The Economic Impact of Legislative Market Intervention on the Life Science Industry: A Texas Perspective

Policy Report

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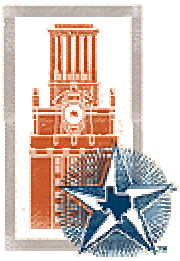

The Center for Pharmacoeconomic Studies
THE UNIVERSITY OF TEXAS AT AUSTIN

The Economic Impact of Legislative Market Intervention on the Life Science Industry: A Texas Perspective

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Since its establishment in 1994, The Center for Pharmacoeconomic Studies at The University of Texas at Austin has conducted economic and policy research on the impact of pharmaceutical services and products on patients' quality of life and health care outcomes in Texas and across the U.S. The Center serves as a bridge in bringing researchers together from different sectors of the health care delivery system, in addition to fostering collaborations with other academic institutions to disseminate scholarly findings. Researchers at the Center provide expertise in the areas of study design, methodology, data collection and analysis, and interpretation of economic and policy research. The Center also develops and presents educational programming to further the understanding of pharmacoeconomics and its role in the decision-making process within the health care delivery system.

Key Findings

- Between FY99 and FY00, overall expenditures increased by 19.4% within the Texas Medicaid Vendor Drug Program. The increase in expenditures was attributable to:
  - Price Inflation: 4.2% (21.6% of the increase)
  - Increased Utilization of Existing Drugs: 7.5% (38.7% of the increase)
  - New Drugs: 7.7% (39.7% of the increase)
- Nearly half of all Texas Medicaid Vendor Drug expenditures in FY00 were attributable to pharmaceutical products that had been approved within the previous 5 years.
- The driving forces in the rising expenditures have been a combination of:
  - State health policy decisions to increase access to prescription drugs (through the gradual movement of Medicaid clients into managed care delivery models); and
  - The introduction of newer pharmaceutical products, and their broad acceptance by Medicaid providers in treating disease.
- It is estimated that nearly $58 million in research expenditures within Texas public health-related institutions came directly from funding by pharmaceutical and biotechnology companies in FY99.
- Private funding by the pharmaceutical and biotechnology industries for research and development initiatives within Texas public health-related institutions contributed an estimated $192.2 million dollars in economic benefit to the state in FY99.
- Over the period of FY95 to FY99, the total economic benefit to the state of Texas derived from pharmaceutical and biotechnology funding within its public health-related institutions amounted to $870 million.
- The number of Texas residents receiving benefits from pharmaceutical industry-sponsored Patient Assistance Programs increased from 165,374 in 1998 to 203,011 in 1999, to an estimated 256,182 in 2000.
- In Texas, the value of the pharmaceuticals provided to indigent residents through Patient Assistance Programs has nearly doubled over the last two years, increasing from $55.2 million in 1998, to an estimated $99.2 million in 2000.
- Price control policies that decrease return-on-investment by up to 20 percent are estimated to shift a minimum of $31 million in funding per year away from the Texas biotechnology industry.
- Proposals that promote price controls on pharmaceuticals are well intentioned but may have unintended adverse consequences. The ability to create incentives for conducting complex, risky research is at the heart of an innovative, thriving drug-discovery industry here in Texas.

Introduction

Pharmaceuticals have been shown to be of value in the U.S. health care system by improving patients' health outcomes, reducing morbidity, and minimizing symptoms related to human diseases. Because of the risks associated with bringing a drug product to market, research and development costs, as a percent of total sales, within the pharmaceutical industry are higher than in all other U.S. industries. As the use of pharmaceuticals increases within the U.S. health care system, expenditures for prescription drugs have steadily risen. Health plan administrators currently use a variety of market-driven mechanisms in addition to cost-sharing arrangements with enrollees to manage the growth of prescription drug expenditures within their plans.

Recently, the steady rise in expenditures for pharmaceuticals has ignited discussion over the use of state-mandated price controls as a market intervention to slow or reverse the growth of spending on pharmaceuticals within publicly-financed prescription drug programs. While the intent of implementing these price controls is to allow citizens within the state continued access to cost-effective prescription drugs, research suggests that price controls may be counterproductive and result in adverse unintended consequences.

The possible implications related to pharmaceutical price controls within the state of Texas have not been critically studied. To address this, researchers at The Center for Pharmacoeconomic Studies at The University of Texas at Austin have authored this report in order to describe the possible intended and unintended effects of price controls here in Texas.

Objectives

The objectives of this report are: (1) to examine and discuss the factors related to increased public expenditures for prescription drugs in Texas; and (2) to describe the role of the pharmaceutical and biotechnology industry within the Texas economy and the resulting effects of state-mandated market interventions as they relate to the following:

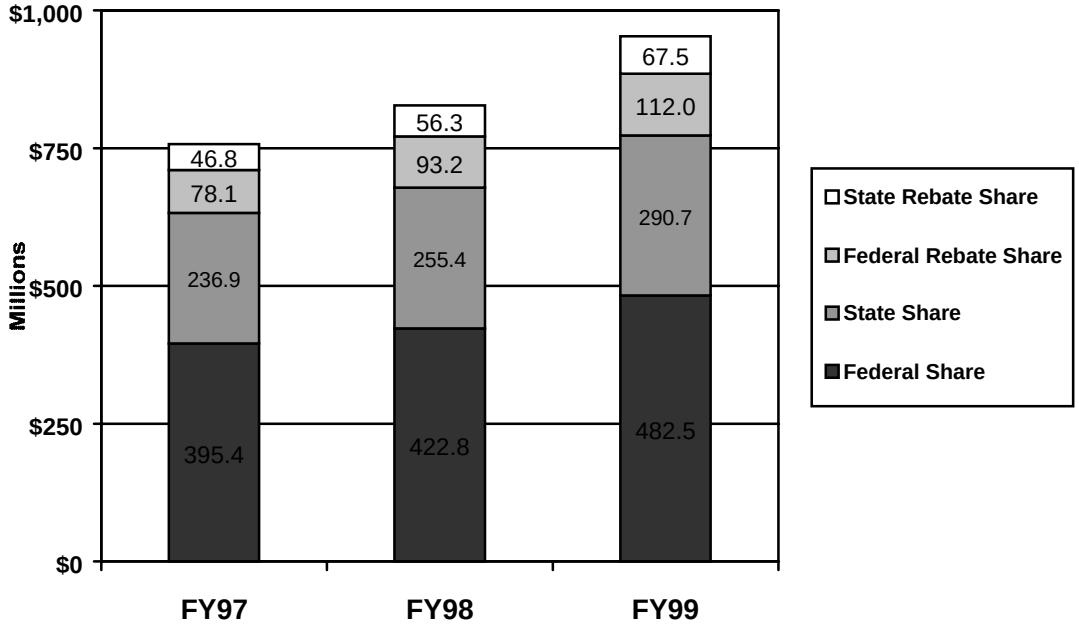
- Pharmaceutical industry-based private funding of research at Texas public health-related institutions;
- Pharmaceutical industry sponsored-patient assistance programs for Texas residents; and
- Growth and expansion of the Texas life science industry.

Trends in Public Spending on Pharmaceuticals in Texas

Expenditure increases over the last several years within state-financed pharmacy benefit programs such as the Employee Retirement System (ERS), the Texas Department of Mental Health and Mental Retardation (TDMHMR), and the Texas Medicaid Vendor Drug Program have drawn attention to the increased use of medications within these health systems. Costs for prescription drugs

within the ERS benefit plan reached $226 million in FY2000.[1] Spending on new generation medications within TDMHMR has put stress on current and future budgets. Finally, total prescription expenditures within the Medicaid Vendor Drug Program topped $1 billion in FY2000, an increase of over 19% in one year, of which the state share reached nearly $300 million (Figure 1).

Figure 1. Method of Financing by Component within the Texas Medicaid Vendor Drug Program



Source: Texas Department of Health

In order to identify the cost drivers behind these increases, The Center for Pharmacoeconomic Studies recently conducted a review of Texas Medicaid Vendor Drug claims data to analyze factors contributing to the expenditure increases over the three most recently completed state fiscal years.[2] In addition, comparisons were made to other published prescription drug expenditure trend data. The analyses focused on measuring changes related to: (1) price inflation, (2) increased prescription drug utilization, and (3) the use of newly approved prescription drugs. A summary of the analyses is discussed below. A description of the methodology used for the analyses can be found in the Appendix of this report.

