

AARP EUROPEAN LEADERSHIP STUDY:

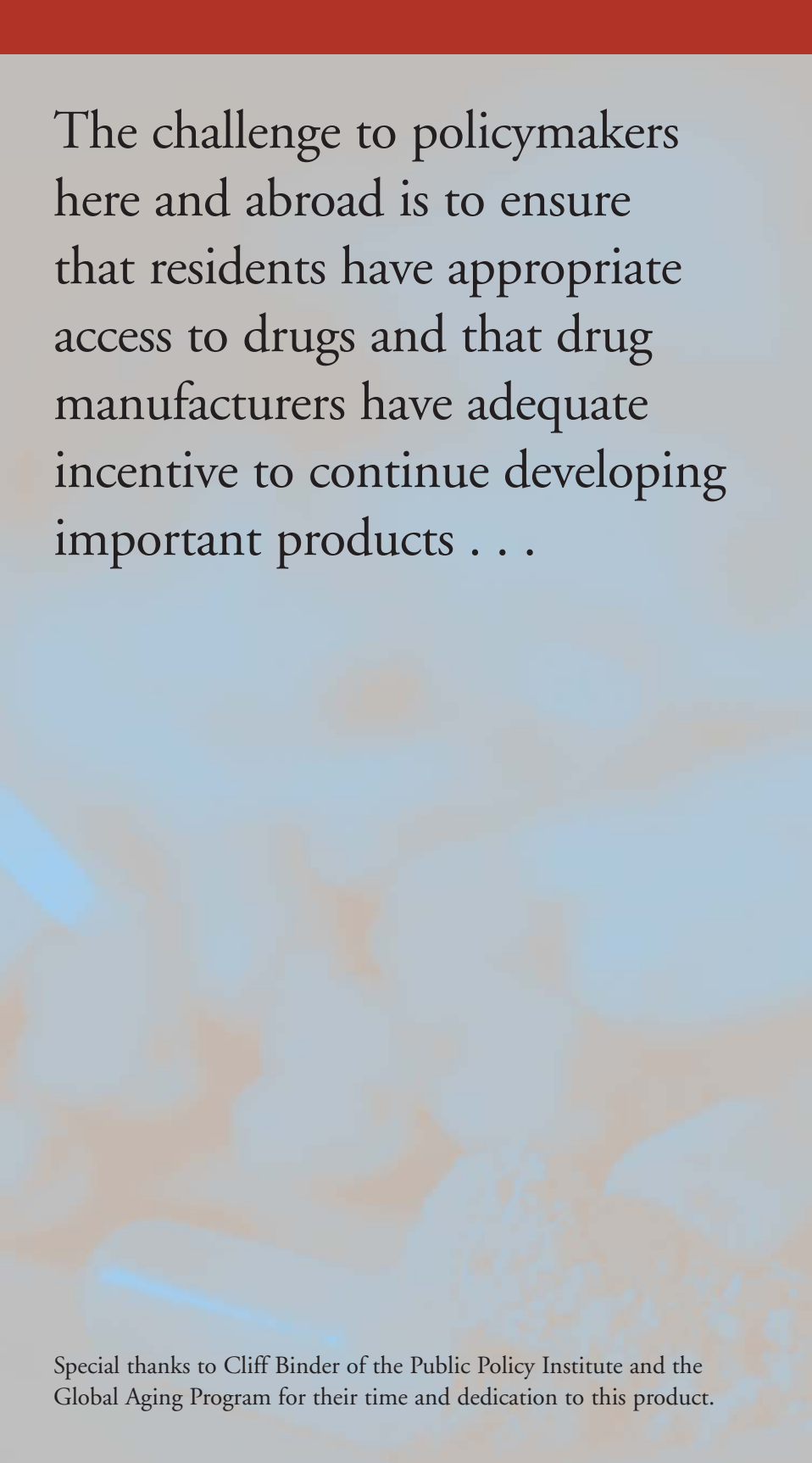
# European Experiences with Prescription Drug Pricing

France, Norway, and the  
United Kingdom

October 2006

AARP®

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The challenge to policymakers here and abroad is to ensure that residents have appropriate access to drugs and that drug manufacturers have adequate incentive to continue developing important products . . .

Special thanks to Cliff Binder of the Public Policy Institute and the Global Aging Program for their time and dedication to this product.

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# Preface

With health care costs rising at unsustainable rates and the Baby Boom Generation nearing retirement, the United States faces essential and imminent debates on the reform of our health care and long-term care systems. As the leading organization in America for positive social change, AARP is poised to lead the discussion on how to achieve better and more affordable health care in the United States and provide long-term care for older Americans. To further inform the discussion, AARP's Board of Directors and senior management traveled to Europe in June 2006 on a fact-finding mission to examine the experiences, trends, and best practices in global aging.

The European Leadership Study (The Study) concentrated on AARP's priority issues of health care and long-term care and examined how certain European countries are addressing challenges similar to those faced in the United States. In particular, The Study provided a deeper understanding of the European experience on pharmaceutical pricing, health information technology, financing and delivery of long-term care services and health care cost containment.

During The Study, the AARP delegation visited France, Norway, the United Kingdom and the Netherlands. The Study provided an opportunity for direct conversations with government officials, representatives from key nongovernmental organizations, consumers, and business leaders. The Study participants held discussions with national health ministers, health care consumers and practitioners, including sessions with the Chief Executive of the United Kingdom's National

Institute for Clinical Excellence (NICE), representatives from Sanofi-Aventis, France's leading pharmaceutical company, and political party officials in the Norwegian Parliament from the Standing Committee on Health and Care Services. The Study also included site visits to hospitals and long-term care facilities that provided invaluable first-hand observation of care as it is practiced abroad.

With the publication of four Issue Papers prepared by the AARP Public Policy Institute, AARP is presenting the background materials prepared in advance of The Study and the lessons learned that were compiled afterwards. The four Issue Papers address: long-term care; health information technology; pharmaceutical pricing; and health care cost containment. The Issue Papers rely on published materials, readily available data sources (such as reports and studies from the Organization for Economic Cooperation and Development and the European Commission, among others) and include, when possible, knowledge from first-hand, in-country experiences.

