Kentucky County Opioid Litigation

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Overview Memorandum

CLAIMS AGAINST OPIOID DISTRIBUTORS

Kentucky is in the midst of a public health crisis stemming from the flood of opioids pouring into the Commonwealth and her Counties. The opioid epidemic has been fueled by the greed of the corporate elite, such as Fortune 500 behemoth McKesson Corp., failing to detect and report "suspicious" orders of opioids, despite being required to do so by federal and state law. ***In January 2017, McKesson, the largest drug distributor in the nation, was fined a record $150 million by the federal government for its blatant failure to report suspicious orders in violation of federal law. Cardinal Health, another member of the "Big Three" drug distributors, was fined $44 million for its own failures to report suspicious narcotic orders to the DEA.***

Substantially all prescribed opioids *must* flow through the distributors: federal law requires that opioids be distributed through a closed system. The role of the distributors in this chain is to spot and report red flags in the distribution chain.

McKesson, Cardinal and their distributor cronies admit that they are the gatekeepers – the watch dogs – for preventing opioid abuse, stating: "***distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances. . . and reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach***."[1] The distributors make this admission in the Industry Compliance Guidelines they themselves created to comply with legal mandates – and then wholly ignored.

Instead of instituting controls to stop opioid abuse and alerting authorities to suspicious orders, the distributors instead have chosen to abuse their privileged position, lining their pockets by shipping massive quantities of drugs to pharmacies and dispensaries without performing any checks. The Counties of Kentucky are left to pay the freight for this malfeasance through increased healthcare and law enforcement costs - and through the lives of Kentucky citizens.

The Counties of Kentucky have the means to hold these distributors accountable their actions and to stop the influx of these powerful drugs. Federal and state laws require distributors identify, investigate, and report suspicious orders of controlled substances.

The distributors' known violations of these laws give rise to strong claims for significant equitable and monetary relief. Distributors of opioid medications are vulnerable to damage claims and penalty actions under theories such as public nuisance and negligence. Potentially recoverable damages may include (1) money wrongfully paid for opioids through government-payor programs including employee insurance; (2) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (3) costs for providing treatment, counseling, rehabilitation services; (4) costs for providing treatment of infants born with opioid-related medical conditions; (5) costs for providing welfare or protective services for children whose parents suffer

[1] *See* Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances ("Industry Compliance Guidelines" or "Guidelines").

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from opioid-related disability or incapacitation; and (6) costs directly associated with law enforcement and public safety relating to the opioid epidemic. Local governments may also be entitled to injunctive relief to prevent further unlawful distribution of these drugs.

This memorandum identifies causes of action through which the Counties of Kentucky can hold responsible the distributors which have fueled the opioid epidemic.

I. Wholesale Distributors Are Required under Federal and Kentucky Law to Monitor for and Report Suspicious Orders of Opioids.

A. The Role of Wholesale Distributors in the Opioid Distribution Chain.

Pharmaceutical distributors are supposed to play the role of "beat cops" in preventing the flow of controlled substances to abusers.

Congress enacted the Controlled Substances Act ("CSA") in 1970 with the express purpose of creating a "closed system" for the distribution of controlled substances designed to prevent the diversion of legally produced controlled substances into illicit markets.[2] Through the CSA, Congress stripped the manufacturers of the ability to sell directly to retailers, intentionally creating a link in the chain of distribution between Big Pharma and the pharmacies. This link is the wholesale distributor.

There are only 800 registered wholesale distributors in the United States. Three Fortune 500 companies own 85% of the market share: Cardinal Health, AmerisourceBergen and McKesson Corporation. Each company generates over $100 billion in revenue annually.

Because the CSA creates a "closed system" in which opioid dispensers – like pharmacies – must obtain opioids from opioid distributors, these distributors are "uniquely situated" to spot red flags in the opioid chain, as they note in their own industry guidelines. The distributors are the first line of defense against the diversion of these drugs that can lead to abuse, addiction, and blight.

The closed chain of distribution under the CSA is designed to ensure that all controlled substances are accounted for as they make their way from the manufacturer to the end user. As would be expected, all who encounter controlled substances within the distribution chain are required to keep meticulous records. For example, pursuant to 21 C.F.R. § 1305.13(d) distributors of controlled substances must forward a copy of every order filled to the DEA.

B. Wholesale Distributors Are Required to Monitor for and Report Suspicious Orders of Opioids under Kentucky Law.

To further combat diversion of controlled substances, the distributors are legally required under both federal and Kentucky law to be on alert for suspicious controlled substance orders by

[2] *See* 21 U.S.C.A. §§ 801-971 (2006); 21 U.S.C.A. §§ 1300-1321 (2009); H.R. Rep. No. 91-1444; 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

pharmacies – such as orders of unusual size, frequency, or pattern – and to report these unusual orders to the relevant authorities so that they can be investigated.

Federal law charges registered wholesale distributors with the non-delegable duty to "design and operate a system to disclose . . . suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

Kentucky has specifically incorporated the suspicious order monitoring and reporting requirements found in federal law into its own laws. ***Pursuant to Kentucky Revised Statute § 218A.170, all sales and "distributions" of controlled substances shall be in accordance with the "federal controlled substance laws."***

C. Wholesale Distributors Have Been Warned of and Have Admitted Their Obligations.

The distributors have been on specific notice of their duties with regard to suspicious orders since at least September 2006, when the DEA sent distributors letters referencing the federal CSA monitoring and reporting requirements and providing guidance on what may constitute a "suspicious order." These letters identified diversion and abuse of controlled prescription drugs as a "serious and growing health problem," commanded that "distributors must be vigilant" in determining who can be trusted to receive controlled substances, reminded distributors of their obligation to identify and report suspicious orders, and provided guidance on what circumstances may be indicative of diversion.

The wholesale distributors have readily admitted their monitoring and reporting obligations. The major pharmaceutical distributors (the potential defendants here) are members of the Healthcare Distribution Alliance ("HDA") (known until mid-2016 as the Healthcare Distribution Management Association, or "HDMA"), a trade association that represents pharmaceutical distributors throughout the Americas. Such members include, for example, McKesson, AmerisourceBergen and Cardinal Health, the heads of which also sit on the HDA executive committee and board. This membership is significant because, in response to DEA requirements that distributors investigate and report any suspicious controlled substance orders, HDA created "Industry Compliance Guidelines" for pharmaceutical distributors. These Guidelines, which were developed with the "strong endorsement and expertise of [HDA] members" not only function as admissions of the member distributors' duties, but also serve to set out the industry standards to which these distributors may be held.

The distributors created these Guidelines "in recognition of a growing problem of misuse and diversion of controlled substances," so that the distributors could "further scrutinize purchase orders for these products," as they were required to do by law. As noted above, the distributors

admit that they "are uniquely situated to perform due diligence in order to help support the security" of controlled substance distribution.[3]

The Guidelines set out "Know Your Customer Due Diligence" standards with respect to all distributor customers – which, in the context of the Guidelines, comprise pharmacies and other legal dispensaries. These due diligence standards include gathering detailed information on the customer base of a pharmacy, the quantity of prescriptions filled each day, the quantity of controlled substance prescriptions filled each day, and the percentage of controlled substance purchases compared to overall purchases, and then utilizing this information to compare orders to a "threshold" profile to identify orders of unusual size, frequency or pattern. When confronted with "unusual" orders, the distributors' own Guidelines dictate that they should stop the shipments, investigate the orders under steps that are listed in the Guidelines, and report the suspicious activity to the DEA. These industry standards clearly establish that the duty of care for pharmaceutical distributors includes identifying, investigating, and reporting suspicious orders of controlled substances.

Distributors have chosen to abandon their duties, thereby enabling the diversion of opioids and helping to create the present epidemic. The distributors have not performed adequate due diligence and have failed to report suspicious orders, breaching the very industry standards they, themselves, created. In doing so, the distributors have violated their duties of care and both federal and Kentucky state law.

D. "ARCOS" Data Contains Key Evidence of the Distributors' Breaches.

One of the ways wholesale distributors are to maintain controls against the diversion of prescription opiates is by inputting all distributions in the DEA Automation of Reports and Consolidated Orders System (ARCOS) database.[4] This database contains monthly reports from each wholesale distributor and documents the number of doses of each controlled substance sold to every pharmacy on a monthly basis.

