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Committee on Energy and Commerce
Hearing on "Prescription Drug Price Inflation: Are Prices Rising Too Fast?"

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Mr. Chairman and members of the Committee, thank you for the invitation to testify today on Prescription Drug Price Inflation: Are Prices Rising Too Fast?" My name is John Vernon and I am a professor in the Department of Health Policy and Management at the University of North Carolina at Chapel Hill and a Faculty Research Fellow with the National Bureau of Economic Research (NBER). I previously was a professor in the Department of Finance at the University of Connecticut and a Visiting Professor at the Wharton School of Business at the University of Pennsylvania, where, among other subjects, I taught MBA-level courses in pharmaceutical finance, economics, and policy. Also, I formerly served as Senior Economic Policy Adviser to the Office of the Commissioner at the U.S. Food and Drug Administration. My testimony today will be based on academic research, published in the peer-reviewed economics literature, that I have undertaken jointly with Joe Golec and other colleagues. The vast majority of these publications were unfunded research projects.

The opinions I am about to express are entirely my own; they do not necessarily reflect those of the institutions and organizations with which I am, or have been, affiliated.

In addition to discussing the evidence, or, more specifically, the lack thereof, of rising U.S. drug prices, I will also discuss the role drug prices play in firm- and industry-level R&D investment, and the subsequent rate of pharmaceutical innovation. The latter is of critical importance because considering drug prices in isolation is not useful: the tradeoff between drug prices and innovation is what is relevant—that is, what are the benefits and costs of higher (or lower) U.S. drug prices? As I will describe, there is strong empirical evidence that 1) Suggests that the marginal benefits of R&D spending far exceed their costs—making a compelling economic case for higher levels of R&D spending by firms; and 2) There is an unequivocal theoretical relationship between U.S. drug prices and profits and R&D investment, one that has consistently been supported by peer-

reviewed publications in leading economics journals (Vernon, 2004; Vernon, 2005; Giaccotto, Santerre, and Vernon, 2005; Golec, Hegde, and Vernon, 2009; Grabowski and Vernon, 2000).

Are U.S. Drug Prices Actually Rising? Flaws with the AARP Report

The conclusions drawn in the AARP report, which has not been evaluated and vetted through peer-reviewed evaluation—the hallmark of academic/economics journal publications—are based on flawed methods, and thus are misleading and biased. The AARP report, as it stands, does not meet peer-review standards for academic publication in reputable journals—especially recognized, quality economics journals. Some of the major flaws with the analysis are:

1) The AARP report is based on wholesale price data, not retail or transaction prices, which are often substantially lower than wholesale prices, because Pharmacy Benefit Managers (PBMs) and insurers negotiate discounts and rebates with manufacturers.

2) The AARP report is an analysis of branded products only. The burden to U.S. consumers associated with access to prescription drugs should also consider generic drugs, which in the U.S., are among the lowest prices in the world; and, according to a December 2008 AARP report, the utilization percentage for generic drugs in the U.S. has risen from 19% in 1984 (the year the Waxman-Hatch Act was passed) to 67% in 2007. The impact of this significant shift towards greater generic competition and utilization is to reduce the overall burden of access to pharmaceuticals.

3) Another flaw with the recent AARP report on rising drug prices, and related to the previous point, is that it ignores the fact that 10 of the top 25 branded pharmaceuticals in their study have generic versions currently on the market. Mandatory generic substitution laws in most states implies that the low-cost generic versions of these 10 branded drugs are dispensed to consumers—not the branded versions.

4) Lower prescription drug prices are also often available to U.S. consumers through mail order pharmacies and discount retail pharmacies—a viable cost savings option for consumers that is not reflected in the AARP estimates.

