Prologue: A key element of the success of any medical regimen is the physician/patient relationship. Because of its potential impact on quality of care, policymakers retain a lively interest in this interaction. In this article, Risa Lavizzo-Mourey and John Eisenberg examine the impact of prescription drug policies on the physician/patient relationship, focusing on the elderly. “As clinicians and health services researchers,” Eisenberg said, “we are interested in how public policy influences physicians’ clinical decision making regarding their elderly patients—particularly policies that affect physicians’ ability to prescribe or dispense pharmaceuticals.” As the nation forges a prescription drug policy, the authors urge that “drug benefits that are not neutral with regard to physicians’ incentives to substitute medications for other therapies or to actually dispense medications should be implemented with caution because of the potentially negative impact on the doctor/patient relationship.” Lavizzo-Mourey and Eisenberg are both on the faculty of the University of Pennsylvania Medical School and are senior fellows at the University of Pennsylvania’s Leonard Davis Institute of Health Economics. Lavizzo-Mourey, a clinically active geriatrician, received a medical degree from Harvard Medical School and a master of business administration degree from the Wharton School. She is affiliated with the Section of General Internal Medicine and the Center for the Study of Aging at the University of Pennsylvania. Eisenberg, an internist, received his medical degree from Washington University in St. Louis, Missouri, and holds a master of business administration degree from the Wharton School. He is chief of the Section of General Internal Medicine and Sol Katz Professor of General Internal Medicine at the University of Pennsylvania and is a member of the Physician Payment Review Commission. Both Lavizzo-Mourey and Eisenberg are alumni of The Robert Wood Johnson Foundation Clinical Scholars Program.
For the elderly, medications are a mixed blessing. Although they are often essential for treating illness, they are a major expense and can cause significant illness as well. Thus, in prescribing medications for the elderly, physicians can do harm as well as good. For the elderly individual with chronic disease, for whom pharmaceuticals are not a discretionary purchase but a necessity, the high out-of-pocket cost of prescription drugs begs for financial relief. The variation in cost among therapeutic alternatives requires that each pharmaceutical agent be compared with other agents as well as with nonpharmacologic treatment options. The high risk of adverse drug reactions among older adults compels the development and implementation of methods to optimize prescribing. For these reasons, policymakers and regulators face the challenge of guiding physicians and their elderly patients in the appropriate use of pharmaceuticals.

The Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360), the recent, ill-fated effort to alleviate the burden of prescription drugs on older Americans, sought to limit financial risk through reimbursement for prescription medications and the risk of adverse drug reactions through drug utilization review. Drug benefits providing partial or complete coverage of medication expenses to beneficiaries are not new to private insurance plans, nor to many Medicaid programs; however, they have not been included in Medicare benefits. We anticipate that three elements of the repealed Medicare drug benefit are likely to reappear in future legislation: copayments and deductibles as a feature of expanded drug benefits, drug utilization review, and provisions to increase physicians’ attention to the cost-effectiveness of specific medications.

Impact Of A Drug Benefit On The Elderly

Because prescribing or receiving medications is fundamental to the doctor/patient relationship, a policy altering patients’ access to medications could affect this relationship. Economic models and empirical evidence suggest that in the presence of a substantial drug benefit, doctors will prescribe more medications, with a potential effect on measurable health care outcomes, such as hospitalization rates or satisfaction with the medical encounter. Even though medical decision making may have become more interactive and patients’ input more seriously considered, physicians still generally make the decision whether to prescribe pharmaceuticals and which drug to prescribe, and patients generally pay for the drugs. A drug benefit that reduces patients’ liability will affect physicians’ prescribing behavior to the extent that they are sensitive to price and willing to act on their patients’ economic behalf.
Economists use the concept of price sensitivity to understand changes in consumption related to changes in the price of a good or service. If consumption changes with price, the consumer is said to be price-sensitive; if it does not change notably, the consumer is considered price-insensitive. The weight of available evidence supports the view that physicians are price-sensitive. However, because opinions differ about the degree to which physicians can be considered consumers in the purchase of pharmaceuticals, we explore the supporting evidence for two models of physician decision making and the behavior that the models would predict. In both cases, the physicians are assumed to be somewhat price-sensitive. In one case, however, they behave as their patients’ agents (doing what the patient would want if the patient had the knowledge available to the physician); in the other, they behave as their own agents. We find that the predictions are the same: physicians will prescribe either more drugs or more services (or both) when their patients have a drug benefit.

