

How Much Would Drug Makers' Profits Rise under a Medicare Prescription Drug Benefit?

A Response to PRI/PwC's Undocumented and Disjointed Critique of Our 31 October 2003 Report

**Alan Sager, Ph.D. and Deborah Socolar, M.P.H.
Directors, Health Reform Program**

Boston University School of Public Health

(617) 638 – 5042

asager@bu.edu, dsocolar@bu.edu

www.healthreformprogram.org

2nd Edition

12 April 2004

Disclaimer: As always, we write only for ourselves,
not on behalf of Boston University or any of its components.

SUMMARY

Introduction: In October 2003, we estimated the new profits that the proposed House and Senate Medicare bills offered to prescription drug makers. If \$400 billion in new federal spending goes to a Medicare drug benefit starting in 2006, we concluded that *drug manufacturers' profits would rise by \$139.2 billion over eight years*. Recently, PricewaterhouseCoopers (PwC) disputed that estimate in a critique commissioned by the Pacific Research Institute. This report identifies the main problems with that critique.

The PRI/PwC criticisms are mistaken. They do not undermine our analyses of any of the three main aspects of the legislation that we identified as contributing to a steep increase in drug makers' profits.

Drug manufacturers' prices would not be restrained under the new law, we concluded. The critique concurs that private plans now get discounts for employers averaging only 15 percent, but claims, without supporting evidence, that such plans will win Medicare discounts of "around 25 percent."

The volume of drugs sold would rise substantially, we predicted. The PRI/PwC critique vastly underestimates the likely rise in volume when Medicare patients gain coverage, even given this law's relatively meager benefits.

Drug makers' new costs would be very low, we emphasized. Almost all of drug makers' revenue from these new prescription sales at high unrestrained prices would be profit, because most of their costs are already covered. The PRI/PwC critique simply ignores the issue of drug makers' low incremental costs.

Our findings last October troubled many. The bill's inadequate benefits and high costs reflected too much money going to drug makers' profits, because prices were not controlled. The PRI/PwC critique says virtually nothing about the new Medicare drug benefit itself. But were the PRI/PwC critique accurate, the overwhelming share of money under the bill would apparently replace existing spending on prescription drugs, and very little would buy medications for patients who do not get needed drugs today.

A. COST OF MEDICATIONS

1. Ignoring Drug Makers' Low Incremental Costs: Profits reflect revenues less costs. Yet the PRI/PwC critique entirely ignores half the equation—drug makers' very low real added costs to manufacture a higher volume of pills for Medicare patients.

B. VOLUME OF MEDICATIONS

2. Underestimating the Number of People in Need: PRI/PwC underestimate by one-third (or more) how many Medicare beneficiaries entirely lack prescription drug benefits. They appear unaware of how limited coverage is for many who do have some benefits.

3. Underestimating Effect of Coverage and Lower Prices: The PRI/PwC critique uses inappropriate, irrelevant data, ignoring the differences between Medicare and non-Medicare patients. It relies entirely on a price-elasticity estimate from a 30-year-old study enrolling only younger, *non-Medicare* patients for different benefits in a radically different pharmaceutical climate—an inappropriate source for at least six reasons. We instead documented Medicare patients’ higher need for medications, and differences in use between Medicare patients with and without drug coverage.

The drug industry itself has cited studies concluding that lower prices can boost the volume of drug sales enough to maintain the same level of revenue. Numerous observers conclude that the new law will substantially raise drug makers’ revenues and profits. PRI/PwC also fails to address the likelihood that any savings from discounts would recycle to buy still more from the drug makers.

4. Extent of Coverage and Circularity of Estimates: The PRI/PwC critique appears to rest heavily on a circular argument. And with today’s huge and growing gaps in drug coverage for people on Medicare, it is simply not credible that, as they claim (without supporting evidence), 58 percent of Medicare beneficiaries’ drug costs were covered by insurance in 2003, leaving only 42 percent to be paid by patients themselves.

5. Failing to Identify the New Rx/Replacement Rx Split: The PRI/PwC critique fails to assess the likely split between new and replacement prescriptions, central to the law’s impact both on industry profits and on patients. PRI/PwC implies, though, that the law will not enable Medicare patients to fill many more prescriptions than they fill now.

6. Hiding Crucial Calculations: Many central calculations in the PRI/PwC critique are not disclosed, especially for crucial estimates of the likely rise in prescription drug use.

C. PRICE OF MEDICATIONS

7. Claiming Implausible Discounts and Rebates: PRI/PwC offer only unsupported and inconsistent estimates that private plans will save Medicare more than they now save employers. Yet the law fragments Medicare’s buying power—as drug makers urged. Perhaps the savings claims rest on little-publicized assumptions that plans will use very restrictive formularies, which would likely be unpopular.

D. PROFITS

8. Claiming Implausible Overall Effects: The PRI/PwC critique claims that the \$400 billion in new Medicare drug spending (equal to about one-fourth of CBO’s projected baseline drug spending for Medicare beneficiaries) could yield a *drop* in drug makers’ revenues, or at most a very small rise. The claim that drug makers might lose money is attributed only to anonymous industry sources. We describe how PRI/PwC make the \$400 billion disappear and fail to follow the trail of their own figures.

9. Refusing to Estimate Profits: The PRI/PwC critique fails to address the probable size of drug makers' new profits, focusing instead on percentage change in revenues. We now note that, over eight years taken together, the industry's expected baseline profits plus new profits from the Medicare law are likely to be at least \$587 billion.

We are grateful, however, that the PRI/PwC critique identified one flaw in our original work: The drug makers' estimated \$139 billion in additional profits over eight years would mean a rise of 31 percent (not 38 percent) from the baseline of a cumulative \$448 billion in projected profits absent the law. Our calculation had understated the industry's expected profits after 2006 without the law, and therefore overstated the *percentage* rise in profits with the law.

E. OTHER PROBLEMS IN PRI/PWC CRITIQUE

10. Ignoring Conservatism of HRP Estimates: Our estimates were conservative in several ways. A contingency table gave a range of estimates. PRI/PwC ignores these.

11. Unquestioning Acceptance of CBO Estimates: The PRI/PwC critique seems to suggest that our disputing CBO estimates is irreverent, or almost uncivilized. Yet the recent CMS cost estimates did not accept the CBO figures on many points. We worry that CBO staff may have faced pressure to develop an estimate consistent with the \$400 billion target cost.

12. Ignoring Need for New Solutions and a Peace Treaty: The PRI/PwC critique assumes that today's high drug prices can and should persist. It ignores the need for and the feasibility of the prescription drug peace treaty we discussed, in which lower prices would benefit drug makers as well as patients and payers. Drug makers would shift from their current business plan of high prices combined with limits on use to a business plan based on lower prices and higher volume, to meet the needs of all Americans.

CONTENTS

Introduction	1
A. Cost of Medications	
1. Ignoring Drug Makers' Low Incremental Costs	8
B. Volume Of Medications	
2. Underestimating the Number of People in Need	10
3. Underestimating Effect of Coverage and Lower Prices	12
4. Extent of Coverage and Circularity of Estimates	21
5. Failing To Identify the New Rx/Replacement Rx Split	25
6. Hiding Crucial Calculations	27
C. Price of Medications	
7. Claiming Implausible Discounts and Rebates	29
D. Profits	
8. Claiming Implausible Overall Effects	33
9. Refusing to Estimate Profits	35
E. Other Problems in PRI/PwC Critique	
10. Ignoring Conservatism of HRP Estimates	37
11. Unquestioning Acceptance of CBO Estimates	39
12. Ignoring Need for New Solutions and a Peace Treaty	40
Endnotes	43

Introduction

In October 2003, while selected members of a Congressional conference committee prepared their Medicare bill behind closed doors, we estimated the increased profits that the House and Senate bills offered for prescription drug makers. If the law were to contribute \$400 billion in new federal spending to a Medicare prescription drug benefit starting in 2006, as Congress proposed, we concluded that *drug manufacturers' profits would rise by \$139.2 billion over eight years*. Drug makers would retain as profits, we estimated, 61 percent of the Medicare dollars that would be spent to buy additional prescriptions that seniors and people with disabilities currently cannot afford to fill.¹

Recently, PricewaterhouseCoopers (PwC) disputed these estimates in a critique commissioned by the Pacific Research Institute.² The PRI/PwC critique asserted that our analysis “grossly overestimates” the Medicare drug benefit’s impact on pharmaceutical company profits (press release, 4 March 2004). This report identifies the main problems with that critique.

In general, PRI/PwC seem to take a posture of anointing or sanctifying their own work. They rely on anonymous industry sources. They do not disclose their calculations. Even as national attention focuses on the disparity between Congressional Budget Office and executive branch actuaries’ cost estimates for the law, PRI/PwC contend that disagreement with CBO’s work constitutes a radical or self-evident failing. They similarly disparage failure to uncritically accept a crucial estimate from a thirty-year-old RAND Institute study—of different drug benefits, enrolling only younger, *non-Medicare* beneficiaries, and conducted in a radically different pharmaceutical climate.

The following response specifically addresses these matters. For example, it describes six reasons why it is inappropriate to rely on the RAND study’s estimate of the price-elasticity of demand for prescription drugs.

Unlike PRI/PwC, we have never pretended to know the precise price-elasticity of demand for prescription drugs under the new Medicare prescription drug benefit. Directly relevant evidence is lacking. Instead, in our original report, we documented Medicare beneficiaries’ needs for higher volumes of drugs and differences in use between Medicare patients with and without prescription drug coverage. We also provided a contingency table that sets out the effects on drug makers’ profits of changes in the values of two of the three key factors bearing on those profits under the new law.

On completing our October 2003 study, we were dismayed by the Medicare prescription drug plan that Congress was considering, because of its inadequate benefits and its high costs, with too much money going to drug makers’ profits because prices were not controlled. And these traits have left many others similarly dismayed.

The PRI/PwC critique seems to focus its energy on a few aspects of our analysis and says virtually nothing about the new Medicare drug benefit itself. Someone who uncritically accepts the PRI/PwC critique might therefore be led to believe that the new

benefit is a good one. But that would not be true, even if the PRI/PwC critique were accurate.

Were the PRI/PwC critique accurate, the overwhelming share of the money under the bill would apparently go to replacing existing spending on prescription drugs—private insurance, Medicaid, and out of patients’ pockets. (We use the word “apparently” because PRI/PwC never specifies this share.) This means that very little money would go to buy medications for patients who now suffer because they cannot afford needed drugs and don’t get them today. The split of dollars under the new law between buying additional prescriptions or replacing dollars that pay for existing prescriptions is therefore a vital matter for patients who can’t now afford needed medications. That split also is strongly associated with the rise in drug makers’ profits under the new Medicare benefit.

Our October 2003 Health Reform Program (HRP) report noted three main reasons why drug manufacturers would likely make enormous windfall profits under the Medicare legislation then about to come before Congress. **Though the PRI/PwC critique attempts to dazzle the reader with a flurry of numbers and appearances of well-documented analysis, its criticisms are mistaken. They do not undermine our analyses of any of the three main aspects of the legislation that we identified as contributing to a steep increase in drug makers' profits.**

1. Drug manufacturers’ prices would not be restrained under the new law, we concluded. Congress agreed, at drug industry insistence, to fragment Medicare’s purchasing power and also bar Medicare from negotiating drug prices. (The new law would also tend to keep prices high for Medicare patients and others because it retained the ban on importing lower-cost medications from other nations.) Discounts under the new law would likely resemble the 15 percent now prevalent in the private market. That’s because it would rely on multiple private insurance companies and plans, despite their long record of failure to contain drug prices for American families, employers, and Medicare HMO enrollees. (HRP, pp. 1, 5) **The PRI/PwC critique (p. 4), while concurring that today’s employer plan discounts average only 15 percent, says Medicare plans will win “discounts of around 25 percent.” PRI/PwC offers no evidence at all to support this claim.**
2. The volume of drugs sold would rise substantially, we predicted. Much of the proposed \$400 billion Medicare subsidy would likely buy prescriptions not filled today. Unmet need is great. (HRP, p. 3) **But the PRI/PwC critique vastly underestimates the likely rise in volume when Medicare patients gain coverage.** Among PRI/PwC’s problems:
 - They underestimate by one-third the number of seniors lacking coverage today.
 - They use a 30-year old price-elasticity estimate that is inappropriate to the Medicare population, to the benefit structure of the new Medicare bill, and to the

nature of today's pharmaceuticals or the climate in which they are marketed. (This is very much like learning, with reasonable accuracy, the size or climate or existence of life on one of the planets in our solar system and then heroically asserting that the other planets must be essentially very similar—without regard to distance from the sun or other empirical evidence.)

- ❑ They assume that a huge but never-specified share of the \$400 billion simply replaces current spending.
 - ❑ They never offer their own estimates of the split of prescriptions under the Medicare drug benefit between new and old prescriptions.
3. Drug makers' new costs would be very low, we emphasized. Almost all of drug makers' revenue from these new prescription sales at high unrestrained prices would be profit. Pre-existing revenues finance their manufacturing, administration, research, marketing, and other costs, so drug makers' only added costs on the higher volumes of prescription drugs they would sell under the new Medicare benefit would be the "remarkably low real cost of producing [and distributing] the added volumes of pills..." (HRP, pp. i, 5-6) **The PRI/PwC critique simply ignores the issue of drug makers' low incremental costs.**

While the PRI/PwC critique erred in these three areas, we are grateful to its authors for identifying a flaw in our original work.

The main estimates highlighted in our 31 October report were these:

- An estimated 61.1 percent of the Medicare dollars that will be spent to buy more prescriptions will remain in the hands of drug makers as added profits.
- This windfall means an estimated \$139 billion in increased profits over eight years for the world's most profitable industry.
- At \$17 billion annually, this means about a 38 percent rise in drug maker profit.

In the third point, the 38 percent figure reflected a \$17 billion rise over prescription drug makers' projected profits of \$45.3 billion in 2006 without the new law. But that **\$139 billion over eight years would represent a rise of 31 percent** from the industry's eight-year cumulative \$448 billion in projected profits in the absence of the law. (We had compared the \$139 billion to a denominator that understated the industry's expected profits after 2006 without the law, so the result overstated the percentage rise in profits for the law's first eight years.)

