APPENDIX

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APPENDIX A

NOT RECOMMENDED FOR PUBLICATION
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UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Case No. 20-3192

[Filed October 16, 2020]

UNITED STATES OF AMERICA, Plaintiff-Appellee,	)
v.	)
MARGARET TEMPONERAS, Defendant-Appellant.	)

BEFORE: SUTTON, THAPAR, and READLER, Circuit Judges.

THAPAR, Circuit Judge. Doctor Margaret Temponeras was in the business of prescribing pain medication. She prescribed too much, too often, with too little regard for the consequences. That was illegal, and she was convicted of violating federal law. We affirm.

Temponeras owned and operated a pain-management medical practice. Many aspects of her work raised eyebrows. She prescribed unusually high

volumes of addictive painkillers. Her patients paid mostly in cash. Some traveled long distances every month to see her. Some had track marks on their arms and other signs of drug addiction. When local pharmacies stopped filling her prescriptions, she pressed forward with her own in-house dispensary. Her suspect practices led to tragic consequences: In less than three years, eight of her patients died from drug overdoses.

Temponeras pled guilty to conspiring to distribute a controlled substance outside the usual course of professional practice. *See* 21 U.S.C. §§ 841(a)(1), (b)(1)(C), 846; 21 C.F.R. § 1306.04(a). In the plea agreement, the parties stipulated to a sentence of 36 to 84 months in prison, significantly less than the applicable Guidelines range of 210 to 240 months. The district court accepted the plea agreement and sentenced Temponeras to 84 months. This appeal followed.

Temponeras provides three reasons we should vacate her sentence. The first is that her conviction is based on an unconstitutionally vague law. The other two focus on alleged misconduct by the government at sentencing. She raised none of these objections before the district court, so our review is for plain error. Fed. R. Crim. P. 52(b). But under any standard of review, we would reach the same result.

Vagueness. The Controlled Substances Act criminalizes the "[un]authorized" distribution or dispensing of controlled substances. 21 U.S.C. § 841(a)(1). When a doctor prescribes medication "for a legitimate medical purpose . . . in the usual course of

[her] professional practice," her actions are authorized. 21 C.F.R. § 1306.04(a); *see* 21 U.S.C. § 829. Otherwise, she violates the Act. 21 U.S.C. § 841(a).

Temponeras says that this standard—a legitimate medical purpose in the usual course of professional practice—is unconstitutionally vague as applied to her. *See Holder v. Humanitarian Law Project*, 561 U.S. 1, 18–19 (2010). But Temponeras admitted that she was "aware of a high probability" that her prescription practices were neither for a legitimate medical purpose nor part of the usual course of professional practice; indeed she "deliberately closed her eyes" to the "obvious." R. 89, Pg. ID 664–65. So she cannot now claim that the law was too vague for her to "understand what [was] prohibited." *United States v. Krumrei*, 258 F.3d 535, 537, 539 (6th Cir. 2001) (citation omitted).

Prosecutorial Misconduct. At Temponeras's sentencing hearing, the government introduced five exhibits not mentioned in its sentencing memorandum. Temponeras believes that this last-minute introduction violated Rule 32's regulation of sentencing proceedings and the district court's scheduling order. *See* Fed. R. Crim. P. 32(i). Though she failed to object before the district court, she asserts now that the violation was so egregious that it constituted prosecutorial misconduct.

One problem with her theory is that a claim of prosecutorial misconduct requires prejudice. *United States v. Coker*, 514 F.3d 562, 568 (6th Cir. 2008). Temponeras claims she was left flat-footed and unprepared to respond to the new exhibits. But the district court expressly disavowed reliance on these materials. Indeed, other than to state it was "not

focused on the[m]," the court never acknowledged their existence or contents. R. 107, Pg. ID 791. So the alleged violation left Temponeras no worse off than she was before.

Breach of the Plea Agreement. Finally, Temponeras contends that the government "flagrant[ly]" breached the terms of the plea agreement by "instruct[ing] the district court" that the agreement precluded consideration of certain mitigating factors. Appellant Br. 22. But the government said no such thing; it explained its belief that no mitigating factors warranted an even greater variance from the Guidelines than the agreement already generously provided. R. 107, Pg. ID 789–90. Nothing in the plea agreement prohibited this argument. *See* R. 89, Pg. ID 658–62.

We affirm.

