Importation of Prescription Drugs
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Testimony

Mr. Chairman, Senator Kennedy, and Members of the Committee. I am pleased to appear today and testify in favor the Pharmaceutical Market Access and Drug Safety Act of 2004 (S2328). The legislation addresses several important issues that were not addressed in the Medicare Prescription Drug Improvement and Modernization Act. Specifically, S2328 gives the Secretary of the Department of Health and Human Services the authority to implement a system for the importation of prescription drugs from Canada within 90 days of enactment and, beginning one year after enactment, from the members of the European Union as of January 1, 2003, Australia, New Zealand, Japan, and Switzerland. Moreover, it provides a rigorous licensing and inspections regime to assure that drugs imported under the program meet the FDA gold standard of safety and effectiveness. Unlike other legislative initiatives in this area, it also assures that drug companies will not be able to manipulate the rules to prevent a significant amount of drugs being imported into the United States. Without such rules, a program of importation and reimportation would likely have little or no impact on U.S prices.

After carefully reviewing the legislation, I conclude that it will reduce rather than increase the likelihood of counterfeit drugs entering the U.S. supply chain from abroad and that drugs imported under the program will meet FDA standards for safety and effectiveness. Moreover, it will provide downward pressure on prices paid by U.S. consumers without leading to a reduction in drug innovation.

Let me deal with the issues of patient safety and drug product quality, safety and effectiveness. Then, I will deal with the issues of drug prices, costs, and cost effectiveness.

Patient Safety and Drug Quality, Safety, and Effectiveness

Last year, prior to enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA 2003), the House of Representatives, by a margin of 243 to 186, passed a bill to allow individual patients, pharmacists, and drug wholesalers to import prescription drugs from Canada and European countries if they had been approved for use in this country by the FDA. Before final action, the House-Senate conference committee rejected this approach and reaffirmed the current policy, which permitted importation only if the Secretary of the Department of Health and Human Services certified that drugs imported under the program authorized by the bill would be safe. Neither Secretary Shalala nor Secretary Thompson has been willing to grant such

certifications. The MMA, while including a new prescription drug benefit (Part D) for Medicare, did not permit the importation of drugs from Canada and Europe. The MMA did, however, request a report to Congress on importation.

To assist in examining the issues related to importation, Secretary Thompson established the Task Force on Drug Importation, chaired by Dr. Richard Carmona, the Surgeon General of the U.S. Public Health Service, and including Dr. William Raub, the DHHS Deputy Assistant Secretary for Science, and Dr. Mark McClellan, the former FDA Commissioner and currently the Administrator of the Centers for Medicare and Medicaid Services.

The Task Force has held five listening sessions, drawing on a wide range of experts. I have had the opportunity to review some of the transcripts and the testimony of some of the witnesses in full. These documents should be carefully reviewed by the Committee staff because they deal with a number of issues of concern to this Committee.

The Pharmaceutical Market Access and Drug Safety Act of 2004 (S2328) deals with the quality, safety, and effectiveness issues very directly. The Act would require that importable drugs must be approved by the Food and Drug Administration (FDA) and manufactured in an FDA inspected plant. In addition, the drug must be administered by the patient; it cannot be injected or infused; and it must not be a drug inhaled during surgery or a controlled substance.

These requirements are essential to any expansion of drug imports, and I believe they deal with the drug quality and safety issues. The process and elements of FDA approval were described by Dr. Carl Peck, former Director of the FDA Center for Drug Evaluation and Research (1987-1993) in his testimony for the DHHS Task Force on Drug Importation on April 27, 2004. The importance of the FDA requirements for safety and effectiveness were also stressed by Pamela Wilkinson, Vice President of Regulatory Affairs/Serono Laboratories, Inc. I agree and do not believe it necessary to repeat their statements in detail. Suffice it to say, the FDA is the gold standard for assuring drug quality, safety and effectiveness. Drugs imported under the Pharmaceutical Market Access and Drug Safety Act of 2004 (S2328) are required by the legislation to meet these standards, and I believe that the regime of licensing and inspection established by the legislation will assure that they will in fact meet these standards.

