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Paying for Medical Value:
A Better Outpatient Prescription Drug Benefit for Medicare

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A number of proposals for including an outpatient prescription drug benefit in Medicare are currently under consideration in Washington. Yet, while the question of what is covered must be at the heart of a successful drug benefit, it is an afterthought in most existing proposals.

This issue brief proposes a different standard for the design of a Medicare benefit: the medical and therapeutic value of the medications covered.

Why a Benefit Is Needed

The need for an outpatient prescription drug benefit for Medicare beneficiaries has been well-documented.[1] The importance of including drug coverage in the federal health insurance program for seniors and the disabled is growing, even as the government's fiscal situation worsens.

About 27 percent of Medicare beneficiaries, perhaps more, currently lack drug coverage altogether.[2] The remainder receive coverage through employer-sponsored plans, supplemental insurance (Medigap), Medicare+Choice plans (Medicare's managed care program), or through other government programs such as Medicaid or the Veteran's Administration health system.

Medicare beneficiaries are the only major *insured* population in the United States who do not receive prescription drug coverage through their primary insurer. Like the uninsured, beneficiaries without supplemental coverage may pay the full list price for drugs unless they qualify for a manufacturer's discount card. As a group, seniors and the under-sixty-five disabled have low incomes (over one-third made less than $16,000 annually in 1998) and modest savings. They suffer from more chronic illnesses, such as diabetes or hypertension, than younger Americans. Thus, they are more likely to benefit from access to newer, more effective, and more expensive drugs and less likely to be able to afford them.[3]

When Medicare was enacted in 1965, the program was modeled on private plans that did not cover outpatient prescription drugs or did so on a limited basis. Drugs now occupy a much more prominent place in the clinical arsenal. They are increasingly used in lieu of surgery and to treat chronic conditions. Breakthrough medications include statins that lower cholesterol and help prevent heart disease and strokes, retroviral drugs that manage AIDS, antidepressants, and anticonvulsant drugs that help control epileptic seizures. As these more versatile drugs were developed and marketed, Medicare failed to keep pace with private sector insurance plans, which generally added outpatient drug coverage over time.

Overcoming the Flaws of Current Proposals

Existing proposals for a drug benefit are flawed in important ways. Plans that envision a benefit within the existing Medicare program are too indiscriminate in the drugs that they would cover. They also are too willing to subsidize the spending of beneficiaries from the first dollar spent on drugs, a feature that may encourage excessive use of prescriptions. On the other hand, plans that leave the issue of access to drugs up to

Headquarters: 41 East 70th Street * New York, NY 10021 * 212.535.4441 * 212.535.7534 (fax) * info@tcf.org
DC Office: 1755 Massachusetts Ave., NW * Washington, DC 20036 * 202.387.0400 * 202.483.9430 (fax) * info@tcf.org
www.tcf.org www.medicarewatch.org

the private marketplace confront the likelihood that many, if not most, of those in need of drugs will not have access.

Taken together, these approaches contribute to the impasse over the enactment of a possible Medicare drug benefit—and to the likelihood that a benefit, if enacted, will lead to runaway expenditures or to high unmet needs, or both.[4]

While many prescription drugs are undeniably of great clinical usefulness, many treat less serious conditions. Others represent new brand-name versions closely related to earlier patented compounds—so-called "me-too" drugs.[5] Some newer drugs are chemically distinct from earlier drugs and therapeutically unique. Others have substitutes—generics (drugs that have the same chemical ingredient as a brand-name drug whose patent has expired) or lower-cost brand-name products—that may be prescribed to most people without resulting in complications.

The government should be willing to absorb large drug costs related to therapies that are potentially lifesaving and critical for the preservation of basic functions among seniors and the disabled.[6] It should not be willing to subsidize such costs for drugs that are principally about the management of symptoms (such as Claritin for allergies, Prilosec for heartburn, or Viagra for impotency).[7]

The point is not to argue that such medications are without merit, or to minimize the relief they afford to sufferers. It is instead to determine whether they are worth supporting through a large taxpayer subsidy, in addition to the premiums charged for coverage.

By covering the drugs most necessary for medical care, this value-based approach is most likely to result in long-term savings to the Medicare program by forestalling spending on hospital care and physicians' services. While cost savings are not the principal justification behind this plan, costs matter a great deal. Both public payers (such as Medicaid) and employers have experienced double-digit annual percentage growth in drug expenditures over the past two years. Government payers cannot sustain such increases without shifting resources from other desired goals (such as education or defense) or raising taxes. Employers cannot absorb these escalating expenses without shifting costs to their employees, forgoing wage increases, or dropping insurance coverage altogether—especially in the case of smaller businesses.

Unlike setting relatively indiscriminate price caps on expensive new drugs, paying for medical value would be less likely to jeopardize the process of innovation in drug research and development that is so critical to bringing breakthrough treatments to market. Instead, this policy could influence the pharmaceutical industry to focus its research and development (R&D) dollars on drugs that will have the most medical significance, not those most suitable to a direct-to-consumer marketing campaign.

How the Plan Would Work

- Like Medicare Part B, the program that pays for physicians' services, this drug benefit would be voluntary. Beneficiaries would be eligible to elect this coverage at age sixty-five or when they qualified through disability.
- Coverage decisions would be made by a new Pharmacy Benefits Board.[8] There is some precedent for doing this under Medicare, as the program already makes recommendations for new coverage of drugs administered in a hospital through the Medicare Coverage Advisory Committee (MCAC).
- The board would create and maintain a managed "open formulary." A formulary is the list of drugs that a particular insurer covers and recommends for prescription. Closed formularies limit enrollees in an insurance plan to only those drugs approved by an insurer. Open formularies, by contrast, do not exclude drugs but may designate particular drugs as preferred through varying the out-of-pocket cost paid by an insured individual.
- Drugs covered under the benefit would be placed in several different tiers of coverage. Each tier would feature a different level of copayment (a flat fee paid before insurance begins payment) or coinsurance (a percentage of the total cost of a drug or medical service paid by the beneficiary). For example, unique brand-name drugs or generic equivalents designated as the best or most critical in their

therapeutic class would be available with a low copayment. Equally effective but more expensive prescription drugs in a critical therapeutic class, or effective drugs in a less important class, would carry coinsurance payments of 20 to 50 percent (much like other medical procedures under Part B of Medicare). Food and Drug Administration (FDA)–approved drugs deemed to have minimal therapeutic or clinical value would require the beneficiary to pay full price—presumably a discounted price, depending on the buying power of the Medicare program.

