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# MEDICAID PATIENTS' ACCESS TO NEW DRUGS

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by Henry Grabowski

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**Prologue:** *Prescription drugs have demonstrated an awesome capacity to ameliorate pain and wage war against infectious diseases. But, unlike most other medical services and products, outpatient drugs are generally not covered either by private health insurance or, until its new catastrophic benefit becomes effective, Medicare. About two-thirds of the population pays for its drugs directly out of pocket. Only Medicaid, among the large public health financing programs, has provided outpatient drug coverage to eligible beneficiaries. As Medicaid programs have faced increasing pressure to moderate the growth of expenditures, though, some states have created drug formularies to restrict the products for which they will reimburse pharmacists. In this paper, Henry Grabowski addresses the question of how formularies affect the availability of drugs proven safe and efficacious by the Food and Drug Administration. Grabowski received his doctorate in economics from Princeton University in 1967. Since 1972, he has been a member of the faculty of Duke University. Currently, he is a professor of economics there and director of the Program in Pharmaceuticals and Health Economics, which is a part of the Center for the Study of Business Regulation. In the past fifteen years, Grabowski has studied many dimensions of the pharmaceutical industry. With support from the National Science Foundation (NSF), Grabowski examined how government regulation affects the structure of the pharmaceutical industry, particularly in research and development. He also has studied with NSF support the relationship between regulation, patents, and drug substitutability. Grabowski's expertise has been recognized by the Federal Trade Commission, the Office of Technology Assessment, and the Institute of Medicine. He is the author of two books published by the American Enterprise Institute: *The Regulation of Pharmaceuticals: Balancing the Benefits and Risks* (1983) with John Vernon, another Duke economics professor, and *Drug Regulation and Innovation* (1976).*

**M**any states have used drug formularies—statewide lists of basic drugs—as criteria for Medicaid drug reimbursement. These formularies account for such factors as the efficacy, safety, benefit/risk ratios, cost, needs of particular regions, side effects, and duplication of drugs. For a new drug to get onto a particular state’s formulary, the introducer generally must petition the appropriate state board. This process can result in significant time lags beyond Food and Drug Administration (FDA) regulatory approval delays. In addition, new drugs of medical value may not make it onto the formulary. While physicians may request reimbursement for unapproved products case by case, the extra hassle and time costs provide strong incentives against prescribing these nonformulary drugs. Hence, formularies can limit the number of new drugs available to Medicaid patients.

From the perspective of the innovating pharmaceutical firm, drug formularies provide an additional regulatory hurdle after FDA approval for a new drug is obtained. The time delays in gaining approval result in lost revenues and lower expected returns to new drug introductions, and can adversely affect the incentives for new drug innovation. The extent of this negative impact on innovation incentives will depend on the size of the market affected, the probability of eventual approval, and the time delays typically experienced in gaining approval.

Although the Medicaid patient population is only one component of the larger total pharmaceutical market, the percentage of drugs subject to third-party reimbursement and potential formulary restrictions has increased significantly over time.<sup>1</sup> Therefore, this article contains an empirical study of drug formularies’ effects on the availability of new drugs to Medicaid beneficiaries. It also examines formularies’ impact on market exclusivity periods and related factors influencing drug innovation incentives. Six states—California, Illinois, Kentucky, Mississippi, South Carolina, and Washington—were selected for study because they have had formularies in place for a significant period of time, and they also provided comprehensive data on formulary approvals of new drugs.<sup>2</sup>

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## Overview And Sample Characteristics

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An initial analysis of the Medicaid drug programs by state indicated that seventeen states had some type of formulary as of 1984. However, several of these states established their formularies quite recently, making them inappropriate for studying the new drug introduction delays. Other states had open formularies.<sup>3</sup> The six states selected for analysis all had restrictive formularies in existence since the early 1970s. They are also demographically diverse.

