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INTERNAL MEDICINE | *Doctors for Adults*

September 30, 2006

Committee on Identifying and Preventing Medical Errors  
Board of Health Care Services  
Institute of Medicine  
500 Fifth Street NW  
Washington DC 20001

Re: The American College of Physician's Response to the IOM Report, *Preventing Medication Errors*

The American College of Physicians (ACP), representing over 120,000 physicians specializing in internal medicine and medical students, would like to comment on the Institute of Medicine's (IOM) report, *Preventing Medication Errors*, which outlines comprehensive strategies for reducing drug-related mistakes. ACP's mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine. ACP thanks the IOM for its continuing efforts to highlight unacceptable quality and safety problems in the nation's health care system.

In its latest report, the IOM estimated that at least 1.5 million people are harmed by medication errors each year at a cost of about \$3.5 billion. Other findings include:

- 400,000 preventable drug-related injuries occur each year in hospitals; another 800,000 occur in long-term care settings; and roughly 530,000 occur just among Medicare recipients in outpatient clinics.
- Medication errors encompass all mistakes involving prescription drugs, over-the-counter products, vitamins, minerals, or herbal supplements. Errors are also common at every stage, from prescription and administration of a drug to monitoring of the patient's response.
- Paper-based prescribing is associated with high error rates, while electronic prescribing is safer because it eliminates problems with handwriting legibility and, when combined with decision-support tools, automatically alerts prescribers to possible interactions, allergies, and other potential problems.
- Information available to consumers online or from pharmacies often is too difficult for many people to understand or otherwise not consumer-friendly.
- Almost nothing is known about the benefits and risks of medications for people over age 80 and those taking medications for multiple conditions.

The IOM recommended a series of actions for patients, health care organizations, government agencies, and pharmaceutical companies. ACP offers the following comments in response to the IOM's recommendations:



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**IOM Recommendation: To improve the quality and safety of the medication-use process, specific measures should be instituted to strengthen patients' capacities for sound medication management. Specifically:**

- **Patient's rights regarding safety and quality in health care and medication use should be formalized at the state/federal level and ensured at every point of care.**
- **Patients should maintain an active list of all prescription drugs, OTC medications, and dietary supplements they are taking; the reasons for taking them; and any known allergies. Providers should have access to this list.**
- **Providers should educate patients about the safe and effective use of medications. They should provide information about side-effects, contraindications, how to handle adverse reactions, and where to find objective, high-quality information.**
- **Consultation on their medications should be available to patients at key points (during clinical decision making in ambulatory/inpatient care, at hospital discharge, and at the pharmacy).**

ACP recognizes the value of patient education and supports public and private efforts to make patients—particularly older patients—aware of diseases/conditions, treatment options, indications, and contraindications. To make health care decisions and work intelligently in partnership with the physician, the patient must be well informed. Information should be disclosed whenever it is considered material to the patient's understanding of his or her situation, possible treatments, and probable outcomes. Information provided to the consumer should be accurate, accessible, and understandable and should include a discussion of the cost and effectiveness of potential treatments.<sup>i</sup>

ACP advises its members to disclose any information that is essential to and desired by the patient, however uncomfortable for the clinician. Most importantly, physicians should disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient's well-being. ACP cautions its members that errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may.<sup>ii</sup>

**IOM Recommendation: Government agencies should enhance the resource base for consumer-oriented drug information and medication self-management support. This includes standardization of pharmacy medication information leaflets, improvement of online medication resources, creation of a national drug information telephone helpline, the development of personal health records, and the development of a national medication safety dissemination plan.**

**IOM Recommendation: Enhancing the safety of medication-use processes and reducing errors requires improved methods for labeling drug products and communicating medication information to consumers and providers. Materials should be designed according to designated standards to meet the needs of the end user. Industry, AHRQ,**



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**FDA, and others should work together to undertake the following actions to address labeling, packaging, and the distribution of free samples:**

- **The FDA should develop two guidance documents to industry: one for drug naming and another for drug labeling and packaging. The FDA and industry should collaborate to develop 1) a common drug nomenclature that standardizes abbreviations, acronyms, and terms to the extent possible and 2) methods of applying failure modes and effects analysis to labeling and packaging.**
- **Additional study of optimum designs for drug labeling and information sheets should be undertaken.**
- **The FDA, the pharmaceutical industry, and others should collaborate to develop a strategy for expansion of unit-of-use packaging for consumers to new therapeutic areas. Studies should be undertaken to evaluate different methods of presenting unit-of-use packaging and design that best support different consumer groups in their medication self-management.**
- **AHRQ should fund studies to evaluate the impact of free samples on overall patient safety, provider prescribing practices, and consumer behavior (e.g. adherence), as well as alternative methods of distribution that can improve safety, quality, and effectiveness.**

