

PHARMACEUTICALS



THE REASON
FOR
INCREASING
HEALTH CARE
COSTS????

EXECUTIVE SUMMARY

NEW YORK HEALTH PRODUCTS COUNCIL
APRIL 16, 2003

NEW YORK
HEALTH
PRODUCTS
COUNCIL

INTRODUCTION

Hosted by the New York Health Products Council, “*Pharmaceuticals. The Reason for Increasing Health Care Costs????*” was presented by E.M. (Mick) Kolassa, Ph.D. as part of a series of health care forums designed to improve the understanding of the important role of pharmaceuticals and the pharmaceutical industry play within our healthcare system. The forum was held at the Empire State Plaza in Albany, New York and was geared to provide information to leaders involved in the development of New York State’s healthcare system.

Dr. Kolassa is the Managing Partner of Medical Marketing Economics LLC, a consulting firm specializing in marketing and pricing strategies for firms in the field of health care. He is also Adjunct Associate Professor of Pharmacy Administration at the University of Mississippi. His academic research focuses on the application of marketing activities in pharmaceutical markets, the value of pharmaceuticals in healthcare systems, and the management of the pricing and economic analysis functions within organizations. Dr. Kolassa received his doctorate from the University of Mississippi and MBA from Eastern Washington University. He has written and lectured extensively on pricing strategies and the management of the pricing function.

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In his presentation, Dr. Kolassa proposed that pharmaceuticals are not the reason for increasing health care costs in this country, but are in fact, the most cost-effective health care resource we have. Further, he believes, that the increased usage of pharmaceuticals and the development of new and innovative medicines will continue to lower the overall cost of health care if used and delivered properly. In his presentation he made the argument that there is nothing inherently wrong with the pricing of pharmaceuticals, rather it is the lack of coverage that is at fault and that if we value longevity and quality of life, pharmaceutical research and development should be of primary importance. To this end Dr. Kolassa examined the role of pharmaceuticals in our healthcare system and highlights the many challenges and oppositions facing the industry including the prices and problems within the U.S, profitability, and international issues. He also discussed the emerging medical and spending paradigm, and examined the effects that government interventions will have on the long term role of pharmaceuticals and overall costs of health care. He provided substantive information to refute widely held beliefs that pharmaceuticals are too costly and that intervention is needed to “fix” the system of increased spending. While expenditures on pharmaceuticals are increasing in our society, they are doing so at an appropriate rate and are, in actuality, saving money for the healthcare system overall.

When determining the value of a medicine, there are three questions that need to be asked.

- How many years will it add to a person's life?
- Does the medicine enable a person to work or live independently, or simply enjoy life more?
- How much money is saved when the medicine helps to avoid surgery, hospitalization or admissions to nursing homes?

These are the questions that pharmaceutical companies have to ask of all their products, and the answers help determine the pricing of the products. The success of their products to meet any, or all, of these needs will determine the value of the medicine to society. The time and the money spent on research and development is based on the needs and desires of society, and societally we seem to value longevity and quality of life; however, we do not have the political will to pay for it.

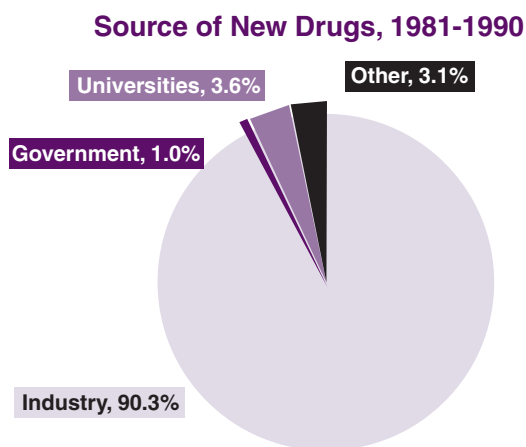
When we view pharmaceutical products from the public's point of view we find that there is often a negative connotation placed on pharmaceuticals because of their high price. There is a lack of understanding that the issues of quality of life, longevity and cost savings to alternative forms of treatment are what should be the focus to determine the true value of pharmaceuticals.