- Some of the drugs that are most effective on a population-wide basis do not work for a few individuals or become less effective over time. More so than younger adults, seniors may not respond well to the therapeutic substitution of one chemically similar drug for another.[9] For this reason, beneficiaries would be able to make an appeal for a substitute drug as a medical exception when supported by a physician. If the appeal is approved by Medicare, the beneficiary would pay the lower cost-sharing typical of the preferred drug in that class.
- The management of the plan would be undertaken by a new division within the Centers for Medicare and Medicaid Services. While pharmacy benefits managers (PBMs) ordinarily manage drug benefits for employers, Medicare should be able to negotiate better prices, educate consumers, and steer beneficiaries toward more judicious use of drugs more effectively than these private companies.[10]
- In addition to coinsurance or copayments, beneficiaries would pay a deductible (the annual amount that an individual must pay out of pocket before insurance begins to pay for his costs) of around $250 and a uniform monthly premium of $35 to $40. After the beneficiary had spent $4000 out of pocket, stop-loss protection would begin. Such protection would be adjusted as necessary due to inflation or the rising cost of pharmaceuticals. (Roughly 6 percent of beneficiaries incur annual out-of-pocket costs that exceed this amount.[11]) Premiums and most cost-sharing would be waived or reduced for those Medicare beneficiaries with incomes of 150 percent or less of the federal poverty level. These features are similar to those incorporated in many proposals for a Medicare drug benefit over the past several years.

How this Plan Resembles, and Differs from, Models Currently in Use

Elements of this plan resemble features of prescription drug coverage programs that are operating in other developed countries. The health systems of many European countries select a preferred drug in various therapeutic classes and cover all or most of its cost to users.[12] If a patient wants to use a different drug, he must pay the difference in price between the preferred drug and the alternative. Some analysts have proposed that Medicare adopt a version of this "reference pricing" scheme.[13]

The administrators of Michigan's Medicaid program have proposed a version of reference pricing for their state. They have commissioned a medical panel to select no fewer than two "best in class" drugs in each of forty therapeutic categories. The state will reimburse fully for these medications regardless of their price. This controversial plan would restrict the formulary to these drugs unless pharmaceutical manufacturers match the price of the approved product, lowering the price of a higher-priced drug if necessary. (PhRMA, the trade association for the pharmaceutical industry, has challenged this plan in court.[14])

Most countries with a national health plan possess a version of the pharmacy benefits board that sets pharmaceutical coverage and reimbursement policies. The most relevant model is Australia's Pharmaceutical Benefits Scheme. Under this plan, which has been in operation for more than fifty years, the board and its committees decide which drugs qualify for coverage based on criteria including cost-effectiveness relative to other treatments. The board also oversees educational efforts aimed at physicians and beneficiaries.[15] Similarly, the National Institute for Clinical Excellence was inaugurated in Great Britain in 1999 to report to the National Health Services on the clinical value of new therapies and other treatments, including prescription drugs.

Other nations increasingly require pharmaceutical manufacturers to provide evidence of cost-effectiveness as a condition of approving a drug and placing it on a national formulary. Like drug approval bodies in other countries, the Pharmacy Benefits Board can be expected to use cost-effectiveness criteria to determine on

which tier of the formulary a drug belongs. The board, however, will also consider other factors, such as the importance of a particular medication to very sick or terminally ill Medicare patients.[16]

Like these approaches, the plan proposed here aims to place the most important drugs in some classes in a preferred category for purposes of reimbursement and beneficiary cost-sharing. Unlike most reference pricing schemes, however, it will not insist that manufacturers lower the prices of their drugs as an incentive for inclusion on the formulary. Michigan's proposal, for example, employs this design with the aim of cutting costs for a financially strapped public program.

This plan relies more heavily on beneficiary cost-sharing and consumer choice among different drugs than do its counterparts in other countries. In this respect, it resembles multi-tier drug benefit plans increasingly used by U.S. employers. It also resembles the higher payment a patient makes when seeing an "out-of-network" physician in a preferred provider health plan.

One objection to this approach is that consumers tend to reduce their consumption both of medically necessary and less necessary therapies when coinsurance or copayments are demanded. This concern carries less weight in this context because the most vital drugs already will have the most favorable cost-sharing under the plan. Researchers have found that the overall use of antihypertensive drugs did not decrease among seniors after reference pricing was introduced in the Canadian province of British Columbia.[17] Moreover, the price differential between the preferred drug and alternative drugs will generally be narrower under this plan than in a traditional reference-pricing scheme, in which the patient pays the full difference in cost between the reference drug and the alternative.

An Example of How This Plan Might Work

An illustration may help to suggest the differential value of prescription drugs and the potential workability of this design.

Two of the most important breakthrough drug categories of recent years are angiotensin-converting enzyme (ACE) inhibitors and antihistamines. The former (known to the public through brand names like Capoten, Univasc, and Vasotec) are antihypertensives used to treat high blood pressure, a condition that is a major cause of heart attacks and strokes. The latter (for example, Claritin and Benadryl) are used to relieve or prevent the symptoms of hay fever or other allergies.[18]

It would be reasonable to give ACE inhibitors a higher preference in Medicare coverage and reimbursement policy than antihistamines. The former are potentially lifesaving therapies while the latter are aimed at treating symptoms, albeit irritating and painful ones. This is not an idiosyncratic judgment. For instance, when 225 leading doctors of internal medicine were asked which of thirty medical innovations of the past few decades would be most and least missed if unavailable, ACE inhibitors ranked second from the top while nonsedating antihistamines ranked second from the bottom.[19]

Evidence from employee benefits managers suggests that a substantial portion of spending takes place on drugs that palliate symptoms rather than addressing underlying medical conditions. This is often the case for new brand-name drugs, which are frequently similar to "blockbuster" drugs that are on the verge of losing patent protections. Schering-Plough, for example, has recently launched Clarinex as a would-be replacement to Claritin, its best-selling antihistamine.

A drug benefit proposal based on medical value is radical in just this respect: certain classes of drugs would be preferred over others in the scheme, in addition to designation of the most effective drugs in a number of particular categories. This feature is essential if Medicare spending is to make the biggest difference to the health of its beneficiaries and to influence pharmaceutical companies to target their drug research and development in this direction as well.

Other Advantages of This Design

The design of this value-based plan, including its stop-loss protection, will contribute to Medicare's importance as an insurance program. For the growing percentage of seniors who incur high and medically necessary costs on prescription drugs, the absence of such coverage within Medicare can lead to financial ruin.

The benefit caps that are prevalent in most supplemental drug coverage run counter to the principles of insurance coverage and to good medical judgment. In the words of James Grisolia, a San Diego-based physician, "Medication caps have the opposite effect from what insurance is supposed to do. A $2,000 cap on annual benefits means that short-course antibiotics and other incidentals are picked up by your plan, but if you are unlucky enough to develop an expensive disease like multiple sclerosis, Alzheimer's, or refractory epilepsy, you're on your own."[20]

Designing a benefit that relates the coverage of prescription drugs to their therapeutic value also has advantages over a benefit targeted only to lower-income Medicare beneficiaries and to those who lack coverage. Under an income-related plan, Medicare would have less leverage to use its buying power to influence the kinds of pharmaceuticals that come to market. Because the incomes of most Medicare beneficiaries are closely clustered, distinguishing those who "deserve" subsidies from those who could afford supplemental coverage would be difficult and somewhat arbitrary.

