Published on *The National Law Review* https://natlawreview.com

Three Dozen States Sue Makers of Opioid Addiction Treatment Medications for Antitrust

Article By:

Judith A. Waltz

James W. Matthews

Katy E. Koski

With opioid abuse continuing to dominate national headlines, manufacturers of opioid overdose medications are facing intense scrutiny over pricing practices that threaten (or those perceived as threatening) public availability of these medications. In March 2015, for instance, Congress investigated "price hikes" by Amphastar Pharmaceuticals, Inc. ("Amphastar") for naloxone (sold under the brand name Narcan®), a generic prescription medicine that blocks the effects of opioids and reverses an overdose. Ranking Members of the House Committee on Oversight and Government Reform and the Senate Committee on Health, Education, Labor and Pensions claimed "[t]he rapid increase in the cost of this life-saving medication in such a short time frame is a significant public health concern" and requested drug profit and cost information from Amphastar "to evaluate the underlying causes of recent increases in the price."

Late last month, meanwhile, Attorneys General from New York, California, Washington D.C., and 32 other states (the "Plaintiff States") sued Reckitt Benckiser Pharmaceuticals, Inc., n/k/a Indivior PLC ("Reckitt"), and MonoSol Rx, alleging the companies colluded and together engaged in an unlawful scheme to preserve their monopoly profits from sales of the opioid addiction drug Suboxone® by preventing or delaying less expensive generic versions from entering the market. *See* Complaint, *State of Wisconsin et al. v. Indivior Inc., et al.*, (E.D.P.A.) ("*Indivior*"). In a 280-paragraph complaint filed in the Pennsylvania federal court in Philadelphia, the Plaintiff States in *Indivior* alleged the Defendants kept generic Suboxone off the market through "product hopping," REMS violations, and by filing a sham citizen petition with the FDA to delay would-be competitors. *Indivior* Complaint ¶ 3. (These allegations are discussed in more detail below.) As a consequence, "consumers and state governments have been limited in their treatment options for opioid addiction" and allegedly are "forc[ed] to pay more for Suboxone than they otherwise would in a competitive market." *Id*. ¶ 7.

While the public spotlight on opioid abuse makes the *Indivior* case one of intense interest, allegedly anticompetitive conduct meant to thwart generic competition has formed the subject of a growing

number of pharmaceutical antitrust suits. Such conduct, including "product hopping" or "product switching," has piqued the interest (and frustration) of government agencies (*e.g.*, Federal Trade Commission) and industry participants and stakeholders alike.

Plaintiff States' "product hopping" allegations assert the *Indivior* Defendants developed and sought approval to market Suboxone in a sublingual film in 2008 ahead of the expiration of Suboxone's orphan drug exclusivity period in 2009. *Indivior* Complaint ¶¶ 55, 57. The reformulated dosage form, they claim, was intended to defeat the substitutability of generic Suboxone (buprenorphine/naloxone tablets). *Id*. ¶ 69. Defendants allegedly drove prescribers and patients to Suboxone film (*i.e.*, a "hard switch") through a "campaign to convert the market on unfounded safety concerns about the Tablets, including concerns regarding accidental exposure to children. These concerns were alleged to be a sham designed to convince prescribers and payors that the Suboxone Film provided increased safety and efficacy over the Tablets." *Id*. ¶ 73.

In addition to alleged "product hopping," Reckitt also is accused of manipulating the Risk Evaluation and Mitigation Strategy ("REMS") program for Suboxone. *Id*. ¶¶ 93-97. REMS are risk management plans required by the U.S. Food and Drug Administration ("FDA") pursuant to the Food and Drug Administration Amendments Act of 2007 ("FDAAA"). REMS use risk minimization strategies beyond professional labeling to ensure the benefits of certain higher-risk prescription drugs outweigh their risks. The Plaintiff States allege FDA approved a REMS for Suboxone tablets in 2011 and, in early 2012, directed Reckitt to cooperate with the Buprenorphine Products Manufacturers Group (comprised of companies filing ANDAs for generic Suboxone tablets) to submit a single, shared REMS. Reckitt supposedly "feigned cooperation with the shared REMS development process and used deceptive tactics for months to hide its true intent, which was to delay the generic industry from obtaining ANDA approvals." *Id*. ¶ 94. Foley & Lardner previously reported on such REMS abuse and delay tactics in analyzing the federal CREATES Act and PRICED Act.

Additionally, the Plaintiff States allege, "[t]o gain more time to complete its product hop scheme, Reckitt engaged in another delay tactic by filing a citizen petition with the FDA." A citizen petition is a request to FDA to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action. *See* 21 C.F.R. § 10.30. Under the Food and Drug Administration Safety and Innovation Act of 2012, FDA must (among other things) respond to certain citizen petitions within 150 days, down from 180 days under Section 505(q) of the FDAAA.

To fend off generic competition, the Plaintiff States claim "Reckitt filed a citizen petition asking the FDA to withhold approval of the ANDAs for generic Suboxone Tablets unless . . . the FDA had determined whether Reckitt had discontinued Suboxone Tablets for safety reasons." *Indivior* Complaint ¶ 102. Reckitt allegedly "used information gained from the generic manufacturers through the shared REMS negotiation to form its citizen petition" and "did not disclose these alleged safety concerns about Suboxone Tablets to the generic manufacturers during the shared REMS negotiation process." *Id*. ¶ 104. The net effect of the Defendants' conduct, according to the Plaintiff States, is that "Reckitt avoided, and continues to avoid, automatic substitution of AB-rated generics under state generic substitution laws and, therefore, has limited, and continues to limit, competition with generic substitutes for Suboxone Tablets." *Id*. ¶ 120.

The Amphastar-naloxone investigation and *Indivior* are but the latest in a string of high-profile enforcement actions aimed at rooting out allegedly anticompetitive or illicit drug pricing schemes. Notably, however, increased second-guessing and government interference with pharmaceutical pricing strategies unintentionally may disrupt the market forces driving down cost in many product markets. Indeed, *Indivior* is a case study of the tension between public health policy, regulatory

oversight, and business strategies to capitalize on high-demand drugs.

National Law Review, Volume VI, Number 287