

Report of the 2008-2009 Standing Committee on Advocacy

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INTRODUCTION

According to the Bylaws of the AACP, the Advocacy Committee:

“will advise the Board of Directors on the formation of positions on matters of public policy and on strategies to advance those positions to the public and private sectors on behalf of academic pharmacy.”

COMMITTEE CHARGE

President-elect Vic Yanchick charged the 2009-2010 Advocacy Committee to:

report on how communities and individual patients can capitalize on the collaboration between the FDA and academic pharmacy to improve medication use safety throughout the drug life cycle.

The committee conducted its business entirely through conference calls and e-mail. Each member of the group was asked to select one of the four strategic goals of the U.S. Food and Drug Administration (FDA) as their primary report submission effort. The committee agreed to a format for reviewing the academy's ability to support and enhance the FDA strategic goals that included:

1. an assessment of evidence that the academy is actively engaged in areas relevant to the goal;
2. determining that, if the academy is not directly engaged in areas relevant to the goal, should it be?; and
3. a review of the literature, including American Association of Colleges of Pharmacy (AACP) educational policy and recommendations, and suggestions of AACP standing committees, to assist in the determination that if the academy should be involved in areas relevant to the goal, what should that engagement be or how should it be presented to the academy to create engagement?

BACKGROUND

The role of the pharmacist in public health continues to evolve. This evolution is establishing the pharmacist, especially the community-based pharmacist, as essential to the identification of potential public health threats through his or her competency to determine patient trends and effectively communicate those trends to public health agencies. Pharmacists in ambulatory and inpatient settings are effective public health advocates as they work with general and disease-specific patient populations. The ability to effectively communicate population health information is supported by both professional and educational documents outlining the role of the pharmacist in public health. [1,2,3,4]

The pharmacist is distinguished from other health professionals by this educational and professional commitment towards medication effectiveness and safety, including all aspects of medication literacy

associated with appropriate use. This focus on the public health impact of medication use creates substantial opportunity for partnering the pharmacist's public health competencies with the missions of federal public health agencies.

During the development of legislation that created the FDA Amendments Act (FDAAA) of 2007, AACP actively engaged in the education of members of Congress, their staff and the FDA. This education focused on the opportunity for the public health mission of the FDA to be strengthened in partnership with academic pharmacy. The AACP issue paper developed to address the FDA legislation included the following:

“Academic pharmacy faculty are exceptionally positioned to help the FDA “keep pace with the rapid evolution of science, technology and the health care system...”Part of the medication safety equation is the appropriate oversight of manufacturers, prescribers, and patients by the Food and Drug Administration (FDA). There is ample empirical and anecdotal evidence that the FDA is currently at a disadvantage in its ability to provide sufficient oversight. Clinical trials are fraught with problems, scientific integrity of clinical trials is often challenged, and little or no post-marketing evaluation of drugs occurs – all of which increase the risks for drug misadventures.”

As a result the FDAAA includes several provisions that direct the FDA to seek the input of “academic institutions.” This report is an opportunity to determine current and future roles of the academy and our graduates in ensuring the FDA is competent and efficient in meeting its public health mission.

The FDA's current strategic action plan focuses on four strategic goals:

1. strengthening the FDA,
2. improving patient and consumer safety,
3. increasing access to new medical and food products,
4. improving the safety and quality of manufactured products and the supply chain.

FDA leadership has undertaken specific measures to address each of these strategic goals. AACP is uniquely positioned to impact and directly influence pharmacy colleges' view and integration of these key topics within their organization's work plans. For each FDA goal, the current report summarizes the evidence that that academy is or is not actively engaged in areas relevant to the goal. In areas where engagement is not currently evident, recommendations are made as to whether the academy should be involved. Where it is concluded that the academy should be engaged in areas relevant to the goal, recommendations are made regarding future steps of the academy.

Overall, the committee believes that the academy is engaged to varying degrees in many activities relevant to each of the FDA's strategic goals. However, the committee also believes that the academy must become increasingly and more visibly engaged in these activities. We agree that the academy should promote what we have to offer and what opportunities are available for our members to contribute to improving access and safety.

RECOMMENDATION 1

AACP should provide resources that direct faculty members and students to opportunities with the FDA and elsewhere that advance the goals discussed in the report of the 2008-2009 Standing Committee on Advocacy.

RECOMMENDATION 2

It is recommended that AACP provide information to outside entities regarding the education and service activities the academy can provide in patient and consumer safety.

Goal 1: Strengthen FDA for Today and Tomorrow

- **Developing world-leading scientific experts capable of discovering and applying innovative technologies and therapeutic products**

Evidence that the academy is actively engaged in areas relevant to this goal

Schools and colleges of pharmacy have, and continue to play an important role in educating future world-leading scientific experts who will be involved with the discovery and application of innovative technologies and therapeutic products through interactions and involvement with the FDA. The question facing the academy is: what is the optimal post-PharmD education and training needed to be successful clinical and pharmaceutical scientists to address these future challenges? There has been controversy over what advanced training these individuals should attain to assume positions in the FDA and other research venues. The controversy remains whether post-doctoral fellowships versus graduate degrees (e.g., masters and doctoral) can provide the necessary foundations and research experiences needed to develop world-leading scientific experts (5, 6). The AACP Educating Clinical Scientists Task Force recommended a need for a new pharmacist clinical scientist program that could be developed and available at selected pharmacy colleges/schools associated with academic health centers (7). It would be essential for these programs to be interdisciplinary, to incorporate clinical experience elements, and to involve pharmaceutical and clinical scientist mentors.

