

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

July 12, 2001

The Honorable George W. Bush President of the United States Washington, D.C. 20500

Dear President Bush:

As a community representing most of the country's leading cancer organizations, we are writing to request your attention regarding an appointment to Commissioner of the Food and Drug Administration (FDA). With jurisdiction over more than a quarter of all consumer products, FDA exerts an influence that is pervasive and powerful in the lives of the American people, and the agency critically requires aggressive, innovative and experienced leadership.

People with cancer have a special concern about leadership at FDA because, as with other serious or life-threatening diseases, they rely on the agency as gatekeeper for access to potentially life-extending new therapies. Delays or other inefficiencies in the review process for these products can literally mean the difference between life and death for patients with cancer, and they seek leadership that is committed to improving the agency's performance in review of drugs, biologicals and devices, particularly those for serious and life-threatening diseases.

FDA faces many challenges as it considers new products that incorporate recent biomedical research discoveries. To meet these challenges, the next FDA Commissioner must be completely conversant with the latest knowledge about the scientific and medical background relevant to disease mechanisms. At a minimum, we believe the new Commissioner should be a physician with sufficient clinical and research experience to enable him or her to engage the FDA staff as they carry out their responsibilities on behalf of the American people. Of course, we also believe that specific experience in cancer or other serious or life-threatening diseases would make an important contribution to the mission of the agency.

Several months ago, we brought to the attention of Secretary Thompson a candidate whom we regard as extremely well qualified to be FDA Commissioner, Dr. Richard Pazdur, currently Director of FDA's Oncology Drugs Division (see enclosed). His work in the review of cancer products has recently attracted public attention when a major new drug for a rare but deadly blood cancer was approved in record

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time. Dr. Pazdur remains an excellent candidate deserving of your consideration, and there may be others equally qualified. It is essential, however, that your Administration not risk loss of confidence in FDA by selecting a Commissioner who lacks the training, experience and vision to lead the agency in meeting the challenges of the future.

Thank you for your consideration of Dr. Pazdur. We look forward to your response.

Sincerely,

Cancer Leadership Council

Alliance for Lung Cancer Advocacy, Support, and Education American Society of Clinical Oncology Association of American Cancer Institutes Cancer Care, Inc. The Children's Cause, Inc. Coalition of National Cancer Cooperative Groups Colorectal Cancer Network Cure For Lymphoma Foundation International Myeloma Foundation

The Leukemia & Lymphoma Society
Multiple Myeloma Research Foundation
National Alliance of Breast Cancer Organizations
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
Oncology Nursing Society
Pancreatic Cancer Action Network
Y-ME National Breast Cancer Organization

Enclosure

cc: The Honorable Tommy Thompson Secretary, Department of Health & Human Services

RICHARD PAZDUR, M.D., F.A.C.P.

Current Position

Director (since late 1999), Oncology Drug Products Division U.S. Food and Drug Administration

Education and Postgraduate Training

B.A. 1973, Northwestern University (with highest distinction)
M.D. 1976, Loyola School of Medicine
Internship, 1976-77, Loyola University
Residency, 1977-79, Loyola University
Medical Oncology Fellowship, 1979-81, Rush-Presbyterian-St. Luke's Medical Center
Oncology/Hematology Fellowship, 1981-82, University of Chicago

Academic and Professional Appointments

1982-88, Assistant Professor, Hematology/Oncology, Wayne State University School of Medicine

1988-96, Associate Professor of Medicine, University of Texas M.D. Anderson Cancer Center

1994-96, Assistant Vice President for Academic Affairs, University of Texas M.D. Anderson Cancer Center

1996-99, Professor of Medicine, University of Texas M.D. Anderson Cancer Center

Major Accomplishments

- Nationally recognized clinical researcher in colorectal and other gastrointestinal cancer treatment
- Principal investigator in numerous drug development trials resulting in new therapies for colorectal cancer
- Co-authored more than 100 peer-reviewed medical journal articles and several oncology texts
- In brief tenure at FDA, moved to reorganize review of oncology products
- Maintained productive dialogue with patient advocates and other members of the oncology community