It does appear that the PRI/PwC critique, after identifying a problem with our original calculation, actually mirrored our error in their own work. Their calculation of the percentage rise in profit was too low. They suggest that our profit estimates (which they dispute) would mean a 26 percent rise (p. 7). Their undisclosed calculations appear to have used the high end of the eight-year period for the baseline, the opposite of our own error in using the first year.

Further, since we wrote in October, the 2003 profit reports from Fortune have been released. They show a slight drop in profits for the ten largest drug makers.³ If the industry's profits before 2006 drop slightly or grow more slowly than the six percent average annual rise that we have projected, the percentage rise in profits owing to the new Medicare benefit would be substantially greater than the 31 percent increase now projected.

Please note that our study was conservative in that it estimated only the higher profits arising from the new \$400 billion in federal financing under the law—the new profits that drug makers will win on *increased* volume under the Medicare law. We therefore excluded profits on beneficiaries' insurance premiums or on their co-payments. The \$139 billion in new profit is only part of the total profits that drug makers will garner on patients covered by Medicare. The total profits on Medicare patients' medications will of course be substantially larger. They will include both the new profits and existing profits on current purchases of Medicare patients' prescription drugs.

The Medicare benefit will take over paying for some current purchases of Medicare patients' drugs. So, as we calculated, drug makers' discounts under the law will result in some reduction in the profits from existing sales. As discussed below, however, the PRI/PwC critique appears to assume that the law will result overwhelmingly in such replacement sales.

We did not attempt to develop our own estimate of the cost of the Medicare law or its drug benefit. Rather, we took as a given the widely-cited Congressional Budget Office estimate that the Medicare prescription drug bills prepared by the House and Senate would each cost approximately \$400 billion over 10 years (including eight years of Medicare drug benefits).

Our report was written before evidence surfaced publicly of higher CMS estimates of the cost of the law. The PRI/PwC critique, though, tries to simply wave away the higher CMS estimate that the law will cost \$534 billion, or about one-third more than CBO estimated. There are many reasons to suspect that the CMS estimate is more accurate—or even low itself—and therefore that drug makers' revenues and profits will be still higher. (Some portions of the higher estimate do reflect additional sums going to HMOs and other parties under the final version of the law.)

As we prepared our original report, however, Congressional leadership had announced their intent to write a law that would not incur more than \$400 billion in net federal cost. In our analysis, we treated the \$400 billion as a commitment by the federal government, and worked to estimate where that new \$400 billion in federally-financed drug spending for Medicare beneficiaries would actually go.

The PRI/PwC critique asserts that drug makers will not win close to the \$139 billion in new profits that we projected, but they do not offer an alternative figure. They offer fragmentary criticisms and alternative calculations, but never put the pieces together into a coherent whole. Among the essential calculations that they ignore are these:

- they never address drug makers' incremental costs to make more pills, so they cannot estimate profits arising from the law (revenue minus costs);
- they focus on price-elasticity but never show how this translates into dollar estimates of the overall rise in spending; and
- they never offer their own conclusions about the split between old and new business paid for under the new law.

If a substantial portion of CBO's projected new \$400 billion in federal spending is not going to profits on new prescriptions, where would all that new money go? The PRI/PwC critique simply doesn't explain. In their critique, the \$400 billion appears to be an incredible vanishing expenditure. As shown later, PRI/PwC think it doesn't even visibly boost drug makers' total revenue. As well, please consider that:

- The PRI/PwC critique suggests that we underestimated discounts and therefore *overestimated* the prices that manufacturers will be paid, so higher prices can't account for the extra money.
- The PRI/PwC critique does not dispute our estimate of the low actual cost of manufacturing and distributing the additional pills to fill new prescriptions.
- Compared to our analysis, however, the PRI/PwC critique assumes that a much smaller share of the new money will go for increased volume, and a much bigger share will take over the cost of paying for existing drugs.

This means that PRI/PwC clearly assert that the law will do much less than we projected it would to bring prescription drugs to patients who cannot afford them today.

Proponents of the law therefore should view our analysis, critical of the bill as it was, as more optimistic than is PRI/PwC's critique. PRI/PwC suggest that the law will mean relatively little rise in new volume, while we suggest that the \$400 billion—despite the law's limited benefit, unnecessarily high patient cost-sharing, and high drug prices—will enable more patients to fill prescriptions that otherwise would go unfilled.

Our report assumes that any discounts—whether on drugs paid for by the plans or drugs that patients purchase while in the \$2,850 hole of no coverage (from \$2,250 in drug costs to \$5,100 in drug costs)—will be passed on to patients as lower prices, enabling patients to afford to fill additional prescriptions. (If HMOs or insurers win large discounts, however, they might keep some of the money and use it to boost their profits, as discussed below.)

The PRI/PwC critique thus falsely claims that we ignored the benefit of lower prices for patients' out-of-pocket purchases. (p.7) Worse, although they themselves then say discounts will be passed on to patients as lower prices or premiums (p. 7), they fail to

follow the money and its impact on drug makers' revenues and profits. They never show where they think the savings from discounts would actually go. PRI/PwC concedes (footnote xxviii) that "additional discounts lead to additional induced demand" but they never provide a clear, explicit, or integrated display of their own calculations of either induced demand or drug makers' revenue.

We contend that, under the new benefit, dollars saved through discounting flow back to drug makers when patients use the saved money to purchase needed medications. Any discounts greater than the 15 percent allowed for in our analysis would, we expect, go to offset some of the effect of the law's high cost-sharing. And that recycled money for new prescriptions again flows to the drug makers—who incur little cost on providing the added volume of medications—so they recoup additional profits on the added volume of drug sales.

The PRI/PwC critique repeatedly condemns our analysis for differing from CBO estimates on various points. Of course, those who make all the same assumptions that CBO makes would end up where CBO ends up. And the PRI/PwC critique's rigid adherence to CBO estimates is not surprising, since the authors from PwC are former longtime staff of CBO (see PRI/PwC, p. 13), apparently imbued with CBO's perspective.

PricewaterhouseCoopers describes itself as a firm which provides "business advisory services...to all market sectors in the health care industry." (PRI/PwC, p. 13) The Pacific Research Institute describes itself as "advancing free-market policy solutions," stating that it "champions...personal responsibility for all individuals" and "demonstrates why the free market is more effective than the government..." (PRI/PwC, p. 14)

The PRI/PwC critique starts by contending that our findings are "well outside the range generally accepted by government and private sector analysts" and those "who track developments in the pharmaceutical industry." (PRI/PwC, pp. 1,2) Yet the authors have few arguably impartial sources for alternative estimates. They cite just one that *tracks* industry developments (Merrill Lynch), and otherwise mention only anonymous and published sources from *inside* the drug industry. (p. 2 and note 4).

Although the PRI/PwC critique purports to be careful and objective analysis resting on valid evidence, most of it is actually suspended on the gossamer threads of fragile, uncoordinated, and often irrelevant factoids. As we document below, PRI/PwC build an elaborate structure on a shaky foundation of non-existent or largely irrelevant evidence.

The reality probably remains apparent to most observers. The federal government's commitment of \$400 billion in new Medicare subsidies for prescription drugs will not be used overwhelmingly to replace existing undiscounted drug spending. The new federal dollars won't vanish into thin air either—something which PRI/PwC astonishingly predicts when it asserts that drug makers' total revenue after the law's implementation will end up within the range of a 1.0 percent drop and a 3.2 percent rise.

Rather, today's enormous unmet need among patients with no drug coverage or very limited coverage means that a very substantial portion of the new spending will finance new drug purchases and thus boost drug makers' revenues. Because drug makers' cost of providing those new medications is so low, even discounted prices will sharply increase their profits.

And there is still no evidence that future price discounts will be any larger than today's discounts. Sadly, the limited discounts and high prices under the new Medicare benefit will mean that this new federal \$400 billion will buy far fewer medications than it could—and that far too much of the money will go to benefit drug makers and their stockholders.

The main body of this response to the PRI/PwC critique is organized into 12 sections. In each section, we generally first summarize the findings or methods employed in an aspect of our report. We describe the PRI/PwC critique of that aspect and then respond to their critique.

The issues in the 12 sections inevitably overlap as we attempt to address the critique's disjointed elements. We address certain central points in more than one of those inter-related sections, and we hope that some repetition is tolerable in the pursuit of clarity.

A. COST OF MEDICATIONS

1. IGNORING DRUG MAKERS' LOW INCREMENTAL COSTS

HRP WINDFALL PROFIT REPORT: Our October 2003 report described three main reasons why drug makers would garner windfall profits under the Medicare legislation then before Congress. Their projected soaring profits reflect unrestrained prices, a growing volume of prescriptions filled, and the “remarkably low real cost of producing the added volumes of pills that Medicare patients need.” (See p. i of our report.)

“Drug makers’ costs don’t change very much if they produce and sell more pills,” we noted:

[M]arketing, administration, and research should not be expected to change very much when sales to Medicare patients grow. **The only added costs for drug makers associated with a new Medicare prescription drug benefit are expected to be in manufacturing and in distribution** Drug makers’ factories are already built, and the ingredients in most prescription drugs are inexpensive. So there will be a very small incremental cost to make the added volume of medications that newly covered Medicare patients will use. Estimates from industry sources are that the actual added cost of making additional pills is only about five percent of the undiscounted full retail price. [See pp. 5-6, and documentation in note 20.]

We therefore estimated the incremental manufacturing cost at 5.9 percent of Medicare’s likely *discounted* retail price. (This reflects our estimate, discussed below, that drug plans are likely to obtain discounts of 15 percent, “so the manufacturing share is 5 divided by 0.85, or 5.9 percentage points.”) Further, we allowed for 2 percent of drug makers’ actual revenues “to cover the added cost of distribution. Manufacturers’ costs of the additional volume of drugs therefore sum to 7.9 percentage points.” Subtracting that from drug makers’ incremental revenues leaves incremental net revenue or added profit.

Our sensitivity analysis (pp. 8-9) showed the effect on drug makers’ estimated rise in profits if their incremental manufacturing costs exceed 5.9 percent, ranging up to 15.0 percent of Medicare’s likely retail prices. The \$139.2 billion figure for new profits over eight years rested on the estimate that the cost of making any increased volume of medications will be 5.9 percent of payments made at retail. Even if incremental manufacturing costs are nearly triple our main estimates, reaching as high as 15.0 percent of retail prices, as shown in the contingency table in our Exhibit 3 (p. 9), the estimated rise in profits would still be \$118.4 billion over eight years.

PRI/PwC: The PRI/PwC critique does not dispute our estimate that drug makers’ incremental costs of making more pills are likely to be only about five percent of full retail prices. Indeed, PRI/PwC totally ignore the issue of drug makers’ costs. Thus, they ignore both the main estimate that we offered and our contingency table with

alternative estimates for those who make other assumptions about drug makers' incremental costs. In other writings, however, PRI has concurred that "Actual production costs for the new drugs – after the huge initial investment in R&D – in most cases are relatively low."⁴ The profits of a business depend on both revenues and costs, but the PRI/PwC critique has nothing to say about the cost side of the equation.

REPLY: Yet drug makers' low actual incremental cost is one of the key elements in the high profits that this law will bring them. Consider a dollar spent at retail to buy new prescriptions, with 25 cents going to pharmacy markup (to cover costs and profit) and wholesalers, and 75 cents going to drug makers. If actual incremental manufacturing cost is 5 cents, a very large share remains for the drug makers' profit— even if 15 cents returns to the patient or insurer in discounts or rebates. Even if manufacturing costs are double that, the sum available for profit is still high. And, as discussed later, this remains true with discounts and rebates paring another 5-10 cents off the sum paid to drug makers. Windfall profits will be large on any new sales because it will cost drug makers so little to make the additional pills that Medicare patients need— an issue that the PRI/PwC critique entirely ignores.

Indeed, the low incremental cost for added volume means that, whatever the rise in revenue for the drug makers, nearly all of it will represent profit.

One additional point is worth noting. The industry commonly asserts that high prices for drugs must be maintained because the costs of research are high, an argument that PRI has strenuously and repeatedly emphasized and supported in other writing.⁵ The PRI/PwC critique does not raise that issue, however. Nor does it address a point noted in our October report (p. 5), that under the new law,

Research costs should not increase either. Today, drug makers say they need high prices to sustain research. They may respond to this report by claiming that they would use their vast new profits to conduct more research. But they have never hinted at any plan to vastly expand research when Medicare sends their revenues soaring. And there is no reason to assume that the drug makers should—or could effectively—expand their research budgets tremendously.

Few Medicare beneficiaries who seek a prescription drug benefit now expect that one of the benefit's main aims or consequences is to give drug makers more money that they would promise to use to finance research. Even if those promises were ultimately kept, such a use of scarce public funds should certainly be debated. Any additional substantial growth in drug research might better be used to expand research budgets at the National Institutes of Health. (Already, for example, developing "me-too" drugs consumes a large share—perhaps 40 percent—of industry-financed research.)

Further, there is no reason to allow for a large rise in marketing costs. Drug makers will face a rise only in production and distribution costs, both of which our analysis reflects.

B. VOLUME OF MEDICATIONS

2. UNDERESTIMATING THE NUMBER OF PEOPLE IN NEED

HRP WINDFALL PROFIT REPORT: We estimated that some 40 percent of some 40 million Medicare beneficiaries lacked any prescription drug coverage in 2003, and that millions more were under-insured. (HRP, p. 4) This reflects a well-respected estimate by Laschober that, as of 1999, at any given time, 38 percent of Medicare beneficiaries lacked coverage.⁶ We used 40 percent because of the steady drop in prescription drug coverage under retiree health plans since 1999. The uncovered share may well worsen substantially further by the time a new Medicare benefit takes hold—owing to cuts in retiree health coverage, Medi-Gap coverage, and Medicare + Choice coverage—but, conservatively, our estimates did not assume that.

PRI/PwC: In asserting that we greatly overestimate the rise in use that will result from added coverage, they say "almost 30 percent of Medicare beneficiaries have no coverage." (PRI/PwC, p.4) They cite no source.

They then state, "Other beneficiaries, such as those with Medicaid or employer-sponsored coverage, will increase prescription drug use by less since they already have at least some coverage."