The wholesale distributors were required to monitor this data for suspicious orders. When "suspicious orders" were identified based on this regularly reported data, the wholesale distributors were required to halt shipment, perform an on-site investigation, determine whether a risk of diversion is present, and report the threat of diversion directly to the relevant authorities, including the DEA. "Suspicious orders" are defined by guidance letters provided by the DEA as well as corporate policies and industrial practices, federal law, and Kentucky law, which further define the term. For instance, any pharmacy order which exceeds 10% of the prior month's order would be considered a "suspicious order." [5]

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[3] *See* HDMA Industry Compliance Guidelines.
[4] *See United States v. Four Hundred Sixty Three Thousand Four Hundred Ninety Seven Dollars & Seventy Two Cents ($463,497.72) in U.S. Currency From Best Bank Account*, 779 F. Supp. 2d 696, 709 (E.D. Mich. 2011).
[5] *See Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007); *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012).

The information in the ARCOS database is confidential. The public has never seen the data related to the volume of prescription opiates distributed in each community. That changed when a journalist from the Charleston Gazette gained access to records sealed in a lawsuit filed by the West Virginia Attorney General against the wholesale distributors. The data revealed that 780 million prescription opiates were distributed in West Virginia (population 1.8 million) during a six-year window of time. The journalist, Eric Eyre, recently won the Pulitzer Prize for his investigative journalism.

The Counties of Kentucky have the ability through local law enforcement and cooperation with the DEA to seek and obtain historical ARCOS data. Because this information contains a record of every order filled by each pharmaceutical distributor, a review of those orders would allow for a determination of how many suspicious orders were not flagged by the distributors.

This lack of real-time monitoring and reporting by the distributors stripped Kentucky and the DEA of their ability to timely identify, investigate, and prevent the diversion of the highly addictive drugs at issue.

Distributor Defendants:

The three largest pharmaceutical distributors, the "Big Three," are McKesson Corp., Cardinal Health, and AmerisourceBergen. 2016 revenues for each were approximately $147 billion, $97 billion, and $133 billion, respectively. The Big Three are all members of HDA, and their presidents and CEOs sit on the HDA Executive Committee and Board.

The Big Three have been subject to heavy fines and/or investigation for their failure to monitor for and report suspicious orders. In January 2017, McKesson entered into an agreement with the DEA in which they agreed to pay $150 million in settlement payments for failing to maintain effective controls against diversion of controlled substances. This specifically included the failure to report to the DEA suspicious orders of controlled substances. In May of 2012, Cardinal Health entered into an agreement with the DEA where they resolved allegations that they failed to maintain effective controls against the diversion of controlled substances by failing to detect and report suspicious orders relating to their distribution center in Lakeland, Florida, and in December of 2016, Cardinal Health agreed to pay a civil penalty of $34 million relating to this conduct. AmerisourceBergen has not yet paid any civil penalties to the DEA, but it has been subjected to similar allegations.

Kentucky Counties:

As noted above, in addition to the federal regulations and industry standards that are outlined in HDMA's "Guidelines," pharmaceutical distributors also have these same obligations under Kentucky law, which requires that all sales and "distributions" of controlled substances shall be in accordance with the "federal controlled substance laws." KY. REV. STAT. ANN. § 218A.170.

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Kentucky county attorneys are statutorily charged with "enfor[ing] all provisions of" Chapter 218. KY. REV. STAT. ANN. § 218A.240.

Causes of Action:

Public Nuisance

Counties in Kentucky are specifically authorized to act to remedy the serious problems caused by the opioid epidemic. Under Kentucky Revised Statutes § 67.080, Fiscal Courts have the authority to "exercise all the corporate powers of the county." Of these powers, § 67.083, authorizes the "abatement of public nuisances," and therefore gives counties the capacity to take action.

The overbearing presence of opioids can be described as a public nuisance in Kentucky counties. A public nuisance is a public wrong that impacts citizens at large. Kentucky follows the Restatement Second, Torts § 821B and recognizes a cause of action for public nuisance. A factor considered when determining whether or not a public nuisance exist includes "whether the conduct involves a significant interference with the public health…." The conduct of the distributor defendants in this matter had a devastating effect on the public health throughout Kentucky.

Violation of Kentucky Statutes

The Commonwealth may bring a cause of action against pharmaceutical distributors through under Kentucky Revised Statutes § 446.070, "Penalty no bar to civil recovery," which provides for the right to recover damages sustained by a violation any statute, stating: "A person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation." Section 446.070 "creates a private right of action in a person damaged by another person's violation of any statute that is penal in nature and provides no civil remedy, if the person damaged is within the class of persons the statute intended to be protected."[6] Here, where the Kentucky General Assembly has found that "[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health," Counties are likely within the class of "persons" the controlled substances laws are intended to protect.

The statutes violated by the distributors include Kentucky Revised Statutes § 218a.170(4) which provides that all distribution of controlled substances shall be in accordance with the "federal controlled substances laws." Under this provision, Kentucky adopts the suspicious order reporting requirement of the federal government and makes a violation of that law, a violation of Kentucky law. Additionally, Kentucky Revised Statutes § 315.402(2) requires that wholesalers "maintain accurate records of all drugs handled" and that these records must be made available upon request to the Pharmacy Board.

Through its administrative regulations, Kentucky further mandates a "wholesale distributor shall not … operate in a manner that endangers the public health." *See* 201 KAR 2:105 at § 7.

[6] *Hargis v. Baize*, 168 S.W.3d 36, 40 (Ky. 2005).

These regulations also provide that "[i]nternal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where legend drugs are held to authorized personnel." *Id.* at § 7.

While Kentucky Revised Statutes § 446.070 only explicitly allows a cause of action for a violation of a "statute," it also provides a cause of action under certain circumstances for violation of a regulation.[7] Where a provision of the enabling statute expressly mandates compliance with regulations, the violation of that regulation is synonymous with a violation of the statute.[8]

Furthermore, Kentucky's Controlled Substances statutes provide that, "[n]otwithstanding the existence or pursuit of any other remedy, civil or criminal, any law enforcement authority may maintain, in its own name, an action to restrain or enjoin any violation of this chapter or to forfeit any property subject to forfeiture under Kentucky Revised Statutes § 218A.410, irrespective of whether the owner of the property has been charged with or convicted of any offense under this chapter." KY. REV. STAT. ANN. §218A.240(5).

Negligence

The distributors face state law liability for negligence. The standard of care is established by the industry standards as outlined in HDMA's "Guidelines," the federal statutes and regulations, and by applicable state law. Kentucky courts have held that applicable federal law may establish a duty of care for purposes of Kentucky tort law, even if no parallel Kentucky law exists.[9]

Distributors violated this standard of care by breaching their duty to identify and report suspicious opioid orders to the DEA or other relevant state agencies. There is no doubt that these violations directly contributed to the opioid epidemic that is running rampant across the nation, and without question, substantial damages have been incurred by the Counties of Kentucky. These costs should be borne by the negligent distributor defendants as opposed to the Counties.

Punitive Damages

Under Kentucky Revised Statutes § 411.184, punitive damages shall be recovered where a plaintiff proves that the defendant acted toward the plaintiff with oppression, fraud, or malice. Malice is defined as "… conduct that is carried out by the defendant both with a flagrant indifference to the rights of the plaintiff and with a subjective awareness that such conduct will result in human death or bodily harm."

The distributor defendants in this matter lined their pockets while blindly filling order after order for highly addictive controlled substances that they knew full-well had a high potential to end

[7] *McCarty v. Covol Fuels No. 2, LLC*, 476 S.W.3d 224 (Ky. 2015).
[8] *Id.*
[9] *See, e.g., T&M Jewelry, Inc. v. Hicks*, 189 S.W.3d 526 (Ky. 2006) (holding that a violation of the federal Gun Control Act imposed a duty of care on Kentucky gun dealers which subjected them to a claim for common law negligence even where there was no parallel state law)

up in the wrong hands. The conduct of the distributor defendants was incredibly reckless and certainly led to both death, and bodily harm.

Conclusion:

The crack in the armor of the ARCOS database that began in West Virginia has revealed just how expansive the scope of the opiate epidemic is, as well as its origin. No one could have imagined how pervasive prescription opioids have become in our communities. We have devised a team of lawyers equipped to cut off the opioid supply at the source – the wholesale distributors - and to stop the infiltration of these drugs to your communities, and to help make a difference in Kentucky.

