Do Open Formularies Increase Access To Clinically Useful Drugs?

The results from an interesting natural experiment in which Congress first withdrew (and subsequently reinstated) states’ ability to restrict reimbursement for specific drugs under the Medicaid program.

by Bryan L. Walser, Dennis Ross-Degnan, and Stephen B. Soumerai

PROLOGUE: As more states turn to Medicaid managed care as a solution to rising costs, policymakers must consider both the economic and the clinical implications of their decisions. The findings here suggest that in the development and analysis of prescription drug formularies (lists of drugs that are approved for reimbursement) specifically and in health care reform more generally, clinical effects are not necessarily correlated with an economic approach. When only one level of analysis is considered, reform can have unintended, and costly, effects.

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**ABSTRACT:** Before 1990 many state Medicaid programs maintained “restrictive” formularies, which denied reimbursement for unlisted prescription drugs. This type of formulary has been criticized for denying important medications to poor, medically needy persons. As part of the Omnibus Budget Reconciliation Act of 1990, restrictive formularies in Medicaid programs were disallowed. Based on research into the 200 top-selling prescription drugs in the United States, we conclude that eliminating Medicaid restrictive formularies improved access to a subset of the 200 best sellers, but that the majority of these products offered only questionable or no additional therapeutic benefit.

**PHARMACEUTICAL PURCHASING PLANS** are a microcosm of other areas of health policy. Drug benefit programs are complicated, are increasingly expensive, and affect many public and private interest groups with often conflicting goals. The largest such pharmaceutical entitlement program—the Medicaid outpatient prescription drug benefit, with total expenditures of about $6.2 billion in 1991—has been the target of legislation aimed at containing rapid spending increases. One major element of this legislation involved drug formularies.

**Drug formularies.** The most basic drug formulary is a descriptive list of the medications available in a given health care setting. Early formularies, such as the 1816 Pharmacopoeia of the New York Hospital, simply listed all of the drugs carried by a hospital pharmacy. Over time, many formularies began to serve a regulatory function by limiting the availability of unlisted agents. These “restrictive” formularies, originally compiled for clinical reasons by local hospital pharmacy and therapeutics (P&T) committees, have been adopted by a number of outpatient drug purchasing programs—especially Medicaid—as a convenient way to contain costs.

This development has been questioned on both scientific and political grounds. Although some studies have shown that restrictive formularies decrease spending for inpatient drug therapy, others have raised the possibility that these savings may be offset by increased spending elsewhere in the hospital budget. In the outpatient arena, although savings from restrictive formularies have been reported in the literature, most studies have not evaluated potential substitution effects (that is, greater use of nonrestricted drugs or other nondrug health services) in a well-controlled manner. Even so, the outpatient setting seems particularly vulnerable to cost shifting and other unintended effects as a result of restricting the availability of drugs. For example, one study observed decreased hospital admissions after drug coverage was increased in South Carolina’s Medicaid plan.
By the late 1980s these potential effects had begun to worry several interest groups. Physicians expressed concern about the infringement of their ability to select whichever drug they felt was most appropriate, while the Pharmaceutical Manufacturers Association (PMA), now known as the Pharmaceutical Research and Manufacturers of America (PhRMA), argued that reduced manufacturer income might affect private spending on research and development (R&D). Groups representing racial minorities and the poor joined the PMA in criticizing restrictive formularies for denying lower-income patients access to medications.

OBRA 1990. In early 1990 Sen. David Pryor (D-AR) introduced the Pharmaceutical Access and Prudent Purchasing Act as a response to increases in prescription drug prices, which had exceeded the Consumer Price Index (CPI) by as much as 150 percent. Among other provisions, this bill would have cut costs by the compulsory substitution of “preferred” drugs for prescribed drugs within “therapeutically equivalent” categories determined by a national P&T committee. Alarmed at this prospect, a number of drug manufacturers instead offered rebates to Medicaid programs based on the “best price” given to other large purchasers, in exchange for a federal mandate to eliminate restrictive state formularies.

This bargain was sealed 26 October 1990. Passed into law as an amendment to the several thousand-page Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) the legislation required rebates based on the greater of either a minimum percentage (around 15 percent) of the average manufacturer’s price offered to all purchasers, or the difference between the Medicaid price and the manufacturer’s lowest price-with the exception, after 1992, of entities such as the Department of Veterans Affairs (VA) and the Indian Health Service (IHS). In addition, rebate amounts for brand-name drugs were to increase if prices rose faster than the CPI.