Due to the nature of available information sources, it was difficult to systematically draw direct comparisons among the four countries visited. Nevertheless, the papers offer important lessons for the United States and teach us that, while we are progressing in some areas of health and long-term care, there is much we can learn from European countries as we address these critical issues.

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# Introduction to Prescription Drug Issues

Do Americans spend more on prescription drugs than residents of other countries and, if so, why? Over the years, this has been a topic of much debate and study, particularly with regard to the price of individual drug products. If the United States adopted policies from other advanced countries, would the pattern of drug spending change? The following report describes key policies, market forces, and trends that influence prescription drug spending in the United States (U.S.) and three European countries—France, Norway, and the United Kingdom<sup>1</sup> (UK). The report also identifies some lessons learned from the experiences of these countries in attempting to control the cost of pharmaceuticals, especially through the regulation of prescription drug prices.

The topic of prescription drugs is prominent in policy discussions because medicines represent life-saving treatment for some patients and substantially improve the quality of life for others. In addition, while prescription drugs contribute to health care spending, some analysts and policymakers believe prescription drugs can reduce overall health expenditures by reducing use of tertiary care, emergency rooms, and inpatient hospital services. Therefore, the overarching prescription drug issues facing the U.S. and other countries are *affordability* and *access*; also important is the issue of *drug development* and its related industrial policy implications. The challenge to policymakers here and abroad is to ensure that residents have appropriate access to drugs and that drug manufacturers have adequate incentive to continue developing important products, while prescription drug expenditures are controlled.

**FIGURE 1: Pharmaceutical Expenditures as a Percentage of Total Health Care Expenditures**

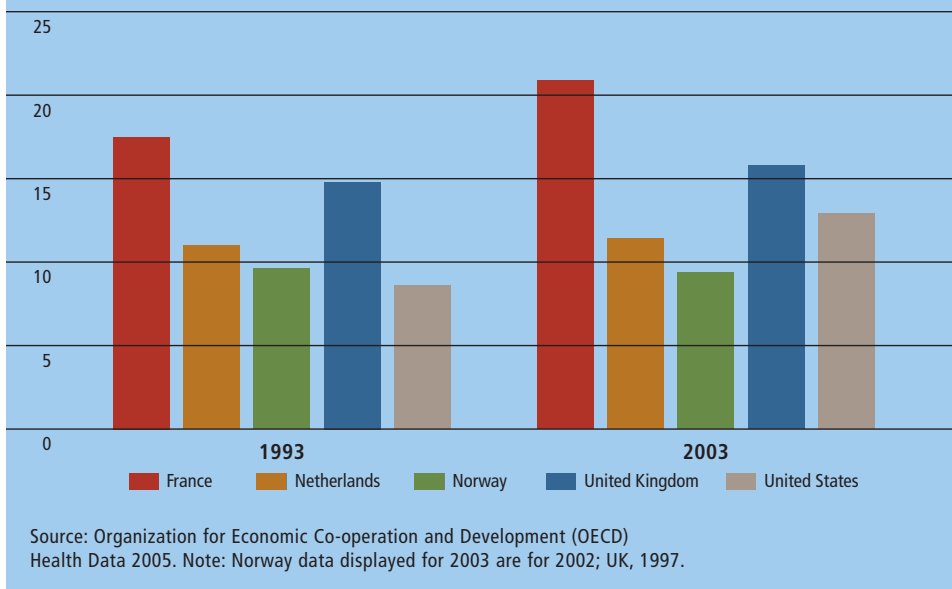
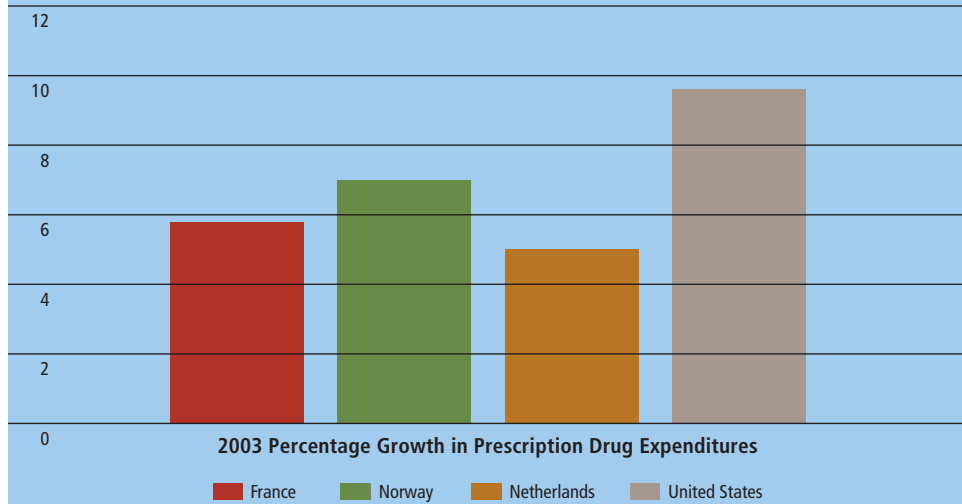


Figure 1 places drug spending in perspective by showing that it is a minor component of total health spending in the study countries, especially in the U.S., where it accounts for 12 percent of total health spending. Still, pharmaceutical expenditures exceed growth rates for most other components of health care spending within the U.S. and the other countries. As shown in Figure 2, aggregate U.S. prescription drug spending in 2003 grew by 10 percent annually, outpacing European countries. Similarly, U.S. per capita prescription drug spending exceeds rates in the other countries, as shown in Figure 3; this occurs despite the fact that one in seven Americans are without health insurance coverage. Among the factors that account for some of these international differences in prescription drug expenditures are demographic composition, national wealth, drug coverage, cultural norms, and medical practice patterns.