Physicians and price sensitivity. Whether or not physicians are trying to protect their own or their patients’ interests, the impact of a drug benefit that limits patients’ financial liability can be predicted on the basis of a price demand model. Simply stated, price and quantity demanded are inversely related; if patients pay less for medications, they will demand more prescriptions. The physician will respond by writing more prescriptions. Several studies support this interpretation of physician behavior.

Physicians as patients’ agents. Although price-sensitive physicians can choose to respond to a drug benefit so that it is beneficial to their patients, they can also respond in more self-interested ways. Practitioners who are interested in improving their own economic lot seem to attempt to ensure themselves a share of their patients’ finite health care dollars. This model of physician behavior suggests that reimbursing medications would free up a larger proportion of patients’ discretionary health care dollars to purchase other goods and services. One study showed that the implementation of a drug benefit led to an increase in the number of physician visits but no increase in the number of prescriptions. However, the paucity of empirical support for this model of physician response to drug benefits may be more related to the short time that prescription benefit plans have been available. The implications are important for regulators and policymakers, because this increase in utilization could represent either the provision of inappropriate services or improved access to care.

There is better evidence that physicians act as their patients’ agents than as self-serving entrepreneurs. Assuming that patients need or want more health-related goods and services, this model of physician behavior
predicts an increase in use of health care services as out-of-pocket expenses for prescription medications decrease. In addition, based on this model, one might expect the type of prescription to change to a more desirable, even if more expensive, medication.

Some research offers support for this model. Robert Zelino suggests that some physicians do not consider price at all in their decision making and that others do so only in conjunction with data on efficacy and side effects. The price-sensitive group seems to be willing to prescribe more expensive medications if the drug is associated with greater benefit for the patient.

Designing a benefit to increase access equitably. Improved access to needed medications is essential to the well-being of many elderly individuals. A likely consequence of a drug benefit, however, is that physicians prescribe more drugs. Because compliance with prescriptions decreases and the probability of an adverse drug reaction increases with the number of drugs prescribed, greater access to medication may not be desirable for all patients. Thus, future legislation should target older people needing better access to prescription medications. Such legislation should enable prescribing decisions to be made on health-improving, not financial, grounds. In the catastrophic coverage act, the copayment and deductible did not differ by ability to pay. For some, the $600 deductible would have been trivial, whereas for others (such as those existing at or below the poverty level), it would have been so high relative to income that the drug benefit itself would have proved catastrophic. A graded, income-based deductible, coupled with a copayment such as that included in the catastrophic coverage act, would be more likely to increase access to prescription medications in a more equitable fashion. For example, a deductible of no more than 5 percent of an older adult’s income or $600, whichever is less, would probably limit out-of-pocket medication cost to an acceptable level.

Incentives for dispensing by physicians. The behavioral model of the self-interested physician suggests that a drug benefit could lead to an increase in other physician services as physicians recognize that their patients have been relieved of a large out-of-pocket medical expenditure. However, such a physician may respond to the increased coverage of pharmaceuticals in another way. If physicians have financial incentives to dispense medications, the number of physicians selling medications for a profit might increase. Such is the case in Japan, where physicians prescribe and dispense medications, apparently because it is economically advantageous. Whereas only 5 percent of U.S. physicians dispense medications, it is the norm among Japanese physicians. Physicians purchase medications at a discount from distributors and then sell them to patients.
at the reimbursement price set by the Japanese Ministry of Health and Welfare. The medications for which physicians get the largest discounts (particularly antibiotics) are the most heavily prescribed, and observers have noted that Japanese doctors have a tendency to dispense more expensive medications to replace lost income.

