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purchase even longer and expose the purchaser to further embarrassment. Moreover, many potential users of all ages — particularly poor women and those from inner-city neighborhoods — have no driver's licenses. Such women would not be able to obtain emergency contraception even if they were older than the arbitrary age limit set by the FDA.

Finally, it is likely that because of the age restrictions, many pharmacies would choose to hold their entire stock of Plan B "behind the counter" to ensure that all purchasers had to document their eligibility. American women should not have to explain their need for such a product in public, in front of their neighbors and friends, at such a painful, frightening, and vulnerable time.

This is a sad day for American women and for the FDA. In the absence of data to support their original decision to reject the advice of their advisory committee and their own staff analysts, one can only speculate about the real reason for the actions of the agency's leadership. Their subsequent delays, dissembling, and shifting justifications of their regulatory maneuvering and manipulation have resulted in the resignation of Susan F. Wood, the assistant FDA commissioner for women's health and director of the agency's Office of Women's Health. Wood's departure is a statement of protest against the decision by the FDA management to bow to political pressure at the expense of women's health.

The FDA has, on occasion, been criticized for being too bureaucratic and slow to approve important new drugs, too quick to approve new drugs to please the corporate patrons who provide much of its budget, and too slow to withdraw drugs that seem to pose a danger to public health. But the agency has previously resisted political pressure to reflect a particular social policy or ideology. The recent actions of the FDA leadership have made a mockery of the process of evaluating scientific evidence, disillusioned many of the participating scientists both inside and outside the agency, squandered the public trust, and tarnished the agency's image. American women and the dedicated professionals at the FDA deserve better. Will we ever again be able to believe in the FDA's independence?

Dr. Wood is a professor of medicine and pharmacology at Vanderbilt University School of Medicine, Nashville, and was a member of the FDA Advisory Committee on Nonprescription Drugs; Dr. Drazen is the editor-in-chief of the *Journal*; and Dr. Greene is an associate editor of the *Journal* and was a member of the FDA Advisory Committee on Reproductive Health Drugs.

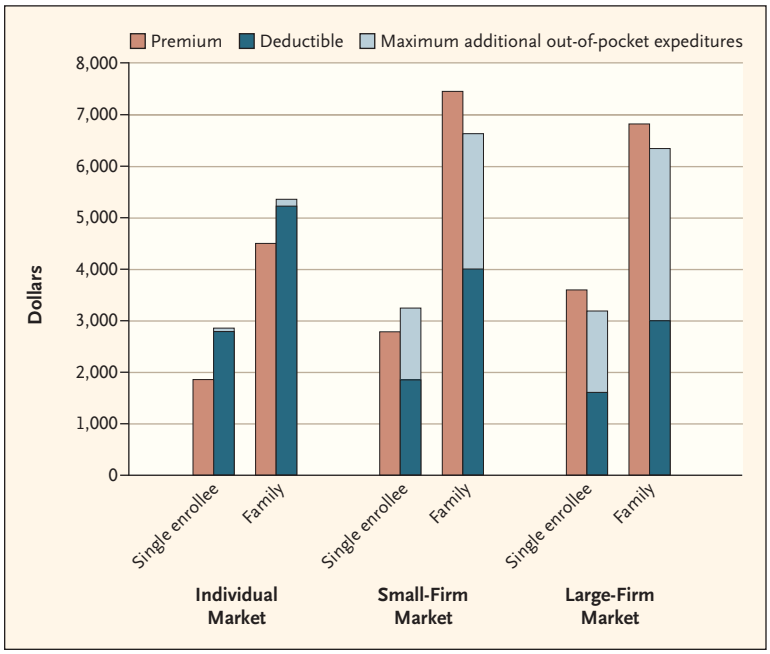
1. Nonprescription Drugs Advisory Committee. (Accessed September 1, 2005, at http://www.fda.gov/ohrms/dockets/ac/cder02.htm#NonprescriptionDrugs.)

Health Savings Accounts — The Ownership Society in Health Care

James C. Robinson, Ph.D.

When President George W. Bush, in his second inaugural address, described his vision of an "ownership society," he specified not only the ownership of homes, businesses, and retirement savings, but also that of health insurance. Today, the most visible embodiment of this goal in the health care sector is the health savings account (HSA), which reflects a philosophical shift in emphasis from collective to individual responsibility for the management and financing of care. HSAs form the core of the emerging "consumer-directed" insurance plans, imposing greater cost sharing on enrollees but permitting broader choices than the health maintenance organization (HMO) plans of the managed-care era. Although they are compatible with employment-based insurance, HSAs were authorized by the Medicare Modernization Act of 2003 in part to facilitate a shift toward tax-favored but individually purchased coverage.

