UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20CR00024
v.	)	
	)	**Violations:**
SHAUN THAXTER	)	**21 U.S.C. §§ 331(a), 352(a), 333(a)(1)**
	)	

INFORMATION

The United States charges that:

DEFENDANT

1. At all times relevant to this Information, the defendant, SHAUN THAXTER, was a resident of Richmond, Virginia.

2. At all times relevant to this Information through on or about December 23, 2014, THAXTER was the highest-ranking executive of Reckitt Benckiser Pharmaceuticals Inc. ("RBP"), a Delaware corporation with offices in Richmond, Virginia, that conducted business in the Western District of Virginia and elsewhere. RBP was a subsidiary of Company A. As the highest-ranking executive of RBP, THAXTER reported to the Chief Executive Officer of Company A.

3. On or about December 23, 2014, RBP was demerged from Company A. Following the demerger, RBP was renamed Indivior Inc. and became a subsidiary of Indivior PLC, a United Kingdom company with offices in Slough, England, and Richmond, Virginia, that conducted business in the Western District of Virginia and elsewhere. After on or about December 23, 2014, THAXTER was the Chief Executive Officer of Indivior PLC.

4. Indivior Solutions, Inc., previously known as Reckitt Benckiser Pharmaceutical Solutions, Inc., is a wholly owned subsidiary of Indivior Inc. Indivior Solutions, Inc. is a Delaware corporation headquartered in Richmond, Virginia. At all times relevant to this Information,

THAXTER had responsibility for and authority over Indivior Solutions, Inc. This Information refers to RBP, Indivior Inc. and Indivior Solutions, Inc. collectively as "Indivior."

5. At all times relevant to this Information, Indivior was engaged in the pharmaceutical business throughout the United States, including in the Western District of Virginia. Indivior's business included marketing, promotion, field sales, managed-care sales, and field-medical functions for drugs containing buprenorphine, an opioid, under brand names including Suboxone and Subutex.

LEGAL BACKGROUND

6. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. ("FDCA"), any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans is a drug. 21 U.S.C. § 321(g).

7. The FDCA prohibits the introduction or delivery for introduction into interstate commerce of a misbranded drug or the causing thereof. 21 U.S.C. § 331(a). Under 21 U.S.C. § 333(a)(1) and applicable case law, a responsible executive with authority to either prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce may be liable for a misdemeanor violation of 331(a).

8. The FDCA provides that a drug is misbranded if, among other things, its labeling is "false or misleading in any particular." 21 U.S.C. § 352(a). "Labeling" includes "brochures, booklets . . . letters . . . exhibits [and] literature . . . descriptive of a drug" whether or not it physically accompanies the drug when distributed. *See* 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(l)(2). Considering whether labeling is misleading requires assessing "the extent to which

the labeling . . . fails to reveal facts" that are "material" in light of "representations made or suggested by statement, word, design, device, or any combination thereof." 21 U.S.C. § 321(n).

SUBOXONE PRODUCTS

9. Opioid addiction/dependence was and is an epidemic. Some individuals seeking to recover from opioid addiction/dependence continue to take opioids under medical supervision to avoid or reduce withdrawal symptoms while they seek to recover. The only opioid medication approved for use in such treatment outside a treatment clinic (*i.e.*, that a patient could take at home) was buprenorphine, an opioid partial agonist and Schedule III controlled substance under the Controlled Substances Act.

10. On or about October 8, 2002, Indivior received approval from the Food and Drug Administration ("FDA") for the first buprenorphine-containing drugs for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Tablet ("Suboxone Tablet") and Subutex Sublingual Tablet ("Subutex Tablet"). Indivior had previously obtained orphan-drug designation for buprenorphine for the "treatment of opioid addiction in opioid users." Among other things, this designation meant that Suboxone and Subutex were potentially eligible for 7-years of orphan-drug exclusivity upon approval (which would prohibit FDA from approving any competing application for buprenorphine for the same indication for 7 years). After approving these drugs, FDA determined that they were eligible and granted them orphan-drug exclusivity.

11. Suboxone Tablet contained buprenorphine and another substance, naloxone. Suboxone Tablet was intended to be taken by placement under the tongue until dissolved. The naloxone generally was not active when taken under the tongue as intended, but it could precipitate withdrawal if the drug were taken in other ways (*e.g.*, injected). Pharmacies typically dispensed Suboxone Tablet in bottles with child-resistant caps.