Dispensing of medications by physicians is not intrinsically undesirable. The U.S. Federal Trade Commission has even encouraged states to allow physicians to dispense drugs because it would encourage competition. The commission argued that “restraining an entire category of transactions by physicians is not justified.” However, the potential for conflict of interest is obvious. Physicians with a limited variety of prescriptions in stock may be tempted to prescribe a medication they have on hand rather than the best medication. Similarly, a medication with a high profit margin might be selected over a more appropriate, but less financially rewarding, medication. However, there is a precedent for the potential conflict of interest physicians could encounter. Pharmacists are placed in a similar position when customers ask for advice about nonprescription drugs. It would seem ludicrous to prohibit drug store pharmacists from advising their customers on the choice of over-the-counter preparations (or from advising physicians on prescription drugs). In addition, dispensing of medications by physicians could improve the quality of care if physicians who both prescribe and dispense can make care more convenient and improve compliance (especially among the very old, frail, or dependent elderly) by simplifying the logistics of securing medications.

The challenge to policymakers designing future drug benefits will be to avoid making the dispensing of medications particularly economically advantageous or disadvantageous to physicians. To be consistent with a physician payment scheme established on a resource-based relative value scale, fees should reflect the cost of dispensing medications in different settings. Requirements for access to computerized information, drug utilization review, and quality assurance should apply to physician, pharmacy, and managed care dispensers alike.

The institution of price controls by Medicare (for example, paying the average wholesale price or some percentage of charges) could have injurious effects on the availability of pharmaceuticals. Price controls could limit the ability of pharmacies or dispensing physicians to provide a wide spectrum of drugs. Pharmacies and physicians would find that they could purchase drugs more inexpensively when purchasing them in bulk. If these discounts were necessary to have sufficient net income in the face of limited allowable charges, a tacit formulary could result. Although this might reduce costs and decrease duplication of equivalent pharma-
ceuticals, too small a formulary, especially in the office of a dispensing physician, could lead to prescription of drugs that are not the best choices. This would limit physicians’ autonomy and flexibility of decision making regarding the use of pharmaceuticals and could decrease the quality of care. Thus, a mandatory essential drug list could be instituted both to limit unnecessary duplication and to assure the availability of a set of necessary drugs.

Effect on doctor/patient relationships. Although a more comprehensive drug benefit could lead to greater access to medications for older adults as a whole, it could also exacerbate some flaws in the doctor/patient relationship. A drug benefit could strengthen the relationship by removing barriers to access and compliance. Conversely, such a benefit could weaken the relationship by threatening physicians’ autonomy, increasing public perception of physicians as rationers of care, and encouraging inappropriate substitution of drugs for other courses of therapy.

Noncompliance with medical therapy is a source of frustration for physicians and may threaten their therapeutic relationship with patients.\textsuperscript{11} While many factors such as side effects and dosing schedules adversely affect compliance, one reason often given by patients for poor compliance is the inability to pay for therapy.\textsuperscript{12} Relieving patients of the financial burden of acquiring medications might improve compliance and, in so doing, enhance their health as well as their relationships with their physicians. After the New Jersey pharmaceutical assistance program was initiated, the number of medications per capita increased; however, the total cost of health care for this population decreased.\textsuperscript{13} Patients may have been more compliant with reimbursed medications and their health may have improved, thus requiring lower-intensity (and therefore lower-cost) medical care.\textsuperscript{14}

On the other hand, the greater flow of prescription medications as a result of a drug benefit might have negative consequences for the doctor/patient encounter. Edward Shorter has argued that the power of the therapeutic relationship between doctor and patient, which formerly was based on the physician’s mystique, now rests in pharmaceuticals.\textsuperscript{15} Patients visit their physicians because they want prescriptions, Shorter suggests, not because they believe physicians can heal them. Thus, drug benefits that decrease patients’ financial burden in obtaining prescription medications may heighten the perception of physicians as the barrier to therapy rather than its purveyor; physicians’ role in the relationship could become that of obstacle rather than healer.

