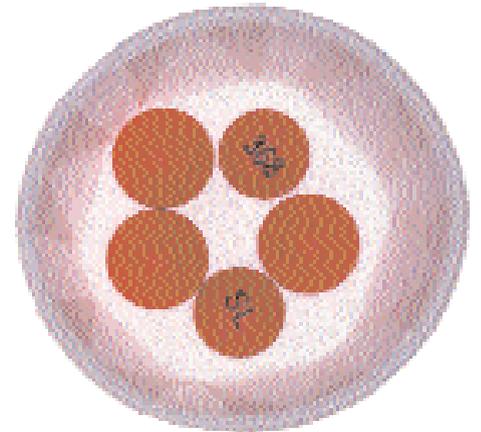
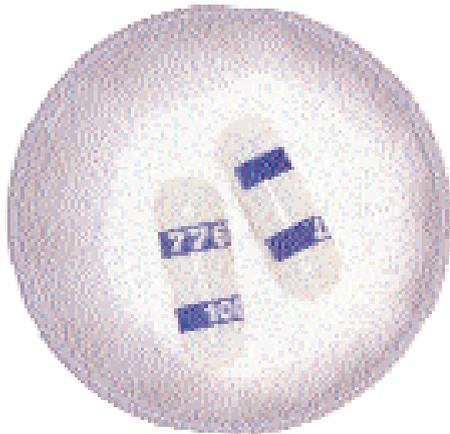




AARP International Forum on Prescription Drug Policy



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SECTION ONE

Executive Summary

As a part of its Global Aging Program, AARP held a one-day forum on June 10, 2003 that examined how European countries, Australia, and Canada are attempting to contain drug costs, ensure adequate access to pharmaceutical products for consumers, and promote innovation among pharmaceutical companies. The primary goal was to understand the lessons that these countries' experiences might offer for the United States.

Welcome and Keynote Address

William D. Novelli, Executive Director and Chief Executive Officer of the AARP, opened the proceedings by welcoming attendees and calling for Congress to show the necessary courage to enact a Medicare drug benefit. He also believes that other countries can offer the U.S. valuable guidance with respect to access, affordability, and maintaining incentives for innovation.

The keynote address was given by F.M. Scherer, PhD, Professor Emeritus at the John F. Kennedy School of Government at Harvard University. Dr. Scherer highlighted the following ways in which the U.S. pharmaceutical industry differs from most other U.S. industries: large size, physicians (not consumers) control most purchasing decisions, product availability is regulated, and that most purchasers are covered by insurance. These factors create a situation where the demand for pharmaceutical products is insensitive to price levels, which tend to be quite high in the U.S. Generally, these high prices, along with strong patent protections and policies that encourage rapid penetration of generics once drugs go off patent, encourage manufacturers to invest in research and development (R&D). Dr. Scherer contrasted the U.S. pharmaceutical industry with that of other countries, noting that the U.S. has lower rates of insurance coverage, a higher degree of generic substitution, and

relatively weak price controls. But Dr. Scherer urged lawmakers to be careful as they consider policies designed to control the price of pharmaceuticals, as such policies could significantly reduce innovation in the U.S. (the biggest supporter of R&D in the world) and potentially raise prices of drugs in less developed countries.

Regulation, Schemes, and Value: Experiences from Europe and Australia

Three panelists discussed approaches to regulation in Europe and Australia. Panos Kanavos, a lecturer at the London School of Economics, highlighted the many ways in which European Union (EU) drug markets differ from those in the U.S., including: a much more limited role for private insurance; near universal access to drugs through national formularies; stronger regulation of drug prices via a variety of mechanisms; more modest copayments, with exemptions for certain vulnerable populations; bans on direct-to-consumer (DTC) advertising; and significant and rising levels of “parallel trade”—that is, prescription drugs manufactured in one EU country that are being freely sold in other EU countries. In highlighting the lessons for the U.S., Mr. Kanavos emphasized the importance of creating the right incentives for stakeholders to control costs, promoting evidence-based use of pharmaceu-

ticals, and considering greater use of “reference pricing” (where prices are pegged to a benchmark drug of similar therapeutic value), although such schemes must be set up carefully.

Anne-Toni Rodgers, Corporate Affairs Director at the National Institute for Clinical Excellence (NICE) in the UK, described the UK’s approach to drug regulation. Facing tensions between equity and choice, efficiency and quality, and demands and available resources, the current UK government developed a 10-year strategic and funding



(left to right) Daniel
Vasella, F.M.
Scherer, Nancy
LeaMond



plan that called for greater use of generic drugs and institution of a quality framework that focused on evidence-based medicine and guidelines. The plan created NICE, an organization that works with relevant stakeholders (e.g., topic experts, physicians) to determine how effective and efficient a product is once on the market, and then to develop guidelines for appropriate use. The 10-year plan also created a monitoring function that evaluates the extent to which NHS providers are complying with national standards. The evidence to date suggests that NHS providers follow NICE guidelines. The net result appears to be better quality prescribing overall and a more rapid “uptake” of effective drugs.

Deborah Freund, PhD, Vice Chancellor and Provost at Syracuse University in Rochester, NY, described the Australian government’s approach to regulating pharmaceutical products which she helped to develop. In Australia, approved drugs must be included on the national formulary to be widely prescribed. Manufacturers apply to be placed on the formulary; these applications include a suggested price, and new drugs are evaluated with respect to their cost-effectiveness versus alternatives at this suggested price. For drugs placed on the formulary, reimbursement is provided only when appropriate guidelines for usage are followed. While it is not yet clear whether the Australian guidelines have been successful in controlling costs,

the system does seem to get appropriate drugs to those who need them.

The Canadian Experience: Myths and Realities

The forum included a discussion of the Canadian experience that was moderated by David Gross, PhD, Senior Policy Advisor with AARP's Public Policy Institute. Tom Brogan, President of Brogan, Inc., described how Canada regulates pharmaceuticals. Federal government policy changes in 1987 led to a restructuring of the patent system, providing significantly greater protection for drugs still on patent. As a part of these policy changes, the industry agreed to at least double its relatively low levels of R&D spending, while the government set up the Federal Patented Medicine Prices Review Board or PMPRB to review drug prices. The PMPRB uses established, transparent guidelines to ensure that the prices charged by manufacturers of patented medicines are not excessive. The board can take action against companies that do not comply with the guidelines, although in most cases the PMPRB and the manufacturer come to a voluntary compliance agreement. The evidence to date would suggest that the PMPRB has been successful in holding prices down. Along with the PMPRB, provincial plans also play a critical role in regulating drugs

in Canada, as they pay for 40% of all pharmaceutical spending. The primary means for influencing the market is through a formulary--that is, a list of drugs that the provincial plans will reimburse. In most provinces, inclusion on the formulary will be determined by a drug's therapeutic and cost advantages versus existing agents.

Bob Nakagawa, Director of Pharmacy Services for the Fraser Health Authority, described changes to British Columbia's PharmaCare Program that were developed in response to costs trends that threatened the fiscal health of the province. The low-cost alternative or LCA program revised the province's policy of paying "full price" for any brand-name drug by establishing the price of the generic drug as the set payment for a given chemical entity. The limited use program required prior authorization for certain drugs, limiting reimbursement to specific situations. The reference drug program sets reimbursement levels based on the "gold standard" in the market for safety and cost-effectiveness. Finally, critical, independent drug reviews compare the effectiveness of a drug to the current gold standard.

The Value of Innovative Drugs: Benefits to Patients and Society

Daniel Vasella, MD, Chairman and Chief

Share of population
with prescription
drug coverage through
public programs.

Australia 100%

Canada 50%

United Kingdom 100%

U.S.A. 12%

Source: AARP Public Policy Institute

Executive Officer of Novartis AG, offered the pharmaceutical company perspective on a variety of issues, including whether the U.S. spends too much on health care in general and on drugs in particular. He believes the answer is no, citing a variety of evidence to support his view, including the role of drugs in reducing death rates from specific diseases (e.g., emphysema, rheumatic fever) and the spillover benefits from drugs in reducing hospital and total health costs. Dr. Vasella also noted that government policies are helping to make the U.S. the primary engine for R&D in the pharmaceutical industry worldwide, and he believes that these policies and high levels of R&D spending are having a positive impact on the U.S. economy and on U.S. consumers, who enjoy quick access to new therapies.

Dr. Vasella noted that pharmaceutical companies do not invest in R&D just as a way to boost profits. They also do it to save lives. Dr. Vasella reviewed some of these programs at Novartis, including subsidies for low-income seniors and other vulnerable populations, deep discounts for special populations (such as those who cannot afford Novartis' revolutionary drug for chronic myeloid leukemia), and free and discounted malaria and leprosy medications for less developed countries and international

agencies that assist them. Dr. Vasella called on the U.S. Congress to pass a Medicare drug benefit and urged governments throughout the world to enact policies to accelerate drug development and speed regulatory approval mechanisms so that patients gain access to needed drugs faster.