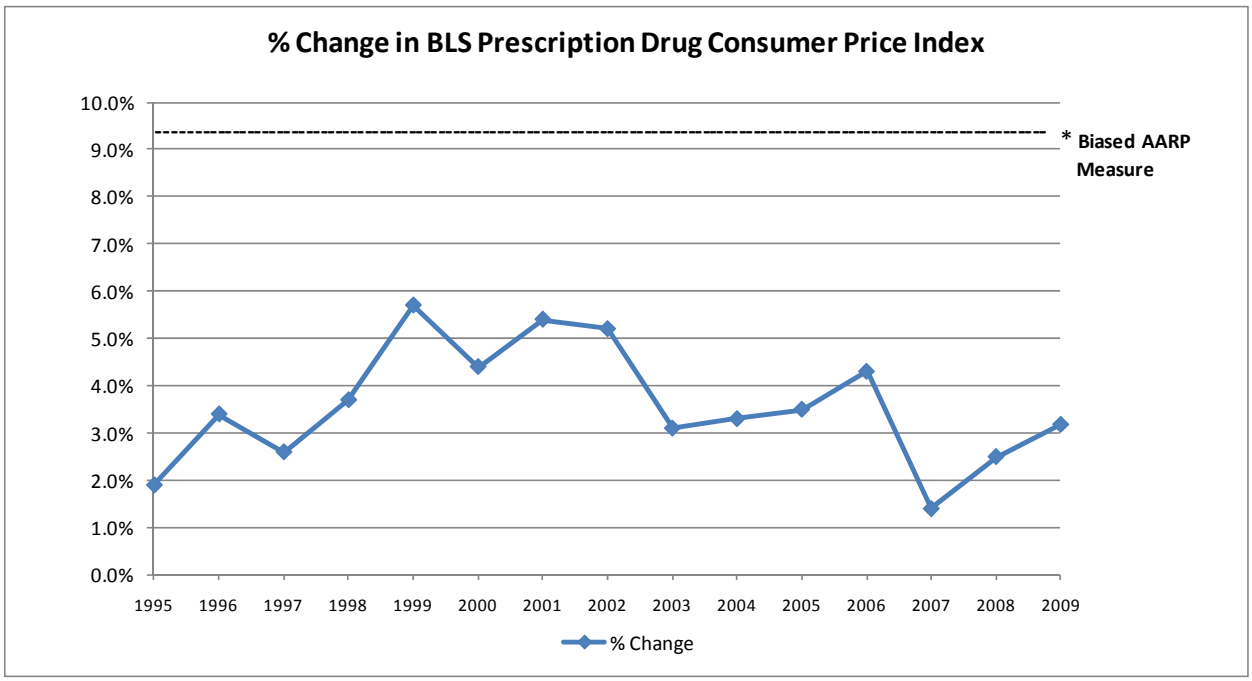
5) Insurance, particularly insurance proposed within the current healthcare reform legislation, results in consumers paying prices well below retail prices.

A much better measure of drug price trends in the U.S., one that is based on retail prices not wholesale prices, and which also captures the cost savings from generic competition and substitution (since 1995), is the prescription drug consumer price index (CPI) reported by the U.S. Bureau of Labor Statistics (BLS). As the BLS reports on their website, their index includes:

"*All drugs dispensed by prescription. Mail order outlets are included, [and] prices reported represent* ***transaction prices*** *between the pharmacy, patient, and third party payer...*"

Figure 1 is a time series of growth rates of U.S. prescription drug prices.

Figure 1: Percentage Changes in Prescription Drug CPI from BLS Data:1995 to 2009



As figure 1 illustrates, the percentage change in the BLS prescription drug CPI is substantially lower than the upwardly biased figure reported by the AARP. Moreover, the 2008 to 2009 (through October) change in prescription drug price inflation rate was approximately half that of the 2008 to 2009 inflation rate for non-prescription drugs and medical supplies (2.5% to 3.18% versus 0.9% to 2.25%). This suggests the small increase in prescription drug prices may reflect broader healthcare-sector market dynamics, and not an isolated increase in prescription drug prices.