For this study, I assembled a list of new drugs (new single chemical entities) approved by the FDA and first marketed in the United States between 1974 and 1982, using FDA and trade data sources.<sup>4</sup> Since Medicaid formularies pertain to outpatient drugs, inpatient drugs were omitted. In addition, only patentable compounds with some effective patent life remaining at the time of first marketing were included. This resulted in a sample of eighty-four new drug entities for which approval dates onto the Medicaid formularies were compiled.

For each new chemical entity in this sample, I assembled data on the drug's therapeutic category, its commercial significance, and its therapeutic significance at the time of marketing as evaluated by the FDA. I also computed the effective patent time remaining at the time of initial commercial introduction.

The data sample of new drug introductions used in this article is similar to that used in a study by Stuart Schweitzer, Hosein Salehi, and Nancy Boling, which analyzed new drug availability to Medicaid patients for 1970–1980.<sup>5</sup> Their work primarily examined how the restricted availability of new drugs affects Medicaid drug program expenditures.<sup>6</sup>

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## The Effect Of Formularies On The Availability Of New Drugs

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**New drug approvals by state.** Exhibit 1 provides basic information on formulary approvals for new drug introductions by state, including number approved and the average time lag for these approvals. It clearly shows a large variance in the approval rate and time delays by state and over time.

Exhibit 2 shows the distribution of acceptances of new drug introduc-

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**Exhibit 1**  
State Drug Formulary Approvals And Time Delays, 1974–1982

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Year	Total new drug introductions	California		Illinois		Kentucky		Mississippi		South Carolina <sup>a</sup>		Washington	
		N	Lag	N	Lag	N	Lag	N	Lag	N	Lag	N	Lag
1974	10	4	55	10	26	4	75	8	40	9	41	9	21
1975	9	5	51	8	16	3	72	5	67	6	27	8	8
1976	6	3	44	6	17	5	66	6	15	5	12	5	6
1977	11	2	25	11	7	1	58	8	8	7	18	6	14
1978	10	4	37	10	13	4	35	8	28	6	6	8	12
1979	7	1	0	6	16	1	26	3	28	4	5	4	10
1980	8	0	-	7	21	0	-	4	24	4	9	5	6
1981	10	3	48	8	13	2	18	7	13	7	21	7	7
1985	13	5	40	11	15	5	20	9	15	10	10	10	13

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**Note:** N is number approved onto a particular state's formulary; Lag is average time delay for approval (in months) measured from the date of first marketing.

<sup>a</sup>South Carolina shifted to an open formulary in late 1984. Nevertheless, since the approval times in this state have been less than two years, the computed lags for the last few years of the sample period should not be materially affected.

**Exhibit 2**  
**Acceptance Of New Drug Introductions Onto State Medicaid Formularies, 1974–1982**

Approved by	Percent of total sample
All six states	20.2%
Five of six states	13.1
Four of six states	24.2
Three of six states	14.3
Two of six states	9.5
One of six states	11.9
Zero states	4.8
Total	100.0

tions onto the six state formularies. Clearly, states employ diverse criteria in their formulary decisions. Here, one does not observe a bimodal distribution with one set of drugs that are accepted by all or most states and another set of drugs that are commonly rejected by these states. Rather, one observes a diffuse distribution pattern. Only 20 percent of the drugs were accepted by all six states, and the acceptances are spread evenly across the other categories in Exhibit 2.

Exhibit 3, which displays the approval rates and average time delays in each state, shows that California and Kentucky had the most stringent formularies for new drug approvals. The average approval rate in these two states was approximately 30 percent, and the average time lag for new drugs' approval exceeded forty months. By contrast, in the other four states, the approval rate ranged from 69 to 92 percent and the average lag, between twelve and twenty-five months.