Even if physicians do provide access to fully reimbursed prescription drugs, the physician/patient relationship could be damaged as a result of
increased prescribing. More physicians might be tempted to substitute prescriptions for counseling or other nonpharmacologic modes of therapy because patients’ financial risk associated with medications is limited and because writing a prescription takes less time. The elderly are likely to be particularly affected by this, because physicians already spend less time with their older patients than with their younger ones. Policymakers must design a drug benefit that neither places physicians as obstacles to desired care nor encourages the dispensing of prescriptions as a substitute for the therapeutic relationship.

Cost containment. Some of the cost-containing measures that will likely be part of any drug benefit program may impose barriers between patients and physicians. A benefit that requires prior approval for certain medications, the establishment of a formulary, or frequent prescriptions for refills of chronically used medications not only would further threaten the therapeutic relationship but also would be perceived by physicians as a threat to their professional autonomy. If patients are forced to visit or call their physicians every month or two to get refills for insulin or antihypertensive medications, the cost of medical care will increase, and the image of physicians merely as vehicles for prescriptions will be difficult to counter. Similarly, if physicians’ prescriptions are routinely interchanged with medications of the same class by pharmacists (as would be the case with mandatory therapeutic substitution), patients might legitimately question the role of the physician in selecting appropriate care. The Medicare drug benefit as proposed under the catastrophic coverage act did not include these more threatening elements; as such, it may serve as a model for the cost containment features of future drug benefits.

**Drug Utilization Review Programs**

Drug utilization review programs, although not yet standardized or fully evaluated, are being implemented in various settings and will probably play a greater role in health policy in the future. This program has already been implemented in over 75 percent of managed care organizations, has been mandated as part of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) requirements, and was mandated by the Medicare Catastrophic Coverage Act. Drug utilization review refers to a process of ensuring that patterns of medication prescribing or dispensing meet certain guidelines for a particular population or setting. Such review is not necessarily a careful inspection of individual patient records and medication regimens to assess the appropriateness of particular regimens or of one medication...
over another. In general, the data on which drug utilization review programs rely are inadequate to make such judgments. Rather, drug utilization review uses individual patient data, often claims data, to assess and, if necessary, modify patterns of prescribing or use.

**Types of drug utilization review.** The four types of drug utilization review, which vary by timing of review and the nature of the criteria being used, are retrospective, prospective, administrative, and therapeutic. The four types are not mutually exclusive; in fact, the Medicare catastrophic drug benefit would have included all four. Reviews can occur retrospectively (up to several months after the medication has been prescribed) or prospectively (when the prescription is written or dispensed). Prospective drug utilization review is often called point-of-sale review because, to date, it has occurred when medications are dispensed.

The criteria used to evaluate the patterns of medication usage fall into two general categories: administrative and therapeutic. Administrative criteria involve detecting patterns that may represent fraud, abuse of controlled substances, or overuse of particular medications or classes of medications. Programs based on these criteria, often called administrative drug utilization review or surveillance. utilization review, are used to enforce the terms of a drug benefit, such as deductibles and caps on the number or cost of prescriptions. For example, under the Medicare drug benefit, pharmacists would have been able to determine, before dispensing a medication, whether the beneficiary's annual deductible had been met. On the other hand, therapeutic criteria are used to assess the appropriateness of the prescription in terms of the drug's indications, contraindications, interactions with other drugs, usual dosage, and adverse reactions, as well as measurable outcomes of therapy. Such criteria might be written to detect cases of underlying diagnoses of peptic ulcer disease or history of gastrointestinal bleeding in patients who were dispensed medications that might cause bleeding (such as nonsteroidal anti-inflammatory agents) or to detect cases in which prescriptions were not justified by the diagnoses.

For drug utilization review, generally a computer program is used to apply criteria to individual patient data. In prospective systems, the pharmacist is alerted to reasons not to fill the prescription as requested. In the case of retrospective review, guidelines and follow-up procedures are established to communicate the results of the review to pharmacists and physicians. These procedures may range from a letter of inquiry to referral to licensing boards.