In return, state Medicaid programs were required to cover participating manufacturers’ new medications for at least six months after Federal Drug Administration (FDA) approval. Medications that had been on the market for longer periods could be excluded from reimbursement only if they belonged to one of several “OBRA-excludable” categories (benzodiazepines; cough and cold remedies; fertility drugs; smoking-cessation drugs; and cosmetic, hair-growth, and over-the-counter [OTC] products), or if prior approval had not been obtained in the case of a drug for which it was required. However, OBRA 1990 mandated that prior-approval programs evaluate all requests within twenty-four hours, which made them expensive and administratively cumbersome.

For a number of reasons, including the swift cancellation of vol-
ume discounts previously offered by manufacturers that were now trying to reduce the size of their legislated rebates, state Medicaid programs that previously had depended on restrictive formularies to contain drug spending experienced rapid cost increases. In 1991-1992, for example, Alabama reported that its drug costs had increased by 62 percent over the previous year, after accounting for revenue obtained from the rebate program. By contrast, Iowa, which previously had an “open” formulary, experienced only a 15 percent increase over a comparable time period. By 1993 the Office of Management and Budget (OMB) estimated that savings from repealing the prohibition on restrictive formularies would reach nearly $70 million over the next four years. Thus, OBRA 1993 again allowed restrictive outpatient formularies under certain conditions.

Research Questions
The OBRA 1990 drug formulary provisions provide an interesting natural experiment with which to investigate a number of the practical effects of such broad changes in drug benefit policy. Did eliminating restrictive formularies from state Medicaid programs actually improve access to pharmaceutical products? Did states resort to alternative methods such as prior-approval requirements to continue restricting access? If so, how successful were they? Finally, given that drug spending increased disproportionately in many states that previously had restrictive formularies, did changes in the availability of products of high aggregate cost offer significant offsetting clinical advantages?

Methods
Given the enormous scope of the U.S. pharmaceutical market, a major concern was to limit our scope of inquiry while protecting the validity of our results. Although many of the tens of thousands of pharmaceutical products available in the United States are vitally important for particular indications, the bulk of pharmaceutical spending goes toward a comparatively small number of widely used products. For example, in 1991 the 200 top-selling drugs by dollar amount accounted for 72 percent of retail purchases. We chose to assess the clinical impact of changes in the availability of this well-defined, carefully watched, and economically important group of drugs because these are the products that are most likely to have substantial aggregate impacts on state pharmaceutical spending.

We first cataloged a subset of the 200 top-selling drugs in 1989 that were widely excluded from Medicaid coverage before the prohibition of restrictive formularies. We also identified policy mechanisms by which states could continue to restrict the availability of
medicines after OBRA 1990. We then identified the specific products that were covered by a reasonably increased number of Medicaid programs after restrictive formularies were prohibited. Finally, we assessed the perceived clinical usefulness of the wider availability of these products.

- **Formulary status and methods of denying coverage.** Data on drug coverage were obtained from First Databank, which tracks data on pharmaceuticals covered by all of the state Medicaid programs, such as allowed drug prices, reimbursement restrictions, and labeling information. These data are used by most Medicaid programs for pharmacy reimbursement and thus are likely to be accurate. The data included the state-specific coverage status of the top 200 drugs, by year, as well as whether prior approval was required before a program would cover a particular item. We chose 1989 as the latest preintervention year before OBRA 1990. We selected 1992 as a postintervention observation point, to allow the system to stabilize and because it was the last year before restrictive formularies were again permitted.

Annual reports from the National Pharmaceutical Council (NPC), an association of drug manufacturers, were used to classify Medicaid formularies as either “open” or “restrictive” before OBRA 1990. Although this classification is based on all marketed compounds, it also effectively divided state programs into two clearly demarcated groups ( Exhibit 1).

Using this information, we determined whether each state had increased its prior-approval requirements for drugs among the 200 top-selling drugs, and whether this behavior varied by NPC formulary status. We used prior approval as a metric of efforts to attenuate the implementation of the formulary ban, for two reasons. First, prior-approval restrictions among the 200 top-selling drugs during this time period were unlikely to have been motivated merely by clinical considerations, since we restricted our attention to the 189 products that had stayed on the list since 1989. In addition, important players in OBRA 1990’s legislative history specifically identified prior approval as a mechanism by which restrictive formularies might be kept intact, regardless of the stated goals of the act.