Perhaps the issue to be addressed is not necessarily the nature of the post-PharmD educational experiences, but rather what types of scientific expertise are needed for world-leading scientific experts to shape the future of drug development, regulatory science, the drug approval process, and drug or medical product safety. There will always be the need for individuals with expertise in specific clinical areas such as product formulation, drug delivery, medicinal chemistry and pharmacokinetics/pharmacodynamics to evaluate key elements in the drug approval process. However, the academy must develop the next generation of scientists that can address the difficult issues associated with the complexities faced in the drug approval process. These include expediting translational research opportunities, utilizing pharmacogenomics/ pharmacogenetics to optimize drug therapy for specific patient groups, the use of pharmacometrics to optimize the clinical trial process, the development of novel delivery systems for small molecules, peptides and genes, while at the same time seeking to improve the cost-effectiveness and safety of drug therapy in our health care system.

Colleges/schools of pharmacy, and other entities, have developed innovative programs to educate the next generation of experts for the pharmaceutical and clinical pharmaceutical sciences (5-19). These include fellowship programs, certificate programs, specific masters programs and PhD level clinical pharmaceutical scientist programs. The importance of enhancing programs in the area of clinical pharmacology and quantitative clinical pharmacology, specifically pharmacometrics, has been proposed by Cohen (20) and Holford and Karlsson (21). Yet, these programs, like other graduate programs in our colleges/ schools, remain challenged to attract our PharmD students. The reasons underlying these challenges in attracting our professional students to post-doctoral studies and fellowship opportunities have been discussed in previous reports and publications and will not be the focus of the current discussion.

If the academy is not directly engaged in areas relevant to this goal, should it be?

Our colleges/schools must be engaged in educating the next generation of scientific experts to the extent that resources and programs are available at each institution. Not all colleges/schools of pharmacy will have the ability to develop programs focusing on a part or all of the above areas. An opportunity that has not been significantly exploited in our programs is the collaboration of our colleges/schools of pharmacy with engineering, computer science and other technology programs to address the many issues we may face with increasing technological advances for the delivery and administration of therapeutic agents, and information management. Given the expertise existing in our colleges/schools, we are in an optimal position to strengthen our involvement through the Critical Pathway Initiative (22-23) and the Sentinel Initiative (24) by refocusing and incorporating additional specific elements into our post-PharmD educational programs.

If the academy should be engaged in areas relevant to this goal, what should that engagement be or how should it be presented to the academy to create engagement?

The missing link needed to enhance the education of the next generation of experts involves additional or novel collaborations between our colleges/schools with the FDA. This could involve exchange programs for our professional students, graduate students, post-doctoral fellows and faculty to have short term research experiences, summer internships, advanced pharmacy practice experiences, research collaborations and faculty sabbaticals located at the FDA. Alternatively, the opportunity for individuals from the FDA to interact with our professional students, graduate students, post-doctoral fellows and faculty members could be achieved through visiting scientist programs and short-term sabbaticals that would enhance knowledge and skill sets of FDA scientists. The development of collaborative short summer workshops, similar to that initiated by the National Institutes of Health to advance whole animal system pharmacology studies, to enhance knowledge and research capacities in specific areas (e.g., product safety, information systems) provides another means to developing future scientists and to enhance the skills of existing scientists.

Distance learning platforms could be used to provide the means for our students and fellows to learn about the challenges and opportunities available at the FDA. These educational programs could involve podcasts, webinars and short courses ranging from several hours, to weeks, to a full semester and could be offered to more than one institution at the same time in the academy. These technologies could also be extended by programs offered by our institutions to enhance the educational opportunities at the FDA.

Another key collaboration is to engage in the similar type of innovative programs being offered outside the United States. Specifically, programs could be offered through collaborations between our schools with the pharmaceutical industry or with non-profit organizations. One such innovative program is the Graduate Research Training Program Pharmacometrics & Computational Disease Modelling. This novel joint initiative in Germany is a collaboration between the Martin-Luther-Universität Halle-Wittenberg, the Freie Universität Berlin and research-driven pharmaceutical companies such as Boehringer Ingelheim Pharma GmbH & Co. KG, Abbott GmbH & Co. KG, Merck KGaA, Bayer Schering Pharma AG, Bayer Technology Services GmbH, and Sanofi-Aventis Deutschland GmbH (<https://pharmacometrics.mi.fu-berlin.de/>) (25).

One example involving a non-profit organization is the Metrum Institute founded in 2005. The Metrum Institute is dedicated to the advancement of quantitative modeling and simulation in biomedical research, with particular emphasis on problems in clinical pharmacology and therapeutics. Their efforts include training courses in modeling and simulation techniques/ methods, development of quantitative tools and software, publications (including a newsletter), methods and applied research, symposia, and collaboration with the academic community in research and training of fellows and graduate students (<http://www.metruminstitute.org/about.html>) (26). Given the expertise and available technologies in our colleges/schools of pharmacy, the academy should consider more extensive use of these alternative educational strategies for the development of world-leading scientists in our programs, the industry and the FDA.

- **Modernize Information Technology Platforms**

Evidence that the academy is actively engaged in areas relevant to this goal

While our colleges/schools of pharmacy are strongly grounded in the foundations for educating students for the pharmaceutical and clinical sciences, our involvement in educating future generations of scientists needed for the development and modernization of the information technology platforms critical for future drug development, database management and regulatory affairs, has not been an area of expertise.