APPENDIX B

UNITED STATES DISTRICT COURT
Southern District of Ohio

Case Number: 1:15-cr-65
USM Number: 73070-061

[Filed February 3, 2020]

UNITED STATES OF AMERICA	)
	)
v.	)
	)
MARGARET TEMPONERAS (1)	)
	)

JUDGMENT IN A CRIMINAL CASE

Jeanne Cors
Defendant's Attorney

THE DEFENDANT:

☑ pleaded guilty to count(s) Count 1 of the Indictment

* * *

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
21 USC §§ 841(a)(1), (b)(1)(C) & 846	Conspiracy to Distribute a Controlled Substance	05/17/2011	1

The defendant is sentenced as provided in pages 2 through 7 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

* * *

☑ Count(s) 2, 3, & 4 ☑ are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments, imposed by, this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

11/12/2019
Date of Imposition of Judgment

s/ Timothy S. Black
Signature of Judge

Timothy S. Black, United States District Judge
Name and Title of Judge

2/3/2020
Date

IMPRISONMENT

The defendant is hereby committed to the custody of the Federal Bureau of Prisons to be imprisoned for a total term of:

Eighty-Four (84) months

☑ The court makes the following recommendations to the Bureau of Prisons:

- Placement in Federal Medical Center at Lexington

* * *

☑ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

☑ as notified by the United States Marshal.

* * *

SUPERVISED RELEASE

Upon release from imprisonment, you will be on supervised release for a term of:

Three (3) years

MANDATORY CONDITIONS

1. You must not commit another federal, state or local crime.

2. You must not unlawfully possess a controlled substance.

3. You must refrain from any unlawful use of a controlled substance. You must submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court.

   ☑ The above drug testing condition is suspended, based on the court's determination that you pose a low risk of future substance abuse. *(check if applicable)*

4. □ You must make restitution in accordance with 18 U.S.C. § 3663 and 3663A or any other statute authorizing a sentence of restitution. *(check if applicable)*

5. ☑ You must cooperate in the collection of DNA as directed by the probation officer. *(check if applicable).*

6. □ You must comply with the requirements of the Sex Offender Registration and Notification Act (34 U.S.C. § 20901, *et seq*.) as directed by the probation officer, the Bureau of Prisons, or any state sex offender registration agency in the location where you reside, work, are a student, or were convicted of a qualifying offense. *(check if applicable).*

7. □ You must participate in an approved program for domestic violence. *(check if applicable)*

You must comply with the standard conditions that have been adopted by this court as well as with any other conditions on the attached page.

STANDARD CONDITIONS OF SUPERVISION

As part of your supervised release, you must comply with the following standard conditions of supervision. These conditions are imposed because they establish the basic expectations for your behavior while on supervision and identify the minimum tools needed by probation officers to keep informed, report to the court about, and bring about improvements in your conduct and condition.

1. You must report to the probation office in the federal judicial district where you are authorized to reside within 72 hours of your release from imprisonment, unless the probation officer instructs you to report to a different probation office or within a different time frame.

2. After initially reporting to the probation office, you will receive instructions from the court or the probation officer about how and when you must report to the probation officer, and you must report to the probation officer as instructed.

3. You must not knowingly leave the federal judicial district where you are authorized to reside without first getting permission from the court or the probation officer.

4. You must answer truthfully the questions asked by your probation officer.

5. You must live at a place approved by the probation officer. If you plan to change where you live or anything about your living arrangements (such as the people you live with), you must notify the probation officer at least 10 days before the change. If notifying the probation officer in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.

6. You must allow the probation officer to visit you at any time at your home or elsewhere, and you must permit the probation officer to take any items prohibited by the conditions of your supervision that he or she observes in plain view.

7. You must work full time (at least 30 hours per week) at a lawful type of employment, unless the probation officer excuses you from doing so. If you do not have full-time employment you must try to find full-time employment, unless the probation officer excuses you from doing so. If you plan to change where you work or anything about your work (such as your position or your job responsibilities), you must notify the probation officer at least 10 days before the change. If notifying the probation officer at least 10 days in advance is not possible due to unanticipated circumstances, you must notify

the probation officer within 72 hours of becoming aware of a change or expected change.

8. You must not communicate or interact with someone you know is engaged in criminal activity. If you know someone has been convicted of a felony, you must not knowingly communicate or interact with that person without first getting the permission of the probation officer.

9. If you are arrested or questioned by a law enforcement officer, you must notify the probation officer within 72 hours.

10. You must not own, possess, or have access to a firearm, ammunition, destructive device, or dangerous weapon (i.e., anything that was designed, or was modified for, the specific purpose of causing bodily injury or death to another person such as nunchakus or tasers).

