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The Ephedra Ban Is Not Enough

It took an unconscionably long time, but the federal government has finally managed to ban an unsafe dietary supplement before it can harm or kill any more unwary users. The Bush administration's health regulators announced last week that they would soon ban ephedra, an herbal supplement used to promote weight loss and increase energy, on the grounds that it poses "an unreasonable risk of illness or injury." That was the only sensible response to mounting evidence that ephedra has been harming thousands of Americans. Yet the tortuous course of this regulatory crackdown underscores the dangerous weakness of a 1994 law that allows the supplement industry to market products whose safety and effectiveness have never been proved while making it extremely hard for health regulators to take them off the market if evidence of harm subsequently emerges.

Ephedra is an adrenaline-like stimulant, derived from plants, that excites the central nervous system, speeds metabolism and increases the rate at which a person burns calories. But it can also drive up blood pressure and stress the circulatory system. Ephedra has generated far more reports of adverse effects than any other supplement and has been linked to cases of heart attack, stroke and sudden death. Ephedra has been banned by three states, including New York, and by some athletic leagues though not others.

Some critics blame the Food and Drug Administration, which has been worried about ephedra for many years now, for moving too cautiously. There is some merit in that complaint, but the major culprit is clearly the 1994 dietary supplement law that requires the F.D.A. to prove that a supplement poses a significant or unreasonable risk of harm instead of requiring the manufacturer to prove that it is safe and effective, the standard used for prescription drugs. The law does not even require manufacturers to report adverse effects to the government.

This is a formula for covering up problems and ensuring regulatory inaction. It is no accident that ephedra will be the first supplement ever banned for safety reasons under the 1994 law. That sluggish response was precisely what the supplement industry and its more zealous customers wanted when they pressed Congress for protection against strict regulation.

When Congress returns for its next session, it needs to revise the ill-conceived 1994 legislation. At a minimum, Congress must require the industry to pass on any adverse health reports to the F.D.A. promptly. Even better, it should require the manufacturers to prove the safety and efficacy of their products before those products are allowed on the market. Under the current lax system, there is no guarantee that the substitutes for ephedra will be any safer.