Preventing the Misuse of Prescription Drugs

Adverse interactions among drugs result in illness, disability, and death for many Americans. Older Americans are the most likely to experience such adverse effects.[21] Researchers at the Agency for Healthcare Research and Quality estimate that more than one in five seniors received prescriptions that were inappropriate or dangerous because of potential adverse interactions.[22] Another study published in the *New England Journal of Medicine* estimated that $1.25 was spent on treating the side effects of medication for every $1 spent on these drugs.[23] Seniors spend the most on prescriptions and take more prescription cycles (an average of twenty-two annually) than younger adults.[24] They also are more likely to have mental and physical impairments that may hinder their ability to follow the detailed package instructions and warnings.

This proposal would include efforts to reduce pharmacy errors, prescribing errors, and inappropriate use of medications. Such errors are blamed for seven thousand deaths annually among the U.S. population as a whole.[25] These efforts would draw on multiple initiatives that are under way in both government and the private sector. For instance, an Internet-based system is being constructed to allow doctors to send their prescriptions directly from their computers to a pharmacy, avoiding the errors caused by famously unreadable physician handwriting.[26]

Addressing Objections to This Plan

The feasibility and strengths of this plan can best be assessed by exploring the most serious objections that are likely to be raised against it.

The evidence for distinguishing the effect of one drug from another on outcomes is insufficient to make decisions of this kind.

The relative lack of authoritative studies on the clinical value of drugs is a valid area of concern. Few current studies definitively show the relationship of drug therapies to medical outcomes, though the field of pharmacoeconomics—the study of the clinical value of drugs relative to their cost—is growing rapidly. This really argues, however, for flexibility and modesty in coverage decisions, at least as the new program is finding its way, not against the value-based approach altogether.

Such an approach would be a boon to research. Wouldn't an evidence-based standard stimulate drug manufacturers to sponsor studies that track the performance of a drug in an actual population? At present, driven by profit concerns related to the length of patent coverage and the timing of patent expirations, much of the industry's spending is directed toward clearing the hurdles of the FDA approval process. However, spurred in part by the prospects of gaining access to European and other markets, companies are stepping up their spending on studies that demonstrate a drug's effects (including effects not considered under the drug's original application for patent approval) after its introduction. The FDA also could become more involved in this post-launch evaluation. Its employees

possess a wealth of knowledge—and the agency has an immense institutional knowledge of the effects of drugs—that is largely untapped for this purpose.[27]

A related concern is that it is impossible truly to distinguish drugs of great medical value from those that have relatively little impact on health. At the margin, this is certainly true. Moreover, some patients will fail to respond to medications that work for most of the population as a whole. However, physicians and pharmaceutical experts should be able to reach a reasonable consensus that distinguishes between the value of broad classes of medications for most beneficiaries, as suggested above.

The benefit will be too expensive.

In March 2002, the Congressional Budget Office estimated that seniors are expected (in the absence of a Medicare drug benefit) to spend $1.8 trillion on prescription drugs during the ten-year period from 2003 to 2012.[28] This large price tag primarily reflects the introduction of new and higher-priced pharmaceuticals, greater intensity of use, and, to a lesser extent, rising prices for existing drugs. Such figures give pause to legislators who are contemplating the possible inclusion of a drug benefit in Medicare. In addition, a benefit that represented a substantial fiscal commitment might not satisfy Medicare beneficiaries.

One advantage of defending a value- and evidence-based approach to medication coverage is that very high spending may be justified—and may be justifiable to the public—if it is seen to be contributing to better health and longer life for seniors.

But there are also reasons to believe that, over time, a benefit organized around this principle will result in some substantial savings and not just additional expenditures for Medicare. As policy experts point out, evidence-based medicine—"the adoption of medical practices whose effectiveness has been demonstrated in a convincing body of well-designed studies"—is not principally a cost-containment measure, because it can and will justify high spending on expensive but groundbreaking therapies.[29] However, it has considerable promise for reducing costs as well.

For instance, effective drugs could reduce the need for expensive hospital care and physician services. Using a detailed survey that tracks hospital and drug use and spending as well as measures of morbidity and mortality, Columbia University researcher Frank Lichtenberg recently concluded that "Use of newer drugs tends to reduce all types of nondrug medical spending, although the reduction in inpatient spending is by far the largest."[30]

A study of Medicare enrollees suffering from hypertension—which, if untreated, can greatly increase the risk of strokes, heart disease, and kidney failure—found that those without any drug coverage were 40 percent more likely not to purchase any hypertensive medicines than those with drug coverage.[31] This suggests that covering them would result in lowered costs over time elsewhere in the medical system.

The health care analyst J. D. Kleinke points out that different kinds of drugs have different profiles in terms of clinical effects and the value delivered. Some drugs—such as anticoagulants, which prevent strokes—save money in the short-run. Others—such as estrogen modulators, which may delay the onset of osteoporosis in seniors, and antihypertensives—may save money in the long-run. Drugs such as cholesterol reducers and most vaccines increase aggregate medical costs because the number of users and the volume of drugs used is very high, yet such medications probably result in substantially lower spending on hospitals and physicians. Many drugs also reduce nonmedical costs such as absenteeism in the workplace.[32]

When deciding on appropriate coverage policy in a possible Medicare benefit, these differential clinical effects and cost scenarios over time need to be carefully weighed. A public insurer like Medicare should be able to take a longer and broader view of the medical and social balance sheet than, say, a for-profit health maintenance organization, which must justify its returns to investors on an annual or even quarterly basis.

The number of truly breakthrough drugs, those that include "new molecular entities," (NMEs), is quite small—fewer than one in five drugs released. Spending is relatively high on such drugs but it is considerably less in the aggregate than for drugs in other categories. The National Institute for Health Care Management recently calculated that 33 percent of new drug spending in 2002 was devoted to breakthrough drugs, while 67 percent went to other prescription drugs.[33] This suggests the possibility of keeping Medicare's costs down under this approach. Other countries, such as Australia, that use a pharmacy board and a somewhat similar scheme are experiencing double-digit annual percentage increases in drug costs. But these nations, unlike the plan suggested here, impose minimal or no cost-sharing requirements, especially for seniors.[34]

The broader use of generic drugs envisioned by the plan also could save money in a Medicare drug benefit. Researchers at the Schneider Institute for Health Policy at Brandeis University have estimated that the Medicare program could save up to $250 billion over a ten-year period by encouraging substitution of lower-cost generics for higher-cost brand-name drugs.[35] This could be accomplished in part by use of the multi-tiered copayments of the kind suggested here. Such designs are gaining popularity in employer-sponsored plans. John Rother, director of policy and strategy for the AARP, the largest association of older and retired Americans, notes that "many consumers today are being pushed inappropriately toward name brand drugs when generics would be just as effective, just as safe, and cheaper."[36]