Fraudulent and Counterfeit Drugs

Let me turn to a related safety and quality issue—fraudulent and counterfeit drugs entering the United States if current policies are modified to permit greater imports into the United States.

I have had a long-standing interest in this problem. In 1990, in an article in the International Journal of Health Services, my late colleagues, Dr. Milton Silverman and, Mia Lydecker, and I wrote an article, “The Drug Swindlers” that described the problem of counterfeit drugs internationally. We developed the story more fully in the chapter,

"The Drug Swindlers," in our book, Bad Medicine, published by Stanford University Press in 1992. After our 1990 article, the story was reported in the November 12, 1990 Newsletter of the Pharmaceutical Manufacturers Association and it received international coverage in the magazine Newsweek ("The Pill Pilots" November 5th, 1990).

Based on our studies, we noted that many drug experts were alarmed by the rapidly expanding growth of counterfeit drugs. I should note that in 1990 and 1992, we did not include China among the countries with serious problems. I have been very concerned about the increase of the problem in recent years, but I am encouraged by the possibilities for dealing with the problem.

Let me elaborate. A number of pharmaceutical industry officials and trade association representatives have expressed concern that counterfeiting may increase with legislation allowing imports. On reading their statements before the DHHS Task Force on Drug Importation, I do not believe that they were speaking about the Pharmaceutical Market Access and Drug Safety Act of 2004 (S2328). I believe the Act provides clear policies to prevent this.

The issue of fraudulent and counterfeit drugs has concerned Congress and the FDA since the enactment of the Prescription Drug Marketing Act (PDMA) of 1988. The Act was amended in 1992, but its benefits have not been realized. The Food and Drug Administration published a Federal Register Notice on February 19, 2004 delaying the final rule published in the Federal Register on December 3, 1999 on certain requirements in the final rule relating to wholesale distribution of prescription drugs. There have been multiple earlier delays in this final rule. In this most recent revision delaying the final rule until December 1, 2006, the FDA states:

FDA is working with stakeholders through its counterfeit drug initiative to facilitate widespread, voluntary adoption of track and trace technologies that will generate a de facto electronic pedigree, including prior transaction history back to the original manufacturer, as a routine course of business. If this technology is adopted, it is expected to help fulfill the pedigree requirements of the PDMA and obviate and resolve many of the concerns that have been raised with respect to the final rule by ensuring that an electronic pedigree travels with the drug product all the time.

On February 18th, the FDA held a press conference to announce the release of its report Combating Counterfeit Drugs. At the press conference, Secretary Thompson noted:

We have started to see a tremendous increase in the volume and, more importantly, the sophistication of counterfeit and other unsafe drugs entering our supply (Young 2004, p. 645).

The then FDA Commissioner, Mark McClellan described the electronic track and trace technologies that would soon be able to provide a high level of confidence that a drug was manufactured safely and distributed under proper conditions. The report is an excellent one and describes the FDA's current strategy, with an emphasis on the track

and trace technologies and the authentication technologies that should be in use by 2007.

The plan is very well thought out, but it did not describe the resources that will be needed, in both the private and public sectors to implement the plan, nor did it deal with the issue of assuring the safety and effectiveness of drugs during the period before these standards are widely adopted.

Section 8, Wholesale Distribution of Drugs (S2328) deals with this issue and is aligned with the FDA Strategy. It amends section 503(c) of the FFDCA to require a pedigree in interstate commerce, including drugs exported from the United States and imported drugs, and allows FDA to require anti-counterfeiting or track and trace technology in lieu of pedigree. A pedigree is a statement of origin of the drug with information about all previous transactions. This is an important provision in S2328. Further, these actions are very appropriate in view of recent developments.