If the academy is not directly engaged in areas relevant to this goal, should it be?

Pharmacy practice and education at the professional and graduate levels should promote the roles of pharmacists, pharmaceutical scientists, and clinical scientists as they relate to the science of the safety of drug products as indicated in the FDA response to the Institute of Medicine Report on drug safety (27). At the professional level, it is critical for our pharmacy programs to provide the knowledge, skills and tools for future pharmacists to be engaged in risk identification, assessment and minimization. The development of these tools could represent scholarly opportunities for faculty members, fellows and graduate students. In addition, our research programs should be encouraged to develop the state-of-the-art information technologies and infrastructure needed for practitioners and scientists to have access to key information, to have the interfaces needed to allow integration of this information and the standards needed for this information during the receiving, managing and communication process as indicated in the Sentinel Initiative (24).

Pharmacy Educational Roles for Pharmacists and for Pharmaceutical Scientists.

Pharmacy education, practice and research must be engaged in the Nationwide Health Information Network (NHIN) through public and private partnerships. It is also important for key individuals in the academy to be actively involved in the organizational structure for the Sentinel Initiative System as this process could be significantly enhanced by the analytical and research capabilities of our clinicians and scientists. This can only occur if we take a critical look and promote the importance of these areas of study and research in our graduate programs and fellowship opportunities.

If the academy should be engaged in areas relevant to this goal, what should that engagement be or how should it be presented to the academy to create engagement?

It is critical that the academy identify those current faculty members who have the requisite expertise in these areas and promote their involvement in the key decision processes as these safety and other new initiatives are planned and initiated in the years to come. Furthermore, our educational programs at the professional, post-PharmD fellowship and graduate level should provide the opportunities for attaining specific knowledge, skills and research opportunities in patient safety as it relates to drugs and the monitoring of medical products. Finally, our continuing professional development programs must provide practitioners with the knowledge and tool sets to become involved in the process needed for better monitoring of patient safety issues in the various settings where they care for their patients.

RECOMMENDATION 3

AACP should offer programming in the areas of FDA and NIH initiatives and provide assistance to colleges and schools to become involved with these initiatives.

Goal 2: To Improve Patient and Consumer Safety

- **Network of Safety Databases and Public Communication about Product Safety**
- **Application of Risk Evaluation and Mitigation Strategy (REMS)**

Evidence that the academy is actively engaged in areas relevant to this goal

The FDA has identified avenues to improve information systems and databases that will support and promote public safety. These include the enhancement and modernization of FDA product safety systems, building an easier safety reporting system through MedWatch Plus, building a National Sentinel Network for Patient Safety, expanding agency officials' real-time access to information related crises and emergencies, and reducing patient injury from medical devices. As an active MedWatch Partner, the Academy works with the FDA to keep the public informed about medical product safety information and reporting.

Many AACP leaders and members have served on past and present FDA Advisory Committees (AdComms) and workgroups such as the Drug Safety Risk Management Advisory Committee, and the Nonprescription Drugs Advisory Committee. These committees provide AACP members

an opportunity to serve the public as a scientific or health professional medication or pharmacotherapy expert. One of the more recently formed AdComms is the Risk Communication Advisory Committee which was developed specifically to counsel the agency on how to strengthen the communication of risks and benefits of FDA-regulated products to the public. More specifically, this AdComm will help FDA better meet the communication needs and priorities of the general public, advise FDA on the development of strategic plans to communicate product risks and benefits, and make recommendations to FDA on what current research suggests about crafting risk and benefit messages, as well as how to most effectively communicate specific product information to vulnerable audiences. The Academy was actively engaged in nominating and supporting an AACP member to join this committee.

Pharmacy faculty, through AACP and other pharmacy professional organizations, regularly comment on the FDA's Risk Evaluation and Mitigation Strategy (REMS) programs. This strategy will manage known or potential serious risks associated with a drug or biological product. Several REMS have already been approved to develop medication guides, communication plans, elements to assure safe use, and implementation systems.

If the academy is not directly engaged in areas relevant to this goal, should it be?

The Committee feels that it is important for the academy to continue to be actively engaged in areas such as safety database enhancement and functionality, FDA AdComms and REMS. Not only is this a benefit for AACP members in their professional roles but it provides members an opportunity to lend their expertise to the FDA as it works to meet its strategic goals for improving patient and consumer safety.

This Committee considers it essential, within conflict of interest guidelines, for the academy to better communicate to its members the opportunity to serve on AdComms with a particular emphasis on medication safety. The purpose of the AdComms is to provide evidence-based recommendations to the FDA, making evidence from clinical faculty, practicing at the forefront of patient care of particular benefit.

Whether through AACP or pharmacy professional organizations, the Academy must become more involved in REMS opportunities and programs. Scientists and pharmacists are capable of developing and promoting all of the following elements that assure safe use of drugs determined to be of high risk: 1) Health care providers who prescribe the drug have particular training or experience, or are specially certified; 2) pharmacies, practitioners, or health care settings that dispense the drug are specially certified; 3) the drug is dispensed to patients only in certain health care settings, such as hospitals; 4) the drug is dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results; 5) each patient using the drug is subject to certain monitoring; or 6) each patient using the drug is enrolled in a registry.

If the academy should be engaged in areas relevant to this goal, what should that engagement be or how should it be presented to the academy to create engagement?

