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The Georgetown Public Policy Review
3600 N Street, NW
Suite 200
Washington, DC 20007
phone: (202) 687-8477
fax: (202) 687-5544
e-mail: gpprevw@georgetown.edu

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Preface

Rapid advances in chemistry, biology and computer science have created a new frontier of medicine, one in which pharmaceuticals are relied upon to save lives and improve the quality of life in ways that humans never dreamed possible when today's Medicare recipients were born. As science has advanced rapidly, so has the cost for medicines. Those costs come at least in part from a more elaborate approval process needed to assure drug safety, and consumers' desires for life-saving or life-improving drugs only seem to increase as more drugs roll onto the market.

Unfortunately, escalating drug prices have made the cost of providing pharmaceuticals prohibitive for public health insurance programs—such as Medicare—and on those in less developed nations who might not make in a year what pharmaceutical companies charge for AIDS treatment.

This issue of Georgetown Public Policy Review examines these problems under the theme, "Pharmaceuticals: Politics, Availability and Pricing." The issue includes a paper by Henry Grabowski on the economic incentives of the patent process for pharmaceutical and biotechnology companies. Another paper, by Rhonda Kay McPherson, focuses on the gaps in drug coverage for the Medicare population and attributes that should be included in any future Medicare drug benefit.

In interviews with the Review, experts on Medicare prescription drug benefits and the problem of getting medicines to AIDS patients in Africa offer their thoughts on those issues. U.S. Senator Jay Rockefeller (D-West Virginia) provides insight into the financial barriers and political problems that Congress has faced in trying to pass a Medicare drug benefit. M. Kenneth Bowler of Pfizer Inc. offers a drug company's perspective on the push for pharmaceutical benefits.

Georgetown research professor of law Timothy Westmoreland and Dr. Eric van Praag of Family Health International discuss the problems and barriers associated with getting drugs to AIDS patients in Africa.

For those who hunger to broaden their policy interests beyond pharmaceutical issues, the book reviews focus on the topics of education policy and environmental policy. Duncan Chaplin, a researcher at the Urban Institute's Education Policy Center and an adjunct GPPI professor, offers thoughts on a new book tackling issues around randomized trials in education research. Monisha Shah of the U.S. Department of Energy analyzes a work on the intersection of the environment and corporate behavior.

On a personal note, I'd like to note the tremendous commitment put forth by the Review staff—in particular a group of dedicated and hard-working editors—who are the driving force behind this journal. As always, we welcome your questions and comments.

Steve Robblee
Editor
Patents and New Product Development in the Pharmaceutical and Biotechnology Industries

HENRY GRABOWSKI
Duke University

This paper examines the rationale for intellectual property protection in the development of new pharmaceutical products. Prior survey studies of R&D executives have found that patents play a more critical role in appropriating the benefits of innovation in pharmaceuticals compared to other high tech industries. This paper considers why this is so, based on an analysis of the economic characteristics of R&D costs and returns in the pharmaceutical and biotechnology industries. The final section examines recent policy developments and issues surrounding patent lifetime and generic competition in this industry.

Editor's Note: This paper is based on a presentation to the Dallas Federal Reserve Bank in April 2002. A similar version of the paper will be published by the Dallas Fed in "Science and Cents: The Economics of Biotechnology."

INTRODUCTION

Grilliches, in a 1992 survey paper, found that high social returns to research and development (R&D) are a major factor underlying the growth in per capita income and consumer welfare during the 20th Century (Grilliches 1992). Many of the studies done by economists on this topic have found that the social returns to R&D are more than twice the private returns. A primary reason for this finding is that positive externalities are generally associated with industrial innovations. As F.M. Scherer stated in his leading graduate text in industrial organization, "Making the best use of resources at anytime is important. But in the long run it is dynamic performance that counts." (Scherer 1980, p. 407)

The pharmaceutical and biotechnology industries, which are among the most research-intensive industries, have been the focus of several studies on cost-benefit and social return on R&D studies. Cutler and McClellan (2001) surveyed a number of studies that investigate the impact of new drugs on increased longevity, worker productivity, and savings in other types of medical expenditures. They find significant aggregate net benefits to society from new drug introductions.
Their analysis is consistent with many cost-benefit analyses targeted toward specific medical conditions such as cardiovascular disease, depression, and infectious disease. These studies have also found high incremental social benefits from new drug innovation.1

Another general finding of the academic literature is that public policy actions can have a significant influence on the rate of innovation in particular industries. Among the key industrial policies influencing the innovative process in pharmaceuticals are the public support of biomedical research, patents, Food and Drug Administration regulatory policy, and government reimbursement controls (Towse 1995). The focus of this paper is the role and impact of patents and intellectual property protection in the discovery and development of new pharmaceutical and biotechnical products.

The importance of patents to pharmaceutical innovation has been reported in several cross-industry studies. Richard Levin et al. (1987) and Wes Cohen et al. (1997), have undertaken surveys of U.S. R&D managers, in a large cross-section of industries, to identify the most important and necessary factors in appropriating the benefits from innovations. These factors included the competitive advantages of being first in the market, superior sales and service efforts, the secrecy and complexity of productions and product technology, as well as patents. Both studies found that the pharmaceutical industry placed the highest importance on patents. By contrast, many other research-intensive industries, such as computer technologies, scientific instruments, and semiconductors, placed greater stress on factors like lead-time and “learning by doing” efficiencies in production accruing to first movers. This reflects the fact that R&D investment periods and product life cycles are typically much shorter in these industries. Furthermore, their new products often involve complex systems of many components as opposed to the discrete nature of new chemical and biological entities. As a consequence, the costs of imitation relative to the costs of innovation are much higher in many other high-tech industries compared to pharmaceuticals.

The findings of these studies are in accordance with an earlier study performed by the British economists Taylor and Silberston (1973). Based on a survey of R&D managers in the UK, they estimated that pharmaceutical R&D expenditures would be reduced by 64 percent in the absence of patent protections. By contrast, the corresponding reduction was only 8 percent across all industries. Similar findings were reported by Edwin Mansfield, in a survey of the research directors of 100 U.S. corporations.2

Some individuals have called for the abolishment of pharmaceutical patents on the grounds that they give rise to excessive profits and high prices on new medicines (Baker 2003). However, the suggestion that the government could replace the $27 billion dollar R&D effort of the private pharmaceutical industry, and produce an equivalent stream of new pharmaceutical products, is highly problematic on both economic and public policy grounds. Opponents of drug patents also ignore the fact that new products lead to social welfare gains for consumers, even when supplied by a single
firm under a patent exclusivity grant. In addition, price competition occurs in the pharmaceuticals market under the current system when closely substitutable medicines in the same therapeutic family are introduced. Finally, there is intensive price competition when the originating brand’s patents expire and generic entry occurs.

The following sections of this paper examine the economic characteristics of the R&D process in pharmaceuticals that make patents so critical. Sections II through IV discuss the costs of innovation in pharmaceuticals and the effects on innovative and imitative competition of the 1984 Hatch-Waxman Act. Section V considers whether the biotech industry is different from the pharmaceutical industry in terms of R&D costs. Section VI considers the distribution of returns on R&D in these industries. The final section presents conclusions and policy considerations.

**R&D Costs for a New Drug**

The explanation for why patents are more important to pharmaceutical firms in appropriating the benefits from innovation follows directly from the characteristics of the pharmaceutical R&D process. It takes several hundred million dollars to discover, develop and gain regulatory approval for a new medicine. Absent patent protection, or some equivalent barrier, imitators could “free ride” on the innovator's FDA approval and duplicate the compound for a small fraction of the originator’s costs. Imitation costs in pharmaceuticals are extremely low relative to the innovator’s costs for discovering and developing a new compound.

One of the reasons why R&D is so costly in pharmaceuticals is that most new drug candidates fail to reach the market. Failure can result from toxicity, carcinogenicity, manufacturing difficulties, inconvenient dosing characteristics, inadequate efficacy, economic and competitive factors, and various other problems. Furthermore, the full R&D process from synthesis to FDA approval involves undertaking successive trials of increasing size and complexity. Typically, many thousands of compounds are examined in the pre-clinical period for every one that makes it into human testing. Only 20 percent of the compounds entering clinical trials survive the development process and gain FDA approval (DiMasi 1995). The pre-clinical and clinical testing phases generally take more than a decade to complete (Kaitin and DiMasi 2000).

In a recently completed study, DiMasi et al. (2003) have examined the average R&D cost for drugs introduced into the market in the late 1990s. Data were collected on R&D costs for a randomly selected sample of 68 investigational drugs from 10 multinational firms. DiMasi, et al. found that the representative new product approval incurred out-of-pocket costs of over $400 million. This includes money spent in the discovery, pre-clinical and clinical phases as well as an allocation for the cost of failures.

Figure 1 shows a breakdown of total R&D costs per approved drug incurred during the pre-clinical and clinical R&D phases. Expenditures in the clinical period account for roughly 70 percent of total out-of-pocket expenditures. This reflects the fact that clinical trials are very expensive on a
per patient basis; many drugs must be tested for every one approved, and drugs that do make it to the final testing phase and FDA submission typically require pre-market testing on thousands of patients.

Figure 1 also shows R&D costs capitalized to the date of marketing at a representative cost of capital for the pharmaceutical industry of 11 percent. The average capitalized R&D cost for a new drug introduction during this period is $802 million, or nearly double the out-of-pocket expenditure. Capital costs are high in this situation because of the long time periods involved in pharmaceutical R&D. More than a decade typically elapses between initial drug synthesis and final FDA approval. Since pre-clinical expenditures occur several years prior to FDA approval, these costs are subject to greater compounding at the industry cost of capital of 11 percent. Therefore, they account for a greater proportion of total capitalized cost compared to total out-of-pocket costs (42 percent versus 30 percent).

R&D costs per new drug approval in the 1990s increased at an annual rate
of 7.4 percent above general inflation when compared to the costs of the 1980s approvals. Major factors driving this increase are the complexity and number of clinical trials, which have increased significantly in the 1990s compared to the 1980s. One important factor underlying this trend is the pharmaceutical industry's increased focus on chronic and degenerative diseases; such conditions require larger trial sizes to establish efficacy and longer time periods for observation.

A number of factors could alter the growth pattern for future R&D costs. Emergent technologies may have profound effects on R&D productivity in the next decade. The mapping of the genome, and related advances in fields like proteomics and bioinformatics, has led to an abundance of new disease targets. Some industry analysts have hypothesized that these developments may actually cause R&D costs to rise in the short run (Lehman Brothers 2001). The basic reason is that these new technologies require substantial investments up front, and to date they have generated many disease targets and receptor sites that are not yet well understood. Eventually, expansion in the scientific knowledge base should lead to substantial efficiencies in the R&D process for new pharmaceuticals.

THE HATCH-WAXMAN ACT: BALANCING INNOVATIVE AND IMITATIVE COMPETITION

The patent system is the public policy instrument designed to balance the trade-offs between property rights protection and imitative competition. Without a well-structured system of global patent protection, neither the research pharmaceutical industry nor the generic industry would be able to grow and prosper, and the rate of new product introductions and patent expirations would decline significantly.

Effective patent life (EPL), defined as patent duration from a product's market launch date, is an important variable influencing R&D incentives in this industry, because it takes many years to recoup the R&D costs and earn a positive return for a typical new drug introduction. Because firms apply for patents at the beginning of the clinical development process, significant patent protection is lost by the length of FDA approval time. This implies a significant reduction in the effective patent life of drugs relative to the nominal life of 20 years. In light of this, the United States, the European Community and Japan have all enacted patent term restoration laws.

The U.S. law in this regard, the Hatch-Waxman Act, has been in existence since 1984. Hatch-Waxman provides for patent term restoration of time lost during the clinical development and regulatory approval periods, up to a maximum of five years additional patent life. This law also facilitates faster generic product introduction by allowing generic firms to file abbreviated new drug applications, in which generic firms must only demonstrate bioequivalence to the pioneer's products to obtain FDA approval. Prior to the passage of Hatch-Waxman, generic firms had to submit their own proof of a compound's safety and efficacy, as well as show bioequivalence.

Under the act, generic firms can also conduct bioequivalence testing
and FDA submissions in the pre-patent expiration period so that they can enter the market immediately after patent expiration or invalidation. In addition, the Hatch-Waxman Act allows a generic drug manufacturer to file a "Paragraph 4 Certification" challenging the validity of the patent granted to the branded drug, which in turn triggers up to a 30-month stay while the matter is being litigated. If the challenge is upheld, the generic drug gets a 180-day exclusivity period where no other generic drug is allowed to enter.\textsuperscript{8}

Grabowski and Vernon (2000) have investigated the effects of Hatch-Waxman on both generic competition and effective patent lifetimes. Figure 2 shows the trends in EPLs by approval year for the new drugs introduced in the first half of the 1990s. This figure indicates that the average EPLs in the 1990s center around an 11- to 12-year range.\textsuperscript{9} The mean for all 126 new drug introductions in the 1990-1995 period is 11.7 years with an average Hatch-Waxman extension of 2.33 years. In the last two years of this period, when virtually all of the drugs involve compounds that entered clinical testing after 1984, the average extension is close to three years in length. The mode of the frequency distribution of EPLs for this sample of annual new drug introductions is in the interval of 12 to 14 years.
GENERIC COMPETITION SINCE THE ACT

In contrast with new product introductions, the development costs of generic compounds are relatively modest. In the United States, since the passage of the 1984 Hatch-Waxman Act, generic products need only demonstrate that they are bio-equivalent to the pioneering brand to receive FDA approval. Generic firms can file an Abbreviated New Drug Application (ANDA), a process that takes only a few years and typically costs a few million dollars (CBO 1998 and Reiffen and Ward 2002). Also, the probability of success is very high, as reflected by the fact that many generic firms file to receive FDA approval and enter the market within a short window of opportunity around patent expiration of the pioneer brand.

A distinctive pattern of competitive behavior for generic and brand name firms has emerged in the wake of the 1984 act. First, commercially significant products experienced a large number of generic entrants within a short time after patent expiration, in sharp contrast to what occurred in the pre-1984 period. Also, in the post-1984 period, a strong positive relationship between the size of the market and the number of generic competitors can be noted in accordance with expectations from economic theory.

Second, generic drugs exhibited a high degree of price competition after 1984. The initial generic product entered the market at a significant discount compared to the brand name product, and this discount grew larger as the number of generic competitors for a particular brand name product increased over time. In a study of commercially significant products from 1984 to 1989, Grabowski and Vernon (1992) found that generic prices averaged 61 percent of the brand name product during the first month of generic competition. This declined to 37 percent by two years after entry.

Third, a more rapid rate of sales erosion in brand name products was observed in the case of more recent patent expirations. This is especially so for the top selling drug products which attract the most intensive generic competition. Three recent cases illustrate this phenomenon. Generic enalapril, launched in August 2000 as a substitute for the brand name drug Vasotec®, obtained 66.4 percent of new prescriptions just four weeks after its launch. Generic lisinopril, launched in May 2001 against the brand name drugs Zestril® and Prinivil®, acquired 84 percent of new prescriptions in four weeks. Generic fluoxetine, launched in August 2001 against the brand name drug Prozac®, acquired 74.9 percent of new prescriptions in four weeks.

The Congressional Budget Office (CBO 1998) has also done an analysis of the economic effects of Hatch-Waxman. As in Grabowski and Vernon’s analysis, they found that generic competition has been a powerful force for price competition since 1984. The CBO estimated annual savings of $8 billion to $10 billion to consumers by the mid-1990s. In terms of R&D incentives, however, they found that Hatch-Waxman has had negative effects on the expected returns on R&D. In this regard, they estimated that the act, together with the increased demand side incentives promulgated by managed care organizations in order to utilize generic products in the 1990s, has resulted in steadily accelerating erosion of pioneer-brand’s sales in the period after generic entry.
Overall, price competition and generic utilization have increased dramatically since the Hatch-Waxman Act was passed. In 1984, generic products accounted for approximately 14 percent of all prescriptions. By 2002, the figure was 51 percent. The growth of managed care and other related demand-side changes have been important factors underlying this rapid increase in generic usage. However, the passage of the 1984 act played a critical role by relaxing the regulatory hurdles for generic firms and facilitating higher levels of generic entry.

