Pharmaceutical Price Controls in OECD Countries, Implications for American Consumers, Pricing, Research and Development, and Innovation

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Introduction

Thank you, Mr. Chairman and Members of this Committee, for inviting me to testify today about the Department of Commerce report, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*. I welcome this opportunity to explain both our findings and methodological approach.

It is no secret that governments of Organization for Economic Cooperation and Development (OECD) member countries maintain a variety of practices that reduce the return on sales of innovative pharmaceuticals. To examine the effect of such practices on prices, revenues, innovation and, ultimately, on consumers, Congress directed the Secretary of Commerce to conduct a study, in consultation with the Department of Health and Human Services, the Office of the U.S. Trade Representative, and U.S. International Trade Commission, of drug price controls in OECD member countries and the implications for American consumers.[1]

Specifically, Congress requested that the study include the following:

- Identification of the countries that use price controls or other such practices, with respect to pharmaceutical trade.
- Assessment of the price controls and other such practices that the identified countries use.
- Estimates of additional costs to U.S. consumers because of such price controls, and the extent to which additional costs would be reduced for U.S. consumers if price controls and other such practices were reduced or eliminated.
- Estimates of the impact that price controls, intellectual property laws, and other such measures have on fair pricing, innovation, generic competition, and R&D in the United States and each identified country.[2]

[1] Section 1123 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173.
[2] See H.R. No. 108-391

This report we issued responds to Congress' request. It details the effect of price controls imposed by various OECD member governments on pharmaceutical prices, R&D, innovation, and American consumers. The study examined the drug price regulatory systems of 11 OECD countries[3] and involved a quantitative analysis of prices, revenues, and R&D effects, based on data available for nine OECD countries.[4]

To complete the project, we brought together a talented team of professionals including economists from the Departments of Commerce and Health and Human Services (HHS), and the United States Trade Representative (USTR) and sought input from the Council of Economic Advisers (CEA). We also consulted closely with experienced academics in the field of health economics. In the early months, inter-agency meetings were held with economists from HHS, USTR and CEA to share research and flesh out methodological issues. These meetings included discussions about the various methodologies used in previous academic and government studies that addressed similar, but not the same, questions posed by the Conference Report.

As those discussions on methodology proceeded, we gathered as much in the way of factual information as possible, as well as the views of outside experts. The Department of Commerce published *Federal Register* notices requesting input from industry, non-profit organizations, trade associations, and the general public. The Department received written testimony from 18 sources.[5] In addition, the Department held a public hearing on August 3, 2004. Three interested parties requested the opportunity to speak.[6] The Department left the record open for an additional ten days following the hearing in order to provide an additional comment period for submission of further comments based on information provided at the hearing or in earlier submissions. Every attempt was made to ensure that all interested parties had the opportunity to provide comments and to address comments from other groups.

The information that we gathered during this development process provided us with the data and tools necessary to make well-informed decisions about the best way to approach the Conference Report questions. Our extensive efforts enabled us to develop a balanced methodology for estimating the impact of foreign drug price controls on consumers, R&D, and innovation. The report, given methodological and data challenges, provides our best approximation of the impact these pricing systems have on consumer welfare and industry innovation

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[3] The overview of drug price regulatory systems corresponds to Australia, Canada, France, Germany, Greece, Japan, South Korea, Mexico, Poland, Switzerland, and the United Kingdom.

[4] The prices effects analysis corresponds to Australia, Canada, France, Germany, Greece, Japan, Poland, Switzerland, and the United Kingdom.

[5] Submissions were received from AdvaMed; Alberto Frati, M.D./Mexico; BIO; Consumer Project on Technology Response; GphA; AEI (Kevin A. Hassett); Aidan Hollis, University of Calgary; Industry Trade Advisory Committee (ITAC) 3; Jana Thompson/Indiana; Donald W. Light, Ph.D., University of Pennsylvania and Joel Lexchin, M.D., York University; Novartis Corp.; Kevin Outterson, West Virginia University; Pedro Reyes Ortego/Mexico; PhRMA; U.K. Department of Health; Dan O'Day, Chairman of the Pharmaceutical Committee of the American Chamber of Commerce; The Manhattan Institute for Policy Research; and The Amyotrophic Lateral Sclerosis Association.

[6] PhRMA, AEI (Hassett), and Dr. Donald W. Light.