What Does This Mean for the U.S.?

Susan Dentzer, on-air correspondent with *The NewsHour*, moderated a final panel that discussed the implications of the day's proceedings for the U.S. Panelists were W. Brian Healy, PhD, of Merck, William Hubbard of the Food and Drug Administration, Judith Wagner of the Institute of Medicine, and Albert Wertheimer, PhD, of Temple University. Key conclusions from this panel include the following:

- Panelists were hesitant to advocate more stringent price and volume controls, although they acknowledged that carefully crafted, "reasonable" approaches to monitoring price and utilization could be effective without having significant negative consequences.
- Panelists expressed concern about the potential impact of re-importation (i.e., allowing drugs that are sold to other countries at cheaper prices to be re-imported into the U.S.) on safety, citing the potential for counterfeiting, inadequate packaging/labeling, and the proliferation of products

with a limited shelf life.

- Panelists expressed concerns about enacting a mandate to conduct studies that explicitly compare the effectiveness of competing drugs, both as a requirement for approval and as a way of providing information to key decision makers after approval. Panelists noted that such information already exists in many instances, but is not being widely used.

Conclusion and Wrap-Up

John Rother, *Director, Policy and Strategy, AARP*, concluded the day's proceedings by thanking the presenters and the audience on behalf of AARP. He also highlighted five "take-away" conclusions: the inevitability that the U.S. should begin to address pharmaceutical price issues, but in a broader context that includes the impact on total health costs, clinical outcomes, and economic growth; the many trade-offs that exist in developing such policies; the fact that no approach can simply be "lifted" wholesale from abroad and that there is no single "magic bullet;" that tools are needed to promote use of information that compares drug efficacy and cost-effectiveness; and that the U.S. (both nationally and at the state level) is just beginning to tackle these issues and has much to learn from the evolving experience from other nations.



SECTION TWO

Agenda

8:00 – 8:30 am **Registration/Continental Breakfast**

8:30 am **Welcome**

William D. Novelli, *Executive Director and Chief Executive Officer, AARP*

KEYNOTE: The State of Pharmaceutical Economics

F.M. Scherer, PhD, *Professor Emeritus at the John F. Kennedy School of Government, Harvard University, and lecturer at the Woodrow Wilson School of Princeton University* USA

9:15 – 10:30 am **Regulation, Schemes, and Value:
Experiences from Europe and Australia**

Panos Kanavos, *London School of Economic Health and Social Care* UNITED KINGDOM

Anne-Toni Rodgers, *National Institute for Clinical Excellence* UNITED KINGDOM

Dr. Deborah Freund, *Syracuse University* USA



10:45 – 11:45 am

The Canadian Experience: Myths and Realities

Tom Brogan, *Brogan Inc.* CANADA

Bob Nakagawa, *Fraser Health Authority* CANADA

12:00 – 1:00 pm

Lunch Address

Dr. Daniel Vasella, *Chairman and Chief Executive Officer, Novartis AG* SWITZERLAND

1:30 pm

Roundtable: What Does This Mean for the United States?

MODERATED BY: Susan Dentzer, *The NewsHour*

W. Brian Healy, *Merck* USA

William Hubbard, *Food and Drug Administration* USA

Judith Wagner, *Institute of Medicine* USA

Albert Wertheimer, *Temple University* USA

3:00 pm

Closing

John Rother, *Director, Policy and Strategy, AARP*

SECTION THREE

Proceedings

Nancy LeaMond, Director, Office of International Affairs, AARP, began the proceedings by introducing William D. Novelli, Executive Director and Chief Executive Officer of the AARP. Noting that Congress is in the midst of its debate on a Medicare prescription drug benefit, Mr. Novelli believes that, after a decade of missed opportunities and continued rising costs, the time is right for Congress to act. On behalf of 35 million AARP members who need and value pharmaceutical products, he called for Congress to show the necessary courage to act. He also believes that other countries can offer the U.S. valuable guidance with respect to access, affordability, and maintaining incentives for innovation.

John Rother, Director, Policy and Strategy, AARP, introduced the keynote speaker for the day, F.M. Scherer, PhD, Professor Emeritus at the John F. Kennedy School of Government at Harvard

University. Dr. Scherer began by noting that the U.S. pharmaceutical industry is different than most other U.S. industries, in terms of the following:

- The industry is large, with over \$200 billion in sales of branded products and generics.
- Physicians rather than consumers make most purchasing decisions.
- Product availability is regulated by the Food and Drug Administration (FDA).
- Most purchasers are covered by insurance; out-of-pocket expenditures currently account for only 31% of all purchases, down from 80% in the 1970s.

These factors create a situation where the demand for pharmaceutical products is relatively “inelastic,” or insensitive to price levels. As a result, prices for branded products tend to be quite high in the U.S., averaging roughly four to five times the actual cost



(left to right) Nancy
LeaMond, Bill Novelli,
John Rother, F.M.
Scherer

of the drug. These high prices encourage manufacturers to invest in research and development (R&D), which averages 16% to 18% of sales, equivalent to \$32 billion in the most recent year. Public investments in R&D are also critical to drug discovery in the U.S., studies suggest that over one-quarter of new products would not have been developed without publicly-funded research at academic centers. Patent protection also plays an important role in the U.S. pharmaceutical industry,

providing protection for a period of time, and therefore an opportunity for companies to reap an adequate return on their R&D costs, which average \$400 million for each approved drug. That said, Dr. Scherer believes that commonly quoted industry profitability comparisons, which suggest that the pharmaceutical industry enjoys a 10 or 15 percentage-point premium over other industries in terms of return on equity (ROE), are misleading. Calculations that operationalize R&D costs (by

depreciating them), suggest that the true premium is between two and three percentage points.

Dr. Scherer contrasted the U.S. pharmaceutical industry with that of other countries, noting that:

- In most other developed countries, insurance covers a higher proportion of drug sales.
- The U.S. has a relatively high degree of generic substitution (roughly 50%, up from 20% in the 1980s), due in large part to laws that encourage rapid, intense competition once patents expire. Rapid penetration of generics is a big stimulus to R&D, since companies know that they must develop new drugs to replace profits from drugs going off patent.
- The U.S. has relatively weak price controls, which leads to higher prices for branded drugs.

Dr. Scherer noted that the lack of price controls in the U.S. creates several problems. For example, some U.S. consumers try to import less-expensive branded drugs from Canada. In addition, U.S. manufacturers face challenges in how to price their drugs in other countries, particularly developing nations that cannot afford the higher prices found in developed nations.

But Dr. Scherer does not believe that price controls are the answer to these problems. In addition,

he prefers use of differential pricing for third-world nations—that is, lower prices (averaging roughly \$6 per prescription) than those found in “rich” nations, which average \$17 per prescription. This approach serves to maximize both market penetration in developing nations and the contribution of such nations to R&D costs.

Dr. Scherer urged lawmakers to be careful as they consider policies designed to control the price of pharmaceuticals, as such policies could significantly reduce innovation in the U.S. (the biggest supporter of R&D in the world), and potentially raise prices of drugs in third-world nations.

Regulation, Schemes, and Value: Experiences from Europe and Australia

Following the keynote presentation, three panelists discussed approaches to pharmaceutical regulation in Europe and Australia.

The European Experience

Panos Kanavos, a lecturer at the London School of Economics, reviewed European regulatory systems and offered relevant lessons for the U.S. from Europe. Kanavos began by suggesting that despite its high prices for branded drugs, the U.S. spends



relatively less on pharmaceuticals than do other countries when measured as a percentage of total health spending. While pharmaceuticals represent only 11% of the total U.S. health budget, they consume more than 20% of total health expenditures in France and Spain. But in terms of drug spending per capita, the U.S. is second only to France.

European Union (EU) countries differ from the U.S. along a variety of characteristics:

- There is a much more limited role for private insurance in paying for prescription drugs.
- EU consumers enjoy near universal access to medicines through national health insurance systems that provide prescription drug coverage. Most countries have a national formulary that determines which medicines are covered under these systems. Manufacturers negotiate inclusion on these formularies for their products.
- Drug prices are either regulated by the government, or are the product of negotiations between government and industry. The United Kingdom, uses a “rate-of-return” regulatory approach, limiting pharmaceutical companies’ return on capital employed. Other EU countries use formal price setting, although there has been a movement away from “command-and-control” pricing (in which the government sets a price) to negotia-

tions that lead to pricing agreements between government and industry.

- Patient copayments tend to be modest, with a significant number of exemptions (e.g., for chronically ill patients). Mr. Kanavos believes the U.S. should consider a similar approach.
- Direct-to-consumer (DTC) advertising is illegal, although patient education is allowed.
- Significant (and rising) levels of “parallel trade” exist—that is, prescription drugs manufactured in one EU country are being freely sold in other EU countries. Some nations actively encourage such trade, especially for high-price, high-volume drugs such as statins. Drugs manufactured in non-EU countries generally cannot be sold in EU nations, nor can EU-made drugs be “reimported” from non-EU countries.

