IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, v. PURDUE PHARMA L.P., *et al.*, Defendants.	Case No. CJ-2017-816 Judge Thad Balkman William C. Hetherington Special Discovery Master

DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON & JOHNSON'S MOTION *IN LIMINE* NO. 4 TO EXCLUDE REFERENCES TO THE ACTIVITIES OF NORAMCO AND TASMANIAN ALKALOIDS

REDACTED VERSION

THIS DOCUMENT WAS FILED IN ITS ENTIRETY APRIL 26, 2019,
UNDER SEAL
PER COURT ORDER DATED APRIL 16, 2018

Defendants Janssen Pharmaceuticals, Inc. ("Janssen")[1] and Johnson & Johnson ("J&J"), by and through their attorneys, hereby move this Court for an order excluding from trial all evidence and argument referencing the manufacture and sale of opioid raw materials and active pharmaceutical ingredients ("APIs") by J&J's former affiliates Noramco, Inc. ("Noramco") and Tasmanian Alkaloids. Noramco and Tasmanian Alkaloid's manufacture and sale of opioid raw materials and APIs is lawful under well-established Oklahoma tort-law principles. And because the federal Controlled Substances Act authorized Noramco and Tasmanian Alkaloid to manufacture and sell opioid raw materials and APIs, claims challenging their conduct are barred by the Oklahoma nuisance statute's safe harbor provision and preempted by federal law. Since multiple legal principles foreclose any theory of liability based on Noramco and Tasmanian Alkaloids, evidence about their alleged conduct is irrelevant. *See* 12 O.S. §§ 2402, 2403.

BRIEF IN SUPPORT

In support of this Motion *in Limine*, Janssen and J&J show the following:

I. BACKGROUND

Noramco is a Georgia corporation that manufactures and sells active pharmaceutical ingredients ("APIs"). *See* Ex. A, Dep't of Justice, Notice of Registration, *Bulk Manufacturer of Controlled Substances Application: Noramco, Inc.*, No. DEA-392, 2014 WL 4961853 (Oct. 7, 2014). From 1979 to 2016, Noramco was a subsidiary of Janssen. Ex. B, Dec. 4, 2018 Deposition Tr. of William Grubb ("Grubb Dep.") at 23:15-24:1. Among the APIs that Noramco manufactures are Schedule II opioid controlled substances including codeine, opium tincture, oxymorphone, and noroxymorphone. *Id.* at 9:4-9; 24:2-9; Ex. C, Dep't of Justice, Drug Enf't Admin., Notice of

[1] "Janssen" also refers to Janssen Pharmaceuticals, Inc.'s predecessors, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.

Application & Registration, 84 Fed. Reg. 44 (Mar. 6, 2019). Pharmaceutical manufacturers use these APIs to create opioid prescription medicines. Ex. B, Grubb Dep. at 19:17-20:21.

Tasmanian Alkaloids, an Australian corporation and former subsidiary of J&J, manufactures narcotic raw material and poppy straw that in turn are used to make APIs for opioid medications. *See, e.g.*, Ex. B, Grubb Dep. at 24:2-25:1. The transnational supply of narcotic raw material and poppy straw is strictly regulated by the United Nations and the DEA. *Id.* at 252:8-14.

II. ARGUMENT

A. All Evidence of Noramco and Tasmanian Alkaloid's Manufacture and Sale of Opioid Raw Materials and APIs Should Be Excluded Because Those Activities Are Not Tortious Under Oklahoma Law.

Oklahoma law does not recognize tort liability for a component supplier that has no role in making the finished product. Such a supplier has no duty to warn the finished product's end-user about the component's risks, and can be held liable "only when [it] . . . 'substantially participates in the design of the final integrated product.'" *Swift v. Serv. Chem., Inc.*, 2013 OK CIV APP 88, ¶¶19-22, 310 P.3d 1127, 1132–33 (citation omitted). The drug manufacturers that bought active pharmaceutical ingredients ("API") from Noramco "made a substantial change in the way the [API] was packaged and distributed, and in instructing how [it] should be used." *Id.* The activities of Noramco and Tasmanian Alkaloids as suppliers of APIs and narcotic raw materials are therefore non-tortious as a matter of Oklahoma law, and cannot be used to prove causation. *Id.* Because those activities cannot support liability, all evidence about them should be excluded as irrelevant. *See* 12 O.S. §§ 2402–03.

