AMERICAN ASSOCIATION
OF COLLEGES OF PHARMACY

February 23, 2007

Food and Drug Administration
Docket Number 2007N-0005

Reauthorization of the Prescription Drug User Fee Act

The American Association of Colleges of Pharmacy (AACP) is pleased to provide these comments on the Food and Drug Association (FDA) proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA) for the fiscal years 2008-2012 published in the Federal Register on January 16, 2007. Founded in 1900, the American Association of Colleges of Pharmacy (AACP) is the national organization representing pharmacy education in the United States. The mission of the Association is to both represent and be an advocate for all segments of the academic community in the profession of pharmacy. That community comprises 100 colleges and schools with pharmacy degree programs accredited by the Accreditation Council for Pharmacy Education, approximately 46,000 professional degree students, 3,400 students enrolled in graduate studies and more than 4,300 full-time faculty. Three-fourths of the schools are publicly supported institutions, with one quarter being private schools. There is at least one pharmacy school in every state but five (Alaska, Maine, Vermont, New Hampshire, and Delaware). A doctor of pharmacy (Pharm.D.) degree is awarded after completion of a four year professional degree program following a minimum of two years of collegiate pre-professional study. Students who successfully complete the requirements for a professional degree must pass a state licensing examination in order to engage in professional practice. Pharmacy is the third largest health profession (after nursing and medicine) with over 220,000 clinicians practicing in community pharmacies, hospitals, and a variety of other health care settings.

Ensure Sound Footing for the Human Drug Review Program

AACP appreciates the opportunity to comment on the FDA's proposed recommendations for PDUFA IV. While AACP supports the timely reauthorization of PDUFA IV legislation, we believe that the functions and duties of the FDA are such a critical component of the medication safety equation that the agency should receive a greater proportion of its funding through general appropriations. Additional allocations to the FDA of $29 million to address safety issues is a good start, however it does not come close to the $100 million recommended in the Institute of Medicine's report on medication safety.

Enhance Pre-market Review Process of Human Drug Applications

AACP supports the efforts of the FDA, through PDUFA IV recommendations, to enhance the pre-market review system. Pharmacy faculty members are uniquely situated to aid the FDA in its oversight in the entire lifecycle of drugs, beginning with pre-market activities. Free from intellectual or financial biases, pharmacy faculty members bring expertise on pharmaceutical research and management to the table. The FDA should actively recruit more academic pharmacy

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faculty to serve on scientific advisory committees to develop and maintain a list of potential committee experts.

We endorse your recommendation to "free up reviewer time to enable greater participation in scientific research collaborations...." Academic pharmacy is a ready partner for this type of collaboration. AACP would recommend that you also look for ways to move the research interest listed (predictive toxicology, biomarker qualification, etc.) to an extramural grant process so conflict of interest is reduced and resource utilization is maximized.

Improve Information Technology Infrastructure

AACP supports the FDA's efforts to improve its information technology infrastructure. Today's research data collection and analysis can be efficiently accomplished only through sophisticated and readily supported IT infrastructure. We would recommend that you consider an extramural approach to your data management needs and expectations to improve efficiencies and consider the benefits of shared resources through universities and other academic units.

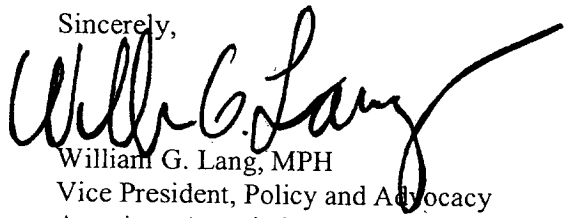
Modernize and Transform the Post-Market Drug Safety System

To strengthen the proposed recommendations set forth by the FDA in PDUFA IV regarding modernization and transformation of the post-market drug safety system, AACP supports partnerships between the FDA and newly developing pharmacy practice-based research networks (PBRN). Pharmacy PBRNs will be situated to provide increased pharmacovigilance once a drug is on the market. They will have the ability to provide real-time data collection. The collected data can be forwarded to FDA for immediate consideration and adverse event reporting. Long-term trend analysis could readily be undertaken by pharmacy faculty FDA post-market surveillance efforts could utilize input from the academic community to achieve consensus regarding epidemiology methods and best practices to optimize use of observational studies

Separate User Fee Program for Review of DTC Television Ads

While AACP does not have formal position on direct to consumer advertising we recognize that DTC advertising does have an impact on patient behavior. We would recommend that the FDA approach the issue of DTC advertising as an opportunity to strengthen the medication management decision process between patients, prescribers, and pharmacists. Finding ways to bring these three important elements closer together in a collaborative framework can only improve patient understanding of appropriate drug use and management and decrease adverse events associated with inappropriate prescribing. The FDA should require all advertising state that patients should contact both their physician and pharmacist when making medication use decisions.

Sincerely,



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