Expenditure Growth in the Texas Medicaid Vendor Drug Program

Medicaid Vendor Drug expenditures increased from $800.1 million in FY98 to $915.5 million in FY99, an increase of $115.4 million (14.4%)(Table 1).

Table 1. Texas Medicaid Vendor Drug Expenditures FY98 to FY00

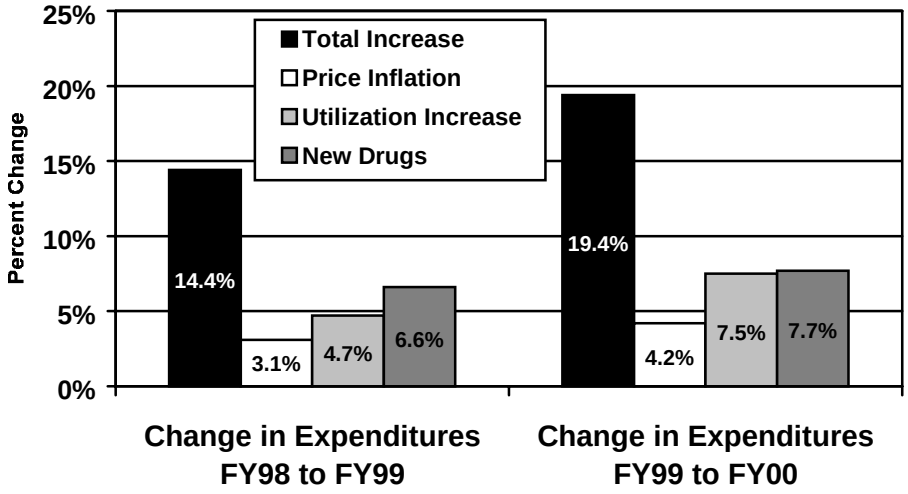
All Clients	FY1998	FY1999	FY2000
Total Expenditures	$800,061,095	$915,504,795	$1,092,912,603
Total Clients	1,901,898	1,836,771	1,838,515
Total Prescriptions	23,874,369	24,379,765	25,596,102
Expenditures/Client	$420.66	$498.43	$594.45
Expenditures/Rx	$33.51	$37.55	$42.70
Prescriptions/Client	12.55	13.27	13.92

Source: The Center for Pharmacoeconomic Studies, 2001

Between FY99 and FY00, the percentage increase rose to 19.4 percent. As a comparison, the FY98 to FY99 percentage increase is slightly less than the 15.4% increase in total U.S. prescription drug expenditures between 1997 and 1998.[3] However, the greater FY99 to FY00 percentage increase is consistent with reports summarizing prescription expenditure trends from other payers.

Between FY98 and FY99, inflation accounted for an increase of 3.1 percent in prescription expenditures (Figure 2). This is very close to the 3.2 percent increase between 1997 and 1998 in prices for existing drugs reported nationally.[4] Between FY99 and FY00, inflation accounted for an increase of 4.2 percent in drug expenditures.

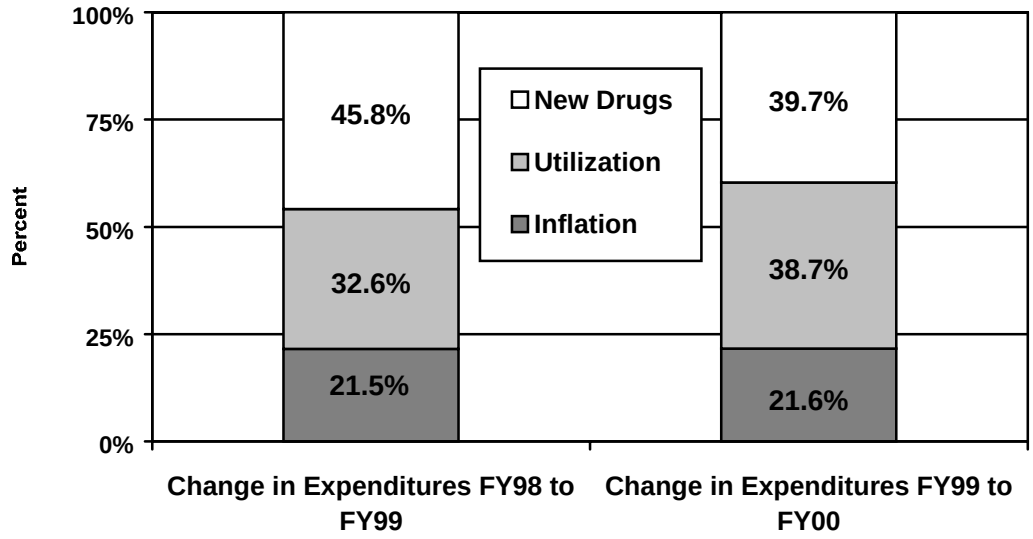
Figure 2. Comparison of Expenditure Component Increases within the Texas Medicaid Vendor Drug Program



Source: The Center for Pharmacoeconomic Studies, 2001

Therefore, of the 14.4% increase in overall costs from FY98 to FY99, price inflation contributed to only 21.5% of the total increase. Inflation rates also remained steady between FY99 and FY00, accounting for 21.6% of the 19.4% increase (Figure 3).

Figure 3. Proportion of Texas Medicaid Vendor Drug Expenditure Increases Accounted for by Inflation, Utilization, and New Drugs



Source: The Center for Pharmacoeconomic Studies, 2001

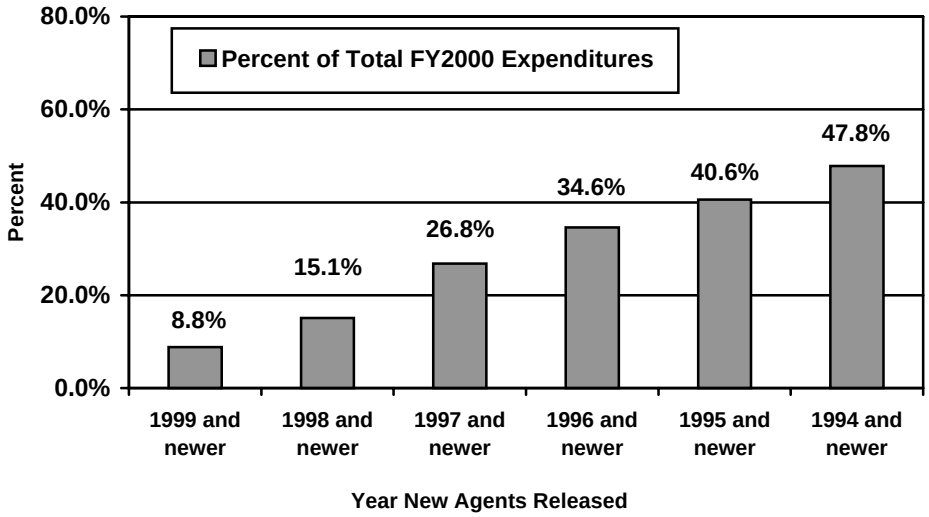
Changes in utilization of medications accounted for an increase of 4.7 percent in prescription expenditures between FY98 and FY99 (Figure 2). This increase represented 32.6 percent of the 14.4 percent total increase in expenditures (Figure 3). Between FY99 and FY00, the increase in expenditures attributed to changes in utilization was 7.5 percent (or 38.7% of the 19.4% total increase), somewhat higher than the FY98-FY99 comparison. A closer analysis seems to indicate that the effects of gradually moving Medicaid clients into managed care pilot programs in Dallas County and other areas has been a contributor to the increase in utilization of prescriptions. Prior to moving into the managed care pilot programs, clients over the age of 21 and not residing in a long-term care facility were limited to three paid prescriptions per month. Once the client enrolled in the managed care plan, the restriction on the number of prescriptions was waived.

