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 STATE OF OKLAHOMA } S.S. CLEVELAND COUNTY } FILED JUN 17 2019 In the office of the Court Clerk MARILYN WILLIAMS

DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON AND JOHNSON'S OFFER OF PROOF FOR EVIDENCE AND QUESTIONING RELATED TO THE REGULATION OF NORAMCO AND TASMANIAN ALKALOIDS IN THE CROSS-EXAMINATION OF DR. ANDREW KOLODNY

The Janssen Defendants[1] hereby submit an offer of proof in response to the Court's exclusion of certain evidence during the cross-examination of State witness Dr. Andrew Kolodny. The excluded evidence related to federal and international regulations governing the production and supply of active pharmaceutical ingredient ("API") and narcotic raw material by Noramco and Tasmanian Alkaloids, respectively. The Court expressly permitted Defendants to submit a written offer of proof.[2]

1. During the cross-examination of Dr. Andrew Kolodny, this Court sustained two objections that prevented the Janssen Defendants from questioning Kolodny about his knowledge of the federal and international regulations governing Tasmanian Alkaloids' production of narcotic

[1] The "Janssen Defendants" are Janssen Pharmaceuticals, Inc. ("Janssen") and Johnson & Johnson ("J&J"), as well as Janssen's predecessors, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.
[2] June 13, 2019 (PM) Trial Tr. 37:12-14.

raw material and Noramco's production of API. The Court sustained an objection to the question "Isn't it the responsibility of the government to decide which drug companies are allowed to manufacture and sell prescription opioids in this country?" as beyond the scope of Kolodny's direct examination.[3] It also granted an objection to exclude a Corporate Integrity Agreement between the federal government and Purdue on the ground that it was not on the Janssen Defendants' pre-trial exhibit list.[4]

2. Had the Court overruled the objections, Defendants would have introduced the following evidence:

First, Defendants would have questioned Kolodny about his knowledge of the international and Tasmanian regulations governing Tasmanian Alkaloids' cultivation of poppy straw and narcotic raw material. The United Nations regulates narcotic raw material on a worldwide basis through the International Narcotics Control Board, and the United Nations Single Convention on Narcotic Drugs requires countries that permit the cultivation of poppy straw, including Australia, to control the manufacture of pharmaceuticals made of poppy straw. And the Tasmanian Poisons Act 1971 requires every poppy grower or producer of narcotic raw material to be licensed by the Tasmanian Poppy Advisory and Control Board. Poisons Act 1971 §§ 16, 54D.

Second, Defendants would have questioned Kolodny about his awareness of DEA regulations under the Controlled Substances Act ("CSA") that govern the importation of narcotic raw material into the United States. The CSA authorizes the importation of "crude opium, poppy straw, [or] concentrate of poppy straw ... as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes." 21 U.S.C. § 952(a)(1). Under DEA

[3] *Id.* 31:18-33:12.
[4] *Id.* 33:14-37:14.

regulations enforcing that statute, any American company wishing to purchase narcotic raw materials must receive authorization from the DEA before doing so. *See* 21 C.F.R. § 1312.11. To secure that authorization, a company must apply to the DEA for an import permit. *See id.* § 1312.12. And, under federal regulations, the DEA can issue an import permit only if, as relevant here, it finds that the importation "necessary to provide for medical, scientific, or other legitimate purposes," *id.* § 1312.13(a)(1), or necessary for "medical and scientific ... or other legitimate needs ... during an emergency where domestic supplies ... are found to be inadequate," *id.* § 1312.13(a)(2). In other words, no entity can import any raw material from Tasmanian Alkaloids without explicit DEA authorization, and the DEA can only grant authorization if it concludes that the material is necessary to the CSA's objective to secure sufficient raw material to meet the nation's medical and scientific requirements.

Third, Defendants would have questioned Kolodny about his awareness of provisions of the CSA and its implementing regulations governing Noramco's production of API and the purchase of API by pharmaceutical manufacturers—including Purdue. The CSA's opening sentence recognizes that many controlled substances "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1). To that end, the Act and its accompanying regulations require the DEA to base quotas for controlled substances on "the estimated medical, scientific, research, and industrial needs of the United States." 21 U.S.C. § 826(a)(1); *id.* § 1303.11(a), (b); *see id.* § 1303.12 (procurement quotas "determine the estimated needs for, and ... insure an adequate and uninterrupted supply of, basic classes of controlled substances").

The DEA follows that mandate by annually setting three levels of API quotas:

- Aggregate quotas dictating how much API should be produced nationwide each year, *see* 21 U.S.C. § 826(a); 21 C.F.R. § 1303.11, 1303.13.
- Manufacturing quotas dictating how much API individual producers like Noramco can manufacture each year, *see* 21 U.S.C. § 826(c); 21 C.F.R. 1303.21-1303.27; and
- Procurement quotas dictating how much API a given drug manufacturer can purchase from producers like Noramco each year, *see* 21 C.F.R. 1303.12.