Mr. Kanavos believes that many countries, not just the U.S., have difficulty limiting total drug spending (which is determined by both price and volume of drugs used) and highlighted several lessons from the European experience. He emphasized the importance of creating the right incentives to reduce total drug spending for stakeholders, including physicians. He suggested greater focus on promoting appropriate clinical use of pharmaceuti-

Share of population
65 and over.

Australia	12.3%
Canada	12.6%
United Kingdom	15.8%
U.S.A.	12.3%

Source: AARP Public Policy Institute

cals based on the scientific evidence (and the setting of copayments to encourage appropriate use). He also suggested that the U.S. consider greater use of “reference pricing” (where prices are pegged to the price of a benchmark product of similar therapeutic value) but cautioned that such schemes must be set up carefully.

Anne-Toni Rodgers, Corporate Affairs Director at the National Institute for Clinical Excellence (NICE) in the UK, built upon Mr. Kanavos’ remarks by describing the UK’s approach to drug regulation. The National Health Service (NHS) provides the vast majority of care to British consumers free of charge, although copayments exist with respect to pharmaceuticals. Drugs are available as soon as they are licensed, and 80% of all prescriptions are written in a primary care setting. Like most countries, the UK faces several challenges with respect to controlling drug costs while maintaining quality, including a graying population, changes in the patterns of disease and available treatments (e.g., genetic drugs), a burgeoning knowledge base, and increasing public demands (fueled by information available on the Internet). Health remains a highly political issue in the UK, while physicians tend to be relatively slow to adopt new technologies.

Facing tensions between equity and choice, efficiency and quality, and demands and available resources, the current UK government used its seemingly solid political position to take the unusual step of developing a 10-year strategic and funding plan for the NHS (British governments seldom plan beyond the current election cycle). The plan called for greater use of generic drugs and institution of a quality framework that focused on evidence-based medicine and guidelines. As a part of this quality framework, the plan created NICE, an organization that works with relevant stakeholders (e.g., topic experts, physicians) to develop clinical guidelines for the management of care, as well as assessments of the clinical- and cost-effectiveness of new drugs and devices. NICE is not a part of the regulatory system in the UK (that is, it plays no role in determining if a product comes to market). Rather, its role is to determine how effective and efficient a product is once on the market, and then to develop guidelines for appropriate use. The 10-year plan also created a monitoring function that evaluates the extent to which NHS providers are complying with national standards, thus creating “accountability” for the delivery of evidence-based care. In some instances, providers must document in the chart why they are providing care that falls



(left to right) Panos Kanavos, John Rother, David Gross

outside of established guidelines.

The evidence to date suggests that NHS providers follow NICE guidelines. Given the conservative culture of UK providers, NICE guidelines have in several instances provided the definitive evidence they need to see before they switch practice patterns. The net result appears to be better quality prescribing overall and a more rapid “uptake” of effective drugs.

The Australian Experience

Deborah Freund, PhD, Vice Chancellor and Provost at Syracuse University in Rochester, NY, described the Australian government’s approach to regulating pharmaceutical products, which she helped to develop.

- The Australian health care system offers universal coverage through a national health plan known as Medicare that provides a fairly comprehensive benefits package, including coverage of all drugs (with modest copayments, especially for retirees and the unemployed) that are a part of the Pharmacy Benefits Scheme or PBS.
- While new drugs are approved for use in Australia much like they are in the U.S. (i.e., after testing of safety and efficacy by government agencies similar to the FDA), approval is not enough to generate sales. Drugs must be included on the PBS to be widely prescribed, since those not on the list are not reimbursed by Medicare.
- Manufacturers must apply to be placed on the

Health System Overview for the U.S.A.

Private and public health insurance provides coverage for 86 percent of the population.

Benefit packages vary by type of insurance, but typically include inpatient and outpatient hospital care and physician services. Insurance may also cover other items such as prescription drugs, dental care, and preventive services.

Source: AARP Public Policy Institute

PBS, with applications submitted to the Pharmacy Benefits Advisory Committee or PBAC, which provides advice to the federal health minister on what drugs to place on the PBS. These applications, often made at the same time as the approval application, must include a suggested price; new drugs are evaluated by the PBAC with respect to their cost-effectiveness versus alternatives at this suggested price.

- The PBAC includes clinicians, pharmacologists, and pharmacists. It meets four times per year, and is generally able to give decisions within 13 weeks of the submission of an application. (In many cases, however, decisions are deferred pending additional information). It is important to note that when the PBAC recommends approval for inclusion on the PBS, it does so only for those clinical indications where cost-effectiveness can be documented. The PBS itself places drugs into different categories based on their comparative effectiveness and their cost-effectiveness in defined patient groups. In other words, reimbursement is provided only when appropriate guidelines for usage are followed. For example, some expensive drugs will only be reimbursed after less expensive options have first been found to be ineffective.

It is not yet clear whether the PBAC-initiated guidelines have been successful in controlling costs. Australia already had enjoyed very low drug prices before the system went into place, and the government is still trying to contain drug costs. But no one knows what would have happened to costs in the absence of the system. The system has also faced a number of problems, including the fact that the doses prescribed in real-world settings do not always match what has been tested in clinical trials. The PBAC is also struggling to find qualified experts to review drug applications, and in some cases has trouble finding an appropriate comparison drug. In addition, comparisons are rarely made between drugs and their non-drug alternatives (e.g., surgery in cases where new drugs might prevent the need for surgery), even though the PBAC is supposed to consider cost-effectiveness broadly across the entire continuum of care. That said, the Australian guidelines systems does seem to get appropriate drugs to those who need them, even if they must try other less-expensive agents first. On the other hand, Dr. Freund noted that low prices for Australian drugs (which is the result of multiple factors, not just the PBAC guidelines) have effectively “killed” R&D in the country, in spite of the country’s good university system.

The experiences of Australia might provide some valuable lessons for the U.S. Assuming a Medicare drug benefit is passed, the U.S. federal government will have to decide what drugs to reimburse, what Medicare will pay for such drugs, and what copayments, if any, to charge to beneficiaries. In other words, the U.S. might be forced to develop a scheme that is similar to that found in Australia, a complex and daunting task.

The Canadian Experience: Myths and Realities

The forum included a discussion of the Canadian experience that was moderated by David Gross, PhD, Senior Policy Advisor with AARP's Public Policy Institute. Dr. Gross noted that while drug prices are often lower in Canada than in the U.S., these lower levels of drug spending in Canada are not solely due to the regulatory activities of the national government (which does not pay for drugs in its health plan), but rather to the actions of provincial and private insurance plans.

Tom Brogan, President of Brogan, Inc. and one of the developers of the main price control agency in Canada, described how Canada regulates pharmaceuticals. He began by noting that the prices for

single-source, brand-name drugs in Canada have historically been 15% to 20% lower than in the U.S. While it is not entirely clear why this difference exists, part of the reason may be due to federal government policy changes in 1987. These changes included a restructuring of the patent system, providing significantly greater protection for drugs still on patent and also making it easier for generic companies to enter the market quickly following patent expiration. (Prior to these changes, patented pharmaceutical products in Canada had virtually no right of market exclusivity, with a select group of generic companies being licensed to manufacture and sell drugs still on patent, and required to pay royalties to the patent holder that were considered inadequate.) As a part of these policy changes, the industry agreed to at least double its low levels of R&D spending, to 10% of sales by 1996 (a figure the industry actually exceeded), while the government set up the Federal Patented Medicine Prices Review Board or PMPRB to review drug prices.

PMPRB does not approve or set drug prices in Canada. Rather, its goal is to ensure that the prices charged by manufacturers of patented medicines are not excessive, and that they maintain balance between industry's interests and the ability of payers to afford new drugs. PMPRB evaluates prices

and sales figures for new drugs in both Canada and in other countries. It uses a set of clear, transparent guidelines to determine if pricing is excessive. Guidelines for new patented drugs call for prices that are equal to or below the highest cost of therapy for existing drugs in the same therapeutic class. Prices for “breakthrough” drugs are limited to the median of the prices charged for the same drug in other industrialized nations. PMPRB will investigate allegations of excessive pricing, and can take action against companies that do not comply with the guidelines. The need for action, however,

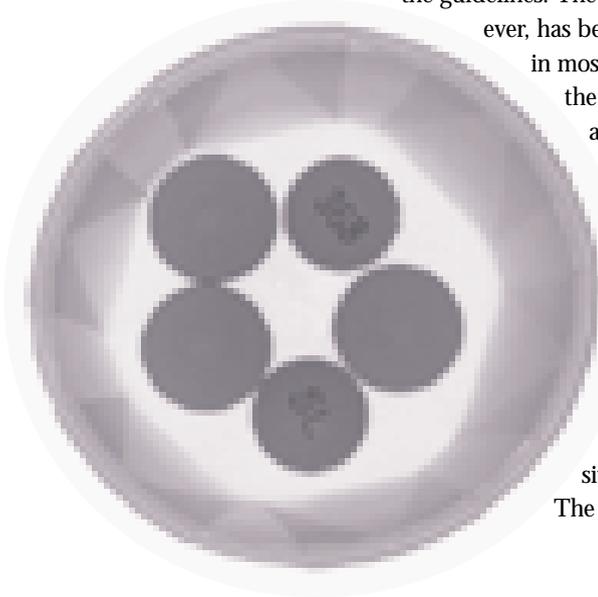
in most cases the PMPRB and the manufacturer come to a voluntary compliance agreement. For example, one company recently agreed to a 20% reduction in the price of its drug, and to pay the government \$7.8 million dollars to compensate for charging an “excessive” price historically. The evidence to date would

suggest that the PMPRB has been successful in holding prices down.