Between FY98 and FY99, the introduction of new drugs accounted for an increase of 6.6 percent in prescription expenditures (or 45.8% of the 14.4% total increase). Between FY99 and FY00, the increase in expenditures attributed to the introduction of new drugs was 7.7 percent (or 39.7% of the 19.4% total increase).

As shown in Figures 2 and 3, the strongest driver of the increase in Medicaid Vendor Drug expenditures during the last three fiscal years was the introduction and utilization of new drugs. Increased utilization of existing drugs was the second strongest factor related to the increase in drug expenditures. Further analysis showed that the increased use of new medications was highest among clients aged 65 years or

older and those clients who may have been affected by the rollout of managed care pilot programs, described earlier.

Figure 4. Expenditures for Newer Pharmaceutical Agents within the Texas Medicaid Vendor Drug Program



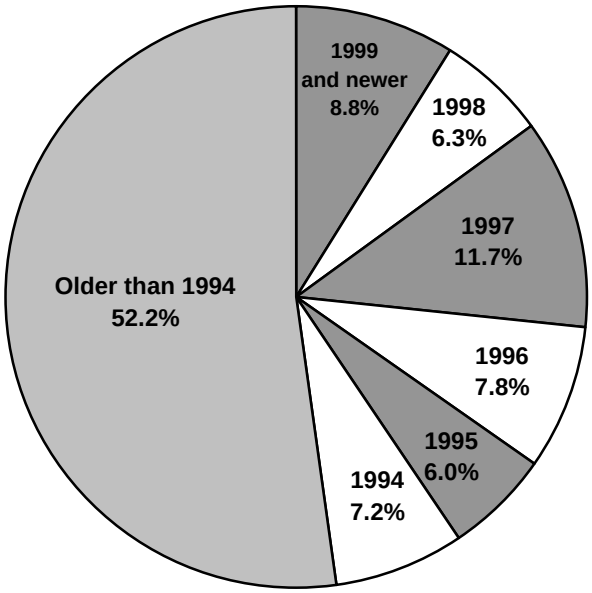
Source: The Center for Pharmacoeconomic Studies, 2001

Clearly, Medicaid clients receiving prescription drugs through the Vendor Drug Program have been allowed access to the most advanced therapies currently available. Figure 4 shows that nearly half of all Vendor Drug expenditures in FY00 were attributable to pharmaceutical products that had been approved within the previous 5 years. A breakdown of the products used during FY00 by the year of introduction into the market is provided in Figure 5.

Of the drugs accounting for the highest increase in expenditures between FY99 and FY00, two products (Celebrex® and Vioxx®) represent new therapies for treating arthritis.[5] In addition, two others (Risperdal® and Zyprexa®) belong to a new generation of treatments for schizophrenia and other mental health disorders.

A recent study by the Center, included in a report by the Texas Health and Human Services Commission, found that where the use of Risperdal® and Zyprexa® had increased within a Medicaid client population in Harris County, inpatient hospitalizations for schizophrenia had moderated, or even decreased, over time.[6] While more research is needed to draw system-wide conclusions, the study supports the anecdotal theory that these new generation medications may be offsetting health care expenditures in other sectors of the Texas Medicaid Program.

Figure 5. FY2000 Proportion of Expenditures for Newer Pharmaceutical Agents within the Texas Medicaid Vendor Drug Program Based on Market Release Date



Source: The Center for Pharmacoeconomic Studies, 2001

It should be noted that: (1) the number of clients decreased between FY98 and FY99, and increased only slightly between FY99 and FY00; and (2) the mean number of prescriptions per client increased by 5.7 percent between FY98 and FY99 (from 12.6 to 13.3) and by 4.9 percent between FY99 and FY00 (from 13.3 to 13.9). Thus, it appears that intensity of use is playing an important role in utilization-related increases.

Finally, inflation effects accounted for the smallest proportion of the drug expenditure increases (Table 1). The Texas Medicaid Vendor Drug Program reported that in FY99, 84 percent of payments to dispensing pharmacies were for drug ingredient costs, leaving 16 percent of payments for dispensing fees.[7] The current prescription payment formula used by Medicaid has been in place since September 1997. Therefore, pharmacists' dispensing fees represent a relatively small proportion of total drug expenditures, and the observed inflation effects are primarily attributable to changes in drug unit costs.

In summary, Texas Medicaid Vendor Drug expenditures growth has not been largely caused by price inflation, as some may have previously suggested. Rather, the driving forces in the rising expenditures have been a combination of: (1) state health policy decisions to increase access to prescription drugs (through the gradual movement of Medicaid clients into managed care delivery models); and (2) the introduction of newer pharmaceutical products, and their broad acceptance by Medicaid providers in treating disease.

Because the newest medications are being heavily used within both public and private health care plans in other states, similar trends in rising pharmaceutical

expenditures have been widespread across the country. While some see this trend as an opportunity to create legislation that injects artificial interventions into the current free-market environment for the development of pharmaceuticals, this trend may also be seen as a transition period where pharmaceuticals play an even greater role in patient therapies, thus increasing their share of total costs without increasing overall costs, proportionately.

Unfortunately, with all of the attention drawn to pharmaceutical expenditures, little discussion has focused on the fact that over the last few years, hospital spending, nationally, has decreased from 37% to 33% of total health care spending and physician services have remained consistent at 20% of spending.[8] We suspect that the increased use of prescription drugs has had a positive impact on those trends.

Pharmaceutical Innovation in the U.S. and Texas

The pharmaceutical industry has long been one of the nation's leading industrial sectors. The degree to which intellectual property is developed and commercialized for distribution to patients by the U.S. pharmaceutical industry earns it the distinction as one of the few American industries that truly leads the world in its class. Nevertheless, as pharmaceuticals increasingly attain a primary role in regimens to treat disease, the industry has been singled out for criticism by some who charge that the industry's requirement for ensuring profitability may come at the expense of reducing access to those who cannot afford the cost of medications.

What, exactly, is the driving force that largely determines the cost of medications used in the U.S.? Consider, that, of every 5,000 drug compounds produced in laboratories across this country, on average, only 5 of those (less than 1 percent) eventually progress on to human testing in clinical trials. Of those 5 that make it to human testing, only 1, on average will clear Food and Drug Administration (FDA) approval for marketing to the public. Even with the great strides in drug discovery, molecular biology, and receptor modeling, 99.98% of drugs discovered in the laboratory will never be safe or effective enough to treat human diseases. On average, the development cost incurred to successfully bring a drug to market is estimated to be $500 million.[9] Through the coordination of the FDA and the assessment of additional fees paid by pharmaceutical companies, noticeable improvements have been made to the approval process. Additional staffing for reviewing clinical trial and new drug application submissions have helped to decrease the time necessary for final review of a drug before marketing. Nonetheless, it takes an average of 12-15 years to take a drug through the discovery and development process before it receives final approval.[10] Obviously, some take less time and others may take longer.

As mentioned earlier, a drug developed to treat schizophrenia, Zyprexa®, is a compound in a new class of agents that shows effectiveness in treating patients with mental disorders while lessening the tendency to cause irreversible side effects that have been linked to earlier generations of antipsychotic agents. These new agents accounted for substantial expenditures within the Texas Medicaid Vendor Drug Program in FY00. The development of the novel drug was not simple and without risk. Researchers at Eli Lilly and Company, the product's manufacturer, formulated a total of 83 separate compounds and took 12 years to develop the molecule that eventually showed safety and effectiveness in one of the largest patient clinical trials ever

