THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release March 29, 1996

REMARKS BY THE PRESIDENT AT CEREMONY FOR ANTI-CANCER INITIATIVE

The East Room

3:06 P.M. EST

THE PRESIDENT: Mr. Vice President, Secretary Shalala, Dr. Kessler, Congressman Richardson, welcome. To all of you who are here, I welcome you and I thank you, each in your own way, for the power of your example.

I thank Stacy, too, especially for being here and telling us her story, and doing it in the way that she did. We know we can thank modern medicine, but you saw a little bit of her steel and grit when she was talking, and it's a great testimony to her faith and to her inner strength. I think that we ought to ask her parents to stand since she mentioned them.

Would you stand up, please, Mr. and Mrs. Oller? Thank you. (Applause.) Thank you very much.

Perhaps more than any other health statistic in America, cancer touches virtually every family. My mother and my stepfather succumbed to cancer; the Vice President lost his sister. Just before coming here today I proclaimed April Cancer Control Month over in the Oval Office, and I was there with several cancer patients and their families. They're all over here, and I want to thank all of them for coming to visit with me, the children and the adults alike, the parents, the brothers, the sisters. As families, they are fighting for a way to win this battle, and the rest of us owe it to them to give them every chance they can to win. That's why we're here today; we want to have more people like Stacy.

More than ever before, we know from the sheer statistics that cancer is treatable and beatable. We know that early detection and prevention are critical. We have, therefore, put more resources in to mammograms for women over 50, and we have taken a very strong stand against the use of tobacco by young people, and against any attempt to induce them to use it.

When cancer does strike, we have an ever-growing arsenal of new drugs and cutting-edge therapies to fight it. But before any treatment can get to patients, we need to make sure it is safe and effective. The development and approval process can take years. When a member of a family gets cancer, the whole family bears the pain, and years are sometimes far, far too long. These families should not also suffer from the stress of knowing that there may be better remedies already out there, but they're somehow not quite

available.

So I'm happy today to say to those patients and to their families, the waiting is over. Today, we announce a major new initiative to speed new cancer therapies to our people. These changes will affect at least 100 drugs now being studied. Dozens of them will get to the market sooner, and that means they can help Americans suffering from cancers of the breast, lung, ovary, prostate

and colon, among others. For these Americans, we cannot guarantee miracles, but at least now new hope is on the way.

With our reforms, cancer patients won't have to leave the country to look for promising treatments. If a drug does demonstrate effectiveness, patients will have access to it here even while the drug continues to undergo tests for approval. Let me emphasize, these steps will speed cancer drugs to patients who need them when they need them. They will help to save lives. They will give cancer patients a better chance. They will do all this by cutting red tape, but they will not -- they will not -- cut corners on safety. We are doing this the right way and it is the right thing to do.

This initiative is part of our National Performance Review, popularly known as REGO, Reinventing Government. This remarkable effort has been chaired brilliantly by the Vice President, and it will, among other things, now cut the development time for drugs by as much as several years. At the same time, the FDA will cut is review time for these drugs from 12 months to six months.

The initiative contains four major proposals. First, we propose to accelerate approval for cancer drugs by allowing companies to apply to market a treatment that is still being tested. In other words, if a drug shows promise by shrinking tumors, for example, it can be considered for approval. That could cut several years off the time needed to get a drug to market.

Second, we propose to expand access to drugs that are already approved in other countries. The FDA will encourage the sponsors of these experimental drugs to apply for permission to distribute the drug to eligible cancer patients before final drug approval is granted here in the United States.

Third, we propose that cancer patients be better represented in FDA advisory meetings. These committees play a major role in policy and product decisions. And cancer patients who have valuable insights and the most at stake should be at the table when these decisions are made.

Fourth, we propose fewer applications for additional uses of approved cancer drugs. Often, these applications are for uses the drug maker does not even intend to market. By cutting out these unnecessary applications we will free investigators from paperwork and allow them to devote more time to cancer research.

These four steps are the results of listening to patients, to their families, to their advocates, to the pharmaceutical industry, the doctors, and the researchers. This initiative shows what we can do when we work together.

Since 1938, our nation has looked to the FDA to protect and improve the public health by making sure that medicines we take help us, not harm us. Our commitment to safety must never waver. Under Commissioner David Kessler, the FDA has reinforced that commitment while working to speed drug approval in the right way. In 1987 it took an average of 33 months to approve new drug applications. In 1994 96 percent of new drug applications were acted on within 12 months.