Sample Of Key Documents

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule Il-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *el seq.,* ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at 14500 East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425,

4. On March **12,** 2013, DEA executed an Administrative Inspection Warrant ("AI W") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration RM0220688, located at 3000 Kenskill Avenue, Washington Court House, Ohio 43160; McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at 38220 Plymouth Road, Livonia, Michigan 48150; McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration PM0000771, located at 1515 Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration PM0020850, located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration RM0380484, located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration RMOI 73055, located at 400 Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

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distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration RM0220537, located at 3003 Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at 7009 South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at 10504 McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration PM0021535, located at 3775 Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . effective controls against diversion of particular controlled substances," 21 U.S,C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Deiran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

En lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

1. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below, The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a, McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R, Part 1300 *et seg.,* at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306,04(a).

4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

It. Terms and Conditions

Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations_

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances, This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkceping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to tile such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [itsj area of suspicious orders," 21 C.F,R. § 1301.74(h), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.govideareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration PM00 I /3425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List i Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number PM0018425.

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List 1 Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number PM0030849. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan *48226,* a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration PM0030849, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration RM0220688, will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (1) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section 11.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number RM0220688. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II.1 e-g.

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration RM0220688, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"), McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration PM0000771, for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, *e.g.,* administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances. McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

J• Any material breach by any McKesson facility of subsections II.l.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. <u>Obligations of DEA.</u>

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301,74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

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negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection IL1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration PM0018425, and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration RM0220688, and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

8. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a, and b.

d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement arid Release; or

e. Any liability based upon any obligation created by or arising under this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion,

5. Execution of Agreement. This Agreement shall become effective *(i.e.,* final and binding) on the date of signing by the last signatory (the "Effective Date"). The government *agrees* to notify McKesson immediately when the final signatory has executed this Agreement

6. Notices. Ail communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOI:

Drug Enforcement Administration, Diversion Control Division, 8701 Morrissctte Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrisseuc Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, 145 N St. NE (2 Constitution Square), 2"d Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post Street, 3& Floor
San Francisco, CA 94104

with copies to:

Vice President, U.S, Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
6535 State Highway 161
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical
McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

7. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8, Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOTA"), 5 U.S.C, § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement,

10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11, Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended,

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

By Louis J. Milione for

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Cardinal Health, Inc., ("Cardinal") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Cardinal and all 28 Cardinal DEA registered distribution facilities.

BACKGROUND

1. Cardinal is registered with DEA at 28 facilities as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., ("CSA" or "the Act"). See Appendix A.

2. In September 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA"). See Appendix B.

3. Cardinal's Lakeland distribution facility ("Cardinal Lakeland") is registered with DEA as a distributor of Schedule II-V controlled substances at 2045 Interstate Drive, Lakeland, Florida 33805, with an expiration date of May 31, 2012.

4. On February 2, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal Lakeland. See Appendix C.

5. The Order to Show Cause referenced above alleged, among other things, that:

   a. Despite the 2008 MOA, Cardinal Lakeland failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal;

   b. Cardinal Lakeland failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b); and

   c. Cardinal Lakeland failed to conduct meaningful due diligence of its retail pharmacies, including its retail chain pharmacy customers to ensure that controlled substances were not diverted into other than legitimate channels.

STIPULATION AND AGREEMENT

The facts alleged in the Order to Show Cause, as well as the facts alleged in the Government's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, constitute grounds under which DEA could revoke the DEA registration of Cardinal Lakeland. Cardinal admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate. In lieu of continuing proceedings to revoke the DEA registration of Cardinal Lakeland, Cardinal and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters involving the conduct described in the Order to Show Cause, as well as DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this administrative matter.

2. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

a. Conduct alleged in the February 2, 2012 Order to Show Cause ("Order to Show Cause"), and in DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D;

b. Failure to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels, including failing to conduct site visits of its retail pharmacy chain customers on or before May 14, 2012;

c. Failure to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before May 14, 2012; and

d. Failure to adhere to the provisions of the 2008 MOA, on or before May 14, 2012.

3. Effect of 2008 MOA. The obligations contained in the 2008 MOA are superseded by the obligations contained within this Agreement.

4. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1. Obligations of Cardinal.

   a. Cardinal agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1.f. This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this Agreement do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

   b. Within 120 days of the Effective Date of this Agreement, for all states, excluding Florida, Cardinal will commence procedures to ensure that any pharmacy, chain or retail, placing orders of controlled substances that are known to be diverted, or should be known to be diverted, at the time of the orders that Cardinal knows or should know are suspicious in nature, given the totality of the circumstances, will receive a site visit or an anonymous site inspection by a Cardinal employee or a qualified third-party inspector to provide an independent assessment of whether that customer's orders are being diverted. For Florida pharmacies, retail and chain, Cardinal, within 20 days of the Effective Date of this Agreement, will commence these site visit procedures. Cardinal will also employ additional field inspectors to perform investigations of Florida pharmacies.

      Cardinal will review and enhance its Quality and Regulatory Affairs ("QRA") processes and practices for establishing and increasing thresholds, including thresholds for Florida retail and chain pharmacies. Under the new processes and practices, two-person concurrence will be required before increasing thresholds for higher volume customers for specific drug classes. Cardinal understands that DEA does not endorse or otherwise approve threshold procedures, and that thresholds do not necessarily determine whether an order is suspicious.

   c. Cardinal will create a Large Volume-Tactical and Analytical Committee to review and make decisions regarding higher-volume retail and chain pharmacy customers, including higher-volume pharmacies in Florida. The committee will include the SVP of QRA (chair), VP Supply Chain Integrity, Regulatory Counsel, and the Director of QRA Analytics or designated equivalent officers.

d. Cardinal will enhance existing processes and practices for conducting due diligence reviews of pharmacies, chain and retail, including those located in Florida.

e. On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, as well as tramadol, through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15th of each month for the previous month's report. This information will be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Cardinal's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

f. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA has previously notified all of the DEA Field Offices that Cardinal is not required to provide suspicious order reports or any other type of report regarding suspicious purchases of controlled substances to the DEA Field Offices. Execution of this Agreement by DEA shall waive the DEA regulatory requirements to report suspicious orders to DEA Field Offices for the duration of the Agreement.

g. Cardinal agrees to the continued suspension of its authority to handle controlled substances at Cardinal Lakeland until May 15, 2014, so long as the provisions of II.2.c are met.

h. Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. § 1301.74(b).

i. Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of Cardinal in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement

authorities. However, nothing in this paragraph shall be construed as a waiver by Cardinal or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

j. Any material breach by any Cardinal facility of subsections II.1.a-f of this Agreement by Cardinal after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Cardinal's DEA certificate of registration for that facility.

k. Cardinal agrees that it will dismiss, with prejudice, the pending appeal by Cardinal in Case No. 12-5061 as well as the pending petition for review by Cardinal in Case No. 12-1126 in the United States Court of Appeals for the District of Columbia Circuit. Cardinal agrees that it will also dismiss, with prejudice, Case No. 12-cv-185 in the United States District Court of the District of Columbia.

2. Obligations of DEA.

a. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) and as described in subsection II.1.g. of this Agreement. DEA agrees to waive the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Offices.

b. In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider Cardinal's entry into this Agreement; all actions taken by Cardinal pursuant to this Agreement; any remedial actions taken by Cardinal to address the alleged or perceived violative conduct; and the compliance history of Cardinal at the particular facility, and at other Cardinal facilities.

c. If Cardinal is in compliance with the terms of this Agreement, DEA agrees that it will take appropriate steps to lift the suspension of Cardinal Lakeland's DEA registration and, if needed, to grant any requisite registration renewal on May 14, 2014.