REPLY: PRI/PwC's assertion that the rise in use will be substantially lower than we project reflects in part their very serious underestimate of the number of people who lack drug coverage today. They also appear unaware of, or intent on downplaying, how skimpy the coverage is for many of those who do have some benefits today.

PRI/PwC underestimate by at least one-third the number of Medicare beneficiaries entirely uninsured for prescription drugs. Their 30 percent estimate may reflect, however, an old but fairly widely-cited estimate of the *share who lack coverage for an entire year*. But that is well below the actual share uninsured at any one time. This is the more useful and appropriate figure for estimating need. (Imagine, for example, a group of ten people, in which five have coverage for the full year, three lack coverage all year, one has coverage only for the first half of the year and one has coverage for the second half. Looking at coverage for the year as a whole and counting the last two people as "covered" would ignore their half-year without protection, while counting them both as "uninsured" would over-estimate the group's level of need. A cross-sectional estimate for the average day in that year avoids that problem.)

Laschober, as just noted, estimated the average share uninsured at any one time at 38-some percent for 1999, and the uninsured share has doubtless risen subsequently. (Similarly, a 2001 Towers Perrin analysis concluded that fully 40 percent of people on Medicare lacked prescription drug coverage.⁷)

Elsewhere, PRI itself—and other conservative organizations as well— have asserted that only 24-25 percent of Medicare patients, or even fewer, lack drug coverage today.⁸ They often do so in documents aiming to dispute the need for a universal Medicare drug benefit and urging a targeted one.

Similarly, CBO itself has emphasized an estimate that “about 25 percent of all seniors did not have prescription drug coverage of any kind,” sometimes without stressing or even noting that such figures represent the share who go the entire year without coverage.⁹ The U.S. Department of Health and Human Services has done the same.¹⁰

There is also a tendency to downplay the problem that today’s prescription drug coverage for many people has very inadequate benefits. When discussing insured patients, PRI/PwC mention those in employer plans and Medicaid, some of whom have fairly comprehensive prescription drug coverage; but PRI/PwC entirely ignore patients with Medicare HMOs, which often provide just \$500 or \$750 in drug benefits annually, and patients in Medigap plans, which require 50 percent coinsurance for drugs.

In other writing, as the new law was on the verge of passage, PRI belittled the financial burden of drug costs for Americans, and stated only that, “Drug spending does appear to be a major problem for two percent of Medicare beneficiaries who earn less than twice the poverty level [about \$18,000] yet spend \$4,000 a year on drugs.”¹¹

They did not explain why, for example, \$3,000 in drug costs should not be considered a major burden for those at such income levels or lower, or even for seniors living on \$30,000, especially considering the high coinsurance and deductibles that many such chronically-ill Medicare patients must pay to obtain other medical care.

Indeed, PRI characterized the new Medicare drug benefit as representing a decision by “Members of Congress...to pander to the entire senior voting block.” PRI stated no concern about the fundamental ways in which the law was shaped to the pharmaceutical industry’s wishes.

The failure in the PRI/PwC critique to acknowledge how many Medicare beneficiaries are uninsured today and how many are underserved by their current drug coverage may result from PRI’s apparent stance *recommending shallow coverage* as desirable for containing costs. In several articles last year, PRI staff criticized co-payment requirements for “shielding consumers from the price differences between drugs,” and urged “a new consumer-driven model that allows consumers to see the full price differences between drugs.”¹²

PRI/PwC’s inaccurate estimate of the number of Medicare beneficiaries lacking insurance badly undermines its subsequent estimate that insurance covers 58 percent of beneficiaries’ current prescription drug costs. (Please refer to section 4, on the extent of insurance coverage and the circularity of PRI/PwC estimates.)

3. UNDERESTIMATING EFFECT OF COVERAGE AND LOWER PRICES

HRP WINDFALL PROFIT REPORT: Our estimates of response to lower prices rest partly on Poisal's data on the difference in prescription drug spending between Medicare "beneficiaries with and without coverage."¹³ Those are real and recent data on drug spending for the population of concern, Medicare patients.

We also considered evidence on inability to purchase prescribed medications, and on substantial price-elasticity of demand associated with drops in drug prices.

PRI/PwC: PRI/PwC assumes that the maximum plausible drug price-elasticity of demand is minus 0.3, the figure they say that CBO uses, one based on RAND research. (PRI/PwC, pp. 5-6, 8) They note that the level of induced demand depends on the level of coverage, but they don't take note that Medicare patients differ from the population as a whole—that Medicare patients are sicker and poorer, so cutting prices might do more to boost their demand than for the average American. They blandly and uncritically assume that the CBO/RAND prescription drug price-elasticity estimate reflects the needs and financial situations of Medicare patients—and the nature of the new Medicare drug benefit itself.

In discussing "induced demand," they criticize our use of Poisal's data, which they describe as "assuming that those without coverage will increase their average spending to the same level as those with comprehensive coverage" (p. 5) PRI/PwC goes on to say that use of these data "ignores any systematic differences in the populations without drug coverage and with full coverage."

REPLY: The PRI/PwC critique is an elaborate construction resting on a narrow, shaky foundation—one single 30-year-old estimate of the response to lower drug prices, an estimate that bears little relation to the real world of today's Medicare patients and the design of the new Medicare prescription drug benefit. Their entire analysis depends on the appropriateness of their assumption (from CBO and RAND) that, for Medicare beneficiaries gaining expanded coverage, a 10 percent drop in out-of-pocket cost would raise drug utilization by 3 percent.

a. Price-elasticity of demand

PRI/PwC ignores the issue of systematic differences—and specifically, any difference in price-elasticity of demand—between Medicare and non-Medicare patients.

PRI/PwC claims that it relies on "accepted research" (PRI/PwC, p. 2). It would be better for them to use appropriate and relevant research.

For example, as discussed above, PRI/PwC mistakenly uses data on the proportion uninsured throughout the year when the proportion uninsured at any one time (in other words, on an average day) is the appropriate figure. The research on the proportion uninsured throughout the year may be accepted in some quarters, particularly among those who would like to portray the problem as relatively small, but it is still starkly inapplicable to the question at hand.

The RAND Health Insurance Experiment research, on which PRI/PwC relies even more heavily, may be accepted and “well-known,” (PRI/PwC, p. 8) but, unfortunately, it does not appear to be very relevant to gauging patients’ price-elasticity of demand under the new Medicare prescription drug benefit.

Even with its restricted benefits and its requirements for patient cost-sharing, the new Medicare law should mean a substantial increase in the number of prescriptions filled.

As we noted, a study in eight states, for example, found that nearly one-fourth of seniors surveyed reported that they skipped doses of medication or failed to obtain prescribed drugs because of high costs. Further, a November 2002 Harris poll found that 18 percent of surveyed adults having failed to ask for prescriptions because of their cost, and 22 percent failed to fill a prescription because of the cost, with higher proportions among sicker adults. (For other detailed evidence suggesting great unmet need, see HRP, p. 4.) These figures ignore patients who do not visit the doctor for non-surgical needs because they rightly anticipate they will not be able to afford the medications they expect to be prescribed.

Marketing to both patients and physicians remains unrestrained under this the new Medicare drug law, and drug makers and advertisers will try hard to drive up demand for both needed and unneeded drugs.

The PRI/PwC critique assumes that the price-elasticity of demand for prescription drugs for Medicare patients will be only minus 0.3 (PRI/PwC, p.5). This is the figure used by CBO, whose work PRI/PwC uncritically accepts throughout its own critique.

The PRI/PwC critique tries to wave away the CMS estimate that the law will cost \$534 billion, or about one-third more than CBO estimated—which in part apparently reflects higher estimates of the rise in spending per person.¹⁴

The estimate of minus 0.3 for price-elasticity of demand for prescription drugs entirely rests on one large RAND study, the Health Insurance Experiment, conducted almost 30 years ago. This is a very shaky foundation on which to build for at least six reasons.

1. Few medications with high annual costs, that could benefit older people, were available at the time of the RAND study—as compared with those available today. Few medications that patients would use daily for many months, many years, or their entire lifetime were then widely available or prescribed. That means it was hard for most patients to spend a great deal of money on medications that provided

substantial or sustained benefits. This has already changed enormously. Patients for whom prescription drugs are made more affordable have much more reason now to increase their use of medications.

And, with the encouragement of a new Medicare drug benefit, it is likely to change even more in the near future. Please consider the growing availability of very costly, new, and potentially effective medications. Many would be unaffordable without the new Medicare benefit.¹⁵

2. Given the prominence of prescription drug advertising on television and other direct marketing to patients, many more patients may be more inclined to use drugs today—and the Medicare law will do nothing to restrain such advertising.
3. The RAND Health Insurance Experiment *did not enroll anyone over age 65 or anyone with substantial disabilities—that is, no one resembling the Medicare population*. Over the years of the study, a small number of participants entered that age group or developed disabilities, but the study population was nonetheless almost completely unrepresentative of the Medicare population. (As discussed elsewhere, PRI/PwC inaccurately criticize us for not highlighting the possibility that there are systematic differences in likely use rates between Medicare patients who have coverage and lack it today— yet they rest their entire analysis of the rise in prescription drug use on data from a non-Medicare population.)
4. The RAND study used co-insurance of varying percentages to measure the price-elasticity of demand. The study looked at differences in use among participants who had no co-insurance, and others who had to pay 25 percent, 50 percent, and 95 percent. Further, all received cash payments equal to their maximum dollar exposure, which was 5, 10, or 15 percent of income, but capped at \$1,000 (roughly \$3,000 in today's dollars). These cash payments were not earmarked for health expenditures—but they were available to offset the out-of-pocket costs of prescription drug and other medical goods and services. There were no separate dollar caps for prescription drugs, so any large medical expenses could exceed the caps, and patients would then face no out-of-pocket costs for drugs. While the RAND Health Insurance Experiment's design was undoubtedly valuable for many purposes envisaged in the 1970s, it does not resemble the structure of the new Medicare drug benefit, so its usefulness as a guide to patient behavior in that plan is low.
5. In the new Medicare drug program, most enrollees would pay a monthly premium. That would orient them to using the benefit they were paying for, particularly since so many costly and potentially drugs are available and are prescribed by physicians.

We simply do not believe it is plausible that a new Medicare drug benefit that includes 75 percent coverage (that is, a 25 percent co-insurance) on drug spending at levels from \$250 to \$2,250 yearly will have a price elasticity of demand remotely close to minus 0.3. As described by PRI/PwC, this price-elasticity of demand of minus 0.3 would mean that a drop in out-of-pocket cost of 10 percent would mean a rise in drug utilization of only 3 percent. (In the promised Medicare drug benefit, each dollar of out-of-pocket spending within this \$2,000-wide band buys four dollars worth of medication because each such dollar mobilizes three dollars of insurance coverage.) Again, that calculation rested on the RAND Health Insurance Experiment, whose design, enrollment, and prescription drug environment did not resemble that of a Medicare drug benefit taking effect in 2006.

An example may be helpful.

As a 70-year-old Medicare patient, imagine that yesterday you had no insurance and must pay for all medications out-of-pocket—a reality that applies to roughly 40 percent of Medicare beneficiaries. Suppose you had two prescriptions, each for \$100 monthly, which your doctor says you must take throughout the year, for a total out-of-pocket cost of \$2,400. You decided that you just couldn't afford the bill.

Now imagine that, today, if you pay a \$420 per year premium and a \$250 deductible, you enjoy 75 percent insurance for the next \$2,000 of your drug costs this year. Once you pay the insurance premium, you are oriented toward trying to get your money's worth. You fill both of the prescriptions. After the premium, your total out-of-pocket spending is \$787.50. But the total rise in your prescription drug spending is \$2400.00. You go from using none to using \$2400.00 of medications.

The PRI/PwC critique seems to suggest that, in this example, a subsidy of 67.2 percent of the \$2400 cost of the medications would yield a typical rise in use of drugs of only 22.4 percent. That doesn't seem to make sense. (But this small rise in use is consistent with PRI/PwC's later-stated small rise in the share of drug purchases covered by insurance from fully 58 percent to 70 percent. See PRI/PwC, p.6.)

6. Economists and actuaries who try to project use of very large new programs from the experience with narrow empirical studies, extrapolation from other populations, and the like, very often miss the mark badly. Recall the explosive growth in use of hospital, physician, and nursing home services in the wake of the passage of Medicare and Medicaid in 1965—growth far beyond what the best actuaries had predicted at the time. Recall the explosive growth in use of many health services in the United Kingdom after the introduction of the National Health Service in 1947.

In these six ways, the PRI/PwC critique rests on narrow and old evidence about a very different benefit in a radically different pharmaceutical climate, while ignoring the history

of under-estimation of actual use under new health care programs. There is little reason to credit the PRI/PwC critique.

What PRI/PwC has done by uncritically accepting RAND's minus 0.3 price-elasticity of demand is very much like learning, with reasonable accuracy, the size or climate or existence of water or of life on one of the planets in our solar system, and then heroically asserting that the other planets must be very similar in all important respects—without regard to distance from the sun or any other actual empirical evidence.

Unlike PRI/PwC, we have never pretended to know the precise price-elasticity of demand for prescription drugs under the new Medicare prescription drug benefit. Directly relevant evidence is lacking. Instead, in our original report, we documented Medicare beneficiaries' needs for higher volumes of drugs and we also provided a contingency table that sets out the effects on drug makers' profits of changes in the values of two of the three key factors bearing on those profits under the new law.