**New drug availability.** In the third column of Exhibit 3, an index of availability is computed that is used extensively throughout this article. This index of availability gives the average amount of time (in years) that a new drug introduction was available to Medicaid patients during the first five years of market life. In effect, this is a composite variable that

**Exhibit 3**  
**Drug Formulary Approval Rates And Time Delays, By State, 1974–1982**

State	Approval rate	Average length of time for approval (months)	Availability during first five years of market life (years)
California	32.1%	42.5	0.5
Illinois	91.7	15.7	3.4
Kentucky	29.8	48.4	0.4
Mississippi	69.0	25.1	2.2
South Carolina	69.0	17.5	2.4
Washington	73.8	11.6	3.0

combines information on the probability of approval and the average time to approval into a single measure of availability. A time span of five years was chosen because drugs placed onto a state formulary generally were approved within this period of time.<sup>7</sup> In addition, the first five years in the drug life cycle are critical to the innovator's revenues and profits. The average effective patent life for a new drug during the period under study was only about half the nominal life of seventeen years.<sup>8</sup>

In Exhibit 4, the availability variable is calculated for different therapeutic categories of drugs. The therapeutic categories with the least availability were anti-infectives, psychotherapeutics, and metabolic and anti-fertility drugs. These three categories had computed mean availability values that were significantly below the overall sample mean. They are among the largest pharmaceutical categories in terms of annual revenues.

In computing the availability index for new drug categories grouped by FDA rankings of therapeutic importance, somewhat surprisingly, the group of new drugs ranked as significant therapeutic advances (class A) was the least available to the Medicaid population. This group, which included only eleven new drugs, was available 1.6 years of the first five years of market life. By contrast, drugs ranked as modest gains (class B) were available 2.1 years, and drugs ranked as little or no gain were available 2.0 years. It is not clear whether these results reflect a problem with the FDA rankings or some other phenomenon.

A fairly strong positive relationship is exhibited between a drug's availability and its commercial significance. The lowest quartile in terms of commercial significance was available 1.4 years, whereas the upper quartile was available 2.7 years. The middle two quartiles were ranked at 2.1 years and 1.7 years. This strong relationship between commercial significance and availability is expected. For drugs in the upper quartile, with fifth-year U.S. sales in excess of \$40 million, an innovator will have

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**Exhibit 4**  
**Availability Of New Drug Introductions On State Medicaid Formularies By Therapeutic Classification**

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Therapeutic category	Availability during first five years of market life (years)
Cardiovascular	2.7
Neurologic, analgesic	2.3
Psychopharmacological	1.7
Metabolic, antifertility	1.6
Anti-infective	1.4
Anti-inflammatory	2.7
Gastrointestinal, respiratory, surgical	2.4

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strong incentives to expend resources to get a new drug approved as quickly as possible. Nevertheless, even given these strong incentives, the average new drug in this category was available in the overall sample only about half of the first five years of market life. In the case of California, the most populous state, the upper quartile was available only 1.2 years.

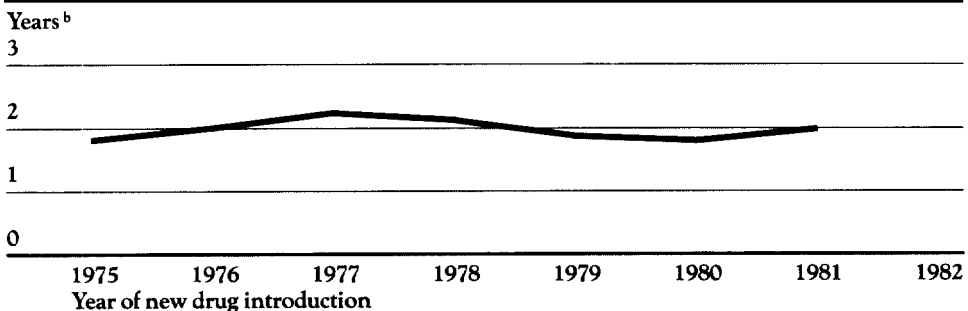
**Trends in drug availability.** Exhibit 5 displays the time trend in new drug availability over the six-state sample. This is computed using three-year moving averages to smooth out year-to-year fluctuations. Exhibit 5 shows no tendency for availability to increase or decrease over time. The observations fluctuate within a relatively narrow range around the mean of two years.

