**UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF VIRGINIA**
**ABINGDON**

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| **UNITED STATES OF AMERICA** | ) | |
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| **v.** | ) | **Case No.** 1:19CR00016 |
| | ) | |
| **INDIVIOR INC. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and INDIVIOR PLC** | ) | **Violations:** **18 U.S.C. §§ 2, 1341, 1343, 1347, 1349** |

## SUPERSEDING INDICTMENT

## OVERVIEW

The Grand Jury charges that:

1. Suboxone Film is an opioid drug used in the treatment of opioid addiction/dependence. Indivior sells Suboxone Film throughout the United States. Beginning in or about 2010, Indivior executed an illicit nationwide scheme to increase prescriptions of Suboxone Film. In particular, Indivior illegally obtained billions of dollars in revenue from Suboxone Film prescriptions by deceiving health care providers and health care benefit programs into believing that Suboxone Film is safer and less susceptible to diversion and abuse than other, similar drugs. Indivior further sought to boost its profits from Suboxone Film by establishing a telephone program for patients to call to be connected with a doctor for opioid addiction/dependence treatment, which Indivior used to connect patients to doctors Indivior knew were prescribing Suboxone and/or other opioids in a careless and clinically unwarranted manner. Indivior's fraudulent scheme lasted for years and hindered patients', health care providers', and health care benefit programs' accurate assessments regarding opioid-addiction treatment in order to increase the company's profits.

## INTRODUCTION

The Grand Jury charges that at times material to this Indictment:

### DEFENDANTS

2. INDIVIOR INC. (hereinafter "INDIVIOR") was a Delaware corporation headquartered in Richmond, Virginia, that marketed and distributed prescription drugs containing buprenorphine, an opioid controlled substance, under brand names including Suboxone and Subutex. Until on or about December 23, 2014, INDIVIOR was a wholly owned subsidiary of Company A, and was known as Reckitt Benckiser Pharmaceuticals Inc.

3. INDIVIOR PLC was an English public limited company headquartered in Slough, England, United Kingdom, that owned, controlled, managed, and operated INDIVIOR after on or about December 23, 2014.

### HEALTH CARE BENEFIT PROGRAMS

4. Medicare was a health care benefit program under Title 18, United States Code, Section 24(b) that provided basic medical coverage to individuals age 65 or older and to certain disabled persons. The United States Department of Health and Human Services, through the Centers for Medicare and Medicaid Services ("CMS"), administered Medicare through contractors. Medicare Part D paid for certain prescription drugs for Medicare beneficiaries.

5. Medicaid was a health care benefit program under Title 18, United States Code, Section 24(b) that was administered by agencies of the various states to provide health care benefits and services to those who qualified. Medicaid was funded jointly by the states and by CMS and paid for certain prescription drugs for Medicaid beneficiaries.

6. Other public health care programs and private health care insurance providers were health care benefit programs under Title 18, United States Code, Section 24(b) that paid for certain prescription drugs for their beneficiaries.

## LEGAL AUTHORITY

7. The Federal Food, Drug, and Cosmetic Act ("FDCA"), Title 21, United States Code, Sections 301, *et seq.*, provided that no drug could be marketed in interstate commerce unless it had been approved by the Food and Drug Administration ("FDA").

8. The Orphan Drug Act ("ODA"), Title 21, United States Code, Sections 360aa, *et seq.*, provided that the FDA could designate a drug as an "orphan drug," and upon approving the drug, would not approve another drug for the same disease or condition for seven years.

9. The Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"), Title 21, United States Code, Section 355(j), provided that the FDA could approve generic drugs without requiring all of the clinical testing required for new drugs.

10. The Drug Addiction Treatment Act ("DATA"), Title 21, United States Code, Section 823(g), authorized registered health care providers to prescribe certain opioid drugs in Schedules III, IV, or V of the Controlled Substances Act ("CSA"), Title 21, United States Code, Section 801, *et. seq.*, for the treatment of opioid addiction/dependence outside a treatment clinic. The DATA limited the maximum number of patients a provider could so treat at any one time. Through in or about July 2016, the maximum limit for any one provider was 100 patients at a time. In or about August 2016, the maximum limit was raised to 275 patients at a time.

11. Title 21, Code of Federal Regulations, Part 1306.04, stated that a prescription for a controlled substance was effective only if issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice.

## SUBOXONE TABLET AND SUBUTEX TABLET

12. Opioid addiction/dependence was and is an epidemic. Some individuals seeking to recover from opioid addiction/dependence continued taking opioids under medical supervision, to avoid or reduce withdrawal symptoms while they sought to recover. The only opioid approved for use in such treatment outside a treatment clinic (*i.e.*, that a patient could take home) was buprenorphine, a Schedule III controlled substance under the CSA.[1]

13. On or about October 8, 2002, INDIVIOR received FDA approval of 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"). The FDA designated both as orphan drugs, meaning the FDA committed not to approve any competitor drug for seven years (the "exclusivity period").

14. 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 could precipitate withdrawal if the drug were taken in other ways (*e.g.*, injected). Daily doses of Suboxone Tablet containing more than 24 milligrams ("mgs") of buprenorphine were not shown to provide any clinical advantage over lower doses. Pharmacies typically dispensed Suboxone Tablet in bottles with child-resistant caps. Before in or about 2013, another subsidiary of Company A manufactured Suboxone Tablet in Hull, England, United Kingdom, and INDIVIOR marketed and distributed it throughout the United States.

[1] Buprenorphine is an opioid partial agonist with a morphine milligram equivalent conversion factor ("MME-CF") 20 times higher than oxycodone.

15. Subutex Tablet was similar to Suboxone Tablet, but did not include naloxone. It was intended for certain patient populations, such as patients hypersensitive to naloxone. Pharmacies typically dispensed Subutex Tablet in bottles with child-resistant caps. Before in or about 2011, another subsidiary of Company A manufactured Subutex Tablet in Hull, England, United Kingdom, and INDIVIOR distributed it throughout the United States.

**SUBOXONE FILM AND THE PLAN TO MARKET IT**

16. By in or about 2007, INDIVIOR's and Company A's annual revenue from sales of Suboxone Tablet and Subutex Tablet had grown to more than $260 million, but they forecast they would lose most of that revenue to competitor drugs, particularly generic versions of Suboxone Tablet, after the exclusivity period ended on October 8, 2009.

17. Between in or about December 2006 and March 2007, INDIVIOR and Company A began developing a new buprenorphine-containing drug for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Film ("Suboxone Film"). They believed Suboxone Film would be protected by patents. They planned to promote Suboxone Film by claiming it was safer than alternative drugs such as tablets, though there were no scientific studies to establish that claim.

18. Additionally, between in or about December 2006 and March 2007, INDIVIOR, Company A, and others discussed ways to delay FDA approval of generic versions of Suboxone Tablet by discontinuing Suboxone Tablet under the pretext of a safety concern, thereby triggering FDA safety-related processes that could take as long as a year. They wrote, "We could tie up generic for 1 year . . . . When we file for film and withdraw tablet [the FDA] is precluded from approving another tablet until they have made a determination in response to a petition from generic company to determine that product was not withdrawn for safety or

efficacy;" a "negative safety issue" could "prevent approval of generic;" "We need to think creatively about a safety story;" "we probably also need to think very negatively about [tablets] and identify aspects that could be unsafe;" "We cannot prevent generics . . . We can delay;" and a timeline for how long generics could be delayed.

19. On or about October 20, 2008, INDIVIOR submitted a new drug application ("NDA") for Suboxone Film to the FDA. (INDIVIOR did not seek approval of a film version of Subutex.)

20. Like Suboxone Tablet, Suboxone Film contained buprenorphine and naloxone, was intended to be taken by placement under the tongue until dissolved, and daily doses containing more than 24 mgs of buprenorphine were not shown to provide any clinical advantage over lower doses. However, Suboxone Film differed from Suboxone Tablet in that it had a thin form; stuck to the tongue/mouth; dissolved more rapidly; potentially had higher bioavailability at certain doses; was formulated to taste better; and typically was dispensed by pharmacies in individually wrapped, child-resistant foil pouches each bearing a serial number.

21. Between in or about May 2009 and August 2010, while awaiting FDA approval of Suboxone Film, INDIVIOR managers drafted marketing plans for the drug. The draft plans listed "Key Success Drivers" for Suboxone Film such as "Driving physician prescriptions for Suboxone film," "Driving formulary support for Suboxone film through payors," and "Driving patient Suboxone film trial," and included the messages that Suboxone Film was "a more responsible medication from a public health perspective," was a "less divertible/abusable formulation," and had a "lower risk of child exposure," and that generic drugs would "jeopardize the entire disease space," though there were no scientific studies to establish these claims. The draft plans noted that public health care benefit programs such as Medicare, Medicaid, and the

Veterans Administration paid for 27% of all Suboxone Tablet and Subutex Tablet prescribed, while private health care benefit programs paid for 55%.

22. On or about June 9, 2009, INDIVIOR's medical director told fellow INDIVIOR medical personnel, "We need to develop a story about childhood exposures to set the stage for switching patients to" Suboxone Film.

23. On or about August 21, 2009, the FDA declined to approve INDIVIOR's NDA for Suboxone Film because it did not contain an adequate risk evaluation and mitigation strategy ("REMS") to address the FDA's concerns about misuse, abuse, and accidental overdose.