3. Joint Obligations of the Parties.

a. Cardinal and DEA agree that upon the execution of this Agreement, DEA and Cardinal shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against Cardinal Lakeland in *The Matter of Cardinal Health*, DEA Docket No. 12-32.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of Cardinal under this Agreement, DEA agrees to:

a. Release Cardinal, together with its subsidiary entities, distribution facilities, and registrants that are listed in Appendix A, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 for the conduct alleged in the Order to Show Cause, DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, and for the conduct alleged in this Agreement; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of May 14, 2012, and the review of the reports and records Cardinal submitted to DEA prior to May 14, 2012. This release applies only to administrative actions brought before or by the Agency.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-covered conduct. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. DEA expressly reserves the right to pursue civil action, through the United States Attorney's Office, against Cardinal for the "Covered Conduct" as described in this Agreement. At Cardinal's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming Cardinal is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Cardinal. Cardinal fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Cardinal has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Cardinal) are the following:

a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any liability other than administrative claims released in Paragraph II.4.a. and b.; or

c. Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Cardinal, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Cardinal represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Cardinal further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices to Cardinal pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by Cardinal providing written notification to DEA:

a. Gilberto Quintero, Senior Vice President, Supply Chain Integrity and Regulatory Operations, 7000 Cardinal Place, Dublin, Ohio 43017; fax: 614-757-6597; email: gilberto.quintero@cardinalhealth.com;

b. With copy to: Steve Falk, Executive Vice-President and General Counsel, 7000 Cardinal Place, Dublin, Ohio 43017, fax: 614-652-7325; email: steve.falk@cardinalhealth.com.

7. Disclosure. Cardinal and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.

8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

9. Authorizations. The individuals signing this Agreement on behalf of Cardinal represent and warrant that they are authorized by Cardinal to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

10. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Cardinal distribution facility at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of Cardinal Health:

_____
Craig S. Morford
Chief Legal and Compliance Officer

Dated:

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Michele M. Leonhart
Administrator

Dated: 5/14/12

Wendy H. Goggin
Chief Counsel

Dated: 5/14/12

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Relevant Federal Statutes

21 U.S.C. § 842 (a) (5)

(a) Unlawful acts

It Shall be unlawful for any person -

(5) to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;

21 U.S.C. § 823 (b) (1)

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, research, or industrial channels;

21 C.F.R. § 1301.74 (b)

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Case No. 12-5061

CARDINAL HEALTH, INC.,
Plaintiff-Appellant,

v.

ERIC H. HOLDER, JR., *et al.*,
Defendant-Appellees.

On appeal from the United States District Court for the District of Columbia in
Case No. 1:12-cv-00185, Judge Reggie B. Walton

Appendix B
To *Amicus Curiae* Brief of the Healthcare Distribution Management Association "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances."

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)
INDUSTRY COMPLIANCE GUIDELINES:
REPORTING SUSPICIOUS ORDERS
AND PREVENTING DIVERSION OF CONTROLLED SUBSTANCES

Introduction

The U.S. healthcare supply chain is one of the most sophisticated in the world, providing a strong system for the safe and efficient delivery of medicines. Manufacturers, distributors, pharmacies and healthcare practitioners share a mission and responsibility to continuously monitor, protect and enhance the safety and security of this system to combat increasingly sophisticated criminals who attempt to breach the security of the legitimate supply chain.

The *HDMA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,* have been developed as part of HDMA member distributors' ongoing commitment to the safe and efficient distribution of all prescription medicines including controlled substances. These Industry Compliance Guidelines are consistent with, and further extend, the distributors' track record of supporting and implementing initiatives designed to improve the safety, security and integrity of the medicine supply. They have been prepared in recognition of a growing problem of misuse and diversion of Controlled Substances (CS) and the critical role of each member of the supply chain in helping to enhance security.

At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers. Due diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them for legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.

These Industry Compliance Guidelines can help identify facts and information about controlled substance product orders, and the customers placing the orders.

Healthcare Distribution Management Association (HDMA)
901 North Glebe Road, Suite 1000 • Arlington, VA 22203
(703) 787-0000 • (703) 935-3200
www.HealthcareDistribution.org

HDMA
Healthcare Distribution Management Association

History

In 1970, Congress enacted into law the Controlled Substances Act (CSA) as part of Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA provides the Drug Enforcement Administration (DEA) within the Department of Justice (DOJ) with the authority to regulate the manufacture, importation, possession and distribution of certain drugs. An additional federal agency, the Food and Drug Administration (FDA), and individual states, regulate many other aspects of drug supply chain safety and security. The CSA also created a closed system of distribution for those authorized to handle CS. Since its enactment in 1970, the CSA has been amended several times, including by the following statutes:

- The Psychotropic Substances Act of 1978;
- The Controlled Substances Penalties Amendments Act of 1984;
- The Chemical Diversion and Trafficking Act of 1988;
- The Domestic Chemical Diversion and Control Act of 1993;
- The Federal Analog Act; and
- The Methamphetamine Precursor Control Act which was superseded by the Combat Methamphetamine Epidemic Act of 2005.

The regulations in Title 21, Code of Federal Regulations (C.F.R.) part 1300 to 1316 apply to all individuals and firms desiring to conduct business in CS. All such individuals and firms must be registered with DEA, and are required to maintain complete and accurate inventories and records of all transactions involving CS, as well as security for the storage of controlled substances. Additionally, Sections 823(b) and (d) of the CSA call for the maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels.

In addition, distributors are required by 21 C.F.R. § 1301.74(b) to report suspicious orders of CS:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. [Emphasis added.]

Distribution Industry Commitment to Prevent Diversion of CS

Although distributors have been required to identify and report "suspicious orders" of CS and listed chemicals, increasing concerns about the potential misuse of prescription CS have elevated awareness within the supply chain and have led to increased expectations by DEA. Therefore, HDMA developed these Industry Compliance Guidelines to further scrutinize purchase orders for these products. For example, in public statements to Congressional Committees, DEA has noted

the growing problem of diversion and abuse of controlled pharmaceuticals, and has indicated the agency is taking stronger measures to address this matter.[1]

With the strong endorsement and expertise of our members, the Healthcare Distribution Management Association (HDMA) has developed the following Industry Compliance Guidelines for preventing diversion and reporting suspicious orders. We believe that implementation of these guidelines will help ensure that CS are appropriately distributed to supply chain customers involved in the legitimate dispensing of these important pharmaceutical products to patients, and will help distributors identify possible diversion activities.

OUTLINE

The *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, contains the following elements:

I. Know Your Customer Due Diligence
II. Monitoring for Suspicious Orders
III. Suspend/Stop an Order of Interest Shipment
IV. Investigation of Orders of Interest
V. File Suspicious Order Reports With DEA
VI. Employees, Training and Standard Operating Procedures (SOPs)
VII. Additional Recommendations
Glossary of Abbreviations

[1] See testimony provided by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; December 13, 2005, July 26, 2006, September 18, 2007, and June 24, 2008; and by Michele M. Leonhart, Acting Administrator, Drug Enforcement Administration, United States Department of Justice, March 12, 2008.

I. KNOW YOUR CUSTOMER DUE DILIGENCE

a. Introduction

Before opening an account for a new customer, the distributor should (i) obtain background information on the customer and the customer's business; (ii) review that information carefully, and, where appropriate, verify the information; and (iii) independently investigate the potential customer. To help ensure that the Industry Compliance Guidelines remain robust and adaptable, the "Know Your Customer Due Diligence" phase also describes "Additional Recommendations and Documentation" containing further suggestions for managing the distributor's procedures.

A distributor may tailor this part of its customer evaluation procedure to the type of customer under review. If a distributor does so, it is recommended that the distributor categorize each potential customer according to the customer's DEA "Business Activity" type as indicated on the customer's DEA registration certificate; for example, Retail Pharmacy, Hospital/Clinic, Practitioner or Distributor.

The following steps are recommended.

b. Information Gathering

All information requested by a distributor should be provided by the owner of the potential customer, the pharmacist in charge; or, in the case of a non-pharmacy customer, an equivalent designee. Each completed application, questionnaire or other document providing information requested by the distributor from the potential customer should be signed by the potential customer's owner, pharmacist in charge or equivalent designee. The signature should be notarized or should be accompanied by the statement: "*I declare under penalty of perjury that the foregoing is true and correct. Executed on [date].*"

The information gathering step would include:

- Provide potential customer with a credit application;
- Provide potential customer with a background questionnaire requesting the following information:
  - Business background,
  - Customer base,
  - Average number of prescriptions filled each day,
  - Average number of CS item prescriptions filled each day,
  - Percentage of CS purchases compared to overall purchases,
  - Verification of physical security controls for CS storage,
  - Questions based on DEA guidance and communications,
  - Copies of all their state and federal licenses and registrations,
  - If the potential customer is not currently conducting Internet prescription fulfillment, certification that they are not doing so, and will notify the distributor before conducting Internet prescription fulfillment;

