AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS®
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May 12, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99N-0386: Talking With Stakeholders About FDA Modernization

TO WHOM IT MAY CONCERN:

The American Society of Health-System Pharmacists (ASHP) is pleased to provide comments on the Food and Drug Administration's (FDA) request for input on specific performance targets of the Food and Drug Administration Modernization Act of 1997 (FDAMA) that was published in the *Federal Register* on March 22, 1999. ASHP is the 30,000-member national professional association representing pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care organizations, and other components of health care systems.

In its *Federal Register* notice, the FDA asked for comments addressing five questions. ASHP is responding to three of those questions:

Strengthening the science base of the FDA

The first two questions that the FDA asked in its March 22 notice are concerned with the role of science in identifying, evaluating, and balancing product risks and benefits:

- What actions do you propose the agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decisionmaking?
- What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's lifecycle?

These questions relate to one of Commissioner Henney's primary objectives that she noted during the April 28 teleconference -- strengthening the science base of the agency, particularly the ability of the FDA to incorporate state-of-the-art science in making its decisions and facilitating the exchange and integration of scientific information about approved products.

99N-0386 C27

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ASHP and its members fully support Commissioner Henney's statement that FDA policy and every decision it makes must be well grounded in science so that those decisions are meaningful. We have consistently emphasized the importance of the increasingly rapid development of science as it relates to the drug development process and clinical therapeutics. Recognizing this, ASHP convened a task force in February 1998 to identify areas of opportunity and responsibility related to science. The task force noted the following in relation to science and public policy (emphasis added):

> The pace of clinical research is changing. In addition to more rapid identification and design of drug entities, the pharmaceutical industry places a premium on completing clinical trials as rapidly as possible.... This emphasis on placing drugs on the market sooner has been fueled by political forces. Patient advocacy groups have exerted pressure that has resulted in changes in FDA's drug review procedures. The time from drug discovery to drug approval has been shortened substantially. The net result is that there is often very little peer-reviewed literature available when drugs reach the market, especially in the case of priority drugs.
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> These situations serve to heighten the importance of postmarketing surveillance. This may present a unique opportunity for pharmacy to fill a vital public need. ***Pharmacists serve the patient at the juncture of medication use and science.*** They are uniquely situated to capture and analyze postmarketing data. The task force believes this is an important public policy issue and one on which there is a tremendous opportunity for pharmacists to have a measurable impact on public health.

The complete "Report of the ASHP Task Force on Science" is attached. ASHP encourages the FDA to take advantage of front-line pharmacist expertise as the agency strengthens its own science base.

Drug Safety Issues

The third question the FDA raised in its announcement of the April 28 teleconference was: What actions can be taken to educate the public about the concept of balancing risks against benefits in public health decisionmaking?

Every day, more and more of our members are interacting with patients in clinical care settings, and their experience indicates that the general public does not have a good idea of what it means when the FDA says that a drug is "safe" enough to enter the marketplace. The public is particularly uninformed about the inherent risks associated with medication use. Drug products, after they enter the marketplace, leave the artificial situation of controlled clinical trials and are

placed in the hands of ordinary human beings -- health professionals who strive to maintain a thorough understanding of the product and patients who have the greatest stake in ensuring the best use of the product, but who may not be well informed about their role in meeting this objective.

Without fully comprehending the benefits and risks associated with taking prescription medications, consumers may have unrealistic expectations of their medication therapy. There is a real need for public education in this regard, and ASHP would like to assist the agency in developing a program to educate the public about what safe medication use is all about. We say "assist," because we recognize that we both -- health professionals and the agency -- have a shared responsibility to educate the public.

As front-line practitioners, pharmacists, along with doctors and nurses, are "safety managers" -- learned professionals who can help patients safely manage the risks of their medication therapy. ASHP has long been an advocate of, and a leader in, the safe use of drug products. The first precept of our current Leadership Agenda, which declares the top professional objectives of ASHP, is to "Foster fail-safe medication use in health systems." Among the key assumptions that ASHP made in establishing its Leadership Agenda included the belief that patient risk associated with medication use will increase as drugs and drug therapy become more complex. Further, the recognition that safe medication use is a growing public concern is reflected in news reports and in the scientific and professional literature.