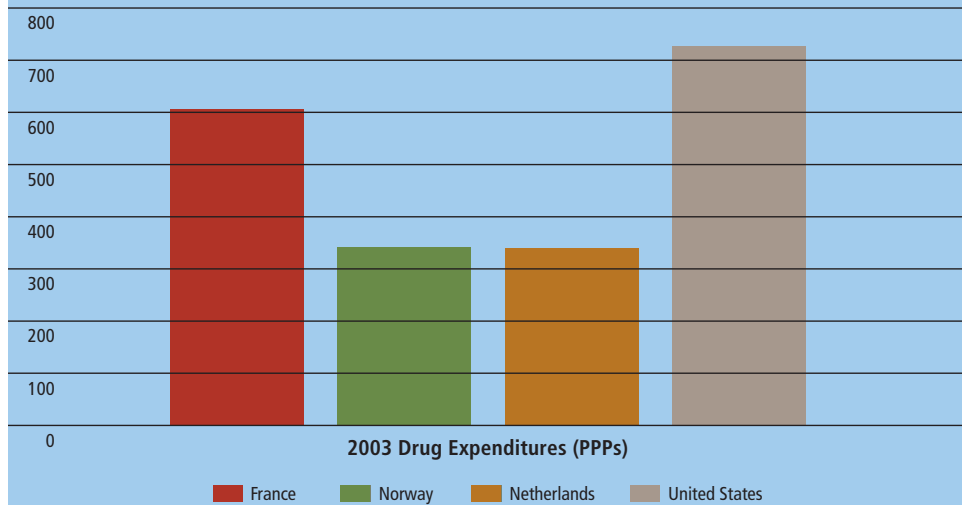
Public policies also drive some of the variation across countries in prescription drug expenditures. One public policy consideration central to the topic of prescription drugs is access. What weight should access be given relative to cost, and under what circumstances are limitations on access appropriate? Attention is turning from the issue of the cost of access alone to the issue of the value (i.e., outcomes) derived from using health care products (e.g., drugs) and services. The value discussion has arisen in large part from the realization that higher spending may be more acceptable if desirable outcomes are achieved as a result. Policies relying on clinical guidelines and comparative effectiveness research are emerging to guide value purchasing decisions.

FIGURE 2: Annual Percentage Growth in Prescription Drug Expenditures



Source: Organization for Economic Co-operation and Development (OECD) Health Data 2005. Note: Norway data displayed for 2003 are for 2002; UK data unavailable.

FIGURE 3: Per Capita Prescription Drug Expenditures



Source: Organization for Economic Co-operation and Development (OECD) Health Data 2005. Note: Norway data displayed for 2003 are for 2002; UK data unavailable.<sup>2</sup>

Another key public policy consideration related to prescription drugs is *pricing*. U.S. prescription drug prices are essentially unregulated;<sup>3</sup> pharmaceutical manufacturers are free to set any price they want for their products. In principle, market mechanisms such as competition, discounts, and rebates may help to moderate drug prices, but the impact of the market can be subtle. Pharmaceutical manufacturers segment the brand-name prescription drug market by charging different prices to different clients, just as the airline industry charges different prices to different fare classes.<sup>4</sup> Drug manufacturers use differential pricing to compensate for income differences across countries and to adjust for regulatory payment systems, with some national system payment systems limiting the prices companies may charge. The U.S. pays the highest prices and bears the greatest portion of the global burden of R&D costs for developing new products. Although prescription drug price regulations are national, prescription drug development and industry benefits are global. Numerous studies have compared brand-name drug prices in the U.S. with prices in other countries. More recently, as prescription drug prices have continued to increase, more sophisticated analyses have confirmed that Americans, to varying degrees, appear to pay higher drug prices than consumers in other countries.<sup>5</sup> Therefore, important unanswered questions include, how much higher are U.S. prescription drug prices than drug prices in other countries? and, what value does the U.S. economy get for bearing these higher prices?

A third public policy consideration regarding prescription drugs is *research and development (R&D)*. Most economists agree that, if drug prices were too low, research investments would decrease; by how much is a question for more discussion. In addition, advanced industrial societies recognize that drug companies are attractive partners that generate jobs and trade and make other valuable economic contributions. Without the potential to recover their investment, drug and other biomedical research companies might divert their investment into more profitable activities. Thus, U.S. policymakers pay attention to the complex interaction between prescription drug pricing and the nurturing of a productive biomedical research industry.

What combination of policies will ensure a balance between access to medications, containment of prescription drug spending, and the desire to continue fueling medical advances? The remainder of this paper explores the role of public policy based on the experiences of France, Norway, and the United Kingdom.

# Country Approaches

## FRANCE

In comparison to most European countries, France has relatively high prescription drug consumption with per capita drug expenditures at €380 per capita in 2000. Prescription drug expenditures have been increasing rapidly in France, averaging 5.3 percent in growth annually since 1990 and considerably higher recently. Sixty-three percent of prescription and non-prescription drug costs are paid for by public funds. The remainder is paid for in equal measures by supplementary insurers (18.5 percent) and consumers (18.5 percent).

**Direct Price Control.** Under direct cost control methods, governments can use product price controls and negotiate directly with manufacturers to set individual product reimbursement. France employs direct cost control methods. In general, under direct cost controls, prices are established after drugs are approved but prior to product launch. Government agencies review manufacturers' price applications and assess whether the price is justified. If prices are unacceptably high, government regulators set lower prices, but there are usually provisions for manufacturers to appeal these decisions. Regardless of how countries set initial drug prices, direct drug price controls require government agency approval for price increases after product launch.

Under price control systems, the process usually takes one of two forms: internal, which primarily focuses on the manufacturer's price justification, or external, which examines the prices charged for the same or similar product in other countries. When *internally* evaluating manufacturers' price justifications, governments may

take into account factors such as the product's expected therapeutic benefit, potential sales volume, and contributions to the country's economy. The government may consider that R&D expenses were incurred and recovered in another country (like the U.S.) where selling prices are higher and, accordingly, set low prices for such products. These inter-country price differences can thus create prescription drug "parallel trade" incentives, where drugs from "low price" countries are imported and resold in other countries at prices that are higher than in their country of origin but lower than prices would be otherwise.

*External* price justifications for new drug products use different criteria. Where the drugs under review are already on the market in other countries, these systems compare prices directly based on dose, strength, and package size considerations. Where the products are not widely marketed elsewhere, countries develop comparative drug market baskets that have the same therapeutic indications. These market baskets vary from system to system depending on which drugs are being compared and whether generics are part of the package, so prices for any given drug can vary across countries.