**Are the Innovation and Imitation Costs of New Biotech Entities Different?**

Most of the analyses of R&D costs for new drug entities and their generic imitators have focused on small molecule new chemical entities. This reflects the relative youth of the biotech industry. New biologic entities were first introduced in the 1980s. By 1994, only 29 new biological entities had been introduced into the U.S. market, but this number has increased dramatically since then. In this regard, 41 new biological introductions occurred between 1995 and 2001.

The newest R&D cost study by DiMasi et al. (2003), includes seven biotech compounds, in a sample of 69 entities, for which data were obtained from ten major pharmaceutical and biopharmaceutical firms. While this sample of biological entities is too small to be representative of all biotech development, the clinical phase costs in the DiMasi, et al. study were similar for the biotech and pharmaceutical projects.

As discussed earlier, capitalized R&D costs per new drug introductions are influenced by a number of factors. These include out-of-pocket costs at the preclinical and clinical phase, the probability of success for new drug candidates at different stages of the R&D process, and the length of time that it takes to move through all the stages of the R&D process and gain FDA approval. Recent studies of the probability of success and the length of the R&D process for biotech drugs indicate a convergence in these parameters toward the values observed for small molecule pharmaceuticals.

Two initial studies found that success rates for biotech drugs were substantially higher than success rates for new chemical entities (Bienz-Tadmor et al. 1992 and Struck 1994). In particular, both studies projected success rates for biopharmaceuticals in excess of 50 percent. However, a basic assumption implicit in the methodology of both studies is that success rates for biotech drugs that entered development in the late 1980s and early 1990s are the same as for the biotech drugs that entered development in the early to mid 1980s. This is a very strong, and potentially hazardous, assumption given that 90 percent of the drugs in their samples were still under active testing.

Subsequently, Gosse et al. (1996), analyzed a comprehensive sample of U.S. biopharmaceutical drugs and compared the success rates of older and newer biotech entities. They found dramatic differences in the time pattern of success rates observed for early versus later biotech drug cohorts. In particular, for the investigational new drugs (INDs) filed in the early 1980s,
the success rate for new recombinant entities is 38 percent. For the INDs filed during the late 1980s the success rate was only 10 percent based on approvals to date (i.e., six years after testing). At a comparable point in time, the new recombinant entities of the early 1980s had a success rate of 26 percent. In fact, the success curve of the recent recombinant entities more closely resembles that of new chemical entities rather than that for the early biological entities.

This result is consistent with the history of biotech research in the U.S. The first biological entities introduced into the market were naturally occurring proteins that replaced purified non-recombinant formulations already in general use as established therapies (e.g., insulin and human growth hormone). It is reasonable to expect that recombinant versions of established therapies would have high success rates, once the technology to manufacture these products was proven. Other earlier targets for biotechnology were naturally occurring proteins with well-known and defined physiologic activity (e.g., erythropoietin and filgrastim). As the biotech drugs moved to targets for which limited knowledge existed about clinical and pharmacological profiles, it is reasonable to expect that success rates would fall back toward those of conventional drug entities.

The prospect of a long and uncertain discovery and development period for a new drug is another factor affecting costs and risks in the drug R&D process. The longer the development and approval process, the higher the interest costs, opportunity costs, and the overall capitalized R&D costs of a new drug introduction. Recently, Janice Reichert of the Tufts University Center for the Study of Drug Development has done a historical analysis of clinical development time for successive cohorts of new biopharmaceuticals. She found that recently introduced biopharmaceuticals had much longer clinical development times than earlier introductions. In particular, the cohort of 2000-2001 new biopharmaceutical introductions had a total clinical development time (including FDA approval) of 86 months, versus 53.2 months for 1982-1989 biopharmaceutical introductions.

Hence, the experience with respect to development times parallels the experience observed with respect to success rates. In particular, there has been a convergence in clinical trial period times observed for new biological and new chemical entities. Of course, the biotech industry is still in the early stages of evolution. It may eventually produce higher success rates and shorter development times as a result of new technologies currently emerging in the discovery period. However, the best evidence at this time shows that biopharmaceuticals, like new chemical entities, are subject to very high rates of attrition and long gestation periods in the clinical development stage.

One aspect in which biopharmaceuticals may differ from small molecule new chemical entities concerns the ease of generic entry when patents expire. To date, there have only been a few patent expirations involving biopharmaceuticals. One case in which there has been entry after patent expiration is that of human growth hormone. However, all entry to
Figure 3:
Present Values by Decile: 1990-1994 NCEs
date has been by other big pharmaceutical firms that have had experience supplying this product in Europe and Japan (Pharmacia, Novo Nordisk and Ares Serono). There are greater hurdles in manufacturing biopharmaceuticals at an efficient scale compared to new chemical entities, and in addition there are greater regulatory requirements for biologicals associated with the manufacturing process (Grabowski and Vernon 1994). These factors may moderate the degree of imitative competition for biopharmaceuticals compared to small molecule chemical entities. Whether or not this is the case will become more apparent when some of the commercially important biopharmaceuticals are subject to patent expiration and potential generic competition in the coming decade.

**Returns on R&D for New Drug Introductions**

Grabowski et al. (2002) have examined the distribution of returns for new drug introductions. This work builds directly on the R&D cost analysis of DiMasi, et al, and considers the sales and net revenues realized over the product life of new drug introductions during the 1970s, 1980s and 1990s. One finding of this work is that the distribution of returns to new drug introductions is highly variable, noting another source of risks for firms developing new drug introductions.

Figure 3 shows the distribution for present value of net revenues (revenues net of production and distribution costs but gross of R&D investments outlays) for new drug introductions between 1990 and 1994. The distribution shows very strong skewness. Roughly one half the overall present value from this sample of 118 compounds is accounted for by the top ranked decile of new drug introductions. The top decile has an estimated after-tax present value that is more than five times the present value of average after-tax R&D costs per approved introduction. Furthermore, only the top three deciles of new drug introductions have present values that exceed average R&D costs.

A major factor underlying the skewed distribution observed in Figure 3 is the level of sales realized by new drug introductions. A few drugs achieve peak sales of several billion dollars and account for a large share of overall revenues. At the other end of the distribution, many compounds achieve peak sales only in the tens of millions of dollars and fail to provide a positive return on investment. Grabowski and Vernon have investigated other periods and time cohorts of new introductions and found that they are characterized by similar patterns (Grabowski et al. 2002).

These returns to R&D analyses confirm that the search for blockbuster drugs is what drives the R&D process in pharmaceuticals. The median new drug introduction does not cover average R&D costs (including allocations for the cost of discovery and the candidates that fall by the wayside). A few top-selling drugs are key in terms of achieving economic success in pharmaceutical R&D over the long run. The large fixed costs of pharmaceutical development and the skewed distribution of outcomes help to explain the clustering of biotech firms at the research stage of the R&D process.
and the large number of alliances between biotech and big pharmaceutical firms at the development and marketing stages.

In Figure 4 (see page 24), the distribution of worldwide sales in 2000 is presented for 30 new biological entities introduced into the U.S. market between 1982 and 1994. All the compounds had been in the market at least seven years, and had progressed beyond the initial rapid growth phase of their life cycle. The sales data presented in Figure 4 indicates that new biopharmaceuticals also exhibit a high degree of skewness, similar to the much larger cohort of new drug introductions.

The high degree of skewness in the outcomes of pharmaceutical R&D projects indicates that there are substantial risks in this endeavor, both for big pharmaceutical firms as well as smaller biotech enterprises. This reflects the dynamic nature of the R&D process, the long time periods from the start of a project to market approval, the unpredictability of clinical trials, as well as regulatory and competitive uncertainties.

Even though many big pharmaceutical firms spend billions of dollars per year on a diversified portfolio of in-house and outsourced projects, this does not guarantee a stable set of outcomes. If a firm invests in a large diversified portfolio of projects that are more tightly clustered around the mean return (e.g., the so-called "normal" or Gaussian distribution), we expect that returns can be predicted with some confidence. When returns are highly skewed, however, individual companies experience highly volatile outcomes even when they invest in large numbers of independent projects.

To illustrate this point, Grabowski and Vernon examined the new product sales for the U.S. drug companies that spent between $300 and $500 million on their global R&D in the mid-1980s (the top tier group in that period). They found that subsequent new product sales emanating from these R&D efforts varied between $100 million and $3 billion (after seven years of market life) (Grabowski and Vernon 2000).

Finally, it is important to note that the distribution of outcomes from pharmaceutical R&D projects has similar characteristics to many other innovation samples, including venture capital funding of high tech start-ups. In this regard, Scherer, et al, have examined the size distribution of profits from investments in innovation projects using a diverse set of data samples (Scherer et al. 2000). Their analysis included two large samples of high technology venture capital investments, as well as a comprehensive sample of venture backed start-up firms that had their initial public offering in the mid-1980s. A common finding was that the size distribution of profit returns from technological innovation is strongly skewed to the right. As in the case of new drug introductions, the most profitable cases contribute a disproportionate fraction of the total profits from innovation.

Table 1 summarizes the results from four data sets employed in Scherer's analysis. The first two data sets, assembled by Venture Capital Incorporated and Horsley Keough Associates, involve an analysis of several hundred venture capital firm investments in high tech start up companies. Scherer's analysis indicates that roughly 60 percent of the returns, mea-
Table 1:
Returns Distribution for Selective Innovation Samples

<table>
<thead>
<tr>
<th>Date Set</th>
<th>Percent of Value From Top Decile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venture Capital (Start-Ups)</td>
<td>62%</td>
</tr>
<tr>
<td>Horsley-Keough (Start-ups)</td>
<td>59%</td>
</tr>
<tr>
<td>1980s IPOs—(1995 Value)</td>
<td>62%</td>
</tr>
<tr>
<td>1990s New Drugs (Grabowski-Vernon)</td>
<td>52%</td>
</tr>
</tbody>
</table>

sured at the time of the final distributions to investors, are realized by the top decile of venture capital projects. At the same time roughly half of the projects in these samples failed to earn positive returns. Similarly, an analysis of the stock market performance of the universe of high tech companies that went public in the mid-1980s found that the top decile of companies realized 62 percent of the sample’s total market value 10 years later. The corresponding value for Grabowski and Vernon’s sample of 1990-1994 new drug introductions is 52 percent. Hence the three samples of risky, high-tech start-up companies exhibit skewed distributions of returns comparable to the pharmaceutical industry.

Conclusions and Policy Considerations

Economic analyses of the R&D process in pharmaceuticals indicate that it is a very costly and risky process, even for large established firms. Most compounds in the R&D pipeline never reach the marketplace. The development process is time consuming and expensive, and the distribution of profits among those products that are marketed is highly skewed. A few blockbuster successes cover the losses on many other R&D investment projects. An important implication for public policy is that reimbursement, regulatory or patent policies that target the returns to the largest selling pharmaceuticals can have significant adverse consequences for R&D incentives in this industry (Grabowski and Vernon 1996).

Many compounds in the top decile of the returns distribution involve the
first mover, or other early entrants, in a new therapeutic class. The family of medicines in a given therapeutic class passes through a well-delineated life cycle. There is dynamic competition involving breakthrough, as well as incremental advances, among the branded products within that class. This dynamic competition, in turn, produces substantial consumer surplus and social returns. When the patents for established products expire, consumers also benefit from imitative competition from generic entrants, which provide social benefits in terms of significantly lower prices.

Patents play a critical role for both the level of R&D investment in pharmaceuticals and the timing of generic competition. The Hatch-Waxman Act was designed to balance the trade-offs between these two objectives. In particular, it sought to produce patent lifetimes sufficient to encourage increased levels of R&D investment by innovators while promoting intense price competition by easing entry regulations to generics when patents expire. The degree of generic competition has increased dramatically since the 1984 act was passed, with more than half of all new prescriptions accounted for by generic products in 2002.

The Hatch-Waxman Act has fostered a vigorous generic industry with substantial benefits to consumers from price reductions. However, the CBO’s (1998) analysis of the act found that from the perspective of R&D returns, the much more rapid loss of sales in the period after patent expiration has dominated the patent term restoration aspects of the law. In particular, using Grabowski and Vernon’s analysis of R&D returns as their conceptual framework, they estimated 12 percent lower expected after-tax profits from R&D for the mean new drug compound as a consequence of the 1984 act. While the mean compound is still moderately profitable in their analysis, the increased generic competition since 1984 can have adverse R&D incentives for compounds of above average riskiness or ones with shorter than average effective patent life.

Overall, Hatch-Waxman has provided a relatively balanced approach to the trade-offs between pharmaceutical R&D and generic competition. Improvements on the margin could be considered by policymakers, such as a longer minimum exclusivity period before an ANDA could be filed for new drug introductions (currently five years in the United States but longer in Europe and Japan). Nevertheless, the law has provided a reasonably well-structured system of incentives for both innovative and generic firms. Both R&D investments and generic utilization have increased dramatically in the period since the passage, consistent with the objectives of the act. Some groups have suggested that Congress consider significantly altering or eliminating the patent restoration aspects of the law in order to further increase generic competition in pharmaceuticals. Given the critical role that patents and effective patent life play in terms of R&D incentives for this industry, this would not appear to be a desirable course of action on social welfare grounds.

Notes
1 See for example Triplett (2000).
2 In a follow-on study, Silberston categorized three groups of industries for
when patents are essential, very important or less important based on both survey responses and objective analyses (patent and R&D intensity). He concluded that, "The first category consists of one industry only, pharmaceuticals." (Silberston, Z.A. 1987. "The Economic Importance of Patents." The Common Law Institute of Intellectual Property. London.) Edwin Mansfield surveyed the R&D directors of 100 U.S. corporations on what fraction of the inventions they introduced between 1981 and 1983 would not have been developed without patent protection. For pharmaceuticals, the value was 60 percent, while the average across all industries was 14 percent. (Mansfield, E. 1986. "Patents and Innovation: An Empirical Study." Management Science. 32:175.


Capitalization takes account of interest payments and foregone earnings from investments of comparable riskiness during the lengthy R&D investment period for a new drug.

For data on the trends in effective patent time, see Grabowski and Vernon 2000.

Title II of the Waxman-Hatch Act provided for partial restoration of the patent time lost during the clinical testing and regulatory approval periods. A formula for patent term restoration was embedded in the law. In particular, new drugs were eligible for an extension in patent life equal to the sum of the NDA regulatory review time plus one-half of the IND clinical testing time. The law capped extensions at five years and also constrained extensions to a maximum effective patent lifetime of 14 years. Drugs in the pipeline at the time the Act was passed, in September 1984, were limited to a maximum extension of 2 years.

For new drug products with little or no effective patent life, generic firms are prohibited from filing an abbreviated new drug application within the first 5 years of the product life. Most European countries prohibit such filing within the first 10 years of market life.


This includes any benefits from the international GATT Agreement passed by Congress in 1994 which harmonized U.S. patent laws with foreign countries, including setting the nominal patent life to 20 years from the date of patent application rather than 17 years from the date of patent grant. It does not include any potential benefits of a 6-month extension granted under the FDA Modernization Act in 1997, which can be awarded if the firm does additional testing and gains FDA approval for a pediatric indication.

This issue also has been examined using a broad sample of products over...


12 These data were obtained in April 2002 from Janice Reichert at the Tufts University Center for Study of Drug Development in Boston, Massachusetts. For further trends and analyses in this regard, see the Tufts Center’s Impact Report, Vol.3, No.6, Nov/Dec 2001.


14 Grabowski and Vernon (2000) found that relatively few new chemical entities are marketed with effective patent lifetimes of less than 10 years.