11. You must not act or make any agreement with a law enforcement agency to act as a confidential human source or informant without first getting the permission of the court.

12. If the probation officer determines that you pose a risk to another person (including an organization), the probation officer may require you to notify the person about the risk and you must comply with that instruction. The probation officer may contact the person and confirm that you have notified the person about the risk.

13. You must follow the instructions of the probation officer related to the conditions of supervision.

U.S. Probation Office Use Only

A U.S. probation officer has instructed me on the conditions specified by the court and has provided me with a written copy of this judgment containing these conditions. For further information regarding these conditions, see *Overview of Probation and Supervised Release Conditions*, available at: www.uscourts.gov.

Defendant's Signature _____

Date _____

SPECIAL CONDITIONS OF SUPERVISION

1. The defendant shall not be employed directly or indirectly in the medical field and shall not prescribe medication.

2. The defendant shall provide the probation officer with access to any requested financial information and authorize the release of any financial information; and

3. The defendant shall not incur new credit charges on existing lines of credit, or open additional lines of credit without the approval of the probation officer.

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	JVTA Assessment*	Fine	Restitution
TOTALS	$100.00		$75,000.00	

* * *

☑ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☑ the interest requirement is waived for the ☑ fine

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties is due as follows:

A ☑ Lump sum payment of $ 75,100.00 due immediately, balance due

☑ in accordance with ☑ F below; or

* * *

F ☑ Special instructions regarding the payment of criminal monetary penalties:

While incarcerated, if Defendant is working in a non-UNICOR or grade UNICOR job, Defendant shall pay $25 per quarter toward her financial obligation. If Defendant is working in a grade 1-4 UNICOR job, Defendant shall pay 50% of her monthly pay toward his financial obligation. Any change in this schedule of payments shall be made

only by order of this Court. Within 30 days of commencement of supervision, Defendant shall begin making payments toward any outstanding portion of her criminal financial obligations, pursuant to a payment plan as determined by the Probation Officer and approved by the Court.

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during the period of imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

* * *

☑ The defendant shall forfeit the defendant's interest in the following property to the United States:

Proceeds gained from the unlawful prescriptions written at Unique Pain Management.

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) JVTA assessment, (8) penalties, and (9) costs, including cost of prosecution and court costs.

APPENDIX C

21 U.S.C. § 841 - Prohibited acts

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

(b) Penalties

Except as otherwise provided in section 849, 859, 860, or 861 of this title, any person who violates subsection

(a) of this section shall be sentenced as follows:

(1)

(A) In the case of a violation of subsection (a) of this section involving—

(i) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(ii) 5 kilograms or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 280 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N- [1-(2-phenylethyl) -4-piperidinyl] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(vii) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 1,000 or more marihuana plants regardless of weight; or

(viii) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 10 years or more than life and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $10,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, such person shall be sentenced to a term of imprisonment of not less than 15 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $20,000,000 if the defendant is an individual or $75,000,000 if the defendant is other than an individual, or both. If any person commits a violation of this subparagraph or of section 849, 859, 860, or 861 of this title after 2 or more prior convictions for a serious drug felony or serious violent felony have become final, such person shall be sentenced to a term of imprisonment of not less than 25 years and fined in accordance with the preceding sentence. Notwithstanding section 3583 of title 18, any sentence under this subparagraph shall, in the absence of such

a prior conviction, impose a term of supervised release of at least 5 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(B) In the case of a violation of subsection (a) of this section involving—

(i) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(ii) 500 grams or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 28 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N- [1-(2-phenylethyl) -4-piperidinyl] propanamide or 10 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(vii) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 100 or more marihuana plants regardless of weight; or

(viii) 5 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 50 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $5,000,000 if the defendant is an individual or $25,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has

become final, such person shall be sentenced to a term of imprisonment which may not be less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $8,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence imposed under this subparagraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to such term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(C) In the case of a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000), or 1 gram of flunitrazepam, except as provided in subparagraphs (A), (B), and (D), such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years or

more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this subparagraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(D) In the case of less than 50 kilograms of marihuana, except in the case of 50 or more marihuana plants regardless of weight, 10 kilograms of hashish, or one kilogram of hashish oil, such person shall, except as

provided in paragraphs (4) and (5) of this subsection, be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment.

(E)

(i) Except as provided in subparagraphs (C) and (D), in the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 10 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 15 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an

individual or $2,500,000 if the defendant is other than an individual, or both.

(ii) If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 30 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both.

