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Assessing The Impact Of Coverage Gaps In The Medicare Part D Drug Benefit

*People with greater-than-average medical need
will be disproportionately affected by coverage gaps
in the new Medicare drug benefit.*

By Bruce Stuart, Linda Simoni-Wastila, and Danielle Chauncey

ABSTRACT:

The new Medicare Part D drug benefit contains major coverage gaps for people who spend moderate to high amounts on prescription drugs who qualify only for the standard coverage. To help policymakers understand the impact such gaps will have on those affected, we studied a representative sample of Medicare beneficiaries with naturally occurring prescription benefit gaps between 1998 and 2000 using data from the Medicare Current Beneficiary Survey. Our findings suggest that discontinuities in drug benefits result in sizable reductions in medication use and spending, which is magnified in people with common chronic illnesses.

The Medicare Part D drug benefit scheduled to commence on 1 January 2006 contains major gaps in coverage. The standard benefit available to beneficiaries with income above 150 percent of the federal poverty level has a \$250 deductible and a benefit gap or “doughnut hole” for prescription spending between \$2,250 and \$5,100. As a result, many beneficiaries with moderate and high drug costs will pay full price out of pocket for much of the year. For example, a person with a \$3,000 annual drug bill in 2006 would be “uncovered” for four months (the first month to meet the deductible and the last three months in the doughnut hole), assuming uniform drug spending throughout the year. Each January 1 the process starts over again with even bigger gaps; by 2008, beneficiaries will face a \$300 drug deductible and a \$3,447 doughnut hole. Predicting the effect of such gaps on beneficiaries’ use of medications is challenging, because there are no plans in the market today with similar benefit designs.

A growing body of research shows that elderly people with no prescription benefits use fewer drugs.¹ Studies also have shown that elderly people who experience gaps in health insurance coverage use fewer services during those spells without coverage, whether voluntary or involuntary.² However, there is very limited evidence of the effect of gaps in prescription coverage on use and spending among Medicare beneficiaries. Results from two recent surveys of Medicare enrollees in health maintenance organization (HMO) plans with prescription benefit caps of \$200–

\$1,200 a year showed that many beneficiaries cut back on their medication use after they exceeded the cap.³

We are aware of no studies that have directly addressed the question of whether cycling in and out of drug coverage has adverse health effects. One might reasonably expect that the risk of poor outcomes would rise if interruptions in drug coverage led to reduced compliance with medication regimens. There is a small but compelling literature showing that gaps in health insurance coverage are associated with negative health outcomes and reduced use of preventive services.⁴

This study provides additional empirical evidence for policymakers about how discontinuities in prescription coverage affect Medicare beneficiaries' spending patterns. It builds on earlier work showing that a surprisingly large percentage of beneficiaries faced interruptions in their prescription benefits during 1995 and 1996.⁵ We updated the analysis to 1998–2000 and evaluated the relationship between benefit discontinuities and drug spending patterns. We make no claim to mimic the Part D benefit, but we evaluated two of the most important consequences of the standard benefit design: namely, that high-spending beneficiaries will tend to have longer gaps in prescription coverage than lower-spending beneficiaries (because they spend more of the year in the doughnut hole), and that most beneficiaries with moderate and high drug spending will cycle in and out of coverage persistently from year to year.⁶ Based on these empirical findings, we conducted a simulation exercise estimating total and out-of-pocket drug spending in 2006 for an average Medicare Part D enrollee and for three cohorts of beneficiaries with common chronic health conditions.

Study Data And Methods

Data. Data for the study were taken from the 1998–2000 Medicare Current Beneficiary Survey (MCBS). The MCBS is a nationally representative, longitudinal survey of Medicare beneficiaries conducted by the Centers for Medicare and Medicaid Services (CMS).⁷ It collects extensive information on individual demographic characteristics, health and functional status, medical and prescription drug insurance supplements (including plan beginning and ending dates, which we used to operationalize measures of prescription coverage gaps), and annual use of and spending for all health services, including prescriptions. We augmented the survey with administrative data on Medicaid and Medicare enrollment and all Part A and Part B Medicare bill records.