REFERENCES


Henry Grabowski has been at Duke since 1972, where he is Professor of Economics and Director of the Program in Pharmaceuticals and Health Economics. He received his undergraduate degree in engineering physics at Lehigh University in 1962 and his doctorate in economics from Princeton University in 1967. He has also served on the faculty of Yale University and held visiting appointments at the Health Care Financing Administration in Washington, DC, and the International Institute of Management in Berlin, Germany. His recent publications have focused on the economics of the research and development process in pharmaceuticals and the costs and returns of new drug introductions.
Figure 4:

Sales in Millions of $ (Year 2000)

First  Second  Third  Fourth  Fifth
Quintiles
Policy Considerations: Medicare and Prescription Drug Coverage

RHO:-JDA KAY McPherson
West Volusia Hospital Authority

Current policy initiatives regarding Medicare and prescription drug coverage lack research and insight that are vital to creating a successful program for America’s elderly citizens. Too often, proposed policies regarding this issue lack effectiveness in both coverage and cost and do not consider the costs associated with our increasing aged population. The problems associated with uninsured elders, rural elders, and rising prescription drug costs are not accounted for in current policy. Policy makers need to be aware of the risks associated with a government-run prescription drug plan and should shift some of the financial burden of such a policy into the private sector. “Policy Considerations: Medicare and Prescription Drug Coverage” analyzes the aforementioned problems as well as uncovers who is in the most need of prescription drug coverage among the elder population.

INTRODUCTION

The baby-boomer generation is the largest socioeconomic group in the United States. The most aged portion of the populace represents what will soon become the largest segment of the American population, and the issues that impact their lives have become prominent themes of current political and social discourse. With advances in technology and medicine, people now live longer, healthier lives. Consequently, issues surrounding the elderly have become contested topics of public argument. Much political debate has developed regarding prescription drug plans for the elderly in light of an insurgence of pressure facing our nation’s leaders to secure a healthy and stable lifestyle for our elders which is both affordable and equitable.

The distinctions between the Republican and Democratic political parties are less significant in today’s political environment. Republicans try to be more moderate; Democrats attempt to appeal to voters in the center - the parties of today’s political system are merging and, often, the differences between the parties are difficult to identify. Such is true in the case of prescription drug plans – both political parties are fighting to provide prescription drug coverage to the elderly, and both are lacking in terms of an adequate and effective plan that will help those most in need. Although the intentions of policy makers are positive, the policies and programs offered as a solution are inadequate. It is known that American society is aging;
the country is facing a new phenomenon with the retirement of the baby-boomer generation. Few politicians understand the full ramifications of the growing elder population, nor are they aware of the needs of the elderly population. Hence, the policies revolving around this section of society are often unsuitable in terms of the true need that exists. It is imperative that Republicans and Democrats develop a joint plan that considers the increase in the number of beneficiaries, a decrease in the tax base, and the identification of those persons most in need of prescription drug coverage. Policy makers need to ensure that current fields of prescription drug coverage are not eliminated or discouraged and address fiscal responsibilities – the government should not assume full financial liability regarding prescription drug coverage for Medicare beneficiaries.

**PROJECTIONS OF THE AGING POPULATION**

In the United States today, people are living longer and retiring earlier. Currently, there are fewer people working to support the older population. It is projected that this trend will continue through the year 2030 (Wise 1997, p. 1). This trend will result in an equal distribution of older and younger people in society rather than a pyramid structure of society which exists today. The equal distribution of age groups in the future will dramatically impact the amount of revenue that the government can collect, as there will be fewer workers and more recipients in the future. The financial crisis that the federal government will face is inevitable. Programs and policies designed to help the elder population should consider the impact of decreased revenues for future programs.

The older-aged segment of American society is growing substantially. In 1998, 5,190 persons celebrated their 65th birthday every day, totaling 1.9 million persons reaching age 65 that year (AARP 2001b, p. 1). Concurrently, 1.75 million persons age 65 or older died, resulting in a net increase in the elder population of 145,000 persons annually (396 per day) (AARP 2001b, p. 12). Those reaching retirement age are expected to live 17.6 years longer than their successors (AARP 2001b, p. 12). To further complicate policy initiatives, the elder population, in and of itself, is getting older. In comparison to the year 1900, the 65 to 74 age group is eight times larger now, the 75 to 84 age group is 16 times larger, and the 85 and older age group is 33 times larger (AARP 2001b, p. 12).

Ethnic distinctions in the elder population must also be noted. The increased elder population also comes at a time where there are increased numbers of minorities in the group. This is important in that different races and ethnicities require targeted and specific care. According to a self-assessment of health, African-Americans (41.6 percent) and Hispanics (35.1 percent) are more likely to report themselves as having ill health than Caucasians (26.0 percent) (AARP 2001b, p. 12). Currently, 84 percent of the elderly population is white, 8 percent is black, and 6 percent is Hispanic. The white population of elders is expected to decrease to 64 percent by 2050, while the black population is expected to increase to 12 percent and the Hispanic population is expected to more than double to
compose 16 percent of the elder population (FIARI 2001). Health care delivery of the future must be specific not only to the needs of the aging, but also to the diversity with which this portion of society will soon compose.

**MEDICARE: CHANGING AGENDA**

The creation of Medicare in 1965 opened a floodgate of rights and entitlements previously foreign to American culture. At the time Medicare was implemented, approximately one-half of seniors were uninsured and had a greater tendency to be living in poverty than any other population in the country (DHHS 2000a). The original components of Medicare include Part A and Part B and are financed through a combination of general revenues, payroll taxes, and the deductible and monthly premiums of persons enrolled in Part B Medicare (KFF 2000b). Although sufficient for the needs at the time it was created, Medicare is now facing demands that were unknown to the original authors of the Medicare program. The Medicare program must be changed to meet the needs of our increasingly aging society.

Medicare does not include prescription drug coverage; however, the progression of pharmaceutical breakthroughs mandates that the Medicare program must reflect the changing needs of its beneficiaries (Horn 2000). Currently, 98 percent of health insurance plans in the United States offer some form of prescription drug coverage to clients (Bush 2000a). Medicare does not provide such an option to its beneficiaries and it must move forward to adapt to the changing needs of 21st Century America.

**UNINSURED AND RURAL ELDERS**

The demand for a prescription drug plan is not without limits as to who needs prescription drug coverage. Roughly two-thirds of seniors have some form of prescription drug coverage (Horn 2000). Of the 26 million Medicare beneficiaries with prescription drug coverage, one-third have employee sponsored insurance, one-tenth are covered by Medigap, one-ninth (the poorest seniors) are covered by Medicaid, and one-twelfth are covered by a Medicare HMO (KFF 2000a). These statistics are skewed in that of those persons with prescription drug coverage, 47 percent do not have coverage year-round (DHHS 2000b). Medicare Parts A and B, combined, only cover 53 percent of health care costs; the remaining 47 percent of cost is partially absorbed by Medigap; however, this program does not cover outpatient drug costs (Bush 2000b). One-half of seniors with Medigap coverage do not have coverage for the duration of the year (SSA 2000c). In addition, employer-sponsored insurance is decreasing. From 1995 to 1998, employer health coverage dropped from 35 percent to 30 percent (AARP 2001). It is evident that, although a majority of seniors have some form of prescription drug coverage, the coverage is limited resulting in higher out-of-pocket expenses for the elderly. This is especially difficult for lower-income seniors that do not qualify for Medicaid but cannot afford additional prescription drug coverage.

The steadily increasing cost of prescription drugs is especially alarming for those persons without insurance coverage. Statistics indicate that the
uninsured usually require more intensive health services, have low incomes, and are less likely to buy the necessary prescriptions as recommended by their physician (SSA 2000b). Seniors without drug coverage do not receive discounts or rebates available to the insured, resulting in a typical prescription price increase of 15 percent (DHHS 2000b). Persons without insurance purchase one-third less the amount of prescription drugs yet still pay two times the amount of out-of-pocket expenses compared to persons that are insured. Persons with prescription drug coverage fill an average of 20 to 25 prescriptions annually; conversely, those without prescription drug coverage fill an average of only 10 to 12 prescriptions (Artz, Hadsall and Schondelmeyer 2002). With a similar physiological composition, it is concluded that persons without prescription drug coverage fill less prescriptions annually due to financial constraints.

More specifically, challenges facing the rural elderly of America are numerous and severe. According to the Domestic Policy Council and the National Economic Council, one-fourth (9 million) of Medicare recipients are classified as rural. Typically, rural elders have lower incomes, limited access to pharmacies, and an out-of-pocket expense greater than urban elders. Although rural elders have increased needs, the coverage options available to them are few. Costs are higher for rural elders, and they are 60 percent more likely to forego filling prescription drugs than urban elders. Because health care costs require a greater percentage of their income, rural elders pay 25 percent more out-of-pocket expenses than urban elders pay. Forty-five percent of rural elders have chronic illnesses in comparison to 36 percent of urban elders resulting in 33 percent of rural elders having out-of-pocket expenses exceeding $500 compared to 25 percent of urban elders (SSA 2000c).

A lack of preventive care for rural elders, as well as the nature of work in such regions, are probably key issues explaining the occurrence of chronic illness among the rural elderly. The rural elderly are 50 percent less likely to have prescription drug coverage; those that have coverage are more likely than urban elders to lack coverage for the entire year (43 percent rural versus 27 percent urban) (SSA 2000c). It is speculated that the benefits reach coverage limitations sooner for rural elders because drugs for chronic illnesses are more expensive. More than half of rural elders age 85 or older do not have prescription drug coverage (SSA 2000c). This figure is 50 percent more than their urban counterparts (SSA 2000c). Several problems for rural elders stem from the fact that 45 percent of those persons without drug coverage in rural areas have an annual income of 150 percent to 400 percent of the poverty threshold, and thus do not qualify for Medicaid assistance, and cannot afford additional insurance for drug coverage (Bush 2000b). Employee-based drug coverage is also lower in rural regions (25 percent rural versus 35 percent urban) (Bush 2000b). Again, the nature of the work in rural areas can attribute to the trend of employee-based insurance.

In an attempt to make prescription drug coverage more readily available to seniors, Medicare+ Choice was de-
developed in the Balanced Budget Act of 1997 and offers private insurance for seniors as an alternative to Medicare. Frequently, insurance plans include a prescription drug benefit; however, Medicare+ Choice is often not available to rural seniors in that the reimbursement rates for providers are too low, and they choose not to participate in the program (Bush 2000c). Also, the Medicare HMO may not be available in rural areas, and the main option left is to purchase a Medigap policy.

Medigap, however, is still very costly to the consumer and additional out-of-pocket expenditures ranging from $300 to $500 annually in premium costs alone (AARP 2001c). The standard Medigap coverage is a $250 deductible, 50 percent rate of cost-sharing, and a cap of coverage ranging from $1,250 to $3,000, depending upon the choice of the enrollee (AARP 2001c). Also, participation in the Medigap program is only guaranteed in the first six months of Medicare enrollment (AARP 2001c). If one does not opt for the insurance coverage at that time, he or she could be denied later. The plight of rural elders is quite different from that of urban elders; regardless, the overarching need for pointed prescription drug coverage is evident regardless of demographics.

The urgency to develop a plan that will be fiscally responsible, yet effectively implemented to those persons that need the benefit, has come to fruition, as the Medicare base is growing rapidly. Currently, Medicare covers 39 million beneficiaries; by 2030, Medicare will be expected to cover seventy-six million recipients (LWV and KFF 2000). With more persons retiring, the tax base from which Medicare draws a portion of its funding will shrink. The coming of retirement age for the baby-boomer generation will lead to the financial deprivation of Medicare if not carefully monitored. The current ratio of workers to Medicare recipients is 4 to 1; in 2030, the ratio of workers to Medicare recipients will be 2 to 1 (Bush 2000b). Due to the decreasing ratio of workers to recipients, the creation of a prescription drug plan could create catastrophic costs for the federal government if the plan is not thoughtfully implemented.

Hindering the current field of prescription drug coverage (e.g. employee-sponsored insurance) will have a devastating effect on the economy by raising the cost of a government-run program which will, in turn, eventually lead to fewer benefits for the recipients or increased taxes for the tax-payer (Horn 2000). Employers that are currently covering a substantial amount of Medicare beneficiaries will be less inclined to continue insurance coverage if a prescription drug program that is based solely on government financing is implemented. As a result, the government may encounter a substantial increase in the number of claims received per benefit period that are not considered when policy makers develop legislation, and this oversight will bankrupt the program. In addition, increased expenses will result in decreased benefits for those most in need, unnecessarily creating a program that will still neglect the needs of recipients. A new prescription drug plan must be specific in terms of beneficiaries, and should recognize the constraints of a decreasing tax base to support such a plan as well as the negative impact of eliminating current,
privately insured prescription drug coverage.

**Universal Coverage?**

The development of a prescription drug plan for seniors will be paid for by tax-paying citizens, not by the persons enjoying the benefits. Although this is the nature of a redistributive policy, some argue that the senior citizen population in America is not as financially unstable as projected. The rate of poverty is decreasing among the elderly; Social Security has assisted in bringing the poverty level of seniors down to 12 percent compared to 28 percent 30 years ago (Brown 2000). According to the U.S. Census Bureau, the median net worth of retirees is $86,000 annually (Brown 2000). Comparatively speaking, the net worth of retirees is fifteen times the net worth of persons age 35 or below, and three times the net worth of persons age 35 to 44 (Brown 2000). The poverty rate for elders is less than 10 percent versus 17 percent for persons under age 18, and this trend is continuously growing (Brown 2000). In the past eleven years, the median income of retirees has increased 8 percent (Sullivan 2000), quite possibly because of the nature of persons retiring. The AARP reports that persons in their sixties have more discretionary income than any other group of the population. Twenty percent of elders have a net worth of $250,000 or more (Sullivan 2000). Persons noted in the latter group are not in need of a governmental prescription drug plan.

**Why Are Health Care-Related Costs Increasing?**

The nature of health care as a field is changing the method in which patients receive care. There is a substantial increase in outpatient facilities, mid-level practitioners, and alternative care as a direct result of health care changing from fee for service to managed care. In an effort to decrease costs, the aforementioned methods of practice have been implemented in health care facilities, and subsequently, out-of-pocket expenses have increased, leaving patients with no alternative but to absorb the additional costs or reject care. Prescription drugs are not covered in outpatient care; therefore, prescription drug costs are subject to having a substantial impact on the person receiving the care.

The rising cost of prescription drugs increases the challenges that policy makers face regarding this issue. Between 1993 and 1998, prescription drug costs increased 12 percent annually nationwide (KFF 2000b). All other health care spending increased only 5 percent annually (KFF 2000b). Of the 5 percent increase in health care spending nationally, 44 percent of the increase is due to prescription drug costs (Bellandi 2000, p. 24). Of health related costs for the elderly, prescription drugs account for one-sixth of annual costs (KFF 2000b). In 1998, 80 percent of Medicare recipients had a regular regimen of prescription drugs, and of the fifty most commonly used drugs among the elderly, the price for those drugs increased four times the inflation rate (LWV and KFF 2000). From January 1994 to January 1999, the price of the 39
most frequently used drugs by the elderly, 31 increased in price at least five times (Hadaad 1999).

For persons under age 65, retail costs for drugs will increase 19.7 percent; for persons over age 65, it is expected that the costs will rise 20.9 percent (Employee Benefit News 2000). The rising cost of prescription drugs is a trend that does not appear to be slowing and will continue to be a cost-containment issue pending the implementation of a prescription drug benefit to Medicare.

Although the actual production of prescription drugs is not expensive, the initial cost of research and development requires monetary compensation and enables drug companies to continue the development of new drugs (Barro 2000). It costs approximately $500 million dollars and 12 to 15 years to research, develop, and test a new prescription drug (PhRMA 2001). Pharmaceutical companies typically exceed revenues over expenses for three out of every 10 drugs developed (PhRMA 2001). Several other reasons exist to explain the increase in prescription drug costs including, but not limited to, the following: increased utilization, new medicine development, and price inflation. Combining the value of a drug in terms of avoiding invasive procedures through using medications rather than surgery, increased inflation rates, and the demand for certain drugs in the market, pharmaceutical companies are finding it necessary to increase their costs (PhRMA 2001). Pharmaceutical companies argue that the value of a saved life is an appropriate benefit per the increasing cost of prescription drugs (PhRMA 2001).