12. Subutex Tablet was similar to Suboxone Tablet, but it did not include naloxone. It was intended for induction and certain patient populations, such as patients hypersensitive to naloxone. Pharmacies typically dispensed Subutex Tablet in bottles with child-resistant caps.

13. In 2007, as Suboxone Tablet and Subutex Tablet neared the end of their period of exclusivity, Indivior began developing a new buprenorphine-containing drug for use in opioid addiction/dependence treatment: Suboxone Sublingual Film ("Suboxone Film").

14. Like Suboxone Tablet, Suboxone Film was a combination of buprenorphine and naloxone, but because aspects of the film formulation were patented, it arguably had patent protection. Suboxone Film differed from Suboxone Tablet in that (among other things) it has a thin form; sticks to the tongue/mouth; dissolves more rapidly; has potentially greater relative bioavailability at certain doses (as stated in the FDA-approved label); is formulated to taste better; and is packaged in individually wrapped, child-resistant foil pouches.

15. In August 2010, Indivior received approval from the FDA to market Suboxone Film for use in the treatment of opioid addiction/dependence.

16. At times relevant to this Information, Indivior marketed Suboxone Film to physicians and healthcare programs throughout the United States, including the Western District of Virginia.

PEDIATRIC EXPOSURE RISK

17. Suboxone Tablet, Subutex Tablet, and Suboxone Film, like many other drugs, carry a risk to children who take them by accident, sometimes called "unintended pediatric exposure." This risk of unintended pediatric exposure is identified in the Important Safety Information in

Suboxone's FDA-approved labeling, on its package, and in a Medication Guide and Physician Brochure with instructions on safe storage of the drug.

18. Indivior executives, including THAXTER, received data from poison control centers on unintended pediatric exposure for all buprenorphine drugs. During 2012 and thereafter, Indivior contracted with the Researched Abuse, Diversion, and Addiction-Related Surveillance System ("RADARS") to analyze the data for rates and trends.

PROMOTION AND DISTRIBUTION OF SUBOXONE FILM TO MASSHEALTH WITH MISLEADING LABELING

19. At all times relevant to this Information, sales of Suboxone Tablet, Subutex Tablet, and Suboxone Film generated substantially all of Indivior's revenue. After Indivior received FDA approval in August 2010 to market Suboxone Film, the company actively promoted only Suboxone Film. THAXTER and other executives structured the bonuses and incentives for sales employees to reward only Suboxone Film sales. Indivior used the RADARS analyses of unintended pediatric exposure to buprenorphine drugs in the marketing of Suboxone Film.

20. Before in or around December 2012, Suboxone Film was not a preferred drug on the Massachusetts Medicaid program ("MassHealth") formulary and had restrictions on approval for reimbursement. MassHealth was the largest Medicaid program in the country by volume of addiction-treatment-drug business. Thus, Indivior, and THAXTER, placed high importance on persuading MassHealth to expand coverage of Suboxone Film.

21. On or about January 11, 2011, THAXTER received an email from an Indivior Senior Manager, indicating that MassHealth was considering expanding coverage of a different, non-opioid drug for use in the treatment of opioid addiction/dependence. In response, THAXTER emailed Indivior's top State Government Affairs employee, copying its Vice President for Sales and Marketing, asking for a "strategy to counter" that drug. Indivior's top State Government

Affairs employee replied by email to THAXTER, laying out a multi-pronged plan that included using "a Strategic Communications approach to bring forward . . . the poison control data that demonstrates the number of unintended exposures and how [Suboxone Film] holds promise to address" the risk of unintended pediatric exposure.

22. On or about May 16, 2012, after THAXTER failed to secure a meeting with a MassHealth official, Indivior's Managed Care Director wrote to THAXTER, "Shaun: Thanks for the efforts . . . . We know how important MassHealth is and it is #1 ranked Medicaid [for us] by volume in the U.S. . . . My suggestions (in confidence not to be shared): 1) We build our pediatric poison campaign with the largest poison control centers in Mass. and we demonstrate the public health impact" to MassHealth.