New drug availability is influenced by the likelihood of obtaining approval in a particular state and the average time lag for approved new drugs to get onto the state's formulary. While the availability index shows no trend over time, these two underlying component variables do show distinctive trends.

Exhibit 6 shows the trend in approval rates, indicating that these six states' formularies have become more stringent in accepting new drugs over time. The average approval rate was 60–70 percent from 1975 to 1977, and dropped to 45–55 percent over 1978–1981. All of the six states had a lower approval rate in the final period.<sup>9</sup>

While the approval rate declined over time, those drugs that were approved onto the formulary at the end of the sample periods obtained faster approval than had earlier drugs (Exhibit 7). In contrast to the experience for approval rates, the decline in average lags is heavily influenced by the situation in one state, Kentucky, where the formulary time lags declined from over seventy months to an average of less than twenty months (Exhibit 1). Much more moderate declines appear in the

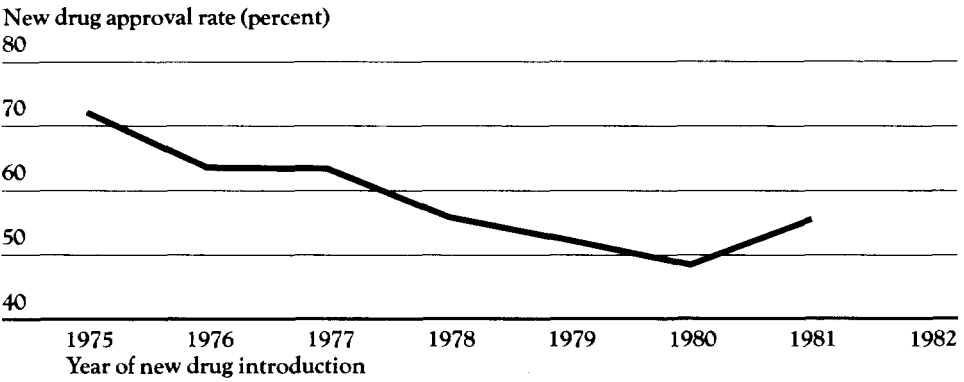
**Exhibit 5**  
Availability Of New Drugs On Medicaid Formularies, 1975–1982<sup>a</sup>



<sup>a</sup>Computed using a three-year moving average.

<sup>b</sup>Mean availability during first five years of market life.

**Exhibit 6**  
**Trend In New Drug Approval Rates, 1975–1982<sup>a</sup>**

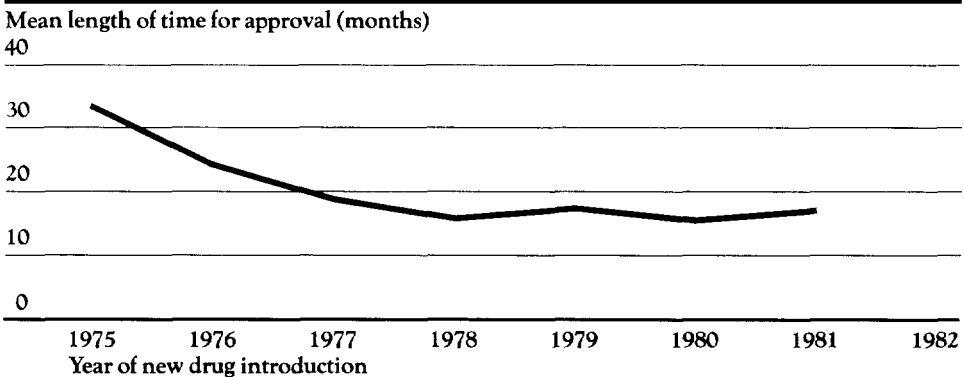


<sup>a</sup>Computed using a three-year moving average.

lags for other states, and a few, such as California, show little trend over time.

