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The Global Picture

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Cancer Drugs and Managed Care
THE GLOBAL PICTURE

by Walter Alexander

The processes behind progress in cancer drug research have always been arduous, speculative, and costly. But in our new era of unleashed market forces in health care, how will oncology research be affected? The relentless 12-year average research elimination process typically reduces 5,000 investigational compounds to one effective therapeutic agent. Will potentially valuable agents be lost in the rush to root out red ink?

Some experts detect a particular vulnerability in U.S. drug research as the snowballing influence of managed care intensifies. Others point optimistically to a robust line-up of oncology drugs in the pipeline.

Optimism seems the case with the fifth survey of *New Medicines in Development for Cancer* by the Pharmaceutical Research and Manufacturers of America (PhRMA). The survey identifies 215 medicines in testing by 98 research-based pharmaceutical companies and the National Cancer Institute. In the brief period elapsed since the last survey (1993), the number of medicines in development for cancer and cancer-related conditions has increased dramatically (from 124 to 215) as has the number of companies involved (from 49 to 98). Overall, U.S. pharmaceutical companies have increased their research and development spending from $12.7 billion in 1993 to $15 billion in 1995.

Multiple agents in development, the survey shows, target a broad range of more than twenty different kinds of cancer (see Table 1). Biotechnology, in particular, appears to be giving a boost to oncology research.

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A WORLD VIEW

A recent international symposium in Lund, Sweden, among senior-level health care policy leaders, industry executives, and medical specialists, provided a global outlook on the health of the pharmaceutical industry. Participants were from four nations (United Kingdom, Germany, Sweden, and the United States), each actively debating health care reform, and all with robust pharmaceutical industries.

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The governments of the European countries participating in the symposium control drug prices and utilization. At the same time, however, they remain aware that they need to protect their pharmaceutical industries' capacity to develop new drugs, according to presenter and symposium cochair Richard Saltman, Ph.D., Emory University, Rollins School of Public Health. The international symposium, "Healthcare: A Global Perspective," was organized by Harvard School of Public Health, cochaired by Harvard assistant professor Nancy Kane, D.B.A., and Saltman, and supported by a grant from Astra USA.

"In the U.K.," Saltman said, "the government has been quite successful in balancing contradictory concerns, preserving healthy research and development while restricting overall expenditures." Drug innovation in both the U.K. and Sweden are helped by less stringent and costly drug approval processes. Although government control is weaker in Germany, Saltman noted that the minister of health recently had refused to implement drug manufacturing restrictions out of concern for the industry's vitality.

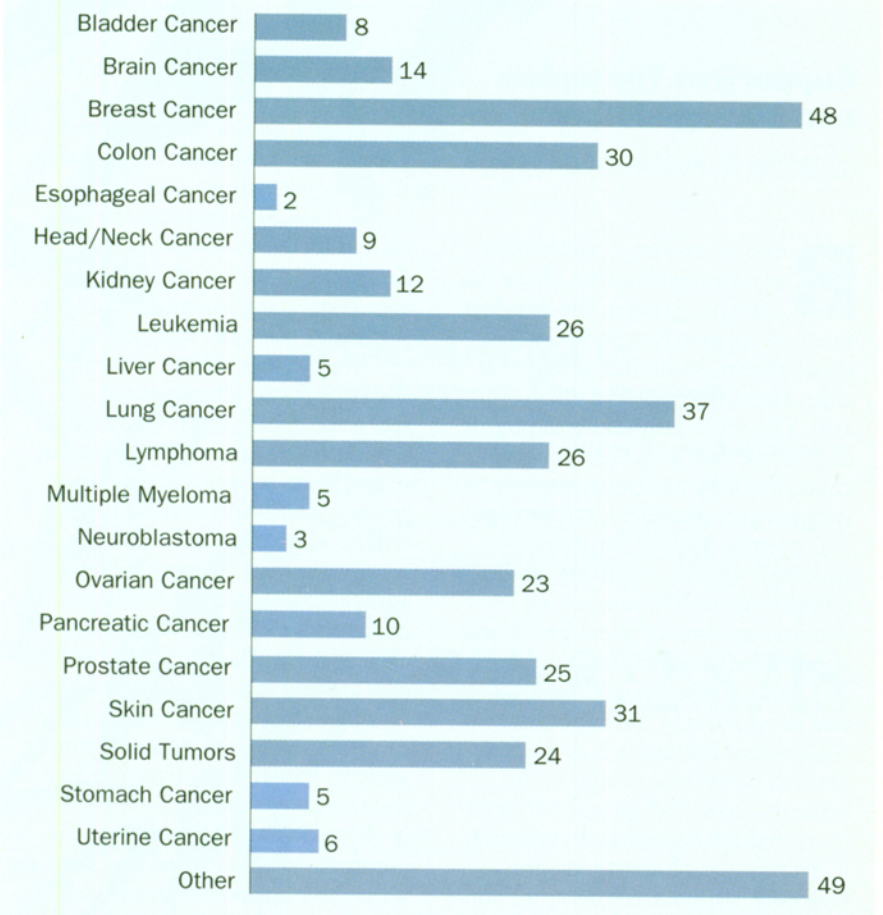
In the U.S., according to Saltman, competing pharmaceutical purchasing groups are concerned with

