The era of enforcement actions targeting large pharmaceutical companies’ off-label promotional practices may be coming to a close, but government lawyers are eyeing a new wave of industry practices for scrutiny and potential prosecution.

Among these are unsupported promotional claims of economic superiority and superior efficacy, manufacturers’ dealings with payers, misrepresentation of scientific studies, and manipulation of the average sales price system, federal prosecutors said at CBI’s Pharmaceutical Compliance Congress on Jan. 24. During a panel discussion on health care fraud enforcement trends and top priorities, two federal prosecutors predicted there will be fewer cases involving big pharma off-label promotion going forward because the industry’s major players have cleaned up their acts.

Sara Bloom, assistant U.S. Attorney for the District of Massachusetts, said she is optimistic that the era of “really big, corporate-wide, off-label” promotional activity has passed. “I think the message is out there,” she said. “There’s been compliance around these issues now in the major corporations for several years, and if you don’t already have it you really ought to get it because you’re behind.”

Bloom said she anticipated that the look of the cases handled by her office will change over the next few years, with a heightened focus on other types of promotional practices. For example, she cited false and misleading claims of superior efficacy or safety, and false or unproven claims of economic superiority, all of which can fraudulently induce a purchaser to select a product. The latter category includes claims that a particular drug will save money or result in patients getting out of the hospital sooner.

That transition reflects the changing pressures on pharma as products going over the patent cliff tip the market to one where brand drugs are going against generic versions of former blockbuster standards of care.

Bloom questioned whether cost-savings claims are backed by double-blind, placebo-controlled trials that have passed FDA muster. “I think that’s an area where people haven’t focused on the fact that you’re really making scientific claims disguised as some kind of economic benefit claim,” she said.

Bloom similarly pointed to concerns about cost effectiveness and superiority claims during a speech two years ago. Speaking just weeks after Pfizer’s Inc.’s $2.3 billion settlement of off-label marketing and kickback allegations, Bloom said that even good corporate compliance programs may not go far enough in changing field force behavior (“Lessons From The Pfizer Off-Label Settlement: Compliance Programs Not Enough To Demonstrate Integrity, DOJ Says” – “The Pink Sheet,” Oct. 5, 2009).

Pushing The Envelope

When an innovator product goes generic, there is a temptation for sponsors of other branded products in the category to make superior efficacy or safety claims over the generic, Bloom told the CBI conference. “A tendency to make unsubstantiated superiority claims, to make unsubstantiated negative safety claims about the competitor is very much out there for the sales force, and so I think those are areas of risk.”

“If you’re competing with a cheap generic drug you’ve really got to push hard to get your more expensive brand drug selected,” she continued. “I think that’s an area where the sales force is very tempted to push the envelope.”

Jill Furman, assistant director of the Department of Justice’s Consumer Protection Branch, subscribed to Bloom’s view that the big off-label promotion cases are on the decline but will be replaced by other targets of enforcement activity. These include misrepresentations by pharmaceutical manufacturers about what studies actually show about a product, Furman said.

Both government attorneys also offered their views on use of the Park doctrine to hold corporate officers strictly liable for failing to prevent or correct violations under the Food, Drug and Cosmetic Act.
Targeting Manufacturer/Payer Relationships

More subtle forms of promotion, such as messages conveyed through manufacturers’ dealings with payers, also appear increasingly ripe for government scrutiny.

Industry attorneys have previously flagged the manufacturer/payer relationship, particularly with regard to formulary placement and payment structure, as a growing source of interest for government prosecutors (“DoJ Bull’s Eye: Off-Label Promotion, Formulary Placements, FCPA Violations Remain Targets” – “The Pink Sheet,” Dec. 19, 2011). In her remarks at CBI, Bloom reinforced that notion.

Up until now there has been less enforcement focus, and therefore probably less industry compliance, when it comes to manufacturers’ relationships with payers and their interactions with P&T committees, Bloom said.

“I think that a lot of sales and marketing these days is actually done in that arena as much as through the sales rep showing up in the doctors’ offices,” Bloom said. “Messages are being delivered through the mechanisms of rebate” in exchange for formulary positioning, she said, adding that other types of contractual arrangements may warrant scrutiny as well.

“It’s a very complicated set of interactions, very important to whether your drug gets on formulary, gets better treatment, but also has perils in it that I don’t think people have focused on” from a compliance and enforcement perspective.

“We’re starting to figure out some pieces of it,” Bloom said. “It can be used for off-label promotion. There can be hidden kickbacks. There can be price concessions that are not showing up in ASP. So I think that’s an area where I would worry if I were on the other side, and I will be looking from my side.”

Abuses under the ASP pricing system also are starting to become apparent, Bloom added, citing this as another area of future enforcement action.

The ASP system for reimbursement of Medicare Part B drugs was established under the Medicare Modernization Act of 2003. “It always takes a few years before you see the frauds under the new system, but I think they’re starting to come to light,” Bloom said. “I think it is time to start paying attention to average sales price and all of the things that companies may do to sell their products, which might be really impacting average sales price but people haven’t necessarily noticed.”

Off-Label Promotion Not Dead, Yet

With all these practices apparently ripe for enforcement scrutiny, that’s not to say the government has stopped looking for traditional off-label promotion.

Now that big pharma has adopted compliance measures, there will be an increased enforcement focus on off-label marketing by small companies, Bloom said, cautioning that smaller firms’ compliance missteps could wind up becoming big pharma’s problem.

“I think there are a lot of people who think they can fly under the radar screen. But if the big companies have cleaned up, we will be turning our attention, and we are turning our attention, to some of the small companies,” Bloom said. “This is also an issue for the big companies in your acquisitions, because you could find some unpleasant surprises after your due diligence is over sometimes.”