Along with the PMPRB, provincial plans also play a critical role in regulating drugs in Canada, as they pay for 40% of all pharmaceutical spending. The primary means for influencing the market is through a formulary—that is, a list of drugs that the provincial plans will reimburse. In most provinces, inclusion on the formulary will be determined by a drug’s therapeutic and cost advantages versus existing agents. Given the current economic situation, it is difficult for non-blockbuster drugs to gain inclusion on a province’s formulary unless they offer economic benefits. That said, the policies and practices of provinces vary considerably, with some provinces being much more receptive to listing new drugs on their formulary than others.

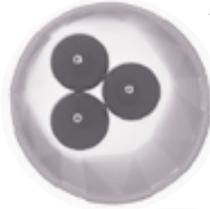
Mr. Brogan concluded by offering implications for the U.S., noting that the Canadian government has disproportionate input into pharmaceutical pricing and expenditures. In some cases, the impact of policy is difficult to measure, and thus it is critical to carefully evaluate the potential ramifications of changing policy on total health expenditures and on incentives for R&D.

Bob Nakagawa, Director of Pharmacy Services for the Fraser Health Authority, built upon Mr.



Brogan's remarks by describing the efforts of one of the more innovative provincial plans in Canada. Fraser Health Authority's goal with respect to pharmaceuticals is to manage the cost of drug therapy while fostering appropriate drug use within British Columbia. The British Columbia plan provides coverage to seniors, low-income populations, and to individuals with certain diseases. The plan also provides universal coverage for everyone against catastrophic expenses. Drug benefits are determined by the relative value or worth of a drug. Not all drugs are equal, so not all drugs are included on the provincial formulary or reimbursed in all situations. As evidence of the wide variation in the relative value of new drugs, Mr. Nakagawa cited a French study of 2,693 new drugs released from 1981-2002 which found that two-thirds of the drugs were "nothing new" and only 3% offered a "real advance."

Mr. Nakagawa described changes to British Columbia's PharmaCare Program, which were developed largely in response to costs trends that began in 1993-1994 that threatened the ability of



the province to keep its budget in balance. The first program, established in 1994, was the low-cost alternative or LCA program that revised the province's policy of paying "full price" for any brand-name drug by establishing the price of the generic drug as the set payment for a given chemical entity. In other words, the government pays the generic price regardless of whether a generic or brand-name drug is used. The second initiative, launched in 1995, was the limited use program, which required prior authorization for certain drugs, reimbursement for which is limited to specific situations (e.g., patients with certain clinical indications, patients for whom less expensive agents have failed), as opposed to the previous policy of reimbursing for these drugs whenever they were used. The goal is to make sure that use of drugs is based on evidence of safety, efficacy, and cost-effectiveness. A third tool involved conducting independent reviews of new drugs designed to compare their effectiveness to the current gold standard. A fourth tool was the reference drug program, which seeks to promote appropriate drug use by funding the "gold standard" treatment in terms of safety and

cost-effectiveness in those situations where multiple drugs are available, such as ACE inhibitors. A Harvard evaluation of a reference drug program for ACE inhibitors found no negative impact in terms of patient compliance.

The Value of Innovative Drugs: Benefits to Patients & Society

Daniel Vasella, MD, serves as Chairman and Chief Executive Officer of Novartis AG, the sixth-largest pharmaceutical company in the world and one of the leading developers of new products, with 10 new drugs introduced since 2000 and another 15 expected by 2006. Dr. Vasella began by addressing the issue of whether the U.S. spends too much on health care in general and on drugs in particular. In his view, the answer is no. As support, he cited the tremendous drop in death rates from diseases that previously used to claim a significant number of lives, including emphysema and rheumatic fever. Many of these gains have been the result of new drug therapies. He also noted that prescription drug spending accounted for only 10% of total health care spending, and only 1.6% of total GDP, in the U.S. in 2001, well below the levels found in France and Italy and only slightly more than in Canada and Germany. Drug price

increases, moreover, have only been slightly higher than the overall inflation rate, with much of the overall spending increase being due instead to increases in volume (fueled by changing demographics) and to changes in mix to more expensive therapies. Most important, perhaps, Dr. Vasella highlighted the tremendous cost-saving potential from drug spending. A recent study found that each \$1 increase in drug spending yielded \$1.11 in net savings to the healthcare system (the study found that hospital costs fall by \$3.65 while expenses increase by \$2.54—the \$1 spent on drugs and another \$1.54 spent on physician services). As an example of this phenomenon, Dr. Vasella cited studies showing that increased use of migraine headache medications, growth factors (G-CSF), and inhaled steroids for asthma patients has been associated with reductions in hospital and overall health costs along with enhancements in quality of life. Conversely, experience from Germany suggests that reductions in drug expenditures can lead to increased hospital costs.

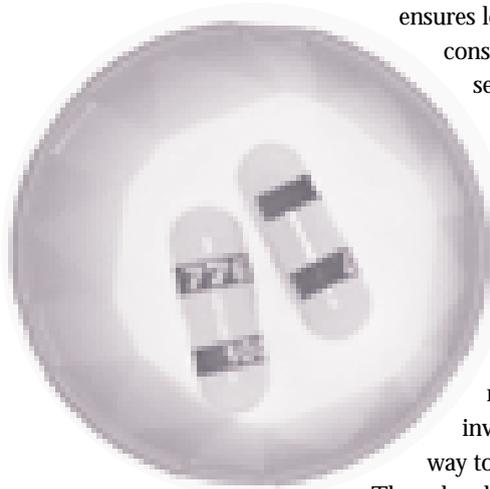
Dr. Vasella also noted that the U.S. is becoming the primary engine for R&D in the pharmaceutical industry, as several European firms are moving their R&D operations to the U.S. This trend can also be seen by comparing the budgets of the U.S.

government to that of EU countries. The U.S. commits \$21 billion annually to the National Institutes of Health, while the governments of EU countries spend approximately \$3.4 billion on similar activities. Not surprisingly, many European scientists and researchers are migrating to the U.S. for both education and professional opportunities. Dr. Vasella believes that the U.S. government is wise to make such investments in R&D, because a strong pharmaceutical industry is in a country's national interest, serving to generate new jobs, ensure early access for patients to new life-saving and life-enhancing therapies, attract new talent (a "brain gain"), and generate spillover benefits for other industries. Most new products are first launched in the U.S., while regulatory and reimbursement delays remain common in many European countries, thus denying valuable products to needy patients. At the same time, the pene-



tration of generic drugs is much slower in Europe than in the U.S., meaning that European consumers are forced to spend more on old drugs, leaving less money available for new, innovative therapies. Dr. Vasella much prefers the U.S. approach, which emphasizes quick penetration of new drugs combined with fast generic substitution once drugs go off patent. Rapid introduction of generics not only

(left to right) Tom Brogan, Bob Nakagawa



ensures lower prices for consumers, but also serves as a powerful incentive for manufacturers to develop new products before important drugs go off patent.

But pharmaceutical companies do not just invest in R&D as a way to boost profits.

They also do it to save lives.

Dr. Vasella believes that nothing is more motivating than bringing therapies to market that can really make a difference in the lives of patients. Dr.

Vasella also discussed programs offered by Novartis and other pharmaceutical companies to help low-income individuals afford drugs. The Novartis Care Plan for Seniors, for example, provides low-cost drugs for seniors who earn less than 200% of the federal poverty line, with discounts extending to those earning up to 300%. More than 50,000 individuals are enrolled in this program. Novartis and several other companies have also developed the

Together Rx Card, which provides approximately 772,000 individuals with discounted drugs.

Novartis' Patient Assist Program also provides millions of dollars in benefits to those who cannot afford chronic drug therapy. For example, more than 10% of patients receiving Novartis' revolutionary drug for chronic myeloid leukemia receive a substantial discount, since this high-priced, highly effective therapy is sometimes out of the reach of financially-strapped patients. Finally, Novartis' activities extend to the developing world as well, as the company is committed to providing free medication for leprosy until the disease is completely eradicated, and to providing the World Health Organization with malaria therapy at cost. A new research center in Singapore, moreover, will focus on developing therapies for diseases that tend to affect the least developed nations.