Pharmaceutical companies have subverted the intent of the 1984 Hatch-Waxman Act—which was intended to promote the swift introduction of generic drugs into the marketplace after brand-name drugs came off patent—by paying off generic producers to file but not actively pursue the legal challenges on which the law relies. Reform of this act would make generic substitution easier and more effective and ultimately reduce the cost of a possible Medicare benefit.[37]

Finally, the profile of drug spending in Medicare, in which a small proportion of beneficiaries accounts for the lion's share of overall drug costs—as is typical for health care in general—suggests opportunities for reducing pharmaceutical use through a regimen of disease management and behavioral change. For example, the Brandeis research team has found that just two medications—Prilosec and Prevacid—accounted for almost 15 percent of the cost increases for seniors whose expenditures on drugs first exceeded $3,000 between 1997 and 2000.[38] These prescriptions are used to treat both serious peptic ulcers and less serious esophegeal acid reflux conditions. Since smoking and alcohol consumption are two of the behaviors highly correlated with these conditions, promoting smoking cessation and alcohol awareness, along with more judicious prescribing of these drugs, might be ways to reduce long-term benefit costs.

As for society's capability to pay, a Medicare drug benefit could surely be afforded. Uwe Reinhardt, the Princeton University health economist, using government estimates on future drug spending and GNP, recently calculated that overall spending on drugs would reach 2.2 percent of GNP by 2010. While drug spending by the elderly will presumably rise as the baby boomers retire, the growing economy anticipated by government forecasters would render such spending feasible, and perhaps manageable.[39]

In addition, freezing the scheduled provisions of the 2001 tax cuts would result in increased revenues of an estimated $741 billion over a ten-year period, enough to cover a large proportion of a drug benefit.[40] Even in the absence of a budget surplus, the United States could afford a drug benefit. The question is one of national priorities, including how the bill for a benefit is paid and whether it would be worth the price tag.

Medicare beneficiaries will not sign up for the benefit.

Compared to her risk of suffering illness or injury, an individual's need for prescription drugs is relatively predictable. For this reason, adverse selection—the tendency for high-risk beneficiaries to opt to purchase insurance while healthy beneficiaries opt out—is nowhere more prevalent than in the area of drug coverage. Insurance plans with drug benefits (including three types of individual Medigap

plans for seniors) disproportionately attract high health risks, driving up premiums and pricing out potential purchasers.

To avoid adverse selection as much as possible—keeping premiums affordable and the size of the public subsidy manageable—it is important that most Medicare beneficiaries sign up for the drug benefit.

Making a drug benefit mandatory for Medicare enrollees, as for hospital coverage (Part A) under the program, would be one possible strategy for achieving this goal. This would be inadvisable, however, because it would alienate those beneficiaries who already have good supplemental drug coverage and would sharply raise the program's costs in the short run.

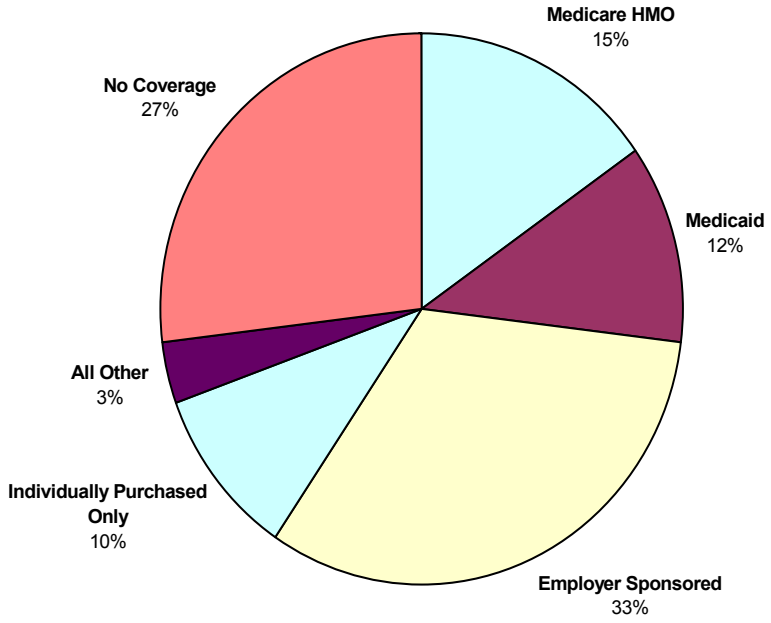
The design of Part B of the Medicare program suggests a better strategy. While enrollment in Part B is voluntary, almost all beneficiaries elect to join because of the attractive terms. If they choose to take up Part B after age sixty-five, beneficiaries currently pay a 10 percent premium penalty for each year after sixty-five that they choose not to elect Part B. A similar condition, with a higher penalty, could be applied to a drug benefit.[41] In addition, a "once in, always in" provision would discourage beneficiaries from joining only when they expected to incur very high pharmaceutical costs.

If the plan discussed in this issue brief was implemented, would Medicare beneficiaries join up? As William Novelli, the CEO of the AARP, recently told Congress: "The challenge is creating a plan that beneficiaries perceive as a good deal and will purchase. Beneficiaries are not asking for free prescription drugs. They are willing to pay for this coverage through premiums, co-pays, and deductibles. But these payments must be seen as reasonable."[42]

There are good reasons to think that beneficiaries will sign up for a value-based drug benefit. The most important of these is that current beneficiaries with supplemental drug coverage (see Figure 1) are seeing their choices narrowing and their out-of-pocket costs increasing. The percentage of large employers offering retiree health coverage, which almost always includes drug coverage, dropped from 88 percent in 1989 to 41 percent in 1999 and to 34 percent in 2001.[43] The percentage of Medicare+Choice enrollees with access to a basic benefit declined from 84 percent in 1999 to 70 percent in 2001.[44] At the same time, two-thirds of these plans now have drug benefit caps—an upper limit on spending covered by the insurer—of $500 or less, compared with less than a quarter of plans in 1999.[45]

Premiums for drug coverage through Medigap plans have risen 37 percent since 1999, compared to 15.5 percent for the plans that do not cover prescription drugs.[46] Finally, state budget shortfalls—which now amount to 8 percent of total budgets—may lead to cutbacks for Medicare beneficiaries who receive coverage through Medicaid and through state pharmaceutical assistance programs.[47] Because of these trends, the Medicare benefit over time will look increasingly like a better deal. This will be especially true if the prediction is borne out of more effective and costlier therapies produced through advances in biotechnology.

Figure 1: Sources of Prescription Drug Coverage for Medicare Beneficiaries, 1998



Source: John A. Poisal and Lauren Murray, "Growing Differences between Medicare Beneficiaries with and without Drug Coverage," *Health Affairs* 20, no.2 (March/April 2001): 74-85.

