by the manufacturer and approved by FDA.

Revisions to the existing drug paradigm would also help to ensure that FDA is prepared for the future with the tools and resources needed to respond to a rapidly evolving health care system, innovations and technologies, and other developments that will continue to challenge the current delivery structures and processes. Additionally, the new paradigm could build upon the successful model already in place for using pharmacist services as practiced for decades by the U.S. Public Health Service (PHS). As part of PHS, pharmacists have for nearly 50 years successfully collaborated with medicine to improve patient care. In the recent report to the Surgeon General, the PHS, Office of the Chief Pharmacist, highlighted improved patient safety, enhanced cost-effectiveness, and care delivery through pharmacist-provided services. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General* also includes more than 30 pages of citations of peer reviewed studies that document the value of pharmacist services.¹

**Comments at Public Hearing**

In our March 22, 2012 testimony at FDA’s public hearing on this potential new drug paradigm (see [Attachment A](#)), we based our comments on 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 be undertreated or 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.

Within the February public hearing notice, FDA solicited comments on specific areas and issues about the potential new drug paradigm. Many of these specific areas and issues align with the eight key focus areas APhA suggested at the March hearing in our testimony:

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1. **Evidence and Clinical Experience:** As currently described, APhA agrees that the 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.

4. **Communication Technology:** Pharmacist-patient care activities could be communicated through phone calls and faxes but more efficiently and effectively through the expanding use of health information technology (HIT) infrastructure and electronic health records (EHRs).

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.

6. **Ability to Bill for Services:** Clinical services required to dispense products with conditions of safe use must be valued by the sponsors, payers or consumers who derive the benefit of those services. We encourage FDA to maintain a system that incorporates such mechanisms. Billing initiated by pharmacists and administrative processes must be straightforward and use standardized mechanisms.

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, and resource materials for the pharmacist.

8. **New Paradigm Authority:** APhA supports pursuing broad and general authority through appropriate legislative and/or regulatory processes.

APhA offers the following in response to FDA’s request as outlined in the hearing notice:

**A. Types of Technology and Conditions of Safe Use**

1. **Can you suggest specific medical conditions or diseases for which consumers may benefit if the treatment drug were available as a nonprescription product with conditions of safe use?**

   There is a wide array of diseases and conditions through which individuals could benefit if the treatment drug were available as a nonprescription product with conditions of safe use. Importantly, we appreciate that any consideration of a drug in a potential new paradigm is dependent upon a manufacturer seeing the value of such availability and submitting an application to FDA for review.

   As FDA considers applications seeking to use conditions of safe use, the drugs and conditions should be determined through an evidence-based system upon submission by drug manufacturers (sponsors) who prove their product(s) to be safe and effective for a conditions of safe use to FDA’s
satisfaction. If a new paradigm is available in the future, APhA recommends that manufacturers and FDA potentially consider medications used for conditions or symptoms including but not limited to the following:

- Conditions requiring an antidote and/or rescue medication
  - Epinephrine
  - Glucagon
- Diabetes
- Hypertension
- High cholesterol
- Asthma
- Migraine
- Diaper rash
- Pediculosis
- Osteoporosis

Not all drugs in any class may be appropriate. There will undoubtedly be limits to the circumstances for an individual drug (e.g. limiting epinephrine to emergency situations or refills, migraines limited to emergencies when the patient has previously taken the medication, or asthma to rescue inhalers or refills). We generally agree that certain medical conditions could benefit from more flexible options in accessing certain medications that may otherwise remain prescription only. FDA's decisions should be supported by actual use studies assessing the safety, efficacy, and appropriateness of such drug products for OTC use per conditions of safe use. APhA relies on the FDA to make science based decisions in its review of drug applications submitted by manufactures and to help establish those market factors that would ensure viability of this initiative.

A revised drug paradigm should facilitate health care professionals to work at the top of their education and training to provide consumers and the health care system the most benefit and produce significant public health gains.

We recommend that FDA provide opportunities for public input on any sponsor’s proposal for a product moving through an application process with conditions of safe use. Opportunity to provide public comment could be offered through FDA Advisory Committee meetings or other appropriate process. There are a variety of diseases and conditions for which individuals could benefit provided the treatment drug(s) was/were available as a nonprescription product with conditions of safe use. We encourage FDA to continue its review and to do so with the confidence that America’s pharmacists will do their part to improve the public’s health.

2. What types of technologies (e.g., kiosks, computer algorithms) are currently in development that could assist in allowing drugs to be used safely and effectively in the nonprescription setting?

As health information technology has and continues to evolve, new and improved tools will be available to help pharmacists work with patients and their prescribers to better manage medications. For example, telepharmacy allows pharmacists to have person-to-person interactions with a patient even if the pharmacist is not physically onsite. Such tools help to ensure that patients have access to a pharmacist and can help facilitate appropriate care through technology. In addition, video
screens, survey screening tools that may print a ticket to purchase a product, and interactive kiosks stations may be utilized, if deemed to create safe conditions for a particular product. However, as we consider tools being used in a pharmacy, we need standardization and compatible electronic platforms to avoid populating pharmacy settings with individual proprietary devices that are only applicable to single drugs. A proliferation of technology platforms in a pharmacy has the potential to confuse both patients and pharmacists. It would seem to make more sense to direct all electronic interfaces with patients through a standard web portal made available near the point-of-care.

In addition, patients could benefit from increased access to point-of-care screening tools, survey instruments, algorithms, and other technologies that could be utilized for appropriate medications. Such tools could support interactions of the patient with the pharmacist and the health care team and further integrate patient data captured in such tools into the pharmacy management system through HIPAA compliant processes. Such integration could help ensure that these products are part of the patient’s medication history at the pharmacy and could be further integrated into a patient’s EHR to share with the patient’s other health care providers allowing for a more complete patient history. Such processes would also help facilitate post-market safety surveillance.

As technology integration continues, the result should be improved access to applicable patient information, lab values, and processes to communicate with the medical staff. These new technologies, aligned with appropriate conditions of safe use, should provide for a sound platform to assist in allowing certain drugs to be used safely and effectively in the nonprescription setting, as well as for advising a patient’s physician (or even medical home as such team-based care evolves) about the encounter or creating a referral based on information gathered. The development of new technologies will also lead to improved communication among members of the health team and better documentation within patients’ health care records.