**Criteria and data sources.** Irrespective of type, the sophistication and quality of drug utilization review depend on the quality of the criteria and data sources. However, the imperfections of drug utilization review are
most obvious in therapeutic drug utilization review programs. Administrative criteria are often based on payer guidelines, such as Medicaid regulations regarding the number of pills that can be dispensed during a specific time, making the construction of criteria relatively unambiguous. Therapeutic criteria, on the other hand, are based on the medical literature about clinical practice as interpreted by the group setting the criteria. Such criteria might include indications, dosage and dosing schedule, contraindications, drug/drug interactions, and expected outcomes. Interpretations of the components may vary. For example, many medications have, in addition to indications approved by the U.S. Food and Drug Administration (FDA), other indications for which they are commonly used. A health maintenance organization (HMO), hospital, or state Medicaid agency that is writing criteria has the discretion whether to define the indications in accordance with FDA, depending on the goals of the specific therapeutic drug utilization review program.

Equally important in determining the quality of drug utilization review programs are the availability, validity, and reliability of data sources to which the criteria are applied. Some drug utilization review programs may only have access to pharmacy data, whereas others may have diagnoses and laboratory tests also. When only pharmacy data are available, diagnoses—and therefore indications and contraindications—must be inferred. For example, the program would assume that a patient given antacids was likely to have peptic ulcer disease and therefore would be at risk for bleeding if prescribed a nonsteroidal anti-inflammatory agent. The availability of complete information on diagnoses, medications, and, when appropriate, medical procedures increases the expected quality of drug utilization review programs.

If diagnoses or drug information is inaccurate or miscoded, of course, the drug utilization review will be useless or misleading. Although studies have been done of the reliability and validity of some state Medicaid claims databases, these have been sporadic, and comparable studies do not exist for Medicare data. The untested nature of claims data has been an ongoing concern for the National Committee for Vital and Health Statistics (an advisory committee to the secretary of health and human services) and has resulted in a recommendation to the secretary that a mechanism for regularly and routinely checking the reliability and validity of claims data be initiated.

Policymakers and other interpreters of drug utilization review (particularly therapeutic review) should scrutinize the criteria, as well as the data to which they are applied, and hold both programs to high standards. Guidelines similar to those used by the U.S. Preventive Services Task Force in judging the quality of research and therefore the quality of the
research conclusions should be used.\textsuperscript{23} If possible, therapeutic criteria should be based on data from randomized clinical trials and, when such data are not available, on the results of well-designed cohort or case control studies. Criteria also should be based on studies that include significant numbers of minority populations and older adults to ensure that the information is generalizable to as many older adults as possible.

Criteria for drug utilization review programs should be developed and reviewed periodically by a multidisciplinary team of experts, including pharmacists, physicians, pharmacologists, information management specialists, and representatives from the pharmaceutical industry. Although such a process may seem cumbersome, the tradition of peer review has generally served well and provides the best opportunity for high-quality therapeutic criteria. Furthermore, full participation in the process has the greatest likelihood of winning acceptance among the physicians and pharmacists who must respond to the warnings generated by a drug utilization review system.\textsuperscript{24}

Finally, an acceptable mechanism for following up on the warnings sent to physicians and pharmacists must exist. To achieve this, an independent, multidisciplinary review board could be established with several sets of responsibilities: (1) to review the appropriateness of warnings under question; (2) to ensure that physicians and pharmacists take action when appropriate warnings are issued; (3) to sanction physicians and pharmacists when their repeated failure to respond to appropriate warnings potentially endangers patients; and (4) to oversee an evaluation of the entire drug utilization review program. These characteristics were not described in the proposed rules for Medicare’s drug utilization review system.

Detecting adverse reactions in the elderly, Older adults often receive several medications. Many of them, particularly women with heart disease, hypertension, and arthritis, take as many nonprescription medications as prescription medications.\textsuperscript{25} In addition to the substantial cost of these drugs, age-related changes in both adult physiology and the ability to eliminate medication from the body often cause older persons to be at higher risk for drug overdosage and misuse. If therapeutic drug utilization review programs are to meet the special needs of the elderly and effectively improve their benefit from medications, they should include the following characteristics. First, therapeutic drug utilization review should be able to recognize most common and clinically significant potential drug/drug and drug/disease interactions in older adults. Second, therapeutic drug utilization review should be able to identify over- and underuse, as well as the potential for overdosage of the medication. Finally, drug utilization review databases should include a brief medica-
tion history, such as patients' allergies to medications or idiosyncratic reactions, and be used to alert physicians and pharmacists to the relative contraindications of prescribing or dispensing those medications.