B. All Evidence of Noramco and Tasmanian Alkaloids' Manufacture and Sale of Opioid Raw Materials and APIs Should Also Be Excluded Because They Are Lawful Under the CSA.

In addition, the federal Controlled Substances Act ("CSA") affirmatively authorized Noramco's sales of raw materials to drug manufacturers. The CSA directs the Drug Enforcement Agency ("DEA") to strike a balance between ensuring the "necessary" supply of controlled substances that have a "useful and legitimate medical purpose ... to maintain the health and general welfare of the American people," and, on the other hand, combatting their "improper use." 21 U.S.C. § 801(1)-(2). To that end, the DEA sets annual quotas for the production and purchase of controlled substances, including active ingredients for opioid medications. *See* 21 C.F.R. §§ 1303.11–1303.12, 1303.21–1303.27. In full compliance with that scheme, Noramco held DEA production quotas that authorized it to manufacture and sell API for opioid medications. *See* 21 C.F.R. §§ 1303.21–1303.27; Ex. B, Grubb Dep. at 19:1-8. And the manufacturers that purchased raw material from Noramco held DEA procurement quotas authorizing them to do so. *See* 21 C.F.R. § 1303.12; Ex. B, Grubb Dep. 46:22-47:18, 48:7-13, 55:7-17. Tasmanian Alkaloids' importation of raw poppy materials was similarly authorized by federal law. *See, e.g.*, 21 C.F.R. § 1304.31. Because they were sanctioned by a complex federal statutory scheme, Noramco's and Tasmanian Alkaloids' raw-material sales fall under the Oklahoma nuisance statute's safe harbor, *see* 50 O.S. § 4 ("Nothing which is done or maintained under the express authority of a statute can be deemed a nuisance."), and any attempt to impose tort liability for them would fatally conflict with federal law, *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (where state tort-law claims "skew[]" the federal government's "delicate balance of statutory objectives," the state law claims are preempted). Accordingly, evidence about those sales cannot support liability and should be excluded as irrelevant.

III. CONCLUSION

For all these reasons, the Court should grant Janssen and J&J's Motion and exclude all evidence and argument regarding Noramco and Tasmanian Alkaloid's manufacture and sale of opioid raw materials and APIs.

Dated: April 26, 2019

Respectfully submitted,

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CERTIFICATE OF MAILING

Pursuant to Okla. Stat. tit. 12, § 2005(D), and by agreement of the parties, this is to certify on April 26, 2019, a true and correct copy of the above and foregoing has been served via electronic mail, to the following:

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EXHIBIT A

79 FR 60498-02, 2014 WL 4961853(F.R.)
NOTICES
DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Noramco, Inc.

Tuesday, October 7, 2014

ACTION: Notice of application.
DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before December 8, 2014.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:
The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, and dispensers of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator") pursuant to section 7 of 28 CFR pt. 0, subpt. R, App.

In accordance with 21 CFR 1301.33(a), this is notice that on July 16, 2014, Noramco, Inc., 1440 Olympic Drive, Athens, Georgia 30601, applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Gamma Hydroxybutyric Acid (2010)	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Morphine-N-oxide (9307)	I
Amphetamine (1100)	II
Methylphenidate (1724)	II

Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium tincture (9630)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Carfentanil (9743)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

Dated: September 26, 2014.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2014-23831 Filed 10-6-14; 8:45 am]

BILLING CODE 4410-09-P

End of Document

EXHIBIT B

[FILED UNDER SEAL]

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,	)	
Plaintiff,	)	CASE NO.
vs.	)	CJ-2017-816
PURDUE PHARMA L.P., et al.,	)	
Defendants.	)	

Videotaped Deposition of WILLIAM B. GRUBB, III, taken on behalf of the Plaintiff, pursuant to notice and agreement, before Judith L. Leitz Moran, Certified Court Reporter, at Alston & Bird LLP, One Atlantic Center, 1201 West Peachtree Street, Suite 4200, Atlanta, Georgia, on the 4th day of December 2018, commencing at the hour of 9:10 a.m.

