

legislation this is. We know that for many patients, experimental treatments represent their best, perhaps their only, chance for recovery. That's why this bill writes into law current FDA policies that allow doctors and patients to use new drugs before they are formally approved. Already, thousands of AIDS, cancer, and Alzheimer's patients have found new hope, even new life, with these experimental therapies. We will also expand the database on clinical trials of drugs that fight serious illnesses so that patients can keep track of their progress.

It's been said that while the century we are about to leave has been an age of physics, the 21st century will be an age of biology, perhaps yielding cures to diseases we thought incurable. We are already witnessing the medical possibilities of the future, as the Vice President said. This fall alone, the FDA has approved new drugs and treatments for everything from HIV

to breast cancer, cardiovascular disease to cystic fibrosis, Parkinson's to epilepsy.

The FDA has served America well. Today, with the bill I'm about to sign into law, we can ensure that it will serve America well into the 21st century and, I hope, serve as a model again for how we can maintain our goals of pursuing the public interest and adjust our means to the possibilities and the challenges of a dramatically new era. The FDA has always set the gold standard for consumer safety. Today it wins a gold medal for leading the way into the future. And thank you all.

I'd like to ask the Congressmen now to join me up here so we can sign the bill.

Thank you.

NOTE: The President spoke at 9:50 a.m. in Room 450 of the Old Executive Office Building. S. 830, approved November 21, was assigned Public Law No. 105-115.

## Statement on Signing the Food and Drug Administration Modernization Act of 1997

*November 21, 1997*

I am pleased to sign into law S. 830, the "Food and Drug Administration Modernization Act of 1997." This bipartisan legislation culminates several years of work by my Administration and the Congress on steps to streamline and rationalize the process by which the Food and Drug Administration (FDA) approves new drugs and medical devices, while ensuring that these products, on which the American people rely, are safe and effective. The Act represents the most comprehensive reform of our Nation's drug, medical device, and food laws in decades. I believe that it is a good compromise on a difficult set of issues and am pleased that the Congress and my Administration were able to work through these issues and enact a bipartisan bill. Most importantly, I am pleased that S. 830 addresses my key concern that any FDA legislation maintain our high standards to protect the American people from dangerous drugs, devices, and foods.

This legislation will extend through Fiscal Year 2002, the Prescription Drug User Fee Act, which requires drug companies to help under-

write the cost of FDA reviews of their products' safety and efficacy. This measure has enabled the FDA to eliminate backlogs and significantly shorten the review time of new human drug applications without compromising quality standards. Supported by the drug industry, the Prescription Drug User Fee Act illustrates the true benefits of a public-private partnership.

Certainly, FDA reform did not start with this bill. The Vice President has been working on reforming and reinventing the FDA since 1993. This bill codifies many of the reforms proposed by the Vice President's Reinventing Government Initiative. For example, it modernizes the regulations of biological products, eliminates the batch certification and monograph requirements for insulin and antibiotics, and streamlines the approval process for drug manufacturing changes. This Act also codifies reforms proposed by the FDA's Center for Devices and Radiological Health that will significantly improve both the rigor and timeliness of its premarket review of medical devices.

Notably, S. 830 will expand FDA's current program to streamline the filing and approval of new therapies for serious or life-threatening conditions. It will also codify FDA regulations and practices designed to ensure that patients will have access to therapies for serious and life-threatening conditions before they are approved for marketing. The Act requires the Department of Health and Human Services to establish a databank, providing information to the public on clinical trials of experimental treatments for serious and life-threatening conditions.

In addition, S. 830 includes a provision that eliminates certain health information dissemination restrictions, while maintaining public health protections. For example, product sponsors, manufacturers, or distributors will now be permitted to furnish to health professionals, providers, and others, peer-reviewed journal articles on an "off-label" use of an approved or cleared drug or device, so long as the manufacturers commit to completing the research needed to approve such use and meet other specified conditions. Drug manufacturers will also be able to give cost data to health maintenance organizations and other institutional purchasers of prescription drugs, so long as it is based on competent and reliable scientific evidence. The Act

will also resolve the issue of pharmacy compounding—the process of making customized medicines—so that legitimate pharmacy compounding is allowed, while the manufacture of unapproved drugs is not.

While I am satisfied with the resolution of the issues in this legislation, I am also pleased that the Congress included sunsets to certain of the Act's provisions so that, at the appropriate time, we can evaluate whether the proper compromises were reached. As FDA reform did not start with this bill, it will not end with this bill. Even with the streamlining provided in S. 830, the FDA will continue to face the challenge of fulfilling its many responsibilities and requirements within available resources. The Vice President and I look forward to continuing our work with patient groups, industry, and the Congress to make sure that the FDA is meeting the challenges of the future and providing safe and effective products to all Americans.

WILLIAM J. CLINTON

The White House,  
November 21, 1997.

NOTE: S. 830, approved November 21, was assigned Public Law No. 105-115.

## Remarks on Receiving the Man of Peace Award *November 21, 1997*

Dalia, Michelle, Members of Congress, members of the administration, General and Mrs. Shelton, Secretary Christopher, Secretary Vance, General Powell, thank you all for coming. To the Ambassadors of Israel and Jordan and Egypt, we thank you for being here today. Shimon and Leah, thank you for your friendship, for your remarks, and for your continued profound and eloquent striving for peace.

I am delighted that this prize will fund scholarships for young Americans to study in Israel, further strengthening the bonds between our nations and deepening the friendship between our people. And I am profoundly honored to be the first recipient of the Man of Peace Award. But actually, as we all know, I can accept this only on behalf of all people in our administration and previous administrations and, indeed,

citizens in this country who have devoted themselves to helping to bring peace in the Middle East. There can be no greater recognition that this award was founded by the family of Yitzhak Rabin and by Shimon Peres, two men who helped to give the world one of its greatest gifts, the hope of a new era of peace in the land of light and revelation.

You know, I was sitting here thinking when Shimon and Leah were talking of all the times that Hillary and I and Al and Tipper were with one or all of them, and it's so hard to say now, but actually, from time to time, we had a lot of fun doing this.

There were times when I thought that my role in the Middle East peace process was to bring to bear the wealth and power of the United States to work in a positive way and