**Standardization – Lessons Learned from REMS**

As discussed at the public hearing, APhA described how the need for standardization of risk evaluation and mitigation strategies, or REMS, programs can similarly translate to utilization and standardization for conditions of safe use. While REMS programs are required by FDA for certain prescription drugs to ensure that the benefits of the drug outweigh its risk, the basis of REMS allows patients to have access to needed medications that may not be approved or remain on the market if not for the REMS program in place. APhA has strongly advocated to FDA, and FDA has recognized, the need for standardization of REMS programs so that REMS programs maximize patient safety while limiting burden on the health care system to implement such risk management programs. We appreciate that FDA and stakeholders, including APhA, continue to explore models to improve REMS communication and standardization of REMS implementation, approaches for using existing practice location technologies and systems to ensure workflow-neutral processes, and options for sustainable business models. Additional information on such topics is available in APhA’s 2011 REMS White Paper publically available online at [www.pharmacist.com/REMS2011](http://www.pharmacist.com/REMS2011).

As the number of REMS programs increases, we appreciate that FDA expects to facilitate dialogue to ensure that REMS programs become more standardized, as outlined in FDA’s 2012 Prescription Drug User Fee reauthorization agreement with manufacturers. In addition, see [Attachment B](#)
which shows how we visualize OTCs with conditions of safe use fitting into the current drug continuum including REMS. Again, similar concepts and processes for standardization for conditions of safe use to limit burdens on the health care system and ease implementation will be important to this initiative.

3. **What other types of conditions of safe use (e.g., pharmacy monitoring or counseling) could be used to help ensure the safe and effective use of certain drug products as nonprescription products?**

APhA believes that a pharmacist intervention is among the best conditions of safe use described by FDA in the hearing notice. FDA's reference to the use of a pharmacist intervention as one of the possible conditions of safe use is important recognition of the underutilized nature of pharmacist services today. We believe that more opportunities for increased pharmacist-patient interactions will improve safe medication use and outcomes.

In addition to a pharmacist intervention as a “condition of safe use,” the patient may appropriately receive based on the specific product requirements from that pharmacist an assessment, screening, consultation, or clinical evaluation pursuant to the product labeling and requirements in which patients could not waive this requirement by signing an opt-out form. A pharmacist’s clinical assessment confirms that the condition for which the patient is seeking care can be addressed appropriately with an available product. If not, the pharmacists, as they do today, would refer the patient to their appropriate medical provider.

**Activities in an Intervention – Follow the Algorithms**

Examples of actions that could be utilized in an intervention could be but are not limited to the following:

- Discuss with the patient their complaint, symptoms, and any appropriate self-diagnosis;
- Conduct an FDA-required patient assessment or screening, which may include conducting point-of-care testing or obtaining/reviewing test results, to determine if the patient meets the product’s indication;
- If the patient’s status does not meet the product’s indications, depending on the circumstances, the pharmacists could recommend, as appropriate, an available OTC product, refer the patient to a primary care physician or other medical provider, or recommend no action be taken by the patient;
- Conduct a medication review to screen for potential adverse drug interactions or contraindications;
- Use screening and assessment tools/aids authorized in the algorithm;
- Recommend or concur with the patient on product selection and dispense the medication;
- Counsel the patient on the product’s proper use and potential side effects, and where appropriate, recommend the best means to minimize side effects;
- Document the intervention and upon consent, communicate relevant information to the patient’s most appropriate health care provider;
- Where appropriate or required, conduct follow-up monitoring; and

- Where the outcome of the algorithm or other health conditions warrant, refer the patient to a physician or other health care provider.

**Health Information Technology**

Related to communication and technology for pharmacist interactions, such care could be communicated to prescribers through phone calls and faxes but more efficiently through the expanding use of health information technology infrastructure and EHRs. The ability for pharmacists to document care encounters in a way that is available to other health care providers is essential, as is the access by pharmacists to data stored in EHRs created in other areas of the health care system, outside the pharmacy.

- APhA and other pharmacy organizations, through the Pharmacy e-Health Information Technology (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.
- Depending on system design, our ability to functionally use an EHR will allow us to enter information about dispensing of OTCs with conditions of safe use to assure that all health care team members have complete medication history information.

APhA will provide FDA with updates as progress is made on this important effort focused on ensuring pharmacists have HIPAA compliant, bi-directional, and interoperable access to read and document into a patient’s EHR. Additional information about the Collaborative’s work is available online ([http://www.pharmacyhit.org/](http://www.pharmacyhit.org/)) and outlined in December 2011 document *The Roadmap for Pharmacy Health Information Technology Integration in U.S. Health Care.*

The Roadmap formalizes the priorities of the pharmacy profession in relation to HIT for the next four years to assure electronic health records facilitate safe and effective medication use. It also provides guidance to provider organizations, policymakers, vendors, payers and other stakeholders involved in the integration of pharmacy HIT into the national HIT infrastructure.4

Importantly, any technology used to qualify patients, document care, transmit information, or other activities pursuant to conditions of safe use must interface easily with pharmacy management systems to assure capture of appropriate information.

Studies, such as the Asheville Project, have demonstrated that referrals to physicians increase when pharmacists are actively engaged in clinical interventions with the patient. These studies further document that pharmacists assist patients to manage their prescription medications, increase patient compliance, improve patient safety, and the patient’s health outcomes improve significantly.5

Pharmacists are well positioned to serve as a key manager of medications with conditions of safe use to help ensure their safe and effective use. To further ensure the safe and effective use of certain drug products as nonprescription products, pharmacists are prepared to provide services

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4 The Roadmap for Pharmacy Health Information Technology Integration in U.S. Pharmacy e-HIT Collaborative. Available at: [http://www.pharmacyhit.org/pdfs/11-392_RoadMapFinal_singlepages.pdf](http://www.pharmacyhit.org/pdfs/11-392_RoadMapFinal_singlepages.pdf)
5 Cranor CW, Bunting BA, Christensen DB. The Asheville Project: Long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. *J Am Pharm Assoc.* 2006;45(2);123-147
such as medication monitoring and counseling services as part of on-going conditions of safe use through utilization of various technologies.

4. **Are there types of diagnostic aids, such as noninvasive blood pressure monitors and urinalysis reagent strips that could be used in the nonprescription setting after appropriate FDA review, either with or without the aid of a pharmacist to diagnose or monitor a disease or condition?**

There are a variety of diagnostic aids, such as noninvasive blood pressure monitors and urinalysis reagent strips that could be used in a wide array of settings, after appropriate FDA review and approval, to monitor various diseases and conditions. Pharmacists today use an ever growing number of screening and assessment tools as point-of-care services in the pharmacy, depending on their practice site and scope of work to safely and effectively guide patients to appropriate care. Generally, such tools can include but are not limited to blood pressure monitors, cholesterol screening devices, pulse oximeters, asthma peak flow meters, blood glucose meters, bone density screening devices, and in some cases devices for rapid response tests and pharmacogenomic testing. In addition, some pharmacies offer access to OTC purchase of such products as blood glucose meters, diabetic test strips, blood pressure monitors, home drug test kits, and other various devices and supplies related to durable medical equipment.