(iii) Any sentence imposing a term of imprisonment under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment.

(2) In the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions

of title 18 or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least one year in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment.

(3) In the case of a controlled substance in schedule V, such person shall be sentenced to a term of imprisonment of not more than one year, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $100,000 if the defendant is an individual or $250,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 4 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $200,000 if the defendant is an individual or $500,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph may, if there was a prior conviction, impose a term of supervised release of not more than 1 year, in addition to such term of imprisonment.

(4) Notwithstanding paragraph (1)(D) of this subsection, any person who violates subsection (a) of this section by distributing a small amount of

marihuana for no remuneration shall be treated as provided in section 844 of this title and section 3607 of title 18.

(5) Any person who violates subsection (a) of this section by cultivating or manufacturing a controlled substance on Federal property shall be imprisoned as provided in this subsection and shall be fined any amount not to exceed—

(A) the amount authorized in accordance with this section;

(B) the amount authorized in accordance with the provisions of title 18;

(C) $500,000 if the defendant is an individual; or

(D) $1,000,000 if the defendant is other than an individual; or both.

(6) Any person who violates subsection (a), or attempts to do so, and knowingly or intentionally uses a poison, chemical, or other hazardous substance on Federal land, and, by such use—

(A) creates a serious hazard to humans, wildlife, or domestic animals,

(B) degrades or harms the environment or natural resources, or

(C) pollutes an aquifer, spring, stream, river, or body of water,

shall be fined in accordance with title 18 or imprisoned not more than five years, or both.

(7) Penalties for distribution.—

(A) In general.—

Whoever, with intent to commit a crime of violence, as defined in section 16 of title 18 (including rape), against an individual, violates subsection (a) by distributing a controlled substance or controlled substance analogue to that individual without that individual's knowledge, shall be imprisoned not more than 20 years and fined in accordance with title 18.

(B) Definition.—

For purposes of this paragraph, the term "without that individual's knowledge" means that the individual is unaware that a substance with the ability to alter that individual's ability to appraise conduct or to decline participation in or communicate unwillingness to participate in conduct is administered to the individual.

(c) Offenses involving listed chemicals

Any person who knowingly or intentionally—

(1) possesses a listed chemical with intent to manufacture a controlled substance except as authorized by this subchapter;

(2) possesses or distributes a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance except as authorized by this subchapter; or

(3) with the intent of causing the evasion of the recordkeeping or reporting requirements of section 830

of this title, or the regulations issued under that section, receives or distributes a reportable amount of any listed chemical in units small enough so that the making of records or filing of reports under that section is not required;

shall be fined in accordance with title 18 or imprisoned not more than 20 years in the case of a violation of paragraph (1) or (2) involving a list I chemical or not more than 10 years in the case of a violation of this subsection other than a violation of paragraph (1) or (2) involving a list I chemical, or both.

(d) Boobytraps on Federal property; penalties; "boobytrap" defined

(1) Any person who assembles, maintains, places, or causes to be placed a boobytrap on Federal property where a controlled substance is being manufactured, distributed, or dispensed shall be sentenced to a term of imprisonment for not more than 10 years or fined under title 18, or both.

(2) If any person commits such a violation after 1 or more prior convictions for an offense punishable under this subsection, such person shall be sentenced to a term of imprisonment of not more than 20 years or fined under title 18, or both.

(3) For the purposes of this subsection, the term "boobytrap" means any concealed or camouflaged device designed to cause bodily injury when triggered by any action of any unsuspecting person making contact with the device. Such term includes guns, ammunition, or explosive devices attached to trip wires

or other triggering mechanisms, sharpened stakes, and lines or wires with hooks attached.

(e) Ten-year injunction as additional penalty

In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, manufacture, exportation, or importation of a listed chemical may be enjoined from engaging in any transaction involving a listed chemical for not more than ten years.

(f) Wrongful distribution or possession of listed chemicals

(1) Whoever knowingly distributes a listed chemical in violation of this subchapter (other than in violation of a recordkeeping or reporting requirement of section 830 of this title) shall, except to the extent that paragraph (12), (13), or (14) of section 842(a) of this title applies, be fined under title 18 or imprisoned not more than 5 years, or both.

(2) Whoever possesses any listed chemical, with knowledge that the recordkeeping or reporting requirements of section 830 of this title have not been adhered to, if, after such knowledge is acquired, such person does not take immediate steps to remedy the violation shall be fined under title 18 or imprisoned not more than one year, or both.