At ASHP's Annual Meeting in June 1998, we adopted a policy "to affirm that pharmacists must assume a leadership role in preventing, investigating, and eliminating medication misadventures across the continuum of care." We have also emphasized pharmacist-patient interaction that will lead toward safe medication use in our practice guidelines and other publications:

- ASHP's guidelines on "Minimum Standard for Pharmacies in Hospitals" states that patient education, coordinated with medical, nursing, and other clinical staff, should "ensure that all patients are given adequate information ... about the medications they receive."

- ASHP's "Guidelines on Adverse Drug Reaction Monitoring and Reporting" suggests that organized health systems develop a comprehensive ADR-monitoring and reporting program that includes patient involvement.

- ASHP's guidelines on "Pharmacist-Conducted Patient Education and Counseling" states that the pharmacy profession has the responsibility to provide patients with information "to improve patient adherence and reduce medication-related problems," with the goal of making patients "effective partners in managing their own care" -- the very essence of patient-practitioner collaboration in safety management to ensure the therapeutic effectiveness of medication use.

- ASHP's "Guidelines on Preventing Medication Errors in Hospitals" contains a section entitled "Recommendations for patients and personal caregivers," which states that "health care providers should encourage patients to take an active role in their drug use by questioning and learning about their treatment regimens." In January of this year ASHP and the ASHP Research and Education Foundation brought together an interdisciplinary group of experts to discuss medication misadventures with the goal of developing a set of ideas that could be used as the basis for generating concrete action plans to foster fail-safe medication use in health systems. Among the major ideas identified by this group was one that would use patients/consumers as allies. Patients have the greatest interest in understanding drug safety. They also have a high level of trust in pharmacists. Consumer representation should be designed into projects formulating public communications (such as public service announcements) about the benefits and risks of medication therapy.

ASHP's members have an ongoing commitment to safety management in their day-to-day practice. Every interaction with a patient is an opportunity for the pharmacist to educate the public about drug safety. We encourage the FDA to take advantage of the pharmacist's role in reducing medication errors, but also recognize that the FDA has some responsibility to educate the public.

ASHP stands ready to assist the FDA and other organizations in research projects related to safe medication use. For example, one area that needs research is the incidence and causes of medication errors in outpatient settings such as home care and ambulatory care. The error-prevention value of collaborative drug therapy management -- arrangements in which pharmacists, prescribers, nurses, patients, and others work closely to ensure the best therapy and safety -- also needs further study, and ASHP is eager to be part of a partnership between the FDA, pharmacy, nursing, medicine, and patients to conduct such research.

At a March 26, 1999, policy forum on drug safety sponsored by the American Enterprise Institute for Public Policy Research, CDER Director Dr. Janet Woodcock said that risk management of drugs once they are approved is not under FDA authority, but that the agency has a role in preventing medication errors through its regulatory requirements for product packaging, labeling, and distribution.

ASHP believes that under "packaging" and "labeling," the FDA has an obligation to quickly review and revise its procedures to eliminate medication errors that occur due to look-alike and sound-alike names, similarities in packaging, and other labeling and packaging problems. As noted above, patients should be considered the allies of health professionals in eliminating medication errors, and they should be involved in providing input into the safety design of drug product labeling.

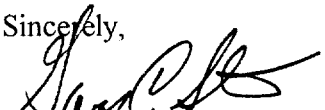
ASHP would also add "advertising" to Dr. Woodcock's list of aspects of the FDA's role in drug safety. Specifically, we think FDA should be reviewing the concept of direct-to-consumer advertising more critically. DTC advertising may induce patient demand for a product that is not in the patient's best interests. We suggest that the FDA thoroughly research the risks and benefits of DTC advertising and its contribution to increased reports of adverse drug events.

