John E. Calfee
American Enterprise Institute
1150 17th St., NW, Washington, D.C.
tel: 202-862-7175 -- fax: 202-862-7177 -- email: calfeej@aei.org

Written testimony
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United States Senate Special Committee on Aging
Public Hearings on
"Seniors Feeling the Squeeze: Rising Drug Prices and the Part D Program"

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I would like to thank the Committee for inviting me to testify in these hearings. I am a Resident Scholar at the American Enterprise Institute for Public Policy Research, where I have conducted research on pharmaceutical and health care markets. I have also occasionally consulted for firms in the pharmaceutical and related industries. The views I present are my own, not those of any organization including the American Enterprise Institute, which does not take institutional positions on specific legislation, litigation, or regulatory proceedings.

My testimony focuses on three topics: (1) Price trends for the most-used drugs among the elderly; (2) The influence of the Medicaid drug price rebate; and (3) International patterns in drug prices.

Recent Trends in Drug Prices for the Elderly

In April 2009, the advocacy and marketing organization AARP published one of its regular reviews of price trends for the most-used drugs purchased by the elderly (AARP 2009). The report contained separate sections on branded drugs, generic drugs, and so-called "specialty"

drugs. The specialty drug category consists mainly of expensive "biologics" (giant molecules that are grown rather than synthesized the way traditional "small-molecule" drugs are). Many of them are relatively new and were designed and often manufactured using biotechnology methods.

Focusing on branded Part D drugs, the AARP report concludes that during 2002-2008, annual price increases ranged from 5.3% to 8.7% (p. 2). This is a very misleading conclusion, however. In the AARP reports, branded and generic drugs are separated into different tables and calculations. Recent years have seen an extraordinary and unprecedented surge of patent expirations and subsequent generic entry among the most popular drugs including many that are heavily used by the elderly. The problem with how the AARP reports deal with price changes and generic entry is evident from looking only at the top-selling drugs. Table 1 in both the 2005 and 2006 year-end updates (p. 11 and p. 10, respectively) provide a list of the top 25 branded drugs for 2005 and 2006 (some of the items are different doses or package sizes of the same drug). The two lists are identical, because they are actually compiled from 2003 sales and prescribing data (see AARP 2006, p. 15). Fifteen of these 25 drugs are now available as generics. (The affected brands are Actonel, Ambien, Aricept, Flomax, Fosamax, Levaquin, Neurontin, Norvasc, Pravachol, Prevacid, Protonix, Toprol, and Zocor.) Although a few of these may have been generics in 2005, most were not. Hence most of these drugs are now far less expensive than they were in 2005, often qualifying for Wal-Mart's special $4 price for a 30-day prescription. In the AARP top-25 list of branded drugs for the year 2007 (AARP 2008, Table 2, p. 13), 12 of the 25 listed drug items are available as generics, usually at very low prices. Because these tables track prices of only the branded versions of those drugs, which are prescribed far less often than generics, the tables provide rather little information about the most relevant changes in drug prices.

The AARP reports simply fail to track prices as drugs go off patent and become available at generic prices. (The greatest price drops come after the first six months, during which the first generic entry has a temporary monopoly among generic versions of the brand in question.) Readers of the reports can see how prices change among brands, and among generics, but they do not see the sharp drop in prices that occur when patients switch from brands to generics. Because Medicare Part D has an extraordinary record of taking up generics soon after they appear, this is a serious omission. Notwithstanding the summaries of the various AARP reports,

the general trend in recent years has been toward far less expensive versions of the most popular drugs.

Specialty Drugs:

Quite aside from the AARP reports on drug pricing, specialty drugs are of great interest. I noted that most of these are relatively new and that most were created through biotechnology methods. Specialty drugs typically address previously untreatable or poorly treated conditions. They have, for example, revolutionized the treatment of rheumatoid arthritis, multiple sclerosis, and certain types of cancer. Most of these drugs are not eligible for the regulatory pathway toward generic substitutes created by the 1984 Hatch-Waxman Act. Although the complex nature of these drugs and their manufacturing processes preclude a simple generic approval process, several proposals have been introduced to create a regulatory pathway for "biosimilars" or "follow-on biologics." Even with such legislation, however, substitutes would be slow to appear, so that prices are unlikely to fall dramatically in the near future, even for drugs near or beyond the end of the patent life (which is itself a complicated matter) (Grabowski 2008; Calfee 2008).

