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New FDA Enforcement Stats Show Shifting Targets

By **Jeff Overley**

Law360, New York (February 13, 2017, 8:41 PM EST) -- Newly released statistics from the U.S. Food and Drug Administration show that enforcement was busier in 2016 for pharmaceuticals but was relatively quiet for medical devices, tobacco and biologics.

FDA officials quietly published the annual numbers late last week, detailing the number of warning letters and recalls targeting FDA-regulated industries. The numbers weren't accompanied by any explanatory text, and agency representatives had little comment, so Law360 surveyed experts for insights on what's driving the latest trends.

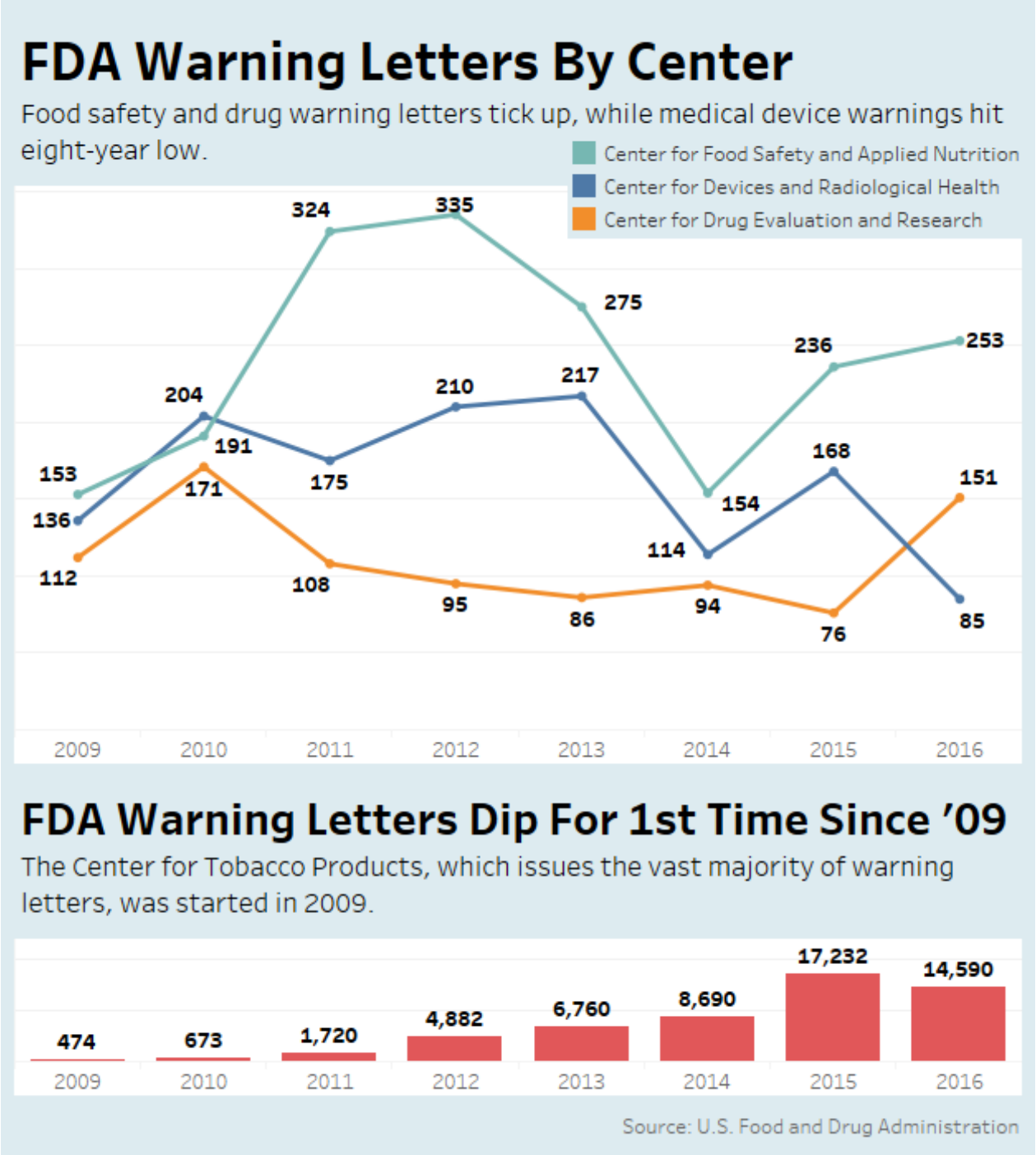
Here's what those experts see behind the numbers.

