State Attorneys General are loading their guns with some potent ammunition against drug companies that run deceptive ads: warning letters from the U.S. Food and Drug Administration.

In recent years, a growing number of states have grabbed hold of FDA warning letters citing unlawful marketing practices and are using them to sue drug companies for false advertising, in some cases winning multimillion-dollar settlements.

The FDA letters are being used as both evidence in lawsuits alleging unfair advertising practices and as a trigger to push attorneys general into action.

Most recently, Bayer HealthCare Pharmaceuticals Inc. agreed to conduct a $20 million ad campaign for its oral contraceptive Yaz to resolve claims by 27 states that it exaggerated the drug's benefits, while downplaying its potential risks.

The states relied, in part, on an FDA warning letter issued last fall about misleading Yaz ads. Bayer also has agreed to submit all Yaz ads for federal screening before airing them. State v. Bayer Corp., No. GIC 878812 (San Diego Co., Calif., Super. Ct.).
'Best evidence'

In West Virginia, a judge ordered Johnson & Johnson to pay $4.5 million to the state after the attorney general sued the company for downplaying the risks of an anti-psychotic drug and a pain-killing fentanyl patch.

The state had used an FDA warning letter in pursuing that case. *West Virginia v. Johnson & Johnson*, No. 04-C-156 (Brooke Co., W.Va., Cir. Ct.).

In Connecticut, Cephalon Inc. agreed to pay the state $6 million in September to end the state attorney general’s investigation of its marketing of three drugs, including its narcolepsy pill Provigil, which was the subject of recent FDA warning letters.

In Florida, the state attorney general is suing Merck & Co. for alleged deceptive marketing of the joint-pain drug Vioxx, citing, among other things, a 2001 FDA warning letter that scolded Merck for allegedly misrepresenting the safety of Vioxx. *State of Florida v. Merck* (Leon Co., Fla., Cir. Ct.).

"It's the best evidence I think you can get," said West Virginia Chief Deputy Attorney General Frances Hughes, who relied heavily on an FDA warning letter in securing the $4.5 million fine against Johnson & Johnson, "That was the crux of our entire case."

Some drug companies defended their drug-marketing practices, stressing that they take FDA warning letters seriously.

"Janssen has always taken correspondence from the FDA seriously," said Sri Ramaswami, a representative for Janssen, a division of Johnson & Johnson whose anti-psychotic drug Risperdal was the target of the West Virginia litigation.

"We have well-established, strictly enforced marketing and promotion policies to ensure that our products are only promoted for their FDA-approved indications," Ramaswami said.

Officials at Merck also defended their drug-marketing practices, stating: "The pharmaceutical industry is highly-regulated by the FDA and every communication from the FDA is taken very seriously at Merck."

In response to the Florida lawsuit challenging the marketing of Vioxx, Merck stated: "We believe the company has acted responsibly, and we intend to defend against the complaint."
Bayer did not return calls seeking comment. Cephalon released a statement that said, "Cephalon has always taken its regulatory responsibility seriously. We have worked diligently to develop procedures and policies to ensure that our products are lawfully promoted."

Florida Assistant Attorney General James Young noted that an FDA warning letter about misleading ads involving the birth-control pill Yaz served as the "canary in the coal mine" that alerted 27 attorneys general about a questionable consumer advertising campaign.

"The FDA warning letters have served as the impetus or trigger for many attorney general investigations," Young said, adding, however, that an FDA letter is not required to open an investigation.

FDA spokeswoman Rita Chappelle said "[t]he bottom line is: This is a collaborative effort. Not only are we here at the FDA reviewing ads online, and things in print, we also get information from the public, or physicians. And we then follow up."

Attorneys representing pharmaceutical companies, meanwhile, believe that their clients are taking FDA warning letters more seriously than they used to.

"In the old days, the VPs in [drug] marketing might say, 'Oh, the worst thing that can happen is getting a warning letter from the FDA,' " said Alan Minsk, a partner at Atlanta's Arnall Golden Gregory who advises drug companies on advertising and marketing practices.

"Now we tell them that it was never a good idea to play that game," Minsk said. "Now the issue is: Not only might you get cited by the FDA, but the states or the U.S. attorney might say, 'this is interesting.' "

T. Reed Stephens, a partner in the Washington office of McDermott Will & Emery who represents drug companies in false advertising and consumer fraud litigation, noted that, "[w]hen you get this type of regulatory action from the FDA that's public, you do need to take proactive measures to better understand what's going on under the hood of your car."