It is critical that valid and reliable information and appropriate decision-support tools are made available to assist consumers to navigate an increasingly consumer-oriented health care system. ACP encourages the federal government, in cooperation with the medical profession, the pharmaceutical industry and others, to continue to evaluate the impact of medication errors on patients and identify ways to ensure that patients and physicians are provided with accurate, complete, truthful, and non-confusing health information.

In order to gain maximum benefit from the use of drugs while minimizing their adverse side effects, ACP has called on prescribers and pharmacists to maintain effective communications not only among themselves, but with their patients as well. The directions for drug use and other information which prescribers indicate on prescription orders and which pharmacists transfer to prescription labels are critical to safe and effective drug therapy. ACP believes that communicating effective dosage instructions to patients clearly and succinctly is a responsibility of both the medical and pharmaceutical professions. Cooperative efforts between the professions are essential to good patient care and significant progress can be made in other areas by initiating discussions between the two professions concerning common interests and goals.

ACP supports the IOM's call for the development of a national plan for widespread distribution and promotion of medication safety information and medication self-management support. Appropriate patient education is integral to quality medical care. ACP also favors a forum in which physicians and pharmaceutical representatives can work together to inform patients with clear information about specific medications. The Chronic Care Model upon which ACP's



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proposal for patient-centered, physician-guided care (Advanced Medical Home) is based encourages patients to engage in the management of their own health.<sup>iii</sup> The ACP Foundation has also worked with the IOM in the past to offer a course at ACP's Annual Session titled, "Health Literacy: Improving Patients' Ability to Take Care of Themselves."

A critical component of enhanced patient involvement with their care is the personal health record (PHR). PHRs allow patients to provide doctors with valuable information that can help improve the quality of care they receive. PHR data should be collected in a structured format that uses standardized medical terminology described in laymen's terms. PHRs should accept, organize and display patient-specific data including diagnoses, medications, procedures, tests, and other data aggregated by payers based on claims information. ACP recommends that vendors take the initiative to improve the use and functionality of PHRs by incorporating basic tools to support consumers' medication self-management.

To improve safety, the IOM also calls for improving the quality of drug information leaflets that accompany prescription drugs, but often have incomplete information or are written in consumer-confusing jargon. ACP agrees that pharmacy medication leaflets should be in a standardized format designed for readability, comprehensibility, and usefulness for consumers, taking into account literacy, language, age, and visual acuity. ACP has long encouraged the FDA to play a stronger role in ensuring that complete, valid, and clear information is provided to both consumers and physicians. Through the Prescription Bottle Labeling Project, the ACP Foundation seeks to build a case for improvement of prescription bottle labeling by exploring legal ramifications, current policies, the imperfections of current labeling practices and by conducting interviews with stakeholders.<sup>iv</sup>

The College is also pleased that the IOM recommends that the government should establish national telephone hotlines to help patients who are confused about prescription drug information. The ACP Foundation continues to partner with the National Library of Medicine in the Information Rx Project, which makes accurate, informative, and free health information available to patients over the Internet.<sup>v</sup>

In terms of the IOM's recommendation that the federal government study the impact of free samples on overall patient safety, provider prescribing practices, and consumer behavior, ACP encourages its members to have an ongoing assessment of their relationship with industry -- and of the potential impact of those relationships on the independence of clinical judgment. Physician-industry relations present many ethical challenges and it is critical that an appropriate balance be maintained.