24. On or about October 5, 2009, INDIVIOR sent a letter to the FDA, asking whether the FDA agreed that Suboxone Film's packaging would protect against diversion (*e.g.*, illegal selling, sharing, and smuggling of Suboxone) and accidental child exposure (*i.e.*, children taking Suboxone by accident). The FDA did not immediately respond. INDIVIOR executives and others internally discussed that the FDA could disagree, for reasons including that it was not clear how physicians would use the serial numbers on Suboxone Film packages to deter diversion, and "there is an incremental risk of the film since once a child ingests the film it will be nearly impossible to remove vs. tablets."

25. On or about November 24, 2009, INDIVIOR resubmitted its NDA for Suboxone Film to the FDA, including a REMS.

26. On or about January 22, 2010, INDIVIOR's chief executive officer told Company A executives, "Our immediate focus is to get the FDA approval for [Suboxone Film] asap to switch the business ahead of the generic."

27. On or about March 29, 2010, the FDA responded to INDIVIOR's October 5, 2009 letter that sought the FDA's agreement that Suboxone Film's packaging would protect against diversion and accidental child exposure, stating:

> The Agency will not comment on whether the serial numbers [on Suboxone Film's packaging] would lead to a decrease in diversion of a drug product, because drug diversion issues are regulated by DEA.
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> * * *
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> No, we do not agree that the packaging for [Suboxone Film] provides meaningful incremental protection against pediatric exposure. Although the foil pouches fulfill the child resistant effectiveness standards and the foil pouch bears warning statements alerting patients to keep out of reach of children, no data were provided to support that these measures will encourage patients to store [Suboxone Film] in a manner which prevents accidental pediatric ingestion. Because patients are known to divide tablets, it may be expected that patients will remove films from the package and have partial doses that are neither in the child-resistant pouch nor in a child-resistant medication bottle. Furthermore, because the film cannot be spit out (unlike a tablet) it is possible that a child who obtains access to even one dose might be more adversely affected than a child who obtains access to a single tablet.

28. INDIVIOR executives, managers, and personnel understood from the FDA's response that they lacked substantiation to inform health care providers that Suboxone Film was safer than alternative drugs such as tablets. INDIVIOR executives and managers wrote to each other, "The FDA has stated that we have no proof that patients will not take the film out of the [pouch] and cut it into multiple doses. Thus not reducing potential exposure . . . . Even then the FDA points out that the film may not be swallowed thus making more buprenorphine available;" that the FDA's response could "be a bigger issue as it may imply the overall risk/benefit is not favorable for our film (vs tablet);" and, "It looks like they are trying to deny us the ability to make a claim on additional paediatric safety of the film." With regard to misuse, abuse, and

diversion, INDIVIOR executives, managers, and personnel knew that Suboxone Film's thin form potentially could make it easier to conceal, and thus more susceptible to smuggling than tablets; its individual packaging could make it more portable, including for reselling and sharing; and the serial numbers on the pouches were not electronically tracked and not shown to deter diversion. With regard to accidental child exposure, they knew that Suboxone Film had attributes that potentially could make it more dangerous to children, including that it stuck and could not easily be spit out if accidentally taken by a child; dissolved more rapidly, leaving less time to remove it from a child's mouth before absorption; had potentially higher bioavailability at certain doses, potentially increasing the severity of an incident; was formulated to taste better, potentially reducing the likelihood that a child would seek to remove it; and could not easily be re-secured in its original packaging, which, unlike a bottle with a child-resistant cap, was not designed to be re-closed.

29. On or about August 30, 2010, the FDA approved Suboxone Film, including the REMS and prescribing information for the drug. None of these materials stated that Suboxone Film was safer than alternative drugs such as tablets, or reduced the risk of misuse, abuse, diversion, or accidental child exposure. Nevertheless, INDIVIOR's chief executive officer told Company A executives including its chief executive officer and chief financial officer, "We will be making the most of every minute between now and generic approval to convert our tablet business to film," including a "Full Blitz campaign for salesforce through Thanksgiving." For the full blitz campaign, INDIVIOR salespeople planned to raise "diversion and misuse and pediatric safety" in sales presentations to physicians, even though there were no scientific studies to establish that Suboxone Film was safer with regard to diversion, misuse, or pediatric safety.

30. Suboxone Film was manufactured by another subsidiary of Company A in Hull, England, United Kingdom, and a third party in Portage, Indiana. INDIVIOR marketed and distributed it throughout the United States.

## THE SCHEME AND ARTIFICE TO DEFRAUD

31. Between in or about 2006 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents did devise and intend to devise a scheme and artifice to defraud and to obtain money and property from health care benefit programs by means of materially false and fraudulent pretenses, representations, and promises, by (A) making materially false and fraudulent statements and representations to health care providers to induce them to prescribe, dispense, and recommend Suboxone Film; (B) preparing and causing to be prepared, and shipping and causing to be shipped, materially false and fraudulent marketing materials promoting Suboxone Film; (C) making materially false and fraudulent statements and representations to and relating to state Medicaid administrators and others to promote Suboxone Film; and (D) marketing Suboxone Film to health care providers to be prescribed and dispensed in a careless and clinically unwarranted manner.

### A. MATERIALLY FALSE AND FRAUDULENT STATEMENTS AND REPRESENTATIONS TO HEALTH CARE PROVIDERS

32. Between in or about 2006 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents made, and caused to be made, materially false and fraudulent statements and representations to health care providers to induce them to prescribe and dispense Suboxone Film, and recommend the prescribing and dispensing of Suboxone Film.

33. On or about September 2, 2010 (about three days after Suboxone Film received FDA approval), Company A's chief executive officer emailed approximately 20 INDIVIOR executives and managers, including INDIVIOR's chief executive officer and marketing personnel, stating that Suboxone Film was "safer," and encouraging them to "convert [patients] from tablets to films, thereby protecting our Net Revenues in the USA."

34. On or about September 6, 2010 (about a week after Suboxone Film received FDA approval), an INDIVIOR national sales supervisor emailed approximately 50 INDIVIOR salespeople, encouraging them to tell physicians that Suboxone Film was "safer because of the packaging."

35. On or about October 17, 2010, INDIVIOR's chief executive officer told INDIVIOR personnel to revise the performance appraisals and incentive programs for salespeople to reward "film sales only." He stated that INDIVIOR's salespeople had "every possible resource to enable them to generate demand for a scheduled narcotic that is being given away for free to an addicted population," and those without "adequate film sales" may be fired. Thereafter, INDIVIOR revised the performance appraisals and incentive programs to be based primarily on the percentage of Suboxone Film compared to tablet sales in the salesperson's territory (sometimes called the "film market share" or "film share").

36. On or about October 25, 2010, INDIVIOR sales supervisors discussed baseless "dialogue points" that INDIVIOR salespeople were using to highlight Suboxone Film's "advantages" to physicians and pharmacists, which included "Reduced misuse/diversion" and "Public safety – reduced pediatric exposure." On or about November 3, 2010, an INDIVIOR sales supervisor emailed the dialogue points to INDIVIOR's chief executive officer.

37. In or about December 2010, INDIVIOR's vice president for clinical affairs met with physicians in California and elsewhere, and in the presence of INDIVIOR salespeople, materially falsely and fraudulently stated to the physicians that Suboxone "Film addresses child safety and abuse and diversion" and was a "safer product."

38. On or about February 14, 2011, an INDIVIOR national sales supervisor instructed a regional sales supervisor in Michigan and a sales representative in Ohio to:

> not be afraid to let the physician know very clearly what you believe. If you believe that Suboxone Sublingual Film will lower pediatric exposure, or lower diversion and misuse let them know. You are the expert and because of all you have done, the relationships you have built, they will be receptive to what you believe.

39. On or about March 11, 2011, Company A's chief executive officer materially falsely and fraudulently stated in Company A's public 2010 annual report that Suboxone Film was "better from a child safety point of view, mak[ing] it more attractive for doctors to prescribe."

40. On or about April 13, 2011, INDIVIOR's chief executive officer materially falsely and fraudulently stated in a corporate newsletter that Suboxone Film "has the potential for greater child safety."

41. In or about July 2012, at a Company A investor presentation, in the presence of Company A's chief executive officer, INDIVIOR's chief executive officer materially falsely and fraudulently stated that Suboxone Film was "less divertable and abusable."

42. On or about the specified dates, in or around the specified states, INDIVIOR sales representatives reported to their supervisors and their fellow sales representatives to use as models for promoting Suboxone Film, the below-described statements and representations made to physicians, pharmacists, and other health care providers to materially falsely and fraudulently

induce them to prescribe and dispense Suboxone Film, and recommend the prescribing and dispensing of Suboxone Film:[2]