On AIDS drugs the United States was the first to approve

five of the six antiviral treatments for the disease. The most recent of these drugs was approved in 42 days -- a record. And the FDA has been the first to approve new drugs for ovarian cancer, for lymphocytic leukemia, for cystic fibrosis, for multiple sclerosis, for Lou Gehrig's Disease and Alzheimer's. Under Dr. Kessler, more than ever, the FDA is a place where advance science and common sense work together for the American people.

Now, using the principles of the National Performance Review, we have an opportunity to help more Americans conquer cancer. These four steps will make a big difference, and we are glad to give them to the American people today.

Now I'd like to ask the Vice President to come up here and talk just a few moments about the reinventing of these regulations -- how we did it, what we hope will happen. And let me say, again, how grateful I am to Secretary Shalala, to Dr. David Kessler and to the Vice President, and to all the other good people at FDA. We can keep our people safe and save more lives, and that's exactly what we're determined to do.

Thank you, God bless you all.

Mr. Vice President, please come up. (Applause.)

END 3:15 P.M. EST

June 26, 1996

Cancer Leadership Council
c/o Ms. Ellen Stovall
National Coalition for
Cancer Survivorship
Fifth Floor
1010 Wayne Avenue
Silver Spring, Maryland 20910

Dear Friends:

Thank you for writing on behalf of America's millions of cancer survivors to offer your strong support of the Food and Drug Administration's anti-cancer initiatives. I appreciate the active involvement of so many concerned organizations, and I'm glad to have your recommendations. I will certainly keep your perspective in mind.

Meanwhile, I have shared your letter with others at the Food and Drug Administration so that they may thoroughly review your suggestions and respond to you directly. Thank you for taking the time to write.

Sincerely,

BILL CLINTON

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Cancer Leadership Council

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June 5, 1996

The President William J. Clinton
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the 10 million cancer survivors in the United States, the undersigned organizations advocate access to optimal health care, including the best possible anticancer therapies. In order to guarantee this access, we support certain modest but necessary reforms of the Food and Drug Administration.

Your recent announcement of FDA's anticancer initiatives brought sorely needed attention to longstanding issues we have repeatedly raised with FDA over many years. It is essential that the country recognize the importance of having timely access to new anti-cancer drugs -- an issue that can mean the difference between life and death. Your newly announced initiatives will take a step towards speeding access to these products. We are also pleased to note that you have responded to a concern raised by patient advocates by increasing patient participation in advisory committees reviewing new products. We would appreciate clarification on the rights and responsibilities of these new representatives and would welcome the opportunity to have input into guidelines for patient representation.

Yet, people with cancer continue to believe more is needed to improve significantly access to anticancer therapies and information about their uses. Therefore, we strongly urge you to support the following necessary legislative reforms.

Expediting the Approval of Supplemental Drug Uses

With today's rapid advances in biomedical research, so-called off-label uses of FDA-approved therapies are especially important to individuals with cancer. FDA-approved labeling of drugs lags far behind scientific advances, with over half of all anticancer therapies involving off-label uses. Organizations representing individuals with cancer have long advocated improvements in the approval mechanism for secondary uses of approved therapies as a means of bringing drug labeling more up-to-date.

In order to encourage companies to file Supplemental New Drug Applications (SNDAs) and to expedite their approval, we believe the agency should rely more on the use of quality peer-reviewed literature as the basis for SNDA approvals. The

agency should not always require as extensive documentation and review for new uses of already approved drugs, particularly in the case of products treating life-threatening conditions, as it does for initial uses. While FDA currently has the authority to approve SNDAs based on peer-reviewed literature (so-called "paper SNDAs"), it almost never does so. Thus, legislation is needed to expand use of this approval mechanism. Increased reliance on quality peer-reviewed studies can expedite the SNDA review process without jeopardizing safety or efficacy.

FDA has indicated that the expansion of the accelerated approval mechanism included in your new anticancer initiatives will expedite the review time for SNDAs. Although this particular initiative arguably may have some effect on the approval of SNDAs, it fails to adequately address the major reason behind the relatively low number of SNDAs approved -- the lack of incentives for companies to file SNDAs. We still believe expanded use of peer-reviewed studies as the basis for SNDA approval is needed to create sufficient incentives for manufacturers to seek approval of new uses for marketed drugs that can already be used off-label without FDA approval.

