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BEFORE THE U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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Mr. Chairman, Ranking Member Davis, and Members of the Committee, thank you for the invitation to participate in today's hearing on the Medicare prescription drug insurance program. My name is Richard I. Smith and I am Senior Vice President for Policy and Research of the Pharmaceutical Research and Manufacturers of America (PhRMA).

PhRMA represents the pharmaceutical and biotechnology research sector, which the Congressional Budget Office (CBO) identifies as "one of the most research-intensive industries in the United States."[1] This research investment is yielding results for patients. As summarized by CBO, "Many examples exist of major therapeutic gains achieved by the industry in recent years…anecdotal and statistical evidence suggests that the rapid increases that have been observed in drug-related R&D spending have been accompanied by major therapeutic gains in available drug treatments."[2] For instance:

- The Centers for Disease Control and Prevention has identified "new drugs and expanded uses for existing drugs" as contributing to the decline in heart disease and stroke mortality.[3]
- Academic researchers have associated new medicines with declines in mortality for breast cancer[4] and other cancers,[5] reduced disability rates among elderly persons,[6] and increased productivity among workers with conditions like rheumatoid arthritis.[7]

The continuing development of new medicines has a key role in improving health and health care. For instance, the prevalence of Alzheimer's Disease will increase sharply in coming years, imposing large human and economic costs. A report for the Alzheimer's Association projects that new treatments that delay the onset or slow the progression of Alzheimer's by five years could save $100 billion annually in Medicare and Medicaid costs by 2020.[8] Likewise, researchers project a doubling of the prevalence of Parkinson's Disease.[9] The authors of this projection note that the answer "will come from more research and new treatments that protect against Parkinson's, or slow its course."[10]

The Medicare Prescription Drug Program (Part D) has greatly improved seniors' and disabled beneficiaries' access to needed medicines, offering improved health outcomes. While improving access, it has also offered beneficiaries low premiums, reduced out-of-pocket expenditures on medicines, and provided choice among medicines. Last week, Congress enacted an important

improvement to the program for beneficiaries, by redefining the income and asset tests in a manner that will allow a greater number of beneficiaries with limited means to qualify for additional assistance.

Part D is a program with many elements balanced to best achieve the range of objectives, including choice, affordability, access, improved use of medicines, and maintaining a competitive and innovative pharmaceutical sector. This range of objectives calls for assessing the program on an overall basis, recognizing that its objectives are interrelated. The remainder of my testimony addresses these issues.

The Committee has requested that I provide information on the nature of financial arrangements between pharmaceutical manufacturers and Part D plans, along with the extent of discounts. As a trade association, PhRMA maintains a strict antitrust compliance policy, which prohibits us from obtaining or discussing our members' proprietary information about the prices or discounts each individual company negotiates with its customers or the ways in which each company determines the prices or discounts it will offer. Therefore, I do not have information concerning any individual company's pricing or discounting policies or practices, and my testimony can address overall trends regarding the Part D program based solely on publicly available information.

Part D and Affordability

Part D was structured to achieve substantial cost containment, along with its other goals. To achieve this full range of goals, Part D structured a highly competitive market among private prescription drug insurance plans. Among the approaches to a Medicare prescription drug benefit considered by Congress, the approach eventually adopted in Part D was scored by CBO as having the highest "cost management factor."[11]

Cost containment in Part D is generated by competing private plans seeking to offer affordable coverage to beneficiaries. One of many strategies that plans use to generate savings is to negotiate with manufacturers for discounts and rebates. Generally, plans offer more favorable coverage of a drug (e.g., listing on the formulary and its preferred tier, fewer utilization management restrictions) in exchange for discounts and rebates. Plans' effectiveness at steering patients to the medicines that receive favorable coverage[12] give plans considerable leverage in negotiations. In Part D, the resulting formularies appropriately need to meet the statute's requirement that they not discriminate against certain beneficiaries and discourage enrollment, among other standards. Prior to the implementation of Part D, CBO noted expectations "that substantial savings will be obtained by the private plans"[13] and economists have subsequently shown this is the case. A recent study reported that due to Part D plans' ability to "negotiate price discounts through their ability to influence the market share of

specific treatments…Part D substantially lowered the average price and increased the total utilization of prescription drugs by Medicare recipients."[14]

With this and other cost saving strategies, Part D has produced a strong track record of affordability for beneficiaries and taxpayers, while simultaneously enhancing beneficiaries' access to medicines and maintaining choice among medicines.