| Par. | Date | State | Report |
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| 43 | 9/1/2010 | NY | INDIVIOR sales representative told physicians that Suboxone Film "offers increased protection against misuse/abuse/diversion and pediatric exposure. Due to this, and the fact that patients will be able to get the film at no cost, they have all stated that they will prescribe the Film when it is available. . . . Most pharmacists have also been impressed with the new formulation and the steps the company has taken to decrease diversion and pediatric exposure" |
| 44 | 9/10/2010 | NC | INDIVIOR sales representative told a physician that Suboxone Film "offers greater protection against pediatric exposure & misuse/diversion" |
| 45 | 9/30/2010 | SC | INDIVIOR sales representative met with a physician and "[d]iscussed pediatric exposure & tablet diversion as reasons for MD to insist that pts switch from tablet to film" |
| 46 | 12/16/2010 | MI | INDIVIOR sales representatives told physicians that Suboxone Film is the "safest choice;" has "less chance of inadvertent use by kids," can "protect the community;" and can "protect office-based treatment" from being banned |
| 47 | 12/21/2010 | CA | INDIVIOR sales representative told physicians that Suboxone Film "is a better safer medication" and "it would be unethical or inappropriate for us to promote the tablet now that we have a better, safer product" |
| 48 | 12/22/2010 | MI | INDIVIOR-paid speaker told physicians that her "big plus for the Film was the packaging and therefore making it a safer product for the community" |
| 49 | 12/22/2010 | TN | INDIVIOR sales representative told physicians that during the holiday season, Suboxone Film gives patients "added comfort in knowing their medication is safer to have in the home as family and friends with small children will be visiting more" |
| 50 | 1/6/2011 | MI | INDIVIOR sales representative met with a physician who was "in the category of trying out the film but not yet sold on it," and stated that "it's important [for the physician] as a physician and mom to convert patients to the Film. The fact that film helps to protect [office-based opioid treatment] and reduces pediatric exposure appeared hard to ignore for the doctor. Hopefully that message will have a louder voice in her head than the patients telling her they are 'happy' with the Tablet" |
| 51 | 1/11/2011 | CA | INDIVIOR sales representative told physician and pharmacists that Suboxone Film is a "safer product vs tablet" |
| 52 | 2/3/2011 | IN | INDIVIOR sales representative told a physician that patients who request tablets do so "in order to divert them. [The physician] said that he may have become a bit too trusting in his several years of treat[ing] patients. We spoke about how the Film can 'weed out' those patients truly not committed to recovery. He promised to convert ALL patients to Film" |
| 53 | 2/3/2011 | UT | Physicians told an INDIVIOR sales representative that patients were "complaining about the Film and asking to be put back on the tablet." INDIVIOR sales |

[2] These are illustrative examples, not an exhaustive list.

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| | | | representative responded by discussing "misuse and abuse of Suboxone tablets and how the Film is the better, safer choice. I know that we will have more followup in this office, due to these doctors' new awareness of what is really happening when some ask to be switched back to the tablet" |
| 54 | 2/9/2011 | TX | INDIVIOR sales representative told physicians "that many other doctors are going 'film only' because they want to provide the best quality care to their patients with the most efficacious, safest, and cost saving treatment and it has influenced several of them and they then have been interested in how others are doing this, how patients are responding, etc. I believe it makes them feel more confident to know that others are doing this and it also makes them want to do the same to keep up with 'quality care' physicians" |
| 55 | 3/2/2011 | TX | INDIVIOR sales representative told physicians that Suboxone Film is "newer, easier, quicker and most importantly safer for the patients and their families, the physicians and community" |
| 56 | 3/2/2011 | IN | INDIVIOR sales representative met with a pharmacist and "had a candid discussion as to why some patients want so badly to stay on the tablet even at a higher price to them (diversion). [The pharmacist] is going to 'hammer away' at [doctors who prescribed tablets] to get these patients on Film" |
| 57 | 4/13/2011 | IL | INDIVIOR sales representative told a physician and a pharmacist about "some of the blogs I have read and about the reported child death. This seemed to really impact them, and [the physician] said he has had some concern about a few patients in the past. We discussed that while the film cannot stop misuse and diversion, it can help prevent it, and our hope is to decrease the misuse and diversion, as well as the number of pediatric exposures. The pharmacist in the building also attended the [presentation] and everyone agreed that if a patient came to the pharmacy with a prescription for the tablet, the pharmacist would call back the office to see if it could be switched to film" |
| 58 | 4/14/2011 | CA | INDIVIOR sales representative told a physician that Suboxone Film is "safer, better, and cheaper than the pills. What reason do you have not to convert all of your patients to the film? She could not give a reason. She said she will switch her patients" |
| 59 | 5/10/2011 | CA | INDIVIOR sales representative told a physician that she would not help the physician enroll in a patient-referral program "unless I knew those patients seeking treatment would get a Comprehensive approach that includes the Safest Medication on the Market for Opioid Dependency which is the Film" |
| 60 | 5/26/2011 | UT | INDIVIOR sales representative told physicians that Suboxone Film is "safer to have around their family members" |
| 61 | 6/8/2011 | VA | INDIVIOR sales representative told physicians that one doctor in the area "converted all patients to Film and no longer give[s] a choice [between tablets and film] due to rampant diversion of the tablet in the area, which borders Virginia, Kentucky and Tennessee. This has been a great win and is something that I've been able to tell all my other docs who have converted most of their patients but not all" |
| 62 | 7/7/2011 | NC | INDIVIOR sales representative met with a physician who was "still giving [some] patients the choice between the Suboxone Film and tablet . . . . I strongly encouraged [the physician] to protect herself, her practice and her medical license |

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| | | | by prescribing Suboxone film to ALL of her patients. I said, 'I don't want any of my physicians to find themselves on a witness stand defending their decision for prescribing Suboxone tablets which caused the death of a child.' Hopefully that statement convinced [the physician] to adopt a fail first policy on the Suboxone film" |
| 63 | 7/7/2011 | OR | INDIVIOR sales representative asked a physician what was "holding [him] back from the patient-preferred Film?" The physician stated that his "tablet patients are doing well and are afraid of changing when they are doing well." The INDIVIOR sales representative then "talked about Tablet exposures to children and how [the physician] can be their safety net by prescribing the Film rather than the Tablets which he agreed with" |
| 64 | 7/7/2011 | CA | INDIVIOR sales representative was "working diligently with [a physician] in order to get him to transition his considerable amount of tablet patients to the Film. I am making progress with him. He's been reluctant and has allowed his patients the choice [between tablets and film]. I believe I've instilled in him the importance of protecting public safety and [office-based opioid treatment], and how, by prescribing the Film, he will help to make that happen" |
| 65 | 7/18/2011 | PA | INDIVIOR sales representative "had an excellent conversation with [physicians] around more of the reasons why [they] might want to move more of their patients off of tablets and onto the Film. They agreed it was a safer option and are proud they are doing their part to protect our community" |
| 66 | 7/21/2011 | DE | INDIVIOR sales representative met with physicians and pharmacists, "capitalizing on the Public Health Message and the importance of providing patients with a safer option in the film" |
| 67 | 7/21/2011 | PA | INDIVIOR sales representative told physicians, "You get the same clinical efficacy [with Suboxone Film] as you get with tablets, possibly greater compliance with improved taste and dissolve time, safety is improved within the public and the home, and most patients get the Film for virtually free with the Savings program. Why take the chance?" |
| 68 | 9/2/2011 | MD | INDIVIOR-paid speaker told physicians that Suboxone Film was "preventing pediatric death in graphic terms" |
| 69 | 10/26/2011 | TN | INDIVIOR sales representative "led physicians to the internet so that they may see how their decisions to prescribe any tablet over [Suboxone Film] may have a negative impact on the community. There are current articles that [the tablet] kills children all over the internet and this helps them to see the reasons to prescribe [Suboxone Film] over the tablets. . . . One of my doctors . . . still has not converted all of his patients to [Suboxone Film]. He was able to visit the internet article to see how [Suboxone Film] could put safe guards in the community as well as in his practice. Once he saw this information he committed to write all of the [tablet] patients [Suboxone Film]. From the look on his face [he] was really concerned about the safety of his patients" |
| 70 | 11/11/2011 | VA | INDIVIOR sales representative made the following presentations to physicians: "The physicians agree that we all have an obligation to protect the public health. I have each physician [say] if they agree that it starts with THEM, the prescriber? They do agree. Then WHY would you not prescribe the SAFEST medication available? Is it worth the risk of pediatric exposure? Is it worth the risk of abuse |

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| | | | and diversion? Is it worth the risk of ending office based treatment? It starts with YOU, DOCTOR! Unfortunately, it does NOT end with you! It can end with unintended consequences in the hands of people suffering from a terrible disease, who are not known for making the best decisions! These discussions have really opened the eyes of quite a few physicians who now realize their obligation." INDIVIOR sales supervisor singled out this presentation as a model presentation, forwarding it to other INDIVIOR salespeople |
| 71 | 12/5/2011 | IL, IN, KY, MI, OH, TN, WV | INDIVIOR sales representative collected "best practices" for convincing doctors, pharmacists, and others to switch patients to Suboxone Film from others across the region, including "Baby Death articles;" "Diversion with Tablets and high street value of $25.00 per pill;" "Film harder to sell on streets;" "if patients call office and ask if doctor writes the tablets (or pills) that is a patient you do not want—they will be diverting and your office can or will be tied to that illicit drug;" "I inform my doctors (and pharmacists) that insurance companies are beginning to view the film the same way we do . . . as the superior (safer) product;" "I focus on the safety for their office as well as the general public, the fact [Suboxone Film] will weed out the drug seekers and it will make their offices respectable and full of patients who are serious about their recovery;" and "Patients are tempted to share especially when they are doing well and want to help people that they care about . . . . [Suboxone Film] will reduce this possibility" |
| 72 | 2011 | AZ, CA, CO, LA, MO, OR, TX, UT | INDIVIOR sales representatives collected "best practices" for convincing doctors, pharmacists, and others to switch patients to Suboxone Film from others across the region, including "Once the dialogue opens up about community, safety etc, I explain that we believe [Suboxone Film] is the safest medication available;" "[by] providing the safest medication (FILM) you (physician, pharmacist, counselor, office staff) are helping the patient 'close the gaps' in their treatment as well as reducing the chance of misuse, abuse and diversion, which increases public safety;" "Do you agree the Film is safer and less abusable than the tablet?;" "[Suboxone Film is] a safer alternative to the tablet – safer for the patients, safer for their families and more aligned with [INDIVIOR's] goal to protect office-based treatment;" and asking physicians "to imagine how devastated [their] patients would be if one of those children were to get into a bottle full of Suboxone tablets" |

73. INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents knew that messages like those described in paragraphs 33-72 of the Introduction to this Indictment materially influenced health care providers to prescribe and dispense Suboxone Film, and recommend the prescribing and dispensing of Suboxone Film. In or about January 2011, an INDIVIOR contractor reported to INDIVIOR executives, managers, and personnel that in a survey of 245 physicians who had

prescribed Suboxone Film, 68 physicians (approximately 28%) stated that they did so because it "[d]ecreases misuse/abuse/diversion," and 26 physicians (approximately 11%) stated that they did so for "[s]afety re: inadvertent use by children." Additionally, the physicians rated "Ability to minimize unintentional pediatric exposure" and "Reduces the likelihood of misuse & diversion" as the second and third leading reasons to prefer Suboxone Film, respectively.[3] More than 80% of the physicians, and 98% of the high-prescribing physicians, stated that they learned about Suboxone Film from INDIVIOR salespeople.

74. INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents knew that the messages described in paragraphs 33-72 of the Introduction to this Indictment, and others like them, were false and fraudulent. In addition to the FDA's letter of March 29, 2010, informing INDIVIOR that it lacked substantiation to claim that Suboxone Film better protects against accidental child exposure (discussed above), on or about June 30, 2011, an INDIVIOR contractor reviewing information as part of the Suboxone Film REMS told INDIVIOR that Suboxone Film was more frequently abused parenterally (*e.g.*, by injection) and involved in more accidental child exposures per million doses than Suboxone Tablet. INDIVIOR did not alert patients, physicians, pharmacists, health care benefit programs, or others to these findings, which cast doubt on INDIVIOR's promotional messages about Suboxone Film. Subsequently, between in or about December 2011 and February 2012, INDIVIOR's compliance committee determined that INDIVIOR salespeople's written reports of their promotional statements to physicians and pharmacists (examples of which are set forth in paragraphs 43-72, above) posed "compliance risks," and discontinued the reports, without contacting patients, physicians, pharmacists, health

[3] "Speed of dissolving" was first.

care benefit programs, or others to correct or retract the promotional statements reflected in the reports. In or about November 2012, INDIVIOR's medical director, vice president for clinical affairs, and others discussed attributes of Suboxone Film that potentially could make it more dangerous to children, such as that, "With a tablet, they've got options. They can spit it out. They can swallow it. With the film, not necessarily. We know, it's stuck" in the child's mouth.

75. In or about 2012-13, INDIVIOR managers discussed that, "Under no circumstances can we make the claim that Suboxone Film is safer or better at reducing pediatric exposures," and "Saying Suboxone Film is safer than any tablet on the market because Film has less ability to be snorted/injected [is an] unsubstantiated superiority claim," but did not contact patients, physicians, pharmacists, health care benefit programs, or others to correct or retract the promotional statements INDIVIOR salespeople had already made.

## B. MATERIALLY FALSE AND FRAUDULENT MARKETING MATERIALS PROMOTING SUBOXONE FILM

76. Between in or about 2010 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents prepared and caused to be prepared, and shipped and caused to be shipped by mail and private or commercial interstate carrier to their executives and employees and others throughout the United States, written marketing materials used to promote Suboxone Film that contained materially false and fraudulent statements and representations, including the following:

a. Suboxone Film was "Helping Address Public Health Needs;"

b. Suboxone Film could "Help Address Misuse and Abuse;"

c. Suboxone Film "Can Be Part of the Solution" to "misuse," "diversion and abuse," and "unintentional pediatric exposure;"

d. "Nearly half of Suboxone Film prescribers surveyed cited 'potential for reduction of abuse and diversion' as a reason to prescribe vs Suboxone Tablet," when in fact, only 28% of the prescribers had cited that supposed reason, many of them after receiving fraudulent sales presentations from INDIVIOR;

e. A false and fraudulent chart with the heading, "Suboxone Film—Helping to Reduce the Risk of Pediatric Exposure," that purported to depict pediatric exposure data for Suboxone Tablet and Suboxone Film, but intentionally omitted other data from the same study that showed that buprenorphine-only tablets also had low pediatric exposure, and therefore called into question the claim that Suboxone Film reduced pediatric exposure. An INDIVIOR employee asked INDIVIOR's medical director, "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!" INDIVIOR's medical director responded, "That chart is now published so nock [sic] yourself out!"

f. A false and fraudulent pair of charts with the heading, "Suboxone . . . Film—associated with lower rates of diversion and abuse . . ." that purported to depict diversion and abuse data for Suboxone Tablet, buprenorphine-only tablets, and Suboxone Film, but intentionally omitted two other charts from the same page of the same study that showed that Suboxone Tablet and buprenorphine-only tablets had diversion and abuse rates similar to Suboxone Film during certain time periods, and therefore called into question the claim that Suboxone Film was associated with lower rates of diversion and abuse.

77. On various dates, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents shipped and caused to be shipped by mail and private or commercial interstate carrier, copies of marketing materials described in paragraph 76 of the Introduction to this Indictment, from a contractor in New Jersey to sales representatives throughout the United States, including:

a. a sales representative in Roanoke, Virginia, who promoted Suboxone Film to physicians, pharmacists, and others in locations including Blacksburg, Cedar Bluff, Charlottesville, Christiansburg, Danville, Galax, Lynchburg, Roanoke, Salem, Staunton, Willis, and Wytheville, Virginia, and

b. a sales representative in Greeneville, Tennessee, who promoted Suboxone Film to physicians, pharmacists, and others in locations including Abingdon, Big Stone Gap, Bristol, Coeburn, Glade Spring, Lebanon, Marion, Norton, Pennington Gap, Pound, Saint Charles, Tazewell, and Wise, Virginia.

## C. MATERIALLY FALSE AND FRAUDULENT STATEMENTS AND REPRESENTATIONS TO AND RELATING TO STATE MEDICAID ADMINISTRATORS AND OTHERS

78. Between in or about 2006 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents made, and caused to be made, statements and representations that INDIVIOR was discontinuing the distribution of Suboxone Tablet due to safety concerns, when in fact, the reason for discontinuing the distribution of Suboxone Tablet was to delay the FDA's approval of generic versions of Suboxone Tablet.

79. Between on or about January 6, 2012, and September 14, 2012, INDIVIOR and Company A, knowing that potential competitors were preparing applications for FDA approval

of generic versions of Suboxone Tablet, retained contractors to review and analyze notes of telephone calls to poison control centers regarding accidental child exposure.

80. On or about June 21, 2012, Company A's investor relations director emailed Company A's chief executive officer, INDIVIOR's chief executive officer, and others, referencing "our plans" to withdraw Suboxone Tablet's FDA approval in order to delay FDA approval of generic versions of Suboxone Tablet. Company A's general counsel responded by emailing Company A's chief executive officer, chief financial officer, and investor relations director, and INDIVIOR's chief executive officer and general counsel, and others, stating, "please do not create any emails or other documents suggesting that we would consider" attempting to delay FDA approval of generic versions of Suboxone Tablet in this way, and "any decision we make will be based on consumer safety."

81. On or about August 31, 2012, INDIVIOR's and Company A's contractors provided them with an "interim report" that failed to include any finding that Suboxone Film was safer than tablets with regard to accidental child exposure, or caused any drop in exposures. The interim report stated, "there remains considerable uncertainty in our ability to use root cause analysis for identifying the role of select factors in these unintentional pediatric exposures," and that the data were "insufficient to make any final conclusions regarding the severity of effects associated with specific buprenorphine medications or the child-resistance efficacy of product packaging types." The INDIVIOR manager overseeing the project stated that the interim report was a "worthless, empty shell."

82. On or about September 14, 2012, INDIVIOR executives caused the preparation of a public relations strategy for discontinuing Suboxone Tablet, indicating that INDIVIOR would dispel the "[p]erception of discontinuation as a means for blunting generic/competitive entry"

and convey a "'[w]e must be responsible' sentiment." On or about the same day, INDIVIOR's and Company A's contractors provided INDIVIOR and Company A with a three-page "executive summary" that failed to include any finding that Suboxone Film was safer than tablets with regard to accidental child exposure, or caused any drop in exposures. The summary stated that there were fewer references to Suboxone Film than tablets in the telephone call notes, but the reasons for this could not be determined, and "any results related to the original packaging should be interpreted with considerable caution" because many of the notes did not indicate whether the drug had been in the packaging or left outside the packaging by an adult.

83. On or about September 18, 2012 (about four days later), INDIVIOR and Company A sent a "Notice of Discontinuance" of Suboxone Tablet to the FDA, stating that the reason for the discontinuance was "increasing concerns regarding pediatric exposure to" Suboxone Tablet. INDIVIOR's and Company A's respective chief executive officers approved the notice, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

84. On or about September 25, 2012, INDIVIOR and Company A submitted a petition to the FDA, signed by INDIVIOR's medical director, stating that INDIVIOR discontinued Suboxone Tablet "due to safety concerns" about tablets, and asking the FDA not to approve generic versions of Suboxone Tablet. INDIVIOR's and Company A's respective chief executive officers approved the petition, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

85. The petition referenced a new, five-page version of the executive summary, which INDIVIOR and Company A executives and others had participated in altering, but kept dated September 14, concealing the fact that it was altered from the version they originally cited for

discontinuing Suboxone Tablet. The alterations included deleting the statement that "any results related to the original packaging should be interpreted with considerable caution," and adding conclusions.