- If the potential customer is conducting Internet prescription fulfillment, obtain the following information from any potential customer utilizing the Internet to receive and fill prescriptions:
  - The date the potential customer began conducting Internet prescription fulfillment,
  - Products the potential customer expects to purchase,
  - The quantity of each product the potential customer expects to purchase,
  - Practitioners who will be writing prescriptions that will be filled by the potential customer, including each practitioner's DEA and state registration and license numbers, address, telephone number(s), and other relevant contact information, and
  - National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (NABP VIPPS) check.
- Names of individuals authorized to sign DEA Form 222[2],
- A description of how the pharmacy/dispenser fulfills its corresponding responsibility to ensure that the prescriptions they receive are issued for a legitimate medical purpose (as required in 21 C.F.R. § 1306.04),
- Inspections:
  - Indicate whether DEA has audited/inspected the pharmacy/dispenser over a period of at least the last two (2) years and if so, explain why,
  - Indicate whether the pharmacy/dispenser has been inspected by the state regulatory/inspection authority such as the State Board of Pharmacy, and
- Identification of physicians and other treatment centers that are the potential customer's most frequent prescribers or highest purchasing doctors.

c. Information Review

After the information is received from the potential customer, it should be reviewed thoroughly. The review should include the following steps:

- Verify that the credit application is complete, and carefully review the information submitted;
- Verify that the customer background information supplied is complete, and carefully review the information submitted;
- Verify that the answers to the questions based on DEA guidance and communications are complete, and carefully review the information contained; and
- Verify the potential customer's state and federal licenses, registrations and CS schedule authorizations.

[2] See: 21 C.F.R. § 1301 regarding *"Orders for Schedule I and II Controlled Substances"* for DEA's regulations for ordering these products by means of either DEA Form 222 or electronically, including signature requirements.

d. Independent Investigation

The distributor should independently investigate the potential customer as follows:

- Check with the distributor's local DEA office for any information regarding the potential customer, such as DEA actions against the potential customer[3];
- Check with state oversight authorities, including the state Board of Pharmacy (for a potential pharmacy customer) and Board of Medicine (for a potential physician customer) to request further background information, such as state actions against the potential customer (some states may provide readily accessible information through the state's Web site);
- Check the DEA Web site and the Federal Register for any actions against the potential customer; and
- Conduct an Internet search to determine whether any potential Internet business can be identified as relating to the potential customer and whether there is any other relevant information that could affect the decision to do business with the potential customer.

e. Additional Recommendations and Documentation

It is recommended that:

- Individuals selected to develop questionnaires for part (a) and to conduct reviews and investigations under parts (b) and (c) above should receive appropriate training.
- The distributor should update the questionnaire(s) periodically, particularly if a concern arises during an investigation.
- The performance and results of all steps in the customer review process should be fully documented as to each potential customer, and such documentation should be retained in an appropriate file.
- After completing the steps outlined above, the reviewer of the potential customer should sign and date the information (in a designated location of the file) to indicate that the reviewer has conducted a thorough/complete review, and that the information contained in the file is accurate and complete to the best of his/her knowledge.
- A distributor may seek further information about a potential customer, including when the distributor determines that obtaining further background information, confirmation, or verification is warranted.
- The distributor may include provisions for notification of state and federal authorities of an unlawful activity identified under the "Know Your Customer Due Diligence" as required by local, state or federal law.

[3] Depending on the direction received from the local DEA office, the distributor may consider contacting the potential customer's local DEA office for further information regarding the potential customer.

II. MONITORING FOR SUSPICIOUS ORDERS

a. System Design

It is recommended that a distributor develop an electronic system, with accompanying written Standard Operating Procedures (SOPs), to meet the DEA's requirement in section 1301.74(b) that a distributor "design and operate a system to disclose to the registrant suspicious orders of controlled substances" (emphasis added). Distributors should assign responsibilities for identifying and investigating potentially suspicious orders, and for reporting suspicious orders. Specific elements of the monitoring system are further described below.

b. Identify Product and Customer Characteristics

Separate/classify/group customers into appropriate/different classes of trade. For example, retail pharmacies, hospitals, doctors, or dentists.

Separate the CS the distributor sells into groups or "families" of drugs (e.g., all CS items containing codeine). The following information may be useful for identifying the "families" of drugs:

- A distributor may use the DEA Web site to obtain DEA's designation of a drug's "controlled substance code number" to aid in developing a drug "family" for purposes of defining a threshold.[4]
  - (See: http://www.deadiversion.usdoj.gov/schedules/schedules.htm or http://www.usdoj.gov/dea/pubs/scheduling.html)
- Distributors may also use the National Technical Information Service (NTIS) system, which (i) identifies each individual CS Stock Keeping Unit (SKU) by National Drug Code (NDC) number, (ii) lists the active ingredient and (iii) lists the corresponding DEA controlled substance code number. The DEA controlled substance code number is set up by NDC number. An electronic copy of this information may be used to help identify the drug "families."
- Alternatively, a distributor may choose to identify "families" of drugs and track the dosage unit (e.g., tablet) order levels for each SKU.[5]
- A distributor should maintain contact with DEA through the local field office or the Office of Diversion Control's Web site, www.deadiversion.usdoj.gov, to ascertain changes in diversion patterns or new "Drugs of Concern" as the information is developed by the agency. Such new information should be made part of the identification of particular CS drugs or "families" to be monitored, as appropriate.

[4] For further information on the controlled substance code numbers, see 21 C.F.R. § 1308.03.
[5] This method may present implementation challenges due to of the different strengths of the drugs.

c. Develop "Thresholds" to Identify Orders of Interest

"Thresholds" for identifying orders of interest, *i.e.*, orders that warrant follow-up inquiry to determine whether they are suspicious, may be made by using averages shipped to a particular customer facility that are consistent with the class of customers to which the particular customer belongs. It is recommended that distributors develop such thresholds by calculating the average single order and the average monthly order per "family," per customer, and class of trade.

When evaluating thresholds, orders of "unusual size" and "unusual frequency" can be used to signal that an order may need further review. Distributors are also encouraged to structure their thresholds to support evaluation of whether the order deviates substantially from a normal pattern and/or is of unusual frequency. The following examples may aid in developing the thresholds:

- Patterns of ordering such as comparing the present order to:
  - past orders from the same customer (including the frequency of orders),
  - orders for extraordinary quantities outside of normal purchasing patterns typically followed by the customer or by other customers within the same class of trade, and
  - geographical area(s) of the country they service (e.g., orders from other establishments of the same type in the locale or region),
- Orders of more than one controlled substance that are known to be taken together (combinations) outside of normal prescribing and patient treatment practices, and
- DEA/State input.

Distributors are also encouraged to consider the following when developing "thresholds":

- Quantities of products the dispenser initially indicated during the "Know Your Customer Due Diligence" phase that it expected to purchase;
- A minimum of six months sales history and a maximum of 24 months sales history are recommended; Maintain contact with DEA through the local field office or the Office of Diversion Control's Web site, www.deadiversion.usdoj.gov, to ascertain changes in diversion patterns or emerging local or regional concerns; such new information may be used to adjust thresholds as appropriate; and
- Thresholds for all new customer accounts should be established at the lowest level indicated by information obtained during the "Know Your Customer Due Diligence" review.

d. Cumulative Reviews/Thresholds

A very important component of the system will be to include a mechanism for periodic review of cumulative orders from the same customer over time, to evaluate trends in purchasing patterns. This would include, for example,

- A mechanism to compare percentages of orders for CS (individual products and/or "families") to orders of non-CS prescription drugs so as to identify a shift in a customer's business focus that may warrant further review.

- Determining if the purchaser's ordering pattern, for a period of several months, shifts in a manner inconsistent with their previous ordering patterns or inconsistent with the class of trade for that customer (e.g., a pharmacy that orders relatively few controlled substances over several months suddenly places a large order or several large orders in a concentrated period of time.)

c. Supplemental Mechanisms for Determining Orders of Interest

Distributors are encouraged to recognize that their methods for identifying an "Order of Interest" do not need to be limited to an electronic "threshold" system. Based on the distributors' knowledge of his/her customers, overall drug purchasing trends, information available from DEA and elsewhere, distributors are encouraged to allow for alternative criteria, in addition to those incorporated into the electronic system, to serve as indicators of an order of interest.

III. SUSPEND/STOP AN ORDER OF INTEREST SHIPMENT

If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.