(g) Internet sales of date rape drugs

(1) Whoever knowingly uses the Internet to distribute a date rape drug to any person, knowing or with reasonable cause to believe that—

(A) the drug would be used in the commission of criminal sexual conduct; or

(B) the person is not an authorized purchaser;

shall be fined under this subchapter or imprisoned not more than 20 years, or both.

(2) As used in this subsection:

(A) The term "date rape drug" means—

(i) gamma hydroxybutyric acid (GHB) or any controlled substance analogue of GHB, including gamma butyrolactone (GBL) or 1,4–butanediol;

(ii) ketamine;

(iii) flunitrazepam; or

(iv) any substance which the Attorney General designates, pursuant to the rulemaking procedures prescribed by section 553 of title 5, to be used in committing rape or sexual assault.

The Attorney General is authorized to remove any substance from the list of date rape drugs pursuant to the same rulemaking authority.

(B) The term "authorized purchaser" means any of the following persons, provided such person has acquired the controlled substance in accordance with this chapter:

(i) A person with a valid prescription that is issued for a legitimate medical purpose in the usual course of professional practice that is based upon a qualifying medical relationship by a practitioner registered by the

Attorney General. A "qualifying medical relationship" means a medical relationship that exists when the practitioner has conducted at least 1 medical evaluation with the authorized purchaser in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other heath [1] professionals. The preceding sentence shall not be construed to imply that 1 medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(ii) Any practitioner or other registrant who is otherwise authorized by their registration to dispense, procure, purchase, manufacture, transfer, distribute, import, or export the substance under this chapter.

(iii) A person or entity providing documentation that establishes the name, address, and business of the person or entity and which provides a legitimate purpose for using any "date rape drug" for which a prescription is not required.

(3) The Attorney General is authorized to promulgate regulations for record-keeping and reporting by persons handling 1,4–butanediol in order to implement and enforce the provisions of this section. Any record or report required by such regulations shall be considered a record or report required under this chapter.

(h) Offenses involving dispensing of controlled substances by means of the Internet

(1) In general

It shall be unlawful for any person to knowingly or intentionally—

(A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this subchapter; or

(B) aid or abet (as such terms are used in section 2 of title 18) any activity described in subparagraph (A) that is not authorized by this subchapter.

(2) Examples

Examples of activities that violate paragraph (1) include, but are not limited to, knowingly or intentionally—

(A) delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity as required by section 823(f) of this title (unless exempt from such registration);

(B) writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of section 829(e) of this title;

(C) serving as an agent, intermediary, or other entity that causes the Internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance in a manner not authorized by sections [2] 823(f) or 829(e) of this title;

(D) offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire; and

(E) making a material false, fictitious, or fraudulent statement or representation in a notification or declaration under subsection (d) or (e), respectively, of section 831 of this title.

(3) Inapplicability

(A) This subsection does not apply to—

(i) the delivery, distribution, or dispensation of controlled substances by nonpractitioners to the extent authorized by their registration under this subchapter;

(ii) the placement on the Internet of material that merely advocates the use of a controlled substance or includes pricing information without attempting to propose or facilitate an actual transaction involving a controlled substance; or

(iii) except as provided in subparagraph (B), any activity that is limited to—

(I) the provision of a telecommunications service, or of an Internet access service or Internet information location tool (as those terms are defined in section 231 of title 47); or

(II) the transmission, storage, retrieval, hosting, formatting, or translation (or any combination thereof) of a communication, without selection or alteration of the content of the communication, except that deletion of a particular communication or material made by another person in a manner consistent with section

230(c) of title 47 shall not constitute such selection or alteration of the content of the communication.

(B) The exceptions under subclauses (I) and (II) of subparagraph (A)(iii) shall not apply to a person acting in concert with a person who violates paragraph (1).

(4) Knowing or intentional violation

Any person who knowingly or intentionally violates this subsection shall be sentenced in accordance with subsection (b).

21 C.F.R. § 1306.04 - Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

(d) A prescription may be issued by a qualifying practitioner, as defined in section 303(g)(2)G)(iii) of the Act (21 U.S.C. 823(g)(2)(G)(iii), in accordance with § 1306.05 for a Schedule III, IV, or V controlled substance for the purpose of maintenance or detoxification treatment for the purposes of administration in accordance with section 309A of the Act (21 U.S.C. 829a) and § 1306.07(f). Such prescription issued by a qualifying practitioner shall not be used to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients.

2005 OAC Ann. 4731-21-02

4731-21-02 Utilizing prescription drugs for the treatment of intractable pain.