In testimony before the HHS Task Force on Drug Importation, officials of Eli Lilly, Pfizer, and Johnson and Johnson all commented on the issue of counterfeit drugs, with the problem increasing in the United States since 1998. John Theriault, Vice President, Global Security, Pfizer, Inc. had appeared before the Senate Special Committee on Aging in July 2002, to describe the problem and the steps taken by Pfizer to counter the problem. He noted in his testimony to the Task Force on April 5, 2004:

It is widely accepted that China is the major source of counterfeit pharmaceutical products marketed throughout the world. Before 1998, the United States and other developed countries were not particularly concerned about counterfeit pharmaceuticals. The security departments of major pharmaceutical companies devoted few, if any, resources to the problem. It was one of the widely accepted ‘truths’ of counterfeiting that it was a problem only in China, India, and less developed countries.

Between 2001 and 2003, the problem seems to have grown rapidly, including Europe, Asia, the Middle East, and the Americas. According to John Dempsey, Executive Director of Trade Relations and Brand Security for Ortho Biotech, the FDA has initiated 73 counterfeit drug investigations since October 1996, the majority in the last two and a half years, resulting in 44 arrests, 27 convictions, with a number of criminal investigations still ongoing. He added, “The Pharmaceutical Security Institute’s 2003 report states that there was a 60 percent increase in the incidence of prescription drug counterfeiting in 2003. They have documented 264 incidents of counterfeiting in 2003” (p. 24 of 38).

Clearly the problem is a serious one throughout the world. I believe that the FDA’s proposed system of modern protection against counterfeit drugs is supported by the Pharmaceutical Market Access and Drug Safety Act (S2328) and that S2328 would provide the necessary authority for the FDA to deal with the problem. Thus, rather than making American consumers less safe, S2328 would make American patients safer.

Let me add a word of caution about the track and trace technologies. These are based on

radiofrequency identification (RFID) tagging of products by manufacturers, wholesalers, and retailers. This appears to be the best approach available and there is an enormous literature on this topic. A web search of this issue for pharmaceuticals leads to more than 100,000 “hits,” and there are professional journals and trade publications solely devoted to RFID.
I believe two issues still need to be fully addressed: (1) security and (2) privacy, particularly when large databases link products purchased by individual patients. I am not an expert in either of these areas, but this committee may wish to review the whole matter after it receives the Secretary’s report on importation.

Let me turn from drug quality, safety, and effectiveness to drug prices and expenditures and the forces that are compelling Congress to revisit the issue of the importation of prescription drugs from Canada and Europe.

Rising Prescription Drug Expenditures: International Comparisons
According to the Directorate for Education, Employment, Labor, and Social Affairs (OECD):

Total expenditure on pharmaceutical goods represents between 0.7 and 2.2% of GDP across OECD countries, with a mean around 1.2%. Expenditure on pharmaceuticals represents between 8 and 29% of total health expenditure with a mean around 15.4%. Although relatively small this order of magnitude is still significant, since in most countries more than half of pharmaceutical expenditures is reimbursed by public funds (Jacobzone 2000, p. 11).

The costs in all the countries reflect both the price of drugs and the use of drugs. The price is a reflection of the number of both new, brand name drug products and the generic products on the market and in use.

In recent years, the price of prescription drugs has been rising rapidly. Before 1981, prescription drug prices tended to rise more slowly in the United States than did the consumer price index (CPI)—in many years, substantially more slowly. Since 1981, the CPI for prescription drugs has risen more rapidly, sometimes triple the CPI for all items (Smith 2004). Price increases in the 1990’s and in the early 21st century have been particularly striking.