All prescription drugs sold in France must be approved by either the European Union's equivalent to the U.S.'s Food and Drug Administration (FDA), or the French Health Products Safety Agency (AFSSAPS). AFSSAPS has three main missions: scientific and medico-economic evaluation of health products; laboratory and advertising control; and inspection of industrial sites. The European Agency for the Evaluation of Medicinal Products (so-called "European Medicines Agency" or EMA) is a London-based, decentralized body of the European Union whose main responsibility is protection and promotion of public and animal health, through evaluation and supervision of human and veterinary medicines. It essentially functions as Europe's FDA, allowing pharmaceutical companies to submit a single marketing application. A positive ruling from the agency is then sent to the European Commission to be transformed into a single market authorization, valid for the entire European Union. Cost-effectiveness decisions are made individually by member states.<sup>6</sup>

To qualify for reimbursement by France's *Sécurité Sociale* or national health insurance plan (NHI), drugs must be included on a formulary (referred to in France as a positive drug list). The list currently includes about 4,500 drugs, which account for about 90 percent of sales in French pharmacies. To be listed, drugs must be recommended by both the Commission on Transparency and the Economic Committee on Medical Products (CEPS). The Transparency Commission plays a role in the clinical assessment of medicines and makes recommendations on which drugs should be included on the positive drug list and their level of reimbursement, but it is purely a consultative body; ultimate decision-making authority resides with government agencies. CEPS negotiates directly with pharmaceutical companies, enters into long-term agreements on product prices, and enforces these contracts. CEPS also has responsibility for monitoring drug expenditures and their relationship to annual budget targets.

Inclusion on France’s NHI plan’s reimbursement drug list is based on two broad considerations. In comparison to other drugs in the same class, the drug must (1) contribute to an improvement in the prescribed treatment; or (2) decrease the cost of treatment. These considerations were translated into five criteria in a 1999 reform. Since the reform, for drugs to be on the covered drug list, the Transparency Commission has assessed evidence (supplied by manufacturers) of the product’s therapeutic value, referred to as “medical service rendered” (SMR). There are five criteria for assessing SMR:

- effectiveness of the drug and possible side effects;
- the product’s role in the therapeutic process in relation to the alternative therapies available;
- the seriousness of the condition it is used to treat;
- the curative, preventive, or symptomatic properties of the drug; and
- the product’s importance in terms of public health.

The SMR describes the therapeutic value of products for each therapeutic indication on a five-level scale: major, considerable, moderate, low, or insufficient. The level of SMR score, along with the seriousness of the disease treated, determines pharmaceutical product reimbursement by the NHI as shown in Figure 4.

**FIGURE 4: Prescription Drug Reimbursement Rates**

Therapeutic Value (SMR)	Serious Pathology (%)	Pathology “not usually of a serious nature” (%)
Major	65	35
Considerable	65	35
Moderate	35	35
Low	35	35
Insufficient	0	0

The Transparency Commission was mandated to re-evaluate all drugs between 1999 and 2001 using these five SMR criteria; it determined that 835 drugs displayed insufficient SMR (18 percent on formulary or positive drug list). The 1999 Transparency Commission decree required that these drugs be removed from the reimbursement list, and 84 were removed in September 2003. Reimbursement was reduced from 65 to 35 percent for another 200 of the drugs with insufficient SMR evidence. NHI reimbursement was reduced for these products as they were reclassified as therapies for treating non-life threatening conditions.

For prescription drugs covered by the national insurance plan, the Sécurité Sociale, CEPS negotiates with manufacturers to set prices for drugs sold through non-hospital channels. The Ministry of Health's CEPS decides which drugs will be covered and also sets the coverage level for drugs. Drug prices are based on therapeutic benefit compared with other drugs on the formulary in the same therapeutic class; drugs with high therapeutic value are likely to have high prices, especially if there are no competing products with similar therapeutic benefits. Drugs with low therapeutic improvements are likely to be priced lower than more effective competitors. Drug prices also are affected by other considerations, such as the expected sales volume or products' daily dosage. Manufacturers enter into agreements with CEPS to lower prices or issue rebates if sales volumes, daily dosages, or daily cost limits are not met. In theory, sales volumes and therapeutic advantages are key negotiation points for CEPS; however, in practice, inconsistencies have been identified that illustrate that pricing rules may sometimes be circumvented. Since 2003, manufacturers may set their own price for highly innovative products without CEPS negotiation, although the agency retains veto power. The manufacturer's price for these exceptionally innovative products must be consistent with prices in Germany, Spain, the UK, and Italy. For drugs not covered by the NHI, pharmaceutical firms may set prices.

**Treatment Guidelines.** France spends more on prescription drugs than most other countries. Prescription drug spending in France as a percentage of total health care spending was at 22 percent in 2003. To help rein in prescription drug spending, France's Ministry of Health recently implemented changes including (1) mandatory physician treatment guidelines (best practices), called physicians' *Références Médicales Opposables* (RMOs); (2) an agreement with the pharmaceutical industry; and (3) creation of regional spending targets. Note that the RMOs encompass a range of therapies, not only prescription drugs. As part of the RMO development process, France's Ministry of Health negotiated a deal with the pharmaceutical industry to exchange sales volume reductions for reimbursement increases. Individual pharmaceutical companies negotiated separate deals that outlined price increase conditions. In return, drug companies reduced promotional expenditures, promoted appropriate drug use through public service announcements, and increased reporting about their activities. France's regional spending targets were established between the Sécurité Sociale and physicians' professional associations. Separate spending targets were set for specialist and general practitioner fees as well as prescriptions. If regional spending exceeded target levels, local physicians could

need to compensate the Sécurité Sociale. Despite these and other reforms, France still has some of the highest prescription drug spending. Nonetheless, these reforms are credited with slightly shifting utilization toward lower cost drug products for conditions where RMOs were established.