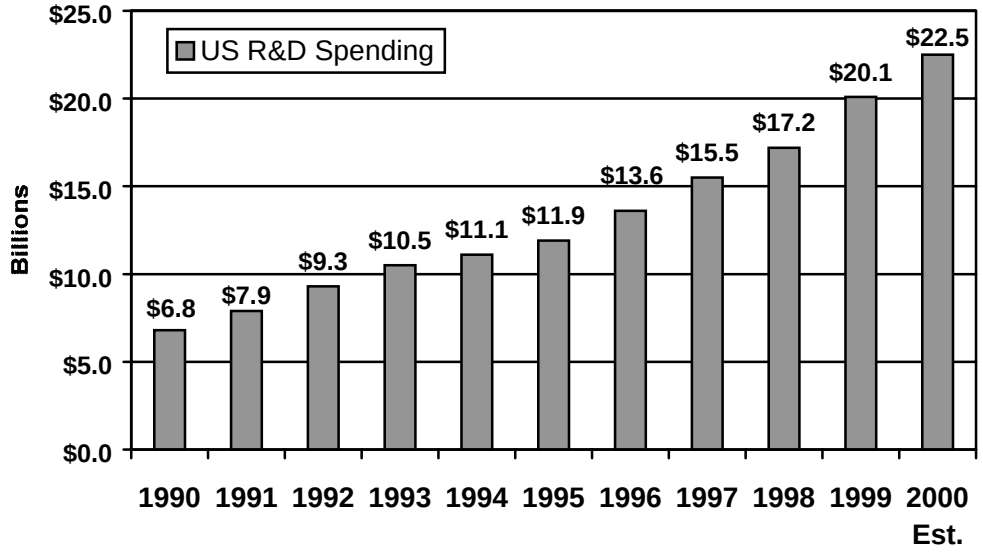
conducted for a drug to treat schizophrenia. After 22 years of development and testing, the drug finally reached the market in late 1996. Along with other agents in its class, it has been used increasingly by Texas residents to treat mental illness while decreasing long-term side effects.

Several Texas biotechnology companies are currently testing products in varying stages of the development process, with funding largely provided by risk-based venture capital firms. Examples of products developed within Texas include: (1) a recently approved product to treat lymphocytic leukemia (ILEX Oncology, San Antonio); (2) a cancer gene therapy product entering the final phase of clinical trials (Introgen Therapeutics, Austin); and (3) a peptide to treat diabetic ulcers in early stages of clinical trials (Chrysalis Biotechnology, Galveston), among many others.

Trends in Research and Development Spending in the U.S.

Pharmaceutical companies spent an estimated $22.4 billion in the United States in 2000 for research and development of promising new drug compounds (Figure 6). These expenditures for 2000 were 10.1% higher than expenditures for 1999.

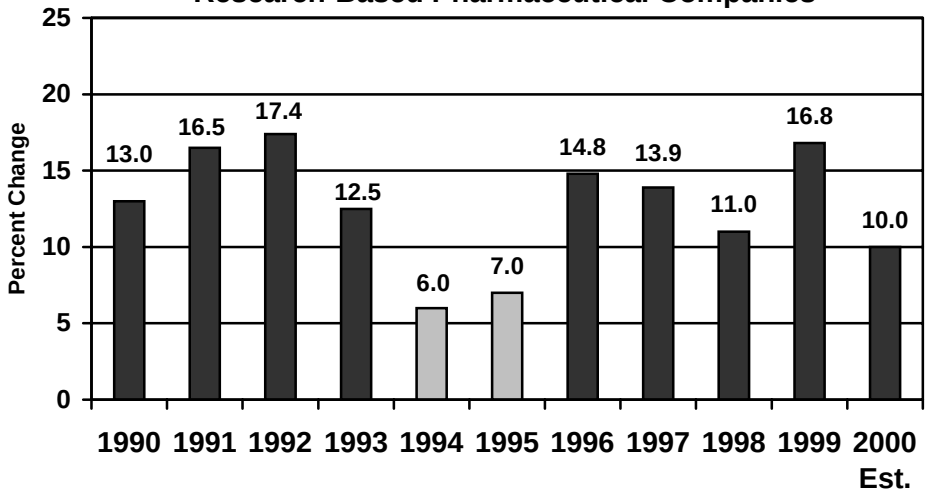
Figure 6. Domestic U.S. R&D Expenditures by Research-Based Pharmaceutical Companies



Source: PhRMA, 2000

Growth in R&D spending has maintained a consistent range of 10 to 18% increases over the last 10 years. The only exception to this trend occurred in 1994 and 1995. At that time, spending for R&D slowed to rates of 6.0% and 7.0% per year, respectively, then resumed its robust growth by more than doubling the rate to 14.2% in 1996 (Figure 7).

Figure 7. Annual Percent Change in Total U.S. Research and Development Spending by Research-Based Pharmaceutical Companies



Source: PhRMA, 2000

The downturn in spending growth was directly attributable to the uncertainty over impending government intervention in the pharmaceutical marketplace as a by-product of the proposed Clinton Health Care Agenda debate of 1993 and 1994. The proposed reforms, which would have augmented the free and open U.S. market for developing drug products, ignited reactionary measures on the part of pharmaceutical companies. One of the responses was to curtail R&D budget growth in order to compensate for marked depletion of future revenue streams within the marketplace. It has been estimated that this period of decreased expansion resulted in a total of $1.8 to $1.9 billion in research spending that was foregone.[11]

Over the last twenty years, spending on research and development, as a percent of total sales, has increased from 11.9 percent of sales in 1980 to an estimated 20.3 percent of sales in 2000. Pharmaceutical companies consistently allocate higher proportions of their sales to research and development, compared to other industries. For example, in 1999, pharmaceutical companies spent significantly more on R&D (20.8% of sales) than the computer software (9.3%), electronics (6.4%) and telecommunications (5.7%) industries.[12] The increasing complexity of discovering molecules, in addition to research in genetic mapping and the additional regulations required for human testing during the clinical trial process have contributed to the increased proportion of spending by the industry.

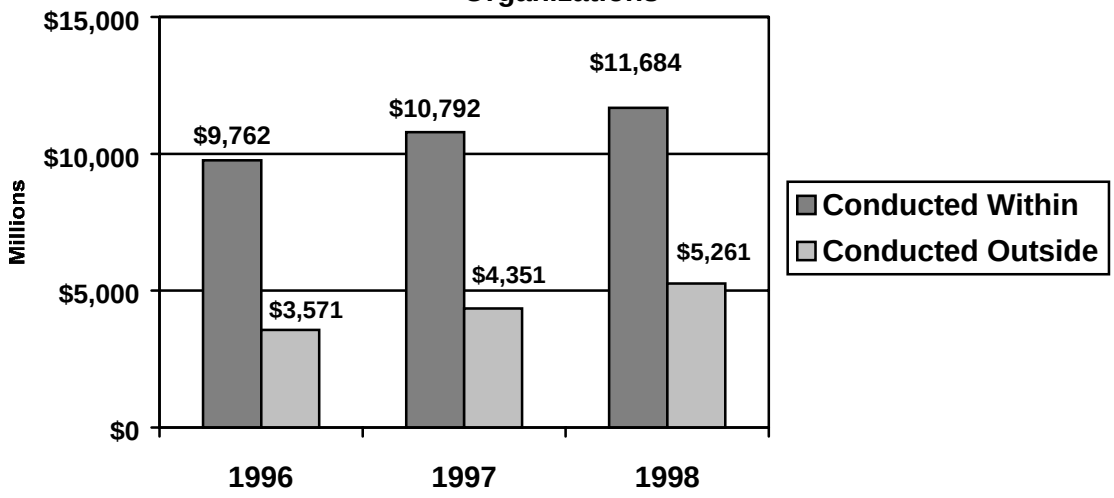
Research and Development Expenditures in Texas

While the majority of research and development expenditures occur within the confines of pharmaceutical companies' own laboratories and organizational sites, an increasing proportion of total expenditures is occurring through contracts with outside entities, such as public and private educational and medical institutions and private contract research organizations and consultants. Figure 8 shows that the proportion of R&D expenditures that are spent outside the firm's walls has increased recently from

26.8% of total domestic expenditures in 1996 to 31.1% in 1998.[13] These "outside of firm" expenditures amounted to over $5.2 billion in 1998, and were distributed to public and private research centers across the U.S.

Research sponsored by the pharmaceutical industry is conducted at every major public and private university and health-related institution in the state. The funds expended to support the ongoing research initiatives within these institutions is used to fund things such as equipment, faculty and researcher salaries, fellowships, graduate research, and all other services that support the research function within the respective departments. Privately-funded research by the pharmaceutical industry complements the institutions' federal and state funding sources acquired through grants and interagency contracts.