**Implications for Medicaid patients.** These results show that access to new drugs for Medicaid patients was curtailed significantly. Medicaid patients in the six states currently have direct access to only half of the new drugs approved as safe and effective by the FDA. The typical new drug was available to these patients only two of the first five years of market life. In California, the most populous state, the approval rate for new drugs is less than one new drug in three, and the typical new drug was available only one-half year of the first five years. Certain categories of drugs, such as anti-infectives, were particularly restricted by the Medicaid

**Exhibit 7**  
**Trend In New Drug Approval Times, 1975–1982<sup>a</sup>**



<sup>a</sup>Computed using a three-year moving average.

formularies. New drugs of medical and commercial importance were not exempt from significant time delays and restricted access.

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### Effect On Pharmaceutical Innovation

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My second basic objective in this study is to gain insights into how widespread use of formularies would influence the incentives for drug innovation. Thus, I analyze the impact of formularies on the returns to innovation from a conceptual standpoint and consider the relevant empirical findings.

**Conceptual considerations.** Medicaid formularies have a direct impact on the expected sales revenues of a new drug. It is therefore useful to examine the potential revenues from drugs sold to Medicaid patients. For a typical new drug, assuming no formulary restrictions are operative, sales go through an initial period of rapid growth, eventually plateau as a drug matures, and then decline when the drug's patent expires and generics enter the market.<sup>10</sup> The delays that occur in states approving the drug onto the formulary cause the life cycle curve to be shortened on the front end and reduce the effective patent life. Hence, if a particular state's drug formulary results in a delay of two years for a new drug, sales to the Medicaid population are lost over this initial period, and the marketing exclusivity period for this population also is reduced by two years. Moreover, to the extent that some states do not approve a new drug onto their formularies, the number of patients potentially able to consume the drug is reduced. This causes the ultimate sales revenues even at the drug's maturity to be lower.

One qualification to this scenario concerns the possibility that a drug accepted onto the formulary will face reduced competition from other drug introductions. This could be the case, for example, if subsequent new product introductions also experience delays getting onto a formulary, thereby leading to higher sales in later phases of the life cycle before these rival products are approved.

While this is a possibility, a pharmaceutical firm generally will fare worse by trading lost sales early in its life cycle for increased sales in later phases. Because of the time value of money, sales in the early part of the life cycle will be worth more in a discounted present value sense compared to those experienced later in the product life cycle.<sup>11</sup> Hence, if all new product introductions experience similar time delays and lost sales opportunities, there still will be a negative effect on the expected return to new product innovation because of this time discount factor.<sup>12</sup>

**Some numerical computations.** The previous analysis indicates that the likelihood of a new drug entity's being approved onto a Medicaid

formulary has diminished over time. By the end of the period studied, the likelihood of approval hovered at 50 percent for the full sample.<sup>13</sup> From the standpoint of innovation incentives, a nonapproval has the maximum adverse effect since it precludes sales to the uninsured population over the entire product life cycle (except through the prior-approval procedure). It is instructive to consider how approval rates of this magnitude would affect innovation incentives if formularies became more widespread. For example, if formularies covered 50 percent of the pharmaceutical market and, at the same time, there is only a 50 percent chance of approval for a representative new drug, this would suggest an expected loss for the typical new drug in sales revenues of 25 percent in every year of the product life cycle.

Sales losses of this magnitude would have a substantial adverse effect on the incentives to develop and market many new drugs, particularly those that have small annual sales (below \$25 million) but that nevertheless contribute to medical therapy and commercial performance. It is important to note that the distribution of returns for new drug products is highly skewed.<sup>14</sup> A few products have very large sales revenues (above \$100 million), but the median new drug product has a relatively small market compared to these few big winners. The economics are such that many new product introductions would be vulnerable to losses in sales revenues of this magnitude. Several medical therapies representing useful incremental advances, or even significant gains in medical treatment, could be lost from the development process.<sup>15</sup>

**Effect on marketing exclusivity periods.** For drugs with a high probability of eventual formulary approval, time delays in approval hinder innovation incentives the most. As discussed above, time delays result in lost sales during the early part of the life cycle and thus compress the marketing exclusivity period available to recoup research and development (R&D) investment costs.