Dr. Vasella ended his remarks by summarizing the key policies that are critical to an effective drug industry. First and foremost, he called on the U.S. Congress to pass a Medicare drug benefit, as seniors need coverage. He called on governments throughout the world to enact policies to accelerate drug development and speed regulatory approval mechanisms so that patients gain access to needed drugs faster. He also called for strict patent protec-

tions that provide the industry with incentives to invest in R&D, combined with rapid, intense generic competition after patents expires, which serves to reduce prices and create further incentives for investment in R&D.

What Does This Mean for the U.S.?

Susan Dentzer, on-air correspondent with *The NewsHour*, moderated the final session, in which a distinguished panel and audience members discussed the implications of the day's proceedings for the U.S. Panelists were **W. Brian Healy**, PhD, Vice President of Economic and Industrial Policy at Merck; **William Hubbard**, Senior Associate Commissioner for Policy and Planning at the FDA; **Judith Wagner**, Scholar-in-Residence at the Institute of Medicine; and **Albert Wertheimer**, PhD, Founding Director of the Center for Pharmaceutical Health Services Research at Temple University.

Issue #1: Should the U.S. Adopt More Stringent Price and Volume Controls?

Noting that the relative lack of regulations in the U.S. has led to both “good” (the U.S. becoming a focal point for R&D) and “bad” (high costs) outcomes, Ms. Dentzer began by asking whether the

U.S. should adopt a more comprehensive system of price monitoring, oversight, and volume controls designed to ensure appropriate utilization.

Most panelists were hesitant to advocate such an approach, although they acknowledged that carefully crafted, “reasonable” approaches to monitoring price and utilization could be effective without having significant negative consequences. Dr. Wertheimer believes that most price and utilization controls have historically “tinkered at the edges” of the problem, and he warned against importing another country’s systems into the U.S. Unique cultures, histories, and systems in each country mean that there is no generic program that can work everywhere. He also is concerned about the potential for unintended consequences from any price or volume control system, particularly with respect to the impact on R&D spending (although he acknowledged that reasonable controls can exist without having a large impact on incentives for R&D). He is attracted to the idea of the government regulating pharmaceutical companies the same way they regulate utilities—that is, limiting overall profitability. Dr. Healy believes that the pharmaceutical industry is already overregulated, and he fears that further regulation will lead to distortions and unhappy patients (especially as consumers age and their expectations

In the US...

Nearly two-thirds of all Americans had some form of drug coverage in 1999.

Outpatient prescription drugs generally are not covered by Medicare and, in the fall of 1999, about 40 percent of beneficiaries lacked drug coverage.

Source: AARP Public Policy Institute

grow), as is common in Europe. He urged the U.S. to evaluate “best practices” from elsewhere, and to adopt those ideas that might make sense for the U.S. market. He believes that the wave of the future is a more “patient-centered” system that strives to eliminate delays in getting medicines to patients. He also warned against mixing (largely unneeded) economic regulation, such as refusing to reimburse a drug because of costs, with scientific and medical regulation (which is critical to ensuring the safety and efficacy of drugs). Dr. Healy acknowledged that the Canadian drug manufacturers did double their investment in R&D even in the face of price controls, but he noted that historic levels of R&D spending in Canada were extremely low due to government policies that provided little if any patent protection for branded drugs. Dr. Wagner believes that greater government oversight might be a good idea, but she is concerned that investments in R&D may be held back in the face of the uncertainty, instability, and unpredictability that often accompanies such government-led programs. She believes that private sector mechanisms tend to be more stable and predictable, and thus encourage appropriate levels of investment. She also cautioned against direct government intervention in pricing, noting that existing Medicaid “rebate” laws (which mandate

that state Medicaid programs get the best prices offered to private plans) may be creating a price floor that limits the ability of companies that manage pharmaceutical benefits to negotiate discounts on behalf of their millions of enrollees. As a result, she would like to see any new Medicare drug benefit rely primarily upon private sector, competitive mechanisms to set prices and to monitor utilization.

Issue #2: What Is the Appropriate Policy with Respect to Re-importation/Parallel Trade?

Re-importation of drugs from Canada and other countries (i.e., allowing drugs that are sold to other countries at cheaper prices to be re-imported into the U.S.) is a politically sensitive issue, as some consumer advocates have suggested it is an effective way to reduce the price of branded products. Mr. Hubbard has testified against re-importation, as the FDA is concerned about the safety and efficacy of such products. Even though prices for these branded products may be lower in Canada and elsewhere, the FDA believes that the practice could undermine the safety of drugs in the U.S. Counterfeit drugs and product tampering are particularly large concerns, as is the lack of quality control and appropriate packaging and labeling for such drugs. Dr. Healy noted that the issue of re-

importation in Europe consists of two parts. Parallel trade—that is, the free movement of drugs within EU nations—is perfectly legal and growing rapidly. Its popularity is likely one reason for the increased interest in re-importation in the U.S. But the EU frowns upon the re-importation of drugs originally sold by an EU country to a non-EU country. For example, an EU nation that sells AIDS drugs at cost to Africa should not then allow that drug to be re-imported for sale within the EU. Several European manufacturers have stopped selling drugs to certain “Internet” pharmacies that are suspected of engaging in this practice. The EU has also seen evidence of counterfeit drugs and the re-importation of products with a short shelf life, and therefore is putting in place safeguards to ban the re-importation of products from outside the EU.

Issue #3: Should Comparisons of New Drugs to Existing Alternatives Be Required?

Current regulations require the FDA to compare a new drug to a placebo to determine its safety and efficacy prior to approval, and there is no mandate for any studies that compare new drugs to existing alternatives. But other countries, such as Australia and some European nations, will not approve reimbursement for a drug until its effectiveness has



Deborah Freund

been compared to other agents within the same therapeutic category (when they exist). Dr. Scherer suggested that a similar approach could be taken in the U.S., not primarily for the FDA to use in determining whether to approve the drug, but rather for health plans, providers, and consumers to use in determining whether to pay for and/or use the drug. Mr. Hubbard noted that such an approach is

Prescription drug
spending, as a share
of national health
care spending

Australia	7.3%
Canada	11.8%
United Kingdom	11%
U.S.A.	9.6%

Source: AARP Public Policy Institute

not currently within the authority of the FDA, whose primary concern is safety and efficacy, not relative effectiveness. Dr. Healy voiced opposition to mandatory testing versus alternative drugs, noting that many European countries have often found it difficult to pick an appropriate comparison drug. Dr. Wertheimer noted that several large purchasers (e.g., the Veterans' Administration) already conduct such tests, and that other buyers already have access to a plethora of information from published academic studies that compare drugs within the same therapeutic class. Unfortunately, such information is not being widely used at this point. Dr. Wagner expressed concerns that large public purchasers might end up politicizing the process by which drugs get covered; she prefers a situation where thousands of actors in the private sector make their own decisions based on available evidence and appropriate, market-based incentives.

Issue #4: Should Pharmaceutical Representatives be “Cut Out of the Loop”?

Even as pharmaceutical companies spend millions of dollars on DTC advertising, they are increasing their already substantial investments in representatives who market directly to physicians. Companies in other industries, such as Wal-Mart, have cut

manufacturer representatives out of the loop in an effort to keep prices down. Should a similar approach be taken by purchasers of drugs? Dr. Wertheimer cautioned that, for better or worse, drug representatives provide physicians with valuable information that they might not otherwise have access to, since most physicians are far too busy to keep up with the rapidly growing knowledge base on their own. While it might be better if physicians received information from a more objective source, such an approach is not likely realistic. Thus, cutting out manufacturer representatives might mean that physicians are unable to stay abreast of the latest scientific evidence, and therefore patients might not receive the best treatment available.

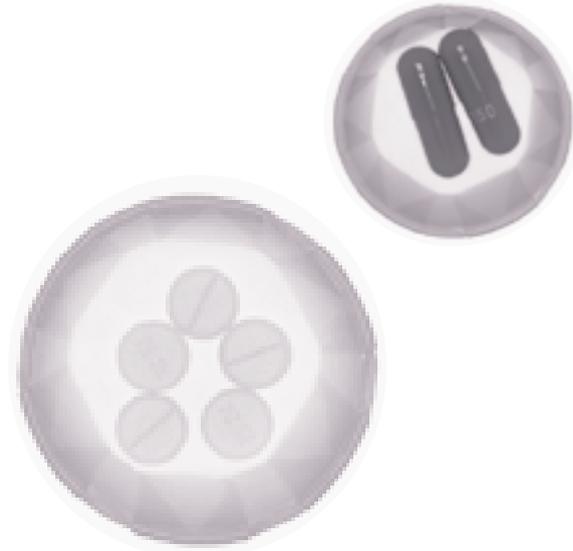
Conclusion and Wrap-Up

Mr. Rother concluded the day's proceedings by thanking the presenters and the audience on behalf of the AARP. He also highlighted five "take-away" conclusions:

- It is inevitable that the U.S. begin to ponder the issues related to pharmaceutical pricing, but in the broader context that also considers issues such as total health costs, clinical outcomes, and the impact of the pharmaceutical industry and R&D on the overall well-being of the economy.
- There are many trade-offs to be considered when developing such policies, including price versus volume, early access to promising new therapies versus lengthier reviews to ensure safety, widespread versus "appropriate" use of new agents, and use of generics versus brand-name drugs.
- The international experience reflects a wide variety of approaches, and is still evolving. There is no single "magic-bullet" solution that we can adopt wholesale from another country. We could use evaluations of best practices for managing both the supply of and the demand for pharmaceutical products.
- A common theme has been the need for more information and evaluation with regard to which medicines work best. More information and

research on the relative value and the comparative efficacy and cost-effectiveness of drugs is now available, yet key stakeholders in the U.S. do not currently make use it. The U.S. needs to develop its own set of tools to better promote value purchasing of pharmaceuticals.