86. On or about September 25, 2012, Company A posted on its website a press release stating that Suboxone Tablet was discontinued "due to increasing concerns with pediatric exposure." INDIVIOR's and Company A's respective chief executive officers approved the press release, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

87. INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents used the discontinuation of Suboxone Tablet to materially falsely and fraudulently market Suboxone Film. Between on or about September 18, 2012, and the date of this Indictment, they prepared and caused to be prepared, and shipped and caused to be shipped by mail and private or commercial interstate carrier to their executives and employees and others throughout the United States, letters signed by INDIVIOR's medical director and used to promote Suboxone Film that contained materially false and fraudulent statements and representations, including the following:

a. "Dear Patient . . . The decision to take Suboxone Tablets off the market was a voluntary choice made by [INDIVIOR] as a result of recent information the company received showing higher rates of accidental pediatric exposure (when a child accidentally takes the medicine) linked with the tablet form. If you are currently taking Suboxone Tablets, continue taking your medication and ask your doctor about how to transition to Suboxone Film. . . ."

b. "Dear Healthcare Professional . . . As we continue to work together to improve the health and well-being of opioid-dependent individuals, we would like to personally inform you about an important medication update . . . . The decision to discontinue Suboxone Tablets was based on accumulating data demonstrating significantly lower rates of accidental pediatric exposure with Suboxone [Film] compared with the tablet form. . . . We remain committed to supporting you with updated information and resources to ensure you have the tools you need to educate and transition your patients to Suboxone Film. . . . We thank you for your continued support of [INDIVIOR] as we uphold our commitment to patients and the safety of the public."

88. On various dates, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents shipped and caused to be shipped by mail and private or commercial interstate carrier, copies of marketing materials described in paragraph 87 of the Introduction to this Indictment from a contractor in New Jersey to sales representatives throughout the United States.

89. On or about December 4, 2012, the lead researcher from one of INDIVIOR's and Company A's contractors that had reviewed and analyzed notes of telephone calls to poison control centers emailed fellow researchers, stating that by using the research to supposedly justify discontinuing Suboxone Tablet, INDIVIOR and Company A "played us as a pawn and continues to do so. They are smart people, and they are playing a Machiavellian game."

90. It was also a part of the scheme and artifice to defraud that INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents made, and caused to be made, materially false and fraudulent statements and representations to and relating to state Medicaid administrators and others, claiming that

Suboxone Film was safer than tablets with regard to misuse, abuse, diversion, and accidental child exposure. These materially false and fraudulent statements and representations included representations by employees, physicians, and agents, acting on behalf of the defendants, including those on or about the dates set forth below, in or around the specified states, and sent by the physician, employee, or agent identified below:[4]

| Par. | Date | State | Sent by | False and Fraudulent Statement and Representation |
|---|---|---|---|---|
| 91 | 5/17/2011 | MA | Physician, at direction of INDIVIOR Gov. Mgrs. | Op-Ed Letter to The Boston Globe, The Boston Herald, and The Patriot Ledger: Suboxone Film was "preventing diversion, recidivism, and the accidental death of inquisitive children," and by declining to provide Medicaid coverage of Suboxone Film, MassHealth officials were "engaging in 21st century biological warfare, no different than giving small pox infected blankets to the Indians" |
| 92 | 5/30/2011 | CA | INDIVIOR Publicist | Quote for article in Alcoholism & Drug Abuse Weekly, News for Policy and Program Decision-makers: "the main value of [Suboxone Film] is that it is less easily diverted because physicians can track the numbered unit-dose packaging, and it is safer because the packaging is child-resistant." INDIVIOR's marketing director emailed INDIVIOR's chief executive officer, president, medical director, and others stating that "[t]here does seem to be some liberty taken with regards to early comments attributed to" INDIVIOR's publicist, but INDIVIOR did not correct or retract the comments |
| 93 | 6/23/2011 | MA | Physician, at direction of INDIVIOR Gov. Mgrs. | Email to MassHealth officials: "there is less opportunity for diversion with" Suboxone Film, "there is less chance that a curious child will ingest the film," and "the inaction by the policy makers of MassHealth can be seen just as Strom Thurmond's filibuster in opposition of the Civil Rights Act of 1957." Physician subsequently emailed INDIVIOR Gov. Mgrs. requesting that INDIVIOR donate $30,000 to his foundation and give him a Harley-Davidson Road King motorcycle as payment |
| 94 | 10/16/2012 | MA | INDIVIOR Med. Mgr. | Email to MassHealth pharmacy director: altered, inaccurate pediatric exposure data for Suboxone Film, Suboxone Tablet, and buprenorphine-only tablets, making it appear as though Suboxone Film had the lowest rate of pediatric exposure in Massachusetts when, in fact, buprenorphine-only tablets did. INDIVIOR Med. Mgr. sent INDIVIOR's medical director email chains showing that she had altered the data, and stating that |

[4] These are illustrative examples, not an exhaustive list.

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| | | | | she sent the altered data to "help us get some movement in Mass" on Medicaid coverage of Suboxone Film. Upon receiving additional data unfavorable to Suboxone Film, INDIVIOR Med. Mgr. declined to provide it to Medicaid personnel, and told INDIVIOR government managers that her rationale for withholding the unfavorable information from Medicaid personnel was, "don't ask, don't tell" |
| 95 | 4/18/2013 | KY | INDIVIOR Gov. Mgr. and INDIVIOR Med. | Email to KY Department for Medicaid Services commissioner and other officials: Compared to Suboxone Film, the tablet form "increases the risk of diversion with adult recipients because it can be crushed and snorted. . . . [S]ometimes leadership requires you to make a decision locally to protect the residents of the State of Kentucky that you serve. You've chosen not to . . . ." |
| 96 | Before 12/2013 | KY | INDIVIOR Sales Representative | Model form letters shown to physicians to send to KY Department for Medicaid Services contractors: request for pre-authorization for payment of Medicaid claims for Suboxone Film because "Suboxone filmstrips are medically necessary to properly manage the post acute withdrawal process. Filmstrips are necessary in lieu of sublingual tablets because many adverse side effects are found to be prevalent in tablet form. Patient's [sic] present with constant salivation, discomfort, agitation, dissolution unnecessary prolonged. Also, feelings of disorientation, plus a craving for tablets in general, thus hindering the addiction recovery process and increasing probability of relapse. Use of filmstrips has diminished the adverse side effects of tablets. Use of filmstrips eliminates the abuse of tablets, and variation from the prescribed method of ingestion" |

## D. MARKETING SUBOXONE FILM TO HEALTH CARE PROVIDERS TO BE PRESCRIBED AND DISPENSED IN A CARELESS AND CLINICALLY UNWARRANTED MANNER

97. Beginning on an unknown date, but no later than on or about April 9, 2009, and continuing through the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents did aid, abet, counsel, command, induce, and procure physicians at various locations throughout the United States who they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than 24 mgs of

buprenorphine (*i.e.*, in excess of the maximum dose of any demonstrated additional clinical advantage), and in a careless and clinically unwarranted manner, to switch their prescribing to Suboxone Film.

98. One way in which INDIVIOR encouraged physicians to prescribe Suboxone Film was by including them in INDIVIOR's internet and telephone referral program, called "Here to Help." Patients and prospective patients could use the "Locate a Doctor" tool on the Here to Help website to find physicians prescribing buprenorphine-containing drugs, and could call the Here to Help hotline to receive information about certain physicians and have the call transferred to a physician's office to schedule an appointment. INDIVIOR salespeople told physicians that Here to Help was "like a concierge service."

99. Additionally, INDIVIOR salespeople provided physicians with marketing materials, billing advice, and access to lunch and dinner events through INDIVIOR's "Treatment Advocate" speaker program, including physicians they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than 24 mgs of buprenorphine (*i.e.*, in excess of the maximum dose of any demonstrated additional clinical advantage), and in a careless and clinically unwarranted manner.

100. INDIVIOR executives, employees, and personnel knew from statistical and firsthand reports that certain physicians had prescribed buprenorphine-containing drugs to substantially more patients at a time than allowed by the DATA, at daily doses higher than 24 mgs of buprenorphine, and in a careless and clinically unwarranted manner. No later than in or about April 2009, INDIVIOR managers began receiving statistical reports that identified physicians overprescribing buprenorphine-containing drugs. One manager emailed another, copying INDIVIOR's medical director, stating, "It takes only a short time perusing the

[statistical reports] to realize that we have some serious breaches of [the DATA law's cap on the number of patients a physician may treat] along with very careless and clinically unwarranted prescribing behaviors (% of patients above 24mg)," and certain physicians "need to be removed from the [buprenorphine] practice arena." INDIVIOR managers also received firsthand reports from INDIVIOR salespeople and medical advisors that particular physicians were engaged in "continuous prescribing to patients known to be trafficking in Suboxone/Subutex;" allowing "prescriptions [to be] given when provider not present in office;" "charg[ing] 400 per month" for prescriptions; and suspected of allowing "overt trafficking in provider's parking lot."

101. INDIVIOR executives were aware of the careless, clinically unwarranted prescribing. On or about July 22, 2009, INDIVIOR's chief executive officer wrote to INDIVIOR's vice president for clinical affairs, "I think that the process for reporting rogue physicians is going to be very important." On or about July 14, 2010, INDIVIOR executives met and discussed data indicating that the 564 highest-prescribing physicians in the United States prescribed buprenorphine-containing drugs to an average of more than 200 patients at a time, and the highest prescribers, which INDIVIOR called "Super P8s," accounted for 33% of INDIVIOR's business.

