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FDA overreaches

Opposing view:

Rule merely adds another hurdle to drug-approval process.

By Sam Kazman

Who could possibly oppose a pediatric-testing rule for drugs?

For starters, physicians and parents who realize that while this rule is supposed to protect children, it is far likelier to hurt them. Remember, the pediatric rule doesn't affect drugs that are specifically developed for children; those are already exhaustively tested under existing law. What the rule targets are adult drugs that physicians have found to be useful for kids, and it threatens to make them unavailable unless more testing is done.

In some cases the result may be useful data, but the risk is that we'll end up with fewer pharmaceuticals if the Food and Drug Administration's demands turn out to be too costly. One pediatrician observed that "there are many drugs that are tremendously useful for children even though they are not labeled for pediatric use. The possibility that the FDA might remove these drugs from use is unimaginable."

Government obstacles to getting new drugs approved are already formidable. In a series of medical-specialist polls conducted

by the Competitive Enterprise Institute (CEI), large majorities of the doctors surveyed viewed the FDA as too slow in approving new therapies. The pediatric rule adds yet another hurdle to this process.

In fact, it radically alters it. Until now, pharmaceutical companies decided what official uses they would claim for their drugs, and the FDA decided whether the companies' clinical data supported those uses. But with its new rule, the FDA itself claims the power to add new uses and require supporting tests. Congress has never authorized this, and the congressional approach of encouraging rather than mandating such pediatric testing contradicts the FDA's tactic.

Most important, perhaps, is that by basing its testing demands on what doctors do in their offices, the FDA is opening the door to regulating the actual practice of medicine.

For these reasons, CEI, Consumer Alert and the Association of American Physicians and Surgeons filed suit against the pediatric rule when it was first issued, and we hope to proceed despite the FDA's newfound desire to re-examine the rule.

"Treat first, examine later" is usually bad medicine, and "promulgate first, examine later" is even worse law.

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