My comments today describe the study's findings, with detailed information about the methodology used to develop each result. In some cases, the findings will not be surprising. Numerous studies have shown U.S. patented drug prices to be more expensive, on an aggregated basis, than drug prices overseas. Other findings reveal that the policies OECD countries use to control pharmaceutical prices impede competition in these countries and, arguably, globally. Competition drives innovation. In attempting to reduce the burden on health care budgets, OECD countries inadvertently employ policies that dampen the incentives for innovation, thus reducing economic and health benefits for consumers. These restrictive policies deny health benefits by reducing the range of choices, and ultimately raising costs for consumers, by limiting competition from generic drugs. I will discuss this in more detail later in my remarks.

Price Controls Are Widespread

The study examined the drug price regulatory systems of 11 OECD countries and found that all rely on some form of price controls to limit spending on pharmaceuticals. The principal methods these governments employ are: reference pricing, approval delays and procedural barriers, restrictions on dispensing and prescribing, and reimbursement. These methods prevent companies from charging a market-based price for their products and tend to be non-transparent; the criteria and rationale for certain pharmaceutical prices or reimbursement amounts are not fully disclosed, even to the pharmaceutical companies marketing drugs.

The most direct method that relevant OECD governments use to control prices is setting sales prices and outlawing sales at any other price. Governments are often the dominant market participant and may negotiate favorable prices with manufacturers, by leveraging this monopsonistic power. Such negotiations generally result in prices that are lower than they would be in a free market. OECD governments in our study also set the reimbursement prices for new drugs at levels well below free market prices. Since any charge above the regulated price is borne by consumers, the reimbursement price often functions as the de facto market price, whenever such mechanisms are employed. Finally, some OECD governments regularly cut the prices of drugs already on the market.

Overview of How the Detailed Analysis of Prices and Revenues Was Conducted

In order to estimate the impact of these price controls, a detailed study of pharmaceutical prices for nine OECD countries was conducted. The nine countries represented both the largest OECD markets and a range of population wealth. To conduct the study, the Department of Commerce, in cooperation with HHS, purchased revenue and related data for all products containing the active ingredient in the 60 best-selling products in the United States from IMS Health, a leading provider of data for the pharmaceutical industry.

The analysis focused specifically on patented pharmaceuticals, which are produced by research-based pharmaceutical companies and biotechnology companies. The study assumed that, in the absence of drug price controls, average prices in the OECD countries for innovative pharmaceuticals would be equal to U.S. prices adjusted for differences in per capita income. These adjusted prices were then used to estimate revenues, in the absence of drug price controls.

Patented Drug Prices in OECD Countries Are Below U.S. Levels

We found that patented drugs that were best sellers in the United States sold for less in other OECD countries. The study also showed that aggregate pharmaceutical prices in the analyzed markets were 18 to 67 percent less than U.S. prices, depending on the country. These results were consistent with recent academic research in this area.

Developing the appropriate data set to conduct international price comparisons presented a number of challenges. For example, since innovative drug manufacturers fund most private R&D spending, any attempt to analyze the effects of foreign drug price regulations on the development of new drugs requires understanding how price regulation affects revenue for such firms. Because their revenue depends primarily on patented drugs, the study uses a set of the best-selling drugs with patented active ingredients (molecules) from the total IMS Health data set[7] to serve as the basis for price comparisons and to clarify the implications for revenue and R&D spending.

Defining the patented data set was additionally complicated by the fact that patent expiration dates vary across nations, and the patent expiration date itself is not a reliable indicator of when generic competition begins, as those two dates don't always coincide. In the United States, by contrast, the Hatch-Waxman Act expedites generics' entry into the marketplace, so the patent expiration date is a good proxy generally for the beginning of generic competition in the United States. Other countries lack similar incentives, and generic competition may occur much later as a result. For example, in some countries, if a generic competitor does not enter the market after an innovative product's legal patent expires, the innovative product will continue to benefit from exclusivity in the marketplace, and there will be no price change. We resolved this difference by identifying and applying the effective patent expiration date – the year when a generic manufacturer enters the market - rather than the legal patent expiration date.