Drug Warnings Rise Sharply

One of the more eye-popping figures in fiscal year 2016 was the 151 warning letters issued by the FDA's Center for Drug Evaluation and Research. That was twice as many as CDER issued in 2015, was its largest total since 2010, and was substantially bigger than its average of 106 letters since 2009.

It's possible that the uptick represents a random fluctuation and little more. But the rise was driven mainly by drugs that were adulterated, meaning their composition was suspect, and by drugs that were misbranded, meaning their labeling was inaccurate. That's according to an analysis shared with Law360 by Boston-based Halloran Consulting Group.

"I would say [FDA officials] are doing a fantastic job of keeping the American people safe from things that don't contain the actual purity, strength and consistent active ingredients in their drugs," Halloran Consulting CEO Laurie A. Halloran said.



Device Letters See Steep Fall

Several experts noted that the FDA's Center for Devices and Radiological Health issued only 85 letters in 2016. That was barely half as many as CDRH issued in 2015, was its smallest tally in recent years and was a much slimmer total than its average of 154 letters since 2009.

Observers say that the dwindling enforcement likely stems from an FDA initiative called Case for Quality, which began in 2011 and kicked into high gear in 2014. The initiative promotes closer ties between regulators and manufacturers, and experts say that a softer disciplinary touch is a logical outgrowth of the program.

"They've been working fairly collaboratively with industry ... so it's not surprising that we see a reduction in warning letters," King & Spalding LLP counsel Steven Niedelman said. "I don't think it's because the agency is less vigilant, necessarily. But I think they're just taking a different tack."

Case for Quality encourages companies to embrace practices that correlate with superior

manufacturing, as opposed to merely doing the bare minimum to satisfy FDA regulations. Experts say that those extra efforts can convince the FDA to hold its fire when missteps occur.

"I've seen a personal trend in the last few years where we've thought, 'Oh boy, we're definitely getting a warning letter,' and we've ended up not having to, because we're taking proactive compliance [steps]," said Bethany J. Hills, FDA practice chair at Mintz Levin Cohn Ferris Glovsky & Popeo PC. "They're seeming to be quite willing to work with manufacturers on that."

