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PRESCRIPTION DRUGS AND THE ELDERLY

Drug Safety

FDA Drug Review: Postapproval Risks 1976–85 is part of a two-phase U.S. General Accounting Office (GAO) study of drug risks that become evident after Food and Drug Administration (FDA) approval. Released in April 1990, this first report identifies the seriousness and frequency of postapproval risks for certain drugs; a second report will examine the relationship between those risks and FDA’s approval process. Of the 198 drugs approved between 1976 and 1985, 51.5 percent had serious postapproval risks. Most serious risks were identified within three years of FDA approval; however, GAO found evidence that new risks may become apparent more than five years after approval.

GAO also found that serious postapproval risk was associated with drugs that (1) were on FDA’s postmarketing surveillance list because of adverse reactions not listed on the current label; (2) had been reviewed for use in children; (3) were approved between 1976 and 1980 (rather than between 1981 and 1985); and (4) among drugs approved in fewer than four years, had been approved in the least amount of time. To reduce predictable risk to the consumer, GAO recommends that FDA establish procedures, such as quantitative risk analysis, for evaluating serious postapproval risks, to use in clinical trials and postmarketing surveillance. Copies are available (first five copies free, additional copies $2) from GAO, P.O. Box 6015, Gaithersburg, MD 20877.

Guideline for the Study of Drugs Likely to Be Used in the Elderly was issued by FDA in November 1989 “to encourage routine and thorough evaluation of the effects of drugs in elderly populations.” Age or age-related conditions (such as diminished renal or cardiac function or multiple drug therapy) can affect the way a drug is absorbed, excreted, or metabolized (pharmacokinetic responses). FDA recommends that sponsors of geriatric drugs focus on detecting pharmacokinetic differences between younger and older people because these responses account for most geriatric drug problems, occur frequently; and are relatively easy to detect. Pharmacodynamic responses, such as drug/dose responses, occur far less frequently and are more difficult to assess.

The guidelines also recommend that when a drug is developed to treat a disease not necessarily characteristic of aging, sponsors should estimate the disease’s prevalence by age to determine the drug’s target population. For drugs likely to be used in the elderly, both young persons and a “reasonable” number of elderly patients should be included in the clinical trials, to compare age-related drug responses. Copies are available from the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Drug Evaluation 1 (HFD-100), 5600 Fishers Lane, Rockville, MD 20857.

Prescription Drugs: HCFA’s Proposed Drug Utilization Review System Ignores Quality of Care Issues is a GAO report issued in July 1989. It examines the drug utilization review system proposed by the Health Care Financing Administration (HCFA) as part of the national Medicare outpatient prescription program mandated in the Medicare Catastrophic Coverage Act of 1988. Although the act was repealed, drug utilization review systems continue to interest both public and private payers. In this report, GAO identifies major issues concerning HCFA’s pro-
posed system and assesses the likelihood of the system’s meeting legislative objectives.

GAO found that, compared to other drug utilization review systems, the one proposed by HCFA is “very basic.” It would compare drug/drug interactions for only a limited number of drugs (225); provide limited information on dosage levels, drug/drug reactions, and therapeutic overlap; and not include any information on interactions between over-the-counter and prescription drugs, drug allergies, and disease/health conditions. Copies are available (first five copies free, additional copies $2) from GAO, P.O. Box 6015, Gaithersburg, MD 20877.

Financing

Home Intravenous and, Immunosuppressive Drug Therapies under the Medicare Program is the focus of a new Office of Technology Assessment (OTA) study to be completed by April 1991. The study would examine the financial impact of covering home intravenous and immunosuppressive drugs, the effect on research and development of new drugs and new forms of delivering drugs, and alternative payment methods. Currently Medicare does not cover drugs administered at home, with a few limited exceptions. The repealed Medicare Catastrophic Coverage Act would have expanded Medicare drug benefits. For more information, contact Elaine Power, U.S. Congress, Office of Technology Assessment, Health Program, Washington, DC 20510-8025.