exacting the deepest drug discounts and optimizing their quarterly statements. They do not worry that squeezing prices excessively may impair industry research and development. Noting that some production of pharmaceuticals has already moved to Puerto Rico, Saltman commented: "If managed care generates sufficient pressure on drug company margins, it could drive drug companies off shore."

Kane agreed in principle but not degree. Presenting a commissioned paper addressing the effects of health care reform on pharmaceutical innovation, she conceded that increasing cost containment pressures in the U.S., which has the largest domestic market for pharmaceutical drugs (one-third of global pharmaceutical sales and an even larger portion of pharmaceutical profits), may have a greater impact than in the participant European countries that directly or indirectly limit consumer drug prices.

Drug spending in 1990 represented only 8 percent of total health expenditure in the U.S., similarly 8 percent in Sweden—compared to 11 percent in the U.K. and 21 percent in Germany (GAO May and July 1994). The U.S., however, had a greater rise in total drug expenditures and drug prices (on top of already substantially higher prices) during 1985-1991 than European countries, Kane said.

Table 1. 1995 Medicines In Development For Cancer



Source: Pharmaceutical Research and Manufacturers of America, 1995 Survey.

GREATER R&D, GREATER PROFITS

The U.S. pharmaceutical industry scores high in terms of its research and development (R&D) and its marketing expenses relative to sales. From the 1970s to the 1990s, R&D grew in the U.S. from around 11 percent of sales to nearly 18 percent. Marketing expenses in the 1990s have been absorbing 20 percent of revenue, Kane stated. Direct production costs, however, are only about 25 percent of sales.

This low direct cost ratio is coupled with extraordinarily high reported profitability, according to Kane. After-tax return on equity (averaging 18.4 percent) and median pharmaceutical returns have remained consistently higher than for all Fortune 500 industrials. Returns remain higher than those found in most other industries even after they are adjusted for the costs and risks of bringing new drugs to market.

Also attesting to the industry's profitability is the fact that U.S. drug firms increased their R&D outlays at an average compounded real rate of 9.8 percent per year as compared to a 3.7 percent average for U.S. industries, Kane suggested.

There are, of course, defenders of the high returns. They point to the need to induce investors to commit capital for the risky venture of drug research and to the lengthening approval times and growing R&D

costs that have emerged as the FDA has added new regulatory hurdles, according to Kane.