Figure 8. Proportion of Domestic R&D Expenditures Conducted Within and Outside Research-Based Pharmaceutical Organizations



Source: PhRMA, 2000

In addition, the state of Texas is home to privately- and publicly-held contract research organization companies that conduct and coordinate clinical trial functions for the pharmaceutical industry. These companies may actually conduct the trials within the state at participating clinical sites or, as is often the case, may coordinate the trials at sites across the US and the world, depending on the particular patient population being studied.

The pharmaceutical industry is a major contributor to privately funded sources of research expenditures within the Texas Higher Education System. Research is supported in many areas, including engineering, biological and life sciences, and physical sciences. However, the greatest amount of funding is directed towards supporting research and development activities within Texas medical schools.

The Economic Impact of Research and Development Initiatives at Texas Public Health-Related Institutions

A December 2000 report by the Texas Comptroller's Office investigated the economic impact of research and development expenditures within the state's higher education system whose source was from out-of-state entities. The report noted that the category defined as "medical sciences" was one of the greatest beneficiaries of research-related expenditures within the Texas higher education system. In 1998 alone, $506 million was expended (not merely awarded) by these institutions in order to research diseases such as cancer, cardiovascular disease, and diabetes, a condition known to have a higher prevalence within the Hispanic population in Texas.[14]

In order to determine the economic impact to the state of total (public and private) out-of-state funded research conducted within the state institutions, a specific multiplier was used to calculate the annual economic impact that the state receives in return. The methodology chosen is a commonly used input/output analysis that has applications across many industries.[15] Based on previous studies in the area, the Texas Comptroller's Office assigned a multiplier of 3.32 for out-of-state funding and revenue within higher education systems. In other words, for every dollar brought in from out-of-state to support research initiatives, $3.32 is derived by the state's economy as a benefit of the additional resources provided.

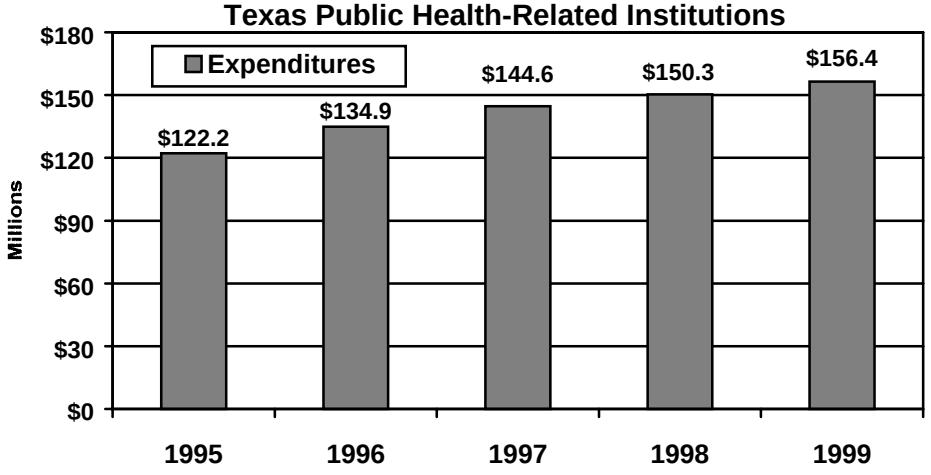
Estimating Life Science Industry-Funded Research in Texas

In order to estimate the expenditures for research conducted within Texas higher education institutions that is directly funded by pharmaceutical and biotechnology companies, the Center collected data from the Texas Higher Education Coordinating Board.[16] The data included research expenditures per fiscal year by the type of research conducted and the source of the research funding. Because the data did not provide information detailed enough for the objectives of this report, additional data was requested from individual institutions in order to determine if the source of expenditures was a pharmaceutical or biotechnology company. Data was not collected from the Baylor School of Medicine, a private institution, as it is does not report expenditures to the Texas Higher Education Coordinating Board. Furthermore, specific data was not available from non-health related institutions. While life science companies are assumed to fund research at all institutions, we focused on the public health-related institutions due to the clinical nature of the research conducted.

Figure 9 shows the total privately-funded research and development expenditures for Texas public health-related institutions since FY95. Growth in expenditures has appeared to moderate over the last two to three years. Figure 10 shows that a large proportion of private funding supports cancer research within the Texas institutions.

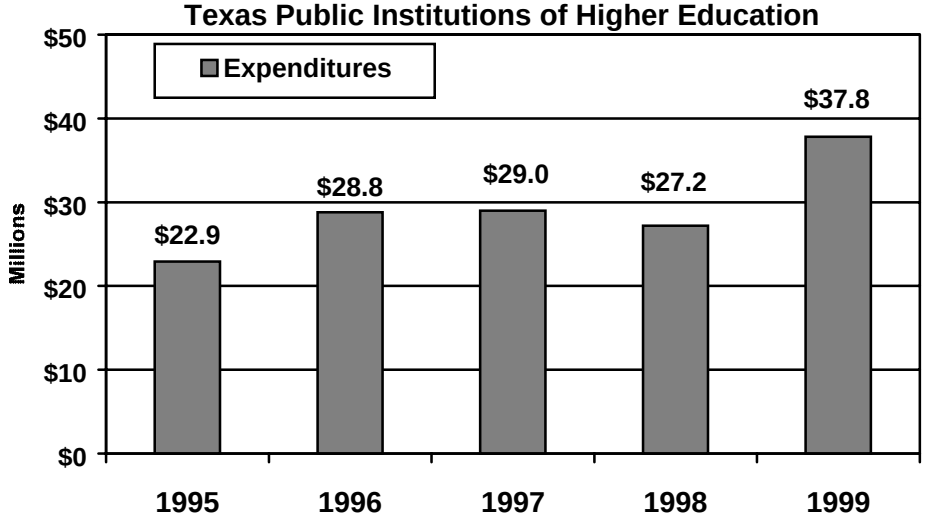
Based on information supplied by a sample of medical schools here in Texas, it is estimated that the life science industry is the source for approximately 40% of all privately-funded research expenditures within these institutions.

Figure 9. Privately-Funded Expenditures for Conduct of Research and Development within Texas Public Health-Related Institutions



Source: Texas Higher Education Coordinating Board, 1996-2000

Figure 10. Privately-Funded Expenditures for Conducting Cancer Research within Texas Public Institutions of Higher Education

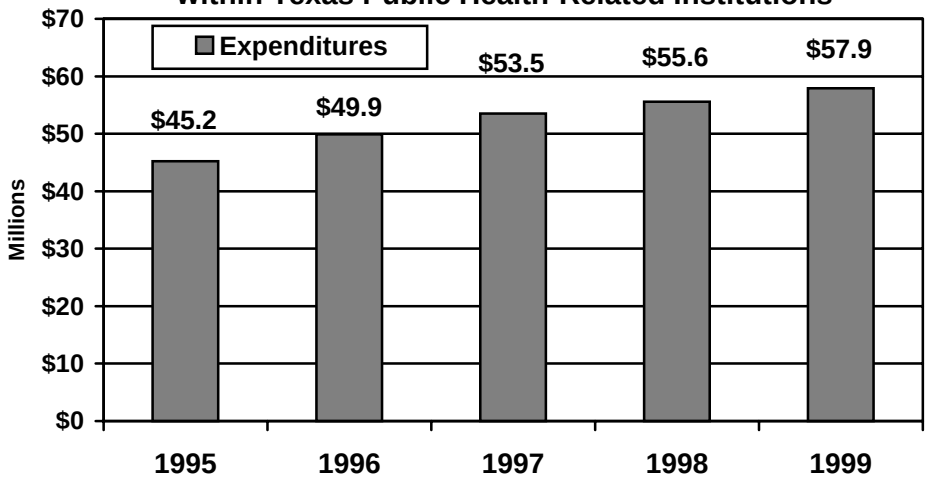


Source: Texas Higher Education Coordinating Board, 1996-2000

As an example, a Texas public health-related institution had nearly $10 million in research expenditures in FY99 that was funded directly by pharmaceutical or biotechnology companies. This represented 37% of the institution's total privately-funded expenditures for research and development.