Recombinant Erythropoietin: Payment Options for Medicare presents findings from OTA on paying for a new therapy for patients with kidney disease. Medicare coverage for recombinant erythropoietin, which can treat anemia associated with chronic renal failure, began in June 1989. Medicare beneficiaries must receive the treatment at dialysis facilities or in physicians’ offices to qualify for coverage. Concerned about the cost of extending this treatment to patients who receive their dialysis at home, the House Ways and Means Subcommittee on Health commissioned this OTA report. This study was originally part of a broader study to evaluate Medicare payment policies for the outpatient drug benefit under the catastrophic legislation.

Since the cost of recombinant erythropoietin is high ($5,000–$6,000 per patient per year) and Medicare is the predominant payer for patients with end-stage renal disease, the cost to Medicare of covering the treatment for the 18,000 home dialysis patients could be significant. The May 1990 OTA report also examines other financial issues, including perverse payment incentives, differences in payment levels, and method of payment. Roger Herdman and Jane Sisk of OTA wrote in testimony (14 June 1990) before the Ways and Means Subcommittee on Health: “The current method of paying dialysis centers per rHuEPO treatment provides a financial incentive for providers to use as few units of rHuEPO as possible, and even to skimp on use.” The report also discusses the clinical significance of the breakthrough treatment, the marketplace structure, and current Medicare payment policies. Copies (stock number 052003-01188-3) are available for $5 from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Skyrocketing Prescription Drug Prices: Turning a Bad Deal into a Fair Deal (January 1990) and Prescription Drug Prices: Are We Getting Our Money’s Worth? (August 1989) are two recent Majority Staff Reports of the US. Senate Special Committee on Aging. The reports present the research that supports Sen. David Pryor’s (D-AR) proposed Pharmaceuticals Access and Prudent Purchasing Act of 1990. In the 1989 report, the committee found that “high prescription drug prices are poorly correlated with innovation.” For its follow-up report, the committee examined cost-saving strategies of the private sector and foreign governments and the commonly held assumption that prescription drug prices correlate to drug manufacturers’ research and development costs. (See D. Pryor, “A Prescription for High Drug Prices,” in this volume of Health Affairs.) Copies of both reports are available from Publications, U.S. Senate Special Committee on Aging, G-31 Senate Dirksen Office Building, Washington, DC 20510.
State Pharmaceutical Assistance Programs for the Elderly and Disabled: Current Status and Policy Issues details the nine state pharmaceutical assistance programs currently in existence to help elderly residents pay for their prescription drugs. The first such program began in New Jersey in 1977; the most recent, ten years later in New York. All nine programs base eligibility on income and are designed to help the “marginally poor.” Both the range of drugs covered and recipients’ copayment amounts vary from state to state. The May 1989 report, released by the American Association of Retired Persons (AARP), includes twenty tables and charts detailing costs and cost controls, generic drug use, drug utilization review, point of sale technology, and establishment of state pharmaceutical assistance programs. Copies are available from AARP Public Policy Institute, 1909 K Street, NW, Washington, DC 20049.

Pharmacy Services

The Older Patient and Pharmacy: Special Needs and Special Opportunities (Schering Report XII) is based on in-home interviews with 2,000 adults across the country to ascertain the special needs of older Americans and how pharmacists might help their elderly customers. The study notes that, according to the Bureau of the Census, of noninstitutionalized adults age sixty-five and over, 22 percent have difficulty reading newsprint (and therefore, prescription labels); 15 percent have difficulty hearing ordinary conversation (such as pharmacists’ instructions); and 38 percent find it difficult to walk one-quarter mile (which relates to pharmacy location and parking lot size).

Friendly, helpful service ranked high on the list of factors older patients consider when choosing a pharmacy—higher, indeed, than fair prices. Survey respondents felt that pharmacists of “independents” were more likely than those of “chains” to provide such service, to be knowledgeable, and to provide patients with additional information and instructions, but that chains had lower prices. In addition, the July 1990 study found that six out of ten older patients were aware that their pharmacy offers senior citizen discounts; three out of ten were aware that their pharmacy offers direct billing to the patient’s insurance company; seven out of ten said that their pharmacist maintains a record of all of their medications; and only 13 percent had ever used a mail order pharmacy. “Most of the people we spoke to, regardless of age, showed no interest in mail order pharmacy,” said Jack Robbins, director of pharmacy affairs. Copies are available free of charge from Pharmacy Affairs Department, Schering/Key Laboratories, Kenilworth, NJ 07033.