Ideally, the electronic system would contain a process to automatically "block" the order or otherwise stop the ordered product from being shipped. The distributor may, however, ship any non-CS included in the order and any other CS products as to which the order did not exceed a threshold or otherwise become characterized as an order of interest. A distributor may choose to report an order of interest to DEA immediately as a suspicious order or may first investigate the order as described in Section IV below and report it at the conclusion of the investigation if, but only if, it is determined to be a suspicious order.

IV. INVESTIGATION OF ORDERS OF INTEREST

a. Preliminary Steps

If a product order meets or exceeds a threshold, and is thereby identified as an order of interest (or on other grounds is characterized as an order of interest), it is recommended that the distributor examine the order further. The examination is intended to aid the distributor in reaching a decision to either ship product to fill the order or to continue to hold the order. Further examination will also aid in determining whether and when to report the order to DEA under 21 C.F.R. § 1301.74(b).

The drug or drugs that cause an order to become an order of interest should not be shipped to the customer placing the order while the order is an order of interest.

It is recommended that the distributor designate a person with suitable training and experience to investigate orders of interest.

b. Initial Review

When initially reviewing an order of interest, a distributor should first examine the specific drug code product order to determine whether the reasons the order met or exceeded the thresholds, or on other grounds was characterized as an order of interest, are not "suspicious" or whether the order warrants still further examination. The examination may include obtaining additional verification from the customer that placed the order. For example, the customer may be able to identify whether the order contained an error, or whether there has been a change in the customer's business circumstances that warrants a shift in its purchasing practices that can be readily identified.

c. Investigating the Order

If, after initial review, it is determined that the order should be examined further, it is recommended that the distributor conduct an additional review as quickly as possible. The following elements are recommended as part of the additional review:

Review prior orders
The distributor should review the customer's past purchasing history for trends/discrepancies to determine whether:

- The distributor had to investigate a prior order and the circumstance and results of any prior investigation, including whether a prior order exceeded the same or a different threshold, and how the present order compares to the past order(s) of interest;
- There has been an increase (or decrease) in orders for this "group" or "family" of CS products;
- There has been other unusual activity, such as "spikes" in prior orders (e.g., a pattern of ordering over several months where the customer has placed no orders, followed by a month with a large order);
- There has been a decrease in orders for other products, (potentially indicating a shift in focus or customer base);
- There has been a change in the customer's operating environment (e.g., a new medical establishment recently opened in the customer's neighborhood);
- There has been a change in availability of drugs (such as a new drug dosage form that has recently been approved by FDA) identified as a Drug of Concern by DEA's Office of Diversion Control; and
- There are end-of-year C-II quota issues.

Interview customer
Ask: Why is there an "unusual" order? What will you do with it? Who is prescribing it? (Who, what, when, where, why, how?)

Verify customer input – (where appropriate)
How and what information provided by the customer needs to be verified will be determined on a case-by-case basis, but examples of information that could be verified include:

- If a customer says there is a new medical establishment located nearby, verify the establishment's existence, name, address, practitioner(s) names and DEA registration numbers.
- If the customer says it called DEA, verify that it actually did so.
- If the customer states that a natural disaster destroyed its pharmacy and that it must restock, verify the disaster.
- If the customer claims it "lost" a shipment, verify the loss[6].

Additional Information
The distributor may seek additional information about the order and/or the customer who placed the order if, during the examination, it is determined that further confirmations or background information is warranted.

d. Documentation

All investigations should be fully documented, and all records of the investigation should be retained in an appropriate location within the firm (such as with other records relating to the particular customer).

At a minimum, documentation should include the name(s), titles(s) and other relevant identification of the representative of the customer contacted (e.g., "pharmacist in charge"), dates of contact, and a full description of questions asked and requests for information made by the distributor and of information provided by the customer. The documentation should include a clear statement of the final conclusion of the investigation, including why the order investigated was (or was not) determined to be "suspicious." That statement should be signed and dated by the reviewer. Copies of any written information provided by the customer should also be retained as part of the documentation of the investigation.

e. Shipment and Reporting Decisions (under 21 C.F.R. § 1301.74(b)); SOPs

At an appropriate point in the examination process, the distributor will decide how to resolve the order, specifically, whether the order is "suspicious," and should be reported. Employees should be selected and authorized to make shipment and reporting decisions based on their knowledge of DEA requirements, the distributor's business, customers and other relevant factors. (Further recommendations as to reporting to DEA can be found in Section V below.)

Orders that are determined to be "suspicious" should be reported to DEA under § 1301.74(b) immediately upon being so determined. It is assumed that the order will continue to be placed on

[6] Distributors should also determine whether there is an obligation to report the loss under 21 C.F.R. § 1301.76(b).

hold and/or cancelled, once it has been identified as "suspicious." An exception can be made if the distributor subsequently obtains additional or alternative information that leads to the conclusion that the order was misidentified as "suspicious," and/or is consistent with the pharmacy/dispenser's practice. In such instances, the order may be shipped. Full documentation of the reasons for the conclusion is recommended.

Each distributor is encouraged to develop SOPs that:

- Describe how an initial review and investigation will be conducted;
- Reflect the distributor's and its customers' business conditions;
- Are sufficiently flexible to adjust the review/investigation to address the individual product/order/customer circumstances that are likely to occur;
- Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";
- Define a process for reporting to DEA under 21 C.F.R. § 1301.74(b); and
- Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.

f. Future Customer Orders

In instances where a distributor concludes that an order is (or remains) "suspicious" after conducting an investigation, in addition to notifying DEA, it is recommended that the distributor evaluate its business relationship with the customer that placed the order. The distributor may consider whether to subject future orders from the same customer for the same drug code product (or all CS) to more rigorous scrutiny than was applied before the determination that the order is suspicious. A distributor may also consider whether to cease filling all future orders of the drug code product (or all CS) placed by that customer.

V. FILE SUSPCIOUS ORDER REPORTS WITH DEA

a. Immediate DEA Notification

Under 21 C.F.R. § 1301.74(b), orders designated as "suspicious" must be reported to DEA "when discovered." Once the distributor has made the determination that an order is suspicious, a phone call to report the order to the local DEA office is recommended to meet this requirement (unless DEA provides other direction). The distributor should provide additional documentation to DEA upon request.

Additional considerations:

- Even if there is some ambiguity regarding a customer or an order's status, occasions may arise when the intended use of an order is questionable. For example, the distributor may identify information that leads them to believe that a potential customer, prior to entering a formal business arrangement with that customer, may

intend to order CS products with a frequency, volume or other indicator that could be considered "suspicious." In such instances, the distributor should provide DEA with a report of this information under 21 C.F.R. § 1301.74(b).

- Distributors are strongly encouraged to regard timeliness of reporting to DEA as a critical component in meeting the requirement to report "when discovered."

b. Correspondence for Reporting

It is recommended that all correspondence to DEA (containing reports of suspicious orders) should be sent registered mail with a return receipt requested, by electronic mail or by another system that creates for the distributor a permanent record that DEA has received the notification. Although correspondence to the local DEA office is encouraged as a follow-up to a telephonic notification, distributors are encouraged to discuss with the local DEA office whether that office prefers to receive a follow-up written notice and the form for such notice.

The cover letter for reports of suspicious orders may read: "This report is submitted to you in accordance with the requirements of 21 C.F.R. § 1301.74(b) and is for (company name)." When the return receipt is received, it should be stapled to the cover letter as proof of submittal. (It is suggested that the distributor title the report "21 C.F.R. § 1301.74(b)" report.)

In some states, additional reporting requirements may apply. Each distributor should determine whether a state report is required, and should comply accordingly.

It is recommended that the same person conduct the investigation, decide (perhaps in consultation with one or more superiors) whether or not to cancel the order, and also provide the report to DEA.

c. Documentation

All additional contact with DEA, either by telephone or in person, should be documented; and a record of the contact should be maintained.

VI. EMPLOYEES, TRAINING AND STANDARD OPERATING PROCEDURES

a. Employees/Training

Individuals working in CS areas should be screened and selected for their attention to detail, ability to recognize the importance of accuracy, length of tenure with the company and work ethic.

It is recommended that employee training:

- Include a review of DEA rules and regulations;
- Fully cover the firm's procedures for compliance;

- Include backup training to cover instances when the employee primarily responsible for monitoring for suspicious orders will not be available (e.g., due to vacation leave or sick leave); and
- Provide for periodic retraining.

It is recommended that training be conducted for all personnel involved in:

- Receiving, shipping, handling and record-keeping with respect to CS items;
- Sales, or in establishing new accounts and persons who interact with customers; and
- Reviewing, investigating and/or deciding whether to fill orders.