The Committee recommends that the Academy search for opportunities to help the FDA continue to improve their safety information systems and databases. This includes the MedWatch Plus Investment project that will create a fully automated system providing up-to-date data facilitating more efficient data sharing and reporting. In addition, the Academy should continue

to evaluate potential opportunities to provide support and act as a resource for the FDA's Sentinel Initiative.

The Committee suggests that the Academy identify opportunities to become more engaged with the FDA's REMS initiatives. An example is to support academic pharmacy programs focused on drug safety that can partner with the FDA such as the University of Maryland's recently launched Center for Drug Safety. This Center will serve to guide and inspire research and scholarship in pharmacoepidemiology and drug safety. The Center plans to collaborate with governmental agencies to provide formal and informal opportunities for professional development and access to a pool of skilled faculty, graduate students, and graduates. This is a creative approach to collaborate with the FDA as well as to identify potential employment opportunities for our graduates at federal agencies such as the FDA.

The Academy is committed to aligning its 3-pronged mission of teaching, research, and service with the FDA's Strategic Goal 2 to support and advance improvements in patient and consumer safety. Public perception of the important role the pharmacist plays in assuring patient safety can be heightened through more closely linking the professional curriculum with the FDA. Academic strategies might include increasing the awareness of students to FDA careers by increasing their exposure to FDA safety tools, databases, and resources. Active participation in drug safety surveillance and MedWatch reporting should be required during pharmacy practice experiences. Academic pharmacy can support the FDA safety efforts by encouraging and committing to research designed to determine the best ways to communicate drug safety information to the public. By developing and refining better methods of database research, more clinically relevant conclusions can be drawn about true drug safety risk. Research focused on the survey and study of practice models may translate the REMS recommendations into clinical practice (i.e. effective distribution of Medication Guides). In keeping with the service aspect of its mission, the Academy should continue to establish resource and reference centers for assisting the public to translate FDA safety warnings into consumer understandable terms.

POLICY STATEMENT 1

The Academy is committed to aligning its 3-pronged mission with the FDA's Science of Safety in order to support and advance improvements in patient and consumer safety.

FDA Strategic Goal 3: Increase Access to New Medical and Food Products

- **Tools**

FDA's Critical Path Initiative is a compilation of key actions supporting the efficient translation of scientific discoveries into medical therapeutic applications. Scientific discoveries, such as genetic mutations, can help clinicians determine a patient's unique metabolic profile. For example, this type of scientific discovery was introduced into a product label update for warfarin. Health care providers now have information on using genetic tests to improve warfarin dosing for an individual patient to avoid unnecessary side effects. Further work in this area is continuing and FDA is collaborating with external organizations with a goal towards developing tools to personalize treatment therapies based on each person's genetic makeup and other individual factors.

Applying modern evaluation tools may also improve our understanding about a product's effectiveness in certain patients or populations prior to commercialization. These evaluations will give practitioners and patients the best available information about using a product to optimize its

benefit and minimize side effects. In fact, many of the tools being considered would help personalize medicine by identifying who is likely to respond to a treatment and who should avoid it.

Evidence that the academy is actively engaged in areas relevant to this goal:

Several faculty members at schools of pharmacy are engaged in areas relevant to this goal in teaching, service, and collaborative clinical and translational research in the study of human and veterinary biomarkers, genomics, proteomics, and the study of metabolomes. Most notable are investigators at the University of California at San Francisco, University of Wisconsin at Madison, University of North Carolina, State University at Buffalo, Rutgers University, and others in a variety of disciplines including, but not limited to, clinical pharmacy, molecular biology, biochemistry, medicinal chemistry, pharmacometrics, biopharmaceutics, biostatistics, and molecular diagnostics (27-36).

The AACP Research and Graduate Affairs Committee Task Force for Educating Clinical Scientists and the Argus Commission have published numerous reports on the current and future work of the AACP in promoting the profession's commitment and advancements in this area. Additionally, these reports have comprehensively outlined the opportunities and challenges associated with engaging the academy in these areas of scientific discovery and development of academic programs focused on T1 and T2 research. Current policy has been adopted as a result of the work of these committees (37-39).

If the academy is not directly engaged in areas relevant to this goal, should it be?

Yes, academic and clinical pharmacists are involved in using these tools as well as educating patients, physicians, and other health care providers regarding the tools (40). Further support for the training of pharmaceutical scientists and the collaboration between private and public funders of research and academic pharmacy should be investigated.

If the academy should be engaged in areas relevant to this goal, what should that engagement be or how should it be presented to the academy to create engagement?

Many of these areas of study are relatively new, and the challenge of increasing the amount of basic science information in the pharmacy school curricula has existed for decades, even as the amount of clinical information required for the immediate use of the graduates of today increases. Further study and review of current pre-requisite and required coursework for pharmacy school should be undertaken to ensure that future practitioners and scientists are well-positioned to promote and utilize translational biomedical research. Advancements in these areas of basic science should be used to promote the preparation of pharmaceutical scientists and clinical pharmacists to improve the utilization of these tools and to improve patient outcomes.

RECOMMENDATION 3

AACP should develop a coalition of professionals from different disciplines and organizations including American Association of Pharmaceutical Scientists (AAPS), American College of Clinical Pharmacists (ACCP), American Pharmacists Association (APhA), American Society of Health-systems Pharmacists (ASHP), American Chemical Society (ACS), American Society for Pharmacology and Experimental Therapeutics (ASPET) and American Society for Biochemistry and Molecular Biology (ASBMB). Meetings and seminars at annual or interim meetings should be arranged to improve collaborative opportunities for its member schools and to increase access to information and networks of scientists involved in biomedical and translational (T1 and T2) research (41).