ASHP appreciates the FDA's hesitancy in getting involved in the safety management of drug products on the patient level. Health-system pharmacists, however, expect the problem of medication misadventures to get worse as more products and more potent products enter the marketplace, and as these products are prescribed for more patients. But this hesitancy must not lead to an renunciation of responsibility. We believe that the issue of safe medication use provides us all -- health care professionals and the agency -- with an opportunity to work together to provide better patient care.

As part of ASHP's commitment to its role and responsibility in helping to solve the problem of medication errors, we are developing a World Wide Web site -- safemedicine.com -- that will be available later this year. This new web site will focus on giving consumers an unbiased, balanced source of drug information that draws on ASHP's expertise as the publisher of the *American Hospital Formulary Service Drug Information* (our 41st edition) and the 7th edition of the *Medication Teaching Manual: The Guide to Patient Drug Information*. The core of the web site will feature a searchable drug database based on MedTeach (the electronic version of our *Medication Teaching Manual*). The site will also offer consumer information on how to use medications safely (such as how to take antibiotics and how to store medications).

ASHP appreciates the opportunity to respond to the FDA's request for comments on the issues the agency brought before its latest stakeholders meeting. As noted above, ASHP is ready to assist the FDA in resolving the issues related to safe medication use -- through exchanging information, developing public education programs, developing partnerships among health care professionals to conduct research related to safe medication use, and providing input to the agency on the safe design of product labeling. Feel free to contact me if you have any questions regarding our comments.

Sincerely,



Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

Attachment

Report of the ASHP Task Force on Science

Am J Health-Syst Pharm. 1998; 55:2519-24

The rapid pace of discovery and the breadth of science in the late twentieth century that has become applicable to drug development and clinical therapeutics have been dazzling. It has become increasingly difficult for practitioners in all health care professions to remain abreast of emerging scientific and technological breakthroughs. The time between scientific discovery and application continues to shorten. Computer technology has had a significant impact on the way scientific research is conducted and the way scientific information is collected, organized, and disseminated.

As we approach the twenty-first century there is no indication that the pace of change is likely to diminish. In fact, in many cases we appear to be on the cusp of translating scientific discovery into clinical applications that will dramatically change the delivery of health care to patients. The pace with which these new treatment modalities are likely to appear, coupled with the explosion of scientific knowledge on which they are based, will seriously challenge practitioners' skills. Practitioners will also face tremendous new ethical dilemmas as they begin to apply their newfound understanding of our genetic and biomolecular makeup.

Recognizing the importance of science to the profession, ASHP convened a task force on science to help identify ASHP's responsibilities and future directions in the area of science. The ASHP Task Force on Science was appointed by President John Murphy with input from the ASHP Section of Clinical Specialists. The charge of the task force was to

- Identify ASHP's responsibilities and opportunities in the area of science,
- Suggest specific activities that would elevate the role of science in ASHP affairs, and
- Recommend a strategic direction for ASHP related to science.

The task force was an interdisciplinary and interprofessional group composed of scientists with varied backgrounds and scientific interests. A complete roster of task force members is contained in Appendix A.

The task force met at ASHP headquarters in Bethesda, Maryland, on February 19, 1998. This report synthesizes the discussions and opinions of individual members of the task force. The meeting was conducted in a manner that encouraged the free interchange of ideas and information. No attempt was made to reach a finite conclusion or to rank suggested ideas in order of priority. Any cases of clear consensus among participants are noted in this report. In some instances, specific numerical data are cited. These figures represent the comments and opinions given by individual task force members during the meeting. No attempt has been made to verify the accuracy of these figures. This report will be used as a part of ASHP's strategic planning by the ASHP Board of Directors and the ASHP staff.

ASHP welcomes additional comments on this report. Comments may be sent to ASHP care of the ASHP Section of Clinical Specialists, 7272 Wisconsin Avenue, Bethesda, MD 20814 or to clinspec@ashp.org.

Defining science

The Random House *Webster's College Dictionary* defines science as

- A branch of knowledge or study dealing with a body of facts or truths systematically arranged and showing the operation of general laws,
- Systematic knowledge of the physical or material world gained through observation and experimentation, and
- Knowledge, as of facts or principles gained by systematic study.

