

on significant developments pursuant to 50 U.S.C. 1703(c).

Sincerely,

William J. Clinton

NOTE: Identical letters were sent to Newt Gingrich, Speaker of the House of Representatives, and Albert Gore, Jr., President of the Senate. This letter was released by the Office of the Press Secretary on August 13.

Remarks Announcing Action on the Safe and Effective Use of Medications To Treat Children

August 13, 1997

You know, one of the most important rules about being President is to never go on after the star of the show. [Laughter] I would like to thank all of you for being here today. The Vice President, the First Lady, and Secretary Shalala have spoken about what we're trying to do and acknowledged the work of many individuals and groups. But I want to thank Dr. David Kessler, who as the Vice President said, used to work at the FDA; Dr. Friedman, the Acting Commissioner of the FDA. I also want to thank Dr. Koop, who wrote us a letter in support yesterday. And Hillary mentioned our good friend Elizabeth Glaser. I got a wonderful letter today from her husband, Paul, about how much this would mean to their son, Jake. And so, all of you who have been in this situation, I thank you for helping this day come to pass. And I thank Regan Ralph for her eloquent speech under some duress. [Laughter] I thank her spouse for doing what I think is a noble duty there. [Laughter] And next time we'll let you give the speech, and the rest of us will handle Sam. [Laughter]

I'm glad Sam came up here today and showed us what childhood should be like. It's what kids that are 1½ year old should be doing, and they should be able to do it. They should be able to do it. And according to the American Academy of Pediatrics, more than 50 percent of the medicines that have proved helpful for children have not been adequately tested for children's use. That is not acceptable.

The executive action that I take today simply is designed to ensure that parents and

pediatricians have the safety information they need. Doctors have known for a long time that children respond differently than adults to many drugs. In cases—many cases, children can only tolerate vastly scaled-down doses. In some cases, their bodies simply haven't developed enough to take any dosage of a medicine that has been perfectly safe for adults.

Moreover, we still don't even have good information about medication for some of the most common childhood illnesses that Hillary mentioned, like asthma, allergic reactions, ear infections. And we certainly don't know enough about medications for treating life-threatening diseases.

Less than half the drugs used to help the estimated 12,000 children with HIV infection in our country have been tested for use in children. Information is especially sparse for children under 2, the time when the medication may be most needed.

Without clear guidance, pediatricians sometimes decide not to prescribe for children drugs used successfully by adults, and this means that the children may well be being deprived of what may be the very best treatment available. And as the Vice President said, the pediatrician's other alternative is to guess, with potentially grave consequences. Some time ago, for example, doctors gave infants small doses of a crucial antibiotic commonly used by adults, but it turned out that the infants were unable to clear the drug from their bodies and large amounts built up in their livers, and because of needed dosage studies which had not been done, 23 infants died.

The rule I announce today will put an end to this guesswork. It will require manufacturers of all medicines needed by children to study the drugs' effects on children. The results will then be displayed on drug labels to help pediatricians and other health care professionals make good decisions about how to treat their young patients. Groups representing patients, physicians, nurses, pharmacists, and drug manufacturers all have indicated their willingness to help us implement this new rule, and we appreciate their willingness to do so.

I also want to applaud Senators Dodd and DeWine and Congressman Greenwood and

Congressman Waxman, all of whom have introduced legislation that would provide additional incentives for drug manufacturers to perform the needed dosage studies in children. Their approach is compatible with the rule we're announcing today, and I look forward to working with them on this issue as Congress continues our bipartisan efforts to pass comprehensive FDA reform this fall.

And I know Congressman Greenwood and his children are here; I'd like to ask him to stand. Thank you, sir, for being here. We appreciate your work. In your new position in the Congress, you may have many more controversial issues to deal with but few that will do more good. And we thank you for your leadership.

Today we take one more significant step toward assuring quality health care for our children, building on our historic commitment in the balanced budget to extend health care coverage to 5 million of them who don't have it today.

Again, let me say when something like this happens, the President gets to give a speech, but the credit goes to all the people who worked on it, to all the parents, to those who kept working for this even after their children suffered terrible injury and sometimes even death, to all the members of the professional groups. You deserve the credit. And I am very grateful to you for bringing this matter to my attention and giving me the power to use what the law has given me as President to do what you know and to do what you have long known is the right thing to do. This is your day.

As the First Lady has often said, children are not rugged individuals; they depend upon us to give them love and guidance, discipline and the benefit of good medical care. Today their dependence has been justified. Their future and ours depends upon how well we continue to do this important work.

Thank you very much.

NOTE: The President spoke at 2:19 p.m. in Room 450 of the Old Executive Office Building. In his remarks, he referred to Paul Michael Glaser, widower of Elizabeth Glaser, founder, Pediatric AIDS Foundation; and Regan Ralph, whose son, Sam, was treated for asthma with drugs not labeled specifically for children.

Statement on Signing the Stamp Out Breast Cancer Act

August 13, 1997

Today, I signed into law H.R. 1585, the "Stamp Out Breast Cancer Act." This legislation requires the U.S. Postal Service to establish a special rate of postage for first-class mail that patrons may use voluntarily to contribute to funding for breast cancer research. Special postal stamps will be made available for this purpose.

Research and the prompt application of research results are the strongest weapons we have against breast cancer. Today, breast cancer remains the most commonly diagnosed cancer among women. It affects one in eight women in their lifetimes and has touched the families of nearly every American, including my own. But we are making great strides in the study of this disease. Our goal must be to find a cure and a way to prevent breast cancer in the near future.

The bill I am signing into law today builds on this Administration's long history of support for breast cancer research and prevention. Between 1993 and 1997, funding for breast cancer research at NIH increased 75 percent. We will work to ensure that the new funds from this legislation are not used as a replacement for our current commitment. It creates another way for Americans to further support the important research that will make a difference in the lives of millions of families.

NOTE: H.R. 1585, approved August 13, was assigned Public Law No. 105-41.

Notice—Continuation of Emergency Regarding Export Control Regulations

August 13, 1997

On August 19, 1994, consistent with the authority provided me under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), I issued Executive Order 12924. In that order, I declared a national emergency with respect to the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States in light of the expiration of the Ex-