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Office of the White House Press Secretary

THE WHITE HOUSE

STATEMENT BY THE PRESIDENT

Today, I have the pleasure of signing into law S. 510, the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act of 1938.

It is almost exactly 70 years since President Theodore Roosevelt signed the Pure Food and Drugs Act of 1906, the nation's first federal food and drug legislation designed to protect the American consumer against health threats arising from harmful substances and deceptive practices. Since then, there have been a number of actions to strengthen and update the structure of protection sought by President Roosevelt.

While we as a nation were able to take justifiable pride in the laws providing for safety, honesty and efficacy in the foods and drugs we consume, it became increasingly clear that there remained a large, significant and growing gap in that security.

Until today, the American consumer could not be sure that a medical device used by his physician, his hospital, or himself was as safe and effective as it could or should be.

In 1906, President Roosevelt had no need to ask for legislation concerning medical devices; for the devices used by physicians of his day were comparatively simple. They stood at the edge of medicine, helpful but not essential, and, therefore, posed no regulatory need.

By the 1960's, however, enormous advances in science and technology moved medical devices from the edge close to the center of the stage. Today devices are routinely implanted in our bodies. They replace limbs, bones, tissues even entire organs. They permit treatment of forms of illness that can be accomplished in no other way. They magnify and speed ten thousandfold the diagnostic power of the human eye and brain.

Medical and diagnostic devices have produced a therapeutic revolution, but in doing so, they have also become more complex and less easily understood by those who use them. When well designed, well made, and properly used they support and lengthen life. If poorly designed, poorly made, and improperly used they can threaten and impair it.

Despite the increasing importance of devices, the Food and Drug Administration has had inadequate authority to deal with them. FDA has had no reliable way of knowing how many devices there are, who is making them, who is selling them what risks to health and life they may present, and when a manufacturer has found it necessary to remove them from the medical marketplace.

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In addition, no device was required to be proven safe and effective prior to marketing, no matter how crucial it might be to the person using it, even if that use involved implantation in his body.

Recognizing these and other deficiencies, the Administration ordered a study of the problem in 1969 and subsequently asked Congress to enact remedial legislation.

In its deliberations since that time, Congress benefited greatly from the cooperation voluntarily extended by the medical device industry who clearly saw the need for legislation that would protect the consumer as well as the manufacturer who refused to compromise with safety. Representatives of consumers and health professionals also played an important role.

The Medical Device Amendments of 1976 eliminate the deficiencies that accorded FDA "horse and buggy" authority to deal with "laser age" problems. It is important not only in what it will do to protect the consumer it is also important as a symbol for the kind of regulation that I feel is most appropriate to government. It does not represent another expansion of government into affairs we might better manage ourselves. Instead, this is an example of government doing for the individual citizen what he or she cannot do unaided.

I welcome this legislation and commend the FDA who identified the need, cooperated in its development, and finally, will be entrusted with its enforcement.

This agency daily faces a most difficult task -- preventing threats to the public health in a way that is not onerous, but fully consonant with the principles of competitive economic development on which this nation was built. It is a task that requires determination, scientific skill, judgment and most of all, compassion for the hopes and needs of our fellow man. Dr. Alexander M. Schmidt, Commissioner of Food and Drugs, has effectively taken on the job of assuring that the hope and expectations of the consumer for life-giving drugs and devices are not false promises.

I reaffirm my support for the fine work of the Food and Drug Administration and the job ahead.

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