- **Generic Initiative for Value and Efficiency (GIVE)**

FDA's generic information for value and efficiency (GIVE) program aims to increase the number and variety of generic drug products available. Having more generic-drug options means more cost-savings to consumers, as generic drugs cost about 30 to 80 percent less than brand name drugs.

Knowledge by pharmacists and communication to patients and their physicians of generic drug product availability is often the first source of information to recommend a substitutable product to an often less expensive alternative as compared with the innovator's drug product.

Evidence that the academy is actively engaged in areas relevant to this goal?

The academy is actively engaged in areas relevant to this goal, particularly in the areas of teaching in drug and biologic product development, managed care, pharmacy benefit design; research at schools of pharmacy regarding pharmacoeconomics and generic drug substitution (Creighton University, University of California at San Francisco, University of Rhode Island, University of Mississippi); and service in multiple schools (University of the Pacific, University of California San Francisco, University of Arkansas), collaborating with AARP, Centers for Medicare and Medicaid Services (CMS), and other organizations providing outreach in the area of generic drug cost-savings to consumers (42-46). Knowledge of generic drug availability is becoming more widespread as pharmacists seek better reimbursement from third party payers, but physicians and patients need comprehensive and scientific data that will give them the confidence to prescribe and utilize these lower cost alternatives. Considering the influence that pharmacists retain in the drug product selection area, and the availability of pharmacists in the community as drug experts, enhanced communication and partnerships between patients, prescribers, and pharmacists should be studied (47-49).

If the academy is not directly engaged in areas relevant to this goal, should it be?

Availability of generic drugs appears to be widely taught in curricula throughout AACP member institutions in the areas of drug development, pharmacoeconomics, pharmacy management, and therapeutic outcomes; however, a focus on drug safety, comparative drug product analysis and selection decision-making, enhanced generic drug utilization, and mechanisms to enhance the communication regarding the safety and efficacy of these products requires further review.

If the academy should be engaged in areas relevant to this goal, what should that engagement be or how should it be presented to the academy to create engagement?

A commission of academic pharmacists in the areas of drug development, managed care, pharmacoeconomics, pharmacy management, and clinical outcomes should consider reviewing the available information from scientific research, available white papers, foundation reports, and other nonbiased literature to develop a statement on the availability and utilization of safe and effective generic drugs.

RECOMMENDATION 5

Collaboration with AACP, APhA, National Community Pharmacists Association (NCPA), Association of Managed Care Pharmacy (AMCP), Generic Pharmaceutical Association (GPhA), AARP, Pharmacy Benefit Management Institute (PBMI), CMS, American Association of Family Physicians (AAFP), America's Health Insurance Plans (AHIP), and other parties influencing the availability and utilization of generic drugs should be considered and the development of a policy statement forwarded to the House of Delegates for consideration.

- **Direct-to-Consumer Advertising (DTC)**

As provided by the FDAA section 901, FDA is requesting scientific research, data and information to assist the agency in its plans to conduct an assessment of DTC advertising and its ability to communicate to subsets of the general population, including the elderly, children, and racial and ethnic minority communities.

The agency's findings will be reported to Congress and must include recommendations on how to effectively present and disseminate information to these groups. DTC advertisements are a source of product information and pharmacists are first-line healthcare providers responding to inquiries derived from information provided in DTC advertisements. At times, this interaction

can be challenging as a pharmacist may be unaware of a product's consumer-directed promotional campaign.

Evidence that the academy is actively engaged in areas relevant to this goal?

Schools of pharmacy are actively engaged in research and teaching relevant to studying how DTC advertising is influencing the attitudes of student pharmacists, patients, physicians, and payers, and have collaborated with other academic disciplines to develop this area of study (University of Mississippi, University of New Mexico, Duquesne Mylan School of Pharmacy, University of North Carolina, University of Wisconsin, Harvard University) (50-58). In the last decade, DTC advertising has been an area of great debate in the profession of pharmacy, as considerations including drug product selection, patient engagement, physician prescribing habits, and First Amendment rights of manufacturers have made the issue increasingly complex. Pharmacists and pharmacy schools are well positioned to actively engage in research to further elucidate the positive and negative influences and outcomes of this information dissemination.

If the academy is not directly engaged in areas relevant to this goal, should it be?

The academy's engagement has been multidisciplinary, and should continue to evolve as providers and patients require more detailed information relevant to DTC on clinical decision-making. More information should be generated through these research and teaching agendas to include how consumers are receiving information and the health literacy challenges associated with consumer demand for pharmaceuticals.

If the academy should be engaged in areas relevant to this goal, what should that engagement be or how should it be presented to the academy to create engagement?

The academy should consider broadening its base of research in this area, as it is clear that patients, pharmacists, and prescribers are in need of better decision-making tools relative to drug product selection.

RECOMMENDATION 6

The academy should consider a collaborative effort between schools of pharmacy, schools of public health and public policy, schools of business, pharmaceutical manufacturers, and government entities to provide research that will allow prescribers and pharmacists to better inform consumers about evidence-based drug product selection.