Finally, in regard to the reasonableness of the claim that manufacturers have raised drugs prices in anticipation of forthcoming healthcare reform legislation, the most directly comparable, and recent, legislative event points to the exact opposite firm reaction (Golec, Hegde, and Vernon, 2009). At the time of the 1992-1993 Clinton administration's proposed Health Security Act, many large drug manufacturers publicly committed to keeping drug price increases at or below the overall inflation rate. This makes sense, theoretically, because firms would want to avoid political controversy regarding drug prices precisely at a time when drug prices are under great scrutiny. The publicly announced commitments by many firms to constrain drug prices at this time attracted the attention of the Federal Trade Commission (FTC), and consequently lead to FTC challenging whether such actions were a violation of anti-trust law (Ellison and Wolfram, 2002). There are numerous similarities between the current healthcare reform legislation being considered and that of the Clinton administration's HSA. This begs the question, "why would the

currently proposed healthcare reform legislation result in a different behavior by firms?" The relatively low rate of drug price increases in recent years suggests they are not acting very differently. Indeed, prescription drug prices in recent years have grown at one of the lowest rates since the 1980s, when annual drug prices increases were near 10% on average.

Even the small price increases in recent years, when they exceed the general inflation rate, can be explained more plausibly by industry dynamics. For example, as Grabowski and Kyle (2007) have shown, increased generic competition and patent challenges have resulted in a compression of the product life cycle for many drugs; thus leading, perhaps, to higher prices. Moreover, the industry's productivity in recent years has declined for pharmaceuticals (chemical molecules), which face very intense generic competition at patent expiration, but increased for biologics (biologic molecules), which currently do not face such competition and which also are more costly to develop (for example, because of the higher cost of R&D capital faced by biotech firms). This shift in the mix of innovative products (relatively more biologics and fewer pharmaceuticals), could easily explain recent price increases greater than the overall inflation rate (however small). Thus, the assertion by the AARP that firms have raised prices in the face of proposed healthcare reform can be refuted by more plausible explanations.

Prescription Drug Prices, Profits, and R&D Spending: Factors Affecting Pharmaceutical Innovation

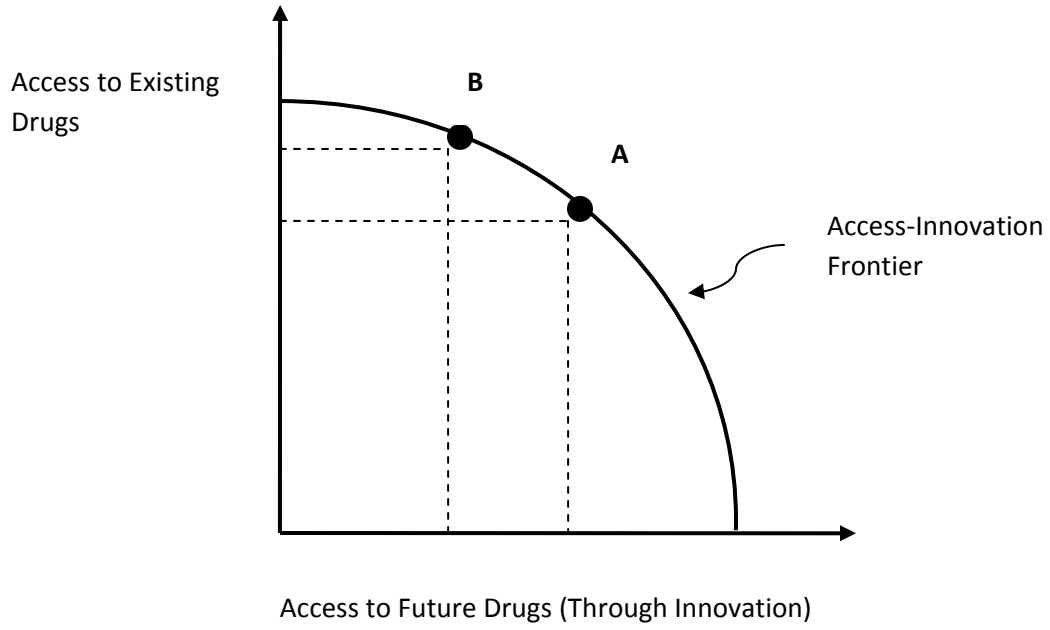
As mentioned in the preceding section of my written testimony, a consideration of prescription drug prices in isolation is an incomplete and misleading exercise. What must be considered are the costs and benefits of higher (lower) drug prices, and specifically the economic tradeoff between access to existing medicines and access to future pharmaceutical innovations (through higher levels of R&D). Prior to discussing this tradeoff, a brief overview of the pharmaceutical R&D process, the costs, risks, and returns, is warranted.