Related to use of monitoring and screening devices, pharmacists must be able to access and share as appropriate required patient medical information in a timely and efficient manner, and document such information through a process that is integrated into the pharmacy management system. Use of such monitoring or screening aids may further facilitate communication with the patient and referral to their physician or other medical provider for appropriate care.

The screening and assessment aids and technology that are currently available provide pharmacists with information crucial to providing improved medication management for the patient. As newer, better devices and technology come on the market, we look forward to working with patients and their other care providers to ensure the patient receives the best outcome possible through their use.

The evolution of technological solutions to identify complex issues will continue. FDA, through this initiative, is setting the stage for health care providers to work together to accommodate these technological changes. Every new technology generally pushes solutions closer to the consumer. Health care practitioners must adapt and harness these advances to continually optimize patient care.

5. **What data or other information exist on the use of conditions of safe use, including novel technologies, and on their effects on health care, access to medication, and/or disease and treatment education or awareness?**

One of the key concepts in healthcare reform and the evolving care delivery model is increased patient involvement in their care by making the patient the center of focus by a team of healthcare providers and active participation by the patient. The proposed new paradigm embraces this concept.
6. Are there data on how expanded access to medication or increased consumer education or awareness could affect patient or consumer behavior (e.g., by promoting patient compliance with a medication dosage regimen) or on health outcomes generally that would be relevant to the discussion of expanding the availability of nonprescription medications with conditions of safe use?

Evidence shows time and again that when pharmacists get involved in health care initiatives costs go down and outcomes improve. Data need to be based on clinical evidence of medication safety and efficacy when determining which products to include in a potential new drug paradigm. Numerous studies of pharmacist-provided patient care services show increased patient access to and adherence with prescription drug therapies, reduced medication errors, improved outcomes, and reduced costs as a result of the pharmacist’s intervention. The health care system would realize similar benefits to improved public health if the new paradigm is implemented.

APhA sees the new paradigm fitting into the overall drug safety continuum by ensuring access to certain OTC’s that otherwise would remain prescription only if not for utilization of conditions of safe use. This is similar in how FDA-approved REMS programs aim to ensure continued access to prescription drugs that may not be approved or remain on the market without a REMS program due to risks associated with the medication. Please see Attachment B for APhA’s visual representation of the drug safety continuum described above.

Studies consistently support pharmacists’ involvement in the on-going care of patients with chronic health problems. Several highlights are listed below:

- The previously cited Report to the Surgeon General including numerous pages of citations of peer reviewed studies.

- The Asheville Project\(^6\) began in 1997 as an effort by the City of Asheville, North Carolina, a self-insured employer, to provide education and personal oversight for employees with diabetes. Through the Asheville Project, employees with these conditions were provided with intensive education through the Mission-St. Joseph’s Diabetes and Health Education Center. Patients were then teamed with community pharmacists who made sure they were using their medications correctly and were “coached” by the pharmacist on the behavior changes to gain control of their disease. Patients with diabetes working with their pharmacist were able to improve vaccination rates, number of patients receiving eye exams, and their blood sugar levels. The project led pharmacists to develop thriving patient care services in their community pharmacies. Employees, retirees and dependents with diabetes experienced improved A1C levels, lower total health care costs, fewer sick days and increased satisfaction with their pharmacist’s services. The program is ongoing today and has expanded to include other chronic conditions such as asthma, hypertension, and high cholesterol.

- In a large managed care group in Colorado, pharmacists with advanced patient care skills managed the drug treatment of patients with heart disease. Researchers found that patients

under the care of these pharmacists showed dramatic improvements in their lipid control. Seventy percent of patients reached nationally recognized treatment goals within six months, compared to only 27% of patients who were not seen by these pharmacists.  

- The Diabetes Ten City Challenge (DTCC) was a multisite community pharmacy health management program for patients with diabetes. DTCC, modeled after Asheville program, successfully implemented an employer-funded, collaborative health management program using community-based pharmacist coaching, evidenced-based diabetes care guidelines, and self-management strategies. Positive clinical and economic outcomes were identified for the patients who participated in the program for at least one year. 

- Studies show that pharmacists can and should play a role in helping patients manage their medications. Specific to the treatment of hyperlipidemia, the APhA Foundation’s Project ImPACT Hyperlipidemia demonstrated that through pharmacist-patient interventions, patient medication persistence and compliance rates improved from the national average of 40% to 90%. In addition, more than 60% of those patients receiving patient care from a pharmacist in their community achieved their target therapeutic goals. 

- In a recent APhA project, pharmacists delivered interventions to improve care for patients with diabetes through implementation of the Discussions on Talking Medications (DOTxMED) Diabetes Pilot Program. The program demonstrated that small, focused interactions by pharmacists addressing patients concerns improve adherence to medication therapy.

For a list and brief overview of these and additional pharmacist-provided care program results, please see the report, Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General which includes numerous pages of citations of peer reviewed studies that document the value of pharmacist services. In addition, a list of APhA resources that may be helpful to FDA is included in Attachment C. These resources support the statement that countless individuals have benefited from pharmacist-delivered care and related services. We strongly encourage FDA to continue in its efforts expand the availability of nonprescription medications with conditions of safe use; we feel the resulting future public health data will support the decision.

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7. **What types of studies could be conducted to evaluate the effects of conditions of safe use on the safety and efficacy of particular drugs and on behavior and health outcomes?**

APhA is aware of many studies related to patient adherence and compliance with medication regimens, reasons contributing to adherence issues, and tools and resources to help improve how patients are taking their medications. We encourage FDA to ensure that such study designs are included in FDA review of sponsor applications seeking to use conditions of safe use. Studies designs, such as label comprehension studies, should also be similar to those already used in prescription to nonprescription switch applications. Please see **Attachment C** for a list of APhA resources and information that highlight the impact of pharmacist interventions and care programs that may be helpful as FDA considers post-market surveillance activities.

8. **What types of studies could be conducted to evaluate the safety and efficacy of any technologies that might be relied upon as conditions of safe use?**

Our recommendation would be to use post-market surveillance studies to evaluate impact on patient access, impact on practice settings, participation by pharmacies, utilization by patients and by practice settings, costs and time to implement and maintain, patient and provider satisfaction, patient and provider awareness, and other information that can review patient safety and impact on public health outcomes.

