

PRICE CONTROLS WHITE PAPER

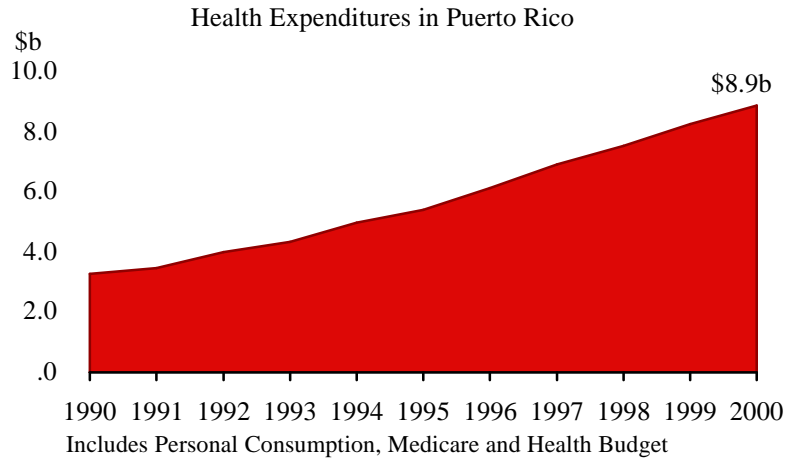
I. INTRODUCTION

The Pharmaceutical Industry Association of Puerto Rico (PIA) welcomes an open discussion regarding the effectiveness and impact of price controls for pharmaceutical products in Puerto Rico. Over the years, increases in drug prices in the US and Puerto Rico, together with increases in expenditures on prescription drugs, have provided the arguments for the adoption of regulatory policies that would manage the situation through price controls.

Conventional wisdom would have us believe that price controls is a viable and effective instrument to control increases in drug prices and thereby, reduce the increases in expenditures on medicines. This perception may be conventional but it certainly is not wisdom. Facts and logic will lead us to the following conclusions: international and US prescription price differences are smaller than has been alleged; and any form of price regulation, including the setting of uniform prices within Puerto Rico or the US would discourage innovation and competition. The end result is a distorted market both in terms of services and prices to the detriment of patients' health. PIA hopes to contribute to the public discussion in Puerto Rico with solid facts and research on the subject of price controls. This paper will contribute positively towards a better formulation of public policy.

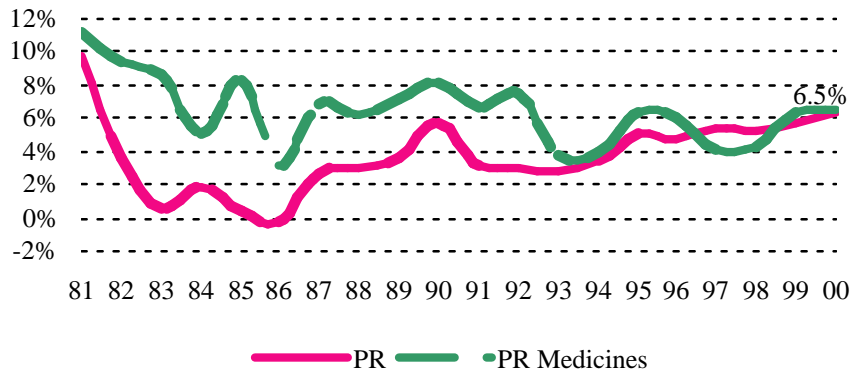
II. PRICE BEHAVIOR IN THE US AND PUERTO RICO

Puerto Rico spends more than \$8.0 billion annually on health care expenditures, including consumers prescription expenditures, medical services, and Department of Health expenditures. To remain competitive in a global economy, Puerto Rico must control these expenditures.