A new pharmaceutical typically takes 12-15 years to bring to market, and most investigational new drugs/molecules never make it to market. Some research suggests only about 1 in 5,000 pre-clinical molecules studied ever become FDA-approved new drugs. Moreover, of the drugs that do make it to market, only 2 out of every 10 generate returns in excess of average R&D costs (Vernon, Golec, and DiMasi, 2009).

The expected returns on individual R&D projects are directly related to expected pharmaceutical prices and profitability. Price controls, or indirect price controls via such mechanisms as re-importation or technology assessment rationing, lower expected net returns for firm shareholders[i]. The result will be a decline in the rate of pharmaceutical innovation: fewer new drugs will be developed and it will take a longer time to find cures for many diseases, all else considered[ii]. Unlike the benefits of a price control policy, explicit or implicit, which will produce immediate and observable savings through lower drug prices, the costs of such a policy are more difficult to appreciate and quantify[iii]. This is because of the considerable time lag and uncertainty associated with the R&D process, which, as already noted, is very long, costly, and risky[iv]. My academic research has focused on these costs, and specifically the economic relationships between pharmaceutical prices, profits, and R&D[v]. There is an unequivocal tradeoff between

access to existing medicines, which is improved with contemporaneous lower prescription drug prices, and access to future pharmaceutical innovations. This may be illustrated by the access-innovation frontier in Figure 2.

Figure 2: The Tradeoff Between Access to Existing Medicines and Future Medicines



The sensitivity of R&D spending to pharmaceutical prices and profits has been studied with a variety of different research methods, including standard retrospective statistical analyses of industry and firm-level data, prospective simulation analyses, and financial event studies (Vernon, 2003, 2004, 2005; Giaccotto, Santerre and Vernon, 2005; Abbott and Vernon, 2007; Santerre and Vernon, 2006; Golec, Hegde, and Vernon, 2006; Golec and Vernon, 2007). The research findings have been strikingly consistent and robust. I will summarize the results from two recent studies (Vernon, 2005; Giaccotto, Santerre, and Vernon, 2005). Both were unfunded studies that have been vetted by the academic peer-review process, and subsequently published in professional economics journals.

The first study utilized publicly available, firm-level financial data and exploited observed differences in U.S. and non-U.S. pharmaceutical profit margins (the latter were used to proxy for profit margins in the presence of price regulation). Using established economic models and statistical techniques, we estimated that a new policy that reduces pharmaceutical profit margins in the U.S. to non-U.S. levels will cause firm R&D spending to decline by between 25 and 35 percent, all things considered. A policy that regulates prices in the U.S., for example re-

importation from foreign markets with forced-sale clauses, will theoretically have this effect on U.S. profit margins.

The second study adopted a slightly different approach and used publicly available, industry-level data to study the direct link between U.S. drug prices and industry-level R&D spending (Giaccotto, Santerre, and Vernon, 2005). In this study, we estimated that for every 10% reduction in U.S. drug prices, industry R&D spending will decline by approximately 6%. This finding is consistent with an earlier study that also analyzed industry-level pharmaceutical R&D (Scherer, 1996; 2001).