Other predictions of price-elasticity

A number of close observers of the drug industry have generally spoken or written in ways that suggest a price-elasticity of demand for medications that exceeds minus 0.3. For example,

- Jordan Schreiber, health fund manager at Merrill Lynch, said in August of 2000 that “Even with drug price cuts I think there’s a good chance the pharmaceutical group will actually come out as a net beneficiary as the presently uninsured become customers, albeit less profitable customers.”¹⁶ Merrill Lynch was, at this time, apparently anticipating that substantial price cuts—in the range of 40 percent from manufacturer’s price— would accompany a new Medicare drug benefit.¹⁷ Since the new Medicare drug benefit enacted in 2003 actually makes drugs more affordable to patients largely through federal subsidies rather than through price cuts, drug makers will be able to sell more pills at prices close to full retail. Resulting profit growth will be substantial.
- David Lipson of IMS Health said in 2001 that “Despite the industry’s initial concern about the effects of such a [Medicare prescription drug] program, the consensus now is that coverage for the elderly will expand the market.”¹⁸ Lipson was speaking at a time when anticipated federal subsidies were substantially below those estimated even by CBO for the benefit enacted in 2003.
- As an Australian government evaluation has observed, PhRMA claims that “price controls do not reduce pharmaceutical expenditure, citing studies by Redwood in 1993 and Gross in 1994 that lower prices lead to a sufficient increase in the volume of drug sales to maintain the same level of revenue.”¹⁹

Specifically, in its *Industry Profile* for 2000, PhRMA wrote that “A 1993 study by Heinz Redwood and a 1994 study by David Gross comparing international pharmaceutical-spending controls across countries found that while price controls produce lower prices, they do not reduce pharmaceutical expenditures (price times volume) or contain health care costs.”²⁰

Thus, in arguing against price controls in the past, PhRMA has apparently endorsed findings that price controls will not save purchasers money because the price reductions will boost sales volume sufficiently to replace the revenue that would otherwise be lost to lower prices.

- Some observers note that expanding coverage is likely to mean the largest jump in sales for those companies that make the costliest prescription drugs, which most uninsured patients cannot afford. “People with insurance for drugs not only use more prescriptions, but they also have more expensive prescriptions,’ says Frank Lichtenberg, a Columbia University health economist.”²¹

Other observers’ estimates of revenue and profit under the new Medicare benefit

It is no surprise that numerous observers have concluded that the law will substantially raise drug makers' revenues and profits—though by amounts that vary widely. Consider these observations and estimates by various parties outside, close to, or inside the pharmaceutical industry:

- The law “should have a positive impact on industry profits, with anticipated price discounting outweighed by increased volume,” at least in the near term, according to a leading Standard and Poor’s analyst.²²
- Calling the new law “A Good Bill for Drug Industry,” and referring to “Massive New Spending on Drugs,” the editor of *The Pink Sheet* recently cited several estimates of the anticipated rise in drug maker revenue and profits (including our estimate of windfall profit to the industry, and the three other figures that follow).²³ He touted “over \$70 billion in spending through 2007” as one of the “reasons for optimism.” He asked rhetorically, “Why Aren’t Drug Companies Happier?” and answered, “Gloating would fuel backlash.”

Thus, in a recent panel discussion, according to Bloomberg News, a Merck lobbyist asserted, “This prescription drug benefit is not a windfall for Merck....There will be tougher bargaining on prices.’ “ But Princeton economics professor Uwe Reinhardt, in the same discussion, reportedly commented, “If any CEO of any drug company says they can’t make money on this, I would volunteer to replace that CEO....I cannot believe this isn’t a boon to the drug industry.”²⁴ Reinhardt concurred with the estimate of a 9 percent rise in revenue for drug makers and said that “the percentage increase in profit is probably higher....”²⁵

- IMS has projected that the Medicare benefit will mean 75-100 million additional prescriptions filled annually in the U.S., an estimate reiterated by Walgreen.²⁶
- AmerisourceBergen has estimated there will be \$10-\$15 billion in new prescription drug spending in 2006 under this law.²⁷

What would this mean over the law's first few years? Assume that the first-year incremental spending is \$12.5 billion. Assume also that incremental spending rises by the same percentage each year as CBO's projected baseline spending on outpatient prescription drugs—increases of 11 or 12 percent annually, through 2013.²⁸ This would mean \$26.7 billion in added spending in 2013, and \$150.8 billion in new prescription drug spending added cumulatively over the first eight years of the benefit (2006-2013).

- Goldman Sachs projected 9 percent incremental growth in drug sales as people gain coverage, which some observers estimated at a \$13 billion increase over a year.²⁹
- An alternative estimate, from Merrill Lynch, is that the pharmaceutical "industry could see up to \$10bn in extra sales and \$4.7bn in additional profits, a rise of 2 per cent, in 2006 when the benefit starts...The study estimates potential sales of \$15.4bn in 2010 and \$7.4bn in profits." They appear to have assumed that only 25 percent (10 million) of the 40 million Medicare beneficiaries lack coverage, rather than 40 percent.³⁰
- As a consultant told the *Washington Post*, "It couldn't be clearer there is going to be a positive effect overall...The volume will definitely go up, There will be a lot of people who didn't have coverage before who will have it now and a lot of people getting an upgrade in terms of coverage."³¹

Because the PRI/PwC critique does not provide either a clear table or a text summary that tracks their view of the flow of the dollars, we have tried to understand what they intended. It seems to be something like the following. What if the minus 0.3 price-elasticity of demand means that \$300 billion in federal Medicare dollars going to manufacturers under the new law (after retailers and wholesalers take their shares) generates a net rise in drug makers' revenue that's as low as \$90 billion. Where does the rest of the money go?

The PRI/PwC critique seems to assume that almost all of it returns to patients as lower prices (through the higher discount that the critique assumes). A 25 percent price discount would mean that \$75 billion of the \$300 billion would not remain with the drug makers. Rather, it would be returned to the insurers, HMOs, PPOs, and other entities that provide drug coverage under the new benefit. What would then happen to the money? PRI/PwC don't clearly explain this.

But (a) we have here, in effect, a federal commitment to a \$400 billion federal prescription drug subsidy, three-fourths of which will go to manufacturers. Further, (b)

Medicare beneficiaries' need for medications won't be met fully by that \$400 billion. (The PRI/PwC critique assumes that the share of beneficiaries' drug costs covered by insurance rises to 70 percent, which we consider high, as discussed below.) Therefore, it can be expected that the savings from the discount would be recycled to buy still more medications from the drug makers.

And the drug makers earn further windfall profits on these additional purchases.

b. Differences in spending between Medicare beneficiaries who were insured and who were uninsured for prescription drugs

PRI/PwC blatantly misrepresents in several ways the evidence we use on differences in spending between Medicare beneficiaries who were insured and who were uninsured for drugs. We plainly described Poisal's data as comparing uninsured Medicare beneficiaries and "beneficiaries with any drug insurance" (HRP, p. 4)—as Poisal put it, "beneficiaries with and without coverage." Poisal's study included people on Medicare with all sorts of drug coverage—Medicare HMOs, Medicaid, employer plans, and more, whether with slim or substantial benefits. Further, our calculations with the Poisal data conservatively brought uninsured beneficiaries only to *average spending for those insured*, not to the level of those with *adequate* coverage.

Yet the PRI/PwC critique repeatedly mis-characterizes the insured group in the Poisal analysis we cited as having "*comprehensive*" or "full" coverage. (PRI/PwC, p. 5) This suggests either extreme carelessness or deliberate distortion. Our term, "any coverage," obviously does not mean "comprehensive" coverage.

The false claim that we use a comparison with comprehensively-insured Medicare patients is consistent with PRI/PwC's mistaken assertion that we anticipate an implausibly large rise in spending.

The PRI/PwC critique argues that we ignore possible systematic differences between insured and uninsured people on Medicare, and implies that this contributes to our alleged overestimate of new spending. But they never themselves address such differences. (And, as discussed above, they also ignore the even bigger issue of systematic differences between Medicare and non-Medicare patients.)

In reality, any difference between Medicare patients who are insured or uninsured for drugs would undermine our estimates only if uninsured people who gain coverage would tend to use fewer medications than people already covered, perhaps owing to better health.

The Medicare population uninsured for drugs likely has a bi-modal distribution—some are low-income patients unable to afford coverage (often despite great need), while others uninsured for drugs are healthy or wealthy, or both, and therefore have not bothered to get drug coverage. But there is good reason to think that Medicare

beneficiaries who lack drug coverage (and would gain it under the new law) are likely to be poorer than average. And lower income people tend to have worse than average health (implying greater prescription drug needs)—so our use of the average was, again, conservative.

Quick calculations from Laschober's data suggest, for example, that Medicare beneficiaries with drug coverage were almost equally divided between people with incomes above and below \$20,000 in 1999, while a noticeably greater number of those without coverage were in the low income group. Laschober and colleagues also found that Medicare beneficiaries between ages 65 and 74 were more likely to have drug coverage than older beneficiaries and than those under 65 with disabilities—though the 65-74 group is doubtless the healthiest.³²

4. EXTENT OF COVERAGE AND CIRCULARITY OF ESTIMATES

PRI/PwC: PRI/PwC estimates “that the Medicare population’s share of total drug spending covered by insurance will increase to 70 percent, compared to 58 percent in the absence of the law.” (p. 4). The implication is that 42 percent of drug spending would be out-of-pocket in 2006 absent the law, and this would fall to 30 percent under the new law.

REPLY: The PRI/PwC critique appears to rest heavily on a circular argument. And unsubstantiated, highly questionable estimates are used for the insured and out-of-pocket shares of drug costs.

a. Circularity of volume estimates

By way of documentation, the authors offer a remarkably uninformative footnote that says they calculated what the text says they calculated. No methods, calculations, or evidence regarding supporting assumptions are provided.

The 58 percent/70 percent calculation appears to rest in part on the assumption of the minus 0.3 price-elasticity of demand. The PRI/PwC’s assumed price-elasticity of demand and its 58 percent/70 percent estimate are its reasons for saying that the overwhelming bulk of the new \$400 billion Medicare prescription drug program would go to replacing existing drug spending by patients or by their insurers, consequently doing very little to buy new medications for patients who today need them but can’t afford them. While this would seem to be a clear conclusion of the PRI/PwC critique, that critique does not ever estimate a split in spending between new prescriptions and replacement prescriptions.

The PRI/PwC critique (p. 6) goes on to use its own 58 percent/70 percent estimate to complain that our calculations rest on a very high price-elasticity of demand of 1.3. They try to back us into that corner through their own unrealistic assumptions about price-elasticity of demand and their own entirely undocumented 58 percent/70 percent estimates of the shares of medications covered by insurance before and after implementation of the new Medicare drug benefit.

In this way, the PRI/PwC critique erects its own world of interlocking or circular assumptions, with the appearance of empirical support, and uses them to say we are wrong. They imagine an unrealistic world and say we are wrong because we refuse to inhabit it with them.

They could have said, “we think they are wrong.” That would have been fair. But when they claim that they are relying on science to argue we are wrong, they badly over-reach.

b. Unfounded estimates of covered and out-of-pocket shares

Moreover, the PRI/PwC's assumption that 58 percent of Medicare beneficiaries' drug spending will be covered by insurance before the new Medicare prescription drug benefit kicks in, in 2006, simply does not square with reality. (PRI/PwC assert, in note ix, that this was "calculated ...by first estimating the average amount of drug spending covered by different types of insurance....," but no underlying data whatsoever are shown.)

CBO had similarly estimated that only 40 percent of drug spending for Medicare beneficiaries was paid out-of-pocket in 1999.³³ This might seem consistent with—and may even have rested in part on—CBO's apparent occasional use of an inaccurate estimate that only 25 percent of Medicare beneficiaries had no drug coverage in 1999. But as discussed elsewhere in this response, that figure reflects an estimate of the *share of beneficiaries lacking insurance for drugs for an entire year*, not the average share of beneficiaries without insurance at a given time. The latter is the better measure of insurance coverage and the lack of it, we believe.

And even if only 40 percent of drug spending for Medicare beneficiaries was out-of-pocket in 1999, that is certainly not true today, and it predictably will be less true in 2006. One reason is the steady erosion of retiree health insurance coverage. In 1999, CBO estimated that employer-sponsored coverage paid 26 percent of Medicare beneficiaries' drug costs. Another reason is the steady rise in beneficiaries with no drug coverage, which we have conservatively estimated at 40 percent, following Laschober and colleagues, as discussed elsewhere in this response.

With 40 percent of people on Medicare lacking insurance for drugs entirely, with the continuing erosion of retiree coverage, with many others lacking adequate drug benefits, and with rising dollar co-payments, the gaps in coverage are great. *It is simply not credible, especially absent supporting evidence, that 58 percent of Medicare beneficiaries' drug costs were covered by insurance in 2003, leaving only 42 percent to be paid by patients themselves.* By this measure, as with the number of people covered, PRI/PwC (and the similar CBO figures) appear to over-estimate Medicare beneficiaries' current level of insurance coverage for prescription drugs.

And the share covered by insurance can be expected to fall further between 2003 and 2006 as retiree coverage erosion continues to drop and as co-payments continue to rise. We doubt that improvements in HMOs/PPOs' drug benefits for Medicare+Choice enrollees will be durable or adequate enough to offset more than a small portion of this coverage erosion and co-payment rise.

The Kaiser Family Foundation (KFF) recently published projections that show a slightly higher, 46 percent, out-of-pocket share for 2006 (up from 43 percent for 2003).³⁴ Notably, however, the out-of-pocket shares were described as being "consistent with" CMS projections for *non-institutionalized* Medicare patients.³⁵ Yet one might expect the

out-of-pocket share for the community-dwelling, non-institutionalized people on Medicare to substantially exceed the share for Medicare beneficiaries overall, because the latter includes many nursing home patients, the great majority of whom have Medicaid drug coverage.³⁶

Other evidence casts the CBO and PRI/PwC out-of-pocket estimates much further into question. It is well recognized that Medicare patients pay out-of-pocket for a far larger share of their prescription drug costs than non-Medicare patients do. Yet evidence from the Medical Expenditure Panel Survey (MEPS) for 1999 showed that the out-of-pocket share of drug costs was 39 percent for *non-Medicare* patients—comparable to the figure cited by CBO and PRI/PwC for Medicare patients. Further, the MEPS survey found that in 1999 *Medicare patients paid fully 57 percent of their drug costs out of pocket. Public and private coverage paid just 43 percent of Medicare beneficiaries' drug costs.*³⁷

These figures are virtually the inverse of those estimated by PRI/PwC and CBO, and of the similar KFF estimates. (The MEPS data appear to exclude drug costs for nursing home patients, as the KFF figures may. But it seems unlikely that prescription drug use by Medicare patients in nursing homes alone could raise the covered share for Medicare patients overall from 43 percent to the 58 percent estimated by PRI/PwC).