(A) When utilizing any prescription drug for the treatment of intractable pain on a protracted basis or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions, a practitioner shall comply with accepted and prevailing standards of care which shall include, but not be limited to, the following:

(1) An initial evaluation of the patient shall be conducted and documented in the patient's record that includes a relevant history, including complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases or conditions; and an appropriate physical examination;

(2) A medical diagnosis shall be established and documented in the patient's medical record that indicates not only the presence of intractable pain but also the signs, symptoms, and causes and, if determinable, the nature of the underlying disease and pain mechanism;

(3) An individualized treatment plan shall be formulated and documented in the patient's medical record. The treatment plan shall specify the medical justification of the treatment of intractable pain by

utilizing prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, the intended role of prescription drug therapy within the overall plan, and, when applicable, documentation that other medically reasonable treatments for relief of the patient's intractable pain have been offered or attempted without adequate or reasonable success. The prescription drug therapy shall be tailored to the individual medical needs of each patient. The practitioner shall document the patient's response to treatment and, as necessary, modify the treatment plan;

(4) (a) The practitioner's diagnosis of intractable pain shall be made after having the patient evaluated by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain. For purposes of this rule, a practitioner "specializes" if the practitioner limits the whole or part of his or her practice, and is qualified by advanced training or experience to so limit his or her practice, to the particular anatomic area, system, or organ of the body perceived as the source of the pain. The evaluation shall include review of all available medical records of prior treatment of the intractable pain or the condition underlying the intractable pain; a thorough history and physical examination; and testing as required by accepted and prevailing standards of care. The practitioner shall maintain a copy of any report made by any practitioner to whom referral for evaluation was made under this paragraph. A practitioner shall not provide an evaluation under this paragraph if that

practitioner would be prohibited by sections 4731.65 to 4731.69 of the Revised Code or any other rule adopted by the board from providing a designated health service upon referral by the treating practitioner; and

(b) The practitioner shall not be required to obtain such an evaluation, if the practitioner obtains a copy of medical records or a detailed written summary thereof showing that the patient has been evaluated and treated within a reasonable period of time by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain and the treating practitioner is satisfied that he or she can rely on that evaluation for purposes of meeting the further requirements of this chapter of the Administrative Code. The practitioner shall obtain and review all available medical records or detailed written summaries thereof of prior treatment of the intractable pain or the condition underlying the intractable pain. The practitioner shall maintain a copy of any record or report of any practitioner on which the practitioner relied for purposes of meeting the requirements under this paragraph; and

(5) The practitioner shall ensure and document in the patient's record that the patient or other individual who has the authority to provide consent to treatment on behalf of that patient gives consent to treatment after being informed of the benefits and risks of receiving prescription drug therapy on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions,

and after being informed of available treatment alternatives.

(B) Upon completion and satisfaction of the conditions prescribed in paragraph (A) of this rule, and upon a practitioner's judgment that the continued utilization of prescription drugs is medically warranted for the treatment of intractable pain, a practitioner may utilize prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, provided that the practitioner continues to adhere to accepted and prevailing standards of care which shall include, but not be limited to, the following:

(1) Patients shall be seen by the practitioner at appropriate periodic intervals to assess the efficacy of treatment, assure that prescription drug therapy remains indicated, evaluate the patient's progress toward treatment objectives and note any adverse drug effects. During each visit, attention shall be given to changes in the patient's ability to function or to the patient's quality of life as a result of prescription drug usage, as well as indications of possible addiction, drug abuse or diversion. Compliance with this paragraph of the rule shall be documented in the patient's medical record;

(2) Some patients with intractable pain may be at risk of developing increasing prescription drug consumption without improvement in functional status. Subjective reports by the patient should be supported by objective data. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in

work or other gainful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient. Compliance with this paragraph of the rule shall be documented in the patient's medical record;

(3) Based on evidence or behavioral indications of addiction or drug abuse, the practitioner may obtain a drug screen on the patient. It is within the practitioner's discretion to decide the nature of the screen and which type of drug(s) to be screened. If the practitioner obtains a drug screen for the reasons described in this paragraph, the practitioner shall document the results of the drug screen in the patient's medical record. If the patient refuses to consent to a drug screen ordered by the practitioner, the practitioner shall make a referral as provided in paragraph (C) of this rule;

(4) The practitioner shall document in the patient's medical record the medical necessity for utilizing more than one controlled substance in the management of a patient's intractable pain; and

(5) The practitioner shall document in the patient's medical record the name and address of the patient to or for whom the prescription drugs were prescribed, dispensed, or administered, the dates on which prescription drugs were prescribed, dispensed, or administered, and the amounts and dosage forms of the prescription drugs prescribed, dispensed, or administered, including refills.