Regulatory hurdles have been relaxed, however, to encourage generic drug development. Over the last few years, generic drug dispensing has increased dramatically at prices 40 to 70 percent below brand name prices. Yet brand name drugs have maintained 40 to 60 percent of market share two to three years after the introduction of generic competition. The majority of prescriptions in the U.S are still dispensed to the undiscounted market. Discounted and generic prices remain higher in the U.S. than in Europe, Kane reported. The same manufacturer offers the same drug at a higher price in the U.S. than in countries with government-constrained prices.

A VIABLE, INNOVATIVE INDUSTRY

Kane concluded that market forces seem to have affected drug industry expectations about the future and that R&D expenditures may indeed diminish. Nevertheless, she remained optimistic about the industry's viability. "It seems likely that the U.S. industry has enough promising new research in the pipeline to maintain substantial future innovation."

Pharmaceutical industry profits, she noted, have remained strong, the American university system has continued to provide a very strong scientific base, and industry research and development have been generously funded. "It is a very creative industry with very smart people. They will figure out a very effective response to the challenge of managed care," Kane stated.

Supportive Therapies and Managed Care

by Jeffrey G. Kaplan, M.D., M.P.S.

Beyond primary cancer treatment interventions, there has been progress in the development of supportive therapies, i.e., those that prevent and ameliorate side effects from cancer chemotherapy. The most frequent and plainly disruptive side effects of cancer chemotherapy are bone marrow suppression (manifest in neutropenia, anemia, and/or thrombocytopenia), nausea, vomiting, and oral complications. By preventing or alleviating some of these problems, supportive therapies help patients live and work more comfortably and productively during treatment. Adjunctive therapies may include growth factors to stimulate the bone marrow and special antiemetics to reduce nausea and vomiting.

In this age of managed care, however, supportive therapies and adjunctive treatments are raising economic eyebrows. Each dose of these agents may be viewed as an added expense, particularly when one considers that supportive therapies do not directly treat the cancer.

While it may be true that supportive therapies are expensive when considered separately from primary therapy, they nevertheless decrease the morbidity of cancer and treatment side effects. In the more progressive "managed care" companies, their cost will therefore be justified. Consider the fact that granulocyte colony-stimulating factor (G-CSF) shortens the interval of febrile neutropenia and decreases infection after chemotherapy, decreasing hospital care and antibiotic use and reducing costs.[1]

Clearly, side effects of cancer chemotherapy affect patient acceptance and, consequently, impact compliance. When patient compliance is optimal, there is a greater likelihood that treatment will be effective. Early and aggressive supportive therapy, when appropriately used to manage some of the more serious side effects of cancer chemotherapy, also enhance care by increasing compliance.

The use of supportive therapies can be justified on ethical grounds as well. When administering any treatment, the medical profession is obliged to try to minimize discomfort—a task entirely in keeping with the Hippocratic tradition. If a patient can be more productive physically, mentally, and spiritually with supportive therapies, it seems both logical and necessary for that treatment to be added to armamentariums.

Survival is not the only outcome of interest in cancer management. For instance, it also may be important to evaluate quality of life and place an economic value on that aspect. The cost of a patient's productivity has not been a factor in the health care economics equation. Nevertheless there is evidence that quality of life and degree of function during or after treatment can be measured and factored into the equation. Health-related quality-of-life instruments will be used regularly in community medicine and will document the benefit of treatments, including supportive therapies, and should improve reimbursement.

The primary medical treatment model in the United States has historically been one of acute intervention for an existing disease state, rather than prevention. The emerging managed care paradigm, however, recognizes the role of prevention[2] as well as cost-effectiveness and patient benefits. Employers and thereby payers should also recognize that the cost of supportive therapies is justifiable when considering the needs of the whole patient. Future policy decisions may enable early and aggressive supportive therapy, when appropriate, to treat the serious side effects of cancer chemotherapy. As in all other aspects of medicine, opportunities to enhance care and create value for both patients and society are "diamonds in the rough."

Jeffrey G. Kaplan, M.D., M.P.S., is senior medical director of Blue Cross/Blue Shield of North Carolina.

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