PRICES & PROBLEMS IN THE UNITED STATES

Fact: Dollar for dollar, Rx medications are the most cost effective health care intervention we have.

Fact: Private industry research and development is the source of most new drug innovation.

RESEARCH & DEVELOPMENT



Ninety percent of new drugs are derived from private industry research and development. And while research is an important part of innovation, it is the starting point, not the end point. The development portion is what brings innovation closer to the market place, and development is what costs money. The government and universities tend to concentrate their activities and spending on research and it is often left to the pharmaceutical companies to fund the development, to figure out how to turn the research into a drug and use it in the patient population. And that is where the real costs are, where the value of our pharmaceutical dollar must be attributed.

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GROWTH IN RX SPENDING

Some contend that drug prices are accused of being out of control in this country and that surging pharmaceutical costs are often considered to be the main contributor to the rising cost of health care. However, when we examine the budgetary issues, we see that that statement is wrong. Pharmaceuticals account for less than 10% of our total health care spending. According to recent national data, drug expenditures represent 20% of total spending in healthcare plans, and spending on prescription drugs grows by 18% a year. This results in a 3.6% increase per year that can be attributed to drug costs (20% x 18% = 3.6%). This increase does not fully account for premium increases of 8-10% or total spending of 12%. Drugs are not the main contributor to rising prices of health care as some contend.

To put spending into perspective, the average American spends more on alcoholic beverages than on prescription drugs and the average senior couple, with an income of \$15,000 or less, spends as much on entertainment and charitable giving, and more on property taxes, than they do on pharmaceuticals.

And while it is true that the U.S. spends more on healthcare as a percent of the economy than any other nation, it is also true that if all prescription drugs were free, the U.S. would still be spending more on health care than any other nation. If all drug spending were taken out of the equation, the portion of our economy dedicated to health care would still be higher than any other country. For example, defensive medicine and malpractice litigation cost, on average, three times more than pharmaceuticals. Therefore, no matter how we manipulate the drug budget, it will not solve the problem of increased spending on health care in the U.S.

LACK OF RX COVERAGE

The medically indigent don't need lower prices on drugs, they need better prescription drug coverage. Economists from the School of Public Health of Boston College argue that if you cut the cost of prescription drugs by 40% it would make drugs more affordable to the population. However, the issue is not the price, the issue is the lack of coverage. If prices were cut in half, the truly needy still couldn't afford their medicines, and future generations would be denied new medicines because of the carry over effect that lower costs would have on future research and development.

Hospitals account for 33% of total health care spending with 3% of the hospital bill paid for out-of-pocket by the patient. Twenty three percent of health care spending is spent on physician's services, and of that 11% is paid out-of-pocket. Pharmaceuticals account for only 10% of every health care dollar, however 35% comes out of an individual's pocket. It is the most noticeable item that patients have to pay for.

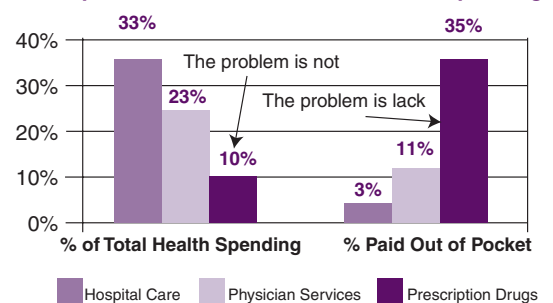
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Comparison of Total and Out of Pocket Spending