Using this same proportion of funding as a standard across all public medical schools in Texas, it is estimated that nearly $58 million in research expenditures came directly from funding by pharmaceutical and biotechnology companies in FY99. Using the same methodology, it is estimated that $55.6 million in research expenditures was funded directly by these industries in FY 1998 (Figure 11.) Again, these figures do not measure awarded or pledged amounts but, rather, actual amounts spent by the institutions.

Figure 11. Estimated Pharmaceutical/Biotech Company Funding of Research and Development Expenditures within Texas Public Health-Related Institutions

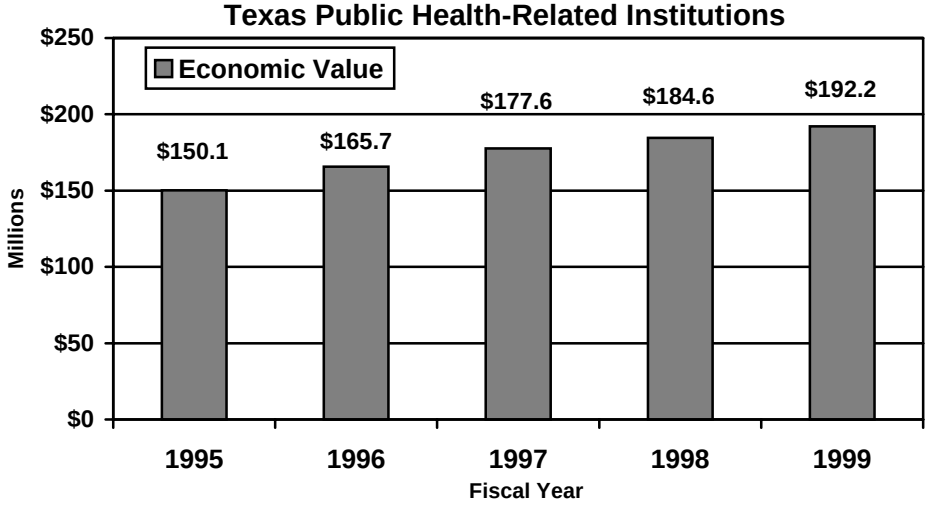


Source: The Texas Higher Education Coordinating Board, 1996-2000
The Center for Pharmacoeconomic Studies, 2001

Based on the pharmaceutical and biotech company-funded expenditure data collected for this report, and using the methodology employed by the Texas Comptroller's Office with the assumption that funding from the pharmaceutical industry meets the standards to be considered out-of-state dollars, private funding by the life science industry for research and development initiatives within Texas public health-related institutions contributed an estimated $192.2 million dollars in economic benefit to the state in FY99 (Figure 12). Over the period of FY95 to FY99, the total amounts to $870 million in economic benefit to the state of Texas.

While pharmaceutical company-sponsored research and development expenditures within Texas public health-related institutions have steadily increased over the last 4 years, the rate of growth is subject to the same variations that were seen during 1994 and 1995, when the rate of increase in total R&D spending slowed dramatically.

Figure 12. Estimated Economic Impact within Texas of Pharmaceutical/Biotech Company-Sponsored Research in Texas Public Health-Related Institutions



Source: The Texas Higher Education Coordinating Board, 1996-2000
Texas Comptroller's Office, 2000, The Center for Pharmacoeconomic Studies, 2001

In the event of widespread state-mandated market interventions, growth in funding would be expected to slow, as it did before, and over time the total amount of out-of-state funds funneled to research programs here in Texas would be expected to diminish, proportionately.

Other Forms of Support Provided by Pharmaceutical Companies

In addition to funding contracted research, pharmaceutical companies also provide resources in the form of outright gifts or unrestricted grants to higher education institutions which are often used for supporting educational programming within departments.

Because the Texas Higher Education Coordinating Board does not collect information on these types of grants, they were not considered in this analysis. The support and funding of medical, nursing and pharmaceutical continuing education programs by the pharmaceutical industry also was not considered.

In addition to providing funding for research and development initiatives within the state of Texas, pharmaceutical companies also contribute to the Texas economy through acts of charitable donations. Among the largest programs are Patient Assistance Programs for indigent citizens.

Industry-Supported Patient Assistance Programs in Texas

Patient Assistance Programs (PAP) represent a voluntary philanthropic endeavor by pharmaceutical companies to improve access to prescription drugs for patients that are, typically, uninsured or lack prescription drug coverage, and lack the means to purchase medications with their own resources. These programs are considered to be a last resort for patients whose health may be jeopardized without prescription drugs, and are not typically designed to offer long-term prescription coverage. Nearly all

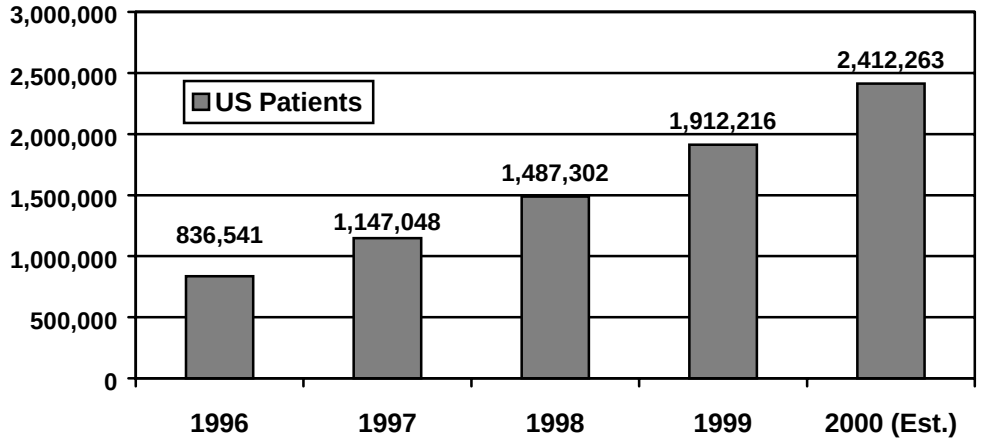
research-based pharmaceutical companies have established a PAP. A recent GAO report detailed the results of a survey of pharmaceutical companies offering PAPs for some or all of their marketed pharmaceutical products.[17] The GAO concluded that these programs may provide valuable assistance to a small share of the uninsured population.

The process for enrolling patients in a PAP is initiated by the patient's health care provider. While the process for verifying eligibility for the program may vary from company to company, most programs require the provider to apply for assistance on behalf of the patient. Some programs, however, do allow a patient to apply directly to the pharmaceutical company. Applications are supplied to providers by pharmaceutical company sales representatives at the request of the provider. Many pharmaceutical companies have coordinated the eligibility process through the establishment of separate organizations that accept applications for many companies.

Typically, the pharmaceutical products are sent directly to the patient's provider after the application for assistance has been approved. It is uncommon for a patient to incur any charges related to shipping costs or other dispensing fees.

Data provided by the Pharmaceutical Research and Manufacturers Association (PhRMA) on the national impact of Patient Assistance Programs is provided in Figure 13. The total number of patients, nationwide, who have received benefits from the voluntary programs since 1996 has nearly tripled in the last five years, increasing to an estimated 2.4 million patients in 2000.[18]

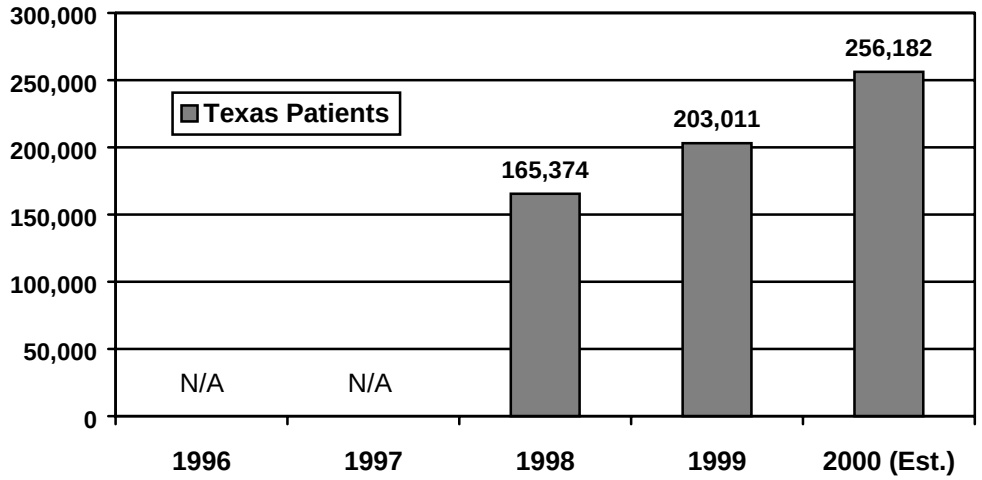
Figure 13. Industry-Sponsored Pharmaceutical Patient Assistance Programs Beneficiaries



Source: PhRMA, 2000

Likewise, in Texas, the number of patients who have been served by the program has seen a steady rise. Over a quarter of a million Texas residents are estimated to have received medications in 2000 (Figure 14). The number of Texas residents receiving benefits from the program increased from 165,374 in 1998 to 203,011 in 1999, to an estimated 256,182 in 2000.