In dealing with the issue of science, task force members encouraged ASHP to think about science in its broadest sense. There is a natural tendency for pharmacists and ASHP to focus on the basic sciences and clinical research. But many other sciences contribute to our understanding of health care delivery and our ability to help patients achieve good outcomes through the proper use of medications. The roles of health care professionals are changing, and if pharmacists are to play a key role in health care delivery they must be capable of more than simply clinical therapeutics. For example, knowledge from the social and behavioral sciences may help us to better understand patients' decisions about taking (or not taking) their medications. Health care is maturing as an industry, forcing health care professionals to become more familiar with economic theories and their application. ASHP should strive to encourage the integration of scientific principles in all aspects of practice to achieve improved outcomes for patients.

Drug development

The task force discussed the impact of science on the development of new therapeutic agents. Drug development is being enhanced by discovery and by the application of science from numerous disciplines. Advances in the biological, physical, and computer sciences have all contributed to new methods of drug discovery and design. The synthesis of libraries of new chemical compounds has been automated; these compounds are now screened by using high-throughput screening methods. Our understanding of molecular biology is rapidly expanding. The results of the human genome project are already beginning to have an effect on drug development and have spurred the development of new industries in

areas such as functional genomics and proteinomics. The merger of computer sciences and bioinformatics with drug design is allowing scientists to explore novel molecular targets and systems.

Public policy toward drug development is also changing and will increasingly affect pharmacists at the patient care interface.

The task force expressed some concern about the impact of economics on drug development. It was noted that, according to the World Health Organization, there are approximately 1700 diseases, but development of drug therapy is focused on only about 350 of these. As major pharmaceutical companies increasingly focus on areas of research with the greatest potential economic rewards, it is important to ensure that the needs of patients with health conditions involving smaller market sizes are not neglected. Consolidation of companies within the pharmaceutical industry is likely to continue and may result in research only in those areas in which the potential for economic gain is quite large. Avenues should be pursued to promote scientific research and development in areas that might be neglected.

Gaps between science and practice

The task force identified numerous gaps between current and emerging scientific knowledge and the ability of the profession to apply this knowledge to optimize the care of patients (Appendix B). The professional of today must be prepared to devote a significant effort to lifelong learning. Many areas of science that were not part of the collegiate curriculum just a few years ago are emerging as distinct disciplines in health care today. The task force believes that, as an organization representing pharmacists practicing in health systems, ASHP has an important role in identifying emerging areas of science and educating its members about the application of this knowledge.

Ethics. Advances in our understanding of the molecular and genetic basis of disease will result in new challenges to society and the health professions in the area of medical ethics. Although behavioral and environmental risk factors will continue to have an important effect on people's health, we will soon be able to accurately predict the long-term outcomes and the costs of care on the basis of an individual's molecular makeup. With this new knowledge will come increased responsibilities and new ethical dilemmas.

Developments in the computer sciences will contribute to new ethical challenges. The rapid explosion of computer databases containing detailed patient information has already raised concerns about privacy and confidentiality. There is a need to assist health care practitioners in understanding and applying ethical principles as they face increasingly complex challenges.

Alternative medicine. The task force believes there is a significant gap between the explosion of interest in alternative medicine and the scientific evidence supporting the benefits of various therapies provided under the rubric of alternative medicine. The public, especially highly educated and affluent consumers, has readily accepted nutritional supplements, herbal products, homeopathy, and other forms of alternative therapy without the assurance of scientific evidence that would normally be required for therapeutic agents. The task force believes it would be a mistake to ignore this trend and has encouraged ASHP to consider this issue in its strategic planning.

Opinions varied among task force members regarding the value of alternative medicine and the extent to which there are adequate data supporting some alternative approaches. The task force noted the creation of the National Institutes of Health (NIH) Office of Alternative Medicine and the efforts of NIH to identify and generate useful data about alternative medicine. Although there was some support for increased research into alternative therapies, not all members of the task force were supportive of investing in clinical research involving these products.

