C L C CANCER LEADERSHIP COUNCIL

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

November 15, 2000

The Honorable ……

Dear ……:

On behalf of national cancer survivor, provider, and research organizations, we are writing to express our deep reservations regarding the drug importation provision included in the FY 2001 Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Bill, P.L. 106-387.

While we support legislative efforts to improve individuals' access to prescription drugs, we do not believe this provision addresses the issue of patient access to drugs. We see no reason to believe that it will necessarily lead to a reduction in prices to consumers, as there is no requirement that lower costs be passed on to consumers or to payers like Medicare, Medicaid or private insurers. Moreover, the importation provision included by the Agriculture Appropriations bill may pose a health risk to all consumers and a special risk to individuals with cancer and other serious and life-threatening illnesses.

The process for approval of drugs and biologicals by the Food and Drug Administration (FDA) is often described by the Administration and the Congress as the international gold standard. This standard will be undermined by a system that encourages FDA to accept a lesser showing of safety and efficacy because the agency lacks the ability to police products through a consistent chain of custody placing responsibility on the manufacturer to maintain quality. Specifically, the concerns of the cancer community include the following:

- There is no assurance under the legislation that imported drugs will be properly stored and shipped to ensure that their potency and effectiveness are not compromised. This is a special concern of people with cancer because many of their treatments are temperature and light sensitive.

- Drugs will not be labeled to indicate the exporting country or other countries through which the drug may have been transhipped. As manufacturing, shipping and storage standards vary widely among different nations, consumers have a right to be informed about the provenance of products being put into their bodies.

Because there may be no way to identify drugs that are sub-potent substitutes for legitimate FDA-approved drugs, the entire cancer clinical trials process may be undermined. Trials of new agents involve comparison with already approved products. If there is uncertainty about the "control" drugs against which new agents are compared, the clinical trial results may not reliably measure their effectiveness.Fax: 301/565-9670

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- The FDA will be required to dedicate significant resources to the implementation and enforcement of this legislation, when patients would be better served by investing more to speed the approval of new therapies.

For cancer patients, there is little margin for error in treatment. If cancer drugs are improperly handled and their safety and efficacy are compromised, patients cannot be assured that their treatment will be optimal. Our cancer specialists assert that they cannot ethically administer anti-cancer drugs if they are not assured that the potency of the drugs is intact and the drugs are not excessively toxic. The current review process ensures quality; the proposed system does not.

The recently-approved legislation would exempt parenteral drugs from coverage if the Secretary determines that their importation under this provision would pose a threat to public health. We request your assistance in assuring that the Secretary implements the law in such a manner that parenteral cancer therapies are excluded from coverage.

We also strongly recommend studies by experts to assess the potential pitfalls of this retreat from the usual standards of drug review in this country. The possible impact on people with cancer is too significant to be taken lightly by regulators or by Members of Congress.

Sincerely,

Cancer Leadership Council

American Society of Clinical Oncology
Cancer Care, Inc.
Cancer Research Foundation of America
The Children's Cause, Inc.
Coalition of National Cancer Cooperative Groups
Colorectal Cancer Network
Cure For Lymphoma Foundation
International Myeloma Foundation
Kidney Cancer Association
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Prostate Cancer Coalition
Pancreatic Cancer Action Network
The Susan G. Komen Breast Cancer Foundation
US-TOO International, Inc.
Y-ME National Breast Cancer Organization

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