All such training should be documented, and the documentation should be maintained.

b. SOPs

It is recommended that, to implement these Industry Compliance Guidelines, specific written company SOPs be developed and maintained.

VII. ADDITIONAL RECOMMENDATIONS

It is recommended that a distributor include in its "system" provisions for:

- Periodic internal audits of suspicious orders, compliance procedures and results;
- Periodic reviews and revisions of internal SOPs for compliance with §§ 1301.71(a) and 1301.74(b) and new DEA guidance, as well as employee training requirements/procedures;
- Periodic review of the distributor's system for monitoring for suspicious orders, including the system design and the thresholds, to determine whether revisions should be developed. For example, if the FDA approves a new controlled substance, or a new indication for use of an existing controlled substance, or if DEA makes new information available regarding a Drug of Concern, revisions to the thresholds may be needed; and
- If appropriate, update customer and/or order records on the basis of information obtained while investigating an order under Section IV above.

Glossary of Abbreviations

	Abbreviation	Explanation of Term
	ARCOS	Automation of Reports and Consolidated Orders System
	C.F.R.	Code of Federal Regulations
	C-I, C-II, C-III, C-IV, C-V	References the DEA's designation of individual controlled substances into one of the five levels under 21 C.F.R. §1308
	CS	Controlled Substances has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.)
	CSA	Controlled Substances Act
	DEA	Drug Enforcement Administration
	DOJ	Department of Justice
	FDA	Food and Drug Administration
	HDMA	Healthcare Distribution Management Association
	NABP	National Association of Boards of Pharmacy
	NDC	National Drug Code
	NTIS	National Technical Information System
	SKU	Stock Keeping Unit
	VIPPS	Verified Internet Pharmacy Practice Sites

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

DBS TRADING INC
11930 KEMPER SPRINGS
CINCINNATI, OH 45240-0000

September 27, 2006

In reference to registration
RD0277409

Dear Sir or Madam:

This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.

Background

As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country.[1] DEA has an obligation to combat this problem as one of the agency's core functions is to prevent the diversion of controlled substances into illicit channels. Congress assigned DEA to carry out this function through enforcement of the Controlled Substances Act (CSA) and DEA regulations that implement the Act.

The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[2]

The Statutory Scheme and Legal Duties of Distributors as DEA Registrants

Although most distributors are already well aware of the following legal principles, they are reiterated here as additional background for this discussion.

The CSA uses the concept of registration as the primary means by which manufacturers, distributors, and practitioners are given legal authority to handle controlled substances. Registration also serves as the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations, as Congress gave DEA authority under the Act to revoke and suspend registrations for failure to comply with these requirements. (Depending on the circumstances, failure to comply with the regulatory requirements might also provide the basis for criminal or civil action under the CSA.)

[1] See National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005); available at www.drugabuse.gov/PDF/RRPrescription.pdf

[2] 21 U.S.C. 801(2)

In Re: Masters Pharmaceutical, Inc.
Docket No. 13-39
Government Exhibit 3

Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S.C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety."

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

In addition, distributors are required to file reports of distributions of certain controlled substances to the DEA ARCOS Unit, in the time and manner specified in the regulations (21 C.F.R. 1304.33). The failure to file ARCOS reports in a complete and timely manner is a potential statutory basis for revocation under section 823(e). Depending on the circumstances, the failure to keep or furnish required records might also be the basis for civil fines or criminal penalties under the CSA, as provided in 21 U.S.C. 842.

In Re: Masters Pharmaceutical, Inc.
Docket No. 13-39
Government Exhibit 3

Circumstances That Might Be Indicative of Diversion

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g. , ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs
4. Ordering the same controlled substance from multiple distributors

A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances?
10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

In Re: Masters Pharmaceutical, Inc.
Docket No. 13-39
Government Exhibit 3

We look forward to continuing to work in cooperation with distributors toward our mutual goal of preventing the diversion of pharmaceutical controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

In Re: Masters Pharmaceutical, Inc.
Docket No. 13-39
Government Exhibit 3

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

MASTERS PHARMACEUTICAL, INC
11930 KEMPER SPRINGS
CINCINNATI OH, 45240-0000

December 27, 2007

In reference to registration
RD0277409

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

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Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

In Re: Masters Pharmaceutical, Inc.
Docket No. 13-39
Government Exhibit 4

Litigation Team

Counsel in Consortium

Baron & Budd, P.C.

Levin Papantonio et al.

Greene, Ketchum, Farrell, Bailey & Tweel, LLP

Hill, Peterson, Carper, Bee & Deitzler, PLLC

McHugh Fuller Law Group

Baron & Budd, P.C. is among the largest and most accomplished plaintiffs' law firms in the country. With 40 years of experience, Baron & Budd has the expertise and resources to handle complex litigation throughout the United States. As a law firm that takes pride in remaining at the forefront of litigation, Baron & Budd has spearheaded many significant cases for entities and individuals. Since the firm was founded in 1977, Baron & Budd has achieved substantial national acclaim for its work on cutting-edge litigation, trying hundreds of cases to verdict and settling tens of thousands of cases in areas of litigation as diverse as pharmaceuticals and defective medical devices, asbestos and mesothelioma, water contamination, fraudulent banking practices, motor vehicles, employment, and other consumer fraud issues.

Baron & Budd has represented hundreds of public entities in pharmaceutical, environmental, consumer and securities litigation. The Firm's attorneys were part of an attorney group that recently negotiated a $553 million settlement with 4 vehicle manufacturers regarding their use of faulty airbags manufactured by Takata. Baron & Budd's environmental litigation group litigated and settled claims on behalf of more than 150 water providers in 17 states regarding Methyl Teritary Butyl Ether (MTBE) contamination in groundwater. The $423 million settlement, reached with many of the country's leading gas companies, requires gasoline refiners to pay water providers' costs to remove MTBE from public drinking water wells and for refiners to pay for treatment of qualifying wells that may become contaminated within the next 30 years. The Firm's attorneys were co-lead counsel in litigation brought on behalf of seven states' attorneys general against GlaxoSmithKline regarding its fraudulent marketing of the diabetes drug Avandia; these cases settled for $177 million. Baron & Budd's environmental litigation group represented 30 mid-west water providers in litigation regarding the contamination of water systems by the agricultural chemical atrazine; these cases settled for $105 million. The firm also served as co-lead counsel for the states of West Virginia, Hawaii and Mississippi for their claims against various financial institutions regarding fraudulent marketing of payment protection plans and related credit card services, ultimately settling the cases for more than $43 million.

Baron & Budd represents thousands of individuals in pharmaceutical, defective medical device, securities, environmental and motor vehicle-related cases. The firm's attorneys have served or continue to serve on Plaintiffs Steering Committees and in key leadership roles in complex, multi-district litigations, including *In Re: 7-Eleven, Inc. Shareholders Litigation*; *In re Semtech Corporation Securities Litigation*; *In Re: Methyl Tertiary Butyl Ether ("MTBE") Products Liability Litigation*; *In Re: Checking Account Overdraft Litigation*; *In Re: Oil Spill by the Oil Rig Deepwater Horizon in the Gulf of Mexico*; the 7 Pelvic Repair System Products Liability MDLs; *In Re: Fresenius Granuflo/Naturalyte Dialysate Products Liability Litigation*; *In re: Cook Medical, Inc., IVC Filters Marketing, Sales Practices and Products Liability Litigation*; *In Re: Bard IVC Filters Products Liability Litigation*; *In Re: Takata Airbag Products Liability Litigation*; *In Re: Fluoroquinolone Products Liability Litigation*; *In Re: Zofran (Ondansetron) Products Liability Litigation*; and *In Re: Volkswagen Clean Diesel Marketing, Sales Practices, and Products Liability Litigation*.

Baron & Budd's attorneys are consistently recognized for excellence in advocacy by both peers and national legal publications and organizations, including the *Best Lawyers in America*, *National Trial Lawyers Top 100 Trial Lawyers List*, and the Firm's attorneys won a 2017 Burton Award, recognizing outstanding legal writing for an article appearing in *Trial* Magazine. *The National Law Journal* has included the firm in its NLJ "Hot List" of exemplary plaintiffs firms in the United States eight years since the list's inception in 2002 (American Lawyer Media). *The National Law Journal* also named Baron & Budd to the list of America's Elite Trial Lawyers, a list is comprised of 50 law firms that have achieved significant results on behalf of plaintiffs within the previous year and have an established track record of delivering impressive results. Baron & Budd has been a finalist for the Public Justice Foundation's "Trial Lawyer of the Year" award four times – most recently in 2013 for the Atrazine litigation and 2012 for the *In Re Checking Account Overdraft Litigation* – and was awarded the honor in 2007 for its work on a decades-long case against fighting water contamination in Tucson, Arizona.