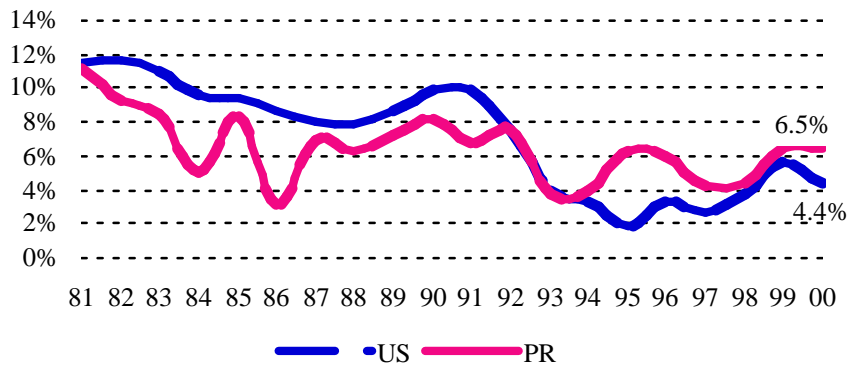
This increase in health expenditures is related to population growth, increasing utilization of medical services and prescriptions through the Health Care Plan and prescription price increases. During the past twenty years, prescription prices in Puerto Rico, as measured by its price index, grew at a higher rate than the overall Consumer Price Index (CPI), until 1996. The trend changed by 1999, when the price index for medicines increased by 6.4%, and the CPI increased by 5.7%. In 2000, they both increased at practically the same rate, 6.5% and 6.4% respectively.

CPI PR Total and Medicines



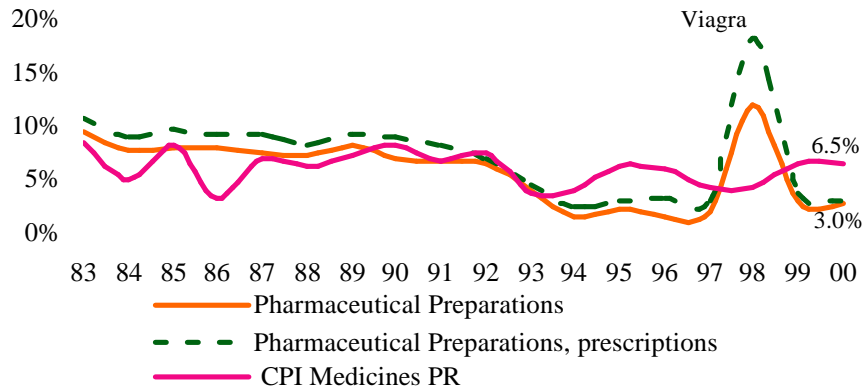
Until 1993, prescription prices in PR, as measured by the consumer price index for medicines, were growing at a lower rate than in the US. The trend breaks down after 1993, the year in which the Health Care Reform Plan started. Thereafter, prices increased at a higher rate than in the US. By 2000, the increase was 6.5% in PR versus 4.4% in the US.

PR and US Medicines CPI



Is it possible that these prescription price increases at the consumer level follow a similar pattern to prescription producers' prices in the US? Since 1993 and with the exception of 1998, the year when Viagra was introduced, prices at the manufacturer level as measured by the producer price index (PPI) for pharmaceutical preparations, have been on a downward trend. In 2000, the PPI for pharmaceutical preparations increased by 2.8%, while in PR the CPI for medicines increased 6.5%. This merits further investigation since prices in PR at the pharmaceutical level is similar to those in the US. Otherwise, trade diversion would take place. If prices at the pharmaceutical level were lower in PR than in the US, then the US would buy from PR instead of from domestic sources and vice versa. Still, why are prescription prices at the consumer level higher in PR than producers' prices and higher than consumer prescription prices in the US? Factors such as the differences in mark-up along the distribution chain, differences in cost structure could account for this outcome. Can local price controls on prescriptions be the answer?

US Producers' Prescription Prices vs. PR CPI Medicines



III. PRICE REGULATION OF PHARMACEUTICAL PRODUCTS

As in other countries, Puerto Rico is trying to remain competitive in an increasingly global economy. To do so, overall expenditures must be controlled, including spending on health care and thus, on pharmaceuticals. Therefore, pharmaceutical price regulation has become endemic in virtually every country, and price controls are getting broader and tougher. This trend has significant implications not only for the future of the pharmaceutical industry and its spending on research and development, but on the health of patients worldwide.

Drug prices are a tempting target for regulators, who notice a vast discrepancy between prices and manufacturing costs. But prices reflect other costs as well, in particular, the costs of research and marketing. Fixing prices at lower levels would inevitably curtail development and distribution of new products that improve and extend life.