**Generic Drug Substitution.** With low out-of-pocket costs due to relatively good insurance coverage, there is little incentive to shop for lower-priced drugs. In 1999, generics represented about two percent of prescription drug sales in France. In fact, the concept of generic drugs was not officially defined until 2000 when a guide to therapeutic equivalents was distributed to doctors and publicized in public outreach campaigns. Pharmacists have the right to make generic substitutions and are guaranteed the same profit margin as if they had used equivalent branded products; and, although through recent changes, consumers must pay more if they elect a branded product, with high penetration rates for supplemental insurance, the effect of the copayment may not be great. There is a target substitution rate in the pharmacists' union contract that can be the basis for the next contract renewals payment rate. To further encourage generic use, physicians were given the right in 2002 to prescribe drugs by their generic names.

In 2000, there were approximately 23,000 pharmacies in France, most of which are privately owned. Creation of new pharmacies, unless there are special circumstances, is regulated and ownership is dispersed since there are prohibitions on pharmacists operating more than one location. Approval to open a new pharmacy takes into account both the size of the population to be served and travel distances. As a result of the reforms passed in 1999, pharmacists are paid both a prescribing fee (€0.53 per item, with an additional €0.30 for some positive list drugs) and sliding scale profit margin. Until recently, consumers paid in full at the retail level for drugs and then submitted invoices for reimbursement to the NHI fund. Now, third-party payers reimburse pharmacists directly for their prescription drug purchases, so consumers have no upfront costs for many prescription drug transactions. Still, not all pharmacies participate with third-party payers, so about one-third of pharmacy transactions are paid for directly by consumers and then reimbursed by NHI funds and supplemental insurers.

## NORWAY

The variety and availability of drug products is more limited in Norway than in other OECD countries, and it takes longer for pharmaceutical companies to obtain clearance to market new products. Norway's Medicines Agency (NoMa) authorizes new drugs. Unlike in the U.S., where the FDA assesses new products for safety and efficacy, cost effectiveness plays an important role in NoMa's consideration of new products. In theory, if future reimbursement of new pharmaceutical products is believed to result in substantial cost increases, NoMa will refer pending approval decisions to Norway's Ministry of Health and Parliament. In practice, however, some expensive new drugs were approved for reimbursement at the request of members of Parliament, as a result of voter pressure. When the process works according

to plan, the Ministry of Health and Parliament decides whether to cover more costly new products as part of the yearly budget-setting process. Thus, the waiting period for listing new drugs for reimbursement can stretch to two or three years.

In historic terms, pharmaceutical expenditures as a percentage of GDP have been lower in Norway than other OECD countries, but more recently public drug expenditures have increased at the rapid rate of approximately eight percent annually. Norway implemented new pharmaceutical regulations in 2001 under the Pharmaceutical Act (PA 2001), which may have played a role in this spending growth. PA 2001 attempted to increase patient access to prescription drugs by expanding the number of pharmacies that could fill prescriptions. PA 2001 removed terminal degree requirements for pharmacy owners (pharmacy owners were required to hold pharmacy or other related discipline doctoral degree), but the Act may have hastened rapid retail pharmacy consolidation, as three national chains and their wholesaler partners acquired most independents. Subsequently, the ceiling on pharmacy locations was removed, and by 2005 the number of pharmacy locations had increased by about one-third. Norway's pharmacy market remains concentrated and dominated by the three retail/wholesale partnerships. These integrated organizations use preferential relationships to help create entry barriers for independents. Recently, there have been proposals to further increase drug availability and reduce market concentration by expanding the range of retail outlets that can sell prescription medications to include gas/convenience stores and other retailers that sell non-prescription products and have extended hours of operation.

**Reference Pricing.** Norway heavily regulates the prices of sole source branded products (i.e., products without competition from other brands of the same product). To constrain costs, branded drug prices cannot exceed the average of the three lowest prices for a market basket of drugs for nine EU countries. One objective of Norway's price setting prescription drug regulation is to minimize patients' cost sharing obligations so that patients can afford any drugs.

In March 2003, the government introduced a type of reference price methodology to the national health system that is referred to as an index-pricing system. Reference prices can be defined as reimbursement ceilings (reference price) set by insurers for specific drugs. The reference price can be based on drugs that have the same drug chemical, are in the same drug class, or are therapeutically equivalent drugs with different active ingredients. If drugs cost more than their reference price, patients or supplementary private insurers pay the difference. Reference prices differ from direct price controls in that pharmaceutical manufacturers are free to sell their products at any price; patients may or may not be willing to pay a premium for the product. Although reference-pricing systems differ in implementation, countries using reference pricing share four common objectives:

- to encourage physicians to prescribe less expensive drugs;
- to influence patients to accept less expensive drugs or higher copayments;

- to pressure pharmaceutical manufacturers to reduce prices to remain competitive; and
- to manage payers' drug budget expenditures.

Reference pricing has been used throughout the world, including the U.S., where it has become more popular among private payers and Medicaid programs. Maximum allowable cost (MAC) pricing approaches for chemically identical drugs are reference pricing schemes that are used by many private insurers and state Medicaid programs. There is general consensus that reference pricing can be effective in restraining prescription drug cost increases, but financial savings are short-term and decrease over time, as prescription consumption shifts towards greater use of the reference-priced product.

**Incentives for Generic Drug Use.** Under Norway's index-pricing approach, pharmacies could share with the government the savings when a generic is dispensed instead of a branded product. (Note: Although generics are relatively expensive in Norway, they are still less costly than branded drugs.) The index pricing was intended, in part, to exert downward pressure on branded drug prices. However, given the smaller price differentials between generics and branded drugs in Norway, the index-pricing measure has not reduced prescription drug expenditures much.

Therefore, a voluntary step-price model was introduced in 2005 to encourage use of lower-cost generic products. Under step-pricing, maximum NHS reimbursement for off-patent drugs is a fixed percentage of the price of the original product when it was under patent. Government payment for prescription drugs is set on a sliding scale based on the monetary value of a drug's sales and the length of time since the patent expired. For instance, for generic versions of branded drugs with aggregate sales greater than NOK 100 million annually (around €12 million), maximum reimbursement (the "step price") in the first six months after the patent expiration is 70 percent of the originally patented product's price; 50 percent after the sixth month and before one year; and 30 percent thereafter. For drugs with sales less than NOK 100 million, maximum reimbursement in the first six months after the patent expiration is 70 percent of the originally patented product's price; 60 percent after the sixth month and before one year; and 50 percent thereafter.