When taking into consideration the overall spending on health care, increased spending on drugs is the most cost effective way to reduce overall health care spending. For example, if a patient is faced with an option of hospitalization and surgery versus a prescription medicine, the cost for taking the medicine, even for a prolonged period of time, will almost always be a great deal less than the cost of the hospitalization. And, with the advancement in drug therapy, the drug treatment will generally offer the patient a higher quality of life and quicker recovery from the ailment. While the surgical option may be cheaper for the patient in terms of co-pay, it is certainly not the cheapest method for the healthcare system overall. This is one of the reasons constituents complain that the problem is not cost; the problem is a lack of coverage. The patients are being punished for choosing the appropriate option, not just for themselves but for the healthcare system overall, by having to pay an increased co-pay. The problem is a lack of understanding and appreciation by insurance companies and governmental agencies of the value we get from our pharmaceutical dollar.

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INDUSTRY CRITICISM & CHALLENGES

The pharmaceutical industry today faces many challenges in its efforts to bring a new drug to market, not just in the United States, but around the world. Government interventions, litigation, increasing expenses and public opinion all affect the development and pricing of pharmaceuticals. Increasing costs for research and development make it harder to discover and develop new drugs. The latest estimated costs for taking a drug from inception to market was placed at \$801 million in a 2001 study by Tufts University.

Criticisms of the pharmaceutical industry are wide spread and often include accusations of being too profitable and spending too much money on marketing. Other countries, where drugs are priced at a much lower rate than in the U.S., are often held up as a comparison to advocate lower prices. As stated previously, high prices for medicine in the U.S., however, are not the problem. Rather, the problem is lack of coverage for prescription drugs by insurance companies and government programs for a great proportion of our citizens.

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As they should be, pharmaceuticals are in fact the fastest growing component of health care. If pharmaceuticals were not continuing to be developed our overall spending on health care in this country would be a lot higher than it is now. While a visit to the doctor or hospital is often much more costly to the overall healthcare system than a prescription medicine, the cost is not often directly felt by the patient, hence the perception that prescription drugs are more costly. In fact, the cost for hospital stays and doctors visits is offset by the increased use of pharmaceuticals that help people stay healthier, longer.

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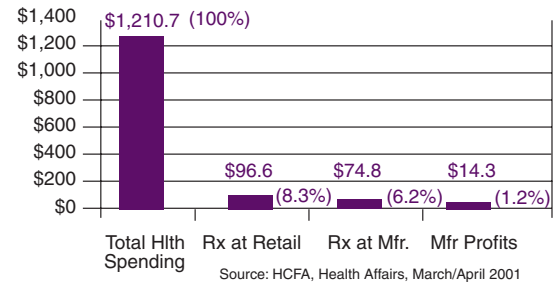
INDUSTRY PROFITABILITY

The pharmaceutical industry is frequently criticized and attacked because of its profitability. The question is, is it too profitable? If we look at some perspectives on profitability, we find that if we took manufacturer profits totally away it would only account for approximately 1.2 % of the total health care budget. Elimination of manufacturing profits would not affect, to any extent, our overall spending on health care.

“Profits are the horses that pull the research and development cart, without them there is no R&D.”

A major point to consider is that these profits serve a purpose, and that purpose is research and development. R&D spending is based on profits. Profits are the horses that pull the research and development cart, without them there is no R&D. It’s that easy. And without R&D there are no new drugs that help us to achieve our desired goal of increased longevity and quality of life.

Eliminating Drug Company Profits Won't Solve the Problem of Increasing Health Care Spending



THE COST OF DRUG DEVELOPMENT

As mentioned earlier, in a study conducted by Tufts University it was found that the fully capitalized cost to bring one new drug to market was, on average, \$801 million dollars. And while \$801 million is a large number we need to put it into perspective to fairly evaluate the pricing by pharmaceutical companies. For example, it would take the sale of two Boeing 747’s at \$400 million a piece to equal the price it would take to develop one new drug. The movie industry’s biggest movies like *Star Wars* and *Titanic*, with their blockbuster sales worldwide, still did not raise enough money to develop one new drug. So when we think about the large earnings by pharmaceutical companies we need to put it into perspective with other industry earnings and evaluate the usage of those monies against future outputs.