Almost all economists hate price controls. But someone is always proposing new controls because he thinks he can get something for nothing or almost nothing. Today, the focus is on pharmaceutical prices. That is no accident. Small molecule drugs are typically produced for a fraction of their sales price. The difference represents the costs of research and development and information dissemination, with most of those costs long since incurred by the manufacturer.¹

A. Opportunity Cost and Research and Development

The pharmaceutical industry, more than most other industries, is particularly vulnerable to regulation because research and development (R&D) is an unusually large component of its total costs. Pharmaceutical spending on R&D is approximately 13 to 20 percent of current sales. However, the R&D for drugs being sold today occurred 12 to 15 years ago. To estimate correctly the percentage of the total costs of bringing those drugs to market, the time value of money must be included (that is, the interest foregone on that R&D spending between the time it is invested and the time the revenues come in). Once we take this opportunity cost of funds into account, R&D accounts for over 30 percent of total costs on a discounted present value basis. It costs over US\$400 million per new drug launched. Factored into this are the many failures for every success, and the opportunity cost of funds.

B. Price Differentials with Other Countries

One argument presented by advocates of price controls is that drug prices in the US are higher than in other industrialized countries. Although the literature appears to support the hypothesis that American drug prices are higher than prices in other countries, studies by Danzon (1997; 1998) indicate that cross-national price comparisons of this type are sensitive to methodological choices, such as unit of measurement of price and volume, weight given to consumption patterns, and exchange rates or purchasing parities for currency conversions.¹ Using accurate pricing information, health economist Patricia Danzon (1997) has found that drug prices in Canada, Germany, Switzerland and Sweden are higher on average than prices in the United States.

When "purchasing power parity," a means by which economists attempt to compare the price of goods in different countries, is considered, the Organization for Economic Cooperation and Development (OECD) found that Americans spend less per capita per year on drugs than do people in Germany or France and only slightly more than those in Canada and Italy - yet these other countries have controls.

According to the study of Patricia Danzon, most of the studies of cross-national price differences for pharmaceuticals are based on a misunderstanding of the facts, the economics, and their potential negative impact on patients both here and abroad. It is true that prices of many brand name drugs are lower in Canada and other countries than in the U.S. But the perceptions that U.S. prices on average are much higher than other industrialized countries are based on inaccurate and biased comparisons. Most price comparisons use small, unrepresentative samples and faulty methods.

The fundamental difficulty in doing drug price comparisons is that the mix of drugs available and their use vary widely across countries. For example, our analysis found that over 40 percent of drug sales in Germany, France, Italy and Japan were for molecules that were not sold in the US. Even when the same molecule is available, it may be sold in different dosage forms, strengths, and packs and by different manufacturers. Moreover, the relative prices of different drugs vary widely for example, one product may cost 50 percent less in Canada, and another may cost 50 percent more. Valid comparisons should therefore be based on large, representative samples of products, including generics, and should use standard, weighted price indexes, which weight the prices of individual products to reflect their relative importance in overall consumption.

¹ Kim J. Danzon (1998) International Price Comparisons for Pharmaceuticals: Measurement and Policy Issues. *Pharmacoeconomics*. 14(Suppl. 1): 115-128; Patricia M. Danzon (1997) **Pharmaceutical Price Regulation: National Policies versus Global Interests**. The AEI Press. Washington, DC.

Most previous comparisons violate these basic principles of price comparisons. They use a small number of leading, branded products, excluding all generics, although generics account for over 40 percent of prescriptions in the U.S. They use a simple unweighted average of the price relatives, although such measures are extremely sensitive to the sample and generally give undue weight to the highest priced products. Some studies use retail-level prices and then draw conclusions about manufacturer-level prices. But retail prices include wholesale and retail pharmacy margins, over and above the manufacturer price, and do not reflect manufacturer rebates given to managed care and government purchasers. Hence, comparisons based on retail prices cannot provide an accurate measure of differences in net prices to manufacturers.²

C. Price Controls and the Consumer

Have price controls actually benefited the consumer? The most direct method of controlling drug costs is product price control, whereby the government negotiates directly with each manufacturer to determine reimbursement level for individual product. A similar mechanism has been suggested for Puerto Rico. Organization for Economic Cooperation and Development (OECD) countries use different varieties of pharmaceutical cost control approaches. In a typical system the price is established after the drug product obtains marketing approval, but prior to market introduction. The government or a government-sanctioned body reviews the manufacturer's price applications and determines whether the requested price is "fair". If the price is not acceptable, the government can set a lower price. If the price determined by the government is lower than what the manufacturer requested, the company can appeal the decision. The price setting usually takes one of two forms: internal, focusing primarily on the manufacturer's price justification, or external, examining the prices charged for the same or similar product in other countries.³

When conducting an internal evaluation of a manufacturer's price justification, government takes into account diverse factors such as the anticipated therapeutic benefit of the new product, anticipated sales volumes, and the company's contribution to the economy, as they do in France.⁴ All governments using direct price controls require approval for any product price increases after market introduction.⁵

² Patricia M. Danzon PhD. "Testimony to the U.S. Senate Committee on Health, Education, Labor and Pensions", June 13, 2000

³ M. Dickinson (1992) "The Pricing of Pharmaceuticals: An International Comparison." *Clinical Therapeutics*, 14 (4); 604-610.