A DEA-issued quota gives its holder a federal-law right to manufacture or procure the specified amount of API. *See* 21 C.F.R. § 1303.23 (describing API producers' "right to manufacture all or any part of such [manufacturing] quota"); *id.* § 1303.12(f) (procurement quotas "authoriz[e]" drug manufacturers to "procure and use a quantity of a basic class of controlled substances.").

Fourth, Defendants would have introduced and questioned Dr. Kolodny about a Corporate Integrity Agreement entered between Purdue and the Office of Inspector General of the United States Department of Health and Human Services (OIG-HHS) in May 2007. Purdue entered into the Corporate Integrity Agreement *contemporaneously* with a Settlement Agreement with the United States related to charges of illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers. In instances of fraud, the OIG-HHS has permissive authority to exclude entities from federal health care programs or—as it chose in the case of Purdue—impose integrity obligations. In other words, the federal government had the discretion to exclude Purdue from federal health care programs and did not exercise this discretion.

3. All of this evidence was admissible and was within the proper scope of cross-examination. Under Oklahoma law, cross-examination is not limited to the precise lines of questioning pursued on direct, but available to "develop relevant truth related to matters covered on direct examination," *Ark. La. Gas Co. v. Bass*, 698 P.2d 947, 949 (Okla. Civ. App. 1985), and

extends to any question that "tends to elucidate, modify, explain, contradict or rebut testimony given in chief by the witness," *Hardin v. State*, 1982 OK CR 124, 649 P.2d 799, 803. The activities of Tasmanian Alkaloids and Noramco were the centerpiece of Dr. Kolodny's testimony. In Kolodny's opinion, Tasmanian Alkaloids' supply of narcotic raw material and Noramco's supply of API was so beyond the pale as to make Johnson & Johnson a "kingpin" for "drug dealers"—that is, other pharmaceutical manufacturers:

> I believe that Johnson & Johnson was a major cause of our opioid crisis. It was Johnson & Johnson's opium that flooded—that flooded into the United States. I think it's fair to characterize Johnson & Johnson as a kingpin in our opioid crisis because it was their opium that they were selling and that other drug dealers or pharmaceutical companies were selling.[5]

This came at the conclusion of a three-day-long direct examination in which Kolodny provided over 50 pages of testimony about how the activities of Noramco and Tasmanian Alkaloids allegedly contributed to the opioid crisis. Kolodny also confirmed that it was his testimony that at some point after 1998, Noramco should have stopped supplying API to Purdue or its affiliates.[6]

Questioning Kolodny about his knowledge of the strict regulatory regime that authorized those entities' activities would have been directly responsive to his incendiary claim that they were tantamount to criminal enterprises, and thus critical to developing the "relevant truth" about his opinion. Specifically, the questioning would have showed that federal government blessed the *exact conduct* that Kolodny opined was criminal and should subject the Janssen Defendants to billions of dollars in liability.

The Corporate Integrity Agreement was also admissible. In objecting to it, the State claimed this Court' pre-trial order barred admission of exhibits that were not listed on the parties'

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[5] Ex. 1, June 13, 2019 (PM) Trial Tr. 21:15-21.
[6] *Id.* 30:13-17.

exhibit list, even if they were introduced during cross-examination.[7] But while the pre-trial conference order specifies "No exhibit shall be admissible in the parties' ***case-in-chief***, unless it's been identified in the parties' exhibit list," *see* Pre-Trial Conference Order (May 23, 2019) at 64 (emphasis added), the parties expressly "reserve[d] the right to offer an exhibit not listed for purposes of ***impeachment, rebuttal***, or if otherwise ordered by the Court," *id.* *See also* May 16, 2019 Hr'g Tr. 62:13-22 (Court requiring inclusion of this language); *id.* 63:24-64:2 ("I expect you to list all the exhibits you're going to use, and I'm not going to include any others, ***unless it's for rebuttal, impeachment***, or otherwise ordered by the Court." (emphasis added)). Here, the Corporate Integrity Agreement would have rebutted Kolodny's testimony that Noramco should have unilaterally ceased doing business with Purdue after Purdue's criminal plea. It would have shown that the federal government itself opted to allow Purdue to continue selling opioid medications to federal clients subject to various conditions. This implies that the federal government viewed Purdue as serving legitimate medical needs, which in turn further establishes that Noramco did nothing wrong—much less illegal—in continuing to do business with Purdue after the plea.

Dated: June 17, 2019

Respectfully submitted,

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[7] June 13, 2019 (PM) Trial Tr. 34:8-14, 35:20-36:14.

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CERTIFICATE OF MAILING

Pursuant to OKLA. STAT. tit. 12, § 2005(D), this is to certify on June 17, 2019, a true and correct copy of the above and foregoing has been served via email to the following:

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