- The U.S. is just beginning to tackle this whole range of issues. States may be at the forefront of these efforts, serving as laboratories to test innovative approaches. The evolving experience of other nations is critically important to inform our efforts.



SECTION FOUR

Biographies

Tom Brogan *President, Brogan Inc.*

Tom Brogan is widely known as an innovator in the field of health economics and pharmaceutical market research. Tom has pioneered drug claim analysis and was among the first to bring together data from large a number of insurers to provide valuable insight into pharmaceutical utilisation behaviour.

Tom spent 15 years in government policy making part of which was on pharmaceutical issues. He headed the team which developed the price control agency in Canada.

Brogan Inc, founded in 1989, now maintains the largest drug claims database in Canada and is a market leader, providing services to governments, insurers and pharmaceutical marketers. Services include health economic reports, analysis of drug utilization patterns, market research to name a few. The company is well regarded for quality and the objectivity of its research.

Brogan Inc has conducted detailed analysis of

both private and public drug plan operations and has published a number of research reports.

Tom graduated from the University of Windsor with a degree in economics.

Susan Dentzer *The NewsHour with Jim Lehrer*

Susan Dentzer is an on-air correspondent with The NewsHour, where she leads a unit dedicated to providing in-depth coverage of health care, health policy and Social Security reform.

The health unit, begun in 1998, was awarded the 2000 Robinson Electronic Media Award by the American Psychiatric Association for its report on schizophrenia. The unit is funded by a grant from the Henry J. Kaiser Family Foundation.

Prior to joining The NewsHour in July 1998, Dentzer was chief economics correspondent and economics columnist for U.S. News & World Report, where she served from 1987 to 1997. In a series of columns and stories for U.S. News, she

reported extensively on the debate over reforming and partially “privatizing” Social Security and over such health policy issues as regulation of managed care. Before joining U.S. News, Dentzer was at Newsweek, where she was a senior writer covering business news until 1987. She has also been a frequent contributor to such publications as *Modern Maturity* and *Working Woman* magazines.

Dentzer’s work in television has included appearances as a regular analyst on ABC’s *Nightline* and PBS’s *Washington Week in Review*. She has also been a panelist on such CNN shows as *Late Edition*, *Inside Politics* and *CNN & Company*, as well as on *The McLaughlin Group*, *Fox Morning News* and *C-SPAN*.

Dentzer’s writing has earned her several fellowships. A Nieman Fellow at Harvard University for the 1986-87 academic year, she studied health economics and other disciplines. A U.S.-Japan Leadership Program Fellow in 1991, Dentzer conducted research on U.S.-Japan economic relations and the effects of the aging Japanese population. She detailed her findings in a series of stories for U.S. News.

A magna cum laude graduate of Dartmouth College, Dentzer is the chairman of the Dartmouth board of trustees. She is also a trustee of the

Dartmouth-Hitchcock Medical Center and a director of the Japan Society of New York. She holds an honorary Master of Arts degree from Dartmouth and an honorary doctorate of humane letters from Muskingum College, New Concord, Ohio. Dentzer, her husband and their three children live in the Washington DC area.

Deborah Freund, PhD Vice Chancellor & Provost, Syracuse University

Deborah A. Freund assumed her position as vice chancellor for academic affairs and provost of Syracuse University on Aug. 1, 1999. She also holds the position of professor of public administration in the Maxwell School of Citizenship and Public Affairs and adjunct professor of orthopedics at SUNY Upstate Medical University.

Prior to her position at SU, Dr. Freund served as vice chancellor for academic affairs and dean of the faculties at Indiana University-Bloomington (IU) from 1994-99, where she also held appointments as professor of public affairs (in health economics) in the IU School of Public and Environmental Affairs (SPEA), and professor of family medicine in the IU School of Medicine. She also directed the Otis R. Bowen Research Center. At SPEA, she served as associate dean and faculty chair with oversight for

undergraduate, professional masters and doctoral components. Prior to joining the faculty at IU, she was on the faculty for nine years at the University of North Carolina at Chapel Hill, where she was a tenured associate professor, director of the interdisciplinary doctoral program in health services research, and director of the Finance and Economics Research Program at the Sheps Center for Health Services Research.

Dr. Freund is an internationally known health economist, recognized particularly in the areas of Medicaid, health care outcomes and PharmacoEconomics, a field she is credited with founding. She has written more than 120 articles and chapters, two books, and has been the principal investigator of grants and contracts totaling more than \$32 million. She has been an editorial board member of 10 journals and is the recipient of numerous honors and awards.

Dr. Freund has been a visiting professor at Harvard, Stanford, London, Australian National and Keio universities and has testified in front of Congress and been a consultant to many states and international pharmaceutical companies. She has been honored with three research prizes and has held numerous leadership positions in professional associations, as well as in nonprofit and

corporate concerns.

She received an A.B. in Classics from Washington University in St. Louis (1973), an M.P.H. in Medical Care Administration (1975), a M.A. in Applied Economics (1975), and a Ph.D. in Economics (1980) all from the University of Michigan.

David Gross, PhD Senior Policy Advisor, Public Policy Institute, AARP

Dr. David Gross, a Senior Policy Advisor with AARP's Public Policy Institute, is responsible for policy research and analysis on prescription drug payment, coverage, and reimbursement. In these roles, he serves as a link between the research and drug policy communities, AARP's advocacy staff, and AARP's volunteer and membership base.

Dr. Gross, who received his Ph.D. in Economics from Syracuse University, is a frequent writer and speaker on prescription drug issues. His most recent publications on Generic Drugs and Canadian Prescription Drug Prices are included in your packet. Dr. Gross has also testified on pharmaceutical access issues on behalf of AARP before state legislative committees, the National Association of Insurance Commissioners, and the Iowa Governor's Consumer Health Advisory Council.

Dr. Gross has represented AARP on RxHealth

Value, the Consumer Advisory Committee of the Pharmaceutical Care Management Association, and a coalition that developed the document Principles of a Sound Prescription Drug Formulary. He is a frequent reviewer for the health policy journal Health Affairs, and has appeared on television's BusinessWeekTV and radio's The Diane Rehm Show.

Prior to his association with AARP, Dr. Gross was a Manager at Barents Group of KPMG, where he worked on pharmaceutical and managed care issues for the federal government, industry associations, and private industry. Previously, Dr. Gross was a Senior Economist at the U.S. General Accounting Office, where he managed GAO's international prescription drug price comparisons and its analyses of the effects of Canadian and European drug pricing regulations. While at GAO, Dr. Gross served a one-year detail as staff economist to the Small Business Subcommittee on Business Opportunity and Regulation of the U.S. House of Representatives.

Chris Hansen Associate Executive Director,
State and National Initiatives, AARP

Christopher W. Hansen is the Associate Executive Director of State and National Initiatives for AARP.

In this position, Mr. Hansen is responsible for all issue advocacy, state operations, community service and volunteer activities. Originally, he joined AARP as Advocacy Director where he was responsible for all federal, state, grassroots and legal issue advocacy. Mr. Hansen was appointed Associate Executive Director in January of 2003.

Prior to joining AARP in April 2002, Mr. Hansen spent 26 years in the aerospace industry, retiring from the position of Sr. Vice President–Government Relations for the Boeing Company. In that capacity he also served as a member of Boeing's Executive Council. Mr. Hansen has worked in government relations in Washington, DC since 1974.

Mr. Hansen has devoted much of his time to a variety of non-profit boards. He currently serves on the Executive Committee of the Board of Directors for the Wolftrap Foundation.

Mr. Hansen received a Bachelor of Arts degree in Political Science from the University of Denver in 1971. He also received a Master's of International Management from the American graduate school of International Management in 1974.

W. Brian Healy, PhD Vice President, Economic
and Industrial Policy, Merck

Dr. Brian Healy is Vice President, Economic and

Industrial Policy, at Merck & Co., Inc., in Whitehouse Station, New Jersey, where he is responsible, among other activities, for representing Merck's interests before governments and in trade and industry associations around the world.