Part D Has Reduced Beneficiary Cost—The Medicare Prescription Drug Program is saving beneficiaries money. According to HHS, "The average Part D premium for 2008 is approximately $25, 40 percent below the original estimate of $41," and "Savings to beneficiaries have been significant as well, averaging $1,200 annually."[15]

Additionally, peer-reviewed research analyzing prescription claims data from Part D enrollees has reported sizable reductions in seniors' monthly out-of-pocket costs, even when combining results from populations that were both with and without coverage previously.[16] Research also points to even larger reductions in out-of-pocket costs by beneficiaries who were previously without drug coverage. For example, a PhRMA-sponsored study by the Amundsen Group based on prescription claims data since the introduction of the program found that average monthly out-of-pocket spending on medicines has been cut by over 40 percent, from $73 to $42, for beneficiaries who were without drug coverage in 2005. Out-of-pocket costs declined even though these beneficiaries are using more medicines than before implementation of Part D.[17]

Part D is Costing Taxpayers Far Less than Previously Projected by Independent Government Agencies—Both CBO and the Medicare Trustees have stated that the Part D program is costing far less than anticipated because plans have been able to negotiate better discounts from prescription drug manufacturers than expected.[18] For instance, comparing CBO's March 2008 10-year projections to its March 2006 projections, the program's total projected cost for FY2007-FY2016 has dropped by $438 billion, or 37 percent.[19] These savings are so large that, if the program were being designed today, the revised estimates would allow for a program with no or a greatly reduced coverage gap within the amount of money originally allocated to the program. Notably, plan bids, the best measure of the program's per capita costs, have markedly declined since 2006—in 2008, they were 12.8 percent lower than in 2006.[20]

While a number of factors have gone into these revised estimates, CBO continues to attribute the bulk of these reductions to competition among private insurers. Speaking last year, CBO Director Orszag said, "…the 'primary cause' of the reduced cost estimate is lower-than-expected bids submitted by prescription drug plans to provide coverage, which were on average 15 percent less than last year… 'The bids are coming in, and the pricing is coming in better

than anticipated, and that is likely a reflection of the competition that's occurring in the private market.'"[21]

Regarding discounts and rebates under Part D, publicly available information includes useful information. According to the Medicare Trustees, savings off retail price from discounts, rebates, and utilization management on all drugs are about double those previously projected—an increase from 15 percent estimated in 2006 to "about 30 percent" in 2008.[22] The Trustees Report also notes, "Many brand-name prescription drugs carry substantial rebates, often as much as 20-30 percent."[23] Medicare's Office of the Actuary reports that prescription drug price growth was 0.8 percentage points lower than that reported by the 2006 Consumer Price Index, "which did not reflect the movement to Medicare Part D coverage of beneficiaries who previously lacked drug coverage or were only partially insured."[24] And according to CBO, Part D plans have "secured rebates somewhat larger than the average rebates observed in commercial health plans."[25]

Part D and Beneficiary Access to and Choice among Medicines

Insurance is key to good access to care, whether such care be hospitals, physicians, or medicines. Part D has greatly expanded seniors' and disabled persons' access to needed prescription medicines. According to a Lewin Group analysis commissioned by PhRMA, in 2006 approximately 14 million senior and disabled Medicare beneficiaries first gained access to comprehensive drug coverage through Part D and the percent of beneficiaries with comprehensive coverage increased from 59 percent to 90 percent.[26] Peer-reviewed literature estimates a 6 percent to 12 percent average increase in the utilization of prescription medicines by Part D enrollees, including both those who were previously with and without coverage.[27] Other research indicates that those who enrolled in Part D and were without prior coverage, experienced better adherence to prescribed therapies.[28, 29]

In addition to offering beneficiaries coverage improving their access to medicines, Part D has offered beneficiaries choice of medicines, through the medicines covered by individual plans and through choice among plans. Two of the largest Part D plans advertise that they offer coverage of all 100 drugs most commonly used by beneficiaries.[30] Clearly, then, offering choice of medicines is compatible with offering an affordable insurance plan.