Spending for retail prescription drugs rose from $2.7 billion in 1960 to $15 billion in 1982 to $48.2 billion in 1992 and $162.4 billion in 2002. The average annual rate of growth was 7.8 percent in 1980, 11.7 percent in 1982, 12.4 percent in 1992, and 15.6 percent in 2002. As a percent of health spending retail drugs rose from 4.9 percent in 1980 to 10.5 percent in 2002, and as a percent of gross domestic product from 0.43 percent to 1.55 percent (Smith 2004, p.161).
Annual increases in spending for prescription drugs in the United States are projected to increase to $207.9 billion in 2004, $233.6 billion in 2005, and $519.8 billion by 2013 (Heffler 2004). It is small wonder that the cost of prescription drugs is of concern to patients, health plans, and state and federal officials. A number of factors have

contributed to the rapid increase in prescription drug costs throughout the developed world, including increased consumption of drugs, shifting of consumption from older, less costly drugs to newer drugs, and increased drug prices. Notably, the United States ranks well above the industrialized world on all dimensions. Our per capita consumption of drugs is higher, and the prices we pay for the drugs we consume are higher. From the point of view of the individual patient, whose goal is to treat illness or maintain health by following the instructions of his doctor, the prices of the drugs prescribed for him is the most important factor.

## National Policies to Control Expenditures

There are two basic approaches to controlling drug expenditures: policies to control prices and policies to manage drug utilization (Morgan et al. 2003).

### Strategies for Controlling Expenditures

In a critical review of the regulation of the market for pharmaceuticals, Maynard and Bloor (2003) make the point that the pharmaceutical market, like all markets, is regulated by government, private agencies (e.g., trade associations) or industry self-regulation. They also note that three objectives of regulation are often cited: (1) expenditure control, (2) quality, and (3) access.

The construct of regulatory interventions includes three categories: (1) influencing patients, (2) influencing doctors, and (3) influencing industry. To influence patients, the emphasis has been on multi-tiered co-payment structures and increasing the amount of deductibles and premium. In addition, shifting drugs from prescription to over-the-counter status shifts costs to patients from third party payers. Also, direct-to-consumer advertising, a practice that is sanctioned only in the United States and New Zealand, attempts to directly influence patients' choice of brand name drug products.
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Policies designed to influence doctors largely have been based on feedback to physicians about their prescribing behavior and the costs of the drugs they prescribe. These policies have been ineffective when compared to the role played by the pharmaceutical manufacturers in promoting their brand name drugs, particularly their newer drugs to physicians. There is no doubt that drug promotion by manufacturers influences physician prescribing behavior, and it is seldom to prescribe the most cost-effective drugs.

Formularies and generic substitution also are used, but they have more impact on cost than modifying physician behavior. One of the most detailed studies of the use of a formulary was carried out by the program in the Veterans Health Administration (VHA) in the U.S. In 1995, the VHA established its own pharmacy benefit manager, the VHA Pharmacy Benefits Management Strategic Health Care Group that implemented a national formulary, including closed, open and preferred contracts (Huskamp et al. 2003). Although only a small number of drugs were included in the closed contracts the aggregate savings over the two-year study period was $82.1 million for the five classes of drugs that were closed at some point during the study period.

European countries and Canada use a mix of policies to control drug costs. Policies that focus on controlling price predominate. Policies to control utilization have been much less widespread. A wide variety of programs to limit prices have been followed, including "reference pricing," negotiation of rates as condition for being included in government insurance programs, and profit limitation.

Price Limitation and Pharmaceutical Research and Development

For the past 35 years, ever since the publication of the Final Report of the DHEW Task Force on Prescription Drugs, I have heard the argument that policies designed to impose government price controls or any other measure to reduce drug prices in the United States will reduce industry profits, which in turn will lead to a decrease in R&D investment by the pharmaceutical industry and a decrease in the number of innovative prescription drugs introduced, resulting in more disease, disability, and premature death. The argument has been made over and over, particularly by the Pharmaceutical Manufacturers Association (PMA) and its successor, the Pharmaceutical Research and Manufacturers of America (PhRMA), as well as by many economists.