- **Drugs with increased coverage: 1989-1992.** We also identified products among the 200 top-selling drugs that had been widely excluded from coverage before OBRA 1990. Drugs restricted by at least 10 percent of the forty-nine Medicaid programs in 1989 were identified and grouped by therapeutic category. We then analyzed the data from 1992 to determine if coverage had increased by at least four Medicaid programs during the intervening period (that is, by at least an additional 10 percent of the remaining total
EXHIBIT 1
Number Of State Medicaid Formularies That Include Top 200 Prescription Drugs, 1989-1992

<table>
<thead>
<tr>
<th>Number of top 200 drugs covered</th>
<th>Number of states with open formularies that include some of the top 200 drugs</th>
<th>Number of states with restrictive formularies that include some of the top 200 drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>200</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>199-198</td>
<td>17</td>
<td>12</td>
</tr>
<tr>
<td>197-196</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>195-194</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>193-192</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>191-190</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>189-180</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>179-170</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>169-160</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>159-150</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>149-140</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>139-130</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

NOTE: Although OBRA 1990 lifted restrictive outpatient Medicaid formularies, for the sake of comparison we list those states as “restrictive” in 1992 that had been so classified in 1989.

We focused on the number of drugs restricted by individual Medicaid programs to identify trends among state policymakers responding to newly changed federal regulations. Assessing the likely impact of changes in drug availability on individual Medicaid enrollees would have required normalizing each state’s policy response according to its population. However, because more than half of all Americans now reside in the nine most populous states, evaluating program responses according to state population would have obscured data originating from the forty remaining areas.

To guard against missing any significant decreased coverage after OBRA 1990, we compared the total numbers of the top 200 drugs covered by each state in both 1989 and 1992. At the level of individual chemical entities, however, we evaluated only increased coverage, since any reduction might have been attributable to market obsolescence, failure to conclude a rebate agreement, or other extrinsic factors.

### Measuring perceived clinical impact.

We measured the perceived clinical impact of these specific changes in coverage by surveying two separate panels of physicians. One panel was composed
of twenty-one physicians practicing in primary care specialties at either Harvard University Health Services or Cambridge Community Hospital. These physicians were asked to complete a one-page questionnaire (78 percent response rate). We asked physicians to indicate whether, in their opinion, greater access to each identified medication would yield a net therapeutic benefit, questionable benefit, or no additional benefit for their patients. Each medication was assigned to the category in which it was ultimately placed by at least 50 percent of responding physicians or, if there was no majority, into the “questionable benefit” category.

The same list of medications was submitted to a second panel of six research physicians affiliated with Harvard Medical Schools Department of Ambulatory Care and Prevention and Harvard Pilgrim Health Care. These physicians ranked each medication on a five-point scale according to their assessment of its “clinical utility,” ranging from “essential” to “not useful.” Responses of “essential” or “very useful” were grouped together, as were responses of “marginally useful” or “not useful.” Drugs were assigned to categories as described above. Physicians in both groups also were asked to briefly describe the reasons for their categorizations.

We chose physicians for the survey who practiced in a wide variety of settings: both full-time primary care (with and without affiliation to a teaching hospital) and academic research. This mitigated the possibility that different practice environments might influence physicians’ perceptions of a medications clinical utility. Although these physicians were all practicing in the greater Boston area, the socioeconomic status of their patients varied widely and included large numbers of Medicaid enrollees. We surveyed only primary care practitioners, to focus on the broad utility of these drugs in the general Medicaid population. Although used in a variety of settings, the drugs identified in the previous stages of this study are principally directed at primary care indications as one might expect from their large aggregate sales figures.

We surveyed physicians rather than clinical pharmacology texts and journal articles for several reasons. First, physicians using these drugs daily—especially in primary care environments—are in a unique position to judge real-world clinical effectiveness. Drug efficacies reported in the literature are usually determined only under optimal study conditions. Also, physicians are more likely to assess the role of a given drug as part of the entire pharmaceutical armamentarium, not in isolation. This is different from considering a medications individual contribution, as is done by the FDA. In any case, physicians’ final ratings of these drugs’ utility corresponded well with the evaluations of experts in clinical pharmacology.
Results

- **Drug categories with reduced availability in 1989.** The 200 top-selling drugs in 1989 included a wide variety of antibiotics, antilipemics, antihypertensives, benzodiazepines, hormonal preparations, nonsteroidal anti-inflammatory drugs (NSAIDs), and psychotropics. Drugs that were excluded by at least 10 percent of Medicaid programs in 1989 were primarily benzodiazepines, antihistamines, corticosteroids, opiates, and certain antibiotics. State Medicaid programs may have focused restrictions in this way for several reasons, such as a category’s “OBRA-excludable” status, legislative allowances for exclusions prior to OBRA 1990, legitimate addiction potential, significant cost, or availability of generic equivalents.