Beneficiary choice among plans and the availability of a range of affordable options are key components of the program, promoting both affordability and access to medicines. According to CMS, in every state this year, beneficiaries have access to at least five freestanding plans with premiums of less than $25 a month.[31] All enrollees can change plans on an annual basis in order to maintain prescription drug coverage that fits their cost and coverage needs. Those who qualify for the low income subsidy (LIS) may change plans at any time

throughout the year. The Lewin Group in a study commissioned by PhRMA found that in both 2006 and 2007, a very large majority of beneficiaries picked plans that combined no deductible, lower-than-average premiums, and a broad choice of medicines, which adds up to high value.[32]

Research conducted prior to Part D on the impact of drug coverage and use of medicines on the elderly indicates there is strong potential for drug coverage to reduce avoidable hospitalizations paid for by Medicare as health outcomes improve.[33]

Medicare Beneficiaries Report That They Are Satisfied With Their Part D Coverage and Are Saving Money—Surveys conducted within the last nine months by AARP and The Wall Street Journal Online/Harris Interactive report that Medicare Part D enrollees are highly satisfied with their Part D coverage and are saving money. In these two surveys, 85 percent and 87 percent of Part D enrollees reported being either "satisfied" or "very satisfied" with their coverage. Additionally, 67 percent and 75 percent of respondents in the two polls indicated that they were saving money.[34]

Medicare Part D's Impact on the Pharmaceutical Innovator Sector

As mentioned above, Part D has cost far less than CBO or the Medicare Trustees had anticipated for both beneficiaries and taxpayers. At the same time, a substantial amount of publicly reported information indicates that since Part D's enactment and implementation, drug cost growth has slowed. While this likely is related to a variety of factors, taken as a whole, these data indicate that even as coverage greatly expanded for Medicare beneficiaries, based on publicly available data discussed below, Part D has had limited impact on pharmaceutical innovators' sales.

Drug Spending Growth Has Slowed Since Part D Was Implemented—Notwithstanding the large-scale expansion of coverage that came with Part D in 2006, when approximately 14 million seniors and disabled Medicare beneficiaries first gained comprehensive prescription drug coverage,[35] IMS Health reported that drug spending increased that year at the second lowest rate of growth since 1995 (8.3 percent).[36] IMS Health also reported that retail drug spending in 2007, the second year of Part D's operation, grew by the lowest rate in 47 years, (since 1961—3.8 percent) and 15 percentage points below the peak growth rate in 1999.[37] Notably, the slowdown in prescription drug cost growth has continued. IMS Health reported earlier this week that total U.S. spending of prescription medicines through retail pharmacies (which includes mail order pharmacies) grew by just 1 percent for the twelve months ending in May 2008.[38]

Part D Has Increased Pharmaceutical Sales by Just Under 1 Percentage Point—According to IMS Health, in its first year of operation, the Medicare Part D program had only "lifted retail prescription volume by an estimated 1 to 2

percentage points and pharmaceutical sales by just under 1 percentage point."[39] The sales figure includes both brand and generic drugs and both manufacturer and pharmacy costs.

Generics Fill Over Two-Thirds of Part D Prescriptions and the Rate Is Increasing —IMS Health reports that in 2007, generics accounted for 13 of the 15 drugs most prescribed to Medicare Part D beneficiaries,[40] and generics accounted for 68 percent of all medicines prescribed in Part D,[41] up from 65 percent in 2006,[42] when the Medicaid program had a 60 percent generic prescribing rate.[43]

The Medicare Trustees and Others Note that Part D Plans Have Put Cost Pressure on the Pharmaceutical Research Sector—As discussed above, the Medicare Trustees have roughly doubled their estimate of the savings off retail price from discounts, rebates, and utilization management achieved by Part D plans—from 15 percent in 2006 to "about 30 percent" in 2008.[44] Additionally, according to the Trustees Report, "Many brand-name prescription drugs carry substantial rebates, often as much as 20-30 percent."[45]

Cost Savings for Those Who Previously Paid Full Retail Prices — It seems likely that Part D plans negotiate rebates for drugs on behalf of their entire covered population.[46] In examining the costs of a program such as Part D, a key factor to consider is aggregate cost savings (including but not limited to discounts and rebates) for the entire Medicare population.