Goal 4: Improve the Quality and Safety of Manufactured Products and the Supply Chain

• **Security of Drug Distribution System**

The FDA has taken steps to protect consumers from counterfeit drugs and to secure the U.S. drug distribution system. These measures include implementation of new technologies (track and trace) to better protect legitimate drugs against tampering or replacement with counterfeits. FDA's framework for public and private sector actions calls for a multi-layer approach to address the problem and includes measures to secure product/packaging, movement through the supply chain and, business transactions (59).

Pharmacists are on the front-lines of observing and effectively reporting counterfeit drugs to the FDA. This reporting helps strengthen FDA's ability to communicate to participants in the drug distribution system so they can respond rapidly to such reports.

Evidence that the academy is actively engaged in areas relevant to this goal

Faculty members at several colleges/schools of pharmacy are actively engaged in research on the drug supply chain. Perhaps most notable is Dr. Marvin Shepherd of the University of Texas at Austin. He currently serves as President of the Partnership for Safe Medicines, an organization that actively combats counterfeit medications (60). Another notable investigator is Dr. Ronald J. Ziance from the University of Southern Nevada (61). There are also individual faculty members researching technology associated with areas relevant to this goal. These activities were highlighted at a symposium on "Counterfeit

Medications: Current Approaches and Research Opportunities” held at Purdue University in October, 2008.

Another area where the academy is engaged is the National Institute for Pharmaceutical Education and Technology (NIPTE) (62). This is a consortium of AACP member schools and engineering schools to improve the pharmaceutical manufacturing process. NIPTE’s goal is to increase science and engineering-based understanding of pharmaceutical production such that novel state-of-the-art technologies can be developed and science-based regulations can be implemented (62). These technologies will also enable new drug discoveries to be brought to market faster with less variability, higher predictability of performance and at a significantly lower cost.

Overall, it is apparent that individuals within the academy are activity engaged in areas relevant to the goal of improving the quality and safety of manufactured products and the supply chain. As an overall entity, the academy has been actively engaged through NIPTE, but could become more directly and visibly involved in this goal.

If the academy is not directly engaged in areas relevant to this goal, should it be?

Some professional pharmacy societies (notably APhA and ASHP) have generated policy statements related to the safety of the supply chain, particularly focusing on the problem of counterfeit drugs. These statements directly address the role of pharmacists in dealing with this significant problem. The academy has not, as a body, been as actively engaged in areas relevant to this goal as it should be. While there are individuals in the academy researching this problem, it has not been adequately addressed through curricular activities nor through formal policy statements from the academy. Overall, the academy should become more directly and actively engage in areas relevant to this goal.

If the academy should be engaged in areas relevant to this goal, what should that engagement be or how should it be presented to the academy to create engagement?

There are three ways the academy should become engaged in areas relevant to this goal.

1. The academy should issue a policy statement on its role in supply chain safety.
2. The academy should become a member of the Partnership for Safe Medicines
3. The academy should help lead the development of curricular material that addresses this goal.

The following policy statement is recommended for consideration by AACP. This statement was derived, in part, from existing statements from ASHP (63) and APhA (64).

POLICY STATEMENT 2

AACP supports enhanced efforts to combat drug counterfeiting which:

- foster awareness in our faculty and students of the problem of drug product counterfeiting;
- educate our students in all aspects of the problem and potential solutions; ensuring that student pharmacist education supports the pharmacist’s role in drug procurement, distribution, surveillance and control;
- support graduate education and research to develop mechanisms by which legitimate drug sources can be identified;
- create appropriate educational scenarios so that patients become partners in identifying changes in the appearance, smell, taste, etc. of dispensed products or their effectiveness; and
- facilitate academic partnerships with the FDA to help develop an effective reporting system of possible supply chain problems (e.g., the Food and Drug Administration’s MedWatch system) (65).

Counterfeit drugs are a reality in today’s drug distribution system. Academic pharmacy has an obligation to proactively work toward enhanced quality and safety of manufactured products and the supply chain, including eliminating the presence of counterfeit products. Because counterfeit products can be visually identical to the real product, it is important for the academy to partner with the efforts of the FDA, the

National Association of Boards of Pharmacy (NABP), drug wholesalers, and drug manufacturers to stem these illegal activities, particularly through enhanced educational activities.

Pharmacists are the penultimate defense in protecting patients from counterfeit medications. Recognition of this role, however, is not consistent across the academy. AACP supports enhanced efforts to combat counterfeiting, including educating our student pharmacists in this area, and supporting graduate education and research on detection and prevention methodologies. As stated by the APhA, pharmacists fight counterfeit drugs in their three roles as:

1. Prudent purchasers,
2. Patient educators, and
3. Reporters of possible counterfeit activities.

RECOMMENDATION 7

It is recommended to the Board that AACP become a member of the “Partnership for Safe Medicines”.

RECOMMENDATION 8

It is recommended that educational resources be coordinated and/or developed to assist colleges and schools of pharmacy in providing education in the areas of drug quality and safety, and the supply chain.

CONCLUSION

Recent legislation, including the Food and Drug Administration Amendments Act (FDAAA) of 2007, encourages and supports partnership and collaboration between the FDA and academic institutions. This report highlights opportunities where academic pharmacy is already contributing to improved medication use safety throughout the drug life cycle as well as opportunities to improve and enhance these attempts with the FDA.