“For every 10% increase in profits over the last ten years there has been an 11% increase in research spending.”

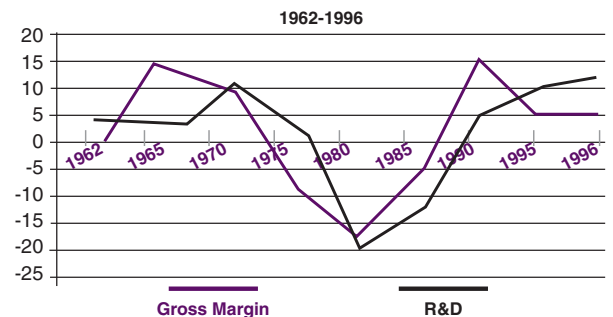
The money for the research and development of new drugs comes from profits. Profits drive research. For every 10% increase in profits over the last ten years there has been an 11% increase in research spending. But that relationship works in both directions. If profits decline, R&D spending has to decline. Companies have to look at where they spend the money they have.

PROFITS AND RESEARCH

The Center for Medicaid/Medicare studies states that it is difficult to show a correlation between R&D spending and the number of new drug launches. Spending money on R&D is not a guarantee of new drug launches. However, if you look at Frenchier’s work out of Harvard, gross margin profit is the best predictor of R&D spending. And while R&D spending is not a predictor of profits, profits *are* a predictor of R&D spending. Profitable companies spend money on R&D. Companies that spend that money the right way, on research that ultimately yields successful medicines, go on to be profitable.

The relationship between R&D and profits is often not that appealing to pharmaceutical companies. A recent study by *Bhagwat et.al.* found that for the average pharmaceutical company, a 1% change in R&D investment yields a 0.25% change in earnings. The R&D leverage in pharmaceuticals is lower than in many other

There is a Direct Relationship Between Gross Margins and R&D Outlays



however, we are finding that in several countries they are being held responsible for the increase in their pricing. For example, a few years ago when the Canadian dollar was rising in value relative to the US dollar it brought about a situation where a couple of pharmaceutical products, for a short period of time, actually cost more in Canada than they did in the U.S. As a result, the companies selling the products were forced to lower their Canadian prices.

THE CANADIAN CONTROVERSY

The price disparity between Canada and the U.S. is of particular concern to many legislators because of their proximity to the U.S., particularly to residents in New York State. Legislators often hear from their constituents that they go to Canada to buy drugs for lower prices. The problem we face is that Canadian law says that they will not accept a price on a pharmaceutical that is higher than 76% of the U.S. price (based on the Federal Supply Schedule price). Since they will not allow a price to go through that has a greater difference than this, Canadian prices will always be at least 1/4 lower than those in the U.S. At the same time, we have people in the U.S. saying that prices in the U.S. should never be higher than they are in Canada. Unfortunately, there is no way we can legislatively mandate these things on opposite sides of the boarder. Pharmaceutical companies will need to make a decision to either continue accepting lower prices or discontinue selling their drugs in Canada and risk losing those profits at the expense of future R&D.

THE EMERGING MEDICAL PARADIGM

The design of most health insurance plans is patterned after Medicare, a thirty-five year old plan from which unfortunately, pharmaceutical coverage got left out. Thirty-five years ago we had much less choice and availability in prescription drugs. Since 1965 pharmaceutical technology has evolved ten-fold with only two of the top 100 drugs listed in 1965 still listed today. That's a 98% increase in new drug development just in regards to our most widely used drugs. The problem we face today is that the system and method for treating illness and disease has changed but our coverage and reimbursement systems have not kept up with the changing technology or societal demands for increased quality of life with less invasive measures (i.e., drug therapy vs. surgery).

