



# American Academy of Physician Assistants

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July 21, 2004

Division of Dockets Management  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20852

RE: Food and Drug Administration  
Docket No. 2003N-0324  
RIN 0910-AC35

Dear Sir or Madam:

On behalf of the more than 50,000 clinically practicing physician assistants (PAs) who are represented by the American Academy of Physician Assistants (AAPA), I am pleased to submit comments on the Food and Drug Administration's proposed rule to bring FDA regulations in compliance with the requirement of the Best Pharmaceuticals for Children Act (BPCA) to provide a toll-free number for reporting adverse effects on the label for human drug products.

## Physician Assistants (PAs)

PAs are graduates of accredited PA educational programs who are authorized by the state to practice medicine with the supervision of a licensed physician. Physicians may delegate to PAs those medical duties that are within the physician's scope of practice and the PA's training and experience and are allowed by state law. Forty-eight states, the District of Columbia, and Guam authorize physicians to delegate prescriptive privileges to the PAs they supervise.

In 2003, approximately 192 million patient visits were made to physician assistants and approximately 236 million medications were prescribed or recommended by PAs. PAs work in every medical specialty and in every medical practice setting in every state and care for patients of all ages. Over 20% of PAs work in rural or underserved areas where they may be the only health care professional on site.

## AAPA

The American Academy of Physician Assistants (AAPA) was founded in 1968 and is the only national organization representing physician assistants (PAs) in all medical specialties. The Academy educates the general public about the PA profession, assures competency of PAs through active involvement in the development of educational curricula and accreditation of PA programs, provides continuing education, and conducts PA-related research. The mission of the

Academy is to promote quality, cost-effective health care, and the professional and personal growth of physician assistants.

The Academy's comments on the proposed rule are restricted to the rule's proposed side effects statement and the proposed options for pharmacies and approved dispensers to distribute the side effects information to consumers. AAPA believes that the most important focus of the proposed rule should be the patient. Clearly, it is important that FDA collect information on side effects experienced from medications. However, the effort to solicit the report on side effects should not inadvertently place patients at greater risk. We are concerned that the proposed wording will do just that. "Call your doctor for side effects. You may report side effects to FDA at 1-800-FDA-1088," may very well misdirect patients to call the FDA for assistance during a medical emergency. The AAPA also believes that the word, "doctor," is too restrictive. Many patients receive primary medical care from physician assistants and others who are not doctors. The AAPA recommends using the following language –

*If you experience a negative reaction from this medication, immediately call your health care professional for medical advice. Call the FDA later at 1-800-FDA-1088 to report the side effect.*

The AAPA does not recommend the use of any single option for use by pharmacies and other authorized dispensers to communicate information on side effects. As we are learning from initiatives to promote health care literacy and patient adherence, patients are not created from a single mold, and health education may need to be presented in various forms to be understood by a larger number of patients. Information on medications and possible side effects is complex, and we encourage the FDA to establish a policy that challenges pharmacies to attempt to communicate the information in a straight forward fashion and in a language that the patient can understand.

Thank you for the opportunity to submit comments to the proposed rule, implementing the BPCA requirements. Should you have any questions or require additional information, regarding the PA profession, the role of the Academy, or the AAPA's comments, please do not hesitate to contact Sandy Harding, AAPA Director of Federal Affairs at (703) 836-2272, extension 3205.

Sincerely,

A handwritten signature in cursive script, appearing to read "Stephen C. Crane".

Stephen C. Crane, PhD, MPH  
Executive Vice President, Chief Executive Officer