If consumers refuse the generic version, the difference between the actual price and the step price is paid by the consumer and is not counted in their out-of-pocket maximum. Pharmacies are obliged to offer at least one product in each pharmaceutical category at the step price. At the same time, pharmacists that are selling products less expensive than the step price can keep the difference as profit. This model was expected to produce saving of NOK 450 million (around €55 million) for the state and NOK 70 million (around €8.5 million) for households in 2005.

A by-product of Norway's price regulations, however, might be a reduced incentive to use generic drugs because branded product prices are lower than they would otherwise be. This situation occurs for several reasons. Weak competition in the

wholesale and retail segments of the pharmaceutical distribution chain prevents generics from being sold more widely and at a lower price. Finally, the government provides nearly comprehensive coverage for prescription drugs so consumers do not search hard for lower prices. As a result, in terms of volume, generics drugs account for about 28 percent of total prescription drug sales in Norway.

**Technology Assessment.** In 2004, the Norwegian Ministry of Health established the Norwegian Knowledge Centre for the Health Services. The Centre is responsible for health technology assessments, early warning (adverse event) reports, systematic (Cochrane) reviews, monitoring quality via performance and clinical indicators, and health services research.

## UNITED KINGDOM

Utilization of prescription drugs in the UK trails most other advanced countries. In 1996/1997, just under 500 million prescriptions were dispensed through England's National Health Service (NHS), a rate that amounted to approximately ten prescriptions per person in England annually. This utilization rate is between 30 to 80 percent lower than rates for other western European countries such as France, Germany, and Italy. UK prescription drug utilization has increased in recent years, but still is well below other European countries and the U.S. Between 1999 and 2004, spending for medicines increased 41 percent in real terms, averaging about six percent annually at the community level (non-hospital), with most of the increase resulting from volume (one percent due to cost increases for new drugs).

**Regulation of Industry Profits.** The United Kingdom employs several drug cost control methods, although the primary method is regulation of manufacturer profits, rather than the prices pharmaceutical companies may charge for products. Under the general category of profit regulation, profit can be defined differently, including as the rate of return on capital attributable to sales in that country or as negotiated profit margins for each company. At regular intervals, a target profit rate is negotiated between each pharmaceutical company and the government. Profit regulation permits companies to initially price products at their discretion. However, if manufacturers' profits exceed the negotiated profit rate, the excess returns are either returned to the government or prices are reduced.

The UK has a strong research-based pharmaceutical industry that makes a significant contribution to export performance. Industry profits for the pharmaceutical industry have been regulated voluntarily since 1957 with the goal of balancing the needs of the NHS to provide universal health care at affordable prices against the needs of a research-based industry for adequate returns to compete internationally and fund continued drug discovery research. The Health Act 1999 gave the Pharmaceutical Price Regulation Scheme (PPRS) the authority to impose statutory prices and profit controls on pharmaceutical companies that elected to not accept PPRS voluntarily prices and profit limits.

PPRS sets the rate of return (ROI) on capital attributable to pharmaceutical sales in Britain, which is used by British government agencies in negotiations with the Association of the British Pharmaceutical Industry to establish each company's ROI based on branded drug sales to the NHS. Under the PPRS, pharmaceutical firms are free to set their own prices for the first five years a drug is on the market, subject only to the profit margin limitation. After the five-year period, any price increases must be approved by the Department of Health.

To reach target ROIs of between 17 and 21 percent, research and development spending (including promotional expenditures) is set at about 9 percent of sales. If manufacturers' profits surpass their target ROIs, they are permitted a 25 percent cushion above the target rate, called the "gray area." If pharmaceutical company profits exceed these gray area limits, they must reimburse NHS or reduce product prices. PPRS excludes generic drugs.

**Drug Formulary.** Most prescription drugs available in Britain are eligible for NHS reimbursement, although a few are "black listed" as excluded drugs, and some others are listed in "gray areas" which means they may only be reimbursed by NHS under certain narrow circumstances. The black list was implemented in 1984 not only to reduce costs but also to improve the quality of prescribing in some areas. For instance, the black list greatly reduced the range of benzodiazepine sedatives and hypnotics available. The black list has not been modified much since it was first developed. The gray list includes what are sometimes described as lifestyle drugs, such as sildenafil for erectile dysfunction, which might be covered only for certain organic diseases. The black listed drugs that are not reimbursed by NHS also includes 16 categories of drugs such as analgesics, cold medicines, and vitamins used to treat minor conditions, most of which are available over the counter. (Note: Some OTC drugs are covered by the NHS.) Most NHS-covered drugs are free or nearly free to patients. Even though certain population groups have copayments, more than half of all citizens are exempt. Patients pay copayments for about only 12 percent of prescriptions filled in the UK; thus cost sharing reduces NHS' drug expenditures very little.

**Generic Drug Prescribing.** In 2003, approximately 53 percent of all UK prescriptions dispensed were for generics, although as high as 76 percent of all prescriptions are written generically by doctors regardless of whether a generic product exists. In 2003, generic drugs accounted for about 19 percent of total drug costs. NHS encourages generic drug prescribing through budget incentives and a drug tariff. Drug tariff prices are determined by major generic drug manufacturers and published and distributed to physicians on a monthly basis. A drug tariff establishes generic drug reimbursement. The NHS allows for reallocation of prescription funds when the physician saves money by prescribing generic drugs.

**Physician Profiling.** Another UK policy to control drug spending also is aimed at doctors' drug prescribing habits. To help educate physicians about prescribing patterns and alternatives, NHS created a Prescribing Analysis and Cost Information

System (PACI). This highly accurate system provides data on what drugs are prescribed by general practitioners (GPs) and the drugs' cost (inpatient, hospital drugs are not captured by this system). PACI provides physicians with monthly reports that compare their prescribing patterns and associated costs with that for theoretical groups of demographically similar patients. PACI data have evolved to include generic drug price information to encourage more generic use. The NHS proscribes a budget for services that each group of physicians provides per patient enrolled with the physician's group. In addition, prescribing budgets were developed as part of local GP budgets and thereby gave fundholders incentives to manage efficiently their prescribing. In 1999, a primary care group approach also was implemented that merged prescribing budgets for GPs with hospital and community health service budgets. These merged budget initiatives were aimed at improving local financial incentives for physicians and systems to independently manage prescription drug utilization.