23. On or about October 2, 2012, THAXTER and other executives received an email from Indivior's Medical Affairs Manager. In the email, the Medical Affairs Manager stated that a MassHealth official had reached out "requesting a meeting with me in his offices." The Medical Affairs Manager noted, "I am very excited at this opportunity to share the pediatric data," but asked to attend the meeting alone because "the situation is very delicate." "You can rest assured," the Medical Affairs Manager wrote, "that we will have a successful meeting and things will change in Massachusetts." THAXTER responded: "Sorry I missed the discussion. My contribution is that I would like [Indivior's Global Medical Director and Vice President for Clinical Affairs] to attend the meeting as well. I agree that we commercial people should not attend this meeting."

24. On or about October 9, 2012, Indivior's Medical Affairs Manager met with the MassHealth official and provided a RADARS analysis of unintended pediatric exposure data from poison control centers nationwide. Following the meeting, the Medical Affairs Manager emailed a report of the meeting to THAXTER and others, stating that the MassHealth official was "very

responsive to the pediatric data," and adding, "[b]ecause RADARS can analyze exposure data to the 3-digit zip code in the US, my next step is that I have asked [RADARS] to do an immediate analysis of the rates of unintended pediatric exposure to buprenorphine tablets in Massachusetts as the utilization of tablets is high there and I expect that the rates of exposure follow suit. I am going to follow up with a telephone meeting with [the MassHealth official] to share this information." The Medical Affairs Manager then asked RADARS for an analysis of unintended pediatric exposure data for Massachusetts only, *i.e.*, a Massachusetts-specific analysis, to provide to the MassHealth official.

25. The next day, on or about October 10, 2012, RADARS provided the Medical Affairs Manager with the Massachusetts-specific analysis. It showed the rates of unintended pediatric exposure in Massachusetts for three categories of drugs: Suboxone Film, Suboxone Tablet, and buprenorphine-only tablets such as Subutex Tablet (sometimes called "mono tablets"). The analysis showed that, in Massachusetts, there were 3.3 exposures per 10,000 units for Suboxone Tablets, 2.7 exposures per 10,000 units for Suboxone Film, and 1.8 exposures per 10,000 units for buprenorphine-only tablets such as Subutex Tablet. These data showed that buprenorphine-only tablets like Subutex Tablet—which are packaged in bottles with child-resistant caps, in the same manner as Suboxone Tablet and many other drugs—had the lowest rate of unintended pediatric exposure among the three categories in Massachusetts.

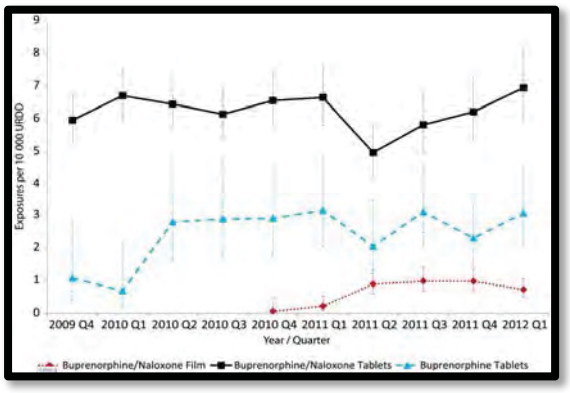
26. Upon receiving the analysis, the Medical Affairs Manager asked RADARS (copying Indivior's Global Medical Director) if she could "just add the mono and combination tablets to see the difference from film."

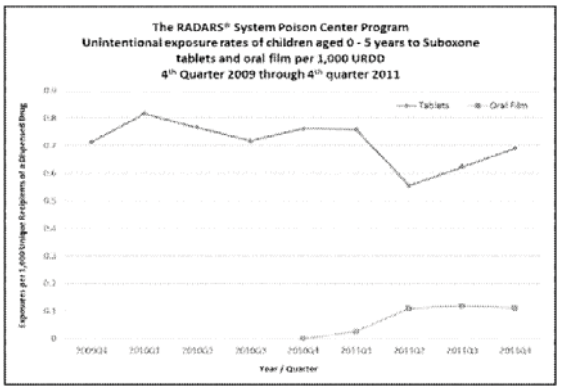
27. On or about October 16, 2012, the Medical Affairs Manager sent the MassHealth official an email containing false and misleading statements. The email contained a calculation of