In addition to studying the impact of free samples, ACP urges the federal government to more thoroughly evaluate direct-to-consumer (DTC) advertising of prescription drugs and other marketing strategies employed by the pharmaceutical industry that can adversely affect safety,



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quality, and effectiveness of prescribing patterns and prescription drug use. The College maintains that the promotion of commercial products does not constitute appropriate patient education about therapeutics. In a recent position paper, ACP stated that that DTC advertising of prescription drugs is an inappropriate practice that undermines the patient-physician relationship and often leaves patients confused and misinformed about medications. In the absence of legislation or regulation to ban DTC advertising, ACP calls on the FDA to play a stronger role in ensuring that complete, valid, and clear information is provided to the public and in making determinations about whether the commercial information in a DTC ad actually will educate and enhance the health of the public. The College also favors a forum in which physicians and pharmaceutical representatives can work together to create advertisements that inform patients with clear information about specific medications and that will facilitate discussion of treatment options between patients and physicians.<sup>vi</sup>

**IOM Recommendation: All health care organizations should immediately make complete patient-information and decision-support tools available to clinicians and patients. Health care systems should capture information on medication safety and use this information to improve the safety of their drug delivery systems. Health care organizations should implement systems to enable providers to:**

- **Have access to comprehensive reference information concerning medications and related health data.**
- **Communicate patient-specific medication-related information in an interoperable format.**
- **Assess the safety of medication use through active monitoring and use these monitoring data to inform the implementation of prevention strategies.**
- **Write prescriptions electronically and all pharmacies to be able to receive them electronically by 2010. All prescribers should have plans in place by 2008 to implement electronic prescribing.**
- **Subject prescriptions to evidence-based, current clinical decision support.**
- **Have the appropriate competencies for each step of the medication use process.**
- **Make effective use of well-designed technologies, which will vary by setting.**

**IOM Recommendation: Industry and government should collaborate to establish standards affecting drug-related health information technologies, specifically:**

- **The National Library of Medicine should take the lead in developing a common drug nomenclature for use in clinical information technology systems based on standards for the national health information infrastructure.**
- **AHRQ should take the lead in organizing safety alert mechanisms by severity, frequency, and clinical importance to improve clinical value and acceptance.**



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- **AHRQ should take the lead in developing intelligent prompting mechanisms specific to a patient’s unique characteristics and needs; provider prescribing, ordering, and error patterns; and evidence-based best-practice guidelines.**
- **AHRQ should take the lead in developing user interface designs based on the principles of cognitive and human factors and the context of the clinical environment.**

ACP believes that the medical profession has a professional and ethical responsibility to engage in activities to continuously improve the management of patient health information, and to help assure the accuracy, accessibility, timeliness, and relevance of the information used in clinical decision-making. To ensure that our members can meet this goal, ACP has engaged in the following activities:

- ACP presents continuing medical education (CME) learning, Train the Trainer sessions, informational brochures, and Web-based information on patient safety through its AHRQ-sponsored project, *Patient Safety: The Other Side of the Quality Equation*. The module on medication errors discusses where and how medication errors occur, medication prescribing system components, common mistakes on written medication orders, look-alike and sound-alike drug names, proven strategies to reduce errors, electronic prescribing, and the role of the patient in reducing medication errors.
- ACP offers courses on improving patient safety and reducing medical errors at its Annual Session.
- ACP is actively involved in multi-stakeholder coalitions addressing issues of quality of care e.g. National Quality Forum (NQF), Joint Commission on Accreditation of Health Organizations (JCAHO), the eHealth Initiative (eHI), and the Physician Consortium for Performance Improvement.
- ACP makes available to its members the Physicians’ Information and Education Resource (PIER), which allows rapid access to evidence based clinical information at the point of care.
- ACP recently created a Center of Practice Innovation, which takes lessons learned from various Medicare quality incentive demonstration projects and applies them in physician practice settings.

ACP is well aware of the potential benefit of health information technology (HIT), including electronic health records, decision-support systems, computerized physician order entries, registries, and information retrieval functions, in terms of decreased medical errors, increased clinical quality of care, and reduced costs for all stakeholders. This technology not only eases the burden of collecting quality data, but it also helps to directly improve care quality through facilitating increased care coordination, allowing for improved tracking and monitoring of patient conditions, and providing helpful clinical decision support.