**Technology Assessment.** NICE presents a model for perhaps the most sophisticated comparative clinical and economic prescription drug review process. NICE is a component of the NHS and is charged with identifying good clinical and public health practices based on the best available evidence. NICE appraisals rely heavily on the cost-effectiveness tool Quality Adjusted Life Year (QALY), as well as the principles of equity, fairness, and freedom of choice among health professionals and patients/caregivers. NICE's clinical guidelines are evidence-based, consultative, transparent and inclusive. The guideline development process includes seven National Collaborating Centers, as well as a Patient Involvement Unit to facilitate patient participation.

NICE includes stakeholder representatives in its assessment process: the pharmaceutical and medical device industries, academia, health care professionals, Hospital Trusts, and the public (the latter are involved via its Citizens Council). When pharmaceutical evaluations are undertaken, stakeholder groups are invited to submit relevant data to be considered as part of the assessment. NICE's final guidance "always draws upon the value judgments inherent to each stakeholder group."<sup>8</sup> The first full technology (and drug) appraisals were published in April 2000. Through April 2005, 87 appraisals on the use of over 200 individual products were completed. Recommendations for routine use within the NHS were made for nearly 40 percent of the assessed products; selective use, which restricts use for some indications, was recommended for over 50 percent. Guidance issued in 2006 has focused on prescription drug treatments for attention deficit hyperactivity disorder; smoking cessation and physical activity; use of beta blocker therapy for hypertension; and laser eye surgery.

Compliance with NICE's guidance is not always mandatory for NHS. However, within three months of technology/pharmaceutical appraisals, every local NHS health care entity is required to provide funding from its overall government allocation to support care for patients who meet NICE's approved indications for treatment.<sup>9</sup> Thus, NICE's rulings can indirectly affect drug costs (i.e., if a drug that fails to receive a positive NICE judgment is usually not stocked in hospitals and obtaining it becomes difficult). Pharmaceutical and device manufacturers have a mixed view of NICE. Some are eager for product appraisal because it can facilitate rapid entry into the UK market. Others, however, claim that economic modeling based on QALYs is unreliable and inappropriate to use as the standard for early evaluations of many new products.

# Lessons for the United States

What policies from France, Norway, and the U.K. are best practices and might be successfully incorporated into the U.S. health system? Policies to control prescription drug expenditures are intrinsically enmeshed in the larger health care system infrastructure of which they are a part. In addition, application of prescription drug cost control strategies is as much a political decision as an economic one. The success of policies can hinge as heavily on the cultural norms and support of the medical community and society as a whole as they do on the wisdom, vision, or potential payoff from a policy. Furthermore, the vision of a key leader might be a significant force in bringing revolutionary or even incremental change. Thus, it may or may not be realistic to suggest that measures that are effective in one country could be adopted and applied to the health care system in another country. Nonetheless, it is useful to review the proposals and approaches promulgated by other societies to address common problems.

## FRANCE

France, the largest European producer of prescription drugs since 1995, is home to more than 300 pharmaceutical manufacturers that employ 90,000 people and account for €24 billion in prescription drug sales. The pharmaceutical industry claims that pricing regulations, similar to those in France, can stifle industry investment in new drug development. The drug industry claims that innovative products generate less revenue and profit in countries with price restrictions, and fewer resources result in less investment in new product research. Drug industry critics of

France's prescription drug expenditure controls believe that the system inhibits drug innovation (R&D) because the system's price regulation does not take pharmaceutical R&D costs into consideration. However, it is difficult to assess the validity of this charge.

In recent years, biomedical research investment has migrated to the U.S., presumably because of unregulated prescription drug prices, but there may be other explanations for the trend (Turner, WSJ, 2005; U.S. Dept. Commerce, 2004). First, operating costs in Europe are high comparatively. The pharmaceutical industry has consolidated so that there are fewer companies making R&D investments, and many more are contracting those activities elsewhere, including Asia and India. Second, U.S. scientific education and research is considered the best in the world. The U.S. government allocates considerable financial support to primary research, which helps to nurture commercial investigations for new drugs. Finally, globalization makes the decision about the location of R&D investment difficult to isolate. France and other European countries are concerned that biomedical research investment and all of the trade, employment, and other economic advantages that accompany a high-value-added industry could have abandoned the continent in favor of the U.S. and other less regulated areas. Europeans are exploring cooperative and independent industrial policies to nurture biomedical R&D and, potentially, to leapfrog into other related pharmacological research areas.

Recent funding reforms have created the opportunity for taxes to play a bigger role in funding France's national health system, such that approximately 50 percent of NHI funding derives from taxes. This change moves some decision-making power away from local control and physicians and strengthens the legitimacy of leaders committed to national health care reform aimed at controlling utilization of all services, including prescription drugs. A reform commission's findings seem to have built consensus for policies that strive to tie reimbursement to treatment value (cost and outcome). Prescription drugs are a part of the value equation through the use of lower cost generics and off-patent brand name drugs. These processes, discussions, and policy initiatives seem nearly parallel to conversations in the U.S. about the value proposition and greater reliance on evidence-based medicine to guide clinical practice toward more cost-effective patterns of care.

French officials are seeking partnerships and collaborative ventures with prescription drug manufacturers to participate in solving public health and industrial policy issues. For instance, French officials have at least tacitly accepted industry complaints that prescription drug regulation may have helped to stifle drug development, by implementing a fast-track approval process for innovative products. Prescription drug manufacturers can get drugs on the market in France more quickly under the fast-track process, and price products at higher levels; at or near median European price levels. Although this change might seem cosmetic, it might contain policy lessons for the U.S. France's development of a fast-track approval and a pricing mechanism for new drugs suggests recognition that international prescription drug pricing dynamics are evolving rapidly and may be too complex to be

viewed at one dimension. Prescription drug pricing policies are evolving to encompass not only national health system goals of access and cost but also their interaction with other countries' policies, public health concerns, and, most importantly, national industrial policy.