- **Mechanisms to avoid increased coverage: 1989-1992.** Drug coverage by Medicaid programs in states without restrictive formularies remained steady at a mean of 196 products in both 1989 and 1992. Predictably, coverage of study drugs by states that previously had maintained a restrictive drug formulary increased substantially after the legislation, from 169.3 products in 1989 to 186.3 products in 1992. Prior-approval requirements increased more in states with restrictive formularies (from 1.4 drugs in 1989 to 3.8 drugs in 1992) than in states with open formularies (from 0.7 drugs in 1989 to 1.4 drugs in 1992). Because this level of prior approval is insufficient to account for the difference in coverage between states with open and restrictive formularies during 1992 (that is, nearly ten products), states that had used restrictive programs must have relied on additional mechanisms for continued exclusions, such as OBRA-excludable categories or program noncompliance.

- **Perceived clinical utility of drugs with increased coverage.** Eighteen medications were covered by at least four more state Medicaid programs in 1992 than was the case in 1989 (that is, 10 percent of the remaining states, after initially being excluded by at least 10 percent of programs). These medications include representatives from every restricted therapeutic category. Both physician panels agreed that four of these eighteen drugs offered an additional net therapeutic benefit and that four offered no additional net therapeutic benefit. The remaining medications either were believed to be of questionable benefit or were the subject of split opinion within or between panels. As mentioned earlier, these categorizations (summarized in Exhibit 2) are similar to assessments published in recognized compendia of clinical pharmacology.

- **Reasons for assessments.** Physicians assigned drugs to a given category for a variety of reasons. Among drugs deemed benefi-
cial, buspirone was included because of its low addiction potential, compared with benzodiazepines; lorazepam because of its low cost, favorable half-life, and renal metabolism; lovastatin because of better patient compliance than with other types of cholesterol-lowering drugs; and terfenadine because of relatively greater effectiveness among the non-sedating antihistamines, despite its high cost. Among drugs rated as not beneficial, cefadroxil was criticized for its high cost among oral cephalosporins, without a compensating therapeutic advantage; dipyridamole for its perceived marginal efficacy; propoxyphene for its addiction potential and side effects; and Tavist-D (phenylpropanolamine/clemastine fumarate) for its high cost, multiple components, and over-the-counter availability.

**Discussion**

- **Study results.** OBRA 1990 increased access to medications in a number of Medicaid programs that previously had relied on restrictive formularies. However, the rationality of this increased coverage was perceived to be mixed. Two physician panels agreed that only a quarter of a subset of the top 200 drugs with increased availability over the study period provided a net therapeutic advantage, and that an additional quarter provided no additional clinical benefit at all. This result must be weighed against the disproportionately increased costs experienced by many states that had previously main-

### EXHIBIT 2

**Likely Therapeutic Impact Of Eighteen Of Top 200 Drugs Whose Availability Increased Significantly After OBRA 1990**

<table>
<thead>
<tr>
<th>Net therapeutic benefit from wider availability</th>
<th>Questionable therapeutic benefit from wider availability, or no agreement</th>
<th>No additional therapeutic benefit from wider availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buspirone&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Hydrocortisone (Anusol HC)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Cefadroxil&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Lorazepam&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Estradiol patch&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Dipyridamole&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Lovastatin&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Florinal&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Propoxyphene&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Terfenadine&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Hydroxyzine&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Tavist-D&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Gemfibrozil&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Poly-vi-Flor&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Cyclobenzaprine&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Mecclizine&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylprednisolone&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td>Minocycline&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

**SOURCE:** Authors' calculations based on physician panel survey.

**NOTES:** Drugs were evaluated by a panel consisting of twenty-one practicing primary care physicians and six research physicians from the greater Boston area, considering alternative compounds and the cost-effectiveness of specific agents. Florinal has the following generic components: butaibital, aspirin, and caffeine. Tavist-D has the following generic components: phenylpropanolamine, clemastine fumarate. Poly-vi-Flor has the following generic components: prenatal vitamins with fluoride.

<sup>a</sup> Placed in the category by at least 50 percent of surveyed physicians.

