Pfizer may be on to something big. The pharmaceutical giant that has improved the lives of millions through its development of some of the world's most valuable and effective drugs is about to unleash its next blockbuster—Torcetrapib. This drug claims to provide a novel approach for treating heart disease.

Unlike the existing cholesterol drugs called statins, Torcetrapib does not attack the bad

long way in insulating itself from antitrust liability. Not because of any explicit antitrust carve-out contained in the FDA Act, which governs the agency's drug-approval process. And not because of any absolute legal cover that is afforded to participants in that process. Rather, the source of Pfizer's likely immunity derives from the ultimate deference most courts give to the FDA to regulate the manner in which drugs are sold and marketed to consumers.

Under the doctrine of implied immunity, conduct that might otherwise violate the antitrust laws may be protected if it arises within the framework of a particular regulatory scheme. The doctrine is a narrow one. It applies only when there is a "plain repugnancy" between the antitrust and regulatory regimes.[2] However, it generally shields conduct that is either compelled or authorized by a government agency.[3] What this means in the context of the FDA process is that the courts are going to be extremely reluctant to condemn conduct to which the agency has given its approval.

There's a good reason for this policy. It ensures that parties are not subject to conflicting standards of antitrust and regulatory conduct. It allows the FDA, or other government agency authorized by Congress to oversee a particular industry, to exercise complete control over the regulatory process. And it reconciles what might otherwise represent two very different sets of government objectives. Ultimately, it elevates the particular agency's agenda—the distribution of safe and effective drugs, in the case of the FDA—over the government's interest in maintaining open competition.

In most circumstances, giving the agencies such "free reign" is critical to their function. Otherwise, a party might be unable or unwilling to follow a particular government protocol or mandate for fear of crossing an antitrust line. Think about it. If Pfizer had to worry about the potential tying implications of its Torcetrapib/Lipitor pair, it might have thought twice about spending the vast amount of time and resources it has to develop the combination. Perhaps, Pfizer would have decided against the investment altogether. A potential medical breakthrough would be lost. The FDA's mission would be undermined. We'd all be the losers.

But there are some circumstances where permitting an agency override of the antitrust ipants in-re loselybackfirne.(Rathes thnr)TjT*0.0049 Tc058309 Twfourtheting a particular agency objectiv,t antitrust
t an olloting a parys togramr the regulatoryr
ysteme forunfpain competitvreagai. Mancy fr
s
witf itsqurest fot

n
prablms. AndtThere's n realy ays tofixt it.
e stcn'ook (bThid Pfizee')547(es efourtsbefoues)TJ-1.0893 -1.1667 TD011799 Tw(the FD. EivenistConhes thnr—the ocstrne