Exhibit 8 plots trends in marketing exclusivity periods for 1974–1982. This exhibit shows that marketing exclusivity periods to the Medicaid population in the six-state sample were reduced by between 1.3 and 3.9 years over 1974–1982. These delays shorten an already brief period for pharmaceutical firms to recoup their R&D investment. The average marketing exclusivity period for new drug introductions in 1980–1982 was 7.3 years. After accounting for formulary time lags, the average marketing exclusivity period for these drugs was reduced to 5.9 years.

In California, an especially stringent state with considerable economic and political prominence, the average exclusivity period was reduced from 12.3 years to 8.4 years as a result of formulary time delays over 1974–1977. For 1978–1982, average exclusivity periods fell from 9.6 to 6.3 years

## Exhibit 8

## Average New Drug Marketing Exclusivity Time, Medicaid Formulary And Nonformulary States, 1974–1982

## Marketing exclusivity time (years)

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11

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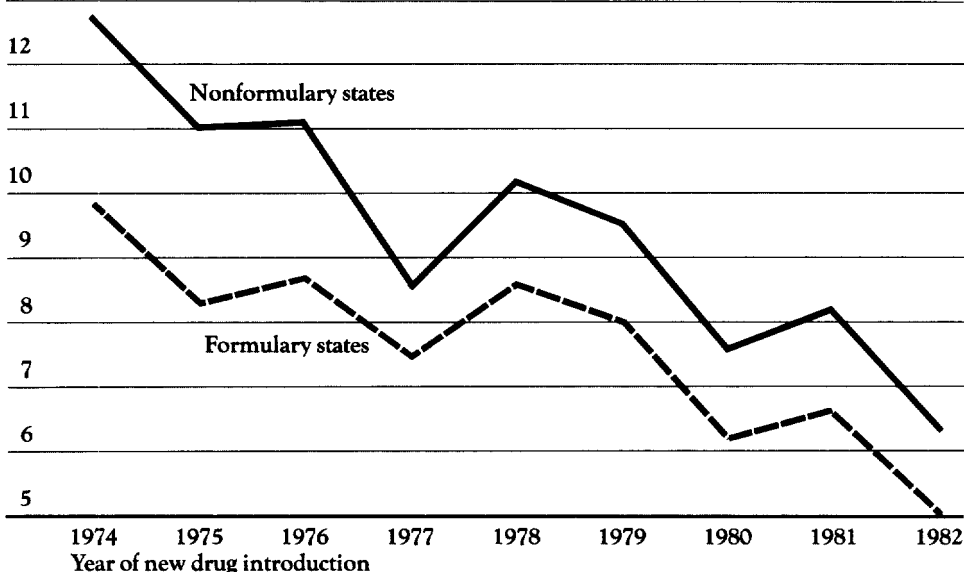
8

7

6

5

1974 1975 1976 1977 1978 1979 1980 1981 1982  
Year of new drug introduction



in the state. Thus, if formularies resembling the California Medicaid (MediCal) formulary became widespread, new drug innovation incentives would suffer acutely. The approval rate for new drugs in this state is only 30 percent, and for those drugs eventually accepted onto the formulary, more than a third of the marketing exclusivity period is lost because of time delays in obtaining approval.<sup>16</sup>

### Public Policy Considerations

This study shows that Medicaid patients in states with closed formularies have significantly restricted access to new drug therapies. The typical new drug was available only two of its first five years of market life for the six states considered. Moreover, restrictions in availability were not confined to drugs that duplicated existing therapies, but also included drugs exhibiting strong market performance and drugs that received high FDA rankings in medical importance.