Many specialty drugs cost thousands or tens of thousands of dollars annually. According to a January 2010 GAO report, they account for only about 10% of Medicare Part D expenses, but that proportion is growing. In general, this market is characterized by three factors (cf. Calfee and DuPré 2006 and Grabowski 2008). First, drug development is very expensive and tends to be targeted at previously unsolved medical problems, so that the few drugs that make it through the lengthy and uncertain development process are of great value. Second, R&D continues long after initial drug approval. The extraordinary cancer drug Avastin, for example, has been involved in hundreds of clinical trials as scientists explore the full therapeutic potential of a product that could be effective against a very diverse range of cancers. This is far from unusual among biotech drugs. And third, these drugs often prove effective against illnesses that are quite different from the ones they originally addressed, so that "cross-over" competition occurs among drugs that started out treating completely different conditions. The cancer drug Rituxan, for example, is also widely used to treat rheumatoid arthritis.

Thus the kind of drugs known as specialty drugs differ from traditional drugs in their costs, their benefits, their research agendas (although some older drugs such as the cholesterol-

reducing statins have also undergone many years of post-approval research), and the nature of competition. So far, they stand as examples of advances in medical technology that are expensive but bring even greater value. On the whole, this kind of research should be encouraged.

The Influence of the Medicaid Drug Price Rebate

Pharmaceutical manufacturers are required to pay an annual rebate to the Center for Medicare and Medicaid Services (CMS) sufficient to reduce the prices of drugs purchased through Medicaid to what is usually 15.1% less than the lowest price paid in the private sector. A recent proposal is that this rebate be applied to Medicare Part D purchases by "dual eligible" Medicare beneficiaries who qualify for Medicaid but receive their drugs through Part D (http://billnelson.senate.gov/news/details.cfm?id=318232&). This would expand the effects of the current Medicaid drug rebate plan. Economic reasoning suggests that pharmaceutical manufacturers take this requirement into account when negotiating sales in the private sector. They know that providing a deeper discount to a private purchaser would also reduce Medicaid prices because of the annual rebates. This would discourage discounting and therefore induce higher prices in the private sector. Scott Morton and Duggan (2006) examined this question using econometric methods. They found that a 10% increase in Medicaid's share of the market for individual drugs was associated with a 7%-10% increase in the drug's average price. This strongly suggests that the effect of expanding the Medicaid drug rebate would mainly be to shift expenses to the private sector rather than reduce drug costs. A second effect, however, would simply be to exercise more stringent control over drug pricing generally. This would be unwise because it would tend to weaken incentives to develop useful new drugs and new uses for existing drugs.

International Patterns in Drug Prices

International disparities in drug prices among advanced nations have three causes. One is that manufacturers naturally tend to charge more in wealthier nations, and the United States is the richest nation. Another is that some drugs save on costs elsewhere in the health care system,

and those costs are typically much higher in the U.S., making cost-saving drugs more valuable here. The most potent cause of international price disparities, however, is national price controls. Several studies have found persistent gaps between prices here and in Canada, the European Union, Australia, New Zealand, and, sometimes, Japan. Recent studies include International Trade Administration (2004); Danzon and Furukawa (2008); and Calfee and DuPré (2006). In our study, we found almost no international differences for unique biotech drugs (most of them so-called "specialty drugs") but very large differences for drugs in competitive therapeutic classes. Earlier studies were generally similar, although ours was the only one to separate out the most innovative drugs.

These disparities have economic implications. Pharmaceutical research and development is motivated and funded by profits. Wealthy nations other than the U.S. enact price ceilings in the expectation that the drugs will continue to be sold because they are cheap to manufacture, leaving plenty of room for profit even at controlled prices. Brands that compete with one or a few others, which include almost all the most-used drugs, usually suffer the largest discounts because price controllers can play the manufacturers against each other. The net effect is lower profits abroad, sometimes cutting out half or more of profits, leaving the United States as the prime source of profits and therefore of R&D funds (cf. the 2004 ITA report). One might think that this does not matter very much for therapeutic classes that have several competing entries, such as the statins (Zocor, Lipitor, Crestor, and others). But history has shown that the arrival of a new brand in a therapeutic class (a "follow-on" drug) tends to generate a new wave of research (Wertheimer and Santella 2005; Calfee 2007). In the case of the statins, for example, it was research on Lipitor and other follow-ons, most recently Crestor, that greatly expanded the patient population known to benefit from statin therapy, while also transforming scientific understanding of heart attacks (Topol 2004; O'Riordan 2008).

The result is that wealthy foreign nations have essentially been free-riding on drug development disproportionately supported by profits in the American market, as pointed out by among others, then-FDA Commissioner Mark McClellan in 2003 and the ITA report of 2004. The solution to the problem is unclear, however.

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