The task force was concerned that current legislation and regulation of alternative therapies is inadequate. The United States has lagged behind other countries in addressing this issue. Current legislation severely restricts the role of the Food and Drug Administration (FDA) in regulating these products. There are insufficient safeguards not only in the area of safety and efficacy, but also in manufacturing, production, and marketing. Members of the task force were encouraged by recent efforts by the United States Pharmacopeial Convention, Inc. (USP) to address the issue of standardization.

While individual members of the task force had differing opinions about some aspects of alternative therapies, there was universal agreement that there is a tremendous need to educate pharmacists and other health care practitioners about these therapies. The alternative medicine industry in the United States is currently worth $13 billion, and pharmacists need to be prepared to provide patients with advice about the potential benefits and risks associated with these therapies. Patients are now receiving advice on these therapies from a variety of sources, many of which are of questionable validity. Pharmacists and other health care professionals are not knowledgeable about these products and are uncertain as to where to locate reliable literature. The task force noted ASHP's efforts to include education on alternative therapies and encouraged ASHP to continue to provide information on this topic to its members through its educational meetings and through *AJHP* and other publications.

Informatics. Members of the task force described bioinformatics as an area of rapid growth and great scientific importance. Developments in bioinformatics will affect all aspects of the profession, from bench research to direct patient care. Genetic data are being placed on microchips, and large warehouses of these

data are being created. Bioinformatics is already having an impact on drug development and the development of novel diagnostic approaches.

The issue of how to manage the huge volume of information coming out of clinical and outcomes research is an important one for ASHP and its members. Information systems will increasingly be applied in patient care. Large databases will be integrated with patient data to improve practice. Improvements in informatics will expand the application of evidence-based decision-making in practice. Practitioners will need to learn new skills to effectively use information gleaned from these new developments and to apply principles of evidence-based decision-making.

Genetics. A tremendous amount of new scientific knowledge is coming from public efforts such as the human genome project and from extensive private research. Entire new industries (e.g., pharmacogenomics, proteinomics) are forming. These advances are already beginning to have a substantial impact on drug discovery, drug design, and diagnosis. In the future, drug therapy may be customized on the basis of the patient's genetic profile to maximize efficacy or to avoid specific toxicities. Drugs may be designed to treat specific disease targets on the basis of genetic profiles. Gene therapy research is rapidly progressing from feasibility studies to accepted therapeutic modalities. Increased understanding and application of molecular biology will have a significant impact on pharmacy and other health care professions. Developments in these areas will change the nature of therapeutic agents and will require that practitioners develop new knowledge and skills.

Social sciences. Pharmacy curricula and continuing-education programs have a strong orientation toward chemistry and clinical science and are insufficiently oriented toward the social sciences. Too little time is spent addressing such issues as reasons for noncompliance. There is a need for more education and training in this area and for further research. One member of the task force captured this issue succinctly: "Drugs don't work if patients don't take them." There is a need for more research into the social factors that influence both patient behavior and disease outcomes.

The changing demographics of the United States also serve to emphasize the importance of the social sciences in pharmacy practice. The U.S. population is becoming more diverse in terms of both race and culture. Pharmacists and other health care professionals are not adequately prepared to account for the impact of religious and cultural beliefs in their communication with patients. This lack of knowledge creates barriers to effective communication and sometimes results in less than optimal outcomes. Practitioners could benefit from educational programs and workshops that expand their knowledge and skills in the social and behavioral sciences.

Economics. Economic research is becoming more integral to the health care system. There have been significant advances in research methods and in the development of economic models over the past decade, but the lack of adequate information systems in health systems continues to be a barrier to conducting quality research in the area of outcomes and economics. The use of economic research in medical decision-making is likely to increase in both volume and reliability as large health systems catch up with other industries through investment in information systems.

The task force noted that there needs to be more training of pharmacists in economic and outcomes research. The task force was complimentary of ASHP's Competitive Edge Program and encouraged ASHP to continue developing programs that provide members with the tools to understand and apply the results of economic research. The task force encouraged ASHP to promote more interdisciplinary collaboration rather than assuming that pharmacists should be the experts on "pharmacoeconomics." Some members of the task force expressed concern about the use of this term, which tends to imply a pharmacy discipline. Rather than attempt to create a new pharmacy discipline, it may be more valuable to build strategic relationships with organizations involved with health care economics and to encourage more interdisciplinary collaboration.