In 1989, better-off seniors with good supplemental drug coverage helped force the repeal of legislation that included a catastrophic Medicare drug benefit, balking at paying a tax that would have subsidized this benefit for less well-situated beneficiaries.[48] Today, however, such supplemental coverage is increasingly precarious and less generous. Moreover, in the face of rising health care costs, employers who retain retiree coverage are unlikely to offer new supplemental coverage that would reduce cost-sharing for their past employees, raising utilization of drugs and Medicare's costs. While the coverage provided under a benefit will be of most assistance to those beneficiaries who currently lack coverage, it should lower out-of-pocket costs for most beneficiaries. Although spending under such a benefit may lag behind seniors' demand for drugs, this benefit is likely to look better than the alternatives.

As a universal federal benefit, moreover, this plan should avoid the enrollment and income verification problems that have plagued Medicaid and means-tested state pharmaceutical assistance programs.

It is unrealistic for beneficiaries and their advocates to hold up recent levels of employer drug coverage—which featured a high level of first-dollar subsidies and low copayments—as a standard for a Medicare drug benefit. Employers were able to subsidize employees heavily because a robust economy made absorbing a higher share of premiums affordable and because they feared defections by workers. Employees paid just 28 percent of the total cost of drugs in 1998, compared to 48 percent in 1990, while the employer share rose from 34 percent to 51 percent.[49] Now that these favorable economic conditions are no longer in place, companies are moving rapidly toward less generous coverage and toward the types of tiered copayment strategies included in this plan.

Physicians will resent the challenge to their authority.

This design—with a board selecting preferred categories of drugs and recommending particular drugs within each category—could appear to take medical discretion out of the hands of individual physicians and put it in the hands of administrators. On could argue in its defense that some tradeoffs between access and cost to medical goods and services are inevitable during a period of rapid advances in medical technology, and that doctors will surely be well-represented on the pharmacy benefit board in any case.

Good advice from physicians—along with sound overall coverage policy and coinsurance—is among the methods of encouraging the use of preferred drugs and discouraging the use of those that are of dubious medical benefit or costlier than an equally effective alternative.[50]

Consider, for example, the findings of a recent study conducted by Express Scripts, a pharmaceutical benefits manager, on the use of Celebrex and Vioxx, two popular anti-arthritis drugs. In some cases, use of these drugs in place of an ordinary painkiller such as ibuprofen prevented painful stomach ulcers from forming. However, about three-quarters of new users were not at high risk from ulcers, suggesting that an ordinary and less expensive painkiller would be equally effective.[51] In this case, judicious prescribing by doctors of these drugs, along with the right level of coinsurance, would keep down plan costs and encourage appropriate use.

However, conservative prescribing practices by physicians are increasingly rare. One survey found that a quarter of respondents had asked their doctors to prescribe a drug they had seen advertised, and three-quarters of this group reported that the doctor had filled this prescription.[52] A study undertaken by the Kaiser Family Foundation found a similar pattern.[53] Researchers at the National Center for Health Statistics reported that 66 percent of patient visits to a physician resulted in the receipt of a prescription or a vaccine in 1999, up from 61 percent in 1985.[54]

To be sure, such findings may reflect the availability of newer and better drugs for a variety of medical conditions. By the same token, there is a strong implication that doctors have abdicated their authority in the face of consumer demand for much-advertised drugs, their sense of their patients' expectations, and an onslaught of sales visits from pharmaceutical salesmen. Real or perceived pressures from managed care plans to expedite patient visits may also play a part. Fewer physicians seem willing to counsel waiting out a cold rather than prescribing unnecessary antibiotics, or to recommend exercise or over-the-counter antacids rather than Prilosec for heartburn.

Most doctors are not pharmaceutical experts and have little time to become well-versed in the characteristics of newer drugs. Many, if not most, may welcome the guidance that an evidence-based Medicare formulary would bring.

The pharmaceutical industry will object to this plan and innovation will be stifled.

This approach should engage the pharmaceutical industry. Under this design, drug manufacturers will retain the opportunity to earn an excellent return on their genuine market leaders, while not being precluded from continuing to market drugs aggressively that are not preferred on the Medicare formulary.

From the industry perspective, however, this proposal undoubtedly looks naive. Pharmaceutical manufacturers would point to the likelihood of enormous pressure being put on the pharmacy board to downplay the medical significance of costlier drugs and to promote the substitution of others that might be less effective and less expensive. This concern could be addressed by scrupulously separating the findings of evidence from the coverage decisionmaking process, a distinction that is currently observed by the Medicare Coverage Advisory Committee.[55]

The possible effect of a drug benefit on innovation is an important issue. Measuring the cost of foregone innovation is difficult, but it seriously affects a nation's long-term living standards. What is significant here is that the drug pipeline is emptier than commonly supposed. The number of new drugs released has been dropping in the past several years despite large increases in R&D spending.

According to one investment analyst, 450 drugs were in the latter stages of development in 2001, the same number as in 1995.[56] This lack of growth in development may partly reflect the industry's concentration on extending the market life of existing products or simply the increasing difficulty in finding new interactions of proteins for pharmaceutical use.

Whatever the precise set of reasons, it suggests that the introduction of a drug benefit is far from likely to retard an innovation cycle that is already becalmed. A value-based benefit would not necessarily impinge on innovation but instead would steer research toward those drugs that show the most clinical promise. Moving in this direction, moreover, might reduce public pressure to cap drug prices, lower the temperature on the criticism of the industry's pricing policies, and generally begin to repair the fraying image of drug manufacturers.[57]

What Would Be Likely to Happen If this Plan Were Enacted?

With a value-based benefit in place, pharmaceutical companies would be likely to seek a very high price from Medicare for their true breakthrough drugs. The Medicare program already negotiates on price over drugs that are used in hospitals and in a few outpatient settings. Given the interest in promoting innovation in the industry, Medicare's goal would be to seek a fair price but not necessarily the lowest one—that obtained by Medicaid programs and the Veteran's Administration.

While neither beneficiary advocates nor the industry are likely to be wholly satisfied by the pricing policies that evolve, an accommodation that doesn't limit access by beneficiaries or handicap manufacturers can probably be reached. With a few exceptions, national health care plans in other countries have been able to include new drugs on their approved lists despite paying less than Medicare almost certainly would.

Medicare beneficiaries, with an assist from drug company advertising and marketing, will press for wider drug coverage and lower cost-sharing. This process will resemble the tug-of-war currently ongoing between the pharmaceutical industry and managed care plans. Plans are finding it difficult to hold the line on coverage and cost. Medicare will have more bargaining power vis-à-vis the industry thanks to its large covered population and its recognized capacity to take a harder line on pharmaceutical prices, even it chooses not to do so. An alliance between taxpayers and beneficiaries who have gained coverage through the addition of the benefit should help insulate the program from having to expand this benefit rapidly.