**B. Pharmacy, Consumer, and Health Care Provider Issues**

1. **Would this new paradigm increase consumer access to necessary medical care?**

APhA strongly believes this new paradigm would increase consumer access to necessary medical care. First, revisions to the drug paradigm would provide an opportunity for individuals to have greater access to important medications that can benefit their health while using the medication expertise of pharmacists or as appropriate other tools to help them use those medications appropriately. We see this as a significant and important opportunity for pharmacists to improve public health, and increase access, much as we have done with immunizations.

APhA applauds FDA for recognizing the clinical value of pharmacists and their ability to address a growing health care concern related to medication use. APhA firmly believes that pharmacists are a valuable and readily accessible resource to help meet patients health care needs regarding access to and the safe and appropriate use of medications. As consumers become more aware of product risks and benefits, pharmacists can play a valuable role in patient’s self-care decisions.

Second, the proposed new paradigm being considered by FDA would also ensure that patients have another access point to life saving emergency and rescue medications, and when appropriate, medications for certain chronic conditions. This is also an opportunity to reconnect patients with the health care system. Pharmacists see millions of patients who may have dropped out of therapy, may be non-compliant with current medication therapy, or may be the “walking well” with an undertreated chronic condition. In an effort to re-channel patients to appropriate care who may be potentially avoiding physician office visits, these patients could visit the pharmacy as an intermediate step and be evaluated and directed to appropriate care. Such options will need approved protocols (some of which may include algorithms), standards of care, documentation, and
other appropriate requirements for conditions of safe use for specific products as pursued by the product sponsor, but these are achievable ends. APhA is prepared to collaborate with professional societies interested in creating such tools.

Pharmacists are the most accessible health care provider to many patients in cities, rural communities and for the underserved population. There are more than 60,000 pharmacies in the U.S. where individuals can walk in during often extended hours and have access to a pharmacist. Improving access to such services from an OTC under conditions of safe use perspective would provide benefits to patients and our nation’s public health as such access could:

- Expand consumer access to formerly prescription-only medications;
- Increase patient adherence;
- Enhance patient safety and education;
- Improve medication use and health outcomes;
- Increase identification of other untreated conditions and increase referrals to physicians;
- Provide potential cost savings to consumers and health care systems; and
- Provide opportunities for provider communication and collaboration.

Finally, studies such as the Asheville Project have demonstrated that referrals to physicians increase when pharmacists are actively engaged in clinical interventions with the patient. These studies further document that pharmacists assisting patients to manage their prescription medications increases patient compliance, improves patient safety, and patients’ health outcomes improve significantly.12

Building on the Success of Pharmacy Improving Access to Immunizations
APhA sees the new paradigm as an opportunity to build on the success of pharmacist-administered immunizations and improvements in immunization rates, access and in public health. Over the last decade or so, all states enacted laws to empower pharmacists to immunize. The Department of Health and Human Services (HHS) and its agencies such as the Centers for Disease Control (CDC) and the Centers for Medicare & Medicaid Services (CMS), and other immunization stakeholders are working with pharmacists across the country to increase immunization rates. More than 175,000 pharmacists have 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. These activities occurred under protocols established with medical and /or public health practitioners.

As recently as June 2011, the CDC’s National Center for Immunization and Respiratory Diseases congratulated APhA and its members on the fifteen year anniversary of APhA’s national certificate training program for pharmacists, Pharmacy-Based Immunization Delivery13 and its extensive work in the area of immunizations. As highlighted in that letter, during the last 15 plus years, APhA has increased the role of pharmacists in immunization and has become a vital and effective partner in this critical area of public health. In October 2010, the CDC also formally expressed its

12 Cranor CW, Bunting BA, Christensen DB. The Asheville Project: Long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. J Am Pharm Assoc. 2006;45(2);123-147
13 The Pharmacy-Based Immunization Delivery program is accredited by ACPE.
appreciation to immunizing pharmacists, thanking them for their service during the 2009 H1N1 influenza pandemic. In that letter (see Attachment D), Assistant Surgeon General Anne Schuchat stated: “Pharmacists, working with the public health community, can assist our nation in meetings its major public health challenges….As CDC intensifies its focus on prevention, I especially welcome the development of new ways pharmacists can increase access to services that will strengthen the health of our nation.” APhA feels strongly that the new paradigm being considered can build on the successful immunization public health model.

Building on the pharmacy profession’s success in processes used to gradually implement and increase access to immunizations, similar tactics could be used for conditions of safe use, including, following standardized algorithms, establish processes for evaluation and assessment of patients, training for awareness, implementation and logistics procedures. For example, guidelines for patient identification and risk assessment should be available. Information about appropriate populations and necessary risk assessment procedures should be provided in product labeling, as well as in educational materials for pharmacists. In addition, pharmacy staff should be educated and trained about the product and the appropriate population for product use.

Again, we strongly believe the new paradigm will increase consumer access to necessary medical care. Pharmacists are among the most accessible members of the health care team. Consumers across the nation seek out their pharmacist for a range of health care needs. Allowing such individuals improved access to needed medications, as was the case with immunizations, will certainly improve the likelihood that these individuals will receive needed care or will be redirected back into the health care system for treatment.

3. Would a lack of oversight from a practitioner, including involvement in diagnosing the condition or monitoring for drug interactions or other drug effects, be a concern? If so, how could these concerns be addressed?

The emerging care delivery model of the future is predicated upon team based care with the pharmacist as a valued member of the health care team. As mentioned previously, the PHS is a highly successful model. APhA views the potential new drug paradigm as an important opportunity for pharmacists to further communicate and collaborate with physicians and other providers. As part of pharmacy practice today, pharmacists in a variety of practice settings across the country provide clinical services to countless patients on a wide range of prescription medications. Typically, these services are guided by established protocol and may include assessing patients, reviewing test results, counseling on usage, monitoring results and drug interactions, modifying dosages, documenting services, and communicating with the physician or other health care provider. In numerous cases initiating, modifying or discontinuing medication therapy under institutional protocols is occurring. Study after study has documented unequivocal improvements in health outcomes and institutional cost savings, and reductions in medication errors and adverse drug reactions, when pharmacists provide patients with these types of clinical services.