Few studies have systematically examined the growth of drug industry sales relative to profits and spending on R&D and drug promotion. Previous analyses of relative revenue allocation indicate that more dollars are spent on marketing, advertising, and administration (MAA) than on R&D. This allocation of revenue raises doubts about the link between drug prices and R&D spending voiced during the Medicare benefit debate. Studies also indicate that the pharmaceutical firms have among the highest returns on revenue of any U.S. business, with profits outpacing other research-intensive industries like medical devices and telecommunications (Fortune 2004). If profits and spending on drug promotion are increasing more rapidly than R&D investments, then R&D is not the only industry expenditure that could be reduced.

New drug innovation also is critical to any drug pricing debate. While some analysts assert that constrained drug prices would limit innovation, recent trends suggest that slowing research productivity and increasing drug prices have gone together. In 2002 the FDA approved only 17 new molecular entities (NMEs) for U.S. sale, a fraction of the 56 NMEs approved in 1996.

In a recent analysis of the decline in the development of antimicrobial agents, Spellberg, Brass, Miller, and Edwards at the Division of Infectious Diseases, Harbor-UCLA Research and Education Institute and the David Geffen School of Medicine, UCLA and Powers from the Center for Drug Evaluation and Research, FDA found a significant decline in the number of antimicrobial agents approved by the FDA during the past 20 years. They concluded:

Despite the critical need for new antimicrobial agents, the development of these agents is declining. Solutions encouraging and facilitating the development of new antimicrobial agents are needed.

The development of new antimicrobial agents are needed especially for naturally occurring and emerging infectious diseases, including infections caused by agents of bioterrorism.

How to account for slowed innovation amidst rising drug revenues? Industry critics say drug companies increasingly develop “me-too” drugs; these incrementally modified drugs (IMDs) usually offer only marginal therapeutic benefits, but may be heavily promoted to increase market share (Angell 2000). A prior analysis of FDA approvals concluded that only about one-third of new drugs were truly innovative (NIHCM 2002). The rest were “me-too” drugs, which contain active ingredients similar to those already available in marketed products. Since both NMEs and IMDs may offer medical or economic benefits over existing therapies, the number of NME approvals does not necessarily reflect the quality of new drug innovation. An analysis of drug innovation would expand current knowledge by examining the chemical novelty and the anticipated therapeutic advantage of new drugs and the changing rates of innovation relative to industry sales and profits.

Such a study would add to the literature by examining pharmaceutical industry spending and innovation over time. Earlier analyses were limited because they examined few drug companies and provided figures for only one year (Families USA 2001, 2002). A separate study used Food and Drug Administration (FDA) data to evaluate innovation over time, but did not consider concomitant changes in R&D or MAA spending (NIHCM 2002). Recent research has examined R&D spending and innovation in the context of drug development decisions, but these studies used data from a trade organization and did not consider marketing, advertising, or administration costs (Cockburn 2004, Croghan 2004, DeMasi 2003).

When the prescription drug benefit was enacted in December 2003, the Congressional Budget Office estimated it would cost $395 billion over the next 10 years. The White House now projects the cost to be $534 billion. With such an enormous outlay of federal dollars for prescription drugs, taxpayers and policymakers should have a systematic understanding of how manufacturers allocate revenues and what level of innovation is derived from R&D investments. This knowledge can inform future dialogue over the appropriate role of government in drug price negotiations.

Such a study could contribute to evaluating the assertion that federal drug price negotiation would inhibit the development of new therapies. It would explore the relationships among R&D investments and patterns of innovation and suggest evolving industry priorities regarding drug research, development, advertising, and marketing.

## Only Part of the Answer

The Pharmaceutical Market Access and Drug Safety Act of 2004 (S. 2328) is only part of

the answer to the rapidly rising expenditures for prescription drugs.

The first step that can be taken without any new legislative authority is the greater use of generic drugs. A recent study by Fischer and Avorn (2003) reported:

Analysis of state-by-state Medicaid prescription drug spending in 2000 identified potential savings of $229 million that could be realized from greater use of generic drugs. If the best available prices from each sate had been used, savings would have increased to $450 million. The majority of savings were concentrated in a small group of medications, including clozapine, alprazolan, and levothyroxine" (p. 1051).