⁴ C. Le Pen (1996) "Drug Pricing and Reimbursement in France: Towards a New Model?" *Pharmacoconomics*. 10 (Suppl. 3): 26-36.

⁵ K. Bloor and N. Freemantle (1996) "Lessons from International Experience in Controlling Pharmaceutical Expenditure III: Regulating Industry," *British Medical Journal*. 313 (7048): 33-35.

According to research done in countries with price control mechanisms, "the current structure and administration of controls have become counter-productive in several ways, both for industry and the consumer. Companies have shied away from investment in and the production of drugs under price control e.g. doxycycline, chlorpropamide etc. resulting in shortage or non-availability of these drugs or increased reliance on imports. This void has, in turn, attracted unscrupulous traders and manufacturers who offer spurious and substandard drugs. There is also a shift to newer drugs, which are outside price control, resulting in the use of more potent medicines than needed. Hence, the cost of treatment to the consumer has gone up several folds. Price controls have not only led to irrational use of drugs and promoted spurious and substandard drugs, but the consumer has also ended up paying more than what he would have in the case of conventional drugs".⁶

Reference pricing has been enacted in several countries, such as Germany, and in Canada in British Columbia. It has become popular among private payers and Medicaid programs in the United States. The maximum allowable cost use reference pricing for drugs that are chemically identical. Although the consensus is that reference pricing is effective in controlling drug costs, the financial savings are short-term and subject to the law of diminishing returns. Over time, the cost savings diminishes as pharmaceutical companies, doctors, and patients alter prescription consumption towards greater use of the reference-priced product.⁷

A study released April 29, 2001 by the Boston Consulting Group (BCG) on the impact of government interventions in the pharmaceutical market, provides further evidence that price controls are not the answer. BCG "found that price controls and other forms of market intervention can actually harm patients. They do this by reducing the rate of adoption of some important new therapies. This effect is particularly important in those diseases such as high cholesterol and depression."

Strict price regulation also tends to undermine competition between therapeutic substitutes and competition from generics and over-the-counter medicines that thrive as cheaper alternatives in countries permitting freer pricing of branded drugs. The net effect is that the overall difference in the price of drug therapy to consumers, between heavily regulated countries, such as France and Italy, and those that permit freer pricing, such as Germany (until 1993) and the United States, is not as great as has been argued in studies that compare only the prices of leading, branded, originator drugs.

⁶ Anju Ghangurde, "Price control has led to irrational drug use".

⁷ M. Dickinson and H. Redwood (1998) " Pharmaceutical Reference Prices: How Do They Work in Practice?", *Pharmacoeconomics*. 14(5): 471-479.

D. Will Pharmacies Pass Lower Prices to Consumers?

According to an article written by William H. Lash III ("Price caps on prescription drugs is bad medicine"), pharmaceutical price controls are based on the mistaken assumption that by imposing price controls on drugs sold to pharmacies, pharmacies will pass on the lower prices to consumers. However, there is no requirement in any of the price control plans that these lower prices are passed on to the consumer or Medicare patients.

According to Lash, price controls on pharmaceuticals simply do not work. From 1990 to 1997, pharmaceutical expenditures grew twice as fast in countries with price controls as compared to the United States. In a 1994 study, the General Accounting Office determined that pharmaceutical price/profit controls imposed by France, Sweden, Germany and the United Kingdom failed to prevent increases in pharmaceutical expenditures.

E. Price Controls "Kill" Innovations

In another study, Patricia M. Danzon (1997) concluded: "price controls dim economic incentives and kill innovation. In her study of pharmaceutical price controls, she concluded "there seems to be a rough negative correlation between the stringency of a country's price controls and the innovative success of its domestic pharmaceutical industry."⁸

In the United States over the past decade, pharmaceutical companies, free of price controls, have discovered 400 new drugs. Additional 400 medicines to treat heart disease, cancer and stroke-the top health threats to senior citizens-are currently in development. This innovation is expensive. American pharmaceutical firms invest \$24 billion annually to discover new medicines. It takes an average of 15 years to develop a new drug with long odds of success. Of every 15,000 compounds tested as potential new pharmaceuticals, only three are ever marketed and only one will make a profit.