Study sample. Our sample frame consists of community-dwelling MCBS respondents first selected in fall 1997 (N = 4,640). We tracked this sample for three years to generate a sufficient time frame for capturing evidence of prescription benefit gaps, including multiple gaps. Beneficiaries enrolled in Medicare HMOs in 1998 were excluded because they lacked the baseline Medicare claims data necessary for risk adjustment. However, those first enrolling in Medicare+Choice (M+C) plans in 1999 or 2000 were retained. Residents in long-term care facilities were excluded because they lacked data on drug spending. These selection criteria resulted in an analytic sample of 3,094 beneficiaries.

We were also interested in studying the impact of prescription coverage gaps on people with chronic conditions for which medications are a mainstay of treatment. We selected diabetes, chronic lung disease, and mental illness—common ailments for which drug therapy can cost thousands of dollars a year. Prior research has shown that beneficiaries with these conditions tend to be price-sensitive in their demand for medication therapy.⁸ In other words, they are among those most likely to be negatively affected by the Part D benefit gaps. We used diagnosis codes on the Medicare bill records to identify them. The subsamples included 549 beneficiaries diagnosed with diabetes, 499 with chronic lung disease, and 382 with mental health conditions at baseline (1998), representing 17.7 percent, 16.1 percent, and 12.3 percent, respectively, of the whole sample.

Variables and analytic strategy. Our outcome variable is drug spending paid from all sources over the three-year study period expressed in constant 2000 dollars and inflated by 17 percent to account for underreporting.⁹

The primary independent variables are “prescription gap months,” the summed number of months over the three-year period during which the beneficiary had no evidence of prescription coverage, and “prescription gap count,” the total number of gaps experienced over the three-year period (that is, the number of continuous periods without coverage bounded by periods with coverage). We were interested in measuring the relationship between the two gap indicators and drug spending during the three years. We hypothesized that spending would decline with more and longer gaps, all else being equal.¹⁰ The analytic challenge was in satisfying the *ceteris paribus* condition given that people might have chosen to move into or out of prescription coverage based on factors that could also influence drug spending (for example, sicker people are more likely to sign up for drug coverage if they can get it, and sicker people use more drugs). To produce unbiased estimates, these potential voluntary selection effects must be neutralized.

Our analytic strategy involved two steps. First, we developed measures to control for “selection on observables.” These measures included indicator variables for Medicare Part A and Part B supplements and beneficiaries’ age, sex, race, marital status, poverty status, education, location, self-reported health status, and mortality.¹¹ Our most important control variable is the Diagnostic Cost Group/Hierarchical Coexisting Condition (DCG/HCC) risk adjuster, which captures the presence of up to 184 medical conditions based on diagnoses recorded on a patient’s Medicare claims (physician, outpatient, and inpatient). The DCG/HCC has been extensively validated and is used to risk-adjust capitation payments to Medicare Advantage (formerly M+C) plans.¹²

The second step in our analytic strategy was to test for potential “selection on nonobservables”—that is, for factors predictive of both prescription gaps and drug spending but not included as covariates in the multivariate model. For this we employed the Durbin-Wu-Hausman (DWH) test.¹³ We applied the DWH test to two versions of our model; a “naïve” version, which excluded the DCG/HCC risk adjuster, and the final version, which included it. The intuition behind this approach is that if (as we believe to be the case) baseline health status is the primary driver for voluntary moves into and out of drug coverage in the population (involuntary moves do not present a selection issue), then the coefficients on the gap variables will be biased in the absence of the DCG/HCC (yielding a significant DWH test finding) but unbiased in the presence of the risk adjuster (in which case the DWH test will be nonsignificant). In previous work analyzing the impact of prescription coverage, we have generally found that the DCG/HCC provides adequate control for selection bias.¹⁴

We estimated regression models of prescription coverage gaps on drug spending using both ordinary least squares (OLS) and a generalized linear model with a gamma distribution and log link. Because signs, significance levels, and effect sizes were very similar across the two models, we report only the OLS results here. The regressions included terms interacting the prescription gap month variable with indicators for the three targeted chronic diseases. These interaction terms tell us whether the impact of prescription coverage gaps is quantitatively different for beneficiaries with diabetes, chronic lung disease, and mental illness.