The potential for generic drugs has long been recognized. The reasons that they are not prescribed more frequently by physicians or dispensed by pharmacists are many. It was not until the 1970's that state laws prohibiting the substitution of a generic name drug product that was chemically, biologically, and clinically equivalent to a brand-name drug product were abolished.

While the generic name drugs have a greater market share in the United States than anywhere in the industrialized world, and they will usually be less expensive than brand name drug products imported from Canada or Europe, they are still underutilized. This is not a new problem. Fifteen years ago, Professor Helene Lipton and I discussed the issue in our book, Drugs and the Elderly, emphasizing the need for greater physician awareness and the removal of financial disincentives for pharmacists to dispense generics.

One important factor has been the detailing of brand name drug products to physicians by the pharmaceutical companies and the recent dramatic increase in direct-to-consumer advertising of prescription drugs (expenditures now approach $3 billion per year). One approach to better informing physicians is the use of academic detailing (a program in which today's highly trained clinical pharmacists provide one-on-one, evidence-based, objective information on drug quality, safety, effectiveness, and costs to prescribing physicians). Studies reported by Avorn and Soumerai (1983) in the early 1980s demonstrated the benefits of this type of educational outreach in improving clinical decision-making. Many studies since then have confirmed their earlier observations.

Much more needs to be done using this approach with both physicians and pharmacists.

In summary, Mr. Chairman, I have carefully reviewed the Pharmaceutical Market Access and Drug Safety Act of 2004, and I encourage the Committee to support it and Congress to enact it.

I have been concerned with issues related to prescription drug policy for the past 39 years, including during both my years of federal service and as a faculty member of the School of Medicine, UCSF.

I believe that the bill provides strong assurances of the safety and quality of imported drugs. It contains appropriate provisions related to counterfeit drugs, and it provides

patients, physicians, pharmacists and wholesalers the opportunity to add a tool—the importation of prescription drugs—to help deal with the problem of the rapidly rising costs of drugs. We all recognize that it is only one of the tools available; others include greater generic prescribing and dispensing and the use of academic detailing to better inform physicians about the many new drugs in the market place.

References

Anderson GF, Reinhardt UW, Hussey PS, and Petrosyan V. (2003) "It's the Prices, Stupid: Why the United States is So Different From Other Countries." Health Affairs 23 (1): 89-104.

Angell, M. (June 2000) "The Pharmaceutical Industry—To Whom is It Accountable?" New England Journal of Medicine. 342: 1902-1904.

Avorn J and Soumerai SB. (1983) "Improving drug-therapy decisions through educational outreach: a randomized controlled trial of academically based 'detailing'." New England Journal of Medicine 308: 1457-1463.

Canadian Institute for Health Information. (2002). "Chapter 6: Medicating Illness: Drug Use and Cost in Canada" Health Care in Canada 2002. Ottawa, Ontario. http://www.cihi.ca/pdf/ec/hlthrpt2002.pdf.

Cockburn, I. (Jan/Feb 2004) "The Changing Structure of the Pharmaceutical Industry." Health Affairs 23: 10-22.

Croghan, T and Pittman, P. (Jan/Feb 2004) "The Medicine Cabinet: What's In It, Why, and Can We Change the Contents?" Health Affairs 23: 23-33.

Danzon PM and Furukawa MF. (Oct. 29 2003) "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries." Health Affairs web exclusive. W3-521 to W3-536.

Davis M, Poisal J, Chulis G, Zarabozo C, and Cooper B. (1999) "Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries." Health Affairs 18 (1): 231-243.

DeMasi JA, Hansen RW, and Grabowski, HG. (March 2003) "The Price of Innovation: New Estimates of Drug Development Costs." Journal of Health Economics 22:325-30.

Department of Health and Human Services. (Apr. 2004) "HHS Task Force on Drug Importation." Accessed online on 5/11/04 at: http://www.hhs.gov/importtaskforce/.

