CANCER RESEARCH: FOR WHOM?

by Robert K. Oldham

Why do we do cancer research? Why have our government representatives authorized more than \$1.7 billion this year to the National Cancer Institute (NCI, Bethesda, MD)? Why have we collectively spent over \$20 billion in the "war on cancer" since 1971? Why do pharmaceutical firms pour billions of dollars into the development of new cancer drugs each year? And perhaps most importantly, why do we as a society contribute billions more to cancer research through our insurance programs, our philanthropic contributions, the American Cancer Society, and various institutions involved in cancer research? Is it simply a process of enhancing our knowledge base about an important disease? Is it a "need to know" exercise in cell biology?

Of course, there are a variety of reasons for cancer research. The economic forces driving the discovery process for new drugs to treat cancer are huge. Cancer affects more than a million new patients in the United States each year. While deaths from the AIDS epidemic total about 150,000 individuals since the beginning of the epidemic, 500,000 Americans die from cancer *every* year. I believe the fundamental answer to the questions posed above is that the cancer patient, with all the attendant suffering and financial damage, should represent the primary focus of the cancer research process.

In a series of peer-reviewed articles over the last several years, I have suggested that the patients' rights should come first. The war on cancer should be refocused from an entitlement program for institutions and researchers to a program more in tune with the patients' needs. We should recognize that drug profits benefit the institutions and individuals involved in cancer research, and that those profits come primarily and directly from patients for whom the research is being conducted. I have suggested that the whole clinical research paradigm needs revision—so that new forms of therapy can be more quickly and efficiently tested in patients with cancer under strong guidelines for insurance reimbursement for the medical care involved. All of these articles have been written to illustrate the need for cancer researchers, university cancer centers, government research institutions, pharmaceutical firms, government regulatory agencies, and all of us involved in cancer research and treatment, to *put the patient first*.

There has been a great deal of rhetoric from the government, particularly the Food and Drug Administration (FDA, Bethesda, MD), on its "revised guidelines" and "fast-track system" for the development of new biological therapies for cancer. Even the FDA fast-track system, however, required seven years for the development and approval of alpha interferon. Cancer patients have a fast-track perspective as

well, but they measure it in weeks or months rather than years or decades. In 1990, I suggested the need to approve interleukin-2 (IL-2) and granulocyte macrophage colony-stimulating factor (GM-CSF) *immediately*. These biologics can be further studied in post-marketing surveys. More can be understood through post-marketing studies and much more efficiently than the continued, laborious conduct of FDA-mandated clinical trials. It is simply unconscionable for this government agency, funded and operated by the people and for the people, to continue to withhold effective therapy under the guise of societal protection. All of the chemotherapy drugs oncologists use are highly toxic. IL-2 is no more toxic than many of these drugs, and GM-CSF is obviously considerably less toxic than most of these drugs. GM-CSF and granulocyte colony stimulating factor (G-CSF) were finally recommended for approval by an FDA advisory committee in early 1991. IL-2 remains in limbo but should be available in our practices *today*.

There are some fundamental flaws in our cancer research system. I have suggested that the whole process of grant application funding, and subsequent research, is fundamentally flawed by the focus on positive studies and continued entitlement funding of the same groups year after year. I have also suggested that our regulatory apparatus needs a major overhaul. It was apparent to me during my tenure as director of the biological response modifiers program for the NCI in the early 1980s that biological drug development needed to be carried forward under a different paradigm than the classical guidelines used for chemotherapy drug development. In dialogue with the FDA, all of the articles I mentioned above have been made available to them, and their response has been minimal. Most recently, the Lasagna Committee, established through President Bush's interest in drug development, has made specific recommendations that very much parallel my original recommendations in 1983. These recommendations, if effected, will cause the FDA to totally revise its guidelines for biological development and could considerably speed the development of new biological drugs. If these guidelines were adopted today, IL-2 would be approved immediately and 5-10 new biological drugs would be available to the oncologist within the next 1-2 years.

Not only do we need to speed drug development, we need to speed drug availability to a broader patient population. It is not sufficient to suggest that cancer patients can travel to various cancer centers for exciting new treatments. It is much more rational to transfer these technologies to private oncologists and the community hospitals in which they practice. Such a transfer requires a revision of our insurance reimbursement programs and our health-care system. Such a transition, however, can quickly come about if we focus the system on the patient rather than the researcher and the institution. *Bio/Technology* readers are interested in the bottom line. The bottom line is: "Put the patient first."

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