The final step in the analysis was a simulation model designed to predict how Part D coverage thresholds would influence drug spending in 2006 for beneficiaries, including those with the three targeted chronic conditions. We used an iterative process that jointly considered predicted drug spending and months of coverage to provide final spending estimates under Part D. This procedure is akin to the solution to the famous economic case of the “dynamic cobweb” that can arise when supply and demand are out of equilibrium.¹⁵ In our study, Part D pushes beneficiaries’ demand for drugs out of equilibrium, but because the effective insurance subsidy and gap periods are simultaneously determined, movement to the final equilibrium may take a number of interim steps. Details of the simulation mechanics are described in an online appendix.¹⁶

Study Results

Sample characteristics. Beneficiaries with mental health conditions were much more likely to be under age sixty-five and female than the full sample ([Exhibit 1](#)). The diabetic population had more nonwhites than the general population. Self-reported health status was much lower for all three disease groups, with the poorest ratings given by those with mental illness. Crude death rates among beneficiaries diagnosed with chronic lung disease were highest of all the groups and more than double the population average. Annual prescription spending over the three years measured in constant 2000 dollars averaged \$1,266 for the full sample and was 42–61 percent higher for the three disease groups ([Exhibit 1](#)).

Exhibit 1.

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Continuity of prescription coverage. Overall, 48.7 percent of the Medicare population had continuous drug coverage for the entire three years, 25.6 percent had no drug coverage whatsoever, and the remaining quarter maintained varying spans of coverage ([Exhibit 2](#)). A majority of those with interruptions in coverage experienced just a single gap, but 42.2 percent experienced two or more gaps. The three disease cohorts experienced higher rates of continuous drug coverage and lower rates of no drug coverage. The mental health cohort had the highest proportion of individuals with one or more gaps in coverage. The diabetes cohort had the highest rate of multiple gaps.

Exhibit 2.

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Predictors of drug spending, 1998–2000. Key findings from the OLS regression are presented in the first eight rows of [Exhibit 3](#). Gap months and gap counts both reduced drug spending, but only the gap-month variable was statistically significant. On average, each added month without prescription coverage reduced drug spending by \$25.13 (95 percent confidence interval: –\$36.04, –\$14.21). Having diabetes increased spending over three years by \$1,384 (95 percent CI: \$900, \$1,869). Chronic lung disease added \$1,666 (95 percent CI: \$1,143, \$2,188), and mental illness added \$2,282 (95 percent CI: \$1,685, \$2,879). The interactions with prescription gap month were negative and significant for chronic lung disease and mental illness ($p < .0001$) and neared significance ($p = .06$) for diabetes. Adding the interaction coefficients to the main gap-month effect generates a predicted decline in drug spending per month without coverage of \$48.55 for diabetes, \$74.81 for chronic lung disease, and \$86.91 for mental illness. The marginal effects are for a single month without coverage over three years; if a beneficiary were uncovered for a month each year, the dollar magnitude would be triple the amount we reported.

Exhibit 3.

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The number of interruptions in basic Medicare supplementation also had a significant negative effect independent of prescription coverage. Age, sex, race, poverty status, and health status were all strong predictors of drug spending. In a version of the model that included the individual HCC indicators, twenty-one were statistically significant (data not shown). The mortality coefficients reflect a balance between foreshortened observation periods and higher spending in the months immediately prior to death. Overall, the model had excellent explanatory power (adjusted $R^2 = .30$). We ruled out “selection on nonobservables” based on nonsignificant DWH test results in the final model. It is noteworthy that the DWH tests run on the “naïve” model version that excluded the DCG/HCC risk adjuster showed significant evidence of endogeneity, thereby confirming our expectation that the DCG/HCC controls for potential selection bias in the prescription coverage variables.