TRADITIONAL VS. EMERGING TREATMENT APPROACH

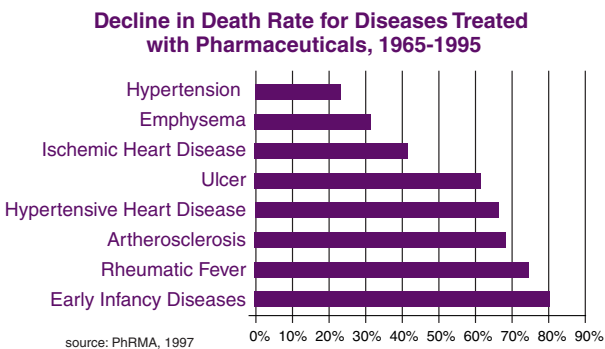
A big part of the problem is that people are fixed on the traditional medical paradigm (pre 1975) when the main focus was on the physician's treatment of acute episodic disorders. Physician training focused on high technology, "last stitch" rescues, and pharmaceuticals played a fairly minor role. Since then, drugs have become more central to the delivery of health care, reducing the need for other interventions but increasing the spending on prescription drugs. The result is that when we look at our budgets compared to historical spending, we note that our pharmaceutical budget used to be much less in proportion to our overall spending. As new drug therapies appear and supplant traditional treatments, expenditures continue to increase. For example, the use of diuretics went up by 18% which reflects an increase in our drug expenditures, but at the same time hospitalizations were decreased by 36%, representing a substantial savings overall.

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PHARMACEUTICALS AS THE NEW PARADIGM

A recent study by *Frech and Miller*, at UC Santa Barbara and the Center for Naval Analysis, looked at the twenty-one most developed nations, the OECD nations, and compared health care spending with the overall health of the nation. Their findings showed that pharmaceutical consumption has a positive and significant impact on life expectancy and a negative impact on health care spending. This means that the more the country as a whole uses pharmaceuticals relative to other health care interventions, the longer people live and the less they spend on other aspects of health care.

Another study by *Frank Lichtenburg* at Columbia University and NBER looked at the 1996 Medical Expenditure Panel Survey and compared the cost and the consequences of using new drugs versus using old drugs. Using federal government numbers, this study found that with every incremental dollar spent on new drugs versus old drugs, direct medical costs were reduced by roughly \$4, with three and a half dollars of that savings in hospitalization costs. In addition, the study found improved patient outcomes from use of the new drugs versus the older drugs. The biggest surprise from the study found that, even while people are spending more on pharmaceuticals for the newer, non-generic drugs, the overall expenditure on health care was lower, indicating that the improved pharmaceuticals are helping treat patients more effectively and saving costs in follow up physician visits and hospitalizations.



These recent research studies indicate that our economic well being in regards to our healthcare system flows from the use of pharmaceuticals through the reduction in other health care costs. Improvements in patient outcomes are leading to more productive, longer lives. And because patients are living longer due to the positive effects of pharmaceuticals, they are using more pharmaceuticals to remain

healthy and to treat new diseases they contract as they continue to age. This paradigm of using pharmaceuticals to remain healthy, which leads to more pharmaceutical use in the future, is the reason for the worry and complaints that are feeding the fear of increasing drug expenditures and overuse. But, if a society values longevity and high quality of life, and sets that as a goal to achieve, then the thinking about medical treatment and spending must be revised. As research has shown, the increased use of pharmaceuticals actually reduces the costs of health care and results in a higher quality of life. As a society improves and advances, a greater proportion of the wealth will need to be spent on medical care as people continue to live longer and longer.

REVISING THE HISTORICAL APPROACH

For the first several thousand years of human existence medical care was all about treating acute diseases. The role of the physician was to fix what was immediately wrong with the patient: a broken bone, an infection, some level of injury. For most of our history that is what physicians have been trained to do, with the ideology that the treatment relies totally in the realm of the provider. The provider (i.e. physician) makes all the decisions while the patient follows orders. Prevention (i.e. vaccines, sanitation, education) and treatment were the responsibility of the providers and public health system.