Families USA. (July 2002) "Profiting from Pain: where prescription drug dollars go." Pub. No. 02-105. Washington, DC. www.familiesusa.org.

Families USA. (July 2001) “Off the Charts: pay, profits, and spending by drug companies.” Pub No.01-104. Washington, DC. www.familiesusa.org.

Fischer MA and Avorn J. (Aug. 2003) “Economic consequences of underuse of generic drugs: evidence from Medicaid and implications for prescription drug benefit plans.” Health Services Research 38 (4): 1051-1063.

Food and Drug Administration, HHS. (Feb 2004) “Combating Counterfeit Drugs: A Report of the Food and Drug Administration.” Rockville, MD: DHHS, FDA. Accessed online on 5/13/04 at: http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html.

Food and Drug Administration, HHS. (Feb. 23, 2004) “Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; policies, requirements, and administrative procedures; delay of effective date.” Federal Register 69 (35): 8105-8107.

Fortune. “How the Industries Stack Up” (April 5, 2004) Fortune, New York. Accessed online on 3/24/2003 at: http://www.fortune.com/fortune/subs/fortune500/industrysnapshot/0,19721,49,00.html

Heffler S, Smith S, Keehan S, Clemens MK, Zezza M, and Truffer C. (Feb. 11, 2004) “Health Spending Projections Through 2013.” Health Affairs web exclusive. W4-79 to W4-93.

Huskamp HA, Epstein AM, and Blumenthal D. (2003) “The Impact of a National Prescription Drug Formulary on Price, Market Share, and Spending: Lessons for Medicare?” Health Affairs 22 (3): 149-158.

Jacobzone S. (April 2000) “Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals.” Labor Market and Social Policy—Occasional Papers No. 40. Paris, France: Organization for Economic Cooperation and Development, Directorate for Education, Employment, Labour, and Social Affairs, Employment, Labour and Social Affairs Committee.

Kanavos P and Reinhardt U. (May/June 2003) “Reference Pricing for Drugs: Is It Compatible With U.S. Health Care?” Health Affairs 22 (3): 16-30.

Maynard A and Bloor K. (2003) “Dilemmas In Regulation of the Market for Pharmaceuticals.” Health Affairs 22 (3): 31-41.

Morgan S. (Oct. 2002) “Quantifying Components of Drug Expenditure Inflation: The British Columbia Seniors’ Drug Benefit Plan.” Health Services Research 37 (5): 1243-1266.

Morgan SG, Barer ML, and Agnew JD. (2003) “Whither Senior Pharmcare: Lessons From (and For) Canada.” Health Affairs 22 (3): 49-59.

National Institute for Health Care Management Research and Education Foundation. (May 2002) Changing Patterns of Pharmaceutical Innovation. Washington, D.C.: NIHCM Foundation, Accessible at: www.nihcm.org/innovations.pdf.

Silverman M and Lee PR. (1974) Pills, Profits, and Politics. Berkeley, CA: University of California Press.

Silverman M, Lydecker M, and Lee PR. (1992) Bad Medicine: The Prescription Drug Industry in the Third World. Stanford, CA: Stanford University Press.

Silverman M, Lydecker M, and Lee PR. (1990) "The Drug Swindlers." International Journal of Health Services 20: 561-572.

Smith C. (Jan/Feb 2004) "Retail Prescription Spending in the National Health Accounts." Health Affairs 23: 160-167.

Spellberg B, Powers JH, Brass EP, Miller LG, and Edwards, JE. (2004) "Trends in Antimicrobial Drug Development: Implications for the Future." Journal of Clinical Infectious Diseases 38 (9): 1279-1286.

White KL, Anderson DO, Kalimo E, Kleczkowski BM, Purola T, and Vukmanovic C. (1977) Health Services: Concepts and Information for National Planning and Management. Geneva: World Health Organization.

Young D. (Apr. 1, 2004) "FDA declares actions to combat counterfeit drugs." American Journal of Health-System Pharmacy 61 (7): 645-646.