Danzon argues that the principal policy challenge is to control the inappropriate use of drugs while guaranteeing the availability of innovative and cost-effective drugs. Policies of price regulation and drug budgeting violate the most basic incentive requirement for innovation and for the efficient use of medical resources,

A Duke University study revealed that only three of every 10 new drugs earned more than their average research and development costs. According to a report by

⁸ P. M. Danzon, Making Sense of Drug Prices.

the Boston Consulting Group, the pretax costs of developing a drug introduced in 1990 were \$500 million. Price controls would cut revenues for the pharmaceutical industry. These revenues are what fund research and new lifesaving innovations. Despite their costs, prescription drugs are one of the best and most cost-effective ways of dealing with health-care costs.

F. Price Controls Promote Parallel Trade

Regulations can also cause international price comparisons and parallel trade. Countries use foreign prices depressed by regulation to set limits on their domestic prices. Importers purchase drugs from countries with regulated low prices and resell them in countries with higher prices. The result is parallel trade, which reduces the incentive to invest in research and development.

The above analysis suggests that market interventions can substantially influence both the way in which new drugs are adopted and the incentives for pharmaceutical companies to invest in research and development. The interventions can reduce access by inducing delays in market introduction and often limiting the number of patients who receive treatment, and, as a result, may decrease the quality of health care delivered and increase the cost. The interventions can also discourage research into innovative therapies and reduce the industry's economic incentives to develop and introduce new drugs. Market interventions have been only partially effective in limiting pharmaceutical spending. Most governments that have regulated pharmaceutical prices have experienced the same rate of long-run pharmaceutical spending growth as those that have not. Furthermore, these interventions have had negative consequences for health outcomes and incentives to innovate.

In summary, most economists argue that government intervention is the worst way to achieve the goal of lower price for medicines because it invariably leads to unexpected second and third order consequences. Instead, they argue that free-market competition is a better impetus toward lower prices and access to innovation.

IV. PHARMACEUTICALS AND HEALTH CARE

In thinking about the effect of interventions in the pharmaceutical market it is important to remember that pharmaceuticals are only one, often relatively small, component of overall health care spending. There are marked differences between countries' health care spending, and the amount of spending that goes for pharmaceuticals. Even within Western Europe, for example, pharmaceutical spending ranges from a high of 1.6 percent of GDP in France to 0.7 percent of GDP in Denmark and Norway. As a share of total health care spending, it ranges from 20 percent in Spain to 9 percent in Norway.

Different levels of spending on pharmaceuticals also reflect marked differences in consumption volume and price level. Although it is very difficult to make cross-country comparisons of consumption and price levels, an indicative analysis suggests that higher consumption is associated with lower prices. Any proposed system of market intervention must therefore address the dynamic of price and volume that drives overall pharmaceutical spending. For example, reducing prices in response to rising consumption may help contain overall drug spending but does nothing to address the drivers of rising consumption, such as inappropriate prescribing.

A. Pharmaceuticals and Imperfect Competition

Some economists argue that the high cost of pharmaceutical products in the United States is caused by imperfect competition, fueled, in part, by governmental interventions in that market. Ronald F. White and Sean Fraley, College of Mount. St. Joseph Cincinnati, Ohio argue that since the pharmaceutical industry profits handsomely from the imperfect competition brought on by these interventions, drug prices ought to be "reasonable." In some cases, this might entail that the government regulates pharmaceutical companies as it would a public utility: a lesson that other liberal democracies have already learned.

On the other hand, according to Patricia Danzon: "Some critics of the pharmaceutical industry use their accounting records to claim that there are large excess profits being generated. However, the Office of Technology Assessment has shown that the return on equity for the pharmaceutical industry is only slightly higher than the average for all industries. This is because accounting figures do not properly reflect large Investments in research and development. If the high costs and risks of drug development had been taken into consideration, even these small differences in industry averages would disappear.