If the federal budget runs higher deficits, a distinct possibility, there will be considerable pressure on Medicare to adopt a much more restrictive formulary and not to cover medically valuable but expensive drugs. This is a good reason for having Medicare itself administer the program rather than turning this function over to private pharmacy benefit managers. The latter would be less visible and accountable to the public and could more easily implement coverage changes. This is also a reason for investing the new Pharmacy Board with a substantial amount of prestige and visibility so that it does not bow easily to pressure and limit access to drugs for seniors. So far, the National Institute for Clinical Excellence, the advisory board to Great Britain's National Health Services, generally has seen its expensive but cost-effective recommendations put into effect.

After a Medicare benefit of this type is enacted, the scope and depth of supplemental drug coverage for seniors is likely to contract further as companies feel less obligated to offer retiree coverage. However, this effect would simply tend to accelerate a trend already well underway, not to bring it about in the first place.

Conclusion: Why Paying for Medical Value Is Desirable

The United States, as a wealthy nation, is capable of paying a great deal for a Medicare drug benefit if it pays dividends in terms of population health. However, taxpayers should not be willing to subsidize the pharmaceutical industry and Medicare beneficiaries if "me-too" drugs and medications of limited therapeutic benefit claim a large portion of the reimbursement dollar.

This Medicare benefit plan offers a coverage and payment structure that matches the growing therapeutic complexity and availability of prescription drugs. The elements of this drug-class and drug-specific plan are already taking shape in the private sector and at the state level. Under this plan, seniors will get a larger price break on drugs that save lives or make the difference between functionality or disability, while premium dollars and tax subsidies will flow toward the pharmaceutical breakthroughs that have the greatest life-or-death impact.

The principle behind this plan cuts in two directions: it raises the price to consumers of drugs that are not as critical, but it also provides a rationale for subsidizing unique but expensive drugs. In the words of Bruce Taylor, a benefits manager at Verizon Communications, it may be prudent to "pay for what people need, but not always for what they want or what their physician prescribes."[58]

A successful Medicare drug benefit should improve the health of its beneficiaries and help protect those beneficiaries who incur very high annual prescription drug costs. It should also balance short-term relief from high prices for effective drugs with the need to keep research into new therapies and the pipeline of drug production flowing. A benefit based on paying for medical value is best suited to fulfilling these multiple goals.

How Does This Plan for a Drug Benefit Compare to Others Under Consideration?

In his annual budget, President Bush called for spending $190 billion over ten years on various changes to Medicare, including a low-income drug benefit and a Medicare-endorsed prescription drug discount card.[59] Various states are pursuing their own efforts to rein in pharmaceutical costs and to expand enrollment in state pharmaceutical assistance programs for Medicare beneficiaries.[60]

Within Congress, two proposals recently have taken center stage. On June 28th, 2002, the House approved a Republican-sponsored bill (H.R. 4954) for a Medicare drug benefit estimated to cost $310 billion over ten years. This plan would be offered through private insurance plans similar to those currently participating in Medicare+Choice, Medicare's managed care option. A beneficiary would be expected to pay a premium in the range of $35 a month (this premium could vary by plan), a $250 annual deductible, 20 percent of drug costs from $251 to $1000 a year, and 50 percent of drug costs from $1,001 to $2000. The beneficiary would be responsible for all drug costs between $2000 and $3700, while the government would offer stop-loss protection for annual spending that exceeded the latter amount.[61]

Democratic Senators led by Robert Graham (D-FL) and twenty-eight co-sponsors have proposed a voluntary benefit (similar to Part B of Medicare) under which beneficiaries would pay a uniform $25 monthly premium and owe no deductible. The government would pay at least 50 percent of a beneficiary's drug costs up to $4000 and all of a beneficiary's out-of-pocket costs that exceed this amount. The cost of this proposal is estimated at around $500 billion over ten years. House Democrats put forward a somewhat more generous and expensive proposal. The AARP previously suggested spending $350 million over this period while setting aside a $400 billion "reserve fund" to cover the potential costs of a comprehensive benefit.

Estimates of future spending on a drug benefit are subject to many variables. These include overall levels of utilization, the effects of a possible "crowding-out" of existing retiree drug coverage by the enactment of a public benefit, and the prices that Medicare negotiates for drugs with manufacturers.

Because the cost-sharing of a value-based drug benefit will vary by drug type rather than by a beneficiary's overall spending on prescription drugs, it is hard to compare the plans directly on these terms. Much of the cost of this plan will depend largely on how many breakthrough drugs are produced by pharmaceutical manufacturers that warrant favorable cost-sharing placement on the formulary.

Written by Leif Wellington Haase, Fellow at The Century Foundation

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ENDNOTES

[1] Leif Wellington Haase and Benjamin Aldrich-Moodie, "An Outpatient Prescription Drug Benefit for Medicare," issue brief no. 13, The Century Foundation, New York, June 2000; *Medicare Tomorrow: The Report of The Century Foundation Task Force on Medicare Reform* (New York: Century Foundation Press, 2001), pp. 47–60; Michael E. Gluck, "A Medicare Prescription Drug Benefit," National Academy of Social Insurance, Washington, D.C., April 1999; Stephen Soumerai et al., "Inadequate Prescription Drug Coverage for Medicare Enrollees: A Call to Action," *New England Journal of Medicine* 340 (March 4, 1999): 722–28; "Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices," Department of Health and Human Services, Washington, D.C., April 2000, http://aspe.hhs.gov/health/reports/drugstudy.

[2] John A. Poisal and Lauren Murray, "Growing Differences between Medicare Beneficiaries with and without Drug Coverage," *Health Affairs* 20 (March/April 2001): 74–85. Mary A. Laschober et al., "Trends in Medicare Supplemental Insurance and Prescription Drug Coverage 1996–1999," *Health Affairs* web exclusive (W127-138) (February 27, 2002), estimates that 38 percent of beneficiaries lacked coverage in fall 1999 based on point-in-time rather than calendar-year estimates.

[3] Medicare beneficiaries pay for about half of their overall drug spending out of pocket, as opposed to 34 percent for working-age adults. *Medicare Tomorrow*, p. 50.

[4] For the most recent proposals in Congress, see the text box that accompanies the text. For a detailed summary and point-by-point comparison of proposals in the 107th Congress (whose designs resemble those of plans likely to be proposed in the future), see Health Policy Alternatives, Inc., "Prescription Drug Coverage for Medicare Beneficiaries: A Side-by-Side Comparison of Selected Proposals," Henry J. Kaiser Family Foundation, Menlo Park, CA., August 2001.

[5] In its approval process for new drugs, the FDA distinguishes between those drugs that contain "new molecular entities" (NMEs) and those that have active ingredients that are already in use in existing products, or "incrementally modified drugs"(IMDs).

[6] Congress looks poised to take a step in this direction if, as expected, it passes a bill that would add oral anticancer drugs to the Medicare benefit package. Robert Pear, "Medicare Payment for Cancer Drugs Is Seen as Likely," *New York Times*, April 29, 2002, p. A1.