Tobacco Rebukes See First Dip

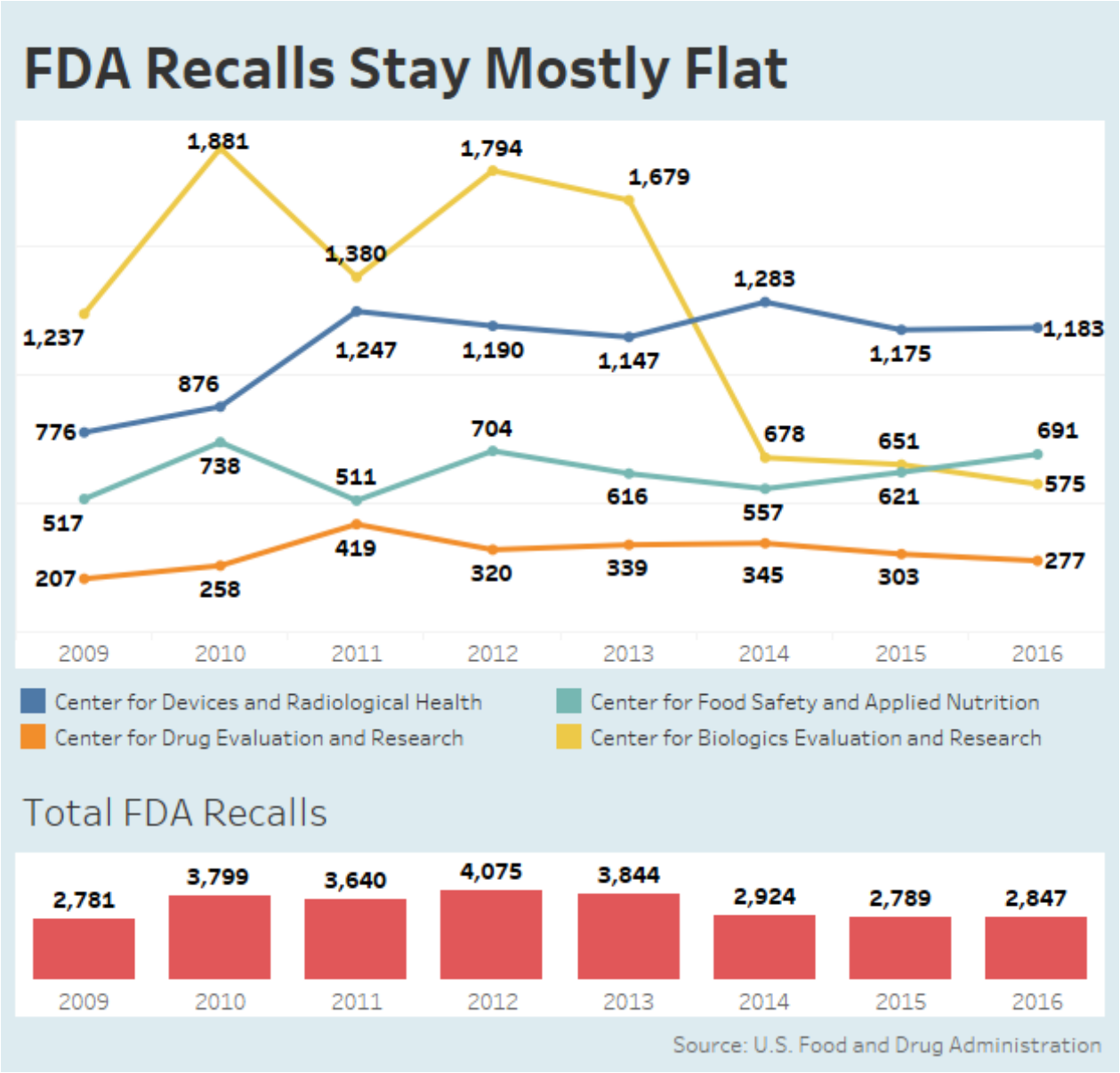
The FDA's Center for Tobacco Products also saw its warning letter output decline to 14,000 in 2016 from 16,600 in 2015, the first dip since it started sending warnings in 2010. One factor could simply be improved compliance, as retailers slowly but surely learn that the FDA is watching their sales and marketing.

Another possible reason is the remedy for repeat violations. If a tobacco retailer gets a warning letter for, say, selling tobacco to kids, then gets busted again, it can be hit with financial penalties as opposed to just another warning. The FDA has issued 50,000 warning letters and 10,000 financial penalties for tobacco violations, and it may simply be drifting into a new phase of enforcement.

Joanne Hawana, of counsel at Mintz Levin, also noted that the FDA in 2016 unveiled a major **"deeming rule"** on tobacco regulation and spent lots of time educating retailers about their obligations, potentially sapping away a bit of attention from enforcement.

"It's probably a function of competing priorities last year," Hawana said.

The decline in tobacco-related warning letters was responsible for a decline in overall warning letters, which dropped by virtually the same amount that tobacco letters fell.



Biologics Recall Volume Stays Lower

The Center for Biologics Evaluation and Research, which rarely sends warning letters, nonetheless stood out in 2016 for continued retrenchment on recalls. CBER oversaw 575 recalls in 2016, roughly in line with 2015 and 2014 but far below its tallies from 2009 to 2013, when it averaged 1,600 annual recalls.

Niedelman said that "a variety of things" could be at play, and he noted that CBER recalls are rarely life-or-death matters. In 2016, only one of the center's 575 recalls was categorized as a Class I recall, the most serious type.

Other centers last year saw little change in the number of recalls, continuing long-term trends in which annual recalls have been fairly stable.

--Editing by Katherine Rautenberg and Philip Shea.