Access to Information about Off-label Uses

Even with improvements in the SNDA approval process, FDA labeling can never keep pace with advances in cancer research. Yet it is crucial that physicians and patients have access to as much accurate information as possible about new medical discoveries. Therefore, we strongly support legislation requiring FDA to ease its restrictions on the dissemination of high-quality peer-reviewed literature about off-label uses to physicians. Physicians should have access to this potentially life-saving information, even if it comes from a pharmaceutical company. By providing our physicians with more accurate medical information, this legislation will also enable patients to make more informed decisions about our course of treatment. For years, we have asked FDA to amend its policy in this important area; given the agency's failure to respond to our concerns, legislation must be enacted.

* * *

Again, we appreciate your interest in expediting access to anticancer therapies. However, additional action is needed. We hope that you will demonstrate your full commitment to this important cause by supporting reasonable FDA reform legislation that addresses the needs of people with cancer. This legislation will help guarantee that the millions of us with cancer and other serious diseases have access to the best possible care.

Cancer Leadership Council
National Coalition for Cancer Survivorship
Cancer Care, Inc.
The Candlelighters Childhood Cancer Foundation
Susan G. Komen Breast Cancer Foundation
National Alliance of Breast Cancer Organizations (NABCO)
North American Brain Tumor Coalition
US TOO International
Y-ME National Breast Cancer Organization

cc: David A. Kessler, M.D.

Reinventing the Regulation of

CANCER DRUGS

PRESIDENT BILL CLINTON
VICE PRESIDENT AL GORE

MARCH 1996

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FDA BACKGROUNDER

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Cancer Therapies: Accelerating Approval and Expanding Access

The Food and Drug Administration is undertaking four new initiatives to improve patient access to promising new cancer therapies. FDA will:

- shorten approval times for cancer treatments by recognizing tumor shrinkage as an early and reliable indicator of a treatment's effectiveness
- make cancer therapies approved by foreign countries more quickly available in the United States by working with companies to bring these therapies into trial use
- improve the therapy review process by insuring that all FDA cancer-therapy advisory committees include an *ad hoc* member who is a cancer patient who has experienced the illness for which a new product is being considered
- make it easier for sponsors to test new uses for cancer therapies already on the market.

Until now, FDA has required that a cancer therapy's sponsor demonstrate improvements in survival time or quality of life before a therapy could be approved. Based on years of accumulated evidence, FDA now believes it is appropriate to approve products that show evidence of tumor shrinkage for patients that have no satisfactory alternative therapy. Companies can more quickly demonstrate tumor regression than improvements in survival time or quality of life. By allowing companies to provide additional evidence of increased survival or improved quality of life associated with that therapy after marketing approval, FDA will substantially shorten (sometimes by years) the total time needed for marketing approval in many situations.

Cancer patients and their families sometimes believe that they must travel to a foreign country to receive the newest cancer therapies. While this is rarely so, FDA will make it even less likely by actively encouraging companies to submit expanded access protocols in the United States for cancer therapies that have been approved by recognized foreign regulatory authorities.

FDA advisory committees play a critical role in product review. FDA will improve the review provided by its cancer-therapy advisory committees by adding on an *ad hoc* basis patient representatives who have experience with the illness for which a therapy is under consideration.

FDA will reduce the number of investigational new drug applications filed for additional studies of already approved therapies. This change will make it easier for researchers to study new uses of already approved therapies.

FDA is undertaking these initiatives after careful consideration of suggestions and advice offered by patients and their advocates, pharmaceutical industry representatives, and physicians and researchers. FDA will continue to seek the views of these interested parties, as well as those of the agency's advisory committees and the National Cancer Institute. FDA's goal is to significantly improve patient access to promising cancer treatments. FDA recognizes that these initiatives may also apply to therapies for patients with other serious and life-threatening diseases. FDA intends to consider expanding these initiatives to cover other serious conditions, as appropriate, if this experience with cancer treatments shows that these initiatives can be applied more broadly.

DRAFT

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3/6/96

Reinventing the Regulation of

CANCER DRUGS

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NATIONAL PERFORMANCE REVIEW

PRESIDENT BILL CLINTON
VICE PRESIDENT AL GORE

MARCH 1996