<sup>b</sup> Placed in the category by at least 50 percent of surveyed primary care physicians.

<sup>c</sup> Placed in the category by at least 50 percent of surveyed research physicians.
tained restrictive formularies.28

Given well-known variations in practice patterns, our physician panels demonstrated a striking degree of consistency.29 Only five drugs that were judged to be of questionable value by one group were judged to be either beneficial or not beneficial by the other, with the research panel being slightly more critical than the primary care physicians. In no instance did the panels place drugs at opposite ends of the rating scale. This impressive concordance of opinion may have offset the relatively small number of physicians surveyed. Although this result may have stemmed from the physicians' limited geographic diversity (although their practice settings differed widely), it also may signal a reasonable level of generalizability outside of the greater Boston area.

Since we evaluated the effects of a nationwide natural "experiment," no control group was possible, and we were required to adopt a simple pre/post observational design. Even so, threats to validity, such as regression to the mean, are likely to have resulted only in the inclusion of some drugs that might have become more widely available even in the absence of a policy change. Such a result is unlikely to threaten our conclusions.

In addition, while some observers have pointed out anomalies in several Medicaid data sets (including First Databanks), which show artifactually decreased coverage between 1989 (when, for example, Kansas covered 64,642 products) and 1992 (when fewer than 15,000 products were covered), these data probably are a result of unreliable reporting to third-party data collectors about infrequently used agents.30 Since this paper focuses only on the 200 most economically important (and most closely watched) medications with increased coverage after OBRA 1990, such errors would tend to attenuate, rather than exaggerate, our reported findings.

Finally, since all of the medications that had significant increases in coverage had been marketed for appreciable periods of time before 1989, it is unlikely that improved market penetration alone accounts for our findings—especially in light of the finding that market equilibrium for some drugs may be reached in as few as two years.31 Instead, the increased coverage seems most likely to be a direct effect of formulary policy changes mandated by OBRA 1990.

### Implications.

Formulary decision making is an intrinsically difficult task. The use of medications is complex and may include important therapeutic niches that do not correlate with labeled indications.32 In addition, assessing costs, benefits, and cost/benefit ratios is a complicated, socially constructed activity about which reasonable people may, and often do, disagree.33 Finally, patients often have complex requirements for pharmacotherapy, based on
both medical and sociocultural needs, which physicians must address at an individual level.\textsuperscript{34}

\textit{Rationales for exclusions.} The rationales for some widespread exclusions from formulary coverage in 1989 seem open to question—for example, those for loperamide, erythromycin, and naproxen sodium may have been clinically unjustified. Even more troublesome, however, is that the availability of certain drugs (especially benzodiazepines) appears to have been significantly determined by negative public preconceptions, despite the drugs’ demonstrated importance in treating conditions such as panic disorders, convulsions, febrile seizures, alcohol detoxification, and short-term reactive insomnia.\textsuperscript{35}

\textit{Formulary design and health system change.} Proper formulary design also must take into account the complexities of our rapidly changing health care delivery system. Increasing administrative oversight is fast becoming a reality for most physicians. Administrators, pharmacists, and other providers have joined doctors in influencing the choice and use of drugs. Limitations in the clinical experience of these nonphysician players often can synergize with physicians’ own misconceptions about formularies and management issues and result in poor decision making.\textsuperscript{36} Of special importance in light of our results is the possibility of confusion between spending on high-priced, high-benefit drugs (which frequently may have an offsetting effect on total health care costs) and the much larger (and thus more budget threatening) amounts routinely allocated for buying widely prescribed but less obviously beneficial drugs.

\textit{Consequences of disallowing restrictive formularies.} Faced with the clinical, administrative, and financial difficulties inherent in proper formulary development, one can understand the impulse to simply disallow restrictive formularies altogether. Our study suggests that such an approach has both intended and unintended consequences and ultimately may prove counterproductive especially if increased expenditures on drugs that physicians perceive as offering little additional therapeutic advantage are less likely to be offset by reductions in other health care spending, as seems plausible.