The second step involved classifying the information in the patented data set in a fashion that would ensure the comparison of similar products' prices. The IMS Health data set contained products that varied across countries. So, we had to determine the best way to classify products across countries. There are many ways to classify pharmaceutical products. Most studies have classified products at the molecular level, which is both the broadest and the most basic definition of any product. Other studies have used more detailed approaches, comparing products by brand name, therapeutic use, dose form (tablets, capsules, injections), strength (milligrams) and package size. We found that

[7] IMS Health is a leading provider of business intelligence services, strategic consulting services, and data for the pharmaceutical and health care industry.

comparing products at more detailed levels, such as strength and package size, severely limited the data set available for analysis. Therefore, this study compared products in the United States and partner countries at the molecular level.

The on-patent drug data set includes details that are reported at the ex-manufacturer levels, before hospital or pharmacy markups or dispensing fees are taken into account. This is an important condition because data at the manufacturing level offer a more reliable basis for comparison internationally than do pharmacy or hospital prices. For example, manufacturing level data does not require further adjustments for differences in tax frameworks or other markups that tend to vary across countries.

Since the IMS Health data set excluded prices, it was necessary to estimate prices based on two other variables in the data set: revenues per molecule and amount of drug consumed (volume). While revenue data were provided in U.S. dollars, the price calculation was complicated by the existence of two alternative volume indicators: standard units and kilograms of the active ingredient. While both volume measures are widely accepted in the academic literature, each generates a different price for the same product.

A standard unit is equivalent to a standard dose of medication, and it is derived from other IMS Health volume measures. Kilograms are the amount of active ingredient in a molecule. While neither measurement has proven superior to the other, each has its own drawbacks. The standard unit measurement, for example, varies across countries, as the smallest common dose in one country is not necessarily the same in another. A second difficulty is the implicit assumption that all pills have the same value to the patient, independent of dose. The drawback to using the kilogram measure is that it can vary according to the individual sample because potency in molecules varies.

Given this challenge, we decided to present a range of results based on both standard units and kilograms. Interestingly, the differences between the aggregate prices, based on the two volume measures, were moderate for all countries except Japan. The consistency between the standard unit and kilogram measures is a function of the consistency between the standard dose and the amount of active ingredient in a given medication. This discrepancy is due largely to the Japanese tendency to prescribe relatively weaker doses at higher frequencies, as documented in prior studies. That is, since the Japanese tend to prescribe a dose of medication (standard units) with smaller amounts of active ingredient (kilograms) at higher frequencies, prices vary greatly depending on the volume measure.

Despite these data quirks, we included Japan in further analysis because (1) Japan is the world's second largest pharmaceutical market and (2) Japanese prices measured in standard units or kilograms were consistently below U.S. prices. The second point was crucial to our decision to include Japan because it showed that the Japanese data were telling a consistent story about Japanese drug prices relative to U.S. prices, increasing our confidence in the Japanese data. If the two Japanese price indices revealed a divergent pattern (one index higher than U.S. prices and the other lower than U.S. prices), then the

reliability of the Japanese data would have been called into question and we would have had to exclude it from further analysis.

Another important detail in our price computation methodology was the decision not to make adjustments for off-invoice manufacturer discounts related to patented drugs. This constituted a break from previous studies, which have tended to factor in such discounts, as U.S. manufacturers are known to provide discounts to managed care and government buyers. Previous studies have estimated the discounts to be between 8 and 11 percent.

The decision not to adjust U.S. prices was based on a recent Department of Health and Human Services (HHS) analysis of discounted U.S. price data from the Center of Medicare and Medicaid Services (CMS). CMS, a division of HHS, collects data from manufacturers about the prices they charge for drugs distributed to pharmacies. These prices factor in discounts and other adjustments, including those that may be excluded from invoices. HHS compared average manufacturers prices (AMP) for sales of brand-name drugs to non-Medicaid retail purchasers (CMS data) and the U.S. invoice prices collected by IMS Health. This analysis found no meaningful difference between the non-Medicaid U.S. prices reported by IMS Health and CMS.

The final step in comparing prices across countries was to produce a price index. There are three generally accepted methods of indexing prices: Laspeyres, Paasche, and Fisher. The methods vary by the quantity (volume) used to weight the prices. The Laspeyres index weights prices based on U.S. volumes, measured in kilograms (or standard units), while the Paasche index uses foreign volumes. The Fisher price index is the geometric mean of the Laspeyres and Paasche indices. We decided to present the Fisher price index, as it avoids a result that is too dependent on either domestic or foreign consumption patterns. However, we also included the results of the Laspeyres and Paasche calculations, for the sake of transparency and because both sets of results are used to calculate the Fisher price indices.