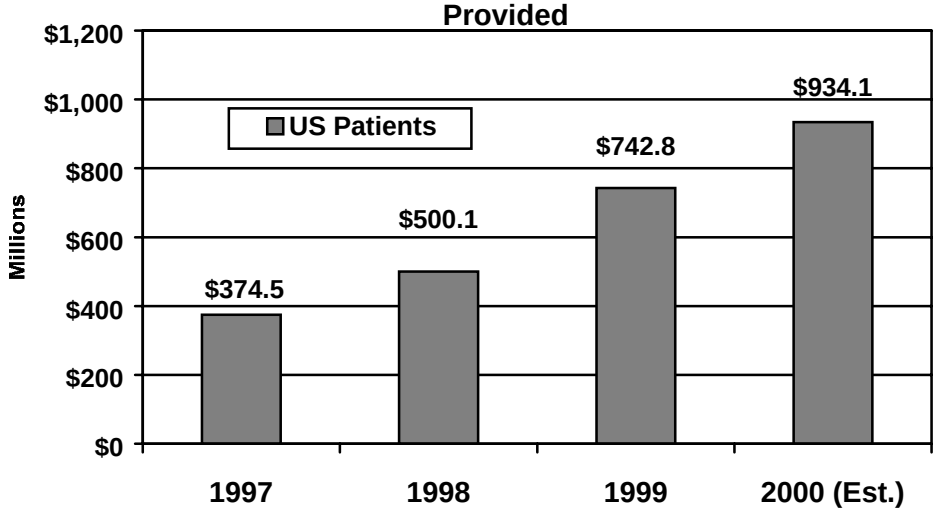
Figure 14. Industry-Sponsored Pharmaceutical Patient Assistance Programs Beneficiaries in Texas



Source: PhRMA, 2000

The value of the medications distributed to needy residents in the U.S. in 2000 amounted to nearly $1 billion when calculated in terms of wholesale pricing of the drugs (Figure 15). Following earlier described trends, this figure has nearly tripled in the last five years.

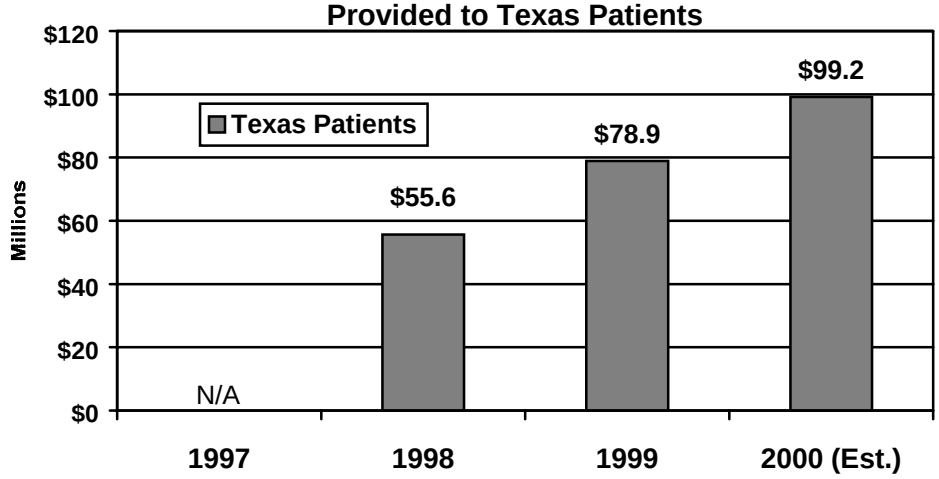
Figure 15. Industry-Sponsored Pharmaceutical Patient Assistance Programs Value of Medications Provided



Source: PhRMA, 2000

In Texas, the value of the pharmaceuticals provided to residents since 1996 has nearly doubled over the last two years, increasing from $55.2 million in 1998, to an estimated $99.2 million in 2000 (Figure 16).

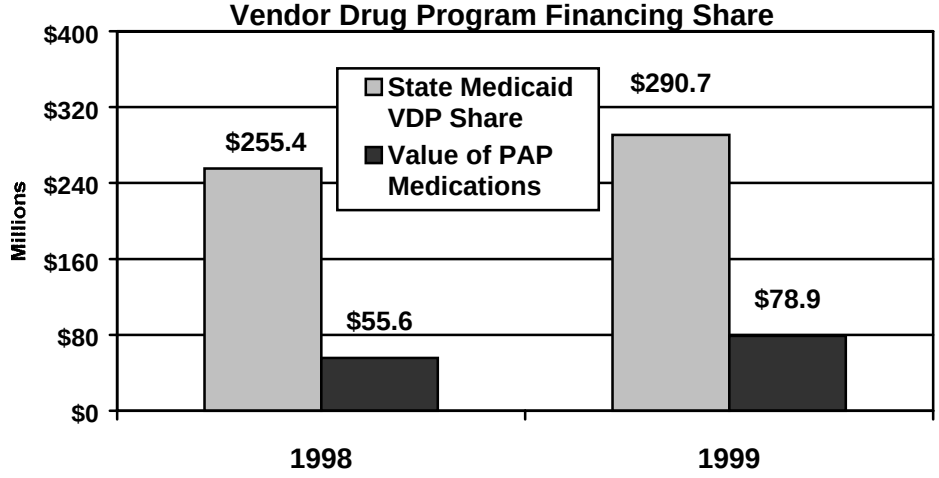
Figure 16. Industry-Sponsored Pharmaceutical Patient Assistance Programs Value of Medications Provided to Texas Patients



Source: PhRMA, 2000

When the value of pharmaceuticals provided to indigent patients in Texas in 1999 is compared to the total state-financed share of the Texas Medicaid Vendor Drug Program from FY99, the impact of the PAPs is put into perspective. In FY99, for every $3.68 that the state financed as part of the Texas Medicaid Vendor Drug Program, pharmaceutical company PAPs contributed an additional $1 in donated pharmaceutical products to needy residents in Texas (Figure 17). Note that while the reporting period for the PAP is given as a calendar year rather than the state fiscal year, comparisons can still be made.

Figure 17. Comparison of the Value Provided by Patient Assistance Programs in Texas and the State Medicaid Vendor Drug Program Financing Share



Source: PhRMA, 2000, Texas Department of Health

While the trend in providing access to medications for these patients as a "last resort" is increasing among the pharmaceutical companies, the degree to which these types of programs can exist depends largely on the revenues derived from paying

segments in the private and public sectors. Market interventions that would disallow free market negotiations between suppliers and purchasers and replace them with a capped revenue scheme of price controls would certainly affect the degree to which companies could afford to support the existence and continued growth of these Patient Assistance Programs here in Texas and across the U.S.

The Growing Healthcare Technology Cluster in Texas

As a means to create synergies among segments within a growing industry such as biotechnology, "clusters" may be formed in geographic locations. As with most high technology industries, the right mix of intellectual resources, entrepreneurship, and capital investment opportunity are necessary to create these synergies. These clusters have been defined as competing, complementary, and interdependent firms that create wealth within the geographic region.

