June 15, 2012

William H. Huffaker, MD  
Chair Reference Committee B  
American Medical Association  
2012 Annual Meeting of the House of Delegates  
Chicago, Illinois

RE: Resolution 218 – Pharmacist Prescribing  
Resolution 235 – Opposition of FDA’s Rx to OTC Paradigm Shift  
Resolution 240 – Pharmacist Prescribing

Dear Dr. Huffaker:

We are writing in response to several resolutions submitted to the American Medical Association’s (AMA) Reference Committee B as part of the 2012 House of Delegates. The American Pharmacists Association collaborated with its colleague pharmacy organizations, including the American Association of Colleges of Pharmacy, Academy of Managed Care Pharmacy, American Society of Health-System Pharmacists, College of Psychiatric & Neurologic Pharmacists, International Academy of Compounding Pharmacists, National Alliance of State Pharmacy Associations, National Association of Chain Drug Stores, and National Community Pharmacists Association, to comment on Resolution 218 – Pharmacist Prescribing, Resolution 235 – Opposition of FDA’s Rx to OTC Paradigm Shift, and Resolution 240 – Pharmacist Prescribing. Our comments reflect our collective organizations’ interests in ensuring an accurate portrayal of the potential new drug paradigm being considered by the Food and Drug Administration (FDA).

Resolution 218 – Pharmacist Prescribing and Resolution 240 – Pharmacist Prescribing
We respectfully request that Reference Committee B recommend in its report to the AMA House of Delegates that Resolutions 218 and 240 not be adopted as they inaccurately represent the publicly stated intent of the potential new drug paradigm being considered by FDA.

Resolution 235 – Opposition of FDA’s Rx to OTC Paradigm Shift
We have some reservations with the title and background material within Resolution 235, but do appreciate the intent of the “Resolve” language, that the authors recognize the value of AMA staying engaged in the discussion, and is supportive of public comment during application reviews. Therefore, we respectfully request Reference Committee B recommend in its report to the AMA House of Delegates that Resolution 235 be adopted in lieu of Resolutions 218 and 240 but with a revised title that better reflects the intent of the resolution which supports AMA’s continued dialogue on this issue.

The rationale for our positions on these resolutions is more fully explained below.

Clarifying Misinterpretations of FDA’s Proposed New Drug Paradigm
We oppose Resolutions 218 and 240 as they incorrectly characterizes what FDA is considering through the potential new drug paradigm that would allow dispensing of certain medications using
“conditions of safe use.” Specifically, the resolutions incorrectly suggest that the concept would enable pharmacists to independently prescribe certain medications. This does not accurately reflect FDA’s intent of the February 28, 2012 public hearing announcement, \(^1\) discussion at FDA’s public hearing on March 22-23, 2012, and statements made by FDA.

Like physicians, pharmacists seek to improve the public’s health. Pharmacists’ work is best characterized as post-diagnostic medication management. In our support of the FDA proposal, we are not seeking independent prescribing authority, but rather an opportunity to provide the care we have been trained to provide to patients in a manner that assures safe medication use and provides a pathway to improved health. We submit that pharmacists will not disaggregate patients from their existing primary care provider or other practitioners, and instead will seek to ensure continuity of care by facilitating communication and team-based care, and importantly re-engage patients who may have disconnected from the health care system.

To further clarify, FDA is considering ways to improve public health and increase patient access to certain medications through conditions of safe use, in which such conditions could include an intervention with a pharmacist or use of innovative technologies. In addition, FDA aims to continue with the two-class drug system of prescription and nonprescription (or over-the-counter (OTC)) medications, with the new concept adding flexibility for certain medications being dispensed with conditions of safe use. Again, based on our ongoing dialogue with FDA and pharmacy colleagues, there is no intent to seek independent prescribing authority for pharmacists, as incorrectly described in the background material and “Resolve” language in Resolutions 218 and 240.

**Fostering Communication and Collaboration between Medicine and Pharmacy**

The pharmacy profession sees FDA’s proposal as an opportunity for physicians and pharmacists to communicate and work together to improve patient care and public health. We agree with FDA’s belief that pharmacists have a key role to play in this potential new drug paradigm. Our view is that pharmacists can help improve care across the health care system in collaboration with physicians, and redirect undertreated individuals back into care, not fragment care as suggested in the background of Resolutions 218 and 240.

We support FDA’s effort to improve public health and efforts to explore opportunities to re-channel patients who may be undertreated back into care, or direct those who may not be receiving any care within the health care system. We see this as an opportunity to reconnect and link patients to care who may have a diagnosed but undertreated conditions – which, as pharmacists do today, often results in the pharmacist referring a patient to an appropriate medical provider. Moreover, we feel that the proposal could serve to ensure that patients with certain diagnosed conditions have increased access to life-saving emergency medications, such as antidotes and rescue medications, that may otherwise remain prescription only. In addition, as the concept evolves, we propose that safe use conditions and interventions be based on established best practices and through approved algorithms, documentation, standards of care, and other appropriate requirements for conditions of safe use as pursued by the manufacturer for specific products.

