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FDA Finally Hitting Sweet Spot With Off-Label Oversight

By **Jeff Overley**

Law360 (November 21, 2018, 6:33 PM EST) -- The U.S. Food and Drug Administration has slowly but surely eased Big Pharma's long-standing concerns about off-label marketing restrictions without antagonizing the plaintiffs bar or public health advocates.

The agency's needle-threading has been achieved through new guidance, a subtle drop-off in enforcement and the postponement of a rejiggered approach to assessing the intent of drug promotion efforts. Those endeavors have mostly played out during the 18-month tenure of FDA Commissioner Scott Gottlieb.

Remarkably, there is significant disagreement about whether Gottlieb has altered the agency's posture much, and yet little in the way of criticism from observers with divergent views of the merits of off-label promotion.

"It's been my sense that little has happened since Gottlieb took over in this regard," Michael Carome, a drug safety expert at consumer group Public Citizen, told Law360.

Others view things differently. They contend that Gottlieb — a sharp critic of off-label restrictions when he was a private citizen — has made great strides within the confines of the federal bureaucracy to help companies communicate responsibly about unapproved uses of prescription drugs.

"Is it less than you would expect? No. I think he has done a lot," Morgan Lewis & Bockius LLP partner Stephen Paul Mahinka said.

Gottlieb has emerged as one of President Donald Trump's most popular regulatory appointees, energetically pursuing a wide range of issues — including e-cigarettes, menu labeling, drug prices and the opioid crisis — without stepping on many political landmines along the way.

The commissioner's middle-of-the-road approach to off-label promotion seems like one reason he has retained broad support. Observers differ on the extent of off-label change under his leadership, but nonetheless are widely supportive of his policies, or at least not strongly opposed to them.

"He's a pragmatist and didn't want to overplay in this area and then have patient groups mad at him," Joanne Hawana, of counsel at Mintz Levin Cohn Ferris Glovsky and Popeo PC, told Law360. "I don't think that would have advanced his interests."

Before becoming commissioner in May 2017, Gottlieb had made it abundantly clear that he saw the FDA's off-label restrictions as too muscular.

In 2012, as a fellow at the American Enterprise Institute, Gottlieb urged Big Pharma to sue the FDA over off-label limits, writing that "the drug industry needs to be willing to take the prerogative to challenge the facts in some of these cases and have that day in court."

In 2015, Gottlieb was paid $600 per hour for work supporting Amarin Pharma Inc. in its landmark challenge to FDA limits on promotion of omega-3 drug Vascepa. As part of that work, Gottlieb filed a declaration in New York federal court criticizing the FDA's "near-total ban on off-label promotion."

But it's possible that his perspective softened after becoming the FDA's leader, or at least adapted to the practical difficulties of upending well-established government policies.

"He's now seeing the agency's point of view, which is … if it's too easy for companies to get a narrow indication and then market it for whatever they want, we're undermining our approval process," Marc Scheineson, FDA practice leader at Alston & Bird LLP, told Law360.

The FDA faces a delicate balance when altering its off-label stance. While the pharmaceutical lobby wants off-label leeway, the conduct is viewed warily by much of the public and has led to billions of dollars in False Claims Act settlements.

When the FDA has called attention to its off-label policy moves, it has sometimes tied them to popular initiatives. For example, when the agency in June finalized two off-label guidances, Gottlieb linked them to efforts to curb drug prices, saying that off-label communications could "enable better access to medical products and possibly more affordable options."

The guidances were originally proposed in draft form at the end of the Obama administration. Reaction was overwhelmingly positive; the right-leaning Washington Legal Foundation said that it "applauds FDA for its effort," while a plaintiffs bar group called the American Association for Justice asked for only two tweaks to guidance language.

After the guidances were finalized, industry groups gushed with praise. As one example, Pharmaceutical Research and Manufacturers of America in June said that the guidances "helpfully provide clarity on how biopharmaceutical firms may communicate" and would eliminate a key barrier to value-based contracts with health insurers.

Significantly, there has been little if any opposition voiced by traditional adversaries of the pharmaceutical industry. In an interview, Public Citizen's Carome told Law360 that one of the guidances was "an unremarkable document" and that the other guidance was "very narrow in scope."

The drug lobby, while pleased with the guidances, isn't yet totally satisfied with off-label policies. In particular, it wants the FDA to abandon a revised approach to assessing the "intended use" of prescription drugs. That's an important concept that examines whether drugmakers intentionally promoted products for off-label uses.

"We are still considering these concerns and remain committed to addressing this important issue," Stephanie Caccomo, an FDA spokesperson, told Law360.

It appears likely that the FDA will ultimately clarify or modify the new intended-use approach, which has been postponed indefinitely. But observers are skeptical that broader latitude for off-label promotion is lurking, arguing that the FDA's recent guidances earned it some breathing room.

"I suspect that FDA is not planning to issue comprehensive guidance regarding sharing off-label information with [health care professionals] at this point because the issuance of the [guidances] took a lot of the pressure off," King & Spalding LLP partner Lisa Dwyer told Law360.

Some observers have also detected a small dip in off-label enforcement by the FDA's Office of Prescription Drug Promotion. In the nearly two years since the Trump administration began, the office has only issued one disciplinary letter about promotion of an approved drug for an unapproved use. In 2015 and 2016, it issued three such letters.

"What's important is that you did not see an uptick in agency ... letters on off-label communication," Peter Pitts, president and co-founder of the Center for Medicine in the Public Interest, told Law360.

Even if Gottlieb would prefer looser off-label limits, there are benefits to the moderate tack he's taken so far. For one thing, it avoids alienating career FDA staffers who have devoted years to defending off-label restrictions. That's not merely a hypothetical concern — the Trump administration has reportedly seen an exodus of employees in some places, such as the Environmental Protection Agency, after new leaders pursued dramatic regulatory changes.

"You have to lay the groundwork for the change internally, so that it takes. So that it's lasting. So that it's effective," Mahinka said. "You have to bring your agency along."

In addition, the agency's current off-label positions, which remain vague in some respects, arguably offer the best of both worlds for regulators. They can crack down when needed, thereby pleasing drugmaker critics, but also hold their fire when appropriate, thereby pleasing the pharmaceutical industry and its allies.

"When it comes to free speech issues ... regulators love ambiguity, because it gives them limitless power," Pitts said. "It allows them to retain the right to do something, but also the ability not to enforce it."

--Editing by Pamela Wilkinson and Alanna Weissman.

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