Through the efforts of public and private entities here in Texas, an evolving healthcare technology cluster that includes biotechnology companies has been developing. While the viability of this cluster is extremely sensitive to changes in the political and economic environment within Texas, a recent report shows that the healthcare technology cluster has continued to grow within Texas, employing 50,650 people in 1999. The rate of job growth in Texas within the industry has slowed over the last three years (1997-1999), however, with an average annual growth rate of 1.4%. This compares to an average annual growth rate of 3.2% over the period 1990 to 1997. The average wage paid for jobs within this industry is $48,623, much higher than the average state wage of $34,936.[19]

The industry also contributes to the Texas economy through indirect means. Economic activity is created within the non-biotechnology industries that support the functions of the biotechnology community here in Texas. Examples include clinical contract research organizations and computer hardware and services industries. The impact of the indirect effect can be measured in terms of a multiplier. A recent report calculated the indirect effect of 2.9 additional indirect jobs that are created for every one biotechnology job that is created.[20]

Perhaps at no other time has the establishment of a growing biotechnology industry in Texas appeared to be so promising. The large contributors of intellectual properties, Texas' public health-related institutions, have steadily increased research and development initiatives that are producing possible candidates for development and commercialization into marketable therapies to benefit the residents of Texas by improving their quality of life and increasing the productivity of its workforce. However, without a means of attracting appropriate entities to license the molecules for potential commercialization, the potential benefits of the work of researchers may never be realized.

In order to ensure adequate capitalization and investment in these high-risk companies, the political and economic environment must be attractive to potential investors. Venture capital remains one of the main sources of funding that is used within the biotechnology industry to create commercialized products from the discoveries of the laboratories.

The trend in attracting venture capital for investments in biotechnology in Texas is promising. In 1999 alone, Texas biotechnology and other health-related companies

received $160 million in funding from venture capital firms. This represents a 101% increase over the two previous years, outpacing the 74% total for the rest of the United States.[21]

However, due to the direct relationship between the degree of capital invested in these high-risk ventures and the expected returns on those investments, perhaps no other segment of the life sciences industry is more susceptible to the unintended adverse consequences of price control policies than the recently-established fragile biotechnology industry in Texas.

Price controls equate to a lowering of return-on-investment and, with a lowered return-on-investment, venture capital would be more likely to seek alternative investment candidates than those offered within the developing cluster here in Texas. Although the cluster in Texas continues to develop, until concentrations of innovative research and commercialization components develop to the degree seen in other locations across the country, the biotechnology industry will remain extremely sensitive to any interventions on ensuring an adequate return to investors.

As a means of predicting the long-term effects of economic policy decisions on the biotechnology industry in Texas, a model is being jointly developed with Arthur Andersen and The Center for Pharmacoeconomic Studies. Preliminary results has estimated that a simulated environment where price control policies decrease return-on-investment by up to 20 percent can have highly negative effects on the Texas biotechnology industry. Over time, these negative effects are estimated to shift a minimum of $31 million in funding per year away from the Texas industry to less risky areas of the country where the life science clusters are more established.

At a time when public and private entities are creating an environment to foster and grow the healthcare technology clusters in Texas, economic policies promoting price controls would have a disastrous effect on the developing and promising biotechnology industry here in Texas.

Why Pharmaceutical Price Controls in Texas Should Be Avoided

Because direct market interventions have been previously avoided in the U.S., the only case studies to draw upon with regard to pharmaceutical price controls are from other countries. Recent history has showed us that mandated market interventions rarely realize the long-term effects that were originally intended. Artificial market interventions have been shown to have a short-lived effect on pharmaceutical spending; however, over the longer run, research has failed to show any difference in long-term spending growth rates between countries with and without price controls in place.[22]

Based on experiences with price control regulation in foreign countries and other U.S. industrial sectors, evidence shows that price controls have never been beneficial. In the 1970s, price controls on oil and natural gas led to a widespread, artificial shortage of the commodity. Price controls on rental property led to housing shortages and the deterioration and neglect of existing housing. The present crisis in electric power in California can also be indirectly attributed to price controls.

Few would dispute the fact that innovative pharmaceutical and biotech products are anything but commodity items; however, implementing price controls within an industry that is constantly driving and advancing science is essentially treating pharmaceutical products, as such. Certainly, any short-term benefits derived from treating research-intensive pharmaceuticals in the same manner as auto insurance would be far outweighed by the negative effects of decreasing incentives for advancing risky cutting-edge research and development. Once in place, pharmaceutical price control legislation would lead down a slippery slope, spilling over into other sectors of health care.

Mechanisms such as capping expenditures on pharmaceuticals are flawed because this creates a "silo" mentality that does not promote the use of cost-effective therapies that provide benefits within other health care delivery sectors. Furthermore, limits that attempt to control the "supply-side" of pharmaceutical spending typically fail because in order to set the limits, an "appropriate" level of prescribing must be determined. As the mix of individuals, and their associated health care needs, changes within a population, so too, will the appropriate level of prescribing particular classes of agents.

Proposals that promote price controls on pharmaceuticals are well intentioned but may have unintended adverse consequences. We assume that Texas residents believe that progress in medical research should go further and that the movement into the next revolution of pharmaceutical discovery is worth the additional costs and risks.

As noted by Calfee, the distinguishing features of the U.S. pharmaceutical marketplace that place it at an advantage over foreign countries is the collective synergies between capital mobility and risk-taking, public willingness to invest in risky projects, flexible labor markets, prudently regulated advertising and promotion, and an absence of controls over prices and essential core activities.[23] In essence, the ability to create incentives for conducting complex, risky research is at the heart of an innovative, thriving drug-discovery industry here in Texas and the U.S.

Notes

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Appendix

Medicaid Claims Analysis Methodology

A tenet central to this analysis is that expenditure changes result from: (1) changes in prices for drugs (inflation), (2) changes in utilization of existing drugs, and (3) the introduction of new drugs into the marketplace. The third factor (new drugs) actually has characteristics of both utilization and inflation. Its utilization effects result because the introduction of a new drug changes utilization from zero to some positive amount. Its inflation effects arise because the new drug may be a close, but more expensive substitute for an existing product. However, allowing the inflation and utilization effects of new drugs to be included with the inflation and utilization effects of existing drugs distorts the effects of both. Therefore, new drugs are treated separately in this report. The methods used to calculate the changes in drug expenditures attributable to inflation, utilization, and new drugs are described briefly below.

The expenditure change from FY98 to FY99 attributed to inflation was calculated by finding the FY98 to FY99 difference in mean per-unit (e.g., tablet or capsule) payment for each unique medication dispensed in both periods, then multiplying this difference by the number of units dispensed in FY99, and summing across all medications. This process was repeated to determine the FY99 to FY00 change. This amount represents the additional expenditures actually incurred over what would have been incurred had prices for existing products not changed. It should be noted that per-unit payments decreased between periods for some medications, but increased for most medications.

The expenditure change attributed to changes in utilization is composed of changes related to population (number of clients) and intensity (number of prescriptions per client). However, changes in population and intensity do not necessarily correspond to equal changes in expenditures. For example, a 10 percent increase in population does not always lead to a 10 percent increase in expenditures. Therefore, the population and intensity effects are combined into the expenditure change attributed to utilization. This was calculated for drugs available during the entirety of both comparison periods (i.e., existing drugs) by the following method. For each drug, the expenditure change between periods due to inflation was subtracted from the total expenditure change between periods. Then, the resulting expenditure changes for each drug attributed to utilization changes were summed across all drugs. As before, expenditure changes attributed to utilization changes were positive for some drugs and negative for others.

The expenditure change attributed to the introduction of new drugs was calculated for the FY98-FY99 comparison by the following method. For drugs that were introduced in FY99, all expenditures were attributed to new drugs. For drugs that were introduced sometime during FY98, the expenditure change between periods due to inflation was subtracted from the total expenditure change between periods. This process was repeated for the FY99-FY00 comparison.

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Texas Life Science Foundation

The mission of the Texas Life Science Foundation is to promote a greater understanding of the Texas bioscience community, which includes medical, agricultural, and environmental sciences, through education and the exploration of new approaches to technology research, development, and commercialization in the State.