Concerns can be addressed by increased awareness and education about a potential new paradigm, increased communication and collaboration between the pharmacist, patient and medical staff (i.e. utilization of EHR and other communication tools), and overall aims to do what is best for the patient in improving their health.
In addition, APhA views the potential new paradigm as building on the team-based approach to patient care and not segmenting or creating silos of patient care activity in the pharmacy. We see this as an opportunity to provide additional access points to life-saving, emergency medications such as antidotes and rescue medications. We also consider a new paradigm as a way for pharmacists to help redirect undertreated patients back into the health care system, provide referrals of patients to appropriate medical care that falls outside the scope of this potential paradigm, and consider opportunities to work with patients who are already diagnosed but may need additional emergency access options or general safety oversight to ensure safe use of the medication.

This proposal is not intended to divert patients to the pharmacy in lieu of seeing their physician. Instead, this is about getting care to patients who in many cases may not be seeing any health professional at all, who may have fallen out of the system, and who would benefit from a conversation with a health professional trained and in a position to refer from community and ambulatory pharmacies where no appointment is required and doors are open extended hours. We would hope that the collaboration that results will be seen as complementing physician care and would actually facilitate assuring that additional resources and access points are available to consumers.

Meanwhile, we are also aware that millions of patients who are receiving excellent primary care would also consider treatment options using non-prescription medications made available through this new paradigm. Physicians may rightly be concerned about gaps in information systems and the ability to capture these important medication therapy purchases. Pharmacists will continue to seek ways to share all medication dispensing information with primary care physicians, as described in numerous other places in these comments. The new paradigm might appropriately require sponsors to work with physicians and pharmacists to assure such systems are in place. This could be as simple as having the pharmacy enter the purchase of an OTC with a condition of safe use requirement in the patient’s medication record in the pharmacy for use or reporting as deemed appropriate.

Success of the Public Health Service
As mentioned earlier, including pharmacists’ interventions as a component of conditions of safe use can build on the successful model already in place for using pharmacist services as practiced for decades by the PHS. As part of PHS, pharmacists have nearly 50 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, Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General,14 further includes 27 pages of studies that document the value of pharmacist services. This information may be helpful as FDA considers further pathways for a new drug paradigm.

Pharmacists nationwide are trained and practice as members of the health care team. Pharmacists communicate daily with physicians and refer those in need to their physician counterparts. Given that the potential drugs eligible to be included in this new paradigm would be those that are tested

by manufacturers and approved by FDA after industry discussion, we feel comfortable that existing communications protocols and post-market safety and surveillance tools will be in place to ensure patients safety and medication success.

4. **How might the new paradigm be expected to affect consumers financially or otherwise affect access to and delivery of health care generally?**

APhA believes this new paradigm has the potential to benefit individuals greatly through saving them costs associated with trips to the emergency rooms and preventable hospitalizations. In addition, people’s quality of life and productivity could improve. For some consumers whose insurance plans may drop reimbursement for a prescription product if it transitions to OTC status, the potential increase in out-of-pocket expenses could potentially limit consumer uptake. However, if this proposal prevents major costs later in the system insurance companies may pay for these medications just as they pay pharmacists to provide immunizations or are beginning to pay pharmacists for medication therapy management (MTM) services.

Additional concerns focus on availability and standardized process for such products across different locations and practice settings. As it stands however, for many with a history of asthma, migraine headaches and other common medical conditions, physician office visits may be postponed due to financial costs, time, and even ability to get to the office. Again, APhA sees the potential new paradigm as a mechanism that, when appropriate based on FDA's review of a drug application, could be offered to the public for helping to maintain medication regimens, screening/referral, and improving overall public health.

5. **Would expanding what could be considered nonprescription drugs under the new paradigm, and thus creating greater consumer access to needed drug products, reduce burden on emergency rooms and on individual health care providers, or otherwise increase the availability of these resources for other consumers? Are there other ways in which the new paradigm might reduce the burden on the health care system?**

We believe a new paradigm has the potential to help reduce costs and the burden on the overall health care system, emergency rooms, and on the individual providers. By increasing patient access to medications provided through conditions of safe use, we would be building on the success of pharmacist-provided immunizations in which patients now have much greater access to vaccines in pharmacies across the country.

In addition, such a paradigm could improve times to first dose for emergency and rescue medications, thereby reducing for example potential hospital visits and readmissions. As such, we see this new paradigm potentially serving not only the patient individually but the health care system as a whole through allowing physician practices and emergency rooms to focus on the truly sick and acute care patients.

It is possible that the new paradigm might result in an increase in physician visits as patients who have fallen out of the system are re-directed back to their health care providers by pharmacists through a referral process. As evidence shows is the case with pharmacist-provided care, the additional costs associated with increased visits to physicians would be offset by reductions in emergency room visits and hospital stays.
6. How might various types of conditions of safe use on nonprescription drug products affect pharmacy business operations? What differences might there be in the operational issues experienced by pharmacies operated by chains and independently operated retail outlets?

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. Numerous outcomes-based studies, pilot programs, demonstration projects, and other activities document and reconfirm pharmacists’ impact on patient health and well-being, process of care delivery, and overall health care costs. The safe and effective use of OTCs medications with conditions of safe use would however require support structures to help consumers navigate this expanding self-care environment. Pharmacy is essential to this support structure. The role of pharmacy as a health care facility and the pharmacist as a health care professional is an increasing component of manufacturer and regulator discussions – the profession must help define the role.

Conditions of safe use could affect pharmacy practice in many ways depending on how it is implemented. In particular, pharmacists’ efforts to coordinate and monitor medication use, the need to prepare pharmacy personnel for the product shift, and the financial impact of the shift need to be proactively addressed.

Should this new paradigm be approved as proposed, we fully anticipate undertreated individuals nationwide will require the time and services of pharmacists creating increased workflow and ultimately demands on staffing requirements. To ensure the viability and longevity of this new paradigm, pharmacists’ services must be valued by consumers, payers and/or sponsors. The clinical services required to dispense products with conditions for safe use will place new demands on pharmacists and pharmacy workflow that will need support to maintain. As demonstrated by the significant uptake in immunization services in community pharmacies, when incentives are aligned, new services can be implemented in community pharmacies in a timely manner.

We understand that such payment solutions for conditions of safe use activities may be market-driven and not under the purview of FDA. As such, we ask that FDA’s initiatives 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.

