Public Citizen

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Joan Claybrook, President

Vote No on S. 830

July 28, 1997

Dear Senator:

Sen. Jeffords' bill S. 830, which seriously weakens the FDA's ability to protect the American public from dangerous drugs and medical devices, will probably come before you for vote on the Senate floor this week. This legislation constitutes the first rollback of FDA protections in 91 years. There are no data nor documented reasons for this weakening of law and order for public health and safety.

S. 830 invites with near certainty the repetition of disasters like those which led to the strengthening of FDA regulatory authority in 1938, 1962, 1976, and 1990. If S. 830 were to become law:

1. Drug and medical device companies could legally promote their products for purposes for which they have not been proven safe and effective. The lesson which was learned from the tragic experience of the many thousands of women who took DES to reduce morning sickness during pregnancy, although it had never been proven safe and effective for that purpose, will have to be retaught by such future preventable tragedies. The toll of those suffering damage to their heart valves from the recently uncovered "fen-phen" catastrophe would more likely have been numbered in the thousands rather than (as far as have been reported to date) dozens of victims, if promotion of the combination of these two drugs for unapproved uses had been allowed.

2. Medical device companies could bypass FDA's professional staff of civil servants and have the safety and effectiveness of their products judged by private, for-profit firms that they select, negotiate terms with, and pay directly. Collusion between manufacturing and reviewing companies to raise the profits of both will be legally permitted to take precedence over the consumer's right to be confident that the medical devices which they and their doctors rely on are as safe and effective as possible.

3. Simultaneously with the lowering of premarket review standards for medical devices, postmarket controls to provide an "early warning system" to catch and act quickly on defective products will also be reduced by repeal of mandatory tracking and surveillance of very high risk implantable devices such as heart valves. Tragedies like the Bjork-Shiley heart valve or the Vitek jaw implants, in which thousands of patients could not be located to be notified of defective, life-threatening devices, will be more likely to recur when there is no mandatory tracking of such devices.

4. S. 830 would change the passable number of clinical investigations required to establish the

safety and effectiveness of drugs from two or more such studies by stating that "one or more clinical investigations" would be acceptable, a significant move toward the weaker standards for drug approval frequently accepted in Europe. As a result of these weaker European standards there were 45 drugs approved in the United Kingdom, Germany or France between 1970 and 1992 which later had to be banned because they were found to be too dangerous, only after hundreds of people in those countries were injured or killed by the drugs. None of these drugs was approved in the United States because of our stricter standards. These standards are seriously threatened by S. 830.

5. S. 830 also nullifies the right of states to enact consumer protection laws for cosmetics - despite the fact that there are no effective national standards to ensure the safety of any cosmetic product, many of which are made from potent chemicals. These include nonmedicinal douches, lotions, lipstick, eye shadow, mouthwash, and thousands of other products which tens of millions of Americans use daily. This $20 billion annual U.S. industry is refusing to accept even minimal improvements - not to mention premarket testing - in the FDA's ability to set national safety standards in exchange for preemption of all state authority.

When the first of a series of disasters that will all too predictably follow S. 830's weakening of health and safety standards occurs, all those who voted for it will share responsibility. Senators are being asked to vote for this bill despite:

- Notwithstanding many requests, not one public hearing on this bill has ever been held.

- The text of the bill that is expected to be brought to the floor this week has not yet been made available to most Senators, the public, or the press.

- The bill has been and continues to be negotiated and written behind closed doors by legislative staff, industry, and the administration.

The sorry excuse to justify this secretive rush to vote on S. 830 has been that it reauthorizes the Prescription Drug User Fee Act (PDUFA), which is noncontroversial and universally supported. PDUFA could, and should, be cut free from this lethal baggage and quickly approved on its own.

We strongly urge you under these circumstances to vote against this measure with such critical consequences for the health and safety of American women, children, and men, including you and your family. Even if you do not choose to go forward and strengthen the FDA by providing subpoena power and authority to levy civil monetary penalties for most of the products the FDA regulates - how can you possibly go backwards and significantly degrade the agency's capability to protect the American people?

Sincerely,

Ralph Nader

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