Prior to joining Merck in 1976, he was Assistant Professor of International Politics and Economics at the University of Pennsylvania. During his career at Merck, he has been charged with increasing responsibilities spanning a range of functions including Business Analysis, Operations Planning, and Economic Affairs. He established and headed for six years the Merck Centre for European Government Affairs in Brussels. In 1993, Dr. Healy moved to Merck's World Headquarters in Whitehouse Station, N.J., to create and lead the Economic and Industrial Policy function.

Dr. Healy received his Doctorate in International Politics and Economics from Cornell University and has a Masters degree from Columbia University where he was a member of the European Institute. He completed his undergraduate studies at Georgetown University, School of Foreign Service.

Dr. Healy is a member of the boards of several Merck entities, a Trustee of the U.S. Council for International Business, a Board Member of the

Business Council for International Understanding, and a member of the Global Economic Council of the National Policy Association.

He resides in New Jersey with his wife, Marie Schelfaut, and their two daughters; his son practices law in California.

William Hubbard Senior Associate
Commissioner for Policy and Planning, U.S. Food
and Drug Administration

Mr. Hubbard advises the Commissioner on agency policy, coordinates the development of the Agency's rulemaking, and oversees the planning and evaluation functions of the Food and Drug Administration. Mr. Hubbard received his B.A. in history and American studies from the University of North Carolina, Chapel Hill, and his M.A. in Public Administration from American University.

Mr. Hubbard began his career in Federal service in the U.S. House of Representatives in 1972. He served as a higher education specialist at the Department of Education from 1973-1978. After one year at the Environmental Protection Agency, he joined FDA as a program analyst in 1979. Since that time, Mr. Hubbard has worked in FDA's Office of the Commissioner in various capacities (as well as serving in the Office of the Secretary of Health and Human

Services). From 1991 to 1999, he held the position of Associate Commissioner for Policy Coordination, and assumed his current position in 1999.

He has received numerous FDA awards for outstanding performance, as well as the Presidential Award for Design Excellence, the Secretary's Award for Excellence in Public Service, the HHS Distinguished Service Award, and the Presidential Executive Rank Award.

Panagiotis Kanavos Lecturer in International Health Policy, School of Economic Health & Social Care, London School of Economics

Panos Kanavos is a lecturer in International Health Policy and course coordinator for the MSc in International Health Policy within the department of Social Policy, at the London School of Economics. He was Harkness Fellow in Health Care Policy and Fellow in Ambulatory Care and Prevention at Harvard Medical School in 2001-2002.

His research interests comprise:

- The economics of health-related high technology industries
- Health system analysis from an international perspective
- Pharmaceutical policy

- Health and pharmaceutical system reform from an international perspective.

He is currently coordinating:

- The database on European Pharmaceutical policies, a project sponsored by the European Commission—DG Enterprise.
- The Clearinghouse/Database on Pharmaceutical Economics & Policy at the London School of Economics (LSE Health), a project sponsored by the World Health Organization—Europe Office.

He has acted as advisor to the World Health Organization and the World Bank on a number of missions related to the following areas:

- Pharmaceutical sector reform in the Philippines
- Global Generic Pharmaceutical Policies
- Pricing and reimbursement of pharmaceuticals in Bulgaria
- Pharmacy privatization in Former Yugoslav Republic of Macedonia
- Development of Training materials in Health Economics; Health Forum on Technology Assessment in Health Care
- Pharmaceutical Economics & Policy with Application to Eastern Europe
- European Health Care Reform; Macroeconomic & Health Constraints in Health Systems Reform

Nancy LeaMond Director of International Affairs,
AARP

Nancy LeaMond is an international public policy expert whose career spans key legislative, executive and advocacy roles.

She currently serves as Director of International Affairs at AARP, a 35 million member nongovernmental organization representing and addressing the interests of persons over age 50. At AARP, Ms. LeaMond's main focus is on the policy issues of the over-50 population in developed countries worldwide. She is responsible for the execution of international affairs campaigns and the expansion of AARP's liaison and cooperation with other like minded international organizations and governments.

Prior to joining AARP in late 2001, Ms. LeaMond served as Chief of Staff to U.S. Trade Representative Charlene Barshefsky, acting as a principal policy and legislative adviser, as well as chief operating officer for the \$30 million, 200-person federal agency. At USTR, Ms. LeaMond coordinated public affairs activities around the enactment of major trade agreements with Jordan and China, as well as the 1999 negotiations of the World Trade Organization.

During President Clinton's first term, she was the

member of the senior policy team serving as the Assistant U.S. Trade Representative for Congressional Affairs, providing strategic and legislative support. Among her accomplishments is the successful management of the passage of major Presidential legislative initiatives including the North America Free Trade Agreement, the Uruguay Round (GATT), and China MFN. Ms. LeaMond also advised then Commerce Secretary Mickey Kantor and William Daley on legislative, policy and management issues.

Ms. LeaMond served five years as President of the Congressional Economic Leadership Institute, a non-profit, non-partisan public policy group focusing on international trade, technology and tax issues related to U.S. competitiveness. Previously, she spent several years on Capitol Hill as the Chief of Staff to U.S. Congresswoman Mary Rose Oaker, managing activities of the Committees on Banking and Finance, Civil Service, and Aging.

Ms. LeaMond also served in the U.S. Departments of Commerce and Education where she was the recipient of the "Professional Achievement Award." She began her career in public policy in the U.S. Department of Health, Education and Welfare.

Ms. LeaMond holds a bachelor's degree in

Sociology and Urban Studies from Smith College and a Master's degree in City Planning and Public Policy from Harvard University's J.F. Kennedy School of Government.

Bob Nakagawa, B.Sc. (Pharm), F.C.H.S.P
Director of Pharmacy Services, Fraser Health
Authority

Bob Nakagawa received his Bachelor of Science in Pharmacy in 1980 from the University of British Columbia and subsequently completed his residency in hospital pharmacy at St. Paul's Hospital in Vancouver. Bob is a licensed pharmacist in British Columbia. He is registered with the Pharmacy Examining Board of Canada and is a Fellow of the Canadian Society of Hospital Pharmacists (CSHP). Bob is currently a Clinical Adjunct Professor in the Faculty of Pharmaceutical Sciences and an Associate Member of the Faculty of Medicine at the University of British Columbia.

During his professional career, he has had extensive involvement with numerous professional organizations, committees and task forces, both at the provincial and national level. Bob has served as President of both the National and BC branch of the CSHP and the College of Pharmacists of BC (provincial licensing body).

Bob has been recognized for his professional contributions and been credited with numerous awards. In 1996, he was awarded the Dean's Certificate of Merit from the Faculty of Pharmaceutical Sciences at UBC. Additionally, he has received the Isabel E. Stauffer Meritorious Service Award (1996) and the Distinguished Service Award (2003) from the Canadian Society of Hospital Pharmacists. He was listed in the International Who's Who of Professionals in 2001.

Bob is an expert in public drug plan management and provides advice to federal, provincial and international governments in this area. In 2001 he was appointed to the Steering Committee of the Reforming States Group in the United States.

Bob has 23 years of experience working in health care in Canada. He has held several directorate level positions since 1992, which included the Directory of Pharmacy and Director of Patient Care Services at Lions Gate Hospital. He has been director of Pharmicare in the British Columbia Ministry of Health and is currently Director of Pharmacy in the Fraser Health Authority in British Columbia.

Bill Novelli Executive Director
and CEO, AARP

Bill Novelli is Executive Director and CEO of AARP, a membership organization of over 35 million people age 50 and older, half of whom remain actively employed. He joined AARP in January 2000 as Associate Executive Director, Public Affairs (Legislation and Public Policy, Public Policy Institute, Communications, Publications, Organizational Relations and International Activities).

Prior to joining AARP, Mr. Novelli was President of the Campaign for Tobacco-Free Kids, whose mandate is to change public policies and the social environment, limit tobacco companies' marketing and sales practices to children and serve as a counterforce to the tobacco industry and its special interests.

Previously, he was Executive Vice President of CARE, the world's largest private relief and development organization (\$450 million budget, 11,000 employees, 40 developing countries plus fundraising and advocacy in the U.S.). He was responsible for all operations in the U.S. and abroad. CARE helps impoverished people in Africa, Asia and Latin America through programs in health, agriculture, environmental protection and small business

support. CARE also provides emergency relief to people in need.

Earlier, Mr. Novelli co-founded and was President of Porter Novelli, now one of the world's largest public relations agencies and part of the Omnicom Group, an international marketing communications corporation. He directed numerous corporate accounts as well as the management and development of the firm. Porter Novelli was founded to apply marketing to social and health issues, and grew into an international marketing/public relations agency with corporate, not-for-profit and government clients. He retired from the firm in 1990 to pursue a second career in public service. In 1999, he was named one of the 100 most influential public relations professionals of the 20th century by the industry's leading publication.

Mr. Novelli is a recognized leader in the international emergence of social marketing, and managed programs in cancer control, diet and nutrition, cardiovascular health, reproductive health, infant survival, pay increases for educators, charitable giving and other programs in the U.S. and the developing world.