Through the recognition that support structures would need to be in place and supported, we feel business operations can be modified to thrive within then new paradigm.
7. **Would additional specialized training be needed for pharmacists if this paradigm were adopted?**

“Specialized training” would not be necessary. Pharmacists are educated about the product availability and indications for use and are well qualified to provide clinical interventions on the safe use of a medication, just as we already do with prescription and OTC products. Pharmacists may however need education about the new paradigm and on the availability of a product, the targeted patient population, process and logistical requirements of the program, the algorithm for each product, resource materials for pharmacists and patients, and necessary materials to comply with implementing and maintaining dispensing of products in a new paradigm. In addition, necessary training and education of pharmacy staff and facility staff would be important to support pharmacist/consumer interactions, including providing consumer education materials. Standardization to the extent possible would simplify this part of the program.

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.

Prior to 2000, most pharmacists received a five-year Bachelor of Science in pharmacy degree (BS Pharmacy). Today, all schools and colleges of pharmacy transitioned to a six-year Doctor of Pharmacy (PharmD) degree, with an increased curricular emphasis on patient care services. Today’s education standards incorporate the team approach to care and pharmacists’ roles in public health, wellness and prevention setting the stage for pharmacists role within the new paradigm to increase consumer access to necessary care through early identification and referral as necessary.

Furthermore, it is also within the scope of practice in every state for pharmacists in all practice settings to obtain medication histories, review the patient’s medications to identify medication-related problems, to engage collaboratively with physicians to resolve identified problems, educate the patient about proper use of medications, encourage adherence with prescribed medications and other therapies, document and communicate information and recommendations to other providers on the patient’s health care team and provide wellness services, including immunizations.

The term “specialized training” suggests significant education may need to be done for each product to be available through conditions of safe use. We do not anticipate such heavy requirements; rather, more refresher and logistical information. As such, we encourage using terminology related to the educational material needed to implement and comply with the program.

Again, we do not feel “specialized training” would be required. Pharmacists are well educated about product availability and appropriate indications for use. Most likely some education would be required to review the new drug paradigm and related topics but we feel such instruction could be delivered through our professional education programs.
8. If availability of a nonprescription product with conditions of safe use were limited to certain outlets (e.g., a chain pharmacy that chooses to offer a particular technology or service), would the situation create confusion or difficulties for consumers seeking to obtain the drug product? Could such a situation create difficulties for practitioners in knowing whether a particular consumer could access the drug with a prescription or would be able to obtain the same product as a nonprescription drug product at a retail outlet? If so, how could these issues be overcome?

APhA believes that by ensuring all pharmacies can participate in the new drug paradigm, consumer confusion will be avoided. We believe any pharmacy that wishes to offer the services and can comply with program requirements should have an opportunity to participate. Pharmacists should be able to choose which services they offer just as they do today. Individuals nationwide should have access to these services in a uniform and standardized process. We would be concerned that health care providers and consumers could be confused if the same product was available only through different pathways at different locations. From an administrative and logistical perspective, it could be challenging to manage.

To this end, we recommend the new paradigm be consistent in the use of standardized, consensus-based, best-practice algorithms for pharmacists to implement and communicate with other providers. Interventions that could be part of a new paradigm could include screening, assessment and counseling, or referral of an individual to the physician or other appropriate medical provider. Such processes may be developed in collaboration among professionals and other stakeholders involved.

Through such an approach, consumers would be aware that all pharmacies can participate, whether they do would be a matter for the pharmacy to decide. We feel strongly that patients’ access to this new paradigm should not be reliant on whether their pharmacy was the correct “type” as pharmacists’ pathway to licensure are similar throughout the U.S. It is not confusing to patients that all pharmacists do not immunize, do not compound medications and do not offer the same type of services just like it is not confusing to patients that all physicians do not offer the same services.

9. What experiences have practitioners, pharmacists, and insurers had with state-authorized arrangements under which access to prescription drugs has been expanded that might be relevant to and inform our consideration of this paradigm (e.g., a collaborative practice agreement between a pharmacist and a practitioner that allows the pharmacist to dispense a prescription drug to a consumer who meets certain criteria under a standing or open prescription, when that consumer did not obtain a prescription directly from a practitioner, or that allows a pharmacist to refill a prescription after an initial prescription from a practitioner pursuant to a similar agreement)?

As previously stated above, when pharmacists get involved, outcomes improve and costs go down. Currently, 46 states have laws authorizing pharmacists to provide pharmacist-provided patient care services through collaborative practice agreements to outpatients. Thousands of these pharmacists manage their patients’ therapy for a host of conditions, including but not limited to diabetes, asthma, high blood pressure, and high cholesterol, typically pursuant to a collaborative practice agreement with a physician where the physician delegates certain agreed upon responsibilities to the pharmacist. In these situations, physicians and pharmacists working as a team use their
particular skills to the best effect for the benefit of the patient. Based on the physician’s diagnosis and protocols outlined in the collaborative drug therapy management (CDTM) agreement, CDTM activities may include, but are not limited to, the following pharmacist activities:

- Initiating, modifying, and monitoring a patient’s drug therapy;
- Ordering and performing laboratory and related tests; and
- Assessing patient response to therapy.

While this is not dispensing OTC medications based on conditions of safe use, as discussed in FDA’s hearing notice, application of the concept is certainly similar to that of CDTM as it aims to increase patients access to pharmacist-services, improve medication use, and collaboration with the patient’s health care team as already authorized in certain states. Again, it is akin to the way care has been delivered in the Public Health Service for decades. Gains through this approach are consistently demonstrated in patient adherence, safety, outcomes, and cost savings.

Beyond patient care management, pharmacists have proven to be an invaluable component in our nation’s efforts to increase influenza immunization rates. Understanding pharmacists’ education, training and unparalleled access in the community, all 50 states, the District of Columbia and Puerto Rico, have authorized pharmacists to administer influenza immunizations, generally through various CDTM or similar arrangements. The extent to which pharmacists have been utilized varies by state in regards to the antigens and the age of patient to which pharmacists may administer vaccine.

Numerous studies in numerous peer reviewed journals articles support the positive health impact(s) pharmacists have through collaborative practice agreements with physicians and other prescribers. We feel the new drug paradigm under consideration is an appropriate extension of these concepts, but to a larger population. Where authority for collaborative practice agreements differs throughout the U.S. as a result of state laws and individual interests of the physician, this new paradigm has the opportunity to make available to patients nationwide, the well documented and supported clinical services of pharmacists. We believe this new paradigm could provide for a consistent, national expansion to certain nonprescription medications leading to greater consumer access and improved public health.

10. What are the public health and regulatory implications of the use of in vitro diagnostic tests as conditions of safe use for nonprescription drug products in a pharmacy setting (e.g., as a laboratory under the Clinical Laboratory Improvement Act of 1988 (CLIA) (Public Law 100–578))? 

