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Drug Comparison Suits May Drive Shift In Pharma Ads

By **Jeff Overley**

Law360, New York (September 25, 2013, 8:09 PM ET) -- Rising demand from Medicare and private insurers for head-to-head studies of pricey drugs is triggering courtroom brawls over how drugmakers use that research in marketing materials — fights that experts say could reshape drug advertising and make or break many products.

Several high-profile suits have been waged over the past year, including a fight that ended in June with the Second Circuit carving out significant protections for speech based on sound scientific research. And experts say more litigation is all but certain.

That's in part because of major congressional investments in so-called comparative effectiveness research, or CER. The 2009 stimulus bill earmarked $1.1 billion for such analysis, and the Affordable Care Act promised another $3.5 billion for the Patient-Centered Outcomes Research Institute, which also focuses on comparative effectiveness.

Those expenditures have been motivated both by a desire for better treatment outcomes as well as eye-popping bills for popular brand-name drugs and sophisticated biologics, the latter of which can carry six-figure annual price tags for a single patient.

"They're not concerned with whether you can save 3 cents on a version of aspirin," said Stephen Paul Mahinka, head of the life sciences group at Morgan Lewis & Bockius LLP, which successfully represented Chiesi Farmaceutici SpA in the Second Circuit case.

Medicare Part D drug plans are forbidden from relying exclusively on CER in deciding which products to cover, but they can take the research into consideration. And when drug plans are not interacting with Medicare, the research can play a greater role in decisions about which medicines to include in formularies.

And insurance plans looking to get their money's worth aren't the only ones turning to CER, according to Joshua P. Cohen, an expert on drug reimbursement and CER at Tufts University. Drugmakers can also wield it to play up the value of their wares, he says.

"It is increasingly being used by payors, but also the biopharmaceutical industry, to evaluate and justify the value of newly approved products," Cohen told Law360.

The Second Circuit case is an example of the type of disputes this can trigger. In the suit, biotech firm ONY Inc. targeted scientists for allegedly publishing inaccurate data about competing lung surfactants, and accused rival Chiesi of misleading use of the data in marketing materials.

The judges rejected the claims, concluding that the findings were more like opinion, intended for evaluation by the scientific community, than like statements of fact — which meant the research was protected under the First Amendment. The judges also disagreed that Chiesi had presented the study in a deceptive light.

While the decision bodes well for companies using CER in promotional activities, Mahinka cautioned that the research they rely on should be rock-solid if they want to avoid serious legal liability. ONY, for example, had wanted at least $30 million in damages.

“It certainly is going to be easy for a challenger to challenge information that is not published in a peer-reviewed journal,” unlike the research in the Chiesi matter, Mahinka said.

While Chiesi was exonerated of promotional misconduct, drugmakers should be very careful when they summarize scientific findings to use in advertising or press releases, he added.

“Those are going to be easier to challenge because they are not, strictly speaking, the actual scientific conclusions — they are summaries,” he said. “The farther away you get … the more questionable the science is.”

In a separate case, a Massachusetts federal judge in November refused to toss a Genzyme Corp. suit accusing a Shire PLC unit of misleading consumers by advertising its genetic disease drug VPRIV as superior to Genzyme’s Cerezyme.

The judge said Genzyme had legitimately questioned whether Shire’s clinical trial findings — normally protected by the First Amendment — could also be considered commercial speech when touted in a statement. The case has since been referred to alternative dispute resolution, with the next hearing set for Thursday.

Elsewhere, Ferring Pharmaceuticals Inc. is suing rival Watson Pharmaceuticals Inc. in New Jersey federal court for allegedly making inaccurate claims about effectiveness through a consultant and in marketing materials. Ferring earlier this year lost a bid for a preliminary injunction, and the case is ongoing.

It's no coincidence that these cases are popping up just as comparative research kicks into high gear, attorneys say.

“Drugmakers are definitely more attuned to the quality of CER and how it is used,” Cohen said.

Many pharmaceutical firms are conducting in-house research in hopes of positioning their products strongly against rivals, and they’re doing so an increasingly early stages — not just after winning regulatory approval, but sometimes as early Phase 2 clinical trials that represent a midpoint in the testing process, according to Cohen.

“Establishing a favorable formulary position is not easy and must be negotiated early, in particular for products that enter already crowded therapeutic classes,” he said.

As more comparisons are performed, more products will inevitably be cast in an unflattering light, and then drugmakers will have to confront a choice of whether to sue or move along, Mahinka said.

“Someone’s ox is going to be gored,” he said. “That company is going to have a decision to make.”

--Additional reporting by Melissa Lipman and Daniel Wilson. Editing by Kat Laskowski and Chris Yates.