The HSA is a financial vehicle, akin to an individual retirement account, to which contributions may be made with pretax dollars and from which balances may be withdrawn to pay medical claims, again without payment of tax. If not spent in the year they are made, contributions accumulate, are invested, and can be spent on health services in subsequent years. Unspent balances belong to the account holder, not the employer, and can be moved when the enrollee leaves his or her job. Funds can be spent only on ser-



Average Annual Premiums, Deductibles, and Out-of-Pocket Spending Limits for Single and Family Enrollees of Health Savings Account (HSA)–Based Insurance.

The average lifetime maximum benefit with individually purchased HSA-based insurance is $4.0 million for a single enrollee and $4.3 million for a family; the corresponding benefits with a plan purchased by a small employer are $3.4 million and $3.5 million, respectively. With a plan purchased by a large employer, the average lifetime maximum is $2.1 million for either a single enrollee or a family. Data are from the Center for Policy and Research, America's Health Insurance Plans.

vices considered by the Internal Revenue Service to be medically related, but the range of qualified services is broader than that often covered by insurance policies and may include dental, vision, and complementary medicine services, for example. The HSA expands the tax preference for health-related expenditures beyond the premium paid by the employer to encompass the out-of-pocket costs incurred by the employee, and it can easily be used by persons who purchase their own insurance without an employer subsidy.

HSAs receive favorable tax treatment only when they are accompanied by an insurance policy with a high deductible, typically managed by a preferred-provider organization (PPO), to cover the expenses of catastrophic illness. By law, HSA-compatible deductibles must be at least $1,000 for an individual and $2,000 for a family, but substantially higher deductibles can be found in the insurance market. As of March 2005, the deductible for the most prominent HSA products purchased in the individual (nonemployer) market averaged $2,790 for single persons and $5,230 for families.[1] When paying for medical services, the enrollee first uses funds from the HSA, until the balance is exhausted, and then uses personal, after-tax income (the so-called doughnut hole) until expenses reach the deductible threshold. The enrollee then continues paying part of the costs incurred, typically 20 to 30 percent, until an annual maximum for out-of-pocket payments is reached, after which the PPO pays all costs.

When combined in this fashion with a high-deductible insurance policy, the HSA is referred to as a consumer-directed health plan. Consumer-directed designs were pioneered by entrepreneurs who were frustrated with the products and policies of managed care. Over time, however, the new designs have been incorporated into the portfolios offered by the dominant insurers, with the savings account sometimes managed by an affiliated banking institution. Most enrollment is still in employer-controlled arrangements for health care reimbursement, in which the unspent balance reverts to the company rather than to the individual, but enrollment in employee-controlled savings accounts is spreading rapidly. Total enrollment in both types of products among all insurers, as of March 2005, was 2.6 million. The largest vendors of consumer-directed products are currently UnitedHealth Group (865,000 covered enrollees), Aetna (370,000 enrollees), and the various Blue Cross and Blue Shield plans (400,000 enrollees).[2,3]

Most enrollment in HSAs comes from persons purchasing coverage outside the employment context. As compared with policies purchased by small companies or large corporate employers, individually purchased HSA products tend to have higher deductibles and lower premiums (see graph), in large part because individual subscribers are subject to underwriting and are not issued policies if they have substantial health problems or a history of using medical care services.

Employers are more likely to purchase health care–reimbursement arrangements than HSA products, in order to retain unspent balances if a worker quits or is fired.

Much of contemporary medical care involves an element of discretion in the decision to seek care and in decisions about the type of provider (e.g., generalist or specialist), the care setting (e.g., inpatient or outpatient), and the type of product (e.g., brand-name or generic drug). HMOs placed their cost-control emphasis on the physician side — using selective physician networks, capitation payment, and utilization controls — rather than on the consumer side, where demand was stimulated by comprehensive benefit designs. This asymmetric incentive structure contributed to the backlash against HMOs, since patients were led to believe that they had unrestricted access to care — but discovered restrictions when they sought to use high-cost services. Consumer-driven product designs reverse the targeting of economic incentives, increasing cost sharing for patients but relaxing the network restrictions, capitation payments, and prior-authorization features of managed care.

The principal challenge to such products as a mechanism for cost control is that they focus their incentives on low-cost primary care services rather than on high-cost tests and specialist interventions. The majority of health care expenditures are incurred by the relatively small fraction of patients with the most severe conditions who have spent beyond their deductible and, in many cases, beyond their annual out-of-pocket maximum. There is considerable variation in the pattern of use for high-cost procedures, yet consumer-directed designs do not impose limits on such procedures after their costs exhaust the HSA and exceed the out-of-pocket maximum. In principle, products with high deductibles could be combined with managed-care mechanisms that target high-cost services. Some health insurance plans are experimenting with new network designs, medical-management programs, quality-based payments, and incentives for the adoption of information technology.[4]

The principle of insured services is "use it or lose it." If a healthy enrollee does not use medical care, the financial benefit goes to sick enrollees who incur claims in excess of their premium payments, instead of remaining with the healthy enrollee. HSA products limit this pooling of health risk to funds that are spent on the high-deductible PPO, whereas contributions to the HSA remain the property of each enrollee. This "use it or save it" principle increases enrollees' responsibility for costs incurred in their own care but decreases their responsibility for costs incurred in the care of strangers.