The KFF data and CBO make use not only of MEPS data but also the Medicare Current Beneficiary Survey (MCBS). Each has advantages—and substantial limitations. Even with the most careful analyses, these surveys simply must be recognized as providing estimates of current drug spending that are unreliable bases on which to rest projections. Consider just one issue on which Poisal reported recently, for example—the complexity of adjusting such surveys to account for patients' under-reporting of their medication use and spending. For the MCBS, he notes, “a difference of just 1 percent in the underreporting estimate can change total projected annual outlays” for prescription drugs among non-institutionalized Medicare patients by over \$500 billion.³⁸

c. Baseline spending estimate disparities

Some of the foregoing difficulty with the PRI/PwC calculations may stem from the apparently very substantial disagreement between the CBO estimates of outpatient prescription drug spending on Medicare beneficiaries and the estimates for spending on Medicare beneficiaries derived from retail drug spending data compiled by the CMS Office of the Actuary. One possible element in the disagreement: CBO's outpatient prescription drug spending may be measuring something different and greater than CMS's retail prescription drug spending. For example, prescription drugs for patients in nursing homes ought to be included in CBO's outpatient estimates, but in CMS data, some of them are tallied as nursing home costs rather than with retail prescription drugs.

Consider the latest data from CMS, for 2002. The CMS Office of the Actuary reported that total U.S. retail prescription drug spending in 2002 was \$162.4 billion.³⁹ Medicare beneficiaries are reported to use some 35-40 percent of that medicine. CBO reports the 40 percent share.⁴⁰ Now, 40 percent of CMS's \$162.4 billion is \$65.0 billion.

But this is visibly different from CBO's own \$87.0 billion estimate of outpatient prescription drug spending by Medicare patients in 2002. CBO's reported figure is 33.8 percent above that derived by applying CBO's own Medicare share of outpatient prescription drug spending to CMS's total retail spending estimate. Worse, CBO's estimates of spending on drugs for Medicare beneficiaries for 2002 rose by \$6 billion from the estimates made in 2001 to the estimates made in 2002, meaning that CBO's number has been drifting farther above CMS's number. The two figures should be very close together if they are gauging the same reality. They appear to differ somewhat in definition, so even baseline spending estimates may be muddled.

5. FAILING TO IDENTIFY THE NEW Rx / REPLACEMENT Rx SPLIT

HRP WINDFALL PROFIT REPORT: Our report's main analysis assumed that the split between new and old prescriptions was 60/40. This assumed a program that meaningfully addressed the great suffering that many Medicare beneficiaries endure because they cannot afford their medications. We also provided a contingency table (Exhibit 3) for those who assumed a different split. Thus, while focusing our discussion on the estimate that 60 percent of the new federal spending would go to fill new prescriptions, we showed the effect on the rise in profits as that share of the federal subsidy ranges from 40 percent to 80 percent.

The contingency table indicated that with new prescriptions getting 40 percent of the new federal spending, drug makers' new profits would be an estimated \$80 billion, rather than \$139 billion, other things equal; with 80 percent going to new prescriptions, the estimated new profits rise to \$198 billion over eight years.

PRI/PwC: The PRI/PwC critique noted the assumption in our main analysis that 60 percent of the subsidy will constitute new spending, but did not mention the contingency table or the range of estimates that it offered. The critique focuses, as discussed elsewhere, on downplaying the potential rise in volume, but does not make explicit its own conclusion, if any, about the likely split between new and replacement prescriptions. When the critique presents its unexplained estimate that insurance coverage will rise from 58 to 70 percent of Medicare patients' drug spending (discussed above), it states only that "some of the new coverage will replace coverage that Medicare enrollees already had." (p. 4).

REPLY: It is important to address this issue explicitly because the calculated rise in drug makers' profits, as we noted (p. 8), is fairly sensitive to this split between new and replacement prescriptions. That is because the new volume means new revenues and profits, whereas drug makers may receive less revenue and profit on replacement sales than they received on those sales in the past. Whether and how much the drug makers' revenues and profits decline on the replacement sales depends, as discussed elsewhere, on the extent to which drug makers give Medicare plans average prices that are lower (because discounts/rebates are greater) than those drugs sold for in the past.

The new/replacement prescription split depends greatly on the extent of new demand under the new coverage—which we discuss under price-elasticity and elsewhere.

While this split has strong implications for drug makers' profits (the focus of our report), it also has important implications for the value of the Medicare drug benefit program.

Much replacement spending does have public benefit. Many Medicare patients today are obtaining all the medications they need but they or others who pay for those drugs

(state Medicaid programs or employers, for example) are struggling under the cost. Replacement spending, however, would only help by easing the cost burden for medications that people were already able to buy—whether through existing coverage or out-of-pocket payments.

But much of the urgent desire for a Medicare drug benefit stems from the concern that many patients are unable to fill the prescriptions they need—or fill them half as often as they should. Will the new benefit address any substantial share of this need?

Compared to our analysis, the PRI/PwC critique assumes that a much smaller share of the new money will go for increased volume, and a much bigger share will take over the cost of paying for existing drugs. **This clearly means that PRI and PwC imply the law will do much less to bring new medical care to patients than we expected.**

But the PRI/PwC critique doesn't make this implication explicit. They never offer an alternative estimate from their calculations of the split between new and replacement prescription.

Proponents of the law should view our analysis as more optimistic than that offered by PRI/PwC. PRI/PwC suggest that the law will mean relatively little rise in new volume, while we suggest that the \$400 billion—despite the law's limited benefits, high patient cost-sharing, and high drug prices—will enable many patients to fill prescriptions that otherwise would go unfilled.

6. HIDING CRUCIAL CALCULATIONS

HRP WINDFALL PROFIT REPORT: All of the calculations in our report are transparent and are explained fully.

PRI/PwC: The PRI/PwC critique announces that it relies on “transparent assumptions and accepted research.” A central element of their critique is the projected rise in purchases of prescription drugs induced by the extent of new drug coverage. They state that they estimate a rise in the share of prescription drug use that would be covered by insurance (see top of p. 4 and note ix) to 70 percent from a current 58 percent. But the analysis itself is not disclosed. The PRI/PwC critique simply and unhelpfully claims in endnote ix that it rests on separate calculations for four or more types of current insurance and three aspects of the new law, including low-income subsidies and others.

REPLY: Some of the PRI/PwC assumptions may be transparent, but most of their calculations are not.

The critique’s main source of “accepted research” is the 30-year-old RAND Health Insurance Experiment, whose relevance to price-elasticity of demand under a new Medicare drug benefit is highly questionable at best, as we documented earlier.

The critique’s two main failures to make transparent assumptions are (1) its presentation of the unsubstantiated CBO estimate of price discounts well in excess of those achieved by bigger buyers today, and (2) the asserted rise from 58 percent to 70 percent in the share of Medicare beneficiaries’ medications covered by insurance, a claim which rests on unreported calculations.

On the latter point, the core of their analysis, their work is cloaked in secrecy. Undisclosed calculations—a “black box,” the workings of which are not disclosed—underlie the crucial estimates of the rise in use, which they assert will be substantially smaller than we suggest. While saying these estimates reflect calculations taking into account four or more types of current insurance and several aspects of the new law, they present no evidence on those calculations, providing no way to evaluate the specific elements therein.

PRI/PwC’s critique takes places at two extremes. At one extreme, it offers a low price-elasticity of demand (relying on 30-year-old studies of a different benefit, a different population, and a different pharmaceutical climate) and a rise in the share of drugs covered by insurance from 58 percent to 70 percent (neither the numbers nor the methods of calculating them is documented).

At the other extreme, as discussed elsewhere, the PRI/PwC critique asserts that drug makers’ revenues after implementing the new benefit will face between a 1.0 percent

drop in total revenue and a 3.2 percent rise. But it does not show how these estimates were derived. Their claim that industry revenues might fall under the law (despite the \$400 billion in new federal spending) is blandly attributed to conversations with anonymous sources in the pharmaceutical industry (PRI/PwC, note 4).

The PRI/PwC critique fails in these separate activities. It also fails to present an integrated, connected analysis of changes in drug makers' revenue, to tie together the individual pieces.

As a result, according to the PRI/PwC critique, the \$400 billion in new federal spending seems to simply to float away into the ether.

C. PRICE OF MEDICATIONS

7. CLAIMING IMPLAUSIBLE DISCOUNTS AND REBATES

HRP WINDFALL PROFITS REPORT: We estimated that discounts and rebates under the new law would average 15 percent of posted retail charges, about what they appear to average today. The law would leave the job of bargaining over prices with drug manufacturers to the several plans in each of numerous regions. The decision to shatter Medicare’s buying power deliberately throws away the chance to use the massive buying power of the whole Medicare population to negotiate substantial drug price reductions.

The nation’s purchasing power would be intentionally fragmented among many plans, just as it is today in the private health insurance market—and as the industry urged.⁴¹ So there is no rationale for expecting discounts any greater than those given to the “private health insurance plans [that] are widely-recognized to have failed to contain drug price for either Medicare HMO enrollees or for the wider array of American workers, families, and employers” (HRP, p. 1).

PRI/PwC: Their critique offers a muddled picture which confuses estimates of overall savings with estimates of price cuts. (The terms “discounts” and “rebates” also often appear to be used interchangeably in this critique.) Whether price reductions or savings, the estimates are unsubstantiated.

Offering no evidence for this conclusion, the PRI/PwC critique simply asserts that the plans “will be able to purchase drugs at discounts of around 25 percent, compared to discounts of 15 percent under current employer plans.” (PRI/PwC, p. 4) They attribute this estimate to CBO. The PRI/PwC report criticizes us for failing to accept CBO’s estimate that the new plans operating under the Medicare drug benefit will win prices that are 10 percentage points lower than those obtained by PBMs today.

Elsewhere, however, they assert that “savings, termed the ‘cost management factor’,...will be about 10 percentage points higher than under current....employer plans.” (PRI/PwC, p. 6)

There, they “assume that the savings estimated by CBO are one-half rebate and one-half increases in other factors,” including generic substitution, utilization review, narrower pharmacy networks, and “other methods used by PBMs to reduce costs.” (p. 6) There is no explicit mention here of restrictive formularies, but that may be what is intended by “other methods.” They conclude that drug maker rebates would rise by 4-8 percentage points. (p. 7)

Earlier, they asserted that use of broad pharmacy networks limits plans' ability to win discounts from pharmacies (p. 4), yet their estimates assume that restricting pharmacy selection will be the source of some savings (p. 6).

Mainly, they claim, without attribution, "Most analysts expect manufacturer rebates to increase under the new benefit, as plan providers compete for enrollees." (PRI/PwC, p.4)

REPLY: All these somewhat contradictory PRI/PwC statements assume that private plans will save more than they now do for employers. All such statements are unsupported. No evidence is offered that private plans can win larger discounts and rebates than they have done until now. And this assertion flies in the face of the willful fragmenting of buying power required by the new bill.

Similarly, when CBO was asked recently to address the relative effects of relying on private plans or allowing Medicare to negotiate drug prices, the agency wrote that there would be "negligible" difference, as

CBO estimates that substantial savings will be obtained by the private plans.... Because they will be at substantial financial risk, private plans will have strong incentives to negotiate price discounts, both to control their own costs...and to attract enrollees.⁴²

But CBO, too, simply asserted this claim, without supporting evidence.

That view appears to contradict expectations of some knowledgeable observers. For example, the previous administrator of the Medicare agency, Bruce Vladeck, observed last year that "A slew of private health plans would have nowhere near the negotiating power that Medicare would have if there was national drug benefit..."⁴³

The PRI/PwC and CBO claim also contradicts the apparent expectations of the pharmaceutical industry itself. The industry had, as just noted, sought to face fragmented private purchasing and strongly resisted earlier proposals for Medicare to directly administer a drug benefit. As the *Wall Street Journal* put it, "The benefit would be administered through private insurance plans or pharmacy benefit managers. Drug makers believe individual private buyers are less able to push down prices than a centralized government purchaser with a pool of 40 million patients...." And therefore, "For the drug industry, the legislation is good news, at least in the short run."⁴⁴

Further, if private plans do have the ability to get greater discounts, why have they not yet done so for employers? With double-digit drug spending increases reported over the past three years (reflecting both price and volume trends), some observers suggest that today's strategies "just aren't curbing costs."⁴⁵

Might Medicare plans win larger discounts under the new law because Medicare covers so many people? That is implausible, since the law would hand the job to new competing private regional plans. The largest pharmaceutical benefit manager firms

have claimed to represent 40, 60, even 70 million “covered lives”⁴⁶ – far more than the future Medicare drug plans are likely to enroll.

Anticipating a “fragmented market” under this law, the editor of *The Pink Sheet* observed that the program may divide the nation into as many as 50 regions.⁴⁷ Indeed, the new Medicare law specifies that prescription drug plan regions shall be, “to the extent practicable,” the same as those for Medicare Advantage plans⁴⁸ – for which “There shall be no fewer than 10 regions, and no more than 50 regions.”⁴⁹

Consider the precedent of market fragmentation in the new drug discount cards to be offered in mid-2004. CMS has just approved 28 card issuers, along with 43 more cards from Medicare HMOs.⁵⁰ The large number approved may be spurred by hope that “competition” between discount card plans will drive down costs. But as discount card plans multiply, the Medicare population and its purchasing power are divided.

Merely wanting to attract Medicare enrollees will not give plans the *power* to “extract greater discounts” (PRI/PwC, p. 3) from drug makers, especially since multiple small private plans would be negotiating with large monopolistic or oligopolistic makers of patented drugs.

We regard the CBO assumption of increased discounts as unsubstantiated and therefore as unrealistically optimistic.

Because we assumed that price discounts would resemble those under current PBM programs, our study retained the manufacturer/wholesaler/retail split of the pharmaceutical dollar that prevails today.

The PRI/PwC report also seems to intermingle references to price discounts and rebates with references to savings from “efficient plans,” which could exert substantial utilization review and the like. The latter are not price discounts.

As just noted, there is no evident reason why drug makers would be motivated to give larger discounts or rebates than they give to today’s large PBMs purely because the new plans and insurance companies are competing for enrollees.