Without Price Controls, Revenues Available for R&D Could Be Significantly Higher

We found that by depressing prices for patented pharmaceuticals, the price controls in OECD countries yield lower revenues for those patented products than would otherwise exist in a competitive market. Our estimates indicate that, after extrapolating to a broader set of OECD countries, the diminished returns are in the range of $18 billion to $27 billion annually. Adding them back would represent a 25 to 38 percent increase in revenues over actual 2003 revenues from sales of patented drugs in the OECD countries considered in this study.

In order to estimate revenue change in the absence of price controls, it was necessary to first estimate prices in such an environment. The market for innovative pharmaceuticals is defined by several characteristics that must be considered when estimating prices in the absence of price controls. First, the high cost of developing and testing a new drug means that no profit-maximizing firm would make the necessary investment to bring new and innovative medicines to the market, in the absence of patent protection. To overcome

this obstacle, countries offer patent protection as a reward for innovation, conferring the right to use the resulting chemical compound for a specific period of time. Such patent protection affords innovative pharmaceutical manufacturers significant pricing power.

Typically, trade in pharmaceuticals cannot take place except through authorized channels. Direct manufacturing costs constitute a relatively small percentage of the overall expense, so prices can vary considerably and still remain above the costs of production, not including R&D. As a result, pharmaceutical firms can be expected to charge different profit-maximizing prices in different markets. That is, given the low cost of production and the absence of trade, the profit-maximizing price can vary across countries because the patent holder will charge a price that reflects demand within each market.

While a variety of factors influence demand for different drugs in different countries, one consistent factor affecting demand is income. Thus, we made the assumption that U.S. pharmaceutical prices are the benchmark for unregulated prices, and relative levels of per capita income determine variances in prices, among developed countries. It is not assumed, however, that variances in prices for each molecule are determined solely by income levels, only that the aggregate prices would vary based on relative income levels.

Prices for pharmaceuticals in the absence of price controls were calculated at the individual drug level, by multiplying each price by a uniform adjustment multiplier. The uniform adjustment multiplier, designed to capture the difference in price between the free and controlled markets, is calculated by dividing the ratio of foreign per capita income to U.S. per capita income by the ratio of aggregate patented drug prices (i.e. the ratio of foreign to U.S. patented drug prices). The mechanics behind the uniform price adjustment multiplier are straightforward: a price adjustment multiplier greater than one indicates that prices are below what would be expected in an unregulated market. Our calculations uncovered only two cases in which the uniform adjustment multiplier was below one (Greece and Poland), indicating that prices are likely at, or above, reasonable levels relative to each country's income level. A further reduction in drug prices in these countries would suggest that some individual drug prices could drop below the direct cost of production – an unlikely scenario. Given these atypical specifics, and further research that indicates these markets are relatively competitive, we decided to exclude them from further analysis.

These new, market-based prices were then used to compute new revenues. It is worth noting that in conducting this calculation, we did not adjust volumes to reflect changes in consumption related to higher drug prices. It was not possible to determine a justifiable and economically sound method for making upward or downward adjustments to consumption for such a scenario. For example, we could have assumed that following the removal of price controls, volumes would rise to levels observed in the United States, adjusted for differences in population. However, prescribing practices vary significantly across countries. Therefore, we assumed the increased drug prices would not affect sales volumes.

The final step in estimating the impact of foreign drug price controls on the global revenues of innovative pharmaceutical manufacturers involved extrapolating the revenue

changes from the patented data set to the total patented market in 11 OECD countries (Australia, Belgium, Canada, France, Germany, Italy, Japan, the Netherlands, Spain, Sweden, and the United Kingdom) for the year 2003. As mentioned earlier, we chose these 11 OECD countries because they collectively represented a significant share of the pharmaceutical revenues generated in developed markets for the year 2003.

Higher Revenues Would Mean More Research and Development and New Drugs

The study uses published academic research to estimate the impact of increased revenues on pharmaceutical R&D. By limiting the return that would otherwise accrue to companies that make risky investments to develop new drugs and bring them to market, the price controls that OECD countries in the study maintain also reduce pharmaceutical R&D globally; research and development spending exists at lower levels than would be the case if these countries maintained market conditions similar to those in the United States. The study estimates that this reduction falls in the range of $5 billion to $8 billion annually, once prices are fully adjusted. This represents between 11 and 16 percent of current private R&D worldwide, based on figures from the CMR International (CMRI).