Simulating the impact of Part D coverage on drug spending. The simulation model results are derived in the online appendix and are discussed in the context of the study questions based on data in [Exhibit 4](#).¹⁷ We estimate that the average Medicare beneficiary with continuous drug coverage would spend \$2,683 on prescription medications in 2006, given the type and generosity of drug benefits available in the period of 1998 to 2000 ([Exhibit 4](#)). Projected mean spending levels for the three chronic disease groups under the same assumption range from \$4,000 (chronic lung disease) to \$4,729 (mental illness). The second row of [Exhibit 4](#) provides estimates of drug spending for beneficiaries with no prescription coverage. We project that if these beneficiaries enrolled under the standard Part D benefit (row 3), their mean drug spending would rise from \$1,584 to \$2,472 for the average beneficiary and by higher amounts for each of the disease groups. Row 4 shows the number of months these newly enfranchised beneficiaries would spend in Part D benefit gaps, and below that we show their estimated out-of-pocket spending during gap periods plus coinsurance payments. The final row shows the estimated spending by newly enfranchised beneficiaries with only Part D coverage as a percentage of that for beneficiaries with continuous coverage.

Exhibit 4.

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This exercise demonstrates that for a Medicare beneficiary with average projected spending, the impact of the Part D benefit gap is modest (less than an 8 percent difference compared with persons who had continuous coverage). However, for a beneficiary with one of the three chronic diseases, the impact of the Part D benefit design is considerable. On the one hand, the availability of the benefit raises predicted drug spending by 43 percent (diabetes) to 61 percent (mental illness) above the level that would occur in the absence of any coverage. On the other hand, the demand-reducing effect of paying full drug prices during benefit gaps will prevent these beneficiaries from approaching the spending levels of those with continuous coverage.

These simulations also suggest that the savings in out-of-pocket spending on prescription drugs under Part D will be unequally distributed. When the 25 percent coinsurance for spending \$250–\$2,250 per year is factored in, total out-of-pocket payments for the average beneficiary with Part D will fall 55 percent, from \$1,584 to \$722. The average beneficiary with diabetes will see a decline of 32 percent, from \$2,320 to \$1,581. However, for beneficiaries with chronic lung disease and mental illness, out-of-pocket spending falls only 19 percent and 16 percent, respectively.

Discussion

The two key empirical findings from this research are that Medicare beneficiaries react to interruptions in prescription coverage by reducing their drug spending and that the impact is magnified for beneficiaries with three common chronic diseases. These findings have consequences that vary depending on who signs up for the standard Medicare Part D drug benefit in 2006.

Impact on beneficiaries. Beneficiaries with average drug spending will have reasonably good coverage under Part D. With slightly more than two months in a benefit gap split about equally between the deductible and the doughnut hole, these beneficiaries are projected to spend almost as much as the average beneficiary with continuous drug coverage. But those with the selected chronic conditions will face a very different scenario. For one, they spend considerably more on medications than the average beneficiary and thus will face longer gaps in coverage, given the design of Part D. More importantly, they exhibit greater sensitivity to interruptions in drug coverage, which exacerbates the impact of a gap of any given duration. Relief comes only when drug spending exceeds the catastrophic cap; based on our calculations, the average beneficiary with diabetes, chronic lung disease, or mental illness will not reach the cap in 2006.

Of course, not all beneficiaries are average, and most of those with above-average spending will experience even longer benefit gaps before the generous catastrophic coverage finally kicks in. Although it is beyond the scope of this study, it would be informative to analyze the distribution of drug spending within the illness subgroups and to empirically determine the effects of coverage gaps as spending approaches the various cost-sharing thresholds in the law. For example, beneficiaries with anticipated spending near the catastrophic cap might behave differently from those with expected spending in the middle of the doughnut hole.

How one views the deterrent effect of cost sharing depends largely on whether one takes an individualist or clinical perspective on the issue. Economists tend to emphasize the social-welfare loss associated with induced demand (moral hazard) in insurance plans with low cost sharing, whereas clinicians are more apt to focus on the possibility that cost sharing will deter use of necessary medications. Nothing in the MCBS data used for this study permits a judgment regarding the efficacy of drugs taken (or deterred) on behalf of survey respondents.

Limitations and strengths. Other limitations of the data and study methods should be noted. First, the MCBS does not capture drug benefit design information, and it is likely that some beneficiaries whom we classify as having continuous coverage also experience gaps in coverage because of deductibles and benefit caps. To the extent that this occurs, we have understated the true impact of benefit gaps on drug spending. But to put this in context, we should also note that Medicare beneficiaries with continuous drug coverage in 2001 had three-quarters of their total drug spending paid for by their insurers, a more generous rate that will be available to any enrollee in the standard Part D benefit.¹⁸

Second, the price information included in the MCBS adjusts for discounts and rebates received by insurers that are not available to cash purchasers. Because beneficiaries in benefit gaps in today's market face retail prices, we have underestimated the extra value in prescriptions they would receive if pharmacy providers extended discounts to beneficiaries during gap periods in

their Part D coverage (that is, assuming the discounts are much greater than the ubiquitous “senior discounts” readily available in today’s market).