Adopting severely restrictive lists of covered drugs, however, could perhaps enable the new private plans to win greater discounts from drug makers. If that method of leverage is assumed, though, it goes largely unmentioned. PRI/PwC’s “background” section suggests that plans with “rich benefit packages and lax formularies” may face “competition [that] will force [them] out of the market.” (p.3) But the PRI/PwC discussion of the claimed 25 percent discounts does not prominently make that argument for restrictive drug lists, perhaps for reasons such as these:

(a) PRI elsewhere has stated opposition to use of formularies, proposing (with some reason) that the choice of drug generally should be left to prescribers and patients.⁵¹

- (b) Restrictive formularies would limit plans' ability to attract enrollees. PRI/PwC and the CBO state that plans will win lower prices from drug makers in order to compete for members (without ever saying how), but many patients are concerned about access to particular drugs as well as about price. If narrow formularies are to be the fragmented new plans' main means of cutting drug prices, the plans indeed will face a dilemma in trying to attract patients.
- (c) The law somewhat limits plans' ability to restrict their formularies by requiring inclusion of drugs in each of a large array of categories.

If an assumed reliance on highly restrictive formularies underlies the belief that this Medicare law will boost drug discounts and rebates, that assumption is not prominently featured in promotion of the law—perhaps because it would be unpopular with patients and physicians. (Patient advocacy groups are, however, cautioning seniors that plans may change the covered drug lists often, and that patient spending would not count towards the out-of-pocket limit if it goes to buy drugs not on the formulary for the patient's plan.)

But even if plans can use restrictive drug lists to win discounts of 25 percent, that would not lower the drug makers' new profits greatly, because the prices that the Medicare plans pay would still vastly exceed the incremental manufacturing and distribution cost discussed earlier. (This is presumably why some Wall Street analysts who believe that 25 percent discounts are likely, nonetheless conclude that resulting "volume increases would more than offset that" revenue loss.⁵²)

Further, as discussed elsewhere, some mix of two things is likely to happen to the money saved through discounts, whether these are 15 percent or 25 percent. First, insurers would recycle the savings from discounts to underwrite the purchase of more medications, which would boost drug makers' revenues still higher, allowing them to garner still higher additional profits, since marginal costs remain extremely low. Second, insurers would retain some of the discounts in the form of higher profits, which would amount to a transfer of drug makers' profits (and also benefits to patients) to insurers' profits.

Thus, absent the leverage of the Medicare program negotiating as a whole, taxpayers will finance huge windfall profits. As U.S. Representative Dan Burton (R, Indiana) has said, "That is unconscionable. The government of the United States negotiates prices in the Defense Department, in every area of government....And here we are, going to spend billions and billions and billions and probably trillions of dollars on pharmaceutical products. And we cannot negotiate the prices with the pharmaceutical industry. That's just not right."⁵³

D. PROFITS

8. CLAIMING IMPLAUSIBLE OVERALL EFFECTS

HRP WINDFALL PROFITS REPORT: Our report concluded that \$400 billion in new federal spending under the Medicare drug benefit would pay in substantial part for new prescriptions, increase drug makers' revenues, and result in \$139 billion in new profits over eight years.

PRI/PwC: The PRI/PwC critique states its intent to "calculate alternative estimates of the impact ... on pharmaceutical industry revenue," and that they "establish a range ... of the potential changes to drug industry revenues and profits," which "can even be *negative*." It concludes, "the Medicare drug benefit could range between an increase in drug industry revenues (net of additional rebates) of 3.2 percent at most to a *decrease* in drug industry revenues of 1 percent." (PRI/PwC, p. 1, 8, 9, emphasis added.)

REPLY: This is astonishing. Is that what was sought through a new \$400 billion program?

CBO now projects that total baseline spending on retail prescription drugs for Medicare patients would equal about \$1.6 trillion from 2006 to 2013.⁵⁴ Ignoring discounts for now, this means that the new \$400 billion would yield a 24.8 percent rise in spending on behalf of Medicare beneficiaries if all of the added revenue bought new prescriptions.

The surprising achievement of PRI/PwC is to make almost all of this money disappear. What does it buy? Very little, apparently.

PRI/PwC's calculation is achieved only by heroic assumptions of a very low price-elasticity of demand and a very high discount. In other words, a great share of the money replaces existing spending. PRI/PwC never offer an estimate of the share of the \$400 billion that replaces existing spending. In still other words—and shifting now to manufacturers' \$300 billion share of the \$400 billion—remarkably high discounts, somehow extracted from manufacturers by fragmented buyers, consume almost all of the remaining money. As a result, claims PRI/PwC, drug makers' total revenues would either fall a little or rise a little. As noted earlier, both of these assumptions are poorly substantiated; their contention that the industry might lose revenue under the law despite \$400 billion in new federal spending is attributed only to anonymous sources within the pharmaceutical industry (PRI/PwC, note 4).

(A disturbing inconsistency also muddies the PRI/PwC estimates. The text, as quoted above, and press release repeatedly say that the -1.0 to 3.2 percent range refers to changes in "drug industry revenues." A table on p. 9 calls those figures the percentage change in "Drug Industry Revenues from the Medicare Population" alone.)

The PRI/PwC calculation fails to clearly follow the trail of its own discounts/rebates. If discounts/ rebates actually do rise to 25 percent, who gets to keep them? This is money that reduces the prices paid to manufacturers, and therefore manufacturers' total revenues, so it must reduce someone else's cost of doing business.

The likely candidates are the HMOs, PPOs, insurers, and other entities that operate the new Medicare drug benefit. They could respond by retaining the savings and thereby boosting their own profits, other things equal. Or they may share some of the savings with patients by improving benefits, as PRI/PwC say is "expected" (p.7).

If the former, some of the profits we calculated for drug makers are simply transferred to a different set of entities. But if the latter, as the PRI/PwC critique assumes, they never explore the implications for profits. They don't take the next steps. Higher discounts/rebates mean lower prices, so patients will be spurred to fill more of their prescriptions (as PRI/PwC mention in note xxviii), and drug makers will sell more drugs (at a tiny marginal cost). Thus, higher discounts/rebates are likely to recycle back to drug makers. And they will retain as higher profits the bulk of these recycled dollars—a point not noted by PRI/PwC.

Although we conservatively did not include the profits from this recycling in the \$139 billion, we had estimated, "On the first round of recycling, \$5.3 billion of this sum accrues to drug maker profit. Successive rounds would add sharply diminishing sums." (HRP, p. 10)

Although PRI/PwC concedes (footnote xxviii) that "additional discounts lead to additional induced demand" they never provide a clear, explicit, or integrated display of their own calculations of either induced demand or drug makers' revenue.

Simply, PRI/PwC fail to follow the money.

And their implausible conclusion contradicts the verdict of the investors. Many observers noted that, as the law neared passage with its bans on importing and Medicare price negotiation, and with only limited expansion of generic drugs' market access, pharmaceutical stocks rose sharply.⁵⁵

The view appears widespread that, at least in the near term, the law will have a positive effect on drug makers' bottom lines. Some do suggest that, over the longer term, drug makers may face a squeeze, but those suggestions generally appear to reflect a belief that soaring costs will force changes in policy and law eventually, including possible implementation of price controls.⁵⁶ Our October 2003 study ignored such responses to high profits because it aimed to measure the effects of the legislation then under discussion.

9. REFUSING TO ESTIMATE PROFITS

HRP WINDFALL PROFIT REPORT: We stated clearly our estimate that under the Medicare bills before Congress, from the \$400 billion in projected federal net cost, drug makers appeared likely to garner \$139 billion in increased profits. Our report title contained another main finding: *61 Percent of Medicare's New Prescription Drug Subsidy is Windfall Profit to Drug Makers.*

PRI/PwC: The PRI/PwC critique declares that its focus is our estimate of profits, and claims repeatedly that our analysis “significantly overstates the potential increase....” But it never offers a dollar figure for the change in profits. It offers numerous estimates of the percentage rise—or even fall—in *revenues*, and a few comments on the projected percentage rise in profits.

PRI/PwC begins by asserting that our “results stand in stark contrast to the opinion of financial analysts who *track developments* in the pharmaceutical industry. [emphasis added]” (p. 2), and are “well outside the range generally accepted by ...private sector analysts.” (p. 1)

The PRI/PwC section on “Presentation of Alternative Estimates” begins by stating, “Our estimates present a more comprehensive picture of the potential change in drug industry revenues and profits.” (p. 8) But no estimates of profits are presented there.

The final assertion about profits is that the “modest change in revenues” that they foresee “could not cause the significant change in profits estimated in the Sager-Socolar study.” (p. 10)

REPLY: The PRI/PwC critique avoids grappling with the probable size of drug makers’ profits under the law, simply asserting that ours is an overestimate.

Despite its opening declaration that our estimates deviate from those of analysts who “track developments in the pharmaceutical industry,” the critique offers little impartial evidence. It mentions just *one* estimate from an organization that *tracks* industry developments, Merrill Lynch. The other two PRI/PwC citations are both *from the pharmaceutical industry itself* :

The critique says “[s]everal drug companies have informed the investment community that the impact of the legislation would be neutral in terms of the benefits or costs to the industry.” It also refers in a footnote to losses predicted anonymously in “unpublished, private conversations by the authors with analysts and strategic planners who work in the pharmaceutical industry.” (PRI/PwC, p. 2 and note 4).

Our earlier sections addressed numerous problems in the PRI/PwC estimates of the law's impact on drug makers' revenues. Those disjointed and often undocumented or irrelevant estimates undermine any conclusions that readers of the PRI/PwC critique might draw about profits. So does the total absence from the PRI/PwC critique of any discussion of drug makers' incremental costs of producing a higher volume of drugs (since determining profits requires knowing costs as well as revenues).

As noted earlier, however, we are grateful to PRI/PwC (p. 7) for calling our attention to one miscalculation, in the percentage rise in drug makers' profits (even though they accidentally made a mistake that mirrored our own miscalculation).

In calculating the percentage increase in profits from the law, we compared the \$139 billion estimated rise to a baseline figure that *understated* the industry's expected baseline profits—the profits that drug makers would gain after 2006 in the absence of the law. We therefore *overstated* the percentage rise for the law's first eight years. The \$17 billion annual average would be a 38 percent rise over prescription drug makers' projected profits of \$45.3 billion in 2006 without the new law. But projecting drug makers' baseline profits forward from 2006 to 2013 (at the same 6 percent annual rate used to project from 2002 to 2006) would mean cumulative eight-year drug industry baseline profits of \$448.4 billion. So the added \$139 billion profit from the new federal Medicare subsidy would be a 31 percent rise from the industry's \$448 billion in projected baseline profits over eight years in the absence of the law.

In the PRI/PwC critique (p. 7), their correction appears to reflect a similar error in the opposite direction, using the high end of the eight-year period for the baseline while we had used the first year. They suggest that our profit estimates (which they dispute) would mean a 26 percent rise. They do not disclose their calculations, but the 26 percent figure appears to derive from dividing \$17 billion by projected 2013 baseline profits, and referring to the result as if it applied to the full eight years, understating the percentage rise. Again, the \$139 billion over eight years amounts to a 31 percent rise in profits.

Finally, it's worth noting the implications of these estimates for total profits in this industry which is already the nation's most profitable:

With \$448.4 billion in baseline profits over eight years, plus \$139.2 billion in new profits from the federal subsidy for the Medicare drug benefit, **total industry profits for the law's first eight years would be at least \$587.6 billion.** And the total would probably exceed that level, because our \$139 billion estimate was conservative, as discussed elsewhere. We did not attempt to tally several sources of possible increased profits under the law.

E. OTHER PROBLEMS IN PRI/PwC CRITIQUE

10. IGNORING CONSERVATISM OF HRP ESTIMATES

HRP WINDFALL PROFIT REPORT: Section C of our report identified several factors not considered in our estimates, each of which would tend to increase the actual level of drug makers' profits resulting from the proposed Medicare law. Thus, the estimates of the rise in manufacturers' profits offered in our study were conservative.

PRI/PwC: The PRI/PwC critique generally ignores this conservatism.

REPLY: The estimates in our report were conservative in at least four ways.

First, we did not factor in the increase in drug-buying and therefore in drug makers' profits associated with recycling the savings won through actual new discounts on replacement prescriptions. That is, we factored in a reduction in drug makers' profits because of discounts on replacement medications. But those discounts, as noted above, will enable patients to buy still more medications, giving drug makers additional revenues and profits, which we did not count in the \$139 billion figure. (HRP, p. 10)

Second, we noted but did not tally the likely loss of discounts and rebates associated with the switch of dually-eligible Medicaid patients to Medicare. Medicaid programs obtain price reductions that are typically somewhat higher than those won by PBMs or insurers today. The switch is therefore likely to increase drug makers' profits somewhat. (p. 10) Analysts at Goldman Sachs and elsewhere concur that the private plans operating the Medicare benefit are likely to pay higher prices than Medicaid has been paying.⁵⁷ PRI/PwC criticize that we did not analyze the impact of that switch as they claim to have done. (PRI/PwC, p. 8, and note ix) Yet they never mention its impact on the prices paid, never disclose their calculations or results, and never even explicitly state whether the Medicaid-Medicare switch will positively or negatively affect drug makers' revenues.

Third, we did not estimate drug makers' increased revenue and profits on patients who may switch to Medicare coverage but previously used steeply discounted drugs at VA and community health center pharmacies, or who previously used samples or free drugs under drug makers' patient assistance programs. (p. 10)

Fourth, we did not consider the drug makers' higher sales that would be financed by the new Medicare premiums or co-payments, or the profits that would be earned on this increase in volume. (pp. 10-11) Some of this would be replacement spending but, especially for patients who were previously uninsured and were not filling prescriptions, even the drugs paid for out of premium revenues likely reflect substantial new spending. We focused only on the profit impact of the \$400 billion in new federal spending.

Strikingly, one brief comment in the PRI/PwC critique appears to recognize that our estimates were conservative in some respects. They claim to have prepared “a more comprehensive picture,” including analysis of the Medicaid-Medicare switch (which, as discussed above, they address only in hidden calculations). They note then that “most of the changes omitted from the Sager-Socolar calculations *increase* pharmaceutical revenues....” (PRI/PwC, p. 8, emphasis added) But this point—that on some scores we under-estimated drug makers’ gains—is alluded to only in passing.

Finally, PRI/PwC ignores our provision of a range of estimates on two key measures. Our report’s main analysis assumed that the split between new and old prescriptions was 60/40. This assumed a targeted program that helped measurably to address the great suffering that many Medicare beneficiaries endure because they cannot afford their medications. We also assumed a marginal manufacturing cost equal to 5.9 percent of manufacturers’ average price.