Q And how long have you worked for Noramco?
A 21 years. Since 1997.
Q I want to start with how you got to where you are today and talk about what your background is --
A Okay.
Q -- both educational and professional.
So can you kind of start with your college education and work your way forward?
A I went to University of Georgia and Georgia State. And graduated in 1991.
Q What did you do after that?
A I worked for a company called Burroughs Wellcome that was acquired by Glaxo Wellcome and -- so from '91 until '97. And then joined Noramco.
Q So you've been with Noramco since '97?
A Yes.
Q What was your first -- your first role at Noramco?
A My first role was as an operations superintendent running a medical device facility that made a -- a hemostat that is used in the body, so we made the active ingredient for that.
Q What does Noramco do?
A So Noramco supplies active ingredients.

Think of them as like powders in a drum, but we're supplying an active ingredient that goes into pharmaceutical finish dosage.

Q How many different active pharmaceutical ingredients does Noramco manufacture?

MS. DAWSON: Object to the form of the question.

A So currently we manufacture around 18 different active ingredients.

BY MR. DUCK:

Q And Noramco manufactures active pharmaceutical ingredients or APIs that are controlled substances, right?

A Some of them are controlled substances, but -- but yes, that's correct.

Q All right.

MR. BARKER: Trey, I'm sorry to interrupt, but we talked about before the deposition having a stipulation.

I just want to make sure the stipulation is on the record, and that is, that if any counsel, including the witness's counsel objects to a question, that objection is good for all counsel; is that correct?

MR. DUCK: Yeah.

MR. BARKER: Okay. And am I correct in understanding that under Oklahoma procedure, the objection of "object to form" covers all grounds for the form of the objection; you don't need to specify the particular grounds?

MR. DUCK: Right, it covers form objections.

MR. BARKER: Okay. Thank you.

BY MR. DUCK:

Q So let's back up.

Noramco manufactures active pharmaceutical ingredients or APIs, some of which are controlled substances?

A That's correct.

Q And what are controlled substances?

MS. DAWSON: Object to the form of the question.

A So there's a specific definition defined in the Controlled Substances Act that -- you know, I -- I'm not a lawyer, but you -- in the Code of Federal Regulations, there's a definition of a controlled substance.

BY MR. DUCK:

Q Can you -- can anyone manufacture controlled substances or do you need a special

warning which is commonly put there to make sure that it's front and center to alert prescribers of side effects. I -- I haven't said that they're dangerous.

Q And you specifically said they're not dangerous, right?

MS. DAWSON: Object to the form of the question.

A I simply stated that there's a black box warning. I haven't stated that they are or are not dangerous.

BY MR. DUCK:

Q Well, what's your view, are they or aren't they?

A I --

MS. DAWSON: Object to the form of the question. Asked and answered.

A Yeah, I can't -- I can't speculate on that. I mean, I'm not a -- I'm not a regulator.

BY MR. DUCK:

Q You don't know whether opioids are dangerous?

MS. DAWSON: Object to the form of the question. Asked and answered.

You can go ahead and answer.

THE WITNESS: Okay.

A I -- again, I'm not a regulator. I know that the active ingredients that we supply go into finished dosage forms. Those finished dosage forms have been reviewed and approved by the FDA. And that every year the DEA has to give us something called manufacturing quota to make them. So that's an annual process.

And all I can surmise is, is that, you know, within the FDA and DEA regulatory framework that we're, you know, making something that is required.

BY MR. DUCK:

Q What do you mean "required"?

A The dosage forms that have been approved are required for medical treatment of pain.

Q Noramco makes oxycodone, right?

MS. DAWSON: Object to the form of the question.

A Noramco, Inc., makes oxycodone hydrochloride API as one of the APIs on our product list.

BY MR. DUCK:

Q What is that API used in? Which pharmaceutical finished products?

MS. DAWSON: Object to the form of the question.

A I'm going to state up front I can't give you a comprehensive list, but, you know, they're -- it's used in both immediate release and sustained release dosage forms for treating pain.

BY MR. DUCK:

Q And one of the -- well, let's back up.

Can you give us some examples of both of those types of oxycodone formulations, the immediate release and the extended release?

MS. DAWSON: Object to --

BY MR. DUCK:

Q Some brand names?

MS. DAWSON: Object to the form of the question.

A Yeah, I -- again, in supplying an active ingredient to typically a company, not to a brand name, you know, generally speaking, I know that, you know, Percocet and Oxycontin are two brand names.

BY MR. DUCK:

Q Purdue Pharma manufactures Oxycontin, right?

MS. DAWSON: Object to the form of the

question.

A I -- I believe that to be true.

BY MR. DUCK:

Q And Noramco sells API to Purdue or at least in the past has sold API to Purdue, right?