[7] The PRIME Institute, University of Minnesota, estimates that Prilosec is the most used drug by the elderly, based on the number of claims submitted. Claritin ranks thirty-seventh. Families USA, "Bitter Pill: The Rising Prices of Prescription Drugs for Older Americans," Washington, D.C., June 2002, p. 9.

[8] Members of this board would be appointed by the president for six-year terms and confirmed by the Senate, as is the case for Social Security and Medicare trustees. The secretary of Health and Human Services would also have a standing place on this board.

[9] Anna Cook, Thomas Kornfeld, and Marsha Gold, "The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit," Henry J. Kaiser Family Foundation, Menlo Park, CA., January 2000, p. 24.

[10] See ibid.; Robin Strongin, "The ABCs of PBMs," issue brief no. 749, National Health Policy Forum, George Washington University, Washington, D.C., October 27, 1999. Administering the plan through Medicare rather than through pharmacy benefit managers (which have close ties to and in some cases are owned by makers of pharmaceuticals) should increase accountability to the public for changes in the formulary.

[11] Cindy Parks Thomas, Grant Ritter, and Stanley S. Wallack, "Growth In Prescription Drug Spending among Insured Elders," *Health Affairs* 20 (September/October 2001): 269.

[12] See Stephane Jacobzone, "Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals," Labor Market and Social Policy Occasional Papers no. 40, Organisation for Economic Co-operation and Development, Paris, April 18, 2000.

[13] Haiden Huskamp et al., "The Medicare Prescription Drug Benefit: How Will the Game Be Played?" *Health Affairs* 19 (March/April 2000): 8–23.

[14] See Andrew Caffrey, "Michigan Is Poised to Reduce Drug Costs by Setting Restrictions on Medications List," *Wall Street Journal*, November 12, 2001, p. B8; Russell Gold, "Industry Suit to Block Michigan's Plan on Price Cuts for Drugs May Send Message," December 3, 2001. *Wall Street Journal*, p. A2.

[15] A full description of the Australian Pharmaceutical Benefits Scheme is available at http://www.health.gov.au/pbs.

[16] The advantage of using cost-effectiveness rather than a cost-benefit analysis as a criterion is that it compares one possible intervention with another (for example, two different drugs, or the benefit of nutrition or exercise in lieu of medical therapies) rather than calculating the dollar value of extending a particular life. It is primarily about comparing means to a given end, not the value of ends themselves. However, the very high cost of some new drugs might force Medicare to confront cost-benefit issues head-on. Pharmacia's colon cancer drug Camptosar may cost as much as $60,000 per patient per year, Novartis's Gleevec for cancer treatment may cost $28,000, and drugs for rheumatoid arthritis may cost $12,000 annually (John Carey and Amy Barrett, "Drug Prices: What's Fair?" *BusinessWeek*, December 10, 2001, p. 61f). New genetically engineered, "designer drugs" may carry an even higher price tag. Practically speaking, however, such breakthroughs are likely to be relatively few in the near future. As these drugs become more common, moreover, better use of genetic information should also help streamline the clinical trials process and bring down R&D costs. As performing such trials in humans is the most substantial part of a drug's cost, this should help bring prices down. If such drugs are used by a few beneficiaries, the program will be able to absorb their cost. If they have a wider market, economies of scale should result in the lowering of these drugs' prices over time.

[17] S. Schneeweiss et al., "Impact of Reference-Based Pricing for Angiotensin-Converting Enzyme Inhibitors on Drug Utilization," *Canadian Medical Association Journal* 166 (March 2002): 737–45.

[18] All descriptions of the effects of prescription drugs are drawn from the online information database compiled by Medline Plus, National Institutes of Health, http://www.nlm.nih.gov/medlineplus/druginfo.

[19] Victor Fuchs and Harold C. Sox, Jr., "Physicians' Views of the Relative Importance of Thirty Medical Innovations," *Health Affairs* 20 (September/October 2001): 30–42.

[20] James Santiago Grisolia, "Sticker Shock at the Pharmacy," *San Diego Union-Tribune*, March 27, 2002, p. B7.

[21] Kim McDonough and Carol Chandor, "New Goals Needed for Pharmacy Benefits," *Employee Benefit News*, May 1, 2001, http://www.benefitnews.com/subscriber/01_07/inside1.htm

[22] Chunliu Zhan, et.al., "Potentially Inappropriate Medication Use in the Community-Dwelling Elderly: Findings From the 1996 Medical Expenditure Panel Survey," *Journal of the American Medical Association* 286 (December 12, 2001): 2823–2829.

[23] Cited in MacDonough and Chandor, "New Goals Needed for Pharmacy Benefits."

[24] Poisal and Murray, "Growing Differences between Medicare Beneficiaries with and without Drug Coverage," p.78.

[25] See "Prescription Errors Rising," ConsumerAffairs.com, June 10, 2000, http://www.consumeraffairs.com/news/pharmacy_errors.html.

[26] Milt Freudenheim, "So Much for Doctors' Bad Handwriting on Drug Prescriptions," *New York Times*, April 9, 2002, p. C4.

[27] Thomas Maeder, "The Food and Drug Administration," The Century Foundation, Understanding Government Project, forthcoming; Vanessa Fuhrmans and Gautam Naik, "Drug Makers Fight to Fend off Cuts in European Prices," *Wall Street Journal*, May 7, 2002, p. A1.

[28] Statement of Dan L. Crippen, Director, Congressional Budget Office, before the Committee on Finance, United States Senate, March 7, 2002.

[29] Alan M. Garber, "Evidence-Based Coverage Policy," *Health Affairs* 20 (September/October 2001): 80. On ways that drug spending may reduce costs elsewhere in the health care system, see also Robert M. Goldberg, "A Better Prescription for Medicare," *Wall Street Journal*, May 7, 2002, p. A26.

[30] Frank Lichtenberg, "Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS," *Health Affairs* 20 (September/October 2001): 241–51; Lichtenberg, "Do (More and Better) Drugs Keep People out of Hospitals, *American Economic Review* 86, no. 2 (1996): 384–88.

[31] Jan Blustein, "Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension," *Health Affairs* 19 (March/April 2000): 219–30.

[32] J. D. Kleinke, "The Price of Progress: Prescription Drugs in the Health Care Market," *Health Affairs* 20 (September/October 2001): 43–60.

[33] "Changing Patterns of Pharmaceutical Innovation," National Institute for Health Care Management Research and Educational Foundation, Washington, D.C., May 2002, p. 11.

[34] Mark Metherell, "No Spoonful of Sugar," *The Sydney Morning Herald*, April 13–14, 2002, p. 32; Mark Kennedy, "Drug Bills Drain Health Funding," *Ottawa Citizen*, April 25, 2002, p. A9.