Our Section C included a contingency table (Exhibit 3) for those who make different assumptions on the split between replacement and new prescriptions, on the marginal cost, or both. The PRI/PwC critique mentions neither this table nor the range of estimates it offered.

11. UNQUESTIONING ACCEPTANCE OF CBO ESTIMATES

PRI/PwC: Their critique repeatedly claims that their estimates are consistent with CBO estimates and ours are not, and seems to suggest that disputing CBO estimates exiled us from civilized discourse.

The PRI/PwC critique also appears to suggest that we should not make use of the \$400 billion figure because we differ with some of the assumptions it was based on.

REPLY: There is no reason why we must accept the CBO estimates. Indeed, the recent estimates from CMS that the law will cost \$534 billion (one-third more than CBO estimated) did not accept the CBO estimates on many points. These points include differences on the cost per participant (about 4 percent higher in the CMS estimates than the CBO estimates). CMS also assumed a higher participation rate in the drug benefit and a greater cost for low-income subsidies.⁵⁸

Further, we know that Republican leadership writing the bill in Congress had promised not to exceed \$400 billion for the drug bill over the coming decade (a total sum that the president approved and administration endorsed even just before the law passed⁵⁹). We know that the CBO works for Congress. And now, in March 2004, we know (from recent widespread news reports and publication of internal email messages) that key CMS staff report having been threatened if they released higher estimates before Congress passed the bill.

We worry that the CBO's staff may have faced parallel pressure to develop an estimate consistent with the \$400 billion target cost. Independence is desirable but may be hard to achieve. CBO analysts are doubtless good, honest, conscientious people. We can imagine, however, the kind of pressure they may have faced in the *Congressional Budget Office*.

In our analysis, as discussed earlier, we did take the CBO estimate of total net federal cost as a starting point, even though the law does not appropriate a flat \$400 billion over the eight years from 2006 to 2013, and that sum is not a cap on spending. That may not be what the law will wind up costing—again, as the differing CMS estimate shows. Further, it is very possible that the law will never be implemented as originally passed and signed. But the \$400 billion figure was being used widely as the estimated federal cost, so that is what our report addressed.

We aimed to show, *if \$400 billion* in federal money were spent under the terms proposed in the House and Senate bills then under discussion, how it would likely be distributed. We found that it would go heavily to drug makers' profits, because of the likely rise in volume at virtually unrestrained prices combined with the low real cost of making more drugs.

12. IGNORING NEED FOR NEW SOLUTIONS AND A PEACE TREATY

HRP WINDFALL PROFITS REPORT: We urged the view that a regime of substantially lower prices, offset by higher volume, is essential to protecting American patients, payers, and even drug makers' ability to finance research. We argued for a prescription drug peace treaty, whereby prices are lowered substantially, but with public guarantees to offset both the revenue lost through lower prices and the cost of manufacturing of added amounts of medications. This makes all needed medications affordable for all Americans with no damage to either profits or pharmaceutical research—at the low added burden of covering the low marginal cost of manufacturing more medications.

PRI/PwC: Their critique ignored our description of the need for a prescription drug peace treaty and of the feasibility of obtaining it. PRI, in other work, appears to enthusiastically approve of higher drug prices because they are deemed essential to financing research, and because of dislike of public efforts to interfere with what PRI perceives as a free market.⁶⁰

REPLY: The PRI/PwC critique assumes both a) that today's regime of high drug prices can persist, and b) that the main purpose and actual function of the new Medicare drug benefit is to buttress that regime by substituting most of the new \$400 billion in public dollars for existing private dollars.

This is a political and human fantasy and, as we have argued above, it is not supported financially by relevant evidence on price-elasticity of demand. An alternative regime of lower prices and high volume is not only possible,⁶¹ but vitally needed.

Too many Americans suffer to pay high drug prices. This has been arousing intense political anger against the drug makers. If not addressed seriously, that fury will help to elect the angriest Congress in the history of the nation, one whose first legislation will be to gut drug prices without regard to the consequences for research.

Prescription drugs can and must be made affordable for *all Americans*, using methods that preserve and enhance breakthrough research, as we wrote in our 31 October report on windfall profits under the Medicare bills then under consideration.

A prescription drug peace treaty is essential to meet the needs of patients, of taxpayers and others who pay for prescription drugs, *and of drug makers*.⁶²

Drug prices would be sharply cut for all Americans, under federal law. If nothing else changed, drug makers' revenues and profits would fall substantially. But two things do change.

First, lower prices will raise private sales volume substantially as prices fall, offsetting much or most of the price cut's effects on industry revenues and profits.

Second, the peace treaty would guarantee that expanded public programs replace any remaining revenue and profit loss by subsidizing drug purchases for patients who can't afford even the newly discounted prices.

Public funds would also pay manufacturers' actual added cost of making more pills, and pharmacies' added dispensing cost—an estimated total of around \$10 billion yearly. This could finance a one-third rise in prescriptions to address today's unmet need. Under this treaty, drug makers fill all doctors' prescriptions for all Americans, and drug makers' own profits and ability to finance research are preserved.

This treaty requires trust among drug makers, public and private payers, patients, and voters. It requires public leadership and also abandonment of fantasies that the market can somehow win affordable drugs for all, adequate research funding, and sustainable profits. Drugs' patent monopolies and other obstacles hinder creation of a free market. A central element of the peace treaty is that lower prices would benefit drug makers as well as patients and payers. Drug makers would shift to a business plan based on lower prices and higher volume from their current business plan of high prices combined with limits on use.⁶³ This will benefit drug makers in the long run—and even in the mid-run—as their current business plan—resting on both high prices and very rapid revenue growth—is absolutely not sustainable.

Over the longer term, as we have described elsewhere, other reforms are also needed to foster innovation (rather than copycat research), to provide caregivers and patients with reliable information on drugs' relative effectiveness and cost, and to fairly allocate drug costs internationally, by nations' abilities to pay.⁶⁴

These steps are not only essential to win adequate and affordable coverage today, they are our obligation to future generations. If Medicare continues to pay high prices, the enormous sums that we would be choosing to throw away in windfall profits for drug makers would not even be our money. Given the size of the federal deficit, the federal government's share of the cost will all be borrowed—borrowed from our grandchildren. The proposals now before Congress would increase the deficit to enrich drug manufacturers while leaving seniors struggling. Both the House and Senate bills intentionally diffuse Medicare's buying power in order to preclude substantial discounts. Instead, let us allow government to act, to hold back the windfall. If we do, we can affordably provide comprehensive drug coverage for sick and vulnerable Medicare patients—and indeed all Americans—while protecting drug makers' current profits and their ability to finance research.

The drug industry is committed to a regime of high prices and sustained rapid revenue growth as a vehicle for financing profits and research, and appears likely to obtain a Medicare drug bill that fosters those aims. Were this bill to pass, it would offer substantial short-term benefits to the industry, as discussed in this report, but these short-term benefits would sustain the industry's business model of high prices and rapid revenue growth in the United States for only a few more years. Indeed, this business model is not sustainable. Depending on revenue growth that doubles every five - six years is not a durable method of protecting research, profits, or stock prices. The drug industry should re-think every aspect of its present business model—pricing, research financing, marketing, and the rest.

For the nation, the main choice is among suffering and dying for lack of needed drugs, paying much more, and reform. Congress and the drug industry can shape a bill that addresses the core needs of patients, payers, and the industry. They have not yet done so.

NOTES

¹ Alan Sager and Deborah Socolar, *61 Percent of Medicare's New Prescription Drug Subsidy is Windfall Profit to Drug Makers*, Boston: Health Reform Program, Boston University School of Public Health, 31 October 2003, www.healthreformprogram.org

² Jack Rodgers and John Stell (PricewaterhouseCoopers, Health Policy Economics), *The Potential Impact of the Medicare Prescription Drug benefit on Pharmaceutical Companies*, San Francisco: Pacific Research Institute, March 2004, www.pacificresearch.org

³ See, The Fortune 500, by industry, *Fortune Magazine*, March 2004, www.fortune.com.

⁴ See, for example, Sally Pipes, "Some Parts Of Medicare Bill Shouldn't Be Stripped Away," *Investor's Business Daily*, 8 March 2004.

⁵ See, for example, Sally Pipes, "Kerry's Drug Policy Is Enough To Make Americans Quite Ill," *Investor's Business Daily*, 9 February 2004, in which she argues that with "Canada's socialist price controls...life-enhancing drugs would become less available -- and more expensive..." Then, referring to the industry's widely-cited but highly inflated estimate of research and development costs (see critiques from Public Citizen and the Consumer Project on Technology), she comments, American companies spend an average of \$800 million to develop a new drug. They must be able to recoup this investment..."

⁶ Mary A. Laschober, Michelle Kitchman, Patricia Neuman, and Allison A. Strabic, "Trends in Medicare Supplemental Insurance and Prescription Drug Coverage, 1996-1999," *Health Affairs*, web exclusive, 27 February 2002. (And see citation in, for example, Diane Rowland and Tricia Neuman, "Medicare's Gaps and Challenges," Kaiser Family Foundation, 21 February 2003, Figure 5, www.kff.org.)

⁷ As cited in Pharmaceutical Research and Manufacturers of America, *Medicare Chartbook*, 2002, <http://www.phrma.org/issues/medicare/chartbook/chartbook4.cfm>.

⁸ At PRI, see, for example, Lance T. Izumi, "Will The Real Republican Party Please Stand Up," 18 December 2003, http://www.pacificresearch.org/pub/cap/2003/cap_03-12-18.html. See also, for example, Deroy Murdock, "Great Society II?" *National Review Online*, 19 August 2003, <http://www.nationalreview.com/murdock/murdock081903.asp>; and Citizens for a Sound Economy, "Key Vote: CSE Urges NO Vote...", 26 June 2003, http://www.cse.org/newsroom/press_template.php?press_id=488. Elsewhere, the Heritage Foundation states that "the JEC found that 78 percent of Medicare beneficiaries already have drug coverage..." (Robert E. Moffit, "Issues of Concern Related to Medicare Reform," WebMemo, 6 June 2003, <http://www.heritage.org/Research/HealthCare/wm288.cfm>.) It is vital to recognize that these estimates presumably indicate the number of people on Medicare who go the entire year with no coverage, rather than showing a cross section at a point in time – and even so, they probably overstate the level of coverage.

⁹ See, for example, CBO Director Douglas Holtz-Eakin in "The Cost of Medicare: What the Future Holds," Heritage Foundation Lecture #815, 15 December 2003, <http://www.heritage.org/Research/HealthCare/HL815.cfm>. Such estimates also entered the major media; see, for example, Ceci Connolly, "Drugmakers Protect their Turf," *Washington*

Post, 21 November 2003, available at *Pittsburgh Post-Gazette*, <http://www.post-gazette.com/pg/03327/242440.stm>.

¹⁰ U.S. Department of Health and Human Services, "Analysis of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," news release, 8 December 2003, <http://www.hhs.gov/news/press/2003pres/20031208b.html>. Strikingly, that release ignored Laschober's higher estimate of the number of people on Medicare who lack drug coverage—at a point in time (see above)—even as it quoted other findings from the same Laschober study.

¹¹ Sally Pipes, "Costly Prescriptions: Lawmakers might want to study their prescription before they make Americans take it.," *National Review Online*, 19 November 2003, http://www.pacificresearch.org/press/opd/2003/opd_03-11-19sp.html.

¹² Sally Pipes and Chris Middleton, "PBM rebates aren't the issue," *Modern Healthcare*, 7 July 2003, posted at http://www.pacificresearch.org/press/opd/2003/opd_03-07-07sp.html; similarly, see Chris Middleton, "The Death of Copays Would Be Copacetic," April 2003, http://www.pacificresearch.org/pub/hpp/2003/hpp_03-04.html.

¹³ John A. Poisal and Lauren Murray, "Growing Differences between Medicare Beneficiaries with and without Drug Coverage," *Health Affairs*, Vol. 20, No. 2 (March/April 2001), pp. 74-85.

¹⁴ Congressional Budget Office, Letter to Rep. Jim Nussle, 2 February 2004, www.cbo.gov.

¹⁵ See, for example, "Specialty Biotech Drugs Offer Amazing Promise, But Carry Whopping Price Tags," *Baltimore Sun*, 16 March 2004.

¹⁶ Ian McDonald, "10 Questions with Merrill Lynch Healthcare Manager Jordan Schreiber," *TheStreet.com Fund Watch*, 14 August 2000.

¹⁷ See Merrill Lynch, *Pharmaceuticals: A Medicare Drug Benefit: May Not Be So Bad*, Industry Update, 23 June 1999.

¹⁸ "A Five-year Forecast: Clear Skies Ahead," *Pharmaceutical Executive*, October 2001.

¹⁹ PhRMA (Pharmaceutical Research and Manufacturers of America) 2001, *Pharmaceutical Industry Profile 2001*, Washington DC, <http://www.phrma.org/publications/publications/profile01/chapter7.phtml>. The citation, summarizing PhRMA's viewpoint, is from Productivity Commission, Government of Australia, *Evaluation of the Pharmaceutical Industry Investment Program*, Research Report, 14 February 2003, Chapter 3, p. 16, <http://www.pc.gov.au/study/piip/finalreport.rtf>.

²⁰ PhRMA, *Industry Profile 2000*, Chapter 7, p. 91 (formerly on PhRMA's website but no longer available).

²¹ As quoted in Scott Hensley, "New Medicare Benefit Is Likely to Be a Boon For Costliest Drugs," *The Wall Street Journal*, 24 February 2004.