From a public health and regulatory perspective, it is our understanding that most point-of-sale testing devices used in pharmacy practice are already CLIA waived. We do not expect the utilization of such services in a potential new drug paradigm to significantly impact what is already implemented in various pharmacy practice settings. If such services were required, access to the product’s accompanying service would be determined by the algorithm, other conditions of safe use that are evidenced based and approved by FDA, the pharmacy itself and market factors.
C. Other Related Issues

1. How would insurance coverage of pharmaceuticals be affected by approving nonprescription products with conditions of safe use for widely prescribed prescription drugs under this paradigm?

2. How would out-of-pocket costs for the insured be affected by making prescription drugs available as nonprescription products with conditions of safe use?

The issue of out-of-pocket costs for the insured is a component of the discussion that should be taken into account. Insurance coverage of products approved in a potential new paradigm would be determined by individual plans. We would expect plans to make coverage decisions based on value to the patient and to the plan for coverage of the product. There could be significant challenges for Medicare patients as the Medicare Part D prescription drug benefit is not authorized to cover non-prescription drugs.

Related, if a product were to require an intervention by a pharmacist, pharmacists must be able to bill, through a standardized mechanism, and be compensated for the services required to dispense products with conditions of safe use. Recognizing that payment solutions may be market driven and not under the purview of FDA, FDA must ensure that its drug approval decisions do not preclude payment for pharmacists’ services by the patient, third-party payer, state program, Medicare, the sponsor, or others. Insurance coverage and/or other payment methodologies for the product and/or the service to dispense the product are key factors to consider for costs shift to individuals and costs to implements services in the pharmacy. A viable business model must be in place or these services will not be sustained and the benefits would not be realized.

While out-of-pocket costs for the insured should be taken into account, it is important to also take into consideration those individuals without insurance. Scores of uninsured individuals are undertreated or without needed medications including emergency rescue medications. The potential new paradigm could reduce costly emergency room visits and hospitalizations for these individuals. APhA believes the new drug paradigm would have a positive impact on those without health insurance.

Finally, some patients, particularly those in emergency situations, would likely voluntarily agree to pay for necessary medications, even out of their own pocket if necessary.

3. Would the new paradigm increase liability concerns for pharmacists and pharmacies? To what extent would these concerns raise the cost of the services provided?

From a liability perspective, we do not foresee an increased liability risk for pharmacists and pharmacies. We believe that the services that could be provided by pharmacists in a new paradigm would generally fall within their existing scope of practice. While there could potentially be minor revisions to liability carrier plans, any questions in potential liability concerns can be worked out through appropriate channels and should not prevent continued work on this initiative. The activity envisioned within the new paradigm would fall under the scope of practice for pharmacists and would ultimately be covered by pharmacists’ liability
insurance plans.

Today, it is also within the scope of practice in every state for pharmacists in all practice settings to obtain medication histories, review the patient’s medications to identify medication-related problems, to engage collaboratively with physicians to resolve identified problems, educate the patient about proper use of medications, encourage adherence with prescribed medications and other therapies, document and communicate information and recommendations to other providers on the patient’s health care team and provide wellness services, including immunizations.

Moving to a new paradigm may benefit the most from educational and awareness outreach, opportunities to provide feedback on proposals as they move through FDA, and ensuring that any legislative and/or regulatory route that is pursued does not impede progress forward or create burdensome barriers to participate.

4. **What proprietary, technological, economic, or competitive barriers might impede widespread implementation of this paradigm? To the extent such impediments exist, are there suggestions for mitigating or avoiding the impediments specific to this paradigm?**

We appreciate that there may be some challenges, logistics, payment issues, and many details to be worked out, none of them are significant enough to stop this initiative from moving forward.

5. **Would overall health care costs decrease if this paradigm were instituted?**

APhA believe that revisions to the drug paradigm would reduce overall health care costs. Pharmacists are willing and prepared to do their part as health care professionals and to proactively work with patients to help them understand, manage, and improve the use of their medications.

Studies show time and again that when pharmacists get involved, costs decrease and quality and outcomes improve. As referenced earlier, the Asheville Project and the Diabetes Ten City Challenge are just two examples. Other examples include:

- **Minnesota MTM Care Program**: estimated annual cost savings amount of $403.30 per patient for MN adults achieving the “optimal care” benchmark for diabetes. Even though a cause and effect relationship cannot be firmly established, potential annual cost savings among the 41 medication therapy management services (MTMS) recipients with diabetes achieving optimal care would be $15,325. Pharmacist-provided MTMS decreased health care costs from $11,965 to $8,197 per patient per year.¹⁵,¹⁶

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• **Department of Veterans Affairs (VA):** by extrapolating the average salary data for pharmacist, the VA expects to see an annual $368,000 in savings from each pharmacist by providing clinical pharmacy services.\(^{17}\)

• **Benefit-to-Cost Ratio:** a systematic literature search was conducted to identify published economic evaluations of pharmacist clinical services. Among studies reporting data necessary to determine a benefit-to-cost ratio (n=15), the pooled median value was 4.81:1—meaning that for every $1 invested in pharmacist clinical services, $4.81 was achieved in reduced costs or other economic benefits.\(^{18}\)

• **Ambulatory Care Settings:** annual savings attributable to pharmacists include $3.5 billion in hospital cost avoidance by coordinating medications from multiple prescribers.\(^{19}\)

• **Anticoagulation Clinic:** annual savings attributable to pharmacists include more than $1,600 in direct health care costs per patient at a pharmacist-run anticoagulation clinic, compared to usual medical care.\(^{20}\)

• **Agency for Healthcare Research and Quality (AHRQ):** “…pharmacists were most likely to prevent the errors from reaching the patients (40 percent of intercepted medication errors), while physicians and patients were almost equally likely to intercept the medication error (19 percent and 17 percent of intercepted errors, respectively).”\(^{21}\)

• **George Halverson, Chairman and CEO of Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals:** “We … had teams of nurses, caregivers, and pharmacists actually, because pharmacists are the most underutilized resource in health care, use[d] pharmacists to help advise if patients were not taking the drug, what the right drug would be, and the result of that was 73% reduction in deaths for heart disease and coronary heart disease for the entire heart population that we have in Colorado.”\(^{22}\)

As evidenced above, we believe overall health care costs will decrease if this paradigm is instituted. More importantly however, we believe the new paradigm will serve as the impetus for a profound improvement in patients’ and the overall public health of the U.S.