MS. DAWSON: Object to the form of the question.

A Purdue is a customer of Noramco, Inc.'s. We have sold API to them in the past in addition to the manufacturing they do for themselves.

BY MR. DUCK:

Q Are you familiar with the manufacturing Purdue does for itself?

MS. DAWSON: Object to the form of the question.

A I am.

BY MR. DUCK:

Q What's the name of their API manufacturing arm?

A Rhodes Technologies.

Q Do you work directly with Rhodes at all?

MS. DAWSON: Object to the form of the question.

A I -- can you define "work with"?

BY MR. DUCK:

Q Have you ever in your role at Noramco, for example, had any contracts or joint ventures with Rhodes?

MS. DAWSON: Object to the form of the question.

A Yeah. So Rhodes Technologies is a -- is a customer of Noramco's. So in our sales data, you would see Noram -- them as a customer.

BY MR. DUCK:

Q What does Rhodes Technology buy from Noramco?

MS. DAWSON: Object to the form of the question.

A So they buy raw materials from us to do manufacturing at their facility, and -- and they're actually buying a raw material that's not a -- a drug in and of itself.

BY MR. DUCK:

Q They buy raw materials meaning that they're actually buying the -- the processed poppies from you? Or is it the poppy straw? What are they buying from Noramco exactly?

MS. DAWSON: Object to the form of the question.

A Yeah. So what they buy from us is

something called -- we call it NATA, which means that it is a technical thebaine. And it is the active ingredient -- or, excuse me, I said it wasn't. It is a raw material that's used to produce oxycodone. They buy that from Noramco.

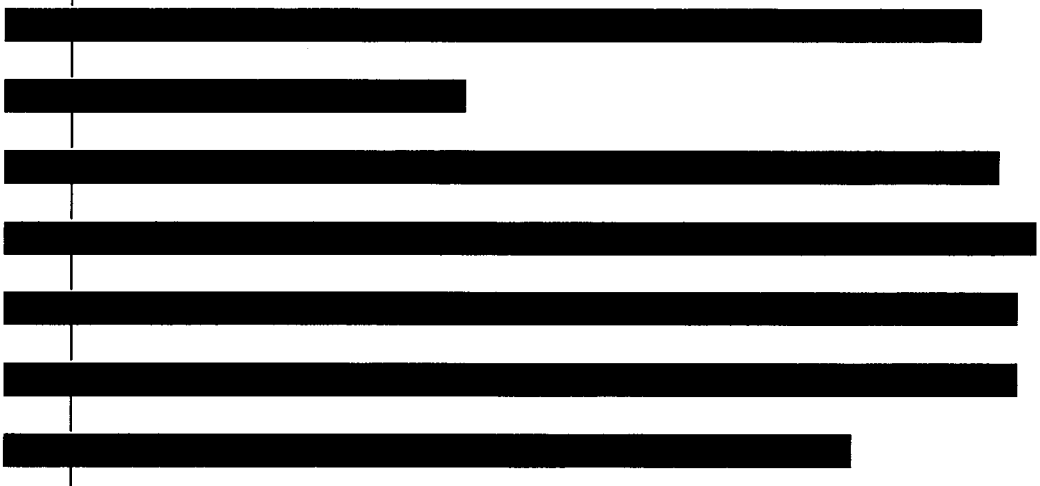
BY MR. DUCK:

Q What does NATA stand for, if you know?

A It's alkaloid -- it's -- frankly, I can't remember exactly how we came up with it. But it -- what it means is, is that we've taken concentrated poppy straw and we've recrystalized it and we supply it to Rhodes Technologies. And we are not their only supplier. They buy from several other people besides us.

Q Noramco used to be owned by Johnson & Johnson, right?

A Up until July 1st of 2016, that's correct.



BY MR. DUCK:

Q Is the poppy straw you're referring to that you just told us about with respect to NATA, does that come from Tasmanian Alkaloids?

MS. DAWSON: Object to the form of the question.

A The NATA is produced by taking something called CPS or concentrated poppy straw thebaine

that is supplied by Tasmanian Alkaloids to Noramco.
BY MR. DUCK:
Q Are there any other suppliers other than Tasmanian Alkaloids for Noramco --
MS. DAWSON: Object --
BY MR. DUCK:
Q -- for this poppy straw that we're talking about?
MS. DAWSON: Object to the form of the question.
A So Noramco has also qualified French CPS thebaine from a company called Francopia. But in large part, you know, Tasmanian Alkaloids is a supplier.
BY MR. DUCK:
Q Has J&J ever owned Francopia?
A No.
MS. DAWSON: Object to the --
THE WITNESS: I'm sorry.
MS. DAWSON: Object to the form of the question.
A J&J has never owned Francopia.
BY MR. DUCK:
Q Do you know who does own Francopia?
A I actually am not sure now today.