Third, our simulations are necessarily speculative. We modeled the impact of Part D on the “average beneficiary” without consideration of the composition of the enrolled pool. Most low-income beneficiaries will qualify for subsidized coverage and will not face the benefit gaps in the standard benefit. Beneficiaries with employer-sponsored coverage may retain it as long as the employer continues to offer it. It is also likely that some beneficiaries with little or no use of prescription drugs will not enroll at all (there is a premium penalty for late enrollment, but that is unlikely to offset the premium costs for the healthiest beneficiaries). Although the absolute risk level of the standard Part D enrollment pool is thus impossible to forecast precisely, there is no reason to believe that the relative impact of benefit gaps should differ markedly from what we have shown.

Finally, we have not examined whether coverage gaps necessarily have a greater deterrent effect on drug use than coverage of equivalent value with no gaps but less generous coverage otherwise. From a clinical perspective, one might expect that cycling into and out of coverage would be more disruptive to care plans than having a stable benefit with higher coinsurance. But until that question has been examined empirically, the expectation is just speculation.

This study also has significant strengths. Most importantly, it is the first study to examine drug spending associated with prescription benefit gaps in a nationally representative Medicare sample. Our analytic approach combined strong covariate control with an internal test for unobserved selection bias (which we were able to reject). Perhaps most important, the analysis demonstrates that drug use by people with greater-than-average medical need, as evidenced by our cohorts with diabetes, chronic lung disease, and mental illness, will be disproportionately affected by the coverage gaps afforded by the Part D drug benefit. It is likely that elders with multiple chronic conditions will be even harder hit by the coverage gaps.

Need for further research. More research is needed to examine the many unanswered questions raised by this study. For one, we need to explore the ramifications of gaps on medication treatment adherence and use of medical services in lieu of prescription drugs. Additional research is needed to determine whether it is necessarily worse to cycle in and out of relatively generous coverage than to have stable coverage with higher coinsurance rates. Finally, research into the experiences of people with other medication-sensitive chronic conditions and combinations of conditions also is needed to establish the generalizability of our findings.

The advent of prescription drug coverage under Medicare is a long-awaited event for the estimated 25 percent of beneficiaries who lack drug benefits, particularly those eligible for the generous coverage provided to the poorest beneficiaries. However, the value of the benefit available to those who fail to qualify for low-income coverage is less certain. The research findings we have presented suggest that policymakers tracking the roll-out of Medicare drug coverage should pay particular heed to beneficiaries with chronic conditions requiring long-term medication therapy. Based on our findings, the standard Part D benefit structure will exact a disproportionate toll on people with diabetes, chronic lung problems, and mental illness in the form of both higher out-of-pocket costs and reduced use of medications compared with beneficiaries with average drug spending. Given the consistency of our findings for these three conditions, there is reason to believe that a similar fate may be in store for beneficiaries with other chronic diseases, including hypertension, chronic heart and circulatory problems, and arthritis, for which drug therapy is essential.