Specifically, the Standing Committee on Advocacy performed a gap analysis on the academy’s current activities that contribute towards supporting each of the FDA’s four strategic goals: 1) Strengthen the FDA for Today and Tomorrow; 2) Improve Patient and Consumer Safety; 3) Increase Access to New Medical and Food Products; and 4) Improve the Quality and Safety of Manufactured Products and the Supply Chain. The committee agrees that the academy should be engaged in activities relevant to each goal. The committee believes that while there is evidence that the academy is currently engaged to varying degrees in many activities, there are many opportunities to improve and bolster those attempts.

In conclusion, this report outlines areas and opportunities for the academy to become more engaged in order to support the FDA’s strategic goals. Recommendations range from supporting educational strategies that promote the development of world leading scientists in academia, industry, and the FDA to encouraging AACP members to play a more active role on the numerous FDA advisory committees.

References

1. Joint Commission of Pharmacy Practitioners, Vision Statement 2015, <http://www.aacp.org/resources/historicaldocuments/Documents/JCPPFutureVisionofPharmacyPracticeFINAL.pdf>, accessed April 27, 2009
2. W.R. Vincent, Smith K.M., Steinke D., Opportunities for pharmacists in public health, *Am J Health Syst Pharm* 2007 64: 2002-2007
3. Center for the Advancement of Pharmaceutical Education, 2004 Educational Outcomes, <http://www.aacp.org/resources/education/Documents/CAPE2004.pdf> ; accessed April 27, 2009
4. Accreditation Council for Pharmacy Education, Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree, http://www.acpe-accredit.org/pdf/ACPE_Revised_PharmD_Standards_Adopted_Jan152006.pdf, accessed April 27, 2009
5. J.L. Bauman, W.E. Evans, Pharm.D.-Only Investigators Are Critical to the Profession: Let's Preserve the Fellowship as an Equally Important Way to Prepare Future Clinical Pharmaceutical Scientists: Or the Case Against the "All-Ph.D." *Pharmacotherapy* 29(2): 129-133, 2009.
6. R.A. Blouin and G.M. Pollock, Training Clinical Pharmaceutical Scientists in Today's Highly Competitive Times: It's Time to Commit to Change *Pharmacotherapy* 29(2):134-137, 2009.
7. The Report of the AACP Educating Clinical Scientists Task Force 2006-2007 Research & Graduate Affairs Final Report
8. S.M. Poloyac, L.C. Rohan, J.M. Janjic, R.B. Gibbs, P.D. Kroboth, and R.B. Smith, Graduate Education and Research at the University of Pittsburgh (GEAR-UP): A Program to Educate Students about Pharmaceutical Research, *American Journal of Pharmaceutical Education* 69 (5) Article 91, 2005.
9. M.A. Tortorici, S.J. Skledar, M.A. Zemaitis, R.J. Weber, R.B. Smith, P.D. Kroboth, and S.M. Poloyac, A Model for Supporting and Training Clinical Pharmaceutical Scientist PhD Students, *American Journal of Pharmaceutical Education* 71 (2) Article 32, 2007.
10. MS: Focus in Pharmacometrics
http://www.pharmacy.buffalo.edu/psci_grad_pharmacometrics.shtml
11. Master of Science Program in Clinical and Translational Research, University of Connecticut, <http://grad.uchc.edu/prospective/programs/mctr/index.html>
12. Translational Science Graduate Program, College Of Pharmacy, The Ohio State University, The Ohio State University, www.pharmacy.ohio-state.edu/academics/graduate/Translational_Science_Grad_Program.pdf
13. Division of Pharmacotherapy and Experimental Pharmaceutics, University of North Carolina at Chapel Hill, The mission of the Division of Pharmacotherapy and Experimental Therapeutics is to optimize drug therapy through the generation, integration, and translation of scientific information between the bench and the bedside, the patient and the population. The Division advances clinical practice by leading the nation's pharmacy schools in innovative translational research, and through the education and training of clinical scientists, future pharmacists and current practitioners, <http://www.pharmacy.unc.edu/faculty-research/divisions/pharmacotherapy-and-experimental-therapeutics/dpet>
14. Translational Research Fellowship, MD Anderson Cancer Center, <http://www.mdanderson.org/departments/pharmacy/display.cfm?id=74729810-eb0f-47a5-ac724e003ed658a6&method=displayfull&pn=6d6e5c75-09b8-11d5-810c00508b603a14>
15. University of Vermont Center for Clinical and Translational Science
http://www.uvm.edu/~ccts/?Page=cts_ed_curriculum.html&SM=submenu1.html
16. Clinical Pharmaceutical Sciences Track, University of Maryland, School of Pharmacy, <http://www2.pharmacy.umaryland.edu/pps/education.html>
17. Master of Science in Pharmacy – Pharmacy Regulation, Applied Pharmacoeconomics, Drug Regulatory Affairs, Institutional Pharmacy Leadership
<http://pharmreg.dce.ufl.edu/index.html>
18. Clinical Pharmaceutical Sciences – University of Florida
<http://www.cop.ufl.edu/centers/genomics/pdf%20files/04Grad%20program%20description.pdf>