Q Other than Tasmanian Alkaloids and Francopia, are there any other suppliers to Noramco --

MS. DAWSON: Object --

BY MR. DUCK:

Q -- of poppies?

MS. DAWSON: Object to the form of the question.

A That's -- yes, there are, depending on which poppy you're talking about. Turkey supplies CPS morphine. And it -- Sun Pharma in -- also in Australia supplies CPS Oripavine. And Tasmania also -- well, we've already covered that Tasmania supplies us materials.

BY MR. DUCK:

Q Other than Tasmanian Alkaloids, has Johnson & Johnson ever owned another poppy supplier?

MS. DAWSON: Object to the form of the question.

A Not that I'm aware of.

BY MR. DUCK:

Q What's your role at Noramco currently?

A My current role with Noramco is I'm vice president of global business development and

question.

A It's -- it's not intended to -- I mean, frankly, I'm just going to say I'm not a clinician. I know that it's used in combination in a number of drugs that are for -- as a component to prevent abuse. I don't know the exact way that happens.

BY MR. DUCK:

Q Okay. So Noramco manufactures opioid APIs, right?

A That is a fact.

Q Noramco manufactures buprenorphine, right?

MS. DAWSON: Object to the form of the question.

A Noramco today does manufacture buprenorphine and buprenorphine hydrochloride. They're actually different.

BY MR. DUCK:

Q And Noramco manufactures Naloxone, correct?

MS. DAWSON: Object to the form of the question.

A Noramco does manufacture Naloxone.

BY MR. DUCK:

Q And Noramco sells all three of those

products to Purdue or Rhodes, right?

MS. DAWSON: Object to the form of the question.

A So Noramco is one of four or five manufacturers that make these APIs, including Rhodes and Purdue themselves. So we certainly are not the only person, but they are a customer, yes.

BY MR. DUCK:

Q So just to summarize that, Noramco sells to Rhodes or Purdue opioid API, buprenorphine and Naloxone, correct?

MS. DAWSON: Object to the form of the question.

A That's a correct statement.

BY MR. DUCK:

Q What does Noramco sell to Teva?

MS. DAWSON: Object to the form of the question.

A Today Noramco sells -- I think this year nothing to Teva.

BY MR. DUCK:

Q What in the past has Noramco sold to Teva?

A Noramco has sold primarily -- again, it varies by year, but we primarily have sold, based

on the quota that we were given to produce APIs, and the quota that they were given to procure the APIs, oxycodone, hydrochloride and hydrocodone bitartrate.

Q Teva is a manufacturer of generic pharmaceuticals, right?

MS. DAWSON: Object to the form of the question.

A I am not sure -- I know they manufacture both branded and generic pharmaceuticals, so I'm not sure that I would say they're only generic.

BY MR. DUCK:

Q Are you familiar with any of the -- the branded drugs at Teva?

A I really am not actually. So I'm supplying an active ingredient that is a controlled substance where the DEA's given me quota. And then they've given my customer quota to procure it.

You know, what it gets used for in the formulation, that -- that's blind to me. I'm not actually sure.

Q What opioid APIs has Noramco sold to -- well, did we say Cephalon? Was Cephalon one of your customers?

A We said that they -- we said they were

not.

Q They were not, okay.

What opioid APIs does Noramco sell to Endo currently?

A Okay. Currently, codeine phosphate I believe is the only API that we will sell them.

Q In the past has Noramco provided other or additional APIs, opioid APIs to Endo?

A So, again, you know, in the construct of us being given manufacturing quota and then being given procurement quota, we've sold them oxycodone hydrochloride, hydrocodone bitartrate, codeine phosphate and methylphenidate hydrochloride.

And I just want to add, you know, I'm not sure that's an exhaustive list, but those are the major -- those are the main ones.

Q All right. You've mentioned FDA approval a few times. It's your understanding, right, that pharmaceuticals in the United States that are allowed to be sold have to be approved by the FDA, right?

MS. DAWSON: Object to the form of the question.