(C) If the practitioner believes or has reason to believe that the patient is suffering from addiction or drug

abuse, the practitioner shall immediately consult with an addiction medicine or other substance abuse specialist. For purposes of this rule, "addiction medicine or substance abuse specialist" means a physician who is qualified by advanced formal training in addiction medicine or other substance abuse specialty, and includes a medical doctor or doctor of osteopathic medicine who is certified by a specialty examining board to so limit the whole or part of his or her practice. Prescription drug therapy may be continued consistent with the recommendations of the consultation, including, if the consulting addiction medicine or other substance abuse specialist recommends that it is necessary, prompt referral to an addiction medicine or other substance abuse specialist for physical examination and evaluation of the patient and a review of the referring practitioner's medical records of the patient. The practitioner shall document the recommendations of the consultation in the patient's record. The practitioner shall continue to actively monitor the patient for signs and symptoms of addiction, drug abuse or diversion. The practitioner shall maintain a copy of any written report made by any practitioner to whom referral for evaluation was made under this paragraph.

2017 OAC Ann. 4731-21-02

4731-21-02. Utilizing prescription drugs for the treatment of chronic pain.

(A) When utilizing any prescription drug for the treatment of chronic pain, a practitioner shall comply with accepted and prevailing standards of care which shall include, but not be limited to, the following:

(1) An initial evaluation of the patient shall be conducted and documented in the patient's record that includes a relevant history, including complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases or conditions; and an appropriate physical examination;

(2) A medical diagnosis shall be established and documented in the patient's medical record that indicates not only the presence of chronic pain but also the signs, symptoms, and causes and, if determinable, the nature of the underlying disease and pain mechanism;

(3) An individualized treatment plan shall be formulated and documented in the patient's medical record. The treatment plan shall specify the treatment proposed, the patient's response to treatment, and any modification to the treatment plan. The treatment plan shall include the medical justification and the intended role of prescription drug therapy within the overall plan, and documentation that other medically

reasonable treatments for relief of the patient's chronic pain have been offered or attempted without adequate or reasonable success. The prescription drug therapy shall be tailored to the individual medical needs of each patient.

(4) (a) The practitioner's diagnosis of chronic pain shall be made after having the patient evaluated by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain. For purposes of this rule, a practitioner "specializes" if the practitioner limits the whole or part of his or her practice, and is qualified by advanced training or experience to so limit his or her practice, to the particular anatomic area, system, or organ of the body perceived as the source of the pain. The evaluation shall include review of all available medical records of prior treatment of the chronic pain or the condition underlying the chronic pain; a thorough history and physical examination; and testing as required by accepted and prevailing standards of care. The practitioner shall maintain a copy of any report made by any practitioner to whom referral for evaluation was made under this paragraph. A practitioner shall not provide an evaluation under this paragraph if that practitioner would be prohibited by sections 4731.65 to 4731.69 of the Revised Code or any other rule adopted by the board from providing a designated health service upon referral by the treating practitioner; and

(b) The practitioner shall not be required to obtain such an evaluation, if the practitioner obtains a copy of medical records or a detailed written summary thereof

showing that the patient has been evaluated and treated within a reasonable period of time by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain and the treating practitioner is satisfied that he or she can rely on that evaluation for purposes of meeting the further requirements of this chapter of the Administrative Code. The practitioner shall obtain and review all available medical records or detailed written summaries of prior treatment of the chronic pain or the condition underlying the chronic pain. The practitioner shall maintain a copy of any record or report of any practitioner on which the practitioner relied for purposes of meeting the requirements under this paragraph; and

(5) The practitioner shall ensure and document in the patient's record that the patient or other individual who has the authority to provide consent to treatment on behalf of that patient gives consent to treatment after being informed of the benefits and risks of receiving prescription drug therapy for chronic pain and after being informed of available treatment alternatives.