Emerging science. The task force identified areas of science in which it anticipates that new discovery is likely to have a significant impact on pharmacy practice in the near future. As noted elsewhere in this report, genomics and molecular biology were both identified as likely to have a dramatic effect. The task force also believes that advances in our understanding of chronobiology will result in important changes in drug design and drug delivery. Drug delivery will be advanced by improvements in biomaterials as well. A closer integration of therapeutics and diagnostics was identified as another area in which change is likely to occur rapidly. This includes not just phenotyping, but advances in biosensors and microdiagnostic techniques that are likely to allow more real-time feedback on the function of biological systems.

Responsibilities and opportunities for ASHP

The task force identified opportunities for ASHP to elevate its role in science and encouraged ASHP to increase its interface with other science professionals and with the scientific community. Appendix C lists those opportunities along with endeavors that the panel identified as responsibilities of ASHP.

The task force recognized a need to identify and prioritize ASHP's efforts in the area of science. Members of the task force urged ASHP to avoid trying to be all things to all people. ASHP might prioritize areas in which it is able to add value, recognizing that some areas may be addressed effectively by other organizations. Bringing science and scientific principles into practice research to optimize the medication-use proc-

ess was cited as an example of a core role for ASHP. Another strategy might be to select scientific issues on which ASHP could provide leadership in galvanizing the efforts of several organizations. The task force recognized that ASHP's science agenda needs to tie in closely with the needs of pharmacy practitioners who constitute a majority of ASHP's membership. Colleges do a good job of providing students with a foundation in the pharmaceutical sciences, but there is a need to enhance the translation of scientific discovery into practice. A major goal of ASHP's efforts related to science should be focused on facilitating the translation of science into practice.

Education and training. The task force voiced concern that the profession is not building an adequate core of qualified research scientists. Task force members observed that academic institutions are often expecting Doctor of Pharmacy graduates with a year of residency or fellowship training to carry out effective research programs. These individuals are not adequately prepared to conduct research or compete effectively with other clinical scientists for external funding. In addition, the current fellowship programs for imparting research skills may be insufficient to meet the needs of the profession. Some schools of pharmacy are offering dual degree (Pharm.D. and Ph.D.) programs. Some members of the task force expressed a belief that the transition to an entry-level Pharm.D. degree program will exacerbate this problem and questioned the depth of problem-solving skills among current pharmacy school graduates.

Fundamental changes in how research is organized and carried out are also affecting the profession and its academic centers. There is an increasing emphasis on interdisciplinary research, for example, the integration of the computer sciences and the biological sciences, molecular biology and molecular medicine, and biology and organic chemistry. Disciplines such as pharmacology, pharmacognosy, physical chemistry, and pharmaceutics that have historically been distinct are being defined in broader ways that involve a greater variety of scientists. ASHP may have a role in helping to integrate pharmacy into the new interdisciplinary research models that arise from these changes.

Assisting in the development of a cadre of clinical scientists was also proposed as a possible role for ASHP. It was suggested that ASHP could serve as a facilitator by helping identify resources for training new researchers. ASHP might begin a dialogue with the NIH general medical sciences section about developing postdoctoral training programs for Pharm.D. graduates. ASHP could also provide leadership in developing new models for fellowships and other types of training programs that would help enrich the clinical sciences.

The task force believes that ASHP should consider more educational programs or workshops directed toward research. Selected topics can be identified in previous ASHP programs, but this has not been a major focus of ASHP meetings. ASHP might consider including a keynote speaker or a plenary session that focuses on a scientific topic. Programs or workshops aimed at junior faculty members and programs to train practitioners in analytical techniques were suggested. Young clinical scientists also need assistance in learning how to build a research program as opposed to just learning how to participate in research. ASHP might consider including a scientific panel composed of scientists from various disciplines as a regular feature of its meetings.

