IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HUMANA, INC.,	:	**CIVIL ACTION**
Plaintiff,	:	
v.	:	**NO. 20-4602**
INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC., et al.,	:	
Defendants.	:	
CENTENE CORPORATION, et al.	:	**CIVIL ACTION**
Plaintiffs,	:	
v.	:	**NO. 20-5014**
INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC., et al.	:	

Goldberg, J. **July 22, 2021**

MEMORANDUM OPINION

In yet another chapter of the ongoing litigation relating to the marketing and distribution of the addiction treatment drug Suboxone®, Plaintiffs,[1] both healthcare providers, have filed lawsuits against Defendants Indivior Inc. f/k/a/ Reckitt Benckiser Pharmaceuticals, Inc. ("Indivior") and

[1] One suit was brought by Humana, Inc. ("Humana"), and the other was brought by The Centene Company, WellCare Health Plans, Inc., New York Quality Healthcare Corporation d/b/a Fidelis Care, and Health Net LLC (the "Centene Plaintiffs"). I refer to all of these entities collectively as "Plaintiffs."

several related entities.[2] The two Complaints set forth multiple claims under the Racketeering Influenced and Corrupt Organizations Act ("RICO"), state law common law fraud, state law antitrust laws, state unfair and deceptive trade practices laws, state insurance laws, and for unjust enrichment.

Defendants have moved to dismiss these Complaints. For the following reasons, I will grant these Motions and dismiss both Complaints against all Defendants.

I. FACTS IN THE COMPLAINTS

The following facts are taken from Plaintiffs' Complaints.[3]

Suboxone® is a drug approved for use by recovering opioid addicts to avoid or reduce withdrawal symptoms while they undergo treatment for opioid-use disorder. Indivior—known at the time as Reckitt Benckiser Pharmaceuticals, Inc.—introduced Suboxone in tablet form in 2002 under an "orphan drug" designation by the Food and Drug Administration ("FDA"). Suboxone tablets soon reached annual United States sales of over $1 billion. (Compl., Civ. A. No. 20-4602 ("Humana Compl."), ¶ 1.)

In 2009, Indivior was facing the expiration of its regulatory exclusivity for Suboxone tablets and the impending entry of generic versions of Suboxone tablets. According to the Complaints,

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[2] Aside from Indivior, Plaintiffs have sued Indivior Solutions, Inc. f/k/a Reckitt Benckiser Pharmaceuticals Solutions, Inc. ("Indivior Solutions"), Reckitt Benckiser Group plc ("RBG"), Reckitt Benckiser Healthcare (UK) Ltd. ("Reckitt UK"), and Aquestive Therapeutics, Inc. f/k/a MonoSol Rx, LLC ("Aquestive"). I refer to all of these entities collectively as "Defendants."

[3] In deciding a motion under Federal Rule of Civil Procedure 12(b)(6), the court must accept all factual allegations in the complaint as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading, the plaintiff may be entitled to relief. Atiyeh v. Nat'l Fire Ins. Co. of Hartford, 742 F. Supp. 2d 591, 596 (E.D. Pa. 2010).

The two Complaints before me here are substantially identical. As such, when discussing the relevant facts pled, I will cite only to the Humana Complaint in Civil Action No. 20-4602. To the extent there is a critical difference between the two Complaints, I will identify that distinction and cite to both Complaints.

Indivior undertook a "complex, sophisticated scheme" to "introduce a fraudulent new product in order to keep its Suboxone drug prices artificially high and unlawfully impede generic manufacturers from competing effectively." (Id. ¶ 2.) The Complaints address the alleged impact of Defendants' actions on Plaintiffs.

A. The Parties

Humana and the Centene Plaintiffs are providers of healthcare related services and insure risk for prescription drug costs for more than eight million members in all fifty states, the District of Columbia, and Puerto Rico. (Id. ¶ 11; Compl., Civ. A. No. 20-5014 ("Centene Compl."), ¶¶ 11–14.)

Defendant Indivior is a wholly-owned subsidiary of Indivior plc and is engaged in the development, manufacture, and sale of Suboxone throughout the United States. Until December 12, 2014, Indivior was a wholly-owned subsidiary of RBG and was known as Reckitt Benckiser Pharmaceuticals. On December 23, 2014, Indivior plc acquired Indivior when Indivior plc was demerged from RBG. (Humana Compl. ¶ 12.)