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Joint Pharmacy Letter to AMA on Resolutions 218, 235 and 240
June 15, 2012

The pharmacy profession occupies an important and longstanding position on the health care team as the medication expert to assist physicians and other providers in managing patients’ medications in both inpatient and outpatient care settings. In contrast to the background language in Resolutions 218 and 240, pharmacists are well prepared to improve patient safety. Today, all schools and colleges of pharmacy have transitioned to a Doctor of Pharmacy (PharmD) degree involving a minimum of six years of education and training, with an increased curricular emphasis on patient care services. Pharmacy curricula also commonly includes extensive medication and patient-care related coursework well beyond that of other health professionals related to pharmacotherapeutics and pharmacology. Pharmacists’ education and training place emphasis on applying knowledge in these areas toward the provision of team-based direct patient care. Importantly, many medical and pharmacy school curricula are being revised to facilitate the education and training of medical students and student pharmacists together, using collaborative team-based models of care.

Furthermore, states have also recognized the value and improvements to public health through physicians and pharmacists working together. Most states now allow physicians and pharmacists to enter into voluntary collaborative practice agreements and all states have enacted laws to authorize pharmacists to immunize. These activities build on team-based care that has been championed for decades through the Public Health Service and provide successful examples as FDA considers its role in improving patient access and public health.

To provide additional clarification regarding the inaccurate independent prescribing language included in the background of Resolutions 218 and 240, pharmacists working in certain settings in which select prescribing activities are occurring are doing so through physician-approved collaborative practice agreements as authorized by state practice acts, not independently. For all these reasons we recommend that Resolutions 218 and 240 not be adopted.

Support for Continued Dialogue between Medicine and Pharmacy
We appreciate and encourage ongoing dialogue with AMA, other medical colleagues, FDA, pharmacy, and other stakeholders regarding any potential new drug paradigm, as outlined in the “Resolved” language in Resolution 235. We support AMA’s continued engagement in dialogue and in seeking review opportunities for any medication being considered in a new drug paradigm. Similarly, pharmacy has also advocated for a transparent review/approval pathway that allows for stakeholder input on any application submitted by a manufacturer seeking to increase access through conditions of safe use.

While we recognize many details remain to be worked out regarding this initiative, none are significant enough to stop or delay efforts to build on ongoing collaboration between our professions. A potential new drug paradigm should not segment or silo patient care activity in a pharmacy but rather provide for redirecting patients back into health care system, where appropriate, to improve public health and decrease costs.

Pharmacists are committed to communicating with our medical colleagues and to a team-based approach to care. We have had ongoing and beneficial discussions with AMA and hope to continue

such collaboration and communication on this important initiative and other issues aimed at physicians and pharmacists working together to improve patient care and public health.

Closing
In closing, we view FDA’s concept of using conditions of safe use as an important opportunity to:

- Communicate and collaborate with the medical community on post-diagnostic team-based patient care.
- Reconnect and refer patients back into the health care system who may have undertreated conditions or may need expanded access to life-saving rescue medications.
- Leverage patients’ access to pharmacists to safely increase the availability of certain medications as pursued by manufacturers.
- Ensure that stakeholders have input as FDA reviews manufacturer applications seeking to utilize conditions of safe use.
- Build upon the success of pharmacist-provided patient care services through managing medications, collaborative practice agreements, immunizations, and through the Public Health Service’s pharmacy practice model.

Again, we respectfully oppose Resolution 218 and Resolution 240 as they inaccurately represent the potential new drug paradigm FDA is considering. We recommend adoption of Resolution 235 in lieu of Resolutions 218 and 240 but with a revised title to better reflect the intent of the resolution which supports AMA’s continued dialogue on this issue.

On behalf of the undersigned pharmacy organizations, thank you for the opportunity to provide comments and clarifications. We look forward to working with AMA and the medical community to find common solutions as FDA considers potential changes to the drug paradigm. If you have questions or need additional information, please contact Marcie Bough, PharmD, APhA’s Senior Director of Government Affairs, at mbough@aphanet.org or 202-429-7538.

Sincerely,

American Pharmacists Association (APhA)
American Association of Colleges of Pharmacy (AACP)
Academy of Managed Care Pharmacy (AMCP)
American Society of Health-System Pharmacists (ASHP)
College of Psychiatric & Neurologic Pharmacists (CPNP)
International Academy of Compounding Pharmacists (IACP)
National Alliance of State Pharmacy Associations (NASPA)
National Association of Chain Drug Stores (NACDS)
National Community Pharmacists Association (NCPA)