An increased emphasis on curricular programming and on Web-based learning was also suggested by the task force. There is a need for education that is of greater depth than traditional continuing education and that provides new skills. The ASHP Research and Education Foundation's traineeships are an example of such programs. The task force also noted that recent developments in credentialing, certification, and competency assessment were indications of the need for more investment in curricular programs. Colleges are increasingly using Internet technology, especially in nontraditional Pharm.D. programs. Some task force members expressed a belief that Web-based education is going to grow dramatically in the future. The World Wide Web is a very effective means of providing education at the student's desktop. ASHP should take advantage of this technology as a means of providing its members with cost-effective curricular programs and participating in the extension of these educational programs around the globe.

ASHP's leadership in residency training might also present an opportunity. ASHP could encourage every resident to participate in some type of scientific project rather than just any project. The profession cannot expect to develop clinical scientists in one year, but it might be possible for the profession to obtain more benefit from the residency projects. It was suggested that residents in one region or throughout the country might participate in a single project designed to answer a key question of interest to the profession. ASHP could also provide some formal instruction to residents in protocol development or provide demonstration grants to residents so that they may answer specific questions of interest to ASHP and the profession.

Advocacy. The task force noted that pharmacy as a profession has not historically been well recognized in the area of clinical research. Pharmacy is not present at the table when decisions are made about support for the clinical sciences for the next 10 to 20 years. Pharmacist involvement and influence in organizations such as NIH are not what they should be. For example, the NIH Director's Panels on Clinical Research did not include a single pharmacist. ASHP may have a role in helping to achieve the integration of pharmacists into these organizations.

However, the task force cautioned ASHP and the profession to avoid paternalism in advocating a role for

pharmacists in clinical research. Clinical research is increasingly organized and conducted as a business. Universities are changing their organizational structures to encourage multidisciplinary collaboration among scientists. The traditional model of research programs that function in compartmentalized divisions and departments is giving way to an environment that requires collaboration and cooperation for programs to successfully compete. Pharmacy cannot afford to be isolated as a profession and must integrate itself into the business of clinical research.

Public policy. The pace of clinical research is changing. In addition to more rapid identification and design of drug entities, the pharmaceutical industry places a premium on completing clinical trials as rapidly as possible. The number of contract research organizations has grown tremendously in recent years. Academic centers must now compete with these organizations for clinical research contracts. This emphasis on placing drugs on the market sooner has been fueled by political forces. Patient advocacy groups have exerted pressure that has resulted in changes in FDA's drug review procedures. The time from drug discovery to drug approval has been shortened substantially. The net result is that there is often very little peer-reviewed literature available when drugs reach the market, especially in the case of priority drugs.

These situations serve to heighten the importance of postmarketing surveillance. This may present a unique opportunity for pharmacy to fill a vital public need. Pharmacists serve the patient at the juncture of medication use and science. They are uniquely situated to capture and analyze postmarketing data. The task force believes this is an important public policy issue and one on which there is a tremendous opportunity for pharmacists to have a measurable impact on public health.

Collaboration. ASHP might capitalize on its relationships with the pharmaceutical industry. NIH has become more interested in partnerships with industry. ASHP should consider partnerships such as cooperative research and development agreements (CRADAs) to develop new products and services. For example, there is now a great interest on the part of the private sector in developing software to capture outcomes data on drug effects and adverse drug reactions. Using the CRADA model, ASHP might establish a partnership with NIH and the private sector to develop software to address societal needs in this area.

The task force also suggested that ASHP pursue collaboration and partnerships with other professions and their respective professional societies to provide education and training to ASHP members. Outcomes research, quality of life, and economics were specifically suggested as areas that should be explored. Evidence-based medicine was discussed in some detail. The task force believes that training pharmacists to use information in clinical decision-making and bioinformatics are issues that will resonate with ASHP's members and should be high priorities for ASHP.