Defendant Indivior Solutions employed the marketing and sales personnel for the Indivior group of companies. Defendant Indivior plc is a British corporation that, according to Plaintiffs, owned, controlled, managed, and operated Indivior. Defendant RBG is also a British corporation that manufactures and markets numerous consumer products and, according to the Complaints, was responsible for the initiation of the conduct at issue in this case. The Complaints allege that, in all relevant respects, Indivior plc is the successor to RBG and has continued RBG's conduct. (Id. ¶¶ 13, 14, 15, 17.)

Reckitt UK is a British company that purportedly established the parameters for the timing of the launch and the formulation of Suboxone film and, according to the Complaints, was intricately involved with the alleged anticompetitive scheme. (Id. ¶ 16.)

Defendant Aquestive is a New Jersey-based corporation, which, during the relevant time period, was known as MonoSol. According to Plaintiffs, Aquestive was integral to the alleged anti-competitive and racketeering scheme through its development of the Suboxone film. (Id. ¶¶ 19–20.)

B. The Regulatory Structure for Approval and Substitution of Generic Drugs

The Hatch-Waxman Act provides regulatory exclusivity for new pharmaceuticals while providing a pathway for entry of low-priced generic drugs. A company seeking to market a new pharmaceutical product must file a New Drug Application ("NDA") with the FDA demonstrating the safety and efficacy of the new product. These NDA-based products are referred to as "brand-name" or "branded" drugs, and they are entitled to regulatory exclusivity for a limited period of time. When regulatory exclusivity is about to expire, a generic drug company may submit an Abbreviated New Drug Application ("ANDA") demonstrating that the generic version is essentially the same as a branded version. (Id. ¶ 25.)

A seven-year regulatory exclusivity period for an NDA approved drug can also be obtained by applying for orphan drug exclusivity with the FDA under 21 C.F.R. § 316, either (a) on the basis that a product is intended to treat a disease or condition that has a United States prevalence of less than 200,000 persons, or (b) where the sponsor can show that there is no reasonable expectation that the costs of developing and making the drug available will be recovered from United States sales, despite the fact that the disease or condition treated has a United States prevalence of more than 200,000 persons. (Id. ¶ 26.)

Generic drugs can be substituted at the pharmacy to fill a prescription for a branded drug. Both the federal government, through the Hatch-Waxman Act, and all fifty states provide drug substitution laws that encourage and facilitate this type of substitution. Thus, when a pharmacist fills a prescription for a branded drug, the laws allow or require that a less expensive generic version

be dispensed, unless a physician or patient directs otherwise. Such state substitution laws were enacted, in part, to correct a "disconnect" between payment obligations and product selections, *i.e.*, the doctor who selects the drug does not pay for it and, therefore, has no incentive to consider price. Due to these substitution laws, less-expensive generic drugs typically capture over 80% of a branded drug's sales within six months. In turn, the lower cost generic drugs save consumers billions of dollars a year. (Id. ¶¶ 27–30.)

C. The Suboxone Hard Switch Scheme

Again, the following facts describing the alleged scheme are taken from Plaintiffs' Complaints.

Indivior obtained FDA approval for Suboxone tablets in 2002. Subsequently, Indivior applied for and received orphan drug exclusivity for Suboxone based on Indivior's claims that it was the first buprenorphine drug approved for the treatment of opioid addiction and Indivior would not recover the costs of developing the tablets. Nonetheless, during its seven-year period of exclusivity, Indivior earned over one billion dollars from marketing and selling Suboxone tablets in the United States. (Id. ¶¶ 33–34.)

As Indivior's seven-year exclusivity was set to expire on October 8, 2009, it became aware that multiple generic manufacturers were seeking FDA approval to market generic versions of Suboxone, which would significantly deplete Indivior's Suboxone sales. Accordingly, Indivior began to devise a strategy to develop a new dosage form of Suboxone and submit another NDA on this new form. (Id. ¶¶ 36–38.)

In connection with this strategy, Indivior discovered Aquestive, whose sole offering as a business is its development of a drug delivery formulation known as sublingual film or "PharmFilm." Aquestive's business model encourages companies to use its dosage form to extend a drug's exclusivity on the market. In December 2006, Indivior and Aquestive executed an initial

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