Based on the estimated cost of developing a new drug, an increase in R&D spending of $5 billion to $8 billion could lead to three or four new molecular entities annually, once markets fully adjust. The U.S. Food and Drug Administration approved, on average, 30 new molecular entities between 2000 and 2003.

The long-term effects of higher revenues and prices for consumers are linked to R&D and innovation. Both economic theory and empirical evidence indicate a close correlation between revenues and profit margins on the one hand and R&D expenditures on the other. We relied heavily on the economic theory and empirical research on the relationship between revenues (cash flow) and R&D expenditures to provide the foundation from which we then estimated the amount of R&D funding that would be available, in the absence of price controls. This included work by Henry Grabowski, John M. Vernon, and John A. Vernon, who developed the parameters for estimating how an increase in revenues following the deregulation of price controls would presumably impact R&D and the number of new drugs available in the marketplace.

We made a few key assumptions about how innovative drug manufacturers would interpret increased revenues, most critically that innovative drug manufacturers would believe that increased revenues from price deregulation were permanent. If they did not view the price changes as permanent, but rather as short-term windfall, there would be much less incentive to make long-term investments in increased R&D spending. In addition, we assumed there would be a fixed corporate tax rate of 33 percent on all additional earnings, and that pretax profits would not be consumed by additional production and distribution costs. The principle weakness in this assumption is that a portion of the increased revenues might be devoted to marketing.

The empirical work necessary to predict industry R&D investment decisions includes examining several financial factors, both separately and together, including: cash flow,

profit margins, prices, and a number of other non-financial factors. Several studies that analyze the effect of changes in cash flow and profits on U.S. pharmaceutical R&D spending are most relevant to the questions posed in the Conference Report. The most recent of these studies are by: Henry Grabowski, John M. Vernon, and John A. Vernon. We used John A. Vernon's cost and profit margin parameters and his regression equation to estimate the impact a change in revenues would have on R&D spending.

The regression equation developed by John A. Vernon required data for expenditures on pharmaceutical R&D and revenues. Consistent and comprehensive data on expenditures and revenues are difficult to find. So, we consulted two independent sources for R&D expenditure data, PhRMA and CMRI. The most widely used source for R&D expenditure data is PhRMA. The association provides data regarding R&D expenditures by all PhRMA members, including non-U.S. firms within American borders. It also provides data about worldwide R&D levels, but it excludes R&D expenditures by non-U.S. PhRMA members outside the United States. PhRMA also provides pharmaceutical revenue data on the same basis. CMRI produces data on global pharmaceutical spending for R&D. This figure is based on the R&D expenditures of "traditional" global pharmaceutical companies, and as such, their contribution to biotechnology expenditures will be captured by the estimate.

The expenditures by specialized biotechnology companies, on the other hand, are not included in the data. CMRI figures differ from PhRMA figures because they include R&D performed outside the United States by non-U.S. pharmaceutical companies. However, CMRI does not provide any information regarding revenues, which means two different data sources informed our analysis: PhRMA's revenues data, combined with CMRI's R&D expenditures. In order to avoid inconsistencies, we used PhRMA data because it provided the most complete and consistent set of pharmaceutical expenditures available for R&D and revenues.

We realized that the estimated increase in R&D would not be devoted exclusively to the development of innovative drugs. Research by the Tufts Center for the Study of Drug Development suggests that only about two-thirds of total out-of-pocket R&D spending furthers the development of new medicines. The other third is spent on post-approval, long-term safety and efficacy studies in broader patient populations, or specific patient groups, and for the development of new indications and/or new formulations. For the purposes of this analysis, we assume that increased spending on R&D will be allocated for new active substances and other purposes in the same proportions as current spending on R&D, i.e., approximately two-thirds, one-third.