²² Kenneth Shea, managing director of S&P's Equity Research Services, as quoted in "A Market Rise in the Low Double Digits," *Business Week* online, 12 March 2004, www.businessweek.com

-
- ²³ Michael McCaughan, "Medicare Rx Law: Change is Coming," 9 February 2004, p. 14, <http://www.higpa.org/events/upcoming/04EXPO/Michael%20McCaughan2.pdf>.
- ²⁴ As quoted in Kristen Hallam and Kristin Reed, "Merck, Lilly Say Medicare Drug Plan Won't Be Windfall," Bloomberg News, 23 March 2004.
- ²⁵ Kristen Hallam and Kristin Reed, "Merck, Lilly Say Medicare Drug Plan Won't Be Windfall," Bloomberg News, 23 March 2004.
- ²⁶ Walgreen Co., "Questions and Answers for Shareholders," *2003 Annual Report*, 17 November 2003, p. 3, www.walgreens.com/images/pdfs/about/press/anreport2003/pages_2_5.pdf. (And see Michael McCaughan, "Medicare Rx Law: Change is Coming," 9 February 2004, p. 14, <http://www.higpa.org/events/upcoming/04EXPO/Michael%20McCaughan2.pdf>.)
- ²⁷ Cited in Michael McCaughan, "Medicare Rx Law: Change is Coming," 9 February 2004, <http://www.higpa.org/events/upcoming/04EXPO/Michael%20McCaughan2.pdf>.
- ²⁸ Percentage rate of increase for 2006-2013 from Tom Bradley, "Projected Spending for Prescription Drugs by and on Behalf of Medicare Enrollees," memorandum, 3 February 2003.
- ²⁹ See Julie Appleby, "What the Medicare bill means to drug companies: Winners without price controls," *USA Today*, 25 November 2003, http://www.usatoday.com/money/industries/health/2003-11-25-medicare-side2_x.htm. Similarly, see Ceci Connolly, "Drugmakers Protect their Turf," *Washington Post*, 21 November 2003, available at *Pittsburgh Post-Gazette*, <http://www.post-gazette.com/pg/03327/242440.stm>; and Kristen Hallam and Kristin Reed, "Merck, Lilly Say Medicare Drug Plan Won't Be Windfall," Bloomberg News, 23 March 2004. See also Michael McCaughan, op. cit.; and "U.S. States Ring 'Alarm Bells' Over Cost of Medicare Drug Plan," Bloomberg News, 24 December 2003, <http://quote.bloomberg.com/apps/news?pid=10000103&sid=a0V2jP0YNED8&refer=us>
- ³⁰ As cited in Christopher Bowe, "Medicare bill hands victory to drug groups," *Financial Times*, 26 November 2003, www.ft.com.
- ³¹ Dan Mendelson, president of Health Strategies Consultancy, cited in Ceci Connolly, "Drugmakers Protect their Turf," *Washington Post*, 21 November 2003, available at *Pittsburgh Post-Gazette*, <http://www.post-gazette.com/pg/03327/242440.stm>
- ³² Mary A. Laschober, Michelle Kitchman, Patricia Neuman, and Allison A. Strabic, "Trends in Medicare Supplemental Insurance and Prescription Drug Coverage, 1996-1999," *Health Affairs*, web exclusive, 27 February 2002, Exhibits 5 and 6.
- ³³ Dan L. Crippen, "Projections of Medicare and Prescription Drug Spending," Testimony before the Committee on Finance, United States Senate, 7 March 2002, Figure 4, www.cbo.gov.
- ³⁴ With a projected \$3160 in total drug spending for Medicare beneficiaries in 2006, and \$1454 of that paid by patients themselves, that would mean 46 percent out-of-pocket, up from an estimate of 43 percent for 2003 in the same report. Estimates prepared by the Actuarial Research Corporation for the Kaiser Family Foundation, "Medicare and Prescription Drug Spending Chartpack," June 2003, p. 5, and see Methods, p. 26, <http://www.kff.org/medicare/6087-index.cfm>.

³⁵ They are described as "consistent with the CMS projections for CY2002 for the *non-institutionalized* Medicare population...." (emphasis added). Kaiser Family Foundation, "Medicare and Prescription Drug Spending Chartpack," June 2003, p. 26, <http://www.kff.org/medicare/6087-index.cfm>.

³⁶ Estimates of nursing home patients' prescription drug costs may be affected by substantial inconsistencies (especially between states) in how those costs are tallied, and how the payments are handled. For example, does the pharmacy directly bill Medicaid and patients who pay their own drug costs, or it have a contract with and bill the nursing home, which itself bills Medicaid and patients?

³⁷ Agency for Healthcare Research and Quality, *Outpatient Prescription Drug Expenses, 1999* (MEPS Chartbook No. 12), Rockville, MD: AHRQ, October 2003, p. i and 12, http://www.meps.ahrq.gov/Papers/CB12_04-0001/CB12.pdf. See also citation by PhRMA, in "Medicare Beneficiaries Cared for with Prescription Medicines," Winter 2004, <http://www.phrma.org/publications/policy//2004-03-23.921.pdf>.

³⁸ John Poisal, "Reporting of Drug Expenditures in the MCBS," *Health Care Financing Review*, Vol. 25, No. 2, http://www.cms.hhs.gov/review/03_04winter/03_04winterpg23.pdf

³⁹ Katharine Levit and others, "Health Spending Rebound Continues in 2002," *Health Affairs*, Vol. 23, No. 1 (January-February 2004), pp. 147-159, Exhibit 1.

⁴⁰ Dan L. Crippen, "Projections of Medicare and Prescription Drug Spending," Testimony before the Committee on Finance, United States Senate, 7 March 2002, Figure 4, www.cbo.gov.

⁴¹ In 2001, for example, Alan Holmer, PhRMA's president, commented that "the pharmaceutical industry has supported strengthening and improving Medicare, by expanding access to drug coverage for seniors and fostering competition among private plans...." (PhRMA press release, 29 January 2001, <http://www.phrma.org/mediaroom/press/releases///29.01.2001.199.cfm>) "Coverage should be offered through competing, private insurance plans that rely on market-place competition to control costs and improve quality.... Plans should be overseen by a new, independent government entity." (PhRMA, *Medicare Chartbook*, 2002, <http://www.phrma.org/issues/medicare/chartbook/chartbook1.cfm>)

An AARP newsletter put it thus: "PhRMA supports a benefit, so long as it is run through private insurance companies rather than by the federal government. That way, critics say, the industry can give smaller price discounts and avoid federal scrutiny...." (See Patricia Barry, "Drug Industry Spends Huge Sums Guarding Prices," *AARP Bulletin Online*, May 2002, archived at www.aarp.org/bulletin/medicare/Articles/a2003-06-23-drugindustry.html.)

⁴² Congressional Budget Office, Letter to Sen. William H. Frist, MD, 23 January 2004, www.cbo.gov.

⁴³ As quoted in Mike Allen, "Bush Plan a Boon to Drug Companies," *Washington Post*, 5 March 2003, <http://www.washingtonpost.com/wp-dyn/articles/A42445-2003Mar4.html>. Vladeck commented on the approach of President Bush's proposal for drug coverage, which similarly fragmented the Medicare program's purchasing power among multiple private plans. He also

noted that the plan "" strikes me as the kind of proposal the pharmaceutical companies would write if they were writing their own bill.' "

⁴⁴ Laurie McGinley and others, "A Guide to Who Wins and Loses In Medicare Bill," *The Wall Street Journal*, 18 November 2003, http://online.wsj.com/article_print/0,,SB106910858582739700,00.html.

⁴⁵ Theresa Agovino, "Curbing costs: New drug plans cut discounts," Associated Press, *Patriot Ledger*, 25 March 2004.

⁴⁶ AdvancePCS claimed the most members, with 75 million people covered, and, observers have suggested, "with those numbers, PBMs can essentially tell drugmakers: 'If you want to market your drug, you have to do business with us or we're going to shut you out of 40, 50 or 60 million lives.'" (Tony Pugh, "A system to save on drugs falters," *Philadelphia Inquirer*, 10 February 2003, <http://www.philly.com/mld/philly/business/5144929.htm?1c>

⁴⁷ Michael McCaughan, "Medicare Rx Law: Change is Coming," 9 February 2004, p. 14, <http://www.higpa.org/events/upcoming/04EXPO/Michael%20McCaughan2.pdf>

⁴⁸ See H.R. 1, Title I, Section 101, creating new Section 1860D-11.

⁴⁹ See H.R.1, Title II, Section 221, creating new Section 1858.

⁵⁰ U.S. Centers for Medicare and Medicaid Services, "HHS Gives Seal of Approval to Medicare Drug Discount Cards," Washington, media release, 25 March 2004, <http://www.cms.hhs.gov/media/press/release.asp?Counter=988>

⁵¹ Sally Pipes and Chris Middleton, "PBM rebates aren't the issue," *Modern Healthcare*, 7 July 2003, posted at http://www.pacificresearch.org/press/opd/2003/opd_03-07-07sp.html. Coverage, however, they argue, should be limited enough "to allow consumers to see the full price differences between drugs."

⁵² Paul Heldman, Schwab Washington Research Group, cited in Laurie McGinley et al., "A Guide to Who Wins and Loses In Medicare Bill," *The Wall Street Journal*, 18 November 2003, http://online.wsj.com/article_print/0,,SB106910858582739700,00.html.

⁵³ "Prescriptions and Profit," *60 Minutes*, 14 March 2004, <http://www.cbsnews.com/stories/2004/03/12/60minutes/main605700.shtml>

⁵⁴ CBO projects that baseline drug spending by or on behalf of Medicare beneficiaries would total \$1,611 billion dollars for fiscal years 2006 through 2013. See Tom Bradley, "Projected Spending for Prescription Drugs by and on Behalf of Medicare Enrollees," memorandum, 3 February 2003.

⁵⁵ See, for example, "Stick to a Strict Stop-Loss Policy," *Credit Suisse Weekly*, 18 November 2003, <http://www.ameinfo.com/news/Detailed/31307.html>, which noted that the "prescription drug benefit could be a windfall for drug makers..., .biotechnology companies... PBM's" See also Ceci Connolly, "Drugmakers Protect their Turf," *Washington Post*, 21 November 2003, available at *Pittsburgh Post-Gazette*, <http://www.post-gazette.com/pg/03327/242440.stm>; William M. Welch and Julie Appleby, "Medicare bill may benefit seniors, but not taxpayers," *USA*

Today, 25 November 2003, http://www.usatoday.com/news/washington/2003-11-24-medicare-cover_x.htm

⁵⁶ See, for example, Brian Gorman, "The Drug Cost Conundrum," *The Motley Fool*, <http://www.fool.com/news/commentary/2004/commentary040318BG.htm>; Paul Heldman, cited in Laurie McGinley et al., "A Guide to Who Wins and Loses In Medicare Bill," *The Wall Street Journal*, 18 November 2003, http://online.wsj.com/article_print/0,,SB106910858582739700,00.html

⁵⁷ "Medicare Rx Agreement Nears; Bill Looks Good for Pharmaceutical Firms," *The Pink Sheet*, Vol. 65, No. 43 (27 October 2003), p. 3. See also "U.S. States Ring 'Alarm Bells' Over Cost of Medicare Drug Plan," Bloomberg News, 24 December 2003, <http://quote.bloomberg.com/apps/news?pid=10000103&sid=a0V2jP0YNED8&refer=us>. In a similar vein, a former U.S. senator asks, "Removing dual eligibles from state formularies enhances drug company income at the expense of state tax-payers. Why is this fair?" (David Durenberger, "Medicare Bill Leaves Many Wondering," *Briefing*, Minneapolis: National Institute of Health Policy, Vol. 2, No. 1, 1 April 2004, http://www.nihp.org/Briefings/Briefing%20Vol.%202%20No.%201%20Medicare_Scully.htm.)

⁵⁸ Congressional Budget Office, Letter to Rep. Jim Nussle, 2 February 2004, www.cbo.gov.

⁵⁹ According to the *New York Times* (Robert Pear, "Medicare Official Testifies on Cost Figures, 25 March 2004), CMS administrator Tom Scully wrote, in a letter that the *Times* published on 20 November 2003, "We are spending \$400 billion." See also Office of the White House Press Secretary, "President Bush Meets with Congressional Leaders on Medicare," media release, 17 November 2003, <http://www.whitehouse.gov/news/releases/2003/11/20031117-7.html>.

⁶⁰ See, for example, Sally Pipes, "Some Parts Of Medicare Bill Shouldn't Be Stripped Away," *Investor's Business Daily*, 8 March 2004; and Pipes' comments in Institute for Policy Innovation/Pacific Research Institute, "Forum on Prescription Drug Price Control Battle," 24 February 2004, www.pacificresearch.org.

⁶¹ Some in the industry recognize that a low price-high volume strategy can be useful. For example, Marc Benoff, director of consultants on pricing at IMS, and formerly director of pricing strategy for Wyeth, commented that, in the face of imports, "From an economic perspective, it makes sense to reduce prices if companies can offset lost revenues through volume gains." ("The Pricing Ecosystem," *Pharmaceutical Executive*, November 2003, http://www.imshealth.com/vgn/images/portal/cit_40000873/44149101The_Pricing_Ecosystem.pdf)

⁶² See, for example, Alan Sager, "Provisions of a Prescription Drug Peace Treaty," 10th Annual Invitational Conference on Pharmaceutical Costs, Tucson, 30 January, 2002; Alan Sager, *Americans Would Save \$38 Billion In 2001 If We Paid Canadian Prices For Brand Name Prescription Drugs: How to Win those Savings and Use Them to Protect All Americans against High Drug Costs without Hurting Drug Makers or Drug Research*, testimony to U.S. Senate Commerce Committee, Subcommittee on Consumer Affairs, 5 September 2001; Alan Sager and Deborah Socolar, *A Prescription Drug Peace Treaty--Cutting Prices to Make Prescriptions Affordable for All and to Protect Research—with State-by-State Savings Estimates*, Boston: Health Reform Program, Boston University School of Public Health, 4 October 2000, all posted at www.healthreformprogram.org.

⁶³ See Alan Sager and Deborah Socolar, “Lower U.S. Prescription Drug Prices Are Vital to Both Patients and Drug Makers, But Instead, U.S. Prices Have Been Rising Rapidly Relative to Those in Other Wealthy Nations,” Boston: Health Reform Program, Boston University School of Public Health, 24 July 2003, www.healthreformprogram.org.

⁶⁴ See, for example, Alan Sager, “Protecting Consumers Completely and Rewarding Drug Makers Fairly: A Prescription Drug Peace Treaty for the U.S.A.,” Trans-Atlantic Consumer Dialogue on Intellectual Property, Washington, D.C. 1 November 2002, www.healthreformprogram.org; Alan Sager and Deborah Socolar, “Do Rx drugs cost too much? The market needs a peace treaty,” *Business and Health*, October 1997.