the unintended pediatric exposure data for Massachusetts that added the two tablet rates together when, in fact, adding the two tablet rates together would not provide an accurate calculation. Further, the Medical Affairs Manager indicated to the MassHealth official that she had received the calculations from RADARS when, in fact, she had not received them from RADARS, but had done the calculations herself. The Medical Affairs Manager stated to the MassHealth official, and her calculations appeared to show, that Suboxone Film had the lowest rate of unintentional pediatric exposure in Massachusetts when, in fact, buprenorphine-only tablets like Subutex Tablet had the lowest rate in Massachusetts, according to the RADARS data. The Medical Affairs Manager also forwarded her email to Indivior's Global Medical Director, stating that she sent it to the MassHealth official to "help us get some movement in Mass."

28. On or about November 19, 2012, responding to a follow-up question about her false and misleading email referenced in the preceding paragraph, the Medical Affairs Manager sent the MassHealth official an email containing a chart with information from an Indivior promotional brochure (see image on right below) that referenced pediatric exposure data comparing the two products that contained both buprenorphine and naloxone, indicating that Suboxone Film had a substantially lower rate of pediatric exposure than Suboxone Tablets. The chart did not include a third line of data known to the Medical Affairs Manager that showed Subutex Tablets (which contain only buprenorphine, and not naloxone) with a lower rate of pediatric exposure than Suboxone Tablets, and with less of a difference in the rate of pediatric exposure than Suboxone Film (see image on left below). Shared in light of the Medical Affairs Manager's prior false and misleading email about unintended pediatric exposure rates in Massachusetts, the chart without the third line of data failed to reveal facts material to MassHealth prior to its updated formulary decision. By not including the data related to Subutex Tablets, the Medical Affairs Manager

reinforced her false and misleading claim that Massachusetts-specific data showed Suboxone Film as having the lowest rate of unintended pediatric exposure in the state.





29. Subsequently, the Medical Affairs Manager received additional unintended-pediatric-exposure data showing that Suboxone Film did not have the lowest rate of unintended pediatric exposure in Massachusetts, but she did not provide the data to MassHealth. The Medical Affairs Manager later told other Indivior employees, but not including THAXTER, that her rationale for withholding the additional data from MassHealth was, "don't ask, don't tell."

30. In or about December 2012, MassHealth issued a press release announcing that it would "provide access to the unit-dosed film formulation to those members prescribed Suboxone who live in households with children less than six years of age," citing to Indivior's nationwide pediatric exposure-rate data.

31. Indivior failed to correct the false and misleading statements made to MassHealth about unintended pediatric exposure in Massachusetts until December 2015, approximately two years after the government's investigation had begun. After learning of the statements, THAXTER approved sending a correction letter to MassHealth.

32. THAXTER, as a responsible Indivior executive, failed to prevent and promptly correct the distribution of the false and misleading unintended pediatric exposure data and marketing claims to MassHealth.

COUNT ONE
Introduction of Misbranded Drugs in Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), 352(a)

33. Therefore on dates set forth in this Information, in the Western District of Virginia and elsewhere, the defendant,

SHAUN THAXTER,

a responsible Indivior executive, caused the introduction and delivery for introduction into interstate commerce of Suboxone Film, a drug that was misbranded in that the drug's labeling was false and misleading. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(a).

NOTICE OF FORFEITURE

1. Upon conviction of the offense alleged in this Information, SHAUN THAXTER shall forfeit to the United States pursuant to Title 21, United States Code, Section 334 and Title 28, United States Code, Section 2461(c), any quantities of drugs which were introduced into interstate commerce in violation of Title 21, United States Code, Section 331.

2. If any of the property described above as being subject to forfeiture, which valued at approximately $500,000, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;
b. has been transferred or sold to, or deposited with a third person;
c. has been placed beyond the jurisdiction of the Court;
d. has been substantially diminished in value; or
e. has been commingled with other property which cannot be subdivided without difficulty.

it is the intention of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek forfeiture of any other

property of the defendant up to the value of the property described above. All pursuant to 28 U.S.C. § 2461(c), and 21 U.S.C. §§ 334 and 853(p).

Dated:

for

Daniel P. Bubar
First Assistant United States Attorney
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515

for

Gustav W. Eyler
Director
Consumer Protection Branch, Civil Division
United States Department of Justice