The role of competition in France's prescription drug marketplace also is worth consideration. Unlike the U.S. where brand name drugs are priced very high relative to other countries, prices for drugs in France were low, and with little or no cost sharing, generic drugs were not important. Now, with drug and other health care spending at unsustainable levels, France is moving aggressively to implement policies to encourage generic drug use. France is adopting components of the U.S. prescription drug marketplace to help reduce spending. French officials are encouraging generic manufacturers to compete with brand manufacturers after patents expire. France believes that this competition can play a role in reducing drug expenditures. In the U.S., generic competition is already important, but perhaps policies are needed to protect and encourage further competition between generic and brand manufacturers.

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France's experiences with government negotiation of prescription drug prices also are a policy approach worth further analysis. France has been relatively successful in negotiating agreements with prescription drug manufacturers to set favorable prices and to enforce market discipline by imposing volume limits on approved drugs. Under Part D, the Medicare program is forbidden from negotiating directly with manufacturers for low prices. Medicare, as the largest single customer, could negotiate the most favorable rates. With calls for Part D reforms or technical amendments, critics of Part D's competitive approach would like to see the Department of Health and Human Services' Secretary required to use Medicare's purchasing power leverage to negotiate the lowest prices from prescription drug manufacturers. France's experience might be cited as evidence that government negotiation can work and that manufacturers can sustain investment in research and development under these terms.

## NORWAY

Norway's health care system is considerably different from that in the U.S. Norway also has a less diverse economy and culture. As a smaller economy with substantial coverage and reliance on reference prices, Norway can provide insight into the complexity of interactions between drug use and pricing decisions. (These discussions are more complicated among European Union member states because parallel trade agreements make importation of cheaper, branded products relatively easy and legal for wholesalers.)

Data on the success of Norway's step-price pharmaceutical reimbursement reform in lowering prices of generic products are not available yet. Norway's health care system features incentives for consumers to seek lower-priced generic drugs rather than relying on pharmacies to substitute voluntarily. However, the way in which

reference pricing has been used, as well as the insulation of consumers from costs by generous coverage, could limit the effectiveness of policies intended to encourage appropriate utilization and limit growth in prescription drug expenditures. Patients have a cap on total out-of-pocket payments, so consumers' financial incentives to seek lower-priced alternatives are weaker than if they had to bear most of the cost of more expensive alternative drug products. Moreover, primary care physicians have no incentives to prescribe lower-priced products or write prescriptions under their generic names. Norway's struggle with aligning financial incentives for prescription drugs reflects a common theme among these European health systems and the American system, as well: it can be difficult for countries to identify measures that will reduce drug expenditures.

## UNITED KINGDOM

The UK's drug pricing schemes attempt to blunt the impact of regulation on R&D spending by pharmaceutical manufacturers. However, pharmaceutical industry critics argue that the UK approach is a poor compromise that still stifles R&D investments. However, if industry is dissatisfied with regulated price levels that guarantee them a basic level of R&D funding, they may not be happy with anything short of unregulated prices. Nevertheless, Britain remains a popular location for among nations preferred by pharmaceutical companies for future R&D facilities along with the United States and Germany.

Although data evaluating the UK's drug cost control reforms are limited, there is general consensus among policy experts that the UK's combination of control mechanisms contributes to lower per capita levels of pharmaceutical expenditures. A distinguishing feature of the UK's approach to regulating prescription drug profits is the government's direct negotiation with pharmaceutical manufacturers. Direct negotiation with the pharmaceutical industry by major purchasers helps to level bargaining power between drug purchasers and manufacturers; more level bargaining can help leverage reduced prices in comparison to the prices manufacturers might otherwise offer to smaller drug purchasers. In a market-based system like that in the U.S., direct bargaining by the biggest purchasers might offer opportunities to lower overall prescription drug expenditures.

Another feature of UK policy to improve prescription drug affordability is the accountability mechanism that gives prescribing physicians an economic incentive to monitor and control drug utilization. In addition, through NICE, GPs have information that can be useful in determining appropriate, efficacious, and cost-effective treatments, including the role of prescription drugs. These evidence- and performance-based approaches are useful examples of how processes can help address inappropriate and excessive drug utilization.

# End Notes

- 1 The United Kingdom includes the countries England, Northern Ireland, Scotland, and Wales.
- 2 Data are expressed in purchasing power parities (PPPs), which provide a means of comparing spending between countries. PPPs are the rates of currency conversion that equalise the cost of a given basket of goods and services in different countries.
- 3 Some could argue that the U.S. regulates prescription drug prices through provisions of the Social Security Act, which require that Medicaid and other public health entities receive manufacturers' best prices. These provisions could be interpreted as weak regulation, because they do not prevent manufacturers from setting any price the market will bear for a product; rather, they merely have to ensure Medicaid gets its best price for the product. The Veterans Administration has its own prescription drug procurement process that could also be considered a regulated market.
- 4 Although airline customers actually receive higher value services when paying higher fares and one could argue that countries, such as the U.S. that pay higher drug prices receive the same products as countries that pay less.
- 5 In a 2004 study, on reimportation, the U.S. Congressional Budget Office found U.S. prices for brand-name products to be 35-55 percent higher than in other industrialized nations.
- 6 A European Network for Health Technology Assessment was established recently, but it is too new to warrant a review of its programmatic success. The objective of this "EUNetHT" would be to connect public national health technology assessment agencies, research institutions, and health ministries, to enable: (1) effective exchange of information, and (2) support of policy decisions by member states.
- 7 The term "gray area" as used in the listing of prescription drugs on formularies has a different meaning from that when used by the PPRS to describe the relationship between prescription drug manufacturer profits and ROI targets.
- 8 P. Littlejohns, Clinical and Public Health Director, National Institute for Health and Clinical Excellence, presentation at Commonwealth Fund/Alliance for Health Reform symposium in Washington, DC, April 22, 2005
- 9 Pearson, SD, Rawlins, MD, "Quality, Innovation, and Value for Money, NICE and the British National Health Service," *JAMA*, Vol. 294, No. 20 (Nov. 23/30, 2005), 2618-2622

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