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As a society we have been very successful in treating acute diseases this way, especially through the advance of pharmaceuticals, that people are now living long enough to get chronic diseases. The person that doesn't have a heart attack and die at age 43 because of an effective drug therapy treatment is now going to live long enough to have hypertension and maybe diabetes. The shift we see taking place with fighting chronic diseases, is that it takes the provider and the patient working together to manage the treatment. If a patient doesn't want to control their hypertension or diabetes, it is not going to get controlled. The physician may continue to treat the diabetes today, however if the patient doesn't play a roll in managing the disease (lifestyle change, diet alteration) the chronic disease will not go away. Likewise, the prevention of many chronic diseases is up to the individual as well.

THE NEW SPENDING PARADIGM

The problem with the allocation in health care spending today is that we continue to view the system from the Treatment-Provider perspective, which is where all of our historic costs have come from. Most of our current, and almost all of our future costs, however, are going to take a fundamentally different structure to ensure that providers and patients work together. Patients will need to become more engaged in the prevention and treatment of their chronic diseases.

In order to successfully make this happen, we need to revise our current system that punishes the individual for using drugs (due to high costs from lack of coverage) and encourages them to use high cost alternatives such as surgery or hospitalization (covered by insurance).

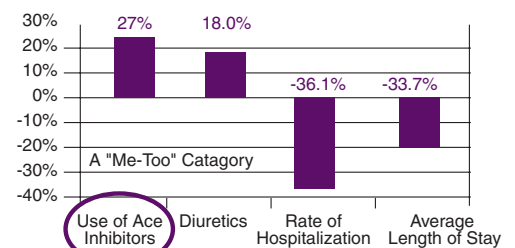
Unfortunately, most current efforts in regards to "fixing" health care spending are aimed at maintaining the status quo. Spending is separated into individual silos with different components and is not viewed as an overall expense. As new and more effective pharmaceuticals are developed the drug budget continues to grow at a much faster rate relative to the other budgetary components. When viewed separately this is seen simply as an increasing expense. When viewed as a portion of the whole, however, it can be shown as a cost saving.

BUDGETARY CONSTRAINTS

A big part of the solution would be to get rid of the budgetary silos that exist in our healthcare system. A solution is needed to provide an environment that enables the various parties to work together with government organizations to understand that health care items are not separate costs but that they are connected and affect one another.

We need to give pharmacy and budgetary authorities the tools and the desire to argue that they are not over budget, they are under funded. An experiment taking place in Asheville, NC, for example, shows pharmaceutical use is up almost two fold while total health care spending is plummeting because they are dealing with the high-cost chronic diseases such as

Effects of Disease Management Program For CHF



Source: PharmacoEconomics and Outcome News, Nov. 10, 2000: 289 9

“...we need to revise our current system that punishes the individual for using drugs (do to high costs from lack of coverage) and encourages them to use high cost alternatives such as surgery or hospitalization (covered by insurance).”

asthma, diabetes and congestive heart failure. They are proving that the cost for treating these diseases is easily manageable by getting patients involved and that proper drug therapy can result in substantial savings overall.

If we spend more money on pharmaceuticals instead of trying to place controls on how much we spend, it will pay us back in terms of overall health care savings. Medicaid recipients who are also on Medicare, have their prescriptions paid for and, as a result, save money for the Medicare system by reducing hospitalization and physicians visits. Instead of viewing prescription drugs as an add-on cost to Medicare we should focus on how much we would save if we got prescription medication to everyone who needed it.

“If we spend more money on pharmaceuticals instead of trying to place controls on how much we spend, it will pay us back in terms of overall health care savings.”

GOVERNMENT INTERVENTIONS

Consumer groups and governmental representatives in the U.S. continue to call for government interventions to slow down spending on prescription drugs and to reign in profits and lower prices. A long list of government interventions has evolved to slow spending but, unfortunately, they do not address the problem of adequate coverage.