Some entities have suggested that price controls be placed on pharmaceutical companies to inhibit profit. However, it is argued that price controls affect quality, which, in turn, will affect the economy of health care through increased illnesses and disease. When price controls have been used in other countries, patients are prescribed mediocre drugs to avoid the cost of top-quality prescriptions. If the sub-standard prescription is inadequate, then further efforts will be made on the part of the provider to prescribe the medication that should have been prescribed initially. At times, it is too late for the patient in that the disease or sickness may have progressed beyond repair, especially among the sick and weak (namely, the elderly). Supporters of price controls suggest that pharmaceutical companies monopolize the market through maintaining secrecy and not allowing generic brands to develop equivalent drugs. Through this monopoly, brand-name prescription drugs are patented, therefore prohibiting replication. It is a popular opinion that pharmaceutical companies practice price gouging and inflate the cost of prescriptions beyond that which is reasonable and customary. Pharmaceutical companies refute this argument and state that research and development compensation account for increases in prescription drug costs.

Research and development are a vital part of pharmaceutical companies. If revenues are lost as a result of price controls, then it will be impossible for pharmaceutical companies to develop and create new, life-saving drugs in the future. The United States is responsible for 45 percent of the world's development in new medica-
tions; the United Kingdom, second to the United States, developed only 14 percent of new medications (PhRMA 2001). It is clear that the United States is the world's leader in researching, developing, and expanding medications (PhRMA 2001). In addition, it has been proposed that the United States re-import drugs from other countries in an effort to help subsidize the increased costs associated with research and development. The re-importation of drugs from foreign countries is risky to the patient if the federal government does not monitor this process. The shelf-life of prescriptions, the quality of prescriptions, and the overall safety and effectiveness of the drug to the patient cannot be guaranteed if the re-importation of drugs continues to be a popular solution to rising prescription drug costs. Without proper regulation, patients may be taking prescriptions that are not suited for their particular case and may cause permanent or fatal damage. Pharmaceutical companies must receive a profit for their services, otherwise, further research and development may not be possible. If the United States does not continue to develop new drugs, then there will be fewer prescription drugs available worldwide.

Consumer affordability is still a relevant issue, as new drugs are not valuable if they are not affordable to those in need of the medication. The life-saving nature of recent discoveries in pharmaceuticals make the value of affordable prescription drugs almost immeasurable; however, patients must be able to access and afford the drugs that will be beneficial to their health. Essentially, Americans have two choices: lower drug prices resulting in decreased production of new drugs; or, higher drug prices resulting in increased production of new drugs (Barro 2000, p. 36-38). Regardless of the reasoning behind increasing prescription drug prices, the issue of consumer affordability is still a serious consideration.

**FULL MEDICARE VERSUS MEDICARE/PRIVATE**

There are two models of prescription drug plan programs that our legislators are using: Full Medicare with Stop-Loss and Medicare/Private. Despite fundamental differences, similarities exist between the two types of plans: low-income subsidization of costs and stop-loss coverage (Fuchs et al. 2000). Current prescription drug plans provide provisions for persons unable to pay for prescription drug coverage and persons that have extraordinary prescription drug costs. The differences between Full Medicare and Medicare/Private plans are substantial. Full-Medicare is typically the Democratic policy, and Medicare/Private tends to be the Republican policy.

When estimating future costs, Full Medicare provides a 5.5 percent increase a year for prescription cost increases. Increases for changes in utilization are not included in projected costs. If the amount of drug spending increased at a faster rate than drug prices (as is predicted to occur), a large amount of stop-loss claims would be filed, and the government would be responsible for payment. In an effort to remove the burden of stop-loss costs from the federal government, the Medicare/Private plan provides for
insurance companies to absorb the financial burden of stop-loss claims. If this were to occur, a possible outcome is that insurance companies may raise the stop-loss threshold to avoid full payment (Fuchs et al. 2000). If the federal government adopts a Medicare/Private policy, it should be mandated that the insurance companies participating in a collaborative effort with Medicare cannot raise premiums, co-pays, deductibles, or stop-loss thresholds without government approval.

Full Medicare with stop-loss provisions mandates that a beneficiary choose whether or not to enroll in the program at the time he or she becomes eligible for Medicare. A single, standard benefits package would be available for enrollment. A national premium, based on a percentage of benefit costs, would be withdrawn from Social Security checks. The government would negotiate drug prices and contracts would be established based on geographical region.

Comparatively, the Medicare/Private plan allows beneficiaries to choose from an array of government-approved private insurance companies. Although the private insurance companies would have to meet certain government criteria, a variety of benefit packages (different premiums, co-pays, deductibles, etc.) would be available to the beneficiary. Rather than insurance risk and loss being borne by the federal government, the Medicare/Private plan places the financial burden in the hands of the insurance companies, therefore shielding the government from extreme financial pressure and loss (Fuchs et al. 2000).

PUBLIC SUPPORT

Without public support, no policy concerning prescription drug coverage for needy seniors can be implemented effectively. In the past two years, public awareness of the prescription drug problem has increased dramatically. In 1998, only 29 percent of the public was aware that Medicare did not cover prescription drug costs (Fuchs et al. 2000). In comparison, 55 percent of people today claim to know the limitations of Medicare regarding prescription drug coverage (Fuchs et al. 2000). Even with the possibility that it may require an increase in federal spending, 76 percent of the public would support an initiative to include prescription drug coverage to persons on Medicare (Fuchs et al. 2000). Fifty-six percent of the public prefer the Full Medicare plan rather than the Medicare/Private form of coverage (33 percent) (Fuchs et al. 2000). Statistically, Americans trust a government-run prescription drug plan rather than a privately-run, government-approved plan (47 percent versus 35 percent) (Fuchs et al. 2000). Despite the fact that not all seniors need free coverage, most Americans support offering free prescription drugs to all seniors (49 percent) rather than to low-income seniors only (38 percent) (KFF 2000c). It is obvious that there is strong support among the American people to change the current system of Medicare.

EFFECTS TO ESTABLISH PRESCRIPTION DRUG COVERAGE

The attempt to pass prescription drug coverage into law is not a new phenomenon. Efforts to establish prescription drug coverage within Medi-
care have been attempted in recent decades but to no avail. No longer can policy makers ignore the necessity of creating a prescription drug plan that meets the needs of the people without sacrificing individual satisfaction within the client base.

In 1988, Congress passed the Medicare Catastrophic Coverage Act in an effort to expand the reach of Medicare; the act established a prescription drug benefit for outpatient care. In 1989, this act was reversed as a result of complaints about an increase in premium cost to the beneficiaries (DHHS 2000). More recent efforts include the RxMedicare 2000 Act (H.R. 4680) which marginally passed in June 2000 with a vote of 217-214. The act provides for voluntary enrollment into Medicare Part D, which allows seniors to choose among private insurance plans for prescription drug coverage. Low-income premiums and catastrophic drugs are covered under the new legislation. It is expected that drug costs will decrease 39 percent. In this plan, Part D benefits are a collaborative effort with private insurance companies; various coverage options, premium rates, and co-payment rates are available for seniors to choose from (Hayworth 2000).

Senate Bill 2541, the Medicare Expansion for Needed Drugs Act (MEND), covers 50 percent of prescription drug costs up to $5,000 annually. Upon complete implementation, the plan would cover catastrophic drug costs. The components of the plan include the following: an addition of Part D Medicare, negotiated prices for drugs, the reduction of premiums with government contributions, free coverage for persons with an annual income at or below 135 percent of poverty, and partial assistance for persons with an annual income between 135 percent to 150 percent of poverty (Fisher 2000).

President Clinton offered a plan designed to cover half of all prescription drug costs up to $5,000 annually. Upon full implementation, a stop-loss component to the coverage would have been added (SSA 2000b). Opponents of Clinton’s plan argued that a government-run, single-option program would not allow for seniors to choose coverage that would best suit their needs, which would result in unnecessary expenditures for the federal government (Horn 2000). Although a fervent effort was made on the part of Congress and the President to develop a bipartisan prescription drug policy, the implementation of such a policy is yet to be seen on a national level.

**BUSINESS PLAN**

President George W. Bush feels that Medicare is a one-size fits all model with outdated benefits (not covering prescription drugs or routine services) that needs to offer seniors a choice of plans from which to pick in order to enroll in a plan that most appropriately fits their needs (Bush 2000b). Under President Bush’s plan, seniors would have an annual deductible of $250 with the government paying one-half of all drug costs up to $2,100 annually. The cap for out-of-pocket expenses would be $6,000 annually with the exception of lower income seniors (McQuillan and Keen 2000). Based on the insurance model of federal employees, the Bush plan would allow beneficiaries to choose between government-approved, private insurance plans or a
Medicare insurance program designed for prescription drug coverage. Bush believes that seniors will be able to pick a plan that is more conducive to their personal needs as there will be more benefits and prescription drug options from which to choose (SSA 2000a).

Bush's plan was intended to be implemented in two parts; however, Congress has denied the passage of part one of Bush's plan (CNN 2001b). Part one would have supplied $48 billion dollars over the next four years to states during the transition period to part two of the plan. The money given to the states was intended to ensure that persons at or below 135 percent of poverty — $11,300 per individual or $15,200 per couple — would have full prescription drug coverage, and those persons at 136 percent to 175 percent of poverty — $14,600 per individual or $19,700 per couple — would have most of their prescription drugs costs covered. Also, the money would have been used to cover any prescription drug costs exceeding $6,000 annually.

Not yet contested in Congress is part two of President Bush's prescription drug coverage plan. Part two of Bush's plan designates $110 billion dollars for Medicare Modernization offering a choice of plans to beneficiaries through the MediCARxES (Medicare Choice and Access to Prescription Drugs for Every Senior) program (CNN 2001b). Bush's plan provides for payment of at least 25 percent of prescription drug premiums for all seniors; moreover, the plan is designed to allow seniors to change their plan annually if they are not satisfied with their coverage (Bush 2000a). Funding for Bush's plan would, at first, remain the same for seniors currently enrolled; however, funding for future generations would change dramatically. Bush proposes the investment of a portion of payroll taxes into safe, sound, and established stocks that yield higher rates of return than the current Medicare fund (6 percent rate of return in the private market versus 2 percent in the current fund). Stocks invested with a portion of payroll taxes can only be used for retirement purposes or as an inheritance (Bush 2000a).

On July 12, 2001, President Bush offered a solution that does not require Congressional approval and that can take immediate effect (CNN 2001b). In early September, a federal judge ruled on behalf of the National Association of Chain Drug Stores which provided for a court injunction to temporarily halt the progression of Bush's discount drug card plan (CNN 2001a). In addition, the impact of terrorist attacks on the United States has had a substantial impact on the agenda of government as a whole.

President Bush expected the discount drug card program to be implemented immediately and quickly; however, the obstacle of the injunction has prohibited the plan's implementation. According to President Bush, the discount card would allow senior citizens to receive discounted pharmaceuticals when prescribed medication. With the discount card, it was expected that the discount would be between 15 and 30 percent (CNN 2001b, p.1-2). Sources outside of the Bush administration suggest that the discounts will be slightly lower and will range from 10 to 25 percent (CNN 2001c). Companies enrolled could charge a one-time $25 fee to each enrollee, and the initial
purchase of the drug card would cost, according to President Bush, approximately $1 (CNN 2001b). The Bush administration expected the plan to be implemented as early as October 2001 and no later than January 2002; however, as mentioned earlier, unforeseen circumstances have altered the administration’s agenda in terms of domestic issues (CNN 2001d). Appendix 1 provides an overall breakdown of proposed prescription drug plans.

How Much Do Senior Citizens Spend on Prescription Drugs?

Most seniors will not reach the stop-loss threshold of each plan. For out-of-pocket prescription costs, only 10 percent of seniors spend more than $1,000 dollars, and only 4 percent spend more than $2,000 dollars annually (Sullivan 2000). One-half of seniors spend less than $200 dollars on prescription drugs per year (Ponnuru 2000, p.22-24), and in 1999, Medicare beneficiaries spent an average of $400 dollars a year for prescription drugs (LWV and KFF 2000). Perhaps these costs are low because some of these seniors already have prescription drug coverage. Persons with above average out of-pocket spending cost tend to be in poor health, limited in the physical capabilities, 75 years of age or older, do not have prescription drug coverage, and have private supplemental insurance. These persons tend to spend between 4 percent to 7 percent of their annual income on prescription drugs alone, while 21 percent to 30 percent of their income is spent on health care costs as a whole (AARP 2001a). In addition, those with higher out-of-pocket spending do not qualify for Medicaid in that their income is between 135 percent to 200 percent of poverty and their drug costs are more expensive than lower income or upper income elders (AARP 2001a).

It is concluded that the out-of-pocket expenses for seniors will remain relatively the same even with the implementation of a new prescription drug policy. Under the Bush plan, seniors have to pay a deductible, which, for half of the population, will not be met within one year. Those that do meet the deductible are still subjected to out-of-pocket expenses up to $6,000 dollars with Bush’s plan. As noted earlier, 96 percent of seniors do not even exceed $2,000 dollars a year for prescription drug costs; the stop-loss threshold will barely be utilized and those seniors that do not require several or expensive prescriptions will be left out of the equation once again.

Policy Recommendations

All factors considered, the goal of a prescription drug initiative must first be established and clearly articulated. What is the true intent and purpose of policy proposals relative to prescription drug coverage? Are policy makers trying to establish a free drug policy or a greater access policy?

Free drug plans are extremely costly and risky to the government; the economy is too unstable and unpredictable to be able to ensure citizens that the services are guaranteed. Secondly, a free drug program sponsored by the government deters employers from purchasing or subsidizing employee based benefits packages during employment and through retirement. Shrinking private sector insurance coverage and absorbing the as-
associated risks is very risky and unnecessary.

Compiled with premium and deductible costs, most senior citizens would save money by not enrolling in a prescription drug plan. Medicaid will continue to cover the costs of low-income seniors under current plans for prescription-drug plans; however, lower-middle and middle-class seniors are still at a disadvantage in the plans being presented. The issues surrounding this part of the senior population still exist. They are not poor enough to qualify for Medicaid yet they are not wealthy enough to purchase prescription drug coverage. It is recommended that the guidelines for Medicaid coverage for the elderly be loosened in order to help a greater portion of the senior citizen population and truly assist those that need the help in this situation.

The stop-loss threshold needs to be decreased if the purpose is to provide affordable prescription drug coverage to all seniors. If the purpose of a new policy is to allow seniors greater access to the purchase of prescription drug insurance, then policy should reflect that agenda. Perhaps the solution is to create an incentive program to private insurance companies that will provide greater access to seniors for prescription drug coverage. This type of a plan would be less costly to the government and the burden of financial loss will be completely lifted off of the government.

Regardless of the type of plan implemented, the legislation should incorporate some type of educational or informative training for the families and providers of care for the elderly. Informing persons of the importance of preventive care, exercise, and resources available to them to avoid high out-of-pocket expenses is important. Although preventive care will only be effective after the generational effect has taken place, starting preventive care now will prevent some complications for the baby-boomer retirees and the cost of caring for these retirees may be less costly to the government. Also, baby-boomer retirees may be of better health than today's retirees in that their health care may have been better throughout their life and some preventive measures may be taking hold. Preventive care requires a generational impact to be fully functional in terms of reducing the health care costs associated with the elderly; however, implementing a provision of preventive and maintenance care in current legislation regarding prescription drug plans may curb some costly procedures in the future.

Policy makers need to be aware that the elder population is typically more active in terms of voting than other age groups in society. Passing legislation that is ineffective will be detrimental not only to those retiring but also to those seeking election or reelection. Regardless, it should be out of genuine concern for the elderly and the associated problems of access thereof, that a collaborative effort between the private sector and the government be utilized to create the ultimate, ideal solution to the prescription drug problem for the elderly.