The data indicate that states with previously restrictive formularies attempted to make somewhat greater use of expensive prior-approval procedures to salvage a portion of their previous exclusions. Even so, these states were unable to use this option effectively, which brings its overall viability as an alternative to restrictive formularies into serious question despite its potential to limit spending on particular agents.\textsuperscript{37}

\textit{Quality and cost.} Proper decision making about pharmaceutical availability remains a vital part of maintaining the quality of medical
care while containing its cost. Current Medicaid regulations place most Medicaid formulary decision-making power in the hands of state drug utilization review (DUR) committees (or specially appointed formulary committees). Since these bodies also are responsible for retrospective and prospective DUR programs, it may be appropriate to delegate this responsibility more specifically to a state (or even a national) P&T committee. Such a body might be better able to evaluate the relative cost/benefit ratios of specific drugs in a manner similar to that of the Pharmaceutical Benefits Advisory Committee in Australia. The responsibilities of such a body, however, would require careful balancing to avoid the criticisms of unconstitutionality, burdensomeness, and discriminatory effect that were leveled at a similar body proposed in 1990.

Medicaid managed care formularies. The practices of managed care organizations now advancing into the Medicaid market also require careful scrutiny. Several states have obtained Health Care Financing Administration (HCFA) waivers for “best-price” contracts with their subcontracting managed care organizations. These managed care formularies recently have been the object of complaints similar to those directed toward pre-OBRA 1990 Medicaid formularies. Given that 44 percent of physicians working for one managed care organization in Texas found the organization’s formulary “difficult to work with,” and 25 percent felt that quality of care was reduced, there may be legitimate cause for concern. A referendum in California that would have implemented strict formulary-based pharmaceutical benefits management for state-funded drug programs was defeated in the recent election, but similar efforts are certain to follow.

Concluding remarks. Because OBRA 1993 and the increasing importance of managed care in the Medicaid market are likely to again decrease access to a wide range of drugs, the importance of well-informed formulary committees and good clinical oversight cannot be overstated. Drug formularies are extremely complex instruments, especially in their regulatory (rather than descriptive) incarnation. Without rigorous data on the effects of outpatient formularies on the quality and total cost of care, no definitive conclusions about their policy implications are possible. However, when considering policy options in light of the results of this study, it appears crucial to recognize that the budgetary impact of a marketed compound may be only distantly related to its clinical utility.
This study was supported by a grant from The Robert Wood Johnson Foundation (no. 19782) and by the Health Care Financing Administration (HCFA) through the RAND/HCFA Center at Harvard University (Cooperative Agreement no. 99-C-98489/9-07). The opinions expressed are those of the authors and do not necessarily represent those of the sponsors.

NOTES
13. Public Law 101-508, sec. 1927(g).


19. Based on the total sales value of a given pharmaceutical product aggregated at the chemical entity level, with branded and generic versions of a given entity and specific delivery systems reported separately “Rx Prices for Second-Tier Products Rising Faster than Top 100, Univ. of Minn. Calculates in New Index for NACDS; 1992 Increases Are 7.7 Percent at Annualized Rate,” FDC Reports (The Pink Sheet) (7 September 1992): 7-8.

20. The single exception was South Dakota, which covered only 169 of the top 200 drugs but was classified for unknown reasons as an "open" formulary state.


27. Ibid.

28. Although a significant portion of the general increase in Medicaid drug expenditures after 1989 was attributable to expanded enrollment and/or price increases, these general trends cannot account for the disproportionately increased costs experienced by states that previously relied on restrictive formularies. To quantify this effect, we analyzed Health Care Financing Administration (HCFA) 2082 figures for the number of Medicaid drug program enrollees, by state, and total Medicaid pharmaceutical vendor payments, by state, adjusted to constant dollars using the drug component of the urban CPI for each year from 1989 to 1993. These figures show that while inflation-adjusted per capita Medicaid drug spending among previously ‘open’ formulary states increased from a stable baseline by approximately 4 percent between 1991 and 1992 (from $281 to $294 per enrollee), constant per capita pharmaceutical spending increased by nearly 10 percent among previously "restrictive" states, from $244 to $266 (p < 0.001). See D. Ross-Degnan et al., “Impact of the Omnibus Budget Reconciliation Act of 1990 on State Medicaid Pharmaceutical Programs” (Manuscript in preparation).


30. Judy Johnson, research fellow, PRIME Institute, University of Minnesota, personal correspondence, 13 November 1994.

31. The most recently licensed of these medications, lovastatin, was approved 14 December 1988. Buspirone, the next most recent, was approved 29 September
ACCESS TO DRUGS


42. "Lilly's Prozac and Humulin Have Exclusive Positions in RxCare Formulary for 360,000 Medicaid Recipients in TennCare Program; BMS Get[s] Pravachol and Capoten," *FDC Reports* (*The Pink Sheet*) (28 February 1994): 6-7.