102. INDIVIOR continued to include physicians it knew were issuing careless, clinically unwarranted opioid prescriptions in the Here to Help and Treatment Advocate programs, and otherwise market Suboxone Film to them. On or about the stated dates, the identified INDIVIOR executives, employees, and agents communicated the information described below relating to aiding, abetting, counseling, commanding, inducing, and procuring Doctor A, located in or around Cedar Bluff, Galax, and Willis, Virginia, to switch prescriptions to Suboxone Film where Doctor A exceeded the maximum number of patients allowed at a time,

where daily doses exceeded the maximum indicated for additional clinical advantage, and where prescriptions were issued in a careless and clinically unwarranted manner:[5]

| Par. | Date(s) | Personnel | Information |
|---|---|---|---|
| 103 | 7/17/2008 | INDIVIOR Risk Mgr. to INDIVIOR Med. Advisor | Email: INDIVIOR Risk Mgr. suspected that Doctor A's clinic was one of two possible sources of "1 to 2 controlled buys of Suboxone per week" by law enforcement |
| 104 | 4/9/2009 | INDIVIOR Risk Mgr. and others | Received statistical report: Doctor A prescribed buprenorphine-containing drugs to 805 individuals in February 2009, at daily doses higher than 24 mgs of buprenorphine to 428 of those individuals |
| 105 | 8/28/2009 | INDIVIOR Sales Spvsr. to INDIVIOR Risk Mgr. | Firsthand report: Doctor A intentionally mislabeled prescriptions for buprenorphine-containing drugs as being for pain management, when also prescribed for opioid addiction, to evade detection for violating the DATA patient limit |
| 106 | 4/30/2010, 6/1/2011, 9/2/2011, 10/6/2011 | "Here to Help" telephone operators | Here to Help operators referred opioid-addiction/dependence patients to Doctor A, using lists of enrolled prescribers in the patients' geographic areas |
| 107 | 2011 | INDIVIOR Sales Rep. to INDIVIOR Sales Spvsr. | Reports: met with Doctor A at least 28 times to encourage Doctor A to prescribe Suboxone Film |
| 108 | 5/1/2012 | "Here to Help" telephone operator | Here to Help operator referred an opioid-addiction/dependence patient to Doctor A, using a list of enrolled prescribers in the patient's geographic area |
| 109 | 5/10/2012 | INDIVIOR Sales Rep. to INDIVIOR Med. Advisor | Email: successfully convinced Doctor A to switch to prescribing Suboxone Film, as "Basically I lived with [Doctor A] last fall, seeing her once or twice a week, every week, even Saturdays; and eventually it paid off and her share of tablet vs film completely flip flopped" |
| 110 | 4/12/2013, 4/26/2013 | "Here to Help" telephone operators | Here to Help operators referred opioid-addiction/dependence patients to Doctor A, using lists of enrolled prescribers in the patients' geographic areas |
| 111 | 9/10/2013 | INDIVIOR Sales Rep. to INDIVIOR Risk Mgr. | Firsthand report: Doctor A is "[m]assively over cap [the maximum patient limit allowed under the DATA] . . . she also overdoses. . . . This has been an ongoing problem since I started that only continues to get worse" |
| 112 | 12/13/2013, 11/3/2014, 3/10/2015, 3/13/2015, 3/18/2015, | "Here to Help" telephone operators | Here to Help operators referred opioid-addiction/dependence patients to Doctor A, using lists of enrolled prescribers in the patients' geographic areas |

[5] These are illustrative examples, not an exhaustive list.

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|---|---|---|---|
| | 4/27/2015, 5/26/2015, 5/26/2015, 6/18/2015, 7/8/2015 | | |

113. On or about the stated dates, the identified INDIVIOR executives, employees, and agents communicated the information described below relating to aiding, abetting, counseling, commanding, inducing, and procuring Doctors B and C, located in or around Johnson City, Tennessee, to switch prescriptions to Suboxone Film where Doctors B and C exceeded the maximum number of patients allowed at a time, where daily doses exceeded the maximum indicated for additional clinical advantage, and where prescriptions were issued in a careless and clinically unwarranted manner:

| Par. | Date(s) | Personnel | Information |
|---|---|---|---|
| 114 | 4/9/2009 | INDIVIOR Risk Mgr. and others | Received statistical report: in March 2009, Doctor B prescribed buprenorphine-containing drugs to 650 individuals, at daily doses higher than 24 mgs of buprenorphine to 618 of those individuals, and Doctor C prescribed buprenorphine-containing drugs to 635 individuals, at daily doses higher than 24 mgs of buprenorphine to 272 of those individuals |
| 115 | 4/9/2009 | INDIVIOR Employee, INDIVIOR Med. Advisor, and INDIVIOR Sales Spvsr. | Email re statistical report: "Notice your favorite, [Doctor B], is still at the top. I think now you can feel much more certain that he is likely a big source of diversion – 95% (618) of his patients are over 24mg. Wow!"<br>Email further discussing report: "It appears that the 'high' doses may be the contributing factor to the diversion that continues to be reported in the Tri-Cities area of SE KY, NE TN, and SW VA" |
| 116 | 5/28/2009 | INDIVIOR Risk Mgr. to INDIVIOR Exec. | Email: "I am concerned about the Tri-Cities area in northeast Tennessee (also includes southeast KY and southwest VA). Physicians are prescribing for too many patients and the dosing is very high in some circumstances. 14 treating over 200 patients – range 200 to 800. 8 of 14 are prescribing doses >24 mg for at least 50% of their patients" |
| 117 | 7/6/2009, 12/14/2009, 12/18/2009 | "Here to Help" telephone operators | Here to Help operators referred opioid-addiction/dependence patients to Doctor C, using lists of enrolled prescribers in the patients' geographic areas |
| 118 | 2/3/2010 | "Here to Help" telephone operator | Here to Help operator referred an opioid-addiction/dependence patient to Doctor B, using a list of enrolled prescribers in the patient's geographic area |

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| 119 | 2/5/2010 | "Here to Help" telephone operator | Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area |
| 120 | 4/8/2010 | INDIVIOR Sales Sprvsr. to INDIVIOR National Sales Sprvsr. | Email: Doctor B is "well over the allowed patient cap," and Doctor C's office "will prescribe to as many patients as they can fit in [while physicians are] in about 2-3 hours each week. In that time they quickly see the patient & provide a script" |
| 121 | 6/2/2010 | "Here to Help" telephone operator | Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area |
| 122 | 11/20/2010 | INDIVIOR Exec. to INDIVIOR Salespeople | Award: INDIVIOR sales rep. marketing Suboxone Film to Doctors B and C named Suboxone Film Marketing Blitz "Contest Winner" and credited with "incredible performance . . . 13 times the initial Contest patient threshold" |
| 123 | 2010 | INDIVIOR Exec. to INDIVIOR Salespeople | Award: INDIVIOR sales rep. marketing Suboxone Film to Doctors B and C recognized as INDIVIOR's sales rep. of the year |
| 124 | 2010-2011 | INDIVIOR Sales Rep. to INDIVIOR Sales Sprvsr. | Reports: met with Doctors B and C at least 75 times to encourage them to prescribe Suboxone Film |
| 125 | 1/23/2012 | "Here to Help" telephone operator | Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area |
| 126 | 4/22/2013 | INDIVIOR Sales Rep. and INDIVIOR Sales Sprvsr. to INDIVIOR Mgr. | Conversation: "It's a liability almost that we're even walking into these offices, these two main clinic offices [of Doctor C], because of how criminal it is. Like they have a Vegas-style cash machine sitting behind the office where they're taking stacks of hundreds and shoving it in there while we're trying to like, detail the nurse. It's like the mob. It's awful" |
| 127 | 8/9/2013 | "Here to Help" telephone operator | Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area |

128. On or about the stated dates, the identified INDIVIOR executives, employees, and agents communicated the information described below relating to aiding, abetting, counseling, commanding, inducing, and procuring Doctor D, located in or around Danville, Kentucky, to switch prescriptions to Suboxone Film where Doctor D exceeded the maximum number of patients allowed at a time, where daily doses exceeded the maximum indicated for additional clinical advantage, and where prescriptions were issued in a careless and clinically unwarranted manner:

| Par. | Date(s) | Personnel | Information |
|---|---|---|---|
| 129 | 6/25/2008 | INDIVIOR Sales Sprvsr. to INDIVIOR Sales Rep. | Coaching form: "Continue to Partner with [Doctor D's clinic] and their growing . . . organization. While it can appear the program is on auto-pilot, they still have much to learn, and we can help" |
| 130 | 7/11/2008 | INDIVIOR Sales Rep. to INDIVIOR Sales Sprvsr. | Report: "The 2nd [office of Doctor D's clinic] opened in Barboursville, the third one is scheduled to open in August and that will be in Frankfurt. The plan is to have 10 physicians in each clinic. Expanding trx in the South, one clinic at a time!" |
| 131 | 12/17/2008 | INDIVIOR Med. Advsr. to INDIVIOR Risk Mgr. and INDIVIOR Sales Sprvsr. | Email: Doctor D "is in difficulties with his organization of 30 MDs related to prescribing of Suboxone. This stems perhaps from a couple of problem patients and led to a state board investigation. Most of their patients are on 24 mg daily. . . . Is this group in Kentucky an area of concern for us? Is there any follow-up needed?" |
| 132 | 7/23/2009, 8/13/2009, 8/31/2009 | "Here to Help" telephone operators | Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas |
| 133 | 9/23/2009 | Doctor D to INDIVIOR Gov. Mgr. and INDIVIOR Sales Rep. | Email: "We are even more excited about the opportunities we have to facilitate each others' [sic] success. . . . We will keep our noses to the grindstone getting our program of care 'refined' and ask that you continue to keep your brain grinding on how to best 'use' us everywhere and any way it makes sense. We will keep [INDIVIOR] updated as we collaborate with Medicaid, private payors, the VA system, and anything/anyone else we come across. We are pursuing multiple grants as of yesterday evening for the call centerdatabase [sic]/website plan and indigent care for opiate addicts (those with no pay source), but if there is any way [INDIVIOR] can get involved financially, there will be great business benefit for [INDIVIOR] in the end (more patients being prescribed SBX) and amazing PR for each state you support" |
| 134 | 9/23/2009 | INDIVIOR Sales Sprvsr. to INDIVIOR Gov. Mgr. | Email: "We have had a difficult time giving [Doctor D] what he wanted, because most of his requests are out of pharma guidelines. . . . I can see you were able to provide him with opportunities and information that he sees as very valuable to his treatment center plans and goals. Thank you for helping [ensure Doctor D's clinic] sees the Integrated Value [INDIVIOR] has to offer" |
| 135 | 1/4/2010, 5/13/2010, 5/17/2010, 9/7/2010, 9/30/2010, 10/19/2010, 10/26/2010, 11/10/2010 | "Here to Help" telephone operators | Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas |

| | | | |
|---|---|---|---|
| 136 | 12/8/2010 | Doctor D to INDIVIOR Gov. Mgrs., INDIVIOR Sales Rep., and others | Report: in one month, Doctor D's clinic had prescribed buprenorphine-containing drugs to 1,659 individuals, at daily doses higher than 24 mgs of buprenorphine to 39% of them, and at daily doses of at least 24 mgs of buprenorphine to 76% of them. INDIVIOR's Public Sector Dir. forwarded the report to others at INDIVIOR, stating, "[w]ith over 76% of the patients at 24 mg and above, we have some serious work today in educating his organization and the physicians about dosing and overall quality care. The reverse should likely be the case" |
| 137 | 12/23/2010, 1/5/2011, 1/10/2011, 1/28/2011, 3/25/2011, 4/21/2011, 4/22/2011, 5/5/2011, 5/11/2011, 5/16/2011, 5/17/2011, 5/25/2011, 6/8/2011, 6/27/2011, 8/12/2011, 8/15/2011, 8/19/2011, 9/15/2011, 10/3/2011, 10/19/2011, 11/4/2011, 11/30/2011 | "Here to Help" telephone operators | Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas |
| 138 | 2011 | INDIVIOR Exec. to INDIVIOR Salespeople | Award: INDIVIOR sales rep. marketing Suboxone Film to Doctor D's clinic recognized as INDIVIOR's sales rep. of the year |
| 139 | 2/2/2012 | INDIVIOR Sales Rep. to INDIVIOR Sales Sprvsr. | Email: INDIVIOR to sponsor Doctor D's clinic's annual meeting, including breakfast and lunch for 46 people |
| 140 | 2/13/2012, 2/16/2012, 3/7/2012, 4/9/2012, 4/18/2012, 5/2/2012, 5/16/2012 | "Here to Help" telephone operators | Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas |

| | | | |
|---|---|---|---|
| 141 | 6/4/2012 | Kentucky Board of Medical Licensure | Indefinite restriction of Doctor D's authorization to prescribe buprenorphine-containing drugs for use in opioid addiction/dependence treatment |
| 142 | 6/25/2012 through 12/2/2016 | "Here to Help" telephone operators | About 140 instances in which Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas |
| 143 | 11/5/2015 through 3/31/2017 | United States District Court for the Eastern District of Kentucky | Doctor D indicted on 11/5/2015 for health care fraud related to urine testing; found guilty of 17 counts on 3/31/2017 |

**SUBOXONE TABLET PRICE INCREASES TO SUPPORT SCHEME**

144. Between in or about 2010 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents also increased the price of Suboxone Tablet to cause patients to switch to Suboxone Film. In or about October 2011, an INDIVIOR manager told colleagues, "I could not support a tablet [price] increase again before next October. That would be essentially another 37% over 24 months. . . . If we are considering the patient in all of this, then we need to understand that 40% will have to remain on the tablet due to supply constraints. . . . We also need to consider the public health backlash and that of physicians." In or about July 2012, INDIVIOR increased the price of Suboxone Tablet by 15%, stating the "Rationale of Price Increase" as "accelerate conversion to Film."

**REVENUE AND PROFIT**

145. In or about the specified years, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.) and Company A received approximately the following revenues from sales of Suboxone Film:

| Year | Revenue |
|---|---|
| 2010 | $83,328,721 |
| 2011 | $400,615,412 |
| 2012 | $666,695,781 |

| | |
|---|---|
| 2013 | $887,469,559 |
| 2014 | $843,047,500 |

In or about the same years, Medicare and Medicaid payments for Suboxone Film were approximately as follows:

| Year | Medicare | Medicaid |
|---|---|---|
| 2010 | $2,134,000 | $7,136,000 |
| 2011 | $26,188,000 | $108,079,000 |
| 2012 | $70,329,000 | $211,294,000 |
| 2013 | $132,984,000 | $326,666,000 |
| 2014 | $147,704,000 | $386,685,000 |

146. In or about September 2012, Company A stated that it would give "special recognition awards" of thousands of shares of Company A stock to about ten INDIVIOR executives and managers for the commercial success of Suboxone Film, saying it had "created a long-term sustainable business model for" INDIVIOR.

147. On or about August 5, 2013, INDIVIOR's chief executive officer emailed Company A's chief executive officer and others, stating that Suboxone Film's share of the market had grown to 69.1%, which was "almost enough to make you wonder when we will break through the 70% share barrier?" Company A's chief executive officer replied-all, "I agree, our US team has done a fantastic job of defending our film share thus far."

148. On or about November 17, 2013, INDIVIOR's chief executive officer stated to an INDIVIOR manager that in switching physicians, pharmacists, health care benefit programs, and others to Suboxone Film, INDIVIOR had achieved "the best format conversion ever in the history of the industry."

## COUNT ONE
**Conspiracy to Commit Mail, Wire, and Health Care Fraud**

The Grand Jury charges that:

1. The Introduction to this Indictment and the factual allegations of Counts Two through Twenty-eight are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury knowingly conspired to commit the following offenses:

a. Mail fraud, in violation of Title 18, United States Code, Section 1341, that is, having devised and intending to devise the scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises described in the Introduction to this Indictment, and for the purpose of executing such scheme and artifice and attempting to do so, did knowingly cause to be delivered by the Postal Service and any private or commercial interstate carrier certain matters and things according to the directions thereon;

b. Wire fraud, in violation of Title 18, United States Code, Section 1343, that is, having devised and intending to devise the scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises described in the Introduction to this Indictment, and for the purpose of executing such scheme and artifice and attempting to do so, transmitted and caused to be transmitted by means of wire communication in interstate commerce writings, signals, and sounds;

c. Health care fraud, in violation of Title 18, United States Code, Section 1347, that is, knowingly and willfully executed and attempted to execute the scheme and artifice to defraud and to obtain by means of materially false and fraudulent pretenses, representations, and promises money and property owned by and under the custody and control of Medicare, Medicaid, private insurance providers, and other health care benefit programs in connection with the delivery of and payment for health care benefits, items, and services, described in the Introduction of this Indictment.

3. In furtherance of the conspiracy, and to effect its object, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury committed the overt acts described in the Introduction to this Indictment, and Counts Two through Twenty-eight of this Indictment.

4. All in violation of Title 18, United States Code, Section 1349.

## COUNT TWO
**Health Care Fraud**

The Grand Jury charges that:

1. The Introduction to this Indictment and the factual allegations of Counts One and Three through Twenty-eight are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC and INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, as principals and aiders and abettors, knowingly and willfully executed and attempted to execute a scheme and artifice to (1) defraud health care benefit programs as defined in Title 18, United States Code, Section 24(b), including Medicaid, Medicare, other public health care programs, private insurance providers, and other health care benefit programs, and (2) obtain by means of

materially false and fraudulent pretenses, representations, and promises, money and property owned by and under the custody and control of said health care benefit programs, in connection with the delivery of and payment for health care benefits, items, and services.

3. It was the object of the scheme and artifice to fraudulently induce physicians to write prescriptions for Suboxone Film, pharmacists to fill prescriptions for Suboxone Film, and health care benefit programs to provide coverage of prescriptions for Suboxone Film, and to cause:

a. Patients to obtain Suboxone Film from pharmacies and others;

b. Patients, pharmacies, and others to submit claims for Suboxone Film to health care benefit programs;

c. Health care benefit programs to pay claims for Suboxone Film;

d. Pharmacies and others to make payments to wholesalers, distributors, and others for Suboxone Film; and

e. Wholesalers, distributors, and others to make payments to INDIVIOR PLC and INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.) for sales of Suboxone Film made as a result of the scheme and artifice to defraud.

4. In furtherance of the scheme and artifice, and to effect its object, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, for the purpose of causing health care providers and others to prescribe and dispense Suboxone Film, and to recommend the prescribing and dispensing of Suboxone Film, did, and aided, abetted, counseled, commanded, induced, and procured others to, make materially false and fraudulent statements and representations, including the following:

a. Representing to physicians, pharmacists, and other health care providers that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, and has other unsubstantiated effects such as weeding out drug seekers, making patients feel less like addicts, protecting physicians from being criminally prosecuted, and protecting office-based treatment of opioid addiction/dependence from being banned;

b. Producing and disseminating printed marketing materials representing that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, containing misleading text, graphics, and charts;

c. Representing to government officials, employees, and agents administering various state Medicaid programs, and others, that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, to cause such government officials, employees, and agents, and others to expand and maintain Medicaid coverage of Suboxone Film at substantial cost to the government and substantial profit to the defendants; and

d. Providing patient referrals, presentations, marketing materials, access to lunch and dinner events, and other benefits to physicians they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than the maximum dose of any demonstrated additional clinical advantage (*i.e.*, 24 mgs of buprenorphine), and in a careless and clinically unwarranted manner.