**OVERALL CONCLUSIONS**

Issues involving the elderly have an impact on all sections of society. Caretakers, families, providers, insur-
### Appendix 1: Examples of Proposed Prescription Drug Plans

#### Coverage Options

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<thead>
<tr>
<th></th>
<th>Full Medicare</th>
<th>Medicare/Private</th>
<th>Bush</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Year to Implement</strong></td>
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<td>2003</td>
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<tr>
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<td>100%</td>
<td>100%</td>
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<tr>
<td><strong>Free Coverage</strong></td>
<td>Up to 135% poverty</td>
<td>Up to 135% poverty</td>
<td>Up to 135% poverty</td>
</tr>
<tr>
<td><strong>Partially Paid Coverage</strong></td>
<td>135%-150% poverty</td>
<td>135%-150% poverty</td>
<td>135%-175% poverty</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td>25% premium cost for all seniors</td>
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<thead>
<tr>
<th></th>
<th>MEND (SB 2541)</th>
<th>Clinton</th>
<th>Rx Medicare 2000 Act (HR 4680)</th>
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<tr>
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<td>Immediate</td>
<td>Immediate</td>
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</tr>
<tr>
<td><strong>Stop-loss Coverage</strong></td>
<td>To be implemented</td>
<td>To be implemented</td>
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<td><strong>Free Coverage</strong></td>
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<td><strong>Partially Paid Coverage</strong></td>
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<td>Yes</td>
</tr>
<tr>
<td><strong>Other</strong></td>
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<td>Single-option</td>
<td>Private, government approved coverage</td>
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<tr>
<td></td>
<td></td>
<td>government run</td>
<td>coverage</td>
</tr>
</tbody>
</table>
ance companies, and tax-paying citizens all play a vital role in the state of the elder population. Ignoring the needs of the elderly will do nothing but perpetuate the problems associated with this sector of society. Conversely, disregarding the risks of implementing costly programs for the elderly will have a devastating effect on society as a whole. Programs designed to expand access to prescription drug coverage or to provide free prescription drugs to the elderly need to be thoughtfully implemented and carefully designed in order to avoid harmful consequences in the federal government. Issues of health, cost, prescription drug prices, and persons currently insured all need to be taken into consideration if the government wants to provide a program that will be helpful to those most in need; namely, the lower-middle and middle class seniors. Prescription drug coverage for the elderly is sure to be a debated topic in the months and years to come; the consequences of implementing a faulty plan will have a greater long-term and far-reaching effect.

REFERENCES


Rhonda McPherson obtained her Bachelor's Degree in history and political science and her Master's Degree in Public and Health Care Administration from West Virginia University. Miss McPherson was recently elected to the West Volusia Hospital Authority of Volusia County, Florida, as one of five commissioners. The hospital authority allocates the funding of indigent health care throughout West Volusia County. As a graduate student, Miss McPherson worked with the West Virginia University Center on Aging, Education Unit, working as the Program Administrator for the Practitioner Certificate in Gerontology. In addition, she worked at University Health Associates as an undergraduate at WVU. Currently, Miss McPherson is an employee of Volusia County Schools serving as a Consultation Teacher for special needs students placed in regular education classrooms.
Feature Interviews

Interview with United States Senator
Jay D. Rockefeller

Under the theory that competition will yield greater efficiency, the Administration has proposed a privatization approach for helping seniors obtain prescription drug coverage. In light of the fact that Medicare+ Choice plans have been raising premiums, increasing cost-sharing and decreasing benefits, how will such a proposal allow seniors, particularly the most needy, to receive affordable, quality drug coverage?

You just answered your own question, really. It really can’t. We have no plans in West Virginia; we have two Medicare+ Choice plans that involve less than 2 percent of the people. Tell me how that works for us. It won’t happen. It’s all very bizarre because I don’t think the president, like his father, understands very much about healthcare. The president makes this big speech for the American Medical Association and I don’t know what comes out of it that’s different in the real essentials. By definition, if you are talking about a Medicare+ Choice model, you are talking about limiting access to physicians. You are talking about risk selection which also means you’re using public money to pay HMOs more than you would pay if that beneficiary were in traditional Medicare.

Private plans don’t want to partici-
pate if they can’t make a profit. At one point several of the proposals contemplated bribing the plans to enter the program — literally bribing. If you didn’t have any plan in your state, they would put a whole lot of money in those states to bribe in the plan. Well, number one, that’s not entrepreneurially sound, and secondly, it will not work because they are only going to stay there if it is in their own interest and it is not going to keep them there unless they can make money. If you cannot make money in a state like West Virginia, New Mexico, or Montana, [health plans] are going to select out the older people and the sicker people; they will try to cream-skim. That money for a Medicare+ Choice plan takes money out of Medicare, out of fee-for-service, which takes money away from my people. All I can be about that is extremely cold-hearted. I do not bend, and I will not have my people sold down the river. Yes, we happen to be poor people but every single state has lots of poor people. So, it is lousy for us.

And it has to be equal; everyone has to get equal coverage. What the Administration is basically saying here is that if you join an HMO, you will get a generous prescription drug plan and if you don’t, you will get no coverage for routine drug costs. There is an easy solution to it, which is to take out the dividend [tax-cut] policy. That is not a popular tax; it is not popular in this Congress among Democrats and Republicans. That’s $396 billion. Just cancel that and then take the $400 billion that you have in your budget, Mr. President, for prescription drug benefits, add the two together, and you, in fact, have a full prescription drug benefit with which you can do everything you want. I just want everyone to get an equal drug benefit and this is the easy way to do it, just sitting there. I don’t know why they don’t see it.

You mentioned risk spreading. A major hallmark of Medicare is the universality of the program — everyone contributes and everyone receives the benefits once they qualify. Since the proposals currently before Congress would formulate a voluntary, and not mandatory, benefit, how can you ensure adequate risk spreading among beneficiaries as exists currently in Medicare?

Well, it has to be voluntary. By definition, it’s voluntary. The majority of proposals are voluntary — rather than mandatory — because that’s what seniors have told us they want. They do not want to be mandated to join the program and pay an extra premium for it.

That’s why you have late-enrollment penalties. Once you make program enrollment voluntary, it’s necessary to institute a late-enrollment penalty. In other words, if a beneficiary does not enroll in the drug benefit as soon as they become eligible for Medicare, they have to pay a late enrollment penalty. This is to prevent seniors from waiting until they incur large drug costs before enrolling in the program. This is another way to guard against risk selection.

In view of the differing approaches offered from both sides of the aisle for a prescription drug benefit — privat-
Consensus could always be reached if they did what I suggested, if they took the $400 billion and $396 billion, they could get it done tomorrow. It is possible, because with the potential war and the situation in the economy and the general level of frustration around here, something's got to break loose. If you've got relatively unpopular tax breaks, and tax breaks really do not have much business being around anyway since we're 300 billion-plus in deficit for the next ten years, it just strikes me as such an easy thing for them to do. This Administration could go down in history for it - the people who did prescription drugs.

Privatizing Medicare won't work but that doesn't mean private managed care plans can't play a role. As part of a compromise, I would support a proposal where private managed care plans can participate. However, lower premiums must be the carrot that gets seniors into these plans, not an enhanced prescription drug benefit. We must provide the same drug benefit to those in traditional Medicare as we do to any senior who chooses to enroll in a private plan.

And, lower premiums must be created through efficiencies - reduced costs without cutting benefits - not unfair federal subsidies. We must create a level playing field between traditional Medicare and the private managed care plans. We cannot give preferred status to privatization.

Let's be honest. It's going to require more than $400 billion over 10 years to add a prescription drug benefit to Medicare. In my judgment, it's the only real reform that the Medicare program needs, and the resources are right there in the president's budget.

Some policymakers would rather see an entire overhaul of Medicare before a prescription drug benefit is added to the program. Given the current economic difficulties and concern about long-term financing for Medicare, is now the ideal time for a new benefit? If so, what is the best mechanism for its financing?

There are three things that need to happen in this country, and two of them, unfortunately, won't right now. The most important, obviously, is universal care. The second most important is long-term care, but that has never gotten traction. We did it in the Pepper Commission back in the late 1980s. We got it passed in Congress, but it has never really gotten anywhere. Long-term care is the largest single factor in health care, I think, that affects everybody at some point. And then very close to that are prescription drugs. Not only can the traditional Medicare program sustain a new benefit but we can afford a new benefit.

And particularly right now, prescription drugs are what people are talking about. What do you do to reform Medicare? I mean, what do you do? What do they do? What do you do? They put in HMOs and more of this and that. Medicare is an efficient program with consistent administrative costs of 2 to 4 percent. Those who try to make it seem as though Medicare will be in huge trouble if drastic steps are not taken are just looking to off-load our responsibility
for America’s seniors.

I don’t think Republicans like Medicare and I understand that because Medicare is very expensive and doesn’t go away and keeps getting more and more in your collective legislative face. But I have been working on this so long that I almost don’t know what to think about it anymore. All I know is that when you come up with reforms it always derails for larger substance. I have not met any seniors asking for reforms. The one thing they love is Medicare. The demand for reform comes from ideological people, political people, and congressional people. These people are asking for reform, not seniors.

If resources for a full prescription drug benefit are not forthcoming, what is the compromise – a limited benefit, a concentration on low-income beneficiaries, or coverage only of catastrophic costs?

You could do that. I’ve voted for that before – low-income or catastrophic. We did that, catastrophic health care, in the early 1990s. They repealed it in the House and I actually led the fight on the floor in the Senate not to repeal it and three times we refused to and then the House kept repealing it so there was no hope and we repealed it. But it was one of the best health care plans. Thirty-seven bucks a month gave you complete catastrophic health care and people were writing in saying 37 bucks was too much. A $35 premium is something I think seniors could live with.

Another problem is that the senior organizations are very much on the sidelines. I gave a speech to AARP a couple of weeks ago in which I essentially told them – because they’re in the business – I told them that they’ve been on the sidelines. You represent all these seniors, but you’re not a factor. It was a good speech, but I haven’t seen any results from it.

So I could support a low-income benefit, but it is not where I want to start. I could end up there. I’d rather do something than nothing. If that could be agreed upon, that could be positive. We have a chance to do more. The problem is that what’s going on in the world, I think, is budgetarily limiting what flexibility we have now. But it’s all a matter of priorities.

If it comes to that, is one option better than another – limiting the benefit to those with low incomes or only covering catastrophic costs?

In July, the Democrats proposed a low-income catastrophic plan that I voted for. The reason I voted in support of this kind of program is that the majority of seniors in West Virginia are low-income. The proposal in the Senate would have provided them total coverage for their drug expenditures. It also would have provided all beneficiaries some protection against catastrophic costs and some assistance with their routine drug costs. But it’s ultimately not where we want to start the conversation. If you say that is what you want to do, the conversation drops back from that point, you see. And I want to exercise the maximum amount of leverage, but I’m just telling you that I voted for it and I could do
that. It would, in fact, help most of the people I represent. This is selfish, if you want to look at it that way, but those are the people I represent and they are not very wealthy.

If the costs of prescription drugs could be kept down, it may be more attractive to implement a prescription drug benefit for seniors. You introduced legislation last year that would make generic medications more affordable by closing loopholes in patent laws that allow pharmaceutical manufacturers to exceed patents. Do you think this legislation or similar bills will be implemented this session?

We’re all for that. It was one of those things that had terrific momentum last year. While seniors urgently need guaranteed drug coverage, others desperately need relief from the increasing cost of prescription drugs. I guess we didn’t end up with very much, did we? The House never took it up and I don’t know if there is momentum to visit that this year. I don’t think so. The major drug companies have made an art form out of using the “orange book” to extend their patents. They wait until the very last moment and then they change the color of the pill and turn it from Tylenol® hard to Tylenol® gel, calling it a different thing. Then they get a new patent and, therefore, more time. It is very bad.

Generic drugs are coming in strong. They tend to be a lot cheaper; they can be up to 60 percent cheaper. They don’t have a lot of the profits in the market now. An interesting point is that generic drugs have a 45 percent utilization rate but that accounts for only 8 percent of the total expenditures on pharmaceuticals. But the answer to your question is yes, it’s a very important thing to have happen. It’s important to costs; it’s important to competition. Pharmaceuticals are stretching the law.

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James D. Rockefeller was elected Governor of West Virginia in 1976 and re-elected in 1980. In 1984, he was elected to the United States Senate, and re-elected in 1990, 1996 and 2002. In the United States Senate, Rockefeller is the vice-chairman of the Senate Select Committee on Intelligence. He also serves as ranking member of the Health Care Subcommittee on Finance, as ranking member of the Aviation Subcommittee on Commerce, Science and Trade Committee. He also serves on the Senate Committee on Veterans’ Affairs and the Senate Committee on Foreign Relations. Rockefeller is nationally known as one of the strongest advocates for health care reform. In the late 1980s, when he served as chairman of the Pepper Commission (the Bipartisan Commission on Comprehensive Health Care), he authored historic legislation reforming the way physicians are paid under Medicare, and, in 1992, he won an historic fight to protect health care benefits for retired coal miners, calling the victory the proudest moment of his career.
Interview with M. Kenneth Bowler, Vice President, Federal Government Relations, Pfizer Inc.

Due to the fact that millions of senior citizens lack prescription drug coverage, have rapidly increasing out-of-pocket drug costs, or have existing drug coverage that is eroding, many proposals have been set forth to provide seniors with access to affordable prescription drug coverage. These proposals include tax credits, subsidies for low-income seniors, expanding state programs, and a privatized approach. President Bush has just outlined his proposal for a benefit that includes subsidies, but also supports privatization. In Pfizer's opinion, what mechanism is most suitable?

Several years ago, the pharmaceutical industry, including Pfizer, endorsed the proposal that came out of the Breaux-Thomas Medicare Commission. I think the proposal, or proposal outline, most recently announced by the White House is similar in its underlying reform objective to the report of the Breaux-Thomas Commission. The most significant element of both proposals is that Medicare beneficiaries could choose from competing health insurance options offered by private entities. I have heard Senator Breaux compare this to the current federal employees' health insurance program. A Medicare beneficiary could choose an HMO, or a Blue Cross/Blue Shield insurance package, as do federal employees. For the low-income beneficiaries, the government would subsidize the cost of the premium. In other
words, the government would help pay insurance premiums; rather than reimbursing health providers for the cost of care, as under the current Medicare program.

As you know, earlier this week, President Bush released a plan regarding a prescription drug benefit for seniors. How do you respond to the critics who believe that the plan outlined by the president would be a windfall for the pharmaceutical industry since more seniors would be able to afford prescription drug coverage and physicians, in turn, would prescribe more drugs?

The underlying issue in the Medicare drug coverage debate is that there are Medicare recipients who don’t have adequate drug coverage; and, therefore, are going without medicines that they need. The intent of all of the proposals, whether it’s the president’s or Senator Daschle’s, is to correct this. If legislation is passed that does this, which does help the elderly get the medicines they need, the industry assumes there would be some increase in the volume of medicines that we sell. I don’t know what that increase would be, or if it would be large enough to be characterized as a “windfall.” Also, everyone assumes that, whatever type of Medicare drug coverage Congress enacts, it will include controls on the prices Medicare or Medicare patients pay for medicines, which will balance the gain to the industry from an increase in volume.

Pfizer is actively advocating enactment of Medicare drug coverage legislation. We are not doing this because we think it will be a “windfall” for the company. We are doing this because we believe all those who need the medicines we discover should have access to them. And, frankly, we don’t like being the political football every campaign year because there isn’t adequate drug coverage for the elderly. Pfizer’s focus is discovering new medicines. It is our success in this endeavor that will increase our revenues; not the passage of a Medicare drug coverage bill.

Considering the three options of President Bush’s plan – seniors can stay in traditional Medicare and receive enhancements such as a discount card, they can choose to receive care through private insurers with a drug benefit integrated into the insurance plan, or they could choose the “Medicare Advantage” option which is viewed as a mix of managed care plans – is one option more favorable than the other for Pfizer?

We support the principles reflected in the outline of a proposal the president recently released. However, we will want to carefully analyze the details of this plan, when they are released. As I said, the president’s plan appears to be comparable in principle to what the Breaux-Thomas Commission recommended, which we support. We have said from the beginning that it is unrealistic to think we are going to eliminate the current Medicare program, and we have never advocated repealing the current benefits. We have advocated adding significant reform elements and options to the current system. With regard to new
elements and options, including those suggested in the president’s recent announcement, we begin our analysis with two questions: Will they ensure the elderly access to the best available medicines as prescribed by their doctors? And will the reimbursement be adequate to allow us to continue to discover new medicines?