The study results also suggest that the incentives to develop many new drug products decrease as formularies become more prevalent. A few big winner drugs return their R&D investment many times. However, the

median drug now has sales revenues that are close to break-even, and this status is achieved only after a decade or more of marketing life. In a world of widespread formulary programs, many new drugs would have difficulty achieving break-even status, given the added time delays of obtaining formulary approval and the possibility of nonapproval. Formulary time delays are often comparable to and sometimes exceed the time delays to obtain FDA approval.

Congress addressed the problem of shortening marketing exclusivity periods in 1984 with passage of the Drug Price Competition and Patent Restoration Act (P.L. 98-417). This act allows part of the time lost in development and FDA approval of new drugs to be restored. At the same time, it facilitates generic imitation after patents expire. The verdict on how this legislation will affect new drug innovation is still out.<sup>17</sup> However, this act covers only patent time lost in clinical development and FDA approval process, not the time lost for innovators to gain admission to product formularies after FDA approval.

**Impact of Medicare catastrophic legislation.** This year, Congress has created a significant new program of outpatient prescription drug benefits for the elderly under the Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360). When the drug benefits become effective in 1990, the percentage of drug prescriptions subject to government reimbursement will increase significantly. However, this legislation prohibits the secretary of health and human services from implementing a formulary to exclude any drug from coverage that has been approved as safe and effective by the FDA.<sup>18</sup> Thus, Congress has ruled out, at least for the present, the establishment of a national formulary under Medicare similar to those that currently exist in several state Medicaid programs.

The prescription drug benefits under the Medicare Catastrophic Coverage Act are supposed to be self-financing. Earmarked "premiums" from participants will go into a prescription drug trust fund. Various cost-containment provisions also are built into the legislation. On the demand side, these include both deductibles and coinsurance payments. On the supply side, there are reimbursement limits for drugs with multiple sources of supply as well as limitations on pharmacy charges.<sup>19</sup>

It remains to be seen, however, whether future program revenues will be sufficient to cover mandated benefits. The history of government-financed health programs does not augur well in this regard. If future revenues are insufficient, Congress and federal administrators may be tempted to institute more far-reaching cost-containment measures such as Medicaid-type drug formularies. If this occurs, policymakers must address the negative effects on the supply of future new drug innovation. The analysis performed in this article indicates that such a development

would deter pharmaceutical R&D investment significantly.

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NOTES

1. The most recent annual survey by *American Druggist* (May 1988) found third-party reimbursements had grown to 35.1 percent of total outpatient prescriptions in 1987 (up from 30.5 percent in 1986). Medicaid-reimbursed prescriptions were approximately half of all third-party reimbursements in 1987 (17.8 percent of total prescriptions).
2. I am indebted to Mark Harris and Lee Hill for their assistance in obtaining the data on formulary approval times.
3. Information on formulary characteristics is provided in "Pharmaceutical Benefits Under State Medical Assistance Programs," *National Pharmaceutical Council*, 1984 ed. In addition to the six states in the study, some limited data were obtained for three other states—Missouri, Tennessee, and Utah—but were too fragmentary to be included here.
4. The FDA provided information on the data of approval for all new single chemicals. *De Haen Survey of New Drug Approvals* (Englewood, Colo.: Paul De Haen International, Inc., various issues) was used to obtain the date of first marketing and other information, such as a drug's therapeutic category classification.
5. S. Schweitzer, H. Salehi, and N. Boling, "The Social Drug Lag: An Examination of Pharmaceutical Approval Delays in Medicaid Formularies," *Social Science and Medicine* 21, no. 10 (1985): 1077–1082. Their study used the same six states in this analysis, plus New York. The latter state shifted to a closed formulary in 1977, and data were available for only a short portion of the time that it has been on closed formulary. Therefore, it was not included in the present analysis.
6. Schweitzer et al., "The Social Drug Lag," 1081. Somewhat paradoxically, they found that states with more restrictive new drug availability have significantly lower Medicaid program expenditures, but not lower Medicaid drug expenditures. This finding is hard to explain in terms of economic savings from restrictive drug formularies. An alternative explanation (suggested by the authors) is that the states with the most restrictive drug formularies are also the states that tend to institute more far-reaching cost-containment measures. In other words, one observes a statistical correlation, but not a causal relationship, between their index of restricted availability and overall Medicaid program costs.
7. Schweitzer et al., "The Social Drug Lag," The authors use a similar measure of availability but base it only on the first two years of market life. Since new drug approval lags frequently exceed two years and have been changing over time, a two-year period does not allow for changes in availability over time.
8. M.M. Eisman and W. Wardell, "The Decline in Effective Patent Life For New Drugs," *Research Management* (January 1981): 18–21.
9. There is the possibility of modest truncation bias in our measures of approval rate and time delays for the final years of the sample. For example, if a drug in the 1982 group was approved onto a state formulary with very long time lags so that it was not yet approved at the time the data were collected (for example, late 1985), the approval rate and time delay measures would be understated. However, since very few drug approvals exceed forty months in our sample after 1978, any such bias is not likely to have a material effect on the results.
10. Sales may start to decline prior to patent expiration if a substitute therapy is introduced into the market. There is also evidence in recent trade publications that sales declines in the postpatent period have intensified significantly since the passage of the Waxman-Hatch Bill (P.L. 98-417) in 1984. This act facilitated generic entry on the market after