Research And Development

Drug Development for the Geriatric Population summarizes a two-day workshop on Drug Development and Aging Populations, held by the Institute of Medicine’s (IOM’s) Division of Health Sciences Policy as part of its May 1989 Forum on Drug Development and Regulation. The August 1990 summary notes recommendations to improve geriatric pharmacology: (1) design drugs specifically for the elderly; (2) when evaluating geriatric drugs, consider the patient’s ability to function normally, not just the drug’s efficacy and physical side effects; (3) consider the possible negative effects of drug “caps” when designing policy; (4) include persons over age eighty-five in drug studies; (5) develop methods for disseminating research findings to physicians; and (6) develop more training programs in geriatric medicine.

Workshop participants reported that “more than two million older Americans take a sleeping pill or tranquilizer every day for at least a year,” well past the medication’s effective term of use. Also, “many of these people are suffering one or more of the side effects or adverse reactions from the drugs.” The workshop also pointed to the need for large, computerized databases for postmarketing epidemiological studies and for a mechanism for alerting doctors to problems with their elderly patients’ drug use. Copies are available from the Institute of Medicine, National Academy of Sciences, 2101 Constitution Avenue, NW, Washington, DC 20418.
Government Policies and Pharmaceutical Research and Development (R&D) is a pending Office of Technology Assessment (OTA) study to examine drug industry R&D trends and costs. The anticipated completion date is 31 May 1991. As part of the project, OTA will propose a system for estimating and tracking R&D costs. Rep. John Dingell (D-MI) and Rep. Henry Waxman (D-CA) of the House Energy and Commerce Committee requested the study to provide “objective and reliable data on the research and development costs of new drug development” to supplement current pharmaceutical industry data. For more information, contact Judith Wagner, U.S. Congress, Office of Technology Assessment, Health Program, Washington, DC 20510-8025.

The Research Gap: The Need for Boosting Research to Achieve Independence for Older Americans was released in March 1990 by the Alliance for Aging Research. It reports on the widening gaps between federal spending on aging research ($425 million in 1990) and health care costs of the elderly ($215 billion in 1990) and between federal and private spending on aging research.

According to US. Census Bureau data, the population over age eighty-five—those most likely to need long-term care—will more than quadruple by 2040. By 2000, approximately two million people over age sixty-five will live in nursing homes; more than half of these will be over age eighty-five. Research to prevent and cure the illnesses of old age could help older Americans retain their independence and thereby substantially reduce the U.S. health care budget. “Each one month reduction in the period of dependency for older Americans would save $5 billion in health care and custodial costs,” the report states.

The report further points out that “the progress of industrial research and development depends in large measure upon a strong biomedical research and training program underwritten by the federal government.” Currently, the pharmaceutical industry spends 50 percent of its budget on aging research, while the National Institutes of Health (NIH) spend less than 6 percent. The exception to this is NIH’s National Institute on Aging (NIA), which spends 100 percent of its research budget on aging. However, under President Bush’s proposed 1991 budget, real spending at NIA is projected to decrease by almost 2 percent, and NIA’s award rate will be the lowest (17 percent) of all thirteen NIH institutes.

The report’s recommendations include an annual aging research budget of $1 billion ($600 million in new funds), with NIA receiving the major share; increased funding for aging research at the Department of Veterans Affairs; and the establishment of a government task force to develop a funding and investment schedule to help older Americans achieve independence. Copies are available for $5 from Alliance for Aging Research, 2021 K Street, NW, Suite 305, Washington, DC 20006.

In Memoriam

Albert Bowers, longtime chairman and chief executive officer of the Syntex Corporation, died in July of this year. Bowers, a research chemist who originated more than 120 patents, published more than 90 scientific papers, and pioneered research on oral contraceptives and topical steroids, was also very interested in public policy and public health. During his tenure as chairman of the board of directors of the Pharmaceutical Manufacturers Association, the industry trade group commissioned numerous policy and economic studies by noted academic researchers. Bowers had a positive vision for the future of the pharmaceutical industry and was strongly committed to corporate leadership in public policy, as evidenced by his company’s leading role in developing compassionate workplace policies for employees and dependents with acquired immunodeficiency syndrome (AIDS). His many contributions to science, education, and community service will be sorely missed.