Our experience with government programs in the U.S. and around the world, whether it be the U.S. veterans program or the government-run program in Canada, has been that when the government bears the financial risk, sooner or later, access to medicines is limited through restricted formularies or other procedures, and reimbursements are reduced. This is why the industry supports a reform model, like the Breaux-Thomas Commission proposal, that involves private entities who are at risk. We know there will be required discounts under any proposal. But, based on current experience, we prefer to negotiate prices with private entities rather than having the government set them by regulation. Again, that is why we support Breaux-Thomas, [and] why we look favorably on what the president has recently proposed.

You just mentioned Pfizer’s preference for a private model. The Administration believes that allowing seniors to opt for a private insurance plan, such as Medicare+ Choice plans, over current coverage will promote competition and increase long-term solvency. How exactly will the plans compete? Will they restrict benefits as is currently occurring in Medicare+ Choice plans?

Whether or not there will be a sufficient number of competing plans in all parts of the country, and whether or not the drug coverage and other medical benefits they will offer will be adequate, are the two major questions and challenges facing the proponents of the private model proposals. These questions won’t be answered for certain until a bill is passed, and a private model program is implemented and in place for a period of time. The assumption is, and I think it’s a safe assumption, that, if Medicare dollars are put on the table, private entities will come forward with competing plans. But, as you know, insurance companies have said that, at least under some of the bills, they won’t participate.

The number and type of plans that choose to participate will be influenced by the critical coverage, benefit and payment features of a private model program, including required benefits and allowed restrictions on covered benefits; limits on premiums, deductibles and other patient co-payments; low-income subsidies; and, reimbursement levels and financial protections for private risk-bearing entities. The challenge for those who draft these critical features will be to provide sufficient latitude to the plans in structuring a benefit, premium levels and cost-sharing provisions to encourage competition, while at the same time imposing some budgetary controls. The financial incentives at the beginning will have to be good enough to encourage a sufficient number of plans to participate and compete, and will have to remain adequate to keep the plans in the program. As you know, a number of plans participated under Medicare+
Choice in the beginning and then dropped out because they said Medicare reimbursement levels did not keep up with costs. There is a significant danger of the same thing happening under the private model proposals like the president's.

*Is one plan better than the other—the plan set forth last year by House Republicans that allows the use of prescription drug-only plans versus the use of regular insurance plans?*

They are not completely alike, but I don't think there are major differences in the different drug-only proposals introduced in recent years. Pfizer believes that competing, integrated, comprehensive insurance options for Medicare beneficiaries, as contained in the Breaux-Thomas Commission recommendation, is highly preferable to a drug-only plan, like the House of Representatives has passed in the last two Congresses.

However, we are fully aware of how difficult it will be to enact a Breaux-Thomas Medicare reform bill. We supported the House drug-only bills both times they passed, because they are based on the private market model of the Breaux-Thomas Commission, and because enactment of Medicare drug coverage in some form is so important. However, insurance companies had trouble supporting the House bills because they were limited to drugs, which they do not think is an insurable event. You recall, they said this is like insuring against the need for a haircut. We are also concerned that drug-only plans continue to fragment the delivery of health care.

*Some researchers assert that a prescription drug benefit for Medicare beneficiaries will end up saving costs in the long run because by providing seniors with access to new and innovative drugs, spending on other services such as hospitalization will be lowered. Do you believe this is so?*

Yes we do. We believe that expanded, appropriate use of medicines can and will reduce costs in other parts of the health care system. This is central to our support for the Breaux-Thomas Commission recommendation. We believe that comprehensive and integrated plans that direct patients to the most effective and efficient medical care can reduce health care costs. In addition, and equally important to reducing overall health care expenditures, we think such plans will provide higher quality health care.

The ulcer medicines, like Zantac® and Pepcid®, that have virtually eliminated ulcer surgery, are great examples of how medicines have changed and improved medical care. There are other examples and studies showing that heart medications keep people out of the hospital and reduce surgery. There are also studies suggesting non-health care savings from appropriate uses of medicines. For example, medicines for anxiety and depression can reduce the number of employee sick days. There are also studies that suggest that restrictions on medicines can increase hospital, nursing home and other health system costs.

*Another approach often lauded by the Administration is the issuance of block grants to the states to expand or*
implement state pharmacy assistance programs. With the costs of drugs rising, many states are seeking to curtail their spending on prescription drugs provided through their Medicaid program or these pharmacy assistance programs. Further, the state pharmacy assistance programs vary widely in terms of structure, eligibility criteria and benefits. How does providing grants to states ensure that needy seniors will have access to affordable prescription drugs?

First, the law authorizing the block grants would have to require that the funds provided be used solely to expand current state drug coverage programs for the elderly, to create such a program, or to expand Medicaid coverage of medicines for the elderly. And I am quite sure any legislation passed by Congress would do just that. It will not be just revenue sharing. Also, the legislation should, and I assume would, include some federal eligibility and benefit standards.

If, because of ideological disagreements, budgetary limitations or other reasons, Congress is unable to reach agreement on a universal drug coverage bill, Pfizer, from the beginning, has said it would support interim measures such as a block grant to states to help the most needy elderly purchase medicines. The Breaux-Thomas Commission report, as I recall, talked about interim measures, including block grants to states. The other group of elderly, other than those with low incomes, who need immediate assistance are those with very high annual expenditures for medicines.

Pfizer would support Congressional consideration of a bill that helps these two groups, as an interim measure. We would analyze these more targeted legislative proposals with the same two questions: Will those who are covered have reasonable access to available medicines as prescribed by their physician? And will reimbursement levels for pharmaceuticals be sufficient to allow us to continue our search for new medicines?

There are some good state-based programs that could serve as models, at least as for the low-income elderly. New Jersey, for example, has a very good program that assists the elderly with limited incomes who are ineligible for Medicaid. Connecticut also has a good program. Again, assistance for the low-income and those with very high pharmaceutical costs are interim measures that Pfizer thinks Congress should consider if it can't reach agreement on a more comprehensive proposal. There is tremendous need, and Congress should take whatever steps it can, as soon as it can, to help those most in need.

Can you comment on the success of the prescription drug discount cards implemented recently by some pharmaceutical manufacturers? Is this a program Pfizer participates in and, if so, how does it work for seniors?

Yes, Pfizer has a program. Ours was unique, because it is not a “discount” program. It is a monthly “co-pay” program. Lilly has also announced a program similar to ours. Under the Pfizer Medicare Share Card Program, if your income is below 200 percent of poverty—which I think is about $16,000
to $18,000 for an individual and $22,000 to $24,000 for a couple – if you are eligible for Medicare, and have no other health insurance coverage, you can get any Pfizer medicine for $15 per monthly prescription. Whether it’s Lipitor® for cholesterol, Celebrex® for arthritis, Xanax®, for depression, Zithromax® for an infection, or any other Pfizer medicine, you pay only $15 a month. There’s no enrollment fee and there’s no premium. After a year on the program, you have to re-enroll. The administrative process is quite simple. You submit your last year’s 1040 tax form and a copy of your Medicare card along with a short application form.

We implemented this program last year and we have about 300,000 people enrolled. A month or so ago we filled the one-millionth Pfizer Medicare Share Card prescription. We expected a higher participation rate, and we are engaged in a number of outreach programs to make more people aware of the program and get more of the eligible elderly enrolled.

We have another excellent program for the low-income that is run through Community Health Care Clinics. Under this program – the Pfizer Sharing-The-Care Program – anyone whose income is below the poverty level can get any Pfizer medicine free of charge at participating clinics. We started this program in 1993 and, as of last year, we had dispensed almost 6 million prescriptions, at a product cost of over $300 million.

Is that why you think the participation rates are lower than you anticipated – because people are not aware of the program?

Getting the elderly to participate in assistance programs is a problem for government programs, like Food Stamps and the Supplemental Security Income program for the elderly, as well as a private program like ours. Awareness is one of the reasons, which is why outreach programs are important for both government and private programs. Complicated application procedures are another problem. There also seems to be a natural resistance among many of the elderly to accept assistance.

That was our last question regarding prescription drugs. We are also conducting two interviews regarding the availability of AIDS medication in Africa. During one of the interviews, it was mentioned that Pfizer contributes roughly $10 million per year to fund a program that provides Diflucan® and medical training in Africa with funding that is not time-delimited. Could you comment on this?

Pfizer has a number of HIV/AIDS and other international philanthropy programs. The Diflucan® Partnership program was jointly initiated in 2000 with the government of South Africa. Under this program, we donate our antifungal medicine, Diflucan®, free of charge for the treatment of AIDS related fungal infections. We have now expanded this program to include other developing countries hardest hit by the AIDS epidemic. In addition to this program, Pfizer, in partnership with a coalition of U.S. and Ugandan doctors and health experts, is building a treat-
ment and training institute at Makerere University in Kampala, Uganda.

Under our International Trachoma Initiative, we provide our antibiotic, Zithromax®, free of charge for the treatment of Trachoma, which is the world’s leading cause of preventable blindness. This program is currently in place in eight countries, including Tanzania, Morocco and Vietnam, and we expect to add additional countries over the next several years. Under this program, we distributed over $200 million of Zithromax® as of the end of last year.

In our most recent annual report, Pfizer Chairman and CEO Hank McKinnell writes that Pfizer donates $2 million every working day to provide medicine, medical care and community service to people who need assistance.

M. Kenneth Bowler heads Pfizer’s Washington, DC, office as vice president, federal government relations, a post he has held since February 1989. He is also a corporate officer of Pfizer Inc. In this position, Mr. Bowler is responsible for Pfizer’s federal lobbying activities, including contacts with the United States Congress, and the Administration and executive departments. Before joining Pfizer, Mr. Bowler served as staff director of the Committee on Ways and Means, U.S. House of Representatives. He was also on the faculty of the University of Maryland as assistant professor in the political science department. Mr. Bowler currently chairs the Johns Hopkins University Oncology Center Advisory Council. He holds memberships in the American Political Science Association and the Business-Government Relations Council. He has served on the Johns Hopkins Health Advisory Council, Johns Hopkins School of Hygiene and Public Health; and the Board of Directors of the Journal of Health Politics, Policy and Law. Mr. Bowler earned a B.A. in political science from Stanford University and a Ph.D. in political science from the University of Wisconsin.
Family Health International has worked extensively in Africa to consult governments on how to combat AIDS. From this experience, are there particular governments in Africa that have been more dynamic and creative in their efforts to combat AIDS? Have partnerships formed between countries or regions on this issue? Are there any other trends in activity you can comment on?

Each government is very different. It is not easy to say which countries have been more "dynamic" because the context in which our relationship with countries works is very different. In one country we may work mainly with community-based organizations, facilitating them to do better intervention and care, and in another country we may be part and parcel of the national anti-retroviral task force. Kenya is an example of this, where we are trying to help the government to decide on setting standards for treatment. So it really differs a lot.

From the Ministry of Health's perspective, I think the tide has turned in all countries where the prevalence of HIV/AIDS is high or moderate to high. In those countries, we, at FHI, feel our work with local partners is definitely a commitment to work for a change. All government officials have themselves seen HIV/AIDS in their families and among close friends. That has translated into a kind of commitment. I think
the days of total government denial—and there are exceptions such as countries where the prevalence is very low—are over. We now feel a commitment on the government level to do something about it. That doesn’t mean there is no stigma—there is a lot of stigma still—but the commitment to do something about it is there.

You mentioned a different type of action on the part of the different governments—some are much more proactive, some more reactive. Financially, how do you receive money from the government for the programs your organization supports? Do a lot of the governments provide money from their budget or do finances come primarily from foundations?

There are several questions here. Let me first clarify how we work. FHI comes in with money primarily from USAID (U.S. Agency for International Development), but also from other governments such as the United Kingdom—DFID—(Department for International Development) or from foundations in the U.S. or Europe. We channel that money into contracts with non-governmental organizations (NGOs) and provide technical assistance to build capacity for those NGOs and government partners. Due to USAID rules and regulations, that money cannot directly go to a government in Africa. So we can go directly to NGOs, large or small. There are ways to help governments to do their job better and get them involved; to invite them to meetings and training workshops, facilitate their work, etcetera. But we cannot directly support the government coffers. There are other mechanisms for that through debt relief, soft loans, grants, etcetera.

At the other end, that commitment I mentioned in the beginning needs to be translated into something. One of the ways to translate commitment at the national level, but in my view not the only one, is to show that your budget shows enough money allocated to that particular problem, for example buying antiretroviral drugs. However determining what is “enough” and how to ensure that that does not go at the expense of other essential national services such as health education, condoms, nurse training, malaria or cholera is difficult. There are so little resources available at country level anyhow. In fact, the absolute number of dollars ministries of health are spending on diseases in general are declining over the last 10 years and people are paying more and more out of their pocket. A virtual absence of health insurance system for the poor and middle classes means, in particular for the HIV affected who have more recurrent illnesses in the first place, a very substantial proportion of their monthly income is going to buy health services.

So in addition to calling for larger national budgets, we need development aid. We need to have organizations like the International Monetary Fund (IMF) and the World Bank negotiate with governments to increase the overall health budget and to provide government employees with salaries on which they can live. But with the current freeze of IMF funding because of debt, there is no mechanism through which salary structures of government
workers can be increased. So we still meet and work with people of similar academic levels as you or me in the ministry of health earning just $100 or $200 per month. How can you expect that that commitment, what he or she says and feels in his heart, can be translated into action if he cannot send his children to a proper school or cannot have a decent and modest life according to his status?

There is a double standard here. On the one hand, we say that we cannot support government, we freeze expansion of government staff, and we freeze income because governments have to pay their debt and have to clean their government structures and increase privatization. On the other hand, we want the government to do more on HIV/AIDS for which they need more staff and facilities. So there is a discrepancy there.

Even at highly discounted rates, most Africans will still be unable to afford the medications needed to fight AIDS. By some estimates, the average African spends little more than $10 annually on health care. How do you address this issue and how do you think Africans can get access to quality healthcare while spending such a small sum?

Well, that's entirely correct. There are many countries in eastern, central and southern Africa where health expenditure per capita is between $10 and $20 a month and you wonder, with all of this new interventions needed to be paid for, how can patients pay for it? Our view is that simply dumping free drugs in such a system won't work.

Our approach with regard to who pays what is that it is up to the government or the mission hospitals or NGOs to determine their payment schedules for patients. If they say this will be done through a subsidized payment and we let patients pay a little bit and there are subsidized rates for the drugs, then that's fine. I still think that we as a donor country should give the medicines for free or almost free to governments, big NGOs, or mission health care organizations. But then it is up to the government to decide what in their system of health care fits best.

We should not make HIV/AIDS different than tuberculosis, malaria, measles, or other diseases. As long as it remains affordable within that local context and exemption rules are maintained, for example for the very poor, orphans, pregnant women. If we are going to disrupt systems because of this massive influx of support for HIV/AIDS, we are unbalancing the way health systems need to be built up. I think we should not make available to countries we work with the same broad variety of drugs available here. We should support the purchase of drugs according to their standards for first and second line regimens set by national decisions. That is different for each and every country.

FHI-USAID is now facilitating HIV care with treatment in three countries – Ghana, Kenya, and Rwanda – where we have strengthened existing health systems at district levels. We have chosen, in close collaboration with our partners, some guiding principles in our approach. First, access to care should be equal within certain geographic areas, say a district or prov-
ince where we focus our support to develop learning sites with multiple entry points for patients, such as a voluntary counseling and testing site, the outpatient department of government and (mission) hospitals, the maternal and child health clinic and the TB, STI clinics. Nationally agreed [upon] eligibility criteria, which include medical and social criteria – for example, proof that you are living in the area of the facility – are put in place.