A preferred drug list is one solution that is often suggested. However, we have seen through practice in other countries that this approach will not work if we want to maintain our desire to continue improving the quality and longevity of life as it will effect profits and as a result, stagnate R&D efforts. In low price, high-control countries, the pharmaceutical industry has been virtually eliminated and research is marginal at best. In other countries, as well as in some U.S. states, we have seen that lengthy approval processes have kept new drugs off the market which impair the ability of physicians to treat diseases more effectively. By limiting availability of new drugs through prior authorization, prescription caps or closed formularies we limit choices, limit successes and harm patients. We also spend more money in overall health care costs.

GOVERNMENT INTERVENTIONS

- Price Controls
- Direct price controls
- Forced price cuts
- Class reference pricing
- Parallel trade
- Cross-country reference pricing
- Volume Controls
- Marketing spending limits
- Product volume caps
- Lengthy approval processes
- Formularies
- Prior authorization (PA)
- Prescription limits
- All are intended to slow spending

Interventions limit innovation and are often based on a flawed premise, yet they continue to be advocated and discussed. Well known in the public policy arena is the desire to control an uncontrolled arena, to compare it with an ideal system and implement control. A common result, however, is that we find the controlled system is often inferior to the previous uncontrolled system. Allowing government interventions will further raise the risks of research and development by slowing the diffusion of new products into the system, and therefore limiting the rate of innovation. This approach will harm patients and cost more money to be poured into the healthcare system overall.

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“Allowing government interventions will further raise the risks of research and development by slowing the diffusion of new products into the system, and therefore limiting the rate of innovation.”

CONCLUSION

The US pharmaceutical industry is at a point where policy makers can have a tremendous impact, negative or positive, on how the healthcare system will operate in the future. In 2000, eight of the top ten medicines came from the US, and more and more companies were seen leaving Europe and other foreign countries due to increasing regulation issues. If the decision makers decide to choose the path of intervention and control we must face the choice that innovation and availability of drugs will be limited, and that must be a choice that we are willing to make. A choice that will result not only in poorer health care for our citizens, but in higher costs as well.


“Without the innovations and advancements in the research and development of new drugs, the overall spending in our healthcare system would be much higher than it is today.”

To summarize, pharmaceuticals are the most cost-effective health care resource that we have. Without the innovations and advancements in the research and development of new drugs, the overall spending in our healthcare system would be much higher than it is today. Budgets are being affected by the increase in drug usage as a result of the increasing availability of more innovative drugs to treat more illnesses effectively. And when examined closely, it is evident that the budgets are being affected positively, with an overall decrease in health care spending. However, with the system of healthcare silos that exist today, only a portion of the overall healthcare system is dealt with at a time and the increasing amount of money being spent on prescription drugs is not viewed in relation to the total spending, or savings, in the healthcare system.

If we want to save money in medical care as a whole, then policy makers need to make sure that they are taking the right approach towards solving the right problems, not just setting the goal of reducing the cost of prescription drugs. They need to consider the whole picture, including expenditures on hospitalization, physician's visits, drug therapy and insurance coverage, and not focus on them as individual silos with separate and individual functions. If we are to ensure a healthcare system that continues to advance in terms of meeting society's desire to maintain quality and longevity of life, than we need to understand the importance that drug research and development plays in meeting that result. And we need to revise our budgetary silos and monetary allocations to service that need.

The opinions expressed are that of the presenter, and do not necessarily reflect the opinions of any institutions with which he is affiliated, or of the sponsor.

The New York Health Products Council is a non-profit educational organization of the research-oriented pharmaceutical companies doing business in New York State. The Council's major objective is to improve the understanding of the important role of pharmaceuticals and the pharmaceutical industry in health care, and demonstrate the value off our member companies' contribution to the economic and technological vitality of the Empire State.



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