**Conclusion**
In conclusion, APhA supports the overall concept of utilizing medications under conditions of safe use to improve patient access and public health. We recognize that a more flexible process for ensuring access to certain medications also required appropriate communication and collaboration with the medical community. We also support legislative and/or regulatory actions that would provide FDA


broad general authority to utilize conditions of safe use for certain nonprescription products, understanding that many logistics, payment, challenges, and other uncertainties can be addressed in the future.

Finally, as we testified at the public hearing, APhA and our members view this activity as “Yes…if” rather than “No…but” and look forward to working with FDA, health care providers, and other stakeholders to answer the “if” questions and make this concept a reality.

If you have any questions or require additional information, please contact Marcie Bough, PharmD, Senior Director of Government Affairs at mbough@aphanet.org or by phone at (202) 429-7538.

Sincerely,

[Signature]

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

TM/mb

cc: Brian Gallagher, BSPharm, JD, Senior Vice President, Government Affairs
    Anne Burns, BSPharm, Senior Vice President, Professional Affairs

Attachment A. APhA Testimony at March 22, 2012 FDA Public Hearing
Attachment B. APhA Drug Safety Continuum Visual
Attachment C. Additional APhA and APhA Foundation Information
Attachment D. HHS 2010 Letter to APhA in Support of Immunizations
Attachment A
APhA Testimony at March 22, 2012 FDA Public Hearing
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.

![Diagram of Draft New Drug Paradigm Being Considered by FDA](image)

**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.
Attachment B
APhA Drug Safety Continuum Visual
Figure 1.
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.
Attachment C
Additional APhA and APhA Foundation Information
Additional APhA and APhA Foundation information of interest available online:

- APhA Foundation Research Projects and Summaries. The APhA Foundation is involved in a number of research projects that establish new models of practice for pharmacists and redefine patient care in pharmacy practice. These are listed on the APhA Foundation Web site and include:
  
  o **Alzheimer's Disease Screening Project**: An Alzheimer’s Disease screening model in ambulatory care practice settings that improves the identification of patient patients who are at risk and treatment referral.  
    » [Alzheimer's Disease Screening Project](#)

  o **Asheville Project**: A community pharmacy-based, diabetes management program taking place in Asheville, North Carolina, that has shown to improve overall health, reduce absenteeism, shorten hospital stays and reduce health care costs.  
    » [The Asheville Project](#)

  o **Diabetes Ten City Challenge**: An innovative project conducted by the APhA Foundation that employers and communities can use to fight diabetes and reduce health care costs.  
    » [The Diabetes Ten City Challenge](#)

  o **Patient Self-Management Program: Diabetes**: To assess the outcomes for the first year following the initiation of a multisite community pharmacy care services (PCS) program for patients with diabetes.  
    » [Patient Self-Management Program: Diabetes](#)

  o **Project IMpACT**: Project IMpACT is a process of care requiring a collaborative effort among three essential health care parties: the patient (or caregiver), the patient's physician, and the pharmacist. The Foundation's landmark demonstration project: Project IMpACT: Hyperlipidemia is the basis for many of the Foundation's current research projects.  
    » [Project IMpACT](#)

  o **Project IMPACT: Diabetes**: A national project designed to bring a proven inter-disciplinary collaborative diabetes care model to 25 high need communities across the U.S  
    » [Project IMPACT: Diabetes](#)

- APhA Resources: [Medication Therapy Management (MTM) Central](#)
  o MTM Services: [Creating a Patient Care Process](#), 2007  
  o MTM Services: [Documenting Patient Care Services](#), 2007

- APhA Project. [DOTx.MED: Pharmacists-delivered interventions to improve care for patients with diabetes](#)

- APhA Highlights Newsletter. October 2010. [Continuity of Care: Proceedings of the Pinnacle Roundtable](#)
• APhA Highlights Newsletter. October 2004. Enhancing Patient Adherence
• APhA Highlights Newsletter. July 2008. COPD: Expanding the Key Role of the Pharmacist
• APhA Resource. Improving Medication Use and Lowering Health Care Costs. Using Pharmacists and Health Information Technology (HIT)
• APhA Resource. Improving Medication Use, Lowering Health Care Costs
Attachment D
HHS 2010 Letter to APhA in Support of Immunizations
October 1, 2010

Dear Pharmacist:

I want to take the opportunity of American Pharmacists Month to thank you as a practicing pharmacist for the service you provided to our nation during the 2009 H1N1 influenza pandemic. Since the beginning of the 2009 H1N1 pandemic, pharmacists provided wise counseling and advice, dispensed antivirals, and administered both seasonal and monovalent 2009 H1N1 vaccine to millions of individuals in the United States.

In particular, I recognize the long-term partnership of the American Pharmacists Association (APhA) and its members with the Centers for Disease Control and Prevention (CDC) in the area of immunizations. During the past fifteen years APhA’s National Certificate Training Program for Pharmacists on Pharmacy-Based Immunization Delivery and its work in the area of immunizations has increased the role of pharmacists in immunization, positioning the profession as a vital, effective partner in this critical area of public health. APhA’s Certificate Training Program for Pharmacists has facilitated the training of more than 100,000 pharmacists to deliver immunizations and serve as a knowledgeable public resource. The program has received national attention and is highly regarded by public health leaders. Since the program’s inception, CDC has and continues to recognize the high quality and content of the training program in preparing pharmacists to assume an active role in immunization education, facilitation and delivery. During the recent influenza season, and especially during the peak of the H1N1 pandemic, APhA, the National Association of Chain Drug Stores, the National Alliance of State Pharmacy Associations, the National Community Pharmacists Association, and pharmacy corporations and pharmacists helped CDC develop and implement immunization policy, strategies and messages focused on protecting the public from vaccine-preventable diseases and provided both seasonal influenza and 2009 H1N1 pandemic influenza immunizations to Americans.

Pharmacists, working with the public health community, can assist our nation in meeting its major public health challenges. Pharmacists are increasingly being recognized for their contributions to improving public health, and new areas for collaboration are being identified within communities for pharmacists to play an expanded public health role. I look forward to partnerships with our nation’s pharmacists as they play an active role to provide needed services with other members of our nation’s healthcare infrastructure. As CDC intensifies its focus on prevention, I especially welcome the development of new ways pharmacists can increase access to services that will strengthen the health of our nation.

Thank you for your dedication to improving the health of your communities. I look forward to continuing our growing partnership.

Sincerely,

Anne Schuchat, MD
RADM, US Public Health Service
Assistant Surgeon General
Director, National Center for Immunization and Respiratory Diseases