An important aspect of this issue is that a full assessment of Part D's impact on pharmaceutical innovators would include the roughly 14 million seniors and disabled persons who previously were uninsured or lacked comprehensive prescription drug insurance and who have now gained coverage through Part D.[47] Previously, this group typically paid prices that did not reflect negotiated discounts and rebates. Now, discounts and rebates are negotiated on their behalf by powerful purchasers, representing millions of covered lives. As noted above, the Medicare Trustees have reported that rebates on brand drugs often are substantial and CBO has reported, based on preliminary data, that beneficiaries are in plans that have "secured rebates somewhat larger than the average rebates observed in commercial health plans."[48]

We also note that for several reasons rebates alone are not the full measure of cost savings achieved in Part D. First, as the Medicare Trustees have made clear, generic manufacturers typically do not pay rebates to Part D plans[49] (though publicly available information suggests generic manufacturers may pay rebates to pharmacies[50]). With generic prescribing rates at an unprecedented high level, overall rebates may diminish even though drug spending is constrained. Similarly, rebates are only one type of price concession; the mix of rebates and discounts may vary from one setting (such as Medicaid) to another (such as Part D) based on many differences in program structure.[51]

Government Price Controls Should Not Be Added to Medicare Part D

Part D includes vigorous cost containment which has produced real cost savings while offering increased beneficiary access to needed medicines. The alternative approach of government price controls and/or access restrictions would not meet the program's objectives.

A study of foreign government price controls by the U.S. Department of Commerce found, "[s]uch controls can also delay or reduce the availability of some innovative medicines in foreign countries, with the effect of limiting competition and requiring national health systems to forego the benefits of these innovations in reducing health care costs."[52] According to the findings, "[t]hese strategies tend to have the most significant impact on the newest and most innovative medicines…" Jack Calfee, resident scholar at the American Enterprise Institute, notes "[o]ther than the dismantling of intellectual property, no policy would be more destructive to innovation than price controls."[53]

A review of empirical literature on government price controls, supported by PhRMA, addresses the negative effects of government price regulation. According to this review, "[t]he adverse effects of price regulation occur through two channels. First, price regulation depresses firms' market performance, thereby depressing R&D and the discovery of new drugs. Declines in the number and innovativeness of new drugs, in turn, lead to decreased longevity and higher expenditures on other forms of medical care. Second, price regulation delays drug launches, distorts consumers' choices toward less innovative drugs, and in some cases actually leads to increases in prices. These effects lead to decreased longevity as well."[54]

Additionally, independent analysts have indicated that price controls inside one payer can have an adverse effect on other payers. According to CBO, "[s]ome private-sector purchasers pay higher prices as a result of the best-price provision in Medicaid's rebate program."[55]

The Competitive, Market-Based Medicare Part D Program Is Working

In conclusion, CBO and the Medicare Trustees have reported that it is primarily the effective operation of the competitive market that has driven down Part D costs for beneficiaries and taxpayers compared to previous estimates. Government negotiation of Part D prices will achieve "negligible" savings according to CBO unless the government restricts access or sets prices.[56] Changing Part D's competitive, market-based structure would undermine the carefully balanced approach that has produced sizable cost savings for Medicare beneficiaries and taxpayers and greatly improved access to needed medicines for seniors and disabled persons. Like any program, Part D may benefit from improvements, as it did last week. We believe improvements should proceed

from and maintain the successful foundation that the program has established to date, along with recognition of its aggregate impact and multiple policy objectives.

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[44] Remarks by Richard Foster, CMS Chief Actuary, in John Reichard, "Foster Offers Little Comfort to Medicare Funding Combatants" CQ HEALTHBEAT NEWS. April 1, 2008.

[45] 2008 Medicare Trustees Report, p. 160.

[46] Consistent with long-standing Medicare policy and practice, many groups worked to integrate the dual eligible population into Part D, so that they would be treated as part of rather than differently than the full Medicare population. Notably, dually eligible beneficiaries also are integrated into Parts A and B, with Medicare coverage and payment policies prevailing for the services covered by Parts A and B.

[47] Lewin Group analysis for PhRMA "Beneficiary Choices in Medicare Part D and Plan Features," http://www.lewin.com/PublicationsInsights/Publications.aspx, September 2006.

[48] March 12, 2007 CBO letter to the Honorable Joe Barton and the Honorable Jim McCrery, page 3.

[49] 2008 Medicare Trustees Report, p. 160.

[50] CBO, "Prescription Drug Pricing in the Private Sector," January 2007, p. 1

[51] See, for example, "Medicare Part D Reporting Requirements: Contract Year 2008" which instructs plans to report a variety of cost saving measures such as, "rebates… non-rebate discounts, price concessions, or other [items]…Available at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_NextYear.pdf

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