B. Pharmaceutical Prices Versus Consumer Prices

Other critics argue that drug prices have increased at a faster rate than the prices of other consumer goods. However, research by well-known economists at major universities has revealed numerous biases in the official reporting of drug prices, making this assertion misleading. For example, the official figures treat a generic drug as a separate drug. The introduction of a generic drug causes a drop in real costs to consumers, but the official data do not reflect this. The official data also generally use list prices, though more pharmacists and pharmaceutical companies are beginning to discount the cost of drugs. Considering these and other biases, it is likely that drug prices rose less than prices of other medical services in recent years.

C. Price Controls and Expenditures in Pharmaceutical Products

Proponents of price controls argue that cuts in drug prices will lead directly to cuts in total drug spending. In fact, the opposite will occur. The empirical evidence further shows that stringent price regulatory systems have failed in their primary goal of controlling drug spending. Over the past two decades, drug expenditure per capita has risen more rapidly in France and Italy, which have regulated drug prices, than in Germany (before 1993), the United Kingdom, and the United States, where greater pricing freedom has prevailed. Moreover, both countries with stringent price regulation have a dismal record of developing innovative drugs. Although France spends roughly the same percent of sales on R&D as other countries, it has produced few, if any, innovative drugs in recent years.

A 1993 study by Heinz Redwood and a 1994 study by David Gross comparing international pharmaceutical spending controls found that: while price controls produced lower prices, they did not reduce total pharmaceutical expenditures (price times volume) nor did they contain total health care spending. Moreover, pharmaceutical expenditures grew faster in countries with price controls than in the United States. Price controls usually are part of a government-run program that provides consumers with prescription drug benefits. Attempts to drive down the drug costs through price controls have two unintended results: (1) they encourage increased consumption of drugs and (2) they lead to the consumption of inferior drugs.

Many European health systems spend more on drugs per capita than is spent in the United States, but Americans use newer and more appropriate medications for such diseases as depression, high cholesterol, high blood pressure, and cancer. That is one reason Americans spend less time in hospitals when they are sick and have a higher quality of life than Europeans. European and Japanese consumers face an entirely different basket of pharmaceutical products than do Americans. The U.K. National Heart and Lung Institute noted that nearly 90 percent of Europeans who have experienced heart failure and who should be receiving ACE-inhibitors are not, despite the availability and demonstrated ability of these drugs to prevent second heart attacks and left ventricle dysfunction. Ninety percent of heart failure patients in France were not receiving an ACE-inhibitor, at a potential cost of 16,000 lives and \$528 million over four years. Europeans are more likely to consume drugs that could never be approved by the U.S. Food and Drug Administration, which despite its reputation for regulatory delay is still the gold standard for drug approval worldwide.

It is Japan, however, that demonstrates most vividly how reducing drug prices through controls affects health care quality. The Japanese government in recent years has cut prices of drug products from global pharmaceutical firms by 50 percent. It allows local drug companies to go to market with new drugs at higher prices but cuts the prices in later years. Patients do not pay for drugs directly; doctors make most of their money by filling their own prescriptions.

Japanese doctors often load their patients with prescriptions, marking up the prices allowed by law and pocketing the difference. On average, a doctor prescribes 13 different medications to people under his care. A study by Tom Thomas, an economics professor at Emory University, points out, the vast majority of Japanese medications marketed and prescribed are useless. Unable to obtain the best drugs to treat their diseases, Japanese consumers are sicker and spend more on other types of health care. Price controls distort the quality of care in many ways, not least by shifting both the production and availability of medications towards older and less innovative compounds. The result is that people cannot have access to the most cost-effective medications and are forced into hospitals. Thus, consumers in countries with price controls often wind up consuming many more drugs that are less effective or totally ineffective than more innovative products. These countries tend to spend more on drugs as a percentage of their health care dollar, but they get less value in the process. Either way, price controls directly drive up total spending on drugs.

V. SUMMARY

In cross-national drug price variations, there are several key factors that play a role in explaining them. The most important reasons are the country's wealth, the extent of prescription coverage, medical practice norms, and demographic differences. Drug price regulation plays a role, but there is presently no body of empirical research that tells us, which of these factors is the most important. **Economic criteria and the evidence examined here tells us that price controls on balance, do not work.**

Consumer interest will be better served by allowing greater interplay of market forces and minimizing government intervention. Public policy decisions, particularly those related to health, should be based on hard facts and research. More research is needed, particularly regarding the prescription distribution chain on the Island, from pharmaceuticals to wholesalers to pharmacies to the consumer. This paper contributes hard facts to enhance Puerto Rico's public decision making process.