Products and services. As a publisher, ASHP should consider the development of books and software that bring new scientific applications to the attention of its members and enhance their skills in applying these new technologies. An example of such a publication was discussed. The American Chemical Society (ACS) recently celebrated its 75th anniversary and published a special edition that featured the landmarks of chemistry. ACS impaneled a group of scientists and asked them to comment about the future of their field. It was an impressive publication that caught the attention of task force members. The task force believes that a format that repeats on a regular basis is more recognizable than a single-issue publication and would call attention to the society's interest in science. Such materials must be presented in a manner that excites the membership. The task force suggested that it might be better to outsource such a publication to writers with specific expertise in writing scientific material for a more general audience. Such a publication could also be an effective recruiting tool for ASHP.

Conclusion

The task force encouraged ASHP to widely publicize the report of its meeting and to seek further input from ASHP members. It was suggested that ASHP think beyond its own membership when disseminating the report and in any subsequent activities resulting from the recommendations of the task force. The report could be posted on the ASHP Web site and distributed to other organizations. Task force members expressed their appreciation to ASHP for undertaking this effort and encouraged ASHP to consider convening such meetings on some regular basis.

Appendix A—ASHP Task Force on Science

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Appendix B—Gaps between science and practice

Drug discovery is focused on only about 350 of 1700 diseases.

Informatics and bioinformatics are not yet sufficient to meet practitioners' needs for managing voluminous and complex data.

Practitioners are not sufficiently prepared to address the challenges presented by gene therapy, new types of therapeutic agents, and ethical dilemmas resulting from the human genome project.

New drugs are entering the market faster; decisions about their use often must be made before peer-reviewed data are available.

New drug products will be more complex and will require more careful monitoring.

Knowledge about drug interactions is still limited.

Practitioners do not receive sufficient training in the social and behavioral sciences.

Drug delivery technology is expanding; practitioners are not adequately trained to use drug delivery devices.

There is not a sufficient safety net to identify adverse effects through postmarketing surveillance.

There is a significant gap between consumer demand for alternative therapies and the scientific support for these therapies.

Economic and outcomes research are maturing and will have a greater impact on patient care decisions; practitioners are not yet prepared to apply these new tools.

Many drugs used in pediatric practice have not been approved by FDA for this population; thus an optimal dosage form or dosage guidelines are not available.

Appendix C—Responsibilities and opportunities for ASHP

Develop strategic alliances both within and outside pharmacy; these alliances could be broad or could deal with specific issues.

Work with NIH or other agencies to secure expanded funding for postdoctoral training of Pharm.D. graduates.

Revise residency standards to require residents to complete a more scientific project.

Consider collaboration with the private sector and NIH through cooperative research and development agreements.

Create programs or other resources to help young investigators to build a research program.

Expand educational sessions and workshops at ASHP meetings that focus on research and science.

Partner with organizations representing other professional scientists (e.g., economists, biochemists) to expand programs, products, and services.

Highlight efforts of the ASHP Research and Education Foundation relating to science.

Act as a catalyst for bringing together pharmacy and other health care professions to focus on priority issues such as adverse drug reactions.

Develop special symposiums by bringing together scientists from various disciplines.

Develop joint conferences with the Federation of American Societies for Experimental Biology, NIH, or other government agencies.

Use the Internet and the World Wide Web to expand educational opportunities for members.

Create a special publication highlighting advances in science that is published on some recurring basis.

Publicize the work of the task force and ASHP efforts in addressing science issues.

Undertake systematic scanning to identify science issues of importance to the profession.

Facilitate an enhanced role for pharmacists in postmarketing surveillance.

Expand efforts to provide members with reliable information about alternative therapies at ASHP meetings and in publications.

Educate members about genetics and its implications and applications in pharmacy practice.

Find ways to help facilitate the development of a pool of well-qualified pharmaceutical scientists.

Strive to help practitioners translate science into practice.

Evaluate current models (e.g., fellowships) for training researchers.

Consider adding a keynote speaker, a plenary session, or a scientist to focus on a scientific issue as a feature of the opening general session at ASHP meetings.

Include at every Midyear Clinical Meeting a session involving a panel of leading scientists to discuss an issue or a series of issues.