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To help promote standardized prescribing protocols and avoid medication errors, ACP has urged its members to:

- Provide complete prescribing information to other members of the health care team.
- Track adverse drug events associated with commonly used drugs more thoroughly.
- Create up-to-date medication-reconciliation record, including information about allergies and over-the-counter or herbal medications.
- Establish tight protocols for high-risk problems, including known drug-drug interactions and high-risk medications.
- Give patients refills only after appropriate monitoring of their response to a drug.
- Make time to read package inserts and medication warnings
- Issue scripts using an electronic medical record or handheld computer, when possible.
- Follow certain criteria for handwritten prescriptions, such as writing legibly; using print instead of cursive; noting the purpose of the drug on each prescription; putting a leading zero before the decimal point if the amount being prescribed is less than one; writing out certain abbreviations; using English directions, not Latin, and using metric weights, not grains; and clearly specifying directions.
- Pay particular attention to prescriptions when patients are discharged from the hospital.
- Let patients know why they're being given a drug, what it is and how often they should take it so that they are more vigilant against errors that can occur at the pharmacy.
- Be particularly cautious when prescribing medications for elderly patients, since alterations in their body composition means they may need lower doses.<sup>vii</sup>
- Report errors and near misses by providing contact information for the [United States Pharmacopeia](#) and the [Institute for Safe Medication Practices](#).<sup>viii</sup>

The federal government can play an important role in creating the mechanisms to assure that HIT products and services used by physicians and other clinicians in medical practices, hospitals, and many other care settings, have the capability to interoperate and exchange the most relevant health summary information, and to do so at a low cost using appropriate industry standards. ACP strongly supports overall efforts in Congress and the Administration to speed the adoption of uniform standards for health information technology. In particular, ACP supports the efforts of the Certification Commission for Healthcare Information Technology (CCHIT) to develop a process to certify specific HIT products that meet or exceed a specified level of functionality, interoperability and security. ACP is also pleased that new federal rules allow physicians to accept donated e-prescribing and electronic health records software and hardware from hospitals without running afoul of fraud and abuse laws. These important protections encourage the adoption of these new technologies.



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The College also agrees with the IOM on the many benefits of e-prescribing, including reduced medication errors, improved quality of care, enhanced administrative efficiency, and lowered costs. These benefits clearly justify efforts to expand the use of e-prescribing systems. Although ACP believes the federal government should move forward with e-prescribing, including fostering technology improvements so that the myriad computer programs used by doctors, hospitals and drugstores are compatible, there are practical and technical barriers to wide scale e-prescribing adoption. These include:

- The need for e-prescribing standards, which take into account the wide variety of clinical settings and specialties and should be flexible and scalable to reflect a practice's size and prescribing volume;
- The need for universal drug classification and coding nomenclature that is accepted throughout the U.S. health care system;
- The need for strong financial incentives to overcome acquisition cost barriers and encourage physician acceptance to change (especially in small, rural and underserved clinical settings);
- The need for careful pilot-testing to assure smooth operability;
- The need to evaluate scenarios where e-prescribing technologies interfere with a physician's clinical judgment, including the need to evaluate how e-prescribing may affect physician personal liability risk and related insurance coverage; and
- Assurance that e-prescribing medication decisions are not driven by proprietary interests.

For e-prescribing to have widespread acceptance and adoption amongst physicians, this new technology must prove itself as speedy or efficient as filling out a paper script, and hold other advantages not possible with a paper-based system. ACP continues to work with the federal government and private industry to make e-prescribing appealing to physicians without adding to practices' administrative burdens.

**IOM Recommendation: Congress should allocate the necessary funds and AHRQ should take the lead, working with other government agencies, in coordinating a broad research agenda on the safe and appropriate use of medications across all care settings.**

**IOM Recommendation: Oversight and regulatory organizations and payers should use legislation, regulation, accreditation, and payment mechanisms and the media to motivate the adoption of practices and technologies that can reduce medication errors and ensure that professionals have the competencies required to deliver medications safely.**

- **Payers and purchasers should continue to motivate improvement in the medication-use process through explicit financial incentives.**
- **CMS should evaluate strategies for delivering medication therapy management.**
- **Regulators, accreditors, and legislators should set minimum functionality standards for error prevention technologies.**

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- **States should enact legislation consistent with the Medicare Modernization Act's e-prescribing provisions and remove existing barriers to e-prescribing.**
- **All state boards of pharmacy should undertake quality improvement initiatives related to community pharmacy practice.**
- **Medication error reporting should be promoted more aggressively by all stakeholders (with a single national taxonomy used for data storage and analysis).**
- **Accreditation bodies responsible for oversight of professional education should require more training in improving medication management practices and clinical pharmacology.**

ACP is pleased the research agenda called for by the IOM would evaluate research methodologies, incidence rates by type and severity, costs of medication errors, reporting systems, and further testing of error prevention strategies.