He holds a B.A. from the University of Pennsylvania and an M.A. from Penn's Annenberg School for Communication, and pursued doctoral

studies at New York University. He taught marketing management for 10 years in the University of Maryland's M.B.A. program and also taught health communications there. He has lectured at many other institutions. He has written numerous articles and chapters on marketing management, marketing communications, and social marketing in journals, periodicals and textbooks.

Anne-Toni Rodgers Corporate Affairs Director,
National Institute for Clinical Excellence

As Corporate Affairs Director Anne-Toni holds responsibility for the Institute's communication strategy. This includes communication of the Institute's purpose and methodologies and dissemination of the Institute's guidance to all stakeholders. As a member of the Board she plays a full role in the corporate management of the Institute and acts as an executive lead on both technology appraisals and clinical guidelines.

Anne-Toni is a pharmacology graduate with a strong track record in communications with the NHS, industry and patients. She is a graduate of the Common Purpose Programme, Vice-Chair of the London Region of the Institute for Health Service Management, an editorial board member for the Journal of Quality in Healthcare and a

member of the management board of the National Prescribing Centre.

Anne-Toni joined the National Institute for Clinical Excellence on July 12th 1999. Prior to joining the Institute she spent 18 years in a variety of roles for the pharmaceutical industry including, pure research, regulatory affairs, sales & marketing, and government & industry affairs.

John Rother Director of Policy and Strategy,
AARP

John Rother is the Director of Policy and Strategy for the AARP. He is responsible for the federal and state public policies of the Association, for international initiatives, and for formulating AARP's overall strategic direction. He is an authority on Medicare, managed care, long-term care, Social Security, pensions and the challenges facing the boomer generation.

Prior to coming to AARP in 1984, Mr. Rother served eight years in the U.S. Senate as Special Counsel for Labor and Health to former Senator Jacob Javits (R-NY), then as Staff Director and Chief Counsel for the Special Committee on Aging under its Chairman, Senator John Heinz (R-PA).

He serves on several Boards and Commissions, including Generations United, the Health Care

Quality Forum, the American Board of Internal Medicine Foundation, National Academy on Aging, Civic Ventures, and Citizens for Long Term Care.

He is a frequently quoted in the news, and regularly presents at conferences and congressional briefings. Throughout 1996, Mr. Rother was on special sabbatical assignment to study the consumer implications of the managed care revolution and the economic challenges facing the boomer generation. John Rother is an honors graduate of Oberlin College and the University of Pennsylvania Law School.

F. M. Scherer Professor Emeritus, John F. Kennedy School of Government, Harvard University, and lecturer at the Woodrow Wilson School of Princeton University.

F. M. Scherer is Aetna Professor Emeritus at the John F. Kennedy School of Government, Harvard University, and lecturer at the Woodrow Wilson School of Princeton University. He has also taught at the University of Michigan, Northwestern University, and Swarthmore College. In 1974-76, he was chief economist at the Federal Trade Commission. His undergraduate degree was from the University of Michigan; he received his M.B.A. and Ph.D. from Harvard University. His research

specialties are industrial economics and the economics of technological change, leading inter alia to books on Industrial Market Structure and Economic Performance (third edition with David Ross); The Economics of Multi-Plant Operation: An International Comparisons Study (with three co-authors); International High-Technology Competition; Mergers, Sell-offs, and Economic Efficiency (with David J. Ravenscraft); Innovation and Growth: Schumpeterian Perspectives; The Weapons Acquisition Process (two volumes, one with M. J. Peck); Industry Structure, Strategy, and Public Policy; and New Perspectives on Economic Growth and Technological Innovation. During the early 1990s he chaired the advisory panel for the Office of Technology Assessment report on pharmaceutical R&D, risks and rewards. Since 1995 he has written extensively on the problems of pricing pharmaceuticals for third world markets. His web home page is found at www.famscherer.com.

Theresa H. Varner Director of Public Policy, AARP

Theresa H. Varner, M.S.W., M.A., is the Director of the AARP Public Policy Institute. The Institute is AARP's focal point for public policy research and analysis on health, long-term care, economic securi-

ty, and consumer issues. Before assuming her current position in 1991, she served for several years as the Senior Coordinator of the PPI Health Team. She came to AARP from the Alabama Department of Mental Health where she directed the state's largest hospital-based pre-release program.

Ms. Varner has presented at numerous national conferences and symposia on a variety of topics related to health care reform. Her publications have focused on health coverage, consumer information needs, and long-term care; she also oversaw the development of AARP's draft proposal for health care reform, Health Care America.

Between 1993 and 1995, Ms. Varner served as a consumer representative on the Institute of Medicine (IOM) Committee on the Future of Dental Education. She was also a member of the IOM Committee on Care at the End of Life (1996-1997). She is currently a member of the Board of Directors of Partnership For Caring, a national grassroots educational organization focused on improving care at the end of life. She also serves as a Co-chair of the Task Force on Financing End-of-Life Care, part of the RWJ Last Acts national initiative. Ms. Varner holds an M.S.W. and an M.A. in English literature, both from the University of Alabama.

Daniel Vasella Chairman and CEO, Novartis AG

Daniel Vasella, MD, is Chairman and CEO of Novartis AG. He was appointed Chairman in April 1999, having served as CEO and Head of the Group Executive Committee since the merger in 1996. His Novartis career began at Sandoz Pharma in 1988, where he assumed the position of CEO in 1994. Prior to joining Sandoz, Dr. Vasella held a number of medical positions in Switzerland.

As the first CEO of Novartis, Dr. Vasella had a leading role in the merger of Sandoz and Ciba-Geigy. Under Dr. Vasella, Novartis has strategically focused the business on healthcare with Pharmaceuticals at its core. During his tenure as Chairman and CEO, Dr. Vasella enhanced the corporate governance policy, listed the company at the NYSE and strengthened its research capacity in leading technologies. He also implemented strong pioneering initiatives in the area of good corporate citizenship.

Dr. Vasella is a member of the Board of Directors of PepsiCo Inc. and of the Chairman's Council of DaimlerChrysler. He chairs the International Business Leaders Advisory Council for the Mayor of Shanghai and is also a member of the International Board of Governors of the Peres Center for Peace. In 2002 Dr. Vasella was awarded

an honorary doctorate by the Faculty of Medicine of the University of Basel.

Dr. Vasella was born in 1953, is married and has three children.

Judith Wagner [Scholar-in-Residence, Institute of Medicine](#)

Judy Wagner recently retired from the Congressional Budget Office as a Senior Analyst. She is currently a Scholar-in-Residence at the Institute of Medicine in Washington D.C. She has more than 30 years' experience in health policy analysis and health technology economics. At the CBO she analyzed prescription drug issues, including the design of a Medicare prescription drug benefit, Medicaid drug payment, and reform of current laws governing the entry of generic drugs into the market place. Before joining CBO, she was a consultant at the Mayo Clinic in Rochester, MN, where she conducted cost and cost-effectiveness analyses of medical of medical procedures and technologies for both research and operational planning at the Clinic.

At the Office of Technology Assessment, a research arm of the US Congress which closed in 1995, she managed many assessments, most notably a 1993 study of the Economics of Pharmaceutical R&D, which estimated the cost and profitability of

private investment in the development of new drugs and examined the impact of public policies on the patterns of drug R&D in the private sector.

Judy has served as a member of the National Cancer Policy Board (NAS/IOM) and on the Boards of the Association for Health Services Research and the International Society for Technology Assessment in Health Care. She holds a Ph.D. from Cornell University.

Albert I. Wertheimer, PhD, MBA [Founding Director, Center for Pharmaceutical Health Services Research, Temple University](#)

Albert I. Wertheimer, PhD, MBA, is Founding Director, Center for Pharmaceutical Health Services Research at Temple University School of Pharmacy. Dr. Wertheimer is internationally recognized in the area of pharmacoeconomics and outcomes research. He is Editor-in-Chief of the newly launched Journal of Pharmacy Finance Economics and Policy and author or co-editor of 19 books, 25 book chapters, and more than 320 journal articles.

The first part of the document discusses the importance of maintaining accurate records of all transactions. It emphasizes that every receipt, invoice, and bill should be properly filed and indexed for easy retrieval. This not only helps in tracking expenses but also ensures compliance with tax regulations.

In the second section, the author provides a detailed breakdown of the company's financial performance over the past year. This includes a comparison of actual results against budgeted figures, highlighting areas of both success and concern. The analysis shows that while revenue has increased, certain operational costs have also risen, impacting the overall profit margin.

The third section focuses on the company's strategic initiatives for the upcoming year. It outlines key goals, such as expanding into new markets and investing in research and development. The author also discusses the challenges that may arise and the strategies to mitigate them, ensuring the company remains competitive in a rapidly changing market.

Finally, the document concludes with a summary of the key findings and recommendations. It stresses the need for continued vigilance in financial management and a commitment to innovation and growth. The author expresses confidence in the company's ability to overcome challenges and achieve its long-term vision.

