

Remarks on Signing the Cancer Control Month Proclamation *March 29, 1996*

Ladies and gentlemen, as you know, we're going to have a ceremony over in the East Room in just a few moments, so I don't want to make my remarks twice. Let me just say that there is hardly a family in America who has not been touched by cancer. We have come a very, very long way in the fight against cancer. More people are survivors than ever before; more people are living longer than ever before. But we have a great deal more to do before we can be confident that we have actually done

everything possible to give our children and our grandchildren the kind of future they deserve.

And that's what this day is about. And that's what this proclamation declaring April Cancer Control Month is all about. And I'm glad to sign it, especially with these children behind me because they are the embodiment of our common endeavors.

NOTE: The President spoke at 3:34 p.m. in the Oval Office at the White House. The proclamation is listed in Appendix D at the end of this volume.

Remarks on the Anticancer Initiative *March 29, 1996*

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 get 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 redtape, 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 its review time for these drugs from 12 months to 6 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.

NOTE: The President spoke at 3:06 p.m. in the East Room at the White House. In his remarks, he referred to cancer survivor Stacy Oller, who introduced the President. The Cancer Control Month proclamation is listed in Appendix D at the end of this volume.