ACP supports the allocation of increased federal funding for the drug safety programs of federal government agencies and opposes any efforts to weaken federal authority to demand rigorous evaluations of drugs for both safety and effectiveness based on sound scientific and medical evidence. Furthermore, ACP believes pharmaceutical manufacturers should be required to perform effective and meaningful ongoing quality assurance studies of the biologic efficacy and purity of prescription medications they are marketing.

ACP also agrees with the intent of the IOM recommendation that medication error reporting should be promoted more aggressively. ACP supports voluntary reporting of incidents that do not result in fatalities or major errors, but could indicate systemic problems. The College recommends that a public/private sector body be responsible for clearly defining what should be reported and developing a uniform reporting format. However, the College is concerned about the role of the federal government and what will be done with the data. Protection of the confidentiality of data is essential to ensure that incidents adversely affecting patient safety are reported. ACP advises that reporting requirements should be narrowly defined, should not be overly inclusive or excessively burdensome to physicians, and should be primarily educational rather than punitive. Adequate resources must be devoted to analyzing reports of adverse outcomes to identify those attributable to error. After physicians are given a fair opportunity to review the data, the results of the analyses should be made available to the public.

## Conclusion

What is most striking about the magnitude of medication errors made evident by the IOM is that these errors are preventable. A variety of strategies and techniques exist for reducing medication errors, many of which have already been tested and shown to work in practice and others that

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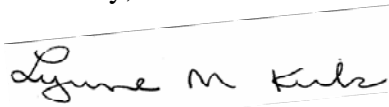
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seem promising but will require further development. ACP agrees with the IOM that the federal government must strengthen efforts to ensure patient safety and access to accurate, complete, truthful and non-confusing health care information.

While most errors can be prevented, we will not find a real solution until the culture of medicine changes. To improve patient safety and eliminate harmful errors, physicians must understand the importance of a multidisciplinary team-based approach for both inpatient and outpatient care; learning how to assemble and work with non-physician members of the health care team; learning how to enhance the role of the patient in managing care; and innovative practice management concepts. ACP continues to encourage its members to let go of the notion of individual physician control in favor of a team-based approach and enhanced health care system accountability.

ACP thanks the IOM for concluding that the current state of affairs is not acceptable and for recommending a series of steps that should be taken to prevent medication errors. ACP looks forward to working with both public and private entities to find the most effective ways to improve the quality of care.

Sincerely,



Lynne M. Kirk, M.D., FACP President

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<sup>i</sup> Snyder L. Leffler C. ACP Ethics Manual. Fifth Edition. The American College of Physicians. 2005. Accessed at <http://www.acponline.org/ethics/ethicman5th.htm#init> on September 5, 2006.

<sup>ii</sup> Snyder L. Leffler C.

<sup>iii</sup> American College of Physicians. The Advanced Medical Home Philadelphia: American College of Physicians; 2006: Position Paper. Accessed at [http://www.acponline.org/hpp/adv\\_med.pdf](http://www.acponline.org/hpp/adv_med.pdf) on September 5, 2006.

<sup>iv</sup> Prescription Bottle Labeling Project. American College of Physicians Foundation. Accessed at <http://foundation.acponline.org/news/LabelReform.htm> on September 5, 2006.

<sup>v</sup> Information Rx Project. A Joint Project of the ACP Foundation and the National Library of Medicine. Accessed at [http://foundation.acponline.org/healthcom/info\\_rx.htm](http://foundation.acponline.org/healthcom/info_rx.htm) on September 5, 2006.

<sup>vi</sup> American College of Physicians. Direct-to-Consumer Prescription Drug Advertising. Philadelphia: American College of Physicians; 2006: Position Paper. Accessed at [http://www.acponline.org/hpp/direct\\_prescript.pdf](http://www.acponline.org/hpp/direct_prescript.pdf) on September 5, 2006

<sup>vii</sup> Maguire P. Strategies to Tackle Outpatient Errors. American College of Physicians-American Society of Internal Medicine *Observer*. June 2002. Accessed at <http://www.acponline.org/journals/news/jun02/errors.htm#tips> on September 5, 2006.

<sup>viii</sup> Darves B. Don't Forget to Tap a Major Safety Resource: Your Patients. American College of Physicians *Observer*. June 2003. Accessed at [http://www.acponline.org/journals/news/jun03/pat\\_safety.htm#report](http://www.acponline.org/journals/news/jun03/pat_safety.htm#report) on September 5, 2006.