Evaluate Vantage

May 08, 2015

The undermining of US off-label marketing rules

Jonathan Gardner

Pressure is growing on US regulators to ease restrictions against off-label marketing of drugs as lawmakers develop a legislative package that would streamline regulations at the FDA and other federal agencies involved in governing drug development.

Yesterday Amarin filed a lawsuit seeking to allow its sales representatives to promote Vascepa in more patients than the fish-oil pill's labelling currently allows. This comes as the FDA prepares to hold a public hearing on its off-label marketing rules, which have been undermined by a 2012 court decision that declared them unconstitutional.

Anchored by off-label rules

Amarin's lawsuit asks the federal district court in southern New York to permit it to use data from the Anchor trial in promoting Vascepa to physicians.

The suit claims that regulations allowing sales reps to discuss only the labelled indication are a violation of first amendment rights to free speech – the same claim that prevailed in Jazz Pharmaceuticals' case defending off-label promotion of Xyrem. The 2012 appellate court decision siding with Jazz has thrown FDA's ability to govern off-label communication into doubt.

The Anchor trial showed that Vascepa when taken with a statin could successfully lower triglycerides in patients with levels of the lipid between 200mg/dl and 500mg/dl, without elevating low-density lipoprotein (*Amarin surges as hopes for heart drug soar, April 18, 2011*). The FDA, however, approved it only in patients with triglyceride levels of greater than 500mg/dl.

Given that Amarin today reported disappointing quarterly sales yet again, it might not be too surprising that it is trying any route to spark growth, not to mention investor enthusiasm. But given the ruling in favour of Jazz, it would not be surprising to see other companies test the limits of the law in the courts.

Change is coming

This state of affairs is why the FDA has said it will convene a public meeting this summer to re-examine the rules. In general, the FDA has sought to restrict off-label claims, allowing drugmakers, for example, to provide published scientific data on such uses when a physician requests it. The Jazz case opened the door to more free-wheeling verbal communication, and Amarin clearly wants to exploit the precedent.

It is in this context that drugmakers have also sought greater clarity from Congress, and the vehicle for achieving changes to the rules could be a bipartisan House of Representatives initiative called 21st Century Cures being debated in the Energy and Commerce Committee.

A discussion draft of legislation released last week does not explicitly propose changes to the off-label marketing rules, even though some physician and patient groups have urged committee members to do so. This initiative would, however, be a logical place for the pharma industry to seek a change by legislative fiat – an earlier draft did include a placeholder section that sought to facilitate "responsible communication of scientific and medical developments".

It is probably too late for the FDA to stop drugmakers from engaging in more robust off-label promotion, given court decisions and the potential for Congress to get involved next. The agency needs to be part of the debate on how to manage the pharma-doctor dialogue to ensure that this is supported by scientific evidence.

To contact the writer of this story email Jonathan Gardner in London at jonathang@epvantage.com or follow @JonEPVantage on Twitter