(B) Upon completion and satisfaction of the conditions prescribed in paragraph (A) of this rule, and upon a practitioner's judgment that the continued utilization of prescription drugs is medically warranted for the treatment of chronic pain, a practitioner may utilize prescription drugs provided that the practitioner continues to adhere to accepted and prevailing

standards of care which shall include, but not be limited to, the following:

(1) Patients shall be seen by the practitioner at appropriate periodic intervals to assess the efficacy of treatment, assure that prescription drug therapy remains indicated, evaluate the patient's progress toward treatment objectives and note any adverse drug effects. During each visit, attention shall be given to changes in the patient's ability to function or to the patient's quality of life as a result of prescription drug usage, as well as indications of possible addiction, drug abuse or diversion. Compliance with this paragraph of the rule shall be documented in the patient's medical record;

(2) Some patients with chronic pain may be at risk of developing increasing prescription drug consumption without improvement in functional status. Subjective reports by the patient should be supported by objective data. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in work or other gainful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient. Compliance with this paragraph of the rule shall be documented in the patient's medical record;

(3) Based on evidence or behavioral indications of addiction or drug abuse, the practitioner shall obtain a drug screen on the patient. It is within the practitioner's discretion to decide the nature of the screen and which type of drug(s) to be screened. If the practitioner obtains a drug screen for the reasons

described in this paragraph, the practitioner shall document the results of the drug screen in the patient's medical record. If the patient refuses to consent to a drug screen ordered by the practitioner, the practitioner shall make a referral as provided in paragraph (C) of this rule;

(4) The practitioner shall document in the patient's medical record the medical necessity for utilizing more than one controlled substance in the management of a patient's chronic pain; and

(5) The practitioner shall document in the patient's medical record the name and address of the patient to or for whom the prescription drugs were prescribed, dispensed, or administered, the dates on which prescription drugs were prescribed, dispensed, or administered, and the amounts and dosage forms of the prescription drugs prescribed, dispensed, or administered, including refills.

(6) The practitioner shall, in accordance with the requirements set forth in section 4731.055 of the Revised Code and rule 4731-11-11 of the Administrative Code, request a report from "OARRS," or the successor drug database maintained by the board of pharmacy.

(C) If the practitioner believes or has reason to believe that the patient is suffering from addiction or drug abuse, the practitioner shall immediately consult with an addiction medicine specialist or other substance abuse professional to obtain formal assessment of addiction or drug abuse.

(1) For purposes of this rule:

(a) Addiction medicine specialist means a physician who is qualified by advanced formal training in addiction medicine or other substance abuse specialty, and includes a medical doctor or doctor of osteopathic medicine who is certified by a specialty examining board to so limit the whole or part of his or her practice.

(b) Substance abuse professional includes a psychologist licensed pursuant to Chapter 4732. of the Revised Code and certified as a clinical health psychologist, an independent chemical dependency counselor, or a chemical dependency counselor III.

(2) The practitioner shall do all of the following:

(a) Document the recommendations of the consultation in the patient's record;

(b) Continue to actively monitor the patient for signs and symptoms of addiction, drug abuse or diversion; and

(c) Maintain a copy of any written report made by the addiction medicine specialist or substance abuse professional to whom referral for evaluation was made under this paragraph.

(3) Prescription drug therapy may be continued consistent with the recommendations of the consultation. If the consulting addiction medicine specialist or other substance abuse professional believes the patient to be suffering from addiction or

drug abuse, prompt referral shall be made to one of the following:

(a) An addiction medicine specialist or substance abuse professional; or

(b) An addiction medicine or substance abuse treatment facility.

APPENDIX D

IN THE COMMON PLEAS COURT OF ROSS COUNTY, OHIO CIVIL DIVISION

[Filed May 31, 2017]

STATE OF OHIO *ex rel.* MIKE DeWINE, Ohio Attorney General,
Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS,

INC. n/k/a ACTAVIS, INC.;)
WATSON LABORATORIES, INC.;)
ACTAVIS LLC; ACTAVIS PHARMA,)
INC. f/k/a WATSON PHARMA, INC.;)
AND DOES 1 THROUGH 100,)
INCLUSIVE,)
Defendants.)
_____)

COMPLAINT

* * *

[p.7]

14. An estimated 1,162,000 Ohio citizens suffer from chronic pain,[12] which takes an enormous toll on their health, lives and families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign deprived Ohio patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

* * *

[12] Report of the Ohio Compassionate Care Task Force (Mar. 2004).

[p.17]

45. Defendants also deceptively marketed opioids in Ohio through unbranded advertising – *i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

* * *

[pp.28-29]

84. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the

panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Ohio during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

* * *

[pp.30-31]

88. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and

overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

89. ***First***, Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website,

PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are"overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

h. Detailers for Purdue, Endo, Janssen, and Cephalon in Ohio minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

* * *