A That is my understanding of how the process works, yes.

BY MR. DUCK:

Q Does FDA approve the APIs that Noramco makes?

A Noramco making an API chemical has to submit to the FDA to obtain a document called a drug master file or, in short, DMF. So that -- that's correct, they do.

Q Is it accurate to say that the opioid APIs or other Schedule II APIs that Noramco makes, that they are FDA-approved active pharmaceutical ingredients?

MS. DAWSON: Object to the form of the question.

BY MR. DUCK:

Q Or is the terminology different?

MS. DAWSON: Same objection.

A Can you repeat the question?

BY MR. DUCK:

Q Sure.

A Yeah.

Q It's -- it's pretty simple.

The phrase "FDA approval" carries a certain meaning with it. Does that phrase apply to active pharmaceutical ingredients or just to finished pharmaceutical products? Does that make

sense?

MS. DAWSON: Object to the form of the question.

A So basically the FDA approves the finished dose. In order to approve that finished dose they have to look at the drug master file. And so when the finished dose is approved, they're effectively approving the drug master file as well.

So the drug master file in and of itself is not approved. It's approved as part of a customer's formulation filing.

BY MR. DUCK:

Q Is Noramco subject to FDA validation processes?

MS. DAWSON: Object to the form of the question.

A The manufacturing processes that Noramco runs have to be validated. That's part of what's called good manufacturing practice.

BY MR. DUCK:

Q Is it required by FDA, though?

A That's a correct statement.

MS. DAWSON: Object to the form of the question.

THE WITNESS: Sorry.

BY MR. DUCK:

Q So FDA could audit the manufacturing processes that Noramco undertakes?

MS. DAWSON: Object to the form of the question.

A Noramco is a FDA-registered, GMP certified producer, and the FDA does, in fact, audit us, yes.

BY MR. DUCK:

Q What does GMP stand for?

A Good manufacturing practice.

Q Got it.

Noramco is also regulated by DEA, right?

MS. DAWSON: Object to the form of the question.

A Noramco is a -- a DEA registrant and we are regulated heavily by the DEA.

BY MR. DUCK:

Q In -- in what ways does DEA regulate Noramco?

MS. DAWSON: Object to the form of the question.

A So Noramco is -- first and foremost is listed annually in the federal register on a renewal process as a registrant. And as I've

mentioned earlier, annually they provide us manufacturing quota to manufacture the APIs that we then in turn sell to customers. That's the main two. And -- and there's a series of inspections that happen along with that.

BY MR. DUCK:

Q What do those inspections consist of?

A I -- that's a -- can you be a little more specific?

Q Sure.

You said there were some inspections that go along with this process of being named as a registrant and all of that. Can you just provide a little more detail on what this inspection process is?

MS. DAWSON: Object to the form of the question.

A So the -- generally speaking, the DEA inspection process is -- looks at our security systems and physically tests them to make sure that they work. And then it is -- we go through what's called an accountability audit where a hundred percent of the transactions that we do are -- are actually audited. And we also go through a series of accountability assessments where we have to

you know, is a drum. It's -- not a lot of -- not a lot of shipments, but I'm not aware of any.

BY MR. DUCK:

Q What do you mean "not a lot of shipments"?

MS. DAWSON: Object to the form of the question.

A Think of -- you know, think of four or five shipments a week on average. That to me is a fairly low number.

BY MR. DUCK:

Q Is that because the -- the API goes a long way that you don't need to deliver a lot of it?

MS. DAWSON: Object to the form of the question.

BY MR. DUCK:

Q Or why is that?

MS. DAWSON: The same objection.

A It's not -- I think that the concept of not a lot is -- I guess it could be a lot if the DEA awarded our customer's quota to procure it. We're not at liberty just to ship. We have to actually obtain a piece of paper called a 222 Form that says that the DEA agrees we can ship our API

that we've made under their quota to a customer.

So I think -- I mean, I don't mean this sarcastically, I think you'd have to ask the DEA. I mean, it's really up to them to say here's how much you can ship.

BY MR. DUCK:

Q Do DEA quotas apply to both Noramco and Noramco's customers?

MS. DAWSON: Object to the form of the question.

A So we -- Noramco in order to produce an API has to have something called manufacturing quota. Our customers have to in turn obtain from the DEA procurement quota. And so, I believe the answer to your question would be yes. They're not the same type of quota as what I was trying to point out, but yes.