HSAs thus shift the locus of rights and responsibilities for financing health care from governments and employers toward individual consumers. As the personal property of each person, HSA funds are not a benefit provided by a third party. This shift reduces the potential scope of debate and legislative mandates concerning covered services. The shift from group to individual payment is analogous to efforts to translate part of the Social Security insurance structure into personally owned and managed retirement accounts. More broadly, the HSA is part of a vision that would increase authority for the individual in all aspects of society, with a commensurate reduction in authority for employers and government.[5]

HSA-based designs are compatible with consumers' desires for control in a world where someone needs to decide which patients will receive which health care services now, which later, and which never. The efforts in the managed-care era to delegate the setting of priorities to employers and insurers failed in part because these payers lacked the social legitimacy to perform ethically and emotionally charged tasks. Most industrialized countries assign the responsibility for setting health care priorities to the government, which uses price controls and capacity limits to restrain expenditures. Americans, however, tend to be skeptical of both big business and big government; many believe that the individual citizen is the appropriate setter of health care priorities. But although some persons can and will function effectively as consumers of health services — pursuing information about quality, comparing prices, and balancing care received today against care that may be needed tomorrow — others will fare less well.

HSAs and other consumer-directed products are receiving widespread attention and undergoing rapid growth, albeit from a small base. Regardless of its eventual market share, the HSA represents a milestone in the ongoing debate about health care reform. Increased cost sharing may cause underuse of effective

health care but may also attenuate overuse of discretionary services by fostering greater awareness of costs. The shift from insurance to savings raises concerns about the distribution of financial responsibility between the healthy and the sick, but it salutarily highlights the imperative to adjust pay-as-you-go entitlement programs according to the demographic realities of an aging population and the budgetary realities of costly technology. The language of individual ownership weakens society's sense of collective responsibility for its most vulnerable members but emphasizes the importance of individual effort in generating the economic resources that underlie any system of care. The HSA moves the nation another step toward a personalized and privatized health care system.

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Do High-Deductible Health Plans Threaten Quality of Care?

Thomas H. Lee, M.D., and Kinga Zapert, Ph.D.

Employers struggling with rising health care costs are implementing their strategy for the post–managed-care era — a shift of costs and responsibility to the consumer. As Robinson describes in this issue of the *Journal* (pages 1199–1202), this shift is likely to be accelerated by the spread of health savings accounts, which are expected to encourage as many as 25 percent of privately insured Americans to enroll in "high-deductible health plans" by the end of the decade. With these insurance products, patients bear a substantial portion of their health care costs ($1,000 or more per year for individuals). Advocates of these products hope that they will do more than shift part of the increase in health care costs to the patient: they believe that financial incentives will turn patients into "activated consumers" who exert pressure on health care providers to improve the efficiency and quality of care.

This approach raises a number of questions. First, are consumers capable of assuming the majority of the responsibility for making decisions about their own health care? Enrollment in high-deductible plans is still low, but it is increasing rapidly, and some tools for comparing hospitals and physicians are already available on the Internet. But will turning patients into consumers actually improve the outcomes of their care? Or might the health of financially concerned patients suffer because they choose not to seek care or not to adhere to medication regimens?

For critics of consumer-directed health plans, these questions were answered two decades ago. The RAND Health Insurance Experiment showed that cost sharing (requiring out-of-pocket expenditures by the patient) reduces costs by lowering health care utilization — but that it has some undesirable consequences. As compared with the provision of free care, cost sharing reduced the percentage of low-income adults who sought "highly effective care for acute conditions" by 39 percent[1] and was associated with worse blood-pressure control and less reliable use of preventive care measures such as Pap smears. In this early trial, patient-consumers did not appear to be able to differentiate necessary from unnecessary care.

Subsequent research confirms that increasing costs for patients leads to decreases in medical expenditures, but the decreases affect care that is strongly supported by evidence as well as interventions that have questionable value. After Medicare instituted reimbursement for mammography in 1991, women with supplemental insurance that covered out-of-pocket costs were found to be two to three times as likely to undergo breast-cancer screening as were women who lacked such coverage.[2] Data from the Medical Outcomes Study showed that patients with low or high copayments were