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The Danger of Promoting As Yet Unproven Drugs

Your Sept. 20 editorial "Free Speech and the FDA" argued that drug companies should be allowed to advertise uses of their medications that have not been proven safe or effective by FDA. But the history of prescription drug promotion in the U.S. shows the cost in human lives of such a system.

Until 1962, drug companies were allowed to promote their products for any use as long as they were shown to be "safe" for one use. Manufacturers were marketing drugs with serious side-effects for minor conditions and to vulnerable populations, resulting in many injuries and deaths. Ineffective drugs were the rule rather than the exception. When a retrospective review of all drugs was conducted after 1962, the National Academy of Sciences found that fully 80% of the uses for which drugs were being promoted could not be shown to be effective.

Promotion of ineffective drugs can be disastrous. The drug diethylstilbestrol (DES) was promoted to millions of women for preventing miscarriage in the 1950s and '60s. Twenty years later, it was learned that DES was responsible for thousands of cases of unusual cancers and serious reproductive abnormalities in the children of women given DES. Perhaps the greatest tragedy of DES is that none of the harm to those young people was necessary: DES turned out to be completely ineffective in preventing miscarriages.

You suggest we shouldn't worry about allowing companies to promote ineffective or dangerous drugs because the government could still "prosecute actual cases of fraud." But this after-the-fact remedy, requiring FDA to prove that a claim is false, was exactly what was in place before 1962.

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