In sum, the empirical evidence suggests that firm R&D spending is very sensitive to pharmaceutical prices and profits, as economic theory predicts. This is in direct contrast to the ubiquitous, non-economic notions one often hears, such as "lower prices and profits won't reduce R&D spending because firms will still have enough profit to cover their R&D" and "these firms have to invest in R&D, what else are they going to do?"

The key point is that the benefits associated with lower drug prices in the U.S. will, unequivocally, come at a cost: lower levels of R&D investment and a reduced rate of pharmaceutical innovation. It is critical that these costs be balanced carefully against the benefits of associated with regulated, explicitly or implicitly, drug prices. This is particularly true in light of the recent evidence on the significant contributions of pharmaceutical and medical R&D to human health and life expectancies in the U.S. (Murphy and Topel, 2003; Lichtenberg, 2002).

Endnotes

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[i] The implicit argument being put forth is a net present value (NPV) argument. A real options framework, in the parlance of modern finance theory, will generate the same prediction (see Golec, Hegde, and Vernon, 2009).

[ii] The phrase "all else considered" is important here. The relevant comparison for assessing the impact of price regulation on R&D spending and innovation is the counterfactual event of no price regulation policy. R&D and innovation are driven by a number of factors and even if a price regulation policy is enacted real R&D spending may continue to grow over time, but it would grow at a slower rate than would have been the case if the policy were not enacted. The relevant measure of the effect of policy is one that holds all other factors constant: the comparison of the reality with the counterfactual. Some of the research I will mention in this testimony can easily be taken out of context. For example, if the statement is made that pharmaceutical price regulation will reduce R&D by x%, this is x% relative to the level of R&D spending in the absence of the policy, not R&D spending in absolute terms.

[iii] To more formally consider the balancing of the costs and benefits of a policy that constrains U.S. drug prices the following may provide some clarification. Once a pharmaceutical product has been brought to market, pricing above marginal cost results in an underutilization of the new product (from a social welfare perspective), and these costs are referred to as static inefficiency costs. Thus, a tradeoff exists between providing incentives for research and development (R&D), and thus innovation, and consumer access to today's medicines: this is the balance the U.S. patent system tries to strike. While there is nothing sacrosanct about the current structure of the U.S. patent system for pharmaceuticals, or indeed the existing rate (and stock) of R&D investment, what is immediately apparent is that regulating prescription drug prices, while it will expand access to medicines already developed (the aforementioned benefits), it diminishes the intended objective of the U.S. patent system. This, as I have mentioned, will reduce the future supply of new drugs. These costs are referred to as dynamic inefficiency costs. The optimal policy (or patent system) will minimize the sum of the static and dynamic inefficiency costs.

[iv] The term risk here refers to the technical risk of an R&D project, which is the likelihood it will make it through the various stages of drug development and become a marketed product. This is quite different from financial risk, which is the risk faced by an investor who holds the market portfolio, i.e., the relevant risk for determining the project's cost of capital (or discount rate).

[v] While understanding how R&D spending may be affected by pharmaceutical price regulation is important, what is most relevant is how this change in pharmaceutical R&D spending will influence innovation and public health. Obviously, measuring the costs associated with forgone future innovation is a near impossible task: there are many variables that can affect the outcome. However, because there is an overwhelming tendency for public policy debate to focus on the short-run benefits of lower (regulated) drug prices, it is critical that efforts be untaken to at least approximate the magnitude of what the corresponding costs would be in terms of lower levels of innovation. Only then can the benefits of lower drug prices be weighed against the costs to

determine if a price-regulation policy is a good one. A very rough first approximation of the social costs associated with various pharmaceutical price-reduction policies (measured in terms of life years and dollars) may be found in Vernon (2004).

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