A second principle is the comprehensiveness of care. Our services meet the medical, nursing psychological and social needs of families affected by HIV from treatment to counseling, from home care to legal support. We then train the staff, make sure the labs are working, develop standard operational procedures for the various interventions and build partnerships with other organizations with expertise in social or legal support or with organizations of people living with HIV/AIDS. We strengthen the drug management systems to ensure that the ARV drugs are available in the same way other drugs are available for that particular hospital or medical service.

There's a bit of a sustainable development philosophy behind it. I know that's different from how many other organizations are working in a more ad hoc way, but we are choosing to proceed through these entry points and we'll see how that goes.

Given the negligibility of the amount of money that most Africans have available to pay for their healthcare expenses, and given that the efforts now to provide drugs in Africa are more on the subsidizing level than just giving these drugs away for free, do you think it will have any impact if there are subsidized drugs? In other words, if these drugs are given out at half the cost most Africans still won't be able to afford them. So do you think the effort to subsidize isn't going far enough?

My view is that even for that $30 a month - that's the cheapest that it can come with generics - is, of course, much too high for most governments of highly affected developing countries. In that case, there is still an obligation of the donor community - being it the World Bank through grants or cheap loans, or bilateral support from rich countries - to buy those drugs for that very low price and give it to those governments. The government, in turn, should then develop cost sharing mechanisms according to what patients can pay.

The pharmaceutical industry doesn't like this because they question why they should subsidize or reduce the price at all when they would like to sell to governments in a competitive market. But this is much too high of a price for governments to pay. It is outrageous for their public health budget where so many other crises need to be dealt with as well. Take malaria or cholera as an example, or the efforts to reduce maternal mortality. Then again, bilateral donors have to grant money to the government for them to buy from the companies at the lowest price, because the companies won't sell for those low prices to USAID, or DFID or CIDA (the Canadian International Development Agency). With U.S. government fund-
ing, however, that is now going to change. Negotiations have started to allow USAID money to buy drugs directly from the industry outlets in developing countries or from the companies at the same price they are charging in a developing country. The procedures have still not been finalized but the movement is there.

Most Africans live in rural and isolated communities and can be difficult to reach, even when governments have AIDS drugs available for distribution. How difficult is the problem of delivery? How can this problem be overcome? How can health professionals provide follow-up care to monitor progress and make sure treatment regimens are strictly followed?

That is very true and the only way is through a phased approach, which by definition is not equitable. So the political slogan, equitable access, is of course in reality not practical because treatment for any condition is more difficult in the most rural areas than in the capital city. We can't overturn that overnight. If it is difficult to get your pneumonia treated with an antibiotic, which is only available in town, then that system will prevail for some time. FHI and many other NGOs are calling for the development of provincial or district based "learning sites." At that level, which is usually the capital and the major towns where there is some infrastructure, we should quickly develop a learning site with proper training, a functional laboratory, a nutritional support and drug distribution and safe regulatory system, and protocol so that people can be assessed. Are they eligible for treatment or not? If they are eligible, they get treatment there. We should make those learning sites operational, document what it takes minimally to provide care and treatment at an acceptable level and then move to more peripheral sites.

For the anti-retroviral therapy, my view is that a physician, somebody who has the authority to prescribe, should be the one who guides this approach. We cannot, as yet, go straight to the health center or dispensary level to have a nurse practitioner or dispenser make the decision that a person should be on treatment and how to monitor that properly. You need to identify that at the district hospital level. Take a country like Uganda. If you say district hospitals are the access points, then you are talking about 70 to 80 sites per country. Those seventy or eighty sites in a country of 22 million people can, of course, never reach the whole country. That would be impossible. A major emphasis will be learning to develop those 70 to 80 sites and strengthen functional referral mechanisms to link peripheral clinics better with the district hospitals. It will take at least five years to reach that. Then see how we can follow up from there. Maybe people could come for the initiation of their therapy and then train the medical workers and the nurses for follow-up treatment and refer properly when there is an issue to refer back to the district hospital, like for any other medical condition.

My point is, let's not make it different for AIDS than for other health issues. But we have to be careful,
because more than any other disease, including tuberculosis, the initiation and adherence to the prescription has to be rather precise in order to avoid resistance. We should not exaggerate this whole resistance issue, but again, it is not just a short course therapy for an acute infection, not even a six-month therapy for TB; it is a life long “contract” one makes with the care providers team to manage a chronic disease with all kind of issues happening over time, which need to be addressed.

**How effective are so-called ‘ABC programs’, which stand for ‘abstinence, be faithful, use a condom’? Are there certain countries or subpopulations where this campaign has been particularly effective?**

There is a political connotation in this question I am afraid. ABC is of course a very hot issue here in this country. Luckily, it is not such an issue in the rest of the world where we have learned that letter represents an intervention has tremendous value for the audience it is directed towards. So the A is key to primary school boys and girls, the B is key to couples, and the C is key to risk situations which are and will continue to happen to most of everybody in certain situations. But in this country there is an emphasis on the A and B at the expense of the C. In my experience, that’s very unfortunate.

What we have learned in prevention is that prevention is not easy. Ensuring that prevention interventions reduce transmission in a sustainable way is tough. Even in this country we don’t see that among populations with high transmission rates in the presence of care and support systems. On the contrary increases in HIV transmission are reported among marginalized women, within gay communities, et cetera.

The A of abstinence, the B of faithfulness, and the continuous proper use of condoms are of equal importance, but it depends on the context. If I go to the primary school of my wife’s village to meet with girls between 8 and 12 years of age, of course the approach would be much more toward postponing first sex and abstinence. But if I go into the bigger town there and work with truck drivers or bartenders, my emphasis would be on the safe and continuous use of condoms. It is context-specific with balance between the A and B and C and other prevention activities.

I think many countries have had success, but not success particular to the A, B or C component, because you can’t split those. We have success because so many things have happened at the same time — there is government commitment, good condom promotion, good health education at school, access to care where patients get respect and dignified care, and sufficient HIV disease that people can see what happens in their families or neighborhood. All these factors together in Uganda, Thailand, Zambia, Tanzania and other countries have meant that the incidence goes down. We can’t single out a particular intervention.

**While the focus of this interview is HIV/AIDS in Africa, the problem is**
much more widespread. A recent article in *Foreign Affairs* highlighted the growing problem in Russia, India and China. How big is the problem? What are the issues of availability in those countries? With the focus now on Africa, is there a fear that the growing problem in these other areas might be neglected?

When I hear this question, which is true – rapid increases in areas until recently with very low prevalence – my gut reaction is why you don’t mention your own country and the high prevalence in the inner-cities of America? What I have seen here in this country, for example in Anacostia [area of southeast Washington, DC], where I’ve visited different welfare clinics, is very surprising indeed. The amount of poverty, broken homes and high HIV/AIDS prevalence rates like many parts of Africa, yet with a sophisticated and beautiful clinic which can only provide care because of the special charity support mechanisms it has with no sustained public support system in which to operate. I think we can learn a lot from Africa in this country about social development in order to prevent and care even better in America. In parts of Russia, because the change in the social-economic system has led to high increases in poverty, prostitution, and sexually transmitted diseases, HIV has crept in as well. In China the situation is a bit different. The bulk of the infection has been linked to selling blood by people who need that money due to poverty, and that’s created a lot of HIV there. And now there is the high mobility of people so people from one place bring that infection to other places. In India, in particular in urban India, not so much rural India, increases there have taken place as well.

So that is as important as it is in Africa because there we are still hopefully at an earlier stage of the epidemic so that maybe we could have more impact on the epidemic. Although I am a bit pessimistic because we really haven’t addressed prevention as we could address it. We don’t know if what we know about prevention methodologies will be effective. Are we sure that we can really change social, cultural norms *vis a vis* sexuality? Can we change drinking culture in sub-Saharan Africa, which is very much linked to casual sex? Can you change the widespread poverty and male-female relationships, which allow no other way for young girls to get money [except] through casual sex? Can those very basic determinants of development be changed with our interventions for HIV prevention? I don’t have a clear answer, but I think that just ABC may help, but it may not be a sustained change if we can’t address poverty and education in general. So I’m pessimistic in that respect.

But I don’t see that there really is a neglect for Russia, India and China. There is a lot of attention in the UN, the WHO and UNAIDS raising the issue directly. Countries are mobilized. It’s true that earlier in the epidemic, that neglect and denial at the policy level is much larger. We are reinventing the wheel; it’s really a disappointment that the rest of the world doesn’t learn from Africa. Where we have really learned in Africa and Thailand, how to address issues, we have to start from scratch. In India, it’s a different culture. Al-
though we've tried to have people learn from each other, it's very difficult. A district in India would take all the lessons learned from a district in Kenya and move the control efforts straight from there. It seems everyone is reinventing the wheel there and starting from scratch. But I think the awareness is there.

_HIV/AIDS is an international issue that requires an international response._ How is U.S. policy blending or clashing with other efforts to combat AIDS in Africa and around the world? Is the U.S. involved in meaningful international coalitions or are countries tending to run their own programs?

The international partners in HIV/AIDS, including America, are indeed coordinating through various fora, and often under an UN umbrella like WHO or UNAIDS. However specific support to countries occurs rather parallel. In fact, it is up to the UN, the WHO, and UNAIDS to ensure that those different bilateral donors work together to help those countries. Ideally, it should be the governments of countries to coordinate all those inputs. Because one week there is a British team at the ministry of health promising "Land Rovers", computers et cetera and next week the Swedes or Americans are coming with a similar package. And of course, you as a poor national AIDS control manager from the Ministry of Health can't say no. But those intervention packages are not coordinated with each other and they have overlapping within the popular geographic areas. Each donor bringing its own reporting systems and with different accountability systems, which makes the work of a national AIDS control manager very complex indeed.

There is a lot to be done in inter-donor coordination and it's very difficult because that money comes from our governments - effectively taxpayers' money. So those institutions have the responsibility to feed back that information, the accountability, to their own government. And the way you do that in America is different from the way you do it in Holland or France. Specific donors won't like the fact that monies put together have one accountability system. A few countries in Latin America and Africa opted for a basket approach where all donor support for the health sector is put in one common account to which regional or district health development plans can draw from, a bottom up approach. But the outcome of that approach can never be traced back to a particular donor, so one would not know how many malaria lives were saved from a specific donor input or how many condoms were bought?

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Dr. Eric van Praag is a physician and epidemiologist from the Netherlands who has worked extensively in tropical public health and HIV/AIDS care and prevention in non-industrialized countries around the world. In July 2000, Dr. van Praag joined Family Health International (FHI), a private non-governmental organization based in the United
States, as FHI's new Director of HIV/AIDS Care and Treatment Division. Prior to coming to FHI, from 1988-2000 Dr. van Praag worked with the World Health Organization in Zambia and in Geneva, Switzerland where he was the Acting Director of the HIV and STI Initiative of WHO.

Dr. van Praag holds a Medical degree from the University of Amsterdam and a Masters degree in Public Health from the London School of Hygiene and Tropical Medicine. He has published extensively and is a member of scientific committees of the major global and regional AIDS conferences.
Everyone agrees that the HIV/AIDS pandemic on the African continent is a crisis. However, there are differing opinions on how to deal with it. Specifically, some feel that allowing pharmaceuticals to be provided free to all Africans will hurt research and development in the industry. Others say that pharmaceutical companies are putting profits before their patients. Discuss this dispute and how a settlement might be reached that would satisfy all parties involved.

I believe that industrial nation pharmaceutical companies should be providing, or at least not standing in the way of, the production of pharmaceuticals for developing nations. The rationalizations they have offered for why they don't do it are implausible and wrong and they're damaging themselves. Even if you wanted to stay within their own cosmology—thinking about the pharmaceutical industry in industrial nations—it seems to me that a lot of people are angry at the way they've been handling this and the public relations damage they've done to themselves is worth a lot more to them than the almost "rounding error" it would cost them to allow these drugs to be supplied.

The pharmaceutical industry, even within its own framework, could do a lot of things with these drugs that would not hurt their Western markets. The first and most obvious one would
be to supply the drugs themselves. In terms of marginal cost, it's not all that expensive to keep the factory running to create one or 10 or 10,000 additional pills. In addition, providing at marginal costs wouldn't affect their Western prices and at the same time could allow the provision of drugs to developing nations quite readily.

The second thing they could do is to voluntarily license their products to generic manufacturers overseas. That "voluntariness" gives them some control over how these drugs are used. They keep bringing up the arguments of trans-shipments and sending drugs back into the Western marketplace. But they could, with a voluntary contract with generic manufacturers, actually make it possible to have some say in how those drugs are manufactured and distributed and at the same time not lose any money on it.

The final opportunity would be at least not to stand in the way of generic manufacturers. Nobody in a Western country is going to be taking those drugs and they're not even going to be able to find a doctor who would be willing to write the prescription. It's just implausible to me that these generic drugs would be trans-shipped back into the U.S. to take the place of something they could have sold at Western prices.

All of these things can be done without even affecting their Western prices and without affecting their Western market. Then we would go to the stronger proposals, such as compulsory licensing — requiring them to give up some of their intellectual property rights when the drugs are being used for urgent problems in developing nations. I'm not sure we even need to go there, but I would support it if they're not going to cooperate in any other way.

It seems that in their own enlightened self-interest they'd want to allow the distribution so that they could stop this hemorrhaging public relations damage that they are having against their Western image. They spend billions of dollars trying to get their image up for all their new products, get brand names and re-name themselves with a computer-generated word that's going to be the name for this pharmaceutical company. And I think a lot of that is defeated having, not just guys in black t-shirts, but good, church-going people getting together and saying, "Why is it you're not helping these people, or at least get out of the way?" It seems to me that they're wasting their public relations money if they end up blowing all their reputation on these types of things.

So I suggest provision at marginal cost, voluntary licensing and getting out of the way of generic manufacturers even without the license, or, if push comes to shove, compulsory licensing for urgent problems.

*Could you please comment on the issues of black markets and reimportation?*

The black markets seem to me a red herring. First of all, there's been one reported instance of something being diverted. Who does it hurt when black market drugs are diverted? It hurts the people overseas who aren't getting access; it doesn't really hurt the drug companies. The idea that they're be-
ing reimported into Western countries that would pay catalog prices for these drugs is preposterous. You have some form of health insurance, I have some form of health insurance, and all of these things are controlled substances that require prescriptions to get. We're not going to take black market drugs if we have any other alternative.

Assume for instance the worst case scenario—homeless on the street with no community health center to go to and they need drugs. How are you possibly going to get drugs from Somalia back to you? How will you pay for them? It seems to me, if anything, it's depriving the Western drug companies of a market that they choose not to participate in. I don't see any way that this could possibly harm their domestic market.

Many African countries engage in a practice called parallel importing, in which antiretroviral drugs are purchased from another country at a lower price than they could be obtained directly from the manufacturer. What are the main regulatory issues related to parallel importing, and how might any regulatory problems be addressed?

Someone looking at this from the U.S. perspective is probably not interested in the importation, but rather in the initial manufacturing in that other country. I assume when someone discusses parallel importing they mean bringing it in from Brazil, India or, someday, from Thailand—although all those countries say they are really near the top of their production capacity for their own domestic needs and they don't have enough to produce it for other countries. The legal or regulatory issue would be: Did that country that manufactured it—not the one who was importing it, although they would probably be considered complicit, but the one who was manufacturing it—violate intellectual property laws or patent laws in the first place? There's been a lot written about India and Brazil in this area.

The initial issue is whether there are intellectual property problems with the country that manufactured it from whom the parallel importer is importing it. As far as importing it—and I'm assuming for the purposes of this discussion we're not routing it through U.S. borders and then back out again—I don't know that there are any other legal problems with parallel importing other than the intellectual property violation that someone would allege.

The other legal problem is if the U.S. government decides to continue to press its intellectual property issues in a trade context. Then I suppose somebody could possibly be trade sanctioned for importing in addition to manufacturing.

In 1997, the government of South Africa was sued by a group of pharmaceutical manufacturers for their violation of the Trade Related Intellectual Property Rights (TRIPs) agreement. A South African law ignited the debate when it allowed the government to bypass patent law and obtain generic pharmaceuticals to handle severe public health problems. What is your position on the case the pharmaceutical firms presented and how
do you think this will play out in the future?