BY MR. DUCK:

Q Oh, that makes sense.

I want to talk about oxycodone specifically. Since you've been at Noramco, has Noramco's manufacturing quota for oxycodone ever gone down?

MS. DAWSON: Object to the form of the question.

A Factually, yes.

BY MR. DUCK:

Q Explain.

A It would depend on the year you're asking about, but -- but the quota that we're awarded is based on the market for our market. I mean, just to be very clear, Noramco doesn't determine the market size. That's prescriptions, you know, with physicians.

What Noramco is doing is working within a market, but -- so our quota is going down based on a combination of the market share we have and the actual market. So that -- but in absolute terms, the -- the number of kilograms, 2.2 pounds per kilogram have gone down.

Q Do you know which years?

A It's been declining every year since 2011.

Q Before 2011, was it steadily increasing?

MS. DAWSON: Object to the form of the question.

A It actually varied by year, so I wouldn't say that it was steadily increasing. Depending on the amount of procurement quota they were going to give customers, they would then in turn give us the

harm, but I didn't really know how.
BY MR. DUCK:
Q Tasmanian Alkaloids does grow poppy so that you can go in and extract opium from and use to get high, correct?
MS. DAWSON: Object to the form of the question.
A So they don't grow opium poppies. And they -- generally speaking, I just mentioned thebaine and Oripavine. They -- they actually are not -- they do not get you high. That's -- they're not directly abusable, they're actually toxic.
BY MR. DUCK:
Q There are poppies, though, that are directly abusable?
MS. DAWSON: Object to the form of the question.
A You know, of the poppies that are grown in the world, there are poppies that are directly abusable.
BY MR. DUCK:
Q And Noramco makes API from those types of poppies that are directly abusable?
MS. DAWSON: Object to the form of the question.

A So Noramco imports -- we don't use the poppies directly, so I think I'll just stop there.

BY MR. DUCK:

Q Noramco obtains ingredients or raw materials from poppies that are directly abusable?

MS. DAWSON: Object to the form of the question.

A So consistent with the U.N. regulations on the movement of narcotic raw materials or concentrated poppy straw around the world, Noramco does rely on the DEA to regulate and provide for import of narcotic raw material that we then chemically convert into active pharmaceutical ingredients.

BY MR. DUCK:

Q Are you aware of the 80/20 rule?

MS. DAWSON: Object to the form of the question.

A I -- I am aware of the 80/20 rule.

BY MR. DUCK:

Q Can you please explain?

A Yes. So the 80/20 rule says that for morphine content, 80 percent of that morphine content must come from traditional sources and 20 percent can come from nontraditional sources, like

Tasmania which is not a traditional source. So that's the -- that's the 80/20 rule.

BY MR. DUCK:

Q What are traditional sources?

A It's not a comprehensive list, but traditional sources would be Turkey, India, the Czech Republic, and there may be a couple of other minor ones. But traditional sources is a -- a State Department term that assures that Turkey, India and Czech Republic have a -- have a legitimate or listed outlet for their material.

Q There are other countries in the Middle East that would be on that traditional resource list as well, right?

MS. DAWSON: Object to the form of the question.

A Yeah, not to my knowledge. So, no, not like -- places like Afghanistan, they're not actually on the list.

BY MR. DUCK:

Q So you said those were not -- that was not an exhaustive list, but now are you saying that Turkey, India and Czech Republic are an exhaustive list?

MS. DAWSON: Object to the form of the

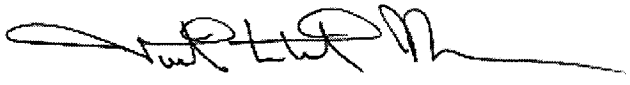
C E R T I F I C A T E

STATE OF GEORGIA:

COUNTY OF HALL:

I hereby certify that the foregoing transcript was taken down, as stated in the caption, and the questions and answers thereto were reduced to typewriting under my direction; that the foregoing Pages 1 through 287 represent a true and correct transcript of the evidence given upon said hearing, and I further certify that I am not of kin or counsel to the parties in the case; am not in the regular employ of counsel for any of said parties; nor am I in anywise interested in the result of said case. The witness did reserve the right to read and sign the transcript.

This, the 6th day of December 2018.



Judith L. Leitz Moran, CCR-B-2312
Certified Court Reporter

EXHIBIT C

international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule I controlled substances to the above listed company.