In addition to these essential components, three other elements should be included in a therapeutic drug utilization review program. First, a program must be able to distinguish potentially severe reactions from those that might be relatively minor and to communicate this distinction to the physician and pharmacist, thus helping them know which warnings need resolution immediately. This element will be particularly helpful for prospective programs. Second, a program should be able to detect duplications at the ingredient level. For example, a patient who takes several nonprescription cold preparations with similar ingredients risks overdoses that should be detectable by therapeutic drug utilization review. Third, although interactions between medications and food are often important, they may be impractical for drug utilization review, except for the few situations in which medications and food can interact to cause severe adverse reactions. Because dietary information is not likely to have been recorded, programs would be limited to issuing general warnings.

Other advantages of drug utilization review. A national drug utilization review system would not only facilitate postmarketing surveillance studies (studies designed to identify adverse drug reactions that were not uncovered during the testing phase of the drug's history), but would also assist physicians in their responsibility to report adverse drug reactions. The types of databases that would be available in a drug utilization review program have been used to make important contributions to the understanding of adverse drug reactions, such as the demonstration of increased risk for depression among users of propranolol, increased risk of hip fracture among users of long-acting sedatives, and increased risk of gastrointestinal bleeding among users of nonsteroidal anti-inflammatory agents. In addition, calculating the risk associated with rare, but serious, adverse reactions will become feasible because the total number of patients taking the medication (the denominator) would be more readily and accurately calculated. Thus, drug utilization review could help to improve decisions about extending the indications for a medication or about allowing a formerly prescription medication to be sold over the counter. Postmarketing studies are particularly relevant for the elderly because older people are often poorly represented in premarketing clinical trials.

Finally, the results of therapeutic drug utilization review programs can form the basis of drug education programs for physicians and pharmacists, as well as older adults. For example, physicians who repeatedly
prescribe long-acting sedatives to older persons (thereby increasing the patients’ risk of falling and sustaining a hip fracture) could be targeted for education on the relative merits and complications of short-acting versus long-acting sedatives. Similarly, review systems could be used to empower older persons to prevent adverse medication reactions. Older people desire more information on health promotion and are often frustrated in their efforts to obtain high-quality information specific to their needs. 

Not all elderly take multiple medications or are at high risk for adverse medication reactions. Rather, those at highest risk tend to be very elderly women living alone and taking several medications at any given time. A drug utilization review system could target such high-risk elderly for interventions.

The effectiveness of drug utilization review. Although the technology exists to provide the components of a high-quality therapeutic drug utilization review programs and such programs are being adopted in both public and private sectors, they have not been adequately evaluated. Already, several pharmacies have well-designed drug utilization review programs, as well as the ability to link between pharmacies. Therapeutic drug utilization review is used by state Medicaid programs, large corporations, HMOs, and hospitals. The few available evaluations report decreases in hospitalization rates and hospital length of stay after implementation of drug utilization review programs. In the request for applications on Pharmacology in Geriatric Medicine, the National Institute on Aging requested proposals on the evaluation of drug utilization review. If that request does not yield studies to evaluate this new technology, it should remain a high priority on the aging and health services research agenda.

In summary, therapeutic drug utilization review systems deserve thoughtful consideration by policymakers. If properly designed and implemented, they hold promise to make physicians and pharmacists more effective in delivering the right drug for the problem. However, care must be taken to involve the professional communities in the development of review criteria. This involvement will not only ensure the best possible criteria for the elderly but will also enhance acceptance by physicians and other professionals.