19. Clinical Sciences Research, The University of Texas at San Antonio, College of Pharmacy, <http://www.utexas.edu/pharmacy/divisions/pharmaco/phd.html>
20. L. Cohen, The PharmD Investigator in Clinical Pharmacology: Supply and Demand, *Clinical Pharmacology & Therapeutics* 84(4): 445–447, 2008.
21. N. Holford and MO Karlsson, Time for Quantitative Clinical Pharmacology: A Proposal for a Pharmacometrics Curriculum, *Clinical Pharmacology and Therapeutics*, 82:103 – 105, 2007.
22. Challenge and Opportunity on the Critical Path to New Medical Products <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html>
23. Critical Path Opportunities Report, www.fda.gov/oc/initiatives/criticalpath/reports/opp_report.pdf
24. The Sentinel Initiative: National Strategy for Monitoring Medical Product Safety www.fda.gov/oc/initiatives/advance/reports/report0508.html
25. The Graduate Research Training (GRT) Program Pharmacometrics & Computational Disease Modelling Initiative, <https://pharmacometrics.mi.fu-berlin.de/>
26. Metrum Institute, <http://www.metruminstitute.org/about.html>
27. <http://www.nature.com/nrd/journal/v5/n6/full/nrd2033.html>; accessed 03-13-09
28. <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2583631>; accessed 03-13-09
29. <http://www.pharmacy.unc.edu/faculty-research/faculty-directory/alexander-tropsha>; accessed 03-13-09
30. http://www.pharmacy.buffalo.edu/school_fac_staff_details_ecv.php?id=0NY0LOLBF; accessed 03-13-09
31. <http://www.uwsc.wisc.edu/projects.php>; accessed 03-13-09
32. <http://www.rci.rutgers.edu/~layla/AnalMedChem511/>; accessed 03-13-09
33. http://www.afpenet.org/archive_of_past_winners/2004_2005_under_research_profile.htm; accessed 03-13-09
34. <http://search.barnesandnoble.com/Pharmacometrics/Ene-I-Ette/e/9780471677833>; accessed 03-13-09
35. <http://www.dbmi.pitt.edu/trainingprogram/faculty.html>; accessed 03-13-09
36. <http://www.newswise.com/articles/view/550034/>; accessed 03-13-09
37. <http://www.aacp.org/governance/COMMITTEES/researchgraduateaffairs/Documents/2007-08%20RGAC%20Final%20Reports.pdf>; accessed 03-13-09
38. <http://www.aacp.org/governance/COMMITTEES/researchgraduateaffairs/Documents/2006-07%20RGAC%20Final%20Report.pdf>; accessed 03-13-09
39. http://www.aacp.org/governance/COMMITTEES/argus/Documents/9387_2007-08ArgusReportfinal.pdf; accessed 03-13-09
40. <http://pharmacy.ucsf.edu/news/2008/10/13/1/>; accessed 03-13-09
41. Woolf S. The Meaning of Translational Research and Why It Matters; *JAMA* 2008; 299:211-213
42. <http://www.medicalnewstoday.com/articles/131543.php>; accessed 03-13-09
43. <http://seniorjournal.com/NEWS/MedicareDrugCards/2007/7-10-05-NewFDA.htm>; accessed 03-13-09
44. http://www.amcp.org/data/jmcp/letter_7771.pdf; accessed 03-13-09
45. <http://www.ajpe.org/legacy/pdfs/aj5804S31.pdf>; accessed 03-13-09
46. http://www.pharmacytimes.com/issues/articles/2006-12_4179.asp
47. <http://www.medscape.com/viewarticle/469844>; accessed 03-13-09
48. <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1876413>; accessed 03-13-09
49. <http://www.ajpe.org/legacy/pdfs/aj5804414.pdf>; accessed 03-13-09
50. <http://www.kff.org/rxdrugs/6085-index.cfm>; accessed 03-13-09
51. <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2064884>; accessed 03-13-09
52. http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B7RN1-4GKFBTK-5&_user=10&_rdoc=1&_fmt=&_orig=search&_sort=d&_view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=64a35a72fc795f7b93c74c08840c9d6b; accessed 03-13-09
53. http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B7RN1-4GKFBTK-1&_user=10&_rdoc=1&_fmt=&_orig=search&_sort=d&_view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=64a35a72fc795f7b93c74c08840c9d6b

- [=1&_urlVersion=0&_userid=10&md5=7b333c0f56053547af6145f25db01376](#); accessed 03-13-09
54. Hansen RA, Shaheen NJ, Schommer JC. Factors influencing the shift of patients from one proton pump inhibitor to another: the effect of direct-to-consumer advertising. *Clinical Therapeutics*. 2005; 27(9):1478-87.
 55. Cline RJW, Young HN (2005). "Direct-to-consumer print ads for drugs: do they undermine the physician-patient relationship?" *Journal of Family Practice*. 54(12):1049-57.
 56. <http://www.kff.org/rxdrugs/6075-index.cfm>; accessed 03-13-09
 57. <http://www.pharmacy.olemiss.edu/cpmm/cpmmprograms.html>; accessed 03-13-09
 58. http://www.medscape.com/viewarticle/501582_1; accessed 03-13-09
 59. FDA, The Future of Drug Safety – Promoting and Protecting the Public Health, FDA’s Response to the Institute of Medicine’s 2006 Report, January 2007
<http://www.fda.gov/oc/reports/iom013007.html>
 60. <http://www.safemedicines.org/>
 61. Ziance RJ, Roles for Pharmacy in Combating Counterfeit Drugs. *Journal of the American Pharmacists Association* 48: e71-e91 (2008)
 62. <http://www.nipte.org/board.php>
 63. (<http://www.ashp.org/Import/PRACTICEANDPOLICY/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/Distribution/PolicyPositions.aspx>)
 64. <http://www.pharmacist.com/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=17885>)
 65. <http://www.fda.gov/medwatch/>