UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.**
v.	)	
	)	**Violations:**
TIMOTHY BAXTER	)	**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, TIMOTHY BAXTER, was a resident of Richmond, Virginia.

2. At all times relevant to this Information through on or about December 23, 2014, BAXTER was the Global Medical Director 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 Global Medical Director of RBP, BAXTER reported to the top executive of RBP.

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, BAXTER was the Chief Medical Officer of Indivior PLC, until he left the company in May 2016.

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,

BAXTER had responsibility for and authority over Indivior Solutions, Inc.'s medical affairs. 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 BAXTER, 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. Indivior's Medical Affairs Manager was Indivior's primary point of contact with respect to RADARS' pediatric exposure analysis projects in 2012, and reported directly to BAXTER.

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. Indivior used 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 placed high importance on persuading MassHealth to expand coverage of Suboxone Film.

21. BAXTER was familiar with the issue of unintended pediatric exposure, and Indivior's use of analyses of unintended pediatric exposure. He attended meetings at which Indivior personnel and others discussed potentially arguing that there was a negative safety issue with tablets, and that Suboxone Film offered superior safety, though at the time no studies on this

issue had been performed. He attended meetings at which Indivior personnel told FDA personnel that Indivior believed Suboxone Film potentially could provide a means of guarding against unintended pediatric exposure, due to its packaging, though no studies on this issue had yet been performed. He attended a working session in which he and other Indivior personnel discussed potentially highlighting the issue of unintended pediatric exposure to doctors, though no studies of whether Suboxone Film had any benefit related to unintended pediatric exposure had yet been performed. And he emailed fellow Indivior personnel, reporting that the FDA appeared to have denied Indivior the ability to make a promotional claim that Suboxone Film provided additional safety with regard to unintended pediatric exposure, noting (among other reasons) that no studies on the issue had yet been performed.

22. In June 2012, BAXTER approved Indivior's retention of RADARS for access to data from poison control centers for use in analyzing unintended pediatric exposure.

23. On or about September 28, 2012, BAXTER and other employees 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" from RADARS, 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."

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 BAXTER 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 (sometimes called "mono tablets"). The analysis showed that, in Massachusetts, there were 3.3 exposures per 10,000 unique recipients for Suboxone Tablets, 2.7 exposures per 10,000 unique recipients for Suboxone Film, and 1.8 exposures per 10,000 unique recipients for buprenorphine-only tablets. These data showed that buprenorphine-only tablets—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.

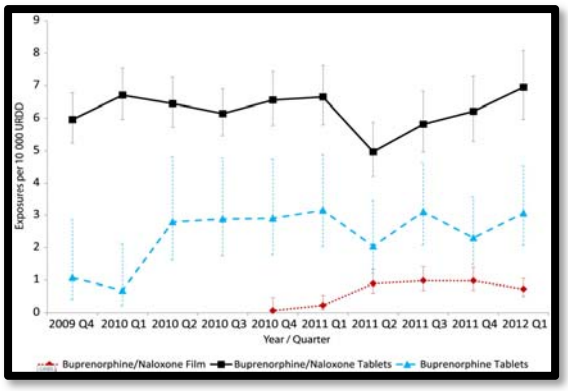
26. Upon receiving the analysis, the Medical Affairs Manager emailed RADARS, copying BAXTER, asking if she could "just add the mono and combo tablets to see the difference from film?" BAXTER responded, to the Medical Affairs Manager only, with the observation that the data RADARS sent "actually appear[ed] to make mono tablets look best or am I mi[s]-

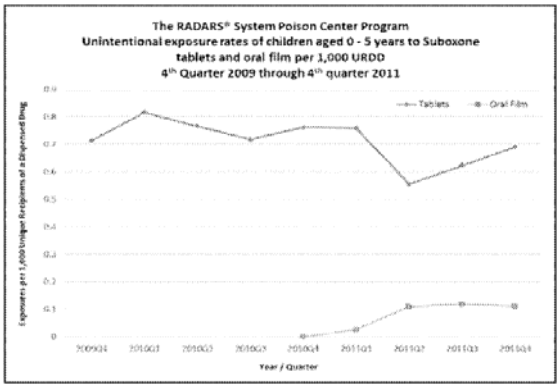
reading?" RADARS replied-all, indicating that it would obtain additional calculations and data that would be needed.

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 in the email, 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 – a fact on which BAXTER had previously remarked. The Medical Affairs Manager then forwarded her email to BAXTER, stating that she sent it to the MassHealth official to "help us get some movement in Mass." BAXTER did not respond to this email.

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 buprenorphine-only tablets (such as Subutex and generic equivalents) 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 buprenorphine-only 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. BAXTER was not copied on this email; however, around the same time, another Indivior employee emailed BAXTER, stating, "I couldn't help but notice that the chart did not show the [buprenorphine-only tablets] line. Does that mean we can also show the graph without [that] line? That would make such a huge difference!" BAXTER responded, "That chart is now published so nock [sic] yourself out!"





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, for one quarter of 2012, but she did not provide the data to MassHealth. The Medical Affairs Manager later told other Indivior employees 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

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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. BAXTER approved sending a correction letter to MassHealth at that time.

32. BAXTER, 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,

TIMOTHY BAXTER,

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).

Dated: August 29, 2020

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

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