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NOTES

1. See, for example, A.D. Federman et al., "Supplemental Insurance and Use of Effective Cardiovascular Drugs among Elderly Medicare Beneficiaries with Coronary Heart Disease," *Journal of the American Medical Association* 286, no. 14 (2001): 1732–1739; J.D. Piette, M. Heisler, and T.H. Wagner, "Problems Paying Out-of-Pocket Medication Costs among Older Adults with Diabetes," *Diabetes Care* 27, no. 2 (2004): 384–391; D.P. Goldman et al., "Pharmacy Benefits and the Use of Drugs by the Chronically Ill," *Journal of the American Medical Association* 291, no. 19 (2004): 2344–2350; B. Stuart and N.E. Coulson, "Dynamic Aspects of Prescription Drug Use in an Elderly Population," *Health Services Research* 28, no. 2 (1993): 237–264; R. Mojtabai and M. Olfson, "Medication Costs, Adherence, and Health Outcomes among Medicare Beneficiaries," *Health Affairs* 22, no. 4 (2003): 220–229; M.A. Steinman, L.P. Sands, and K.E. Covinsky, "Self-Restriction of Medications Due to Cost in Seniors without Prescription Coverage," *Journal of General Internal Medicine* 16, no. 12 (2001): 793–799; J.A. Poisal and L. Murray, "Growing Differences between Medicare Beneficiaries With and Without Drug Coverage," *Health Affairs* 20, no. 2 (2001): 74–85; and A.S. Adams, S.B. Soumerai, and D. Ross-Degnan, "Use of Antihypertensive Drugs by Medicare Enrollees: Does Type of Drug Coverage Matter?" *Health Affairs* 20, no. 1 (2001): 276–286.
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6. B. Stuart et al., "Riding the Rollercoaster: The Ups and Downs in Out-of-Pocket Spending under the New Medicare Drug Benefit," *Health Affairs* (forthcoming).
7. For more information on the MCBS, see Centers for Medicare and Medicaid Services, "Medicare Current Beneficiary Survey," 23 September 2004, www.cms.hhs.gov/mcbs/default.asp? (10 March 2005).
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9. J.A. Poisal, "Reporting of Drug Expenditures in the MCBS," *Health Care Financing Review* 25, no. 2 (2003): 23–36.
10. Standard economic theory would suggest that if people expect to spend through a coverage gap, they would be influenced only by the marginal price in effect after the gap has been cleared (that is, if a beneficiary expects to reach the Part D catastrophic threshold, the relevant marginal price is about 5 percent of the unsubsidized price for all drugs consumed during the year). By this reasoning, for high spenders at least, there is no difference between a small deductible and a

large gap in the middle of the benefit. However, the empirical health insurance literature cited above suggests that time spent without coverage has a negative independent affect on utilization behavior.

11. These controls are necessary because changes in Part B supplementation can affect access to physician services, thereby influencing medication regimens. The supplement and prescription-gap variables are obviously correlated (a loss of a supplement would also entail loss of any prescription benefits provided by that supplement), but much of the movement into and out of drug coverage occurs independently. This is particularly true for public coverage such as provided by a state pharmaceutical assistance program, but it is also common within employer-sponsored plans.

12. The DCG/HCC measure captures the cumulative effect of multiple diagnoses from both inpatient and outpatient encounters. It has been shown to have better predictive ability than other risk adjustment approaches, such as Principal Inpatient-Diagnostic Cost Group (PIP-DCG), Ambulatory Clinical Groups/Adjusted Diagnostic Groups (ACG/ADG), and the RxRisk-Vs risk adjuster based on pharmacy claims. See G.C. Pope et al., "Risk Adjustment of Medicare Capitation Payments using the CMS-HCC Model," *Health Care Financing Review* 25, no. 4 (2004): 119–141; G.C. Pope et al., "Principal Inpatient Diagnostic Cost Group Model for Medicare Risk Adjustment," *Health Care Financing Review* 21, no. 3 (2000): 93–118; R.P. Ellis et al., "Diagnosis-based Risk Adjustment for Medicare Capitation Payments," *Health Care Financing Review* 17, no. 3 (1996): 101–128; and P.A. Fishman et al., "Risk Adjustment using Automated Ambulatory Pharmacy Data: The RxRisk Model," *Medical Care* 41, no. 1 (2003): 84–99.

13. The DWH test formally assesses the presence of unobserved heterogeneity in the error term by forming a regression of the potentially endogeneous independent variable on the exogenous variables in the original model. The residuals from this prediction are then inserted into the original model as a separate term. If the residuals term is independently significant, then one can reject the null hypothesis of exogeneity. See R. Davidson, ed., *Estimation and Inference in Econometrics* (New York: Oxford University Press, 1993).

14. Stuart et al., "Impact of Prescription Coverage."

15. See P. Samuelson, *Economics*, 9th ed. (New York: McGraw-Hill, 1973), 403–405.

16. See content.healthaffairs.org/cgi/content/full/hlthaff.w5.167/DC2.

17. Ibid.

18. Computation by the authors from the 2001 MCBS.

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