patents expire, while extending effective patent life for future new drug introductions. See the analysis in H. Grabowski and J. Vernon, "Longer Patents for Lower Imitation Barriers," *American Economic Review* (May 1986): 195–198.

11. An earlier study found that a one-year reduction in FDA approval time resulted in a more than three-year reduction in break-even lifetimes. This reflects the fact that the present value of sales at the end of the life cycle were worth much less economically than those at the beginning. H. Grabowski and J. Vernon, "A Sensitivity Analysis of Expected Profitability of Pharmaceutical Research and Development," *Managerial and Decision Economics* 3, no. 1 (1982).
12. In addition, some states remove older products as the number of products on a formulary increases. This will cause a truncation of earnings potential in the later stages of the life cycle. An analysis of product removals is beyond the scope of this article, since data on the timing of removals were unavailable.
13. If one used population-weighted averages to compute the approval rate, the average rate in my six-state sample would be less than 50 percent. This is because California, by far the most populous state, had an approval rate significantly below the average. A lower average approval rate would cause the loss of sales in this example to increase.
14. H. Grabowski and J. Vernon, *The Regulation of Pharmaceuticals: Balancing the Benefits and Risks* (Washington, D.C.: American Enterprise Institute, 1983), 51–56; and P. Joglekar and M. Patterson, "A Closer Look at the Returns and Risks of Pharmaceutical R&D," *Journal of Health Economics* 5 (1986): 153–177.
15. Joglekar and Patterson, "A Closer Look at the Returns and Risks of Pharmaceutical R&D," 165–173, find that the median new drug introduction does not cover fully allocated R&D costs. The drugs in the top few deciles provide the dominant share of the returns from pharmaceutical R&D.
16. The drugs approved onto the California formulary have somewhat different characteristics than the representative new drug in the overall sample. In particular, the California drugs have a higher average patent life (before considering formulary lags) and higher average sales revenues than for the sample as a whole. This is not surprising, since an innovator in this situation has very little incentive to seek approval for a new product with a very short patent life or very small market size.
17. A preliminary analysis of this legislation suggests that the returns to the average new drug introduction would be negatively affected. Grabowski and Vernon, "Longer Patents for Lower Imitation Barriers."
18. U.S. Congress, House Conference Report on the Medicare Catastrophic Coverage Act of 1988 (HR 2470) 100th Cong., 2nd sess. (31 May 1988), Report 100-661, 28.
19. *Ibid.*, 21–41.