5. All in violation of Title 18, United States Code, Sections 2 and 1347.

## COUNTS THREE THROUGH SIX
**Mail Fraud**

The Grand Jury charges that:

1. The Introduction and the factual allegations of Counts One through Two and Seven through Twenty-eight are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, with the intent to defraud, devised and willfully participated in, with knowledge of its fraudulent nature, the scheme and artifice to defraud and obtain money and property by materially false and fraudulent pretenses, representations, and promises described in the Introduction and in the factual allegations of Counts One through Two and Seven through Twenty-eight of this Indictment.

3. On or about the date specified as to each count below, in the Western District of Virginia, for the purpose of executing and attempting to execute such scheme and artifice to defraud, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury caused to be delivered by mail and private or commercial interstate carrier according to the direction thereon, the named matter and thing, namely, marketing visual aids containing materially false and fraudulent representations that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, including misleading text, graphics, and charts, to an INDIVIOR sales representative in Roanoke, Virginia, who promoted Suboxone Film to physicians, pharmacists, and others in locations including Blacksburg, Cedar Bluff, Charlottesville, Christiansburg, Danville, Galax, Lynchburg, Roanoke, Salem, Staunton, Willis, and Wytheville, Virginia:

| COUNT | DATE |
|---|---|
| THREE | February 6, 2012 |
| FOUR | January 4, 2013 |
| FIVE | March 21, 2013 |
| SIX | August 19, 2013 |

4. All in violation of Title 18, United States Code, Sections 2 and 1341.

**COUNTS SEVEN THROUGH TWENTY-EIGHT**
**Wire Fraud**

The Grand Jury charges that:

1. The Introduction and the factual allegations of Counts One through Six are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, with the intent to defraud, devised and willfully participated in, with knowledge of its fraudulent nature, the scheme and artifice to defraud and obtain money and property by materially false and fraudulent pretenses, representations, and promises described in the Introduction and the factual allegations of Counts One through Six of this Indictment.

3. On or about the date specified as to each count below, in the Western District of Virginia and elsewhere, for the purpose of executing and attempting to execute such scheme and artifice to defraud, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, caused to be transmitted by wire communication or radio communication in interstate and foreign commerce, writings, signs, signals, pictures, and sounds, namely, reports of clinical liaisons falsely and fraudulently representing to physicians, pharmacists, and other health care providers that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child

exposure than other, similar drugs, transmitted from Florida and New Jersey to locations in the Western District of Virginia, and referrals of prospective patients to Doctor A, transmitted from Pennsylvania to locations in the Western District of Virginia, as described below:

| COUNT | DATE | ITEM |
|---|---|---|
| SEVEN | April 30, 2010 | Referral to Doctor A |
| EIGHT | October 9, 2010 | Activity Report with Model Safety Claims |
| NINE | October 24, 2010 | Activity Report with Model Safety Claims |
| TEN | November 29, 2010 | Activity Report with Model Safety Claims |
| ELEVEN | June 1, 2011 | Referral to Doctor A |
| TWELVE | July 8, 2011 | Activity Report with Model Safety Claims |
| THIRTEEN | September 2, 2011 | Referral to Doctor A |
| FOURTEEN | October 6, 2011 | Referral to Doctor A (1 of 2 on this date) |
| FIFTEEN | October 6, 2011 | Referral to Doctor A (2 of 2 on this date) |
| SIXTEEN | May 1, 2012 | Referral to Doctor A |
| SEVENTEEN | April 12, 2013 | Referral to Doctor A |
| EIGHTEEN | April 26, 2013 | Referral to Doctor A |
| NINETEEN | December 13, 2013 | Referral to Doctor A |
| TWENTY | November 3, 2014 | Referral to Doctor A |
| TWENTY-ONE | March 10, 2015 | Referral to Doctor A |
| TWENTY-TWO | March 13, 2015 | Referral to Doctor A |
| TWENTY-THREE | March 18, 2015 | Referral to Doctor A |
| TWENTY-FOUR | April 27, 2015 | Referral to Doctor A |
| TWENTY-FIVE | May 26, 2015 | Referral to Doctor A (1 of 2 on this date) |
| TWENTY-SIX | May 26, 2015 | Referral to Doctor A (2 of 2 on this date) |
| TWENTY-SEVEN | June 18, 2015 | Referral to Doctor A |
| TWENTY-EIGHT | July 8, 2015 | Referral to Doctor A |

4. All in violation of Title 18, United States Code, Sections 2 and 1343.

**NOTICE OF FORFEITURE**

1. The Introduction and the factual allegations of Counts One through Twenty-Eight of this Indictment are realleged and made part of this Notice.

2. Upon conviction of one or more of the felony offenses alleged in this Indictment, INDIVIOR PLC and INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.) shall forfeit to the United States:

a. pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), any property, real or personal, which constitutes, or is derived from proceeds traceable to a violation of any offense constituting "specified unlawful activity" (as defined in section 1956(c)(7)), or a conspiracy to commit such offense; and

b. pursuant to 18 U.S.C. § 982(a)(7), property, real or personal, that constitutes, or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

3. The property to be forfeited to the United States includes, but is not limited to, the following:

a. **Monetary Judgment:** Not less than $3,000,000,000 (three billion dollars) in United States currency and all interest and proceeds traceable thereto, in that such sum in aggregate was obtained directly or indirectly as a result of said offenses or is traceable to such property.

b. **Business Entities (including all assets, inventory, and property related thereto):** Indivior Finance (2014) LLC; Indivior Finance SARL; Indivior Global Holdings Ltd (a/k/a RBP Global Holdings Limited); Indivior Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.); Indivior PLC; Indivior Solutions Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Solutions Inc.); and Indivior US Holdings Inc. (f/k/a RBP US Holdings Inc.).

c. **Bank Accounts, all funds received and on deposit as set forth below:**

| | Bank | Account Name | Account # |
|---|---|---|---|
| (1) | JP Morgan Chase | Indivior Inc. | [redacted]299 |
| (2) | JP Morgan Chase | Indivior Inc. | [redacted]419 |
| (3) | JP Morgan Chase | Indivior Inc. | [redacted]420 |

| | | | |
|---|---|---|---|
| (4) | JP Morgan Chase | Indivior Solutions Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Solutions Inc.) | [redacted]148 |
| (5) | Institutional Cash Distributors (ICD), LLC | Indivior Inc./Indivior plc | |

4. If any of the above-described forfeitable property, as a result of any act or omission of the defendant, cannot be located upon the exercise of due diligence; has been transferred or sold to or deposited with a third person; has been placed beyond the jurisdiction of the Court; has been substantially diminished in value; or has been commingled with other property which cannot be subdivided without difficulty; it is the intent of the United States to seek forfeiture of any other property of the defendant up to the value of the above described forfeitable property pursuant to 21 U.S.C. § 853(p), including the assets described above, and including but not limited to the following assets:

a. **Trademarks:**

| | **Serial No., Registration No.** |
|---|---|
| (1) | 86779039 |
| (2) | 86779033 |
| (3) | 86779029 |
| (4) | 86779026 |
| (5) | 79151424, 4718643 |

b. **Patents:**

| | **Patent Number** | **Patent Title** |
|---|---|---|
| (1) | 8,475,832 | Sublingual and buccal film compositions |
| (2) | 8,497,280 | Medicinal compositions comprising buprenorphine and nalmefene |

| | | |
|---|---|---|
| (3) | 8,697,718 | Pack of medicinal tablets |
| (4) | 8,912,211 | Medicinal compositions comprising buprenorphine and naltrexone |
| (5) | 8,921,387 | Injectable flowable composition comprising buprenorphine |
| (6) | 8,975,270 | Injectable flowable composition comprising buprenorphine |
| (7) | 9,101,625 | Buprenorphine-wafer for drug substitution therapy |
| (8) | 9,180,197 | Sustained delivery formulations of risperidone compounds |
| (9) | 9,186,413 | Sustained delivery formulations of risperidone compounds |
| (10) | 9,272,044 | Injectable flowable composition buprenorphine |
| (11) | 9,370,512 | Buprenorphine-wafer for drug substitution therapy |

c. **Accounts Receivable, all amounts due from the following entities:**

| | |
|---|---|
| (1) | Amerisource Bergen |
| (2) | ANDA |
| (3) | Besse Medical |
| (4) | Burlington Drug |
| (5) | Capital Wholesale |
| (6) | Cardinal Health |
| (7) | Dakota Drug Inc |
| (8) | Dixon Shane LLC |
| (9) | DMS Pharmaceutical Group |
| (10) | Harvard Drug Group |
| (11) | HD Smith Wholesale |
| (12) | Integrated Commercialization Solutions |
| (13) | JM Smith |
| (14) | Louisiana Wholesale Drug Company |

| | |
|---|---|
| (15) | Luis Garraton |
| (16) | McKesson |
| (17) | Miami-Luken Inc. |
| (18) | Morris Dickson |
| (19) | MWI Vet Supply |
| (20) | NC Mutual Wholesale |
| (21) | Prescription Supply Company |
| (22) | Quality King Distributors |
| (23) | R & S Sales |
| (24) | Rochester Drug Cooperative |
| (25) | Smith Drug Company |
| (26) | Valley Wholesale Drug Company |
| (27) | Value Drug Company |

A TRUE BILL, this 14 day of August, 2019.

/s/ Grand Jury Foreperson

Randy Ramsey
for DANIEL P. BUBAR
First Assistant United States Attorney
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515

GUSTAV W. EYLER
Director
Consumer Protection Branch
Department of Justice