[35] "Greater Use of Generics: A Prescription for Drug Cost Savings," Schneider Institute for Health Policy, Brandeis University, Waltham, MA., March 2002, http://www.gphaonline.org/news/index.php?id=31.

[36] Diane West, "Are Generic Drugs the Cure to Medicare's Ills?" *Discount Store News*, March 4, 2002, p. 26.

[37] See Robin J. Strongin, "Hatch-Waxman, Generics, and Patents: Balancing Prescription Drug Innovation, Competition, and Affordability," National Health Policy Forum, George Washington University, Washington, D.C., Background Paper, June 21, 2002.

[38] Cindy Parks Thomas, Grant Ritter, and Stanley S. Wallack, "Growth in Prescription Drug Spending among Insured Elders," *Health Affairs* 20 (September/October 2001): 265–77.

[39] Uwe E. Reinhardt, "Perspectives on the Pharmaceutical Industry," *Health Affairs* 20 (September/October 2001): 139.

[40] Alan J. Auerbach, William G. Gale, and Peter R. Orszag, "The Budget Outlook and Options for Fiscal Policy," Brookings Institution, April 2002, Washington, D.C., April 2002, p. 17.

[41] The penalty would need to be higher because the incentive only to join when drug coverage is needed is greater than for other types of health care.

[42] April Fulton and Julie Rovner, "Panels Continue Partisan Medicare Drug Benefit Debate," National Journal's *CongressDaily*, April 17, 2002. Proposals considered realistic in Washington may not be what Medicare beneficiaries want. For instance, just one-third of beneficiaries polled by the AARP in March 2002 said that they would sign up for a plan with a $35 monthly premium, 50 percent coinsurance, and a $4,000 stop-loss cap.

[43] Kaiser Family Foundation, Commonwealth Fund, and Health Research and Educational Trust, *2001 Retiree Health and Prescription Drug Coverage Survey*.

[44] "The Medicare Program: Medicare+Choice," *Henry J. Kaiser Factsheet*, Kaiser Family Foundation, Menlo Park, CA., September 2001.

[45] Marsha Gold, "Recent Research Findings on Medicare+Choice," November 2001.Princeton: Mathematica Policy Research.

[46] "Prescription Drug Trends: A Chartbook Update," Henry J. Kaiser Family Foundation, Menlo Park, CA., November 2001, p. 4.

[47] Robert E. Pierre, "The Budget Squeeze," *Washington Post National Weekly Edition*, March 25–31, 2000, p. 6.

[48] On the passage and repeal of the Medicare Catastrophic Coverage Act, see Marilyn Moon, *Medicare Now and in the Future*, 2nd ed., Ch. 5, pp. 115–44, The Urban Institute Press, Washington, D.C. 1996.

[49] "Prescription Drug Trends," fact sheet 3057, Henry J. Kaiser Family Foundation, Menlo Park, CA., September 2000, quoted in Veronica Goff, "Pharmacy Benefits: New Concepts in Plan Design," issue brief no. 772, National Health Policy Forum, March 8, 2002, p. 2. See also Glen P. Mays, Robert E. Hurley, and Joy M. Grossman, "Consumers Face Higher Costs as Health Plans Seek to Control Drug Spending," issue brief no. 45, Center for Studying Health System Change, Washington, D.C., November 2001.

[50] See Andrea Mant, *Thinking about Prescribing* (New York: McGraw Hill, 1996), for ways doctors can prescribe drugs more appropriately.

[51] Melody Petersen, "2 Big-Selling Arthritis Drugs Are Questioned," *New York Times*, June 4, 2002, p. C16; *2001 Drug Trend Report*, Express Scripts, June 2002, http://www.express-scripts.com/other/news_views/2001drugtrend/2001ESIDrugTrendReport.pdf.

[52] Michael S. Wilkes, Robert A. Bell, and Richard L. Kravitz, "Direct-to-Consumer Prescription Drug Advertising: Trends, Impact, and Implications," *Health Affairs* 19 (March/April 2000): 111.

[53] "Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising," Henry J. Kaiser Family Foundation, Menlo Park, CA., November 2001.

[54] Susan Okie, "Survey Finds Multiple Prescriptions on the Rise," *Bergen County Record*, August 20, 2001. p. F1.

[55] See Garber, "Evidence-Based Coverage Policy," p. 73. A major concern, from the program's perspective, would be whether it would have to pay whatever price the drug companies wished for unique drugs. For other services and therapies, Medicare's reimbursement policies often set a benchmark for other payers. In this case, given the global market for drugs and the presence of multiple payers in the United States and overseas, it should be possible for Medicare to negotiate a fair price—perhaps the average of the price paid by a set of other payers. The aim of the program should be a reasonable price but not (as for Medicaid) the lowest possible price. Early experience with Great Britain's National Institute for Clinical Excellence (NICE) suggests that weighing clinical criteria in deciding whether to cover drugs under a public program need not result in lower revenues for pharmaceutical companies. In the words of Alan Milburn, Britain's health secretary, "I think the fear is being dispelled that NICE would somehow reduce NHS expenditures on drugs. It's driven costs up—and how! If that means that we get better and more cost-effective drugs to patients more quickly, that is a good thing, not a bad thing." Nicholas Timmins, "A Time for Change in the British NHS: An Interview with Alan Milburn," *Health Affairs* 21 (May/June 2002): 132.

[56] Andrew Pollack, "Despite Billions for Discoveries, Pipeline of Drugs Is far from Full," *New York Times*, April 19, 2002; Amy Barrett and Michael Arndt, "No Quick Cure: Why the Drug Industry's Down Cycle Won't Be Over Soon," *BusinessWeek*, May 6, 2002, p. 30. Pharmaceutical manufacturers contend that 294 medicines currently in the pipeline are aimed at diseases that disproportionately affect older Americans. See "Pharmaceutical Research is Focusing on the Elderly," *New York Times*, June 30, 2002, p. 4 (Business Section).

[57] Bill McInturff, Public Opinion Strategies, National Health Policy Conference, "The Public's Perception," Washington, D.C., January 16, 2002.

[58] Quoted in Goff, "Pharmacy Benefits: New Concepts in Plan Design," p. 8.

[59] Health Policy Alternatives, Inc., "Prescription Drug Discount Cards: Current Programs and Issues," Henry J. Kaiser Family Foundation, Menlo Park, CA., February 2002.

[60]Kimberly Fox, Thomas Trail, and Stephen Crystal (Rutgers Center for State Health Policy), "State Pharmacy Assistance Programs: Approaches to Program Design," The Commonwealth Fund, May 2002.

[61] Robert Pear, "House Votes to Place Prescription Drugs Under Coverage by Medicare," New York Times, June 28, 2002, p. A16; Janelle Carter, "GOP Prescription Drug Bill Passes," *Associated Press*, June 28, 2002; Marilyn Werber Serafini, "An Rx for the Democrats," *National Journal*, June 22, 2002, p. 1880.