Dated: February 22, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019–04026 Filed 3–5–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Patheon Pharmaceuticals, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 5, 2019. Such persons may also file a written request for a hearing on the application on or before April 5, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division ("Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on December 24, 2018, Patheon Pharmaceuticals, Inc., 2110 E Galbraith Road, Cincinnati, Ohio 45237, has re-applied to be registered as a bulk manufacturer of the Schedule I controlled substance Gamma Hydroxybutyric Acid (2010), a basic class of controlled substance.

The Gamma Hydroxybutyric Acid will be produced during the process of converting gamma-butyrolactone (GBL) into a new product for development. The company plans to manufacture the above listed controlled substance as Active Pharmaceutical Ingredient (API) that will be further synthesized into dosage forms of a new product. No other activities for this drug code are authorized for this registration.

Dated: February 18, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019–04029 Filed 3–5–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrant listed below has applied for and has been granted a registration by the Drug Enforcement Administration (DEA) as a bulk manufacturer of various classes of schedule I and II controlled substances.

SUPPLEMENTARY INFORMATION: The company listed below applied to be registered as a bulk manufacturer of various basic classes of controlled substances. Information on the previously published notice is listed in the table below. No comments or objections were submitted for this notice.

Company	FR Docket	Published
Cambrex Charles City	83 FR 49579	October 2, 2018.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of this registrant to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing their physical security systems, verifying their compliance with state and local laws, and reviewing their background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed company.

Dated: February 22, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019–04027 Filed 3–5–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as bulk manufacturers of schedule I or schedule II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as bulk manufacturers of schedule I or schedule II controlled substances. Information on previously published notices is listed in the table below. No comments or objections were submitted for these notices.

Company	FR docket	Published
Patheon API Manufacturing, Inc.	83 FR 58596	November 20, 2018.
Insys Manufacturing, LLC	83 FR 60899	November 27, 2018.
Cayman Chemical Company	83 FR 60900	November 27, 2018.
Noramco Inc.	83 FR 60898	November 27, 2018.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of the listed registrants to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each company's maintenance of effective controls against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed companies.

Dated: February 18, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019–04033 Filed 3–5–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrant listed below has applied for and has been granted a registration by the Drug Enforcement Administration (DEA) as a bulk manufacturer of schedule I controlled substances.

SUPPLEMENTARY INFORMATION: The company listed below applied to be registered as a bulk manufacturer of various basic classes of controlled substances. Information on the previously published notice is listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for this notice.

Company	FR Docket	Published
Insys Manufacturing, LLC	83 FR 54611	October 30, 2018.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of the listed registrant to manufacture the applicable basic classes of schedule I and II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed company.

Dated: February 18, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019–04032 Filed 3–5–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrant listed below has applied for and has been granted a registration by the Drug Enforcement Administration (DEA) as bulk manufacturer of schedule I and II controlled substances.

SUPPLEMENTARY INFORMATION: The company listed below applied to be registered as a bulk manufacturer of various basic classes of controlled substances. Information on the previously published notice is listed in the table below. No comments or objections were submitted for this notice.

Company	FR Docket	Published
Organix, Inc	83 FR 58601	November 20, 2018.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of this registrant to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and

The company plans to import the listed controlled substances for analytical research, testing and clinical trials.

Dated: November 16, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–25869 Filed 11–26–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Noramco Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before January 28, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division ("Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on July 4, 2018, Noramco Inc., 1550 Olympic Dr. Athens, Georgia 30601 applied to be registered as a bulk manufacturer for the basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Cathinone	1235	I
Gamma Hydroxybutyric Acid	2010	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Codeine-N-oxide	9053	I
Dihydromorphine	9145	I
Hydromorphinol	9301	I
Morphine-N-oxide	9307	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Nabilone	7379	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium tincture	9630	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Sufentanil	9740	II
Carfentanil	9743	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to manufacture bulk active pharmaceutical ingredients (APIs) and reference standards for distribution to their customers.

In reference to drug codes 7360 (marihuana) and 7370 (tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

Dated: November 16, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–25874 Filed 11–26–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrant listed below has applied for and has been granted registration by the Drug Enforcement Administration (DEA) as an importer of schedule I or II controlled substances.

SUPPLEMENTARY INFORMATION: The company listed below applied to be registered as an importer of various basic classes of controlled substances. Information on the previously published notice is listed in the table below. No comments or objections were submitted and no requests for a hearing were submitted for this notice.