Enthusiasm for drug utilization review programs must be tempered by an understanding of their limits. A carefully designed, scientifically based program would seem to have the power to reduce the number of adverse drug reactions. However, as with the recent catastrophic coverage legislation, the professional community will have reservations and resistance if drug utilization review programs are not perceived to have the scientific base to be helpful.
Cost-Effectiveness As A Criterion For Drug Policy

Concern has been expressed about the degree to which economic analysis of pharmaceuticals will be used in policy decisions about their approval, coverage, and provision. FDA has clearly interpreted its charge by Congress to exclude the use of cost-effectiveness analysis in its decisions about approving pharmaceuticals.

However, FDA could use data on efficiency, even if the more limited role of cost-effectiveness information were accepted. For example, such policies would enable a drug with an important economic impact to be moved through more quickly, as is currently the case for drugs addressing unmet medical needs. In addition, FDA could consider using data on efficiency to guide the language in the package insert, which describes the indications for drugs and the relative importance of various adverse events. Inclusion of these data would encourage presentation of information in drug utilization review criteria. Thus, even if the information on efficiency is not to be used in the drug’s release to the market, the way in which the drug is used is likely to be influenced by economic considerations. Guidelines and review of economic analyses could assure that standards of quality and assurances of investigators’ independence are similar to the standards for efficacy and safety. In the future, as concern grows about introducing new drugs that have little clinical value compared with available agents, information on the economic impact of pharmaceuticals should become much more integrated into the new drug approval process. If economic factors were considered in new drug approval, then regulators might become more concerned about whether more liberal approval of similar drugs would lead to increased competition on the basis of cost.

In the decision about whether to cover a pharmaceutical product in programs that pay for prescription drugs, use of cost-effectiveness data might be considered. For example, some state Medicaid formularies already use cost-effectiveness analysis in determining whether they will cover a drug. Even so, the consideration of economic factors in these decisions is often rudimentary and sometimes misguided. Often the only costs considered are those of the drug and the disease that it is intended to treat. Much less often considered are the other economic impacts of pharmaceuticals, such as the costs of dispensing, preparing, and monitoring the drug; the costs of managing adverse events; or the savings of using medical therapy rather than surgery. The inclusion of drug benefits in a package of benefits would allow use of these data to guide cost-effective decision making.

Finally, the question arises whether individual physicians should use cost-effectiveness analysis in their decisions about which drugs to pre-
Some ethicists argue that physicians should not have to consider cost-effectiveness analysis but rather should follow guidelines provided by expert groups who have analyzed the cost-effectiveness literature. This simplistic approach is unrealistic in suggesting that guidelines and practice parameters will be promulgated to guide all clinical decisions made by physicians in daily practice. Physicians will need to consider cost-effectiveness analysis in their daily decisions, including those concerning pharmaceuticals. Availability of high-quality, rigorous cost-effectiveness analyses can only improve the doctor/patient encounter.

Summary And Policy Implications

The large numbers of older adults with adverse drug reactions or who are at risk of medical indigence because of high out-of-pocket medication costs will continue to seek financial relief from policymakers and the medical community. Thus, a drug benefit for older adults is as necessary a part of future health policy as is improving the quality of health care through more effective prescribing by physicians.

Because physicians are price-sensitive, an expanded drug benefit is likely to result in the writing of more prescriptions. For this reason, copayment should help counter physicians’ tendency to write more prescriptions. However, because cost-containing strategies that impose administrative barriers between patients and their physicians (such as prior approval and formularies) may weaken the already fragile patient/physician relationship, other strategies such as copayments are preferable. Drug benefits that are not neutral with regard to physicians’ incentives to substitute medications for other therapies or to actually dispense medications should be implemented with caution because of the potentially negative impact on the doctor/patient relationship and, more importantly, on the quality of care. Therapeutic drug utilization review, although promising, should be implemented only when the therapeutic criteria have been developed and reviewed by experts who can attest to the quality and relevance of these criteria to the elderly; when the data on which the therapeutic drug utilization review program relies provide reliable information on diagnoses; and when a rigorous evaluation of its cost and effectiveness by an outside evaluator is incorporated in the implementation plan.

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