That case is what I think of as drug companies doing terrible damage to themselves as far as domestic public relations. The news media coverage of the case in the U.S. reminds me of the “dog in the manger” analogy. A dog is lying in a cow’s manger where the fodder is for the cow to eat. The dog doesn’t want it; the dog doesn’t eat fodder, it eats dog food. But the dog is unwilling to move in order for the cow to get to something it could use. The “dog in the manger” is someone who is in your way; doesn’t need it for themselves but is unwilling to get out of the way for your needs.

This is a classic “dog in the manger” situation with the U.S. and European pharmaceutical companies. They’re just getting in the way of people who need it desperately, even though the U.S. pharmaceutical companies would be unwilling to supply it themselves. I think they’ve done themselves grave harm. I’m glad they (the government of South Africa) won. I think the decision will continue to reverberate.

AIDS is only the first kind of major publicity maker. As health care goes from what happens to you in a surgical operating room in a hospital where they treat you to being what you get by prescription and it becomes more transportable or easily distributed around the world, these issues are going to continue to crop up as equity issues between first and third world countries. When it was all about high-tech things you could have on the surgical ward, that was not something that was easily transportable back and forth from first to third world. When it’s something that all you need, at most, is a refrigerator — and in most situations you don’t even need that — I think these issues are going to continue to crop up and I think the initial loss of public relations will reverberate through the pharmaceutical companies for years.

Brazil and India have moved into the market of producing generic AIDS medicines. Through the act of compulsory licensing — the manufacture and issuing of generic drugs without the agreement of the patent holder — these countries have become an important source of anti-retrovirals for Africa. They have also used these drugs at home. Brazil, in particular, has been able to treat more AIDS patients by using cheaper drugs produced domestically. How is this movement toward compulsory licensing affecting the world market and what do you see happening if the trend continues?

First of all, those two countries say they’re close to their own manufacturing capacity to meet their domestic needs and they’re not going to be able to send drugs worldwide and cover every third world country. So I’m not sure that it affects the world market in a big way right now. At the Barcelona AIDS meeting (XIV International AIDS Conference held July 7-12 in Barcelona, Spain), both those countries said they were going to be able to help but they wouldn’t be able to do much. So I’m not sure it affects the market except in the two countries themselves — which are huge markets that most drug com-
companies don’t want to supply. But they are huge markets that can never in any way afford even the deeply discounted U.S. prices. The idea of even a 90 percent discount from the catalog price in the U.S. is not a reasonable thing. And it’s probably not good for the per capita GDP for those countries. I don’t see how it affects the market place worldwide.

If compulsory licensing were to move into Western countries, eminent domain seizure of patents or something like that would affect their markets; but we’re so far away from that. People are building more and more protections of intellectual property. There are various and sundry tricks and games that are played to keep from going generic in the U.S., but no one is talking about seizure of patents in the domestic market.

Even under current TRIPs agreements in intellectual property law, there’s a question that lawyers refer to as one of jurisdiction. Where is it to be tried? Whose law are you violating? If drugs are made domestically for that country, you have to be violating that country’s law. For a plant inside China, for example, or any other country that doesn’t currently have manufacturing capacity and isn’t already a signatory to TRIPs, the drug companies would have to bring the case in that country’s court; at least until the trade agreements start making a trade court in Europe. None of these drug companies is going to go to a Somalian court, for example, and say we want you to find that our patents matter more than your people’s lives. They’re just not covering these cases. So, to some extent, I don’t think compulsory licensing is necessary if it’s possible to manufacture the product domestically.

When you get to compulsory licensing there is the question you were asking earlier – what if you make the compulsory license to somebody who’s a signatory to TRIPs and who could be tried somewhere else? That reminds me of the most interesting presentation in the [Barcelona] AIDS conference in this area: the Thai government. Thailand is now making its own generic drugs as well. They are clearly making it only for Thailand, only to be used within that country because they just don’t have the capacity to produce more. The Thai official gave a presentation saying that they were not able to manufacture Thai generic drugs to supply to the world, but they were willing to do technology transfer. If other third-world countries would put together a plant of their own, the Thai government would train their technicians and perform quality control once a year to make sure they have good manufacturing practices in place.

Brazil and India are already drug-producing countries. They have the manufacturing capacity. A lot of these countries don’t have anything; but if Thailand is willing to export technology, training and review of good manufacturing practices, I think that Thailand can possibly help everybody to be self-sustaining for the production of generic drugs for this epidemic and other epidemics like malaria and tuberculosis as well. And if they do then we run back to the question of jurisdiction. Then the drug companies would have to sue domestically to get jurisdiction of the issue. It doesn’t seem to
me that anybody's going to have a leg to stand on this. You don't need to go to the hot flashpoint issue of compulsory licensing, which many drug companies have press releases on. You can go to the domestic manufacture of drugs and take the attitude: "Sue me and come to my jurisdiction to sue me. I'm only making it for my own purposes and my own country and I'm not trans-shipping it and I'm not interfering with your markets. I'm just providing it to my own people and you'll have to defend it on my home court."

Since Thailand has become so involved and offered their assistance, how have they handled their own AIDS problem?

Thailand is such an extraordinary AIDS country. In the 1980s, when the epidemic was beginning to be recognized worldwide, Thailand had a huge — and I assume it still does — commercial sex industry, sex tourism and a lot of prostitution. And they had a lot of drug use as well. Their rate of new infections among drug users was going up 7 percent a month. Stop and compound that in your head. But Thailand had a minister of health who went into the government and said that they had to give condom and safe sex advice to everybody immediately and they actually brought their infection rate not only under control, but I think it's declined. It's one of the only places in the world where the infection rate is declining. They're not at the point that Brazil is in guaranteeing antiretroviral drugs to anybody else, but they're getting there.

In his State of the Union address, President Bush highlighted his new $15 billion AIDS initiative for Africa, $10 billion in new funds. How does the Bush plan compare to those of previous administrations? Given the current economic climate, do you believe this funding will become a reality?

On its face it seems like so much more than the Clinton, Bush and Reagan Administrations did. I say on its face because I still have some questions on how this money adds up and it's still nowhere near what everyone thinks a fair U.S. contribution should be — given our economic size and our ability to pay for all those pharmaceuticals. It is, on its face, so much better than anything else that's been done, but I still want to look underneath to see what's included in that figure.

Mr. Bush actually named a $300 per person price in his State of the Union. The only people who produce at the $300 price are India and Brazil, and yet this Administration is still holding out against "compulsory licensing" or "illegal" generic manufacturer. So where is the $300 coming from? I've asked this question of the Administration and I haven't gotten an answer. I've asked congressional staff people as well and they haven't said. Do we have a Western pharmaceutical company who is actually going to charge $300 a person? I've never seen it. Maybe they're doing it. Maybe they're actually going to provide it at that rate. If we're paying anywhere near Western catalog price for this, then the money is one big plus to the pharmaceutical companies. It's not about providing
aid, it’s about showering money on the pharmaceutical industry. So I’m skeptical. I want to know where the money is going and at what price the drugs are purchased. If the catalog price is $15,000 per person instead of $300, then it seems to me there’s a lot of waste here and the American taxpayer is paying to reward pharmaceutical companies.

The newly elected Senate majority leader, Bill Frist, the only medical doctor in the U.S. Senate, strongly backs the President’s proposal. How much influence will he be able to muster in this process?

If Dr. Frist wanted to make this an issue that he held onto, he would have incredible influence. This is the point man for the Administration for their tax policy, their war policy, their budget policy, for everything. He’s the number one man in the country for them right now. His statements and his commitments have been terrific in the past. But also in the past, he has been talked down by the White House. How much influence can he have? Infinite. How much will he have? It depends on how much he negotiates, because it seems clear to me that their money is not where their mouth is.

Even at highly discounted rates, most Africans will still be unable to afford the medications needed to fight AIDS. By some estimates, the average African spends little more than $10 annually on health care. How do you address this issue and how do you think Africans can get access to quality health care while spending such a small sum?

It will always be a “MASH (mobile army surgical hospital)” hospital situation in developing nations to provide current medical technology to people at $10 per year. Having said that, $300 per year is achievable. That’s not paying for the diagnostics, the anti-infective drugs, or for any of their other health care needs like maternal child health, heart disease, cancer, and tobacco addiction that would have to fit into that $10. Again, the question is not what you can provide from your surgical ward but what can you provide from your pharmacy, and thus what is more readily available? The more you can reduce some of these things to the ability of having the pharmaceutical that you can simply provide, albeit with a diagnostic, the more chance you have of providing medical care at that price. But that can’t be done without a lot of Western assistance and pharmaceutical companies backing up saying they are choosing not to enforce their full intellectual property rights in some fashion — otherwise it won’t be there at all.

Tim Westmoreland is a visiting professor of law and a research professor of public policy at Georgetown University. He teaches classes on federal budget policy and legislation and statutory
He spent 15 years as a staff member for the House Subcommittee on Health and the Environment and served for about two years under President Bill Clinton as Director of the Medicaid program at the Health Care Finance Administration. Westmoreland also has worked as a senior policy fellow at the Georgetown Law Center, where he taught in the clinical program on federal legislation; as legal counsel to the Koop-Kessler Advisory Committee on Tobacco Policy and Public Health; as a senior advisor on HIV/AIDS to the Kaiser Family Foundation; and as a lobbyist for the Elizabeth Glaser Pediatric AIDS Foundation.

Academic outcomes have changed little for U.S. students over the last few decades in spite of large increases in funding and many innovative reform efforts. One explanation for this stagnation is that we lack good information on how to improve our educational system. Perhaps in response to this dilemma, the use of randomized experiments in the field of education is increasing quite dramatically. Indeed, the U.S. Department of Education is explicitly encouraging the use of more experimental research designs with over $40 million in funding per year. Consequently, Mosteller and Boruch's new book, which focuses on the use of experiments in education, has arrived at a very propitious time. The book is based on proceedings of a conference that took place in May 1999 and covers the history, ethics, and politics of experiments in education; how, where, and when experiments should be used, and the pros and cons of alternative evaluation methods compared to experiments.

One of the strongest arguments in favor of experiments is that theory and non-experimental methods alone seldom provide convincing policy implications without fairly rigid assumptions that are hard to justify. The most rigid of these is that the non-experimental method provides unbiased estimates, a claim that can seldom be confirmed without a true experiment. Experiments, in contrast, can generally make do with far weaker assumptions. Among the assumptions that are needed to use experiments, perhaps the least palatable is that the results can be applied to groups not analyzed in the experiment. This assumption is far from innocuous, but may not be nearly as strong as it first appears, especially when compared to the assumptions needed to use other types of evidence. There are a number of reasons for this.

First, many non-experimental methods also estimate impacts that are only valid for a subset of the population studied. Second, convincing information on the impacts of a treatment on one subgroup of a population is likely to be considered useful for estimating impacts on other subgroups, perhaps better than potentially biased information on a more relevant group. Third, in some cases the subgroup included in the experiment may be the group most likely to be affected by the treatment. This could happen if, for instance, many people do not want to receive the treatment being studied by the experiment. Such people might also be resistant to accepting the treatment when it became a standard policy.

Another assumption that is often needed in order to use experimental results for policy purposes is that the effects are localized to the units being randomized – for example, using students rather than schools. Indeed this
is a major point of the last chapter of this book. However, many non-experimental studies also look at micro-level effects (i.e. at the student level) and thus, tend to ignore the macro-effects that occur at higher levels (such as the classroom, school, or geographic area). The assumptions needed to use experiments for making policy decisions are generally far easier to justify than those for non-experimental methods.

One of the strongest arguments against experiments, or at least a concern that could help to explain why many people are against experiments, is that imprecise results can be presented as evidence of no program impacts and consequently used incorrectly as evidence to cut back on important programs. Evidence that this may be a problem is that one seldom hears of experimental results that were judged to be too imprecise to draw strong conclusions. This suggests that great caution should be taken to ensure that experiments not be used in this way. One possible solution (not mentioned in this book) would be that rather than accept the norm of testing against the standard null hypothesis of "no impact," scientists be encouraged to test against estimates of how large program impacts would need to be to justify continued funding based on cost benefit analyses. Of course it is extremely difficult to judge how large such program impacts need be.

Future work will, no doubt, provide additional insight on these issues. In the meanwhile this book helps to set the stage for what should be an exciting era of growth in the use of more rigorous education evaluation methods, especially those based on randomized experimental designs.

DUNCAN CHAPLIN

The Urban Institute


From climate change policy to land management, environmental policy is an integral component of the political landscape. Often, its formulation is considered fraught with tension between two seemingly opposed forces: environmentalists versus corporate interests. However, George E. Gonzalez, in his historically rich book, Corporate Power and the Environment, discusses the intertwined relationship between the "economic elite" and the environment.

Gonzalez first describes the previous work of Domhoff, Miliband and Edelman to discuss the foundations of various policy formulation models. He then identifies four main policy formulation models, which form the basis of his thesis; namely, the Pluralist, Plural Elite, Issue or Policy Networks and Economic Elite models. Gonzalez asserts that environmental policymaking follows more of an economic elite model rather than the more traditional pluralist model. He also maintains that issue or policy networks are not as fragmented as some policymakers may infer, but rather are coordinated by economic elites.

To support his hypothesis, Gonzalez presents examples revolving around the following: the U.S. Forest Service, the U.S. Park Service, Redwood National Park, Yosemite Park, the Jackson Hole National Monument, and the Clean Air Act of 1990. Further, through thorough research and compilation of testimonies, letters, and other forms of correspondence, Gonzalez not only creates solid case studies on the process of environmental policymaking, but also gathers unique historical documentation regarding several of
the cases. The Jackson Hole example is particularly illustrative of the economic elite model of policymaking, focusing on the elite Rockefeller family and its impact on the policymaking process.

Finally, Gonzalez details the creation of different entities within the context of political models, and elaborates on how these bodies have shaped environmental policy. In particular, he notes the contributions made by Gifford Pinchot and Stephen Mather in shaping both the U.S. Forest Service and National Park Service. In terms of forestry, for example, Pinchot’s alliance with politicians who were linked to the timber industry and other corporate liberals led him away from the European forestry or purist philosophy on land use.

Although Gonzalez is able to support his hypothesis with detailed historical evidence for many cases, his last case, detailing air pollution policy, does not capture this thesis as well. The Clean Air Act follows the Issue Networks Model with the creation of the CAWG (Clean Air Working Group). It can hardly be argued that this is a fragmented approach; however, adherence to the Economic Elite model is not as markedly apparent. More attention to some of the backroom negotiations of the Clean Air Act of 1990 may have allowed a better study of its adherence to the economic elite or issue networks.

The environmental policy landscape has also changed considerably since the 19th century. There is a “paradigm shift when public at large grows an environmental conscience.” This level of household activism is mirrored in the growth of public interest groups and powerful environmental lobbying groups. This increased level of public mobilization creates a much more complex scenario than that prescribed by Gonzalez in his previous case studies. The model of the Sierra Club fits in exactly with George Gonzalez’s economic elite theories as combination of “academic reformers and civic-minded business men”. However, as the Sierra Club morphed into a more grassroots organization, the initial organizational structure loses ground (p. 62).

In closing, Gonzalez contends that “non economic actors” cannot influence policy even though they have the power of the vote. He argues that the vote determines who enters office, but cannot control what is done while in office. This argument is in contrast with the policymaking process of the civil rights movement— one where non-economic actors played a large role in policymaking.

Overall, Corporate Power and the Environment brings environmental policymaking into the complex paradigm of the Economic Elite and Issue Network policy formulation models instead of relegating corporate interests and environmentalist interests to separate sides of the issue. Gonzalez has elucidated, through original investigative work, the process through which corporate liberals and academic purists simultaneously formulate policy on forests, national parks, and wilderness reserves. It remains to be seen if such political models can be applied to the highly evolved environmental playing field. However, Gonzalez’s work has established the relationship between coordinated policymaking and the environment, thus laying the groundwork for future studies.

Monisha R. Shah
U.S. Department of Energy, Energy Information Administration
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