Various studies have been done regarding the cost of developing new drugs; the most recent and often cited study is that by DiMasi, Hansen, and Grabowski, who report that the total cost per new drug was $802 million in 2000. The estimate reflects capitalization of the out-of-pocket costs to ten multinational pharmaceutical firms developing self-originated new molecular entities (NME) with a mean approval date of 1997, including losses on unsuccessful research. Assuming the same rate of growth in the inflation-adjusted capitalized costs of drug development, between this most recent work and a

comparable earlier work, the authors estimated that the capitalized cost for drugs approved in 2001 would be $1.1 billion. Applying these same assumptions would suggest that the cost of drugs approved in 2003 was about $1.3 billion in 2003 dollars.

U.S. Consumers Would Benefit from the Elimination of Price Controls Abroad

Due to time and data constraints, we could not complete a rigorous investigation of the short- and long-term effects of a price deregulation on U.S. prices and consumers. However, we were able to posit some conclusions about the impact price deregulation would have in the short- and long-term. In the short-term, the deregulation of OECD prices is not likely to have any impact on U.S. drug prices. This conclusion can be explained largely by the basic characteristics of the pharmaceutical industry. Price, expected revenues and profits are all critical factors in making investment decisions to launch R&D efforts. The nature of pharmaceutical markets and economic theory suggests that the prices in one market will behave relatively independent of prices in other markets, absent more fundamental changes in the competitive forces operating in those markets.

In the long-term, the "increased competition" in the U.S. market as a result of an increase in the flow of new drugs, could have some effect on U.S. prices. Relaxation of foreign price controls, if coupled with appropriate reform of foreign generic markets, could potentially bring about significant gains from the flow of new drugs leading to improved health outcomes, even without increasing foreign spending on prescription drugs. This conclusion was based on written comments and testimony submitted to the Commerce Department that suggested increased competition would lead to long-term changes in U.S. prices.

Using More Generic Drugs at Lower Prices in OECD Countries Means Potential Savings

Analysis by the Departments of Commerce and HHS found that higher utilization of generic drugs at lower prices could result in significant savings to OECD countries. The estimated savings, after extrapolating to a broader set of OECD countries, range from $5 billion to $30 billion annually. This range of potential savings suggests that if prices of on-patent drugs rose to competitive market levels, then a more competitive generic market could significantly, or even fully, offset any additional cost to OECD countries.

Specifically, we examined how foreign price controls impact the off-patent (generic) drug market, using a second data set from IMS Health composed of 29 of the world's top selling off-patent drugs. HHS did much of this analysis, on behalf of the Department of Commerce, because HHS had access to proprietary data from the Center for Medicare and Medicaid Services (CMS) that illuminated the analysis of generics. HHS analyzed both the prices and utilization of generic drugs across the same nine OECD countries that the Department of Commerce examined in its empirical analysis of innovative drug prices.

Generic drugs were defined within this data set as those drugs not produced by an innovator or licensed company. All drugs using the same active ingredient are treated as one product. The quantity sold is measured as the total kilograms of the active ingredient (with an adjustment for the salt factor) or number of standard units. U.S. prices in the IMS Health data set were discounted by approximately 24.2 percent. This discount is based on a comparison of U.S. prices from IMS and average manufacturer prices (AMP) collected by CMS, which include off-invoice discounts, rebates, and charge-backs. HHS found that the AMP collected by CMS were 24.2 percent lower than the invoice prices in the IMS Health data set. Finally, Fisher price indices – averaging the price indices using both U.S. and foreign weights -- were constructed.

HHS went on to consider a scenario in which foreign countries would shift their usage of generic drugs to match U.S. proportions and adopt policies that foster U.S. prices for generic drugs. HHS found that such a shift in generic drug prices and utilization would yield potential savings, which varied according to the volume measure used to estimate prices. We then extrapolated the estimated potential savings from the data set of 29 molecules to the total generic market in 11 OECD countries using market share data from IMS Health.

Conclusion

OECD governments in various countries have relied heavily on government fiat rather than competition to set prices, thereby lowering drug spending, as price controls are applied to new and old drugs alike. Such controls, when applied to new drugs, reduce company compensation to levels closer to direct production costs, leaving less revenue available for R&D efforts. Collectively, individual nations' efforts to limit prices can diminish investments in R&D that would provide substantial health benefits to all. Improvements in health care and life sciences are important for health and longevity worldwide. The development of innovative pharmaceutical products plays a critical role in ensuring these continued gains. To encourage the continued development of new drugs, it is essential that we preserve sound economic incentives to develop and market new health technologies.