Baron & Budd has frequently contributed resources and finances to a number of worthwhile nonprofit organizations including the International Mesothelioma Program at Brigham and Women's Hospital, Asbestos Disease Awareness Organization, Lung Cancer Alliance, the National Comprehensive Cancer Network (NCCN), Attorneys Serving the Community (a Dallas-Ft. Worth area women's attorney group), Genesis Women's Shelter and the Dallas Children's Advocacy Center.

BARON B BUDD®

Russell W. Budd, a shareholder of Baron & Budd since 1985 and president and managing shareholder since 2002, has devoted his entire career to championing the rights of people and communities harmed by corporate malfeasance. As chair and member of several asbestos creditors' bankruptcy committees, Budd has successfully resolved over 100,000 victims' claims with some of Wall Street's biggest companies, including establishing trust funds and settlement funds valued at nearly $11 billion to protect present and future asbestos victims throughout the United States.

Budd has also been instrumental in conducting national negotiations for non-asbestos claims. Budd was a leader in settlement negotiations in *In Re Checking Account Overdraft Litigation* that resulted in settlements valued at more than $500 million in cash and more than $100 million in business practice changes. Budd was one of the negotiators of a $177 million settlement for litigation brought on behalf of seven states' attorneys general against GlaxoSmithKline regarding its fraudulent marketing of the diabetes drug Avandia, and was a key negotiator of settlements valued at more than $43 million for the states of West Virginia, Hawaii and Mississippi for their claims against various financial institutions regarding fraudulent marketing of payment protection plans and related credit card services.

Baron & Budd shareholder Burton LeBlanc has successfully represented both individuals and governmental entities, including the States of Hawaii, Mississippi, Louisiana, and West Virginia in complex consumer fraud litigation. He was part of Baron & Budd's team that pursued litigation on behalf of seven states' attorneys general against GlaxoSmithKline regarding its fraudulent marketing of the diabetes drug Avandia, litigation which settled for $177 million. LeBlanc is a recent (2013-2014) past-president of the nation's largest non-profit trial lawyer group, American Association for Justice (AAJ). He remains actively involved with AAJ and shares their commitment to relentlessly advocate for the protection of America's civil justice system and the fundamental right to a trial by jury. LeBlanc is a 2017 recipient of the Lifetime Achievement Honor from America's Top 100 Attorneys for his career dedicated to the protection of America's civil justice system. He was named as one of the top 75 plaintiff's attorneys in the United States by *The American Lawyer* in 2014 and has also been selected for inclusion in the *Louisiana Super Lawyers®* list from 2012 to the present.

Roland Tellis' practice focuses on complex, high-profile litigation, including consumer class actions, financial fraud, business torts, corporate misconduct, automobile defect, food labeling, false advertising, securities fraud and environmental contamination. He holds leadership roles in numerous multi-state, complex class action cases, including *Bias v. Wells Fargo Bank*, a certified nationwide RICO class action involving millions of mortgage loans that settled for more than $50 million; *In re: Volkswagen "Clean Diesel" Marketing, Sales Practices, and Products Liability Litigation*, a multi-state class action in the process of settling with values and fines totaling in the billions of dollars, involving hundreds of thousands of vehicles equipped with "defeat devices" designed to evade emissions laws; and *In Re: Takata Airbag Products Liability Litigation*, which has received preliminary approval for a settlement valued at $553 million. Tellis received commendation from the U.S. Department of Justice and the Federal Bureau of Investigation for his assistance in a successful parallel prosecution of a $120 million securities Ponzi scheme perpetrated by foreign currency traders. He has served on the Board of Governors of the Association of Business Trial Lawyers and as a Lawyer Representative to the Ninth Circuit Judicial Conference. Tellis has also served as a Co-Chair of the Settlement Panel of the U.S. District Court for the Central District of California. He was selected for the 2017 edition of *The Best Lawyers in America®*.

Former Baron & Budd Shareholder S. Ann Saucer is an Of Counsel lawyer with the firm, focusing her practice on appellate advocacy and briefing in complex litigation for both individuals and public entities. She has successfully argued before the U.S. Fifth Circuit Court of Appeals, the U.S. Ninth Circuit Court of Appeals, the Texas Court of Appeals (Dallas) and federal and state trial courts across the country, often as the key author of briefings and presenter of oral argument. Ms. Saucer has also spoken and published articles on federal procedure issues. Her background covers the spectrum of commercial, financial, pharmaceutical and defective medical devices, environmental law, consumer protection, product liability and toxic torts.

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www.baronandbudd.com

Levin Papantonio was founded in 1955, in Pensacola, Florida, and is one of the largest plaintiff's law firms in the country with nearly 40 attorneys and more than 150 support staff.

Levin Papantonio has a longstanding reputation as one of America's premier trial firms. Levin Papantonio attorneys have tried more than 150 cases resulting in jury verdicts exceeding $1 million, and the firm has recovered more than $3 billion through verdicts and settlements over the last 25 years. The National Law Journal recognized Levin Papantonio as the fourth most successful law firm in America based on total jury verdicts in 2002. Fred Levin was named one of the nation's "Top Ten Litigators." After securing a $380 million verdict in 2007, three of the firm's attorneys were nominated as one of the top trial teams in the country by the Public Justice Foundation. Through multiple trial verdicts against Dupont regarding C8, Levin Papantonio lead a $920 million settlement in 2017. Over 60 years, Levin Papantonio attorneys have been committed to aggressively pursuing our clients' rights through trial.

Levin Papantonio routinely holds leadership positions in some of the country's most complex multi-district litigations, including the Plaintiffs' Executive Committee for In re Deepwater Horizon (BP) Oil Spill in the Gulf, MDL 2179 (E.D. LA), helping to bring about the recent $20.8 billion settlement in that action. The firm's attorneys also served on the Plaintiff Steering Committee and as co-chair of the Discovery Committee for the Bayer Yaz/Yasmin pharmaceutical litigation, in which Bayer has paid approximately $2 billion to date. Levin Papantonio has decades of leadership experience spearheading America's most complex litigation. Levin Papantonio routinely represents cities, counties, and government agencies in lead counsel roles ranging from areas such as pharmaceutical, environmental, derivative, securities, and antitrust litigation, to a key role in the landmark tobacco cases brought by states to recover health care expenditures.

Levin Papantonio is "AV" rated, and its attorneys have been inducted into the National Trial Lawyer Hall of Fame, listed in Best Lawyers in America, and profiled by national publications and news outlets including the New York Times, Los Angeles Times, Forbes, Time Magazine, Newsweek, Fox News, ABC News, and CNN. The attorneys at Levin Papantonio have the experience and resources necessary to hold large corporations accountable for their wrongful conduct. As a nationally recognized litigation firm, Levin Papantonio has built a reputation on its willingness to litigate to verdict complex disputes against some of the world's largest companies.

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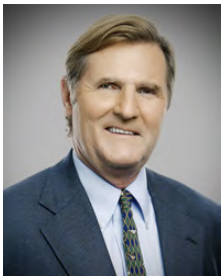


Mike Papantonio is a senior partner of Levin Papantonio and is a Board Certified Civil Trial Lawyer by the Florida Bar and the National Board of Trial Advocacy. He is a member and leader of both national and international legal associations, including the National Trial Lawyers Association, of which he was the 2012 President.

Mr. Papantonio is recognized as one of the Best Lawyers in America and a Leading American Attorney, was awarded the Florida Justice Association 2011 Perry Nichols Award, and has been selected by the Public Justice Foundation as a finalist for its Trial Lawyer of the Year Award. Mr. Papantonio also founded Mass Torts Made Perfect, which has trained thousands of lawyers in how to better their legal practice, and featured speakers including United States Presidents.

Mr. Papantonio has obtained multiple settlements and verdicts in the tens and hundreds of millions of dollars. In 2001, Mr. Papantonio obtained a $70 million settlement against polluters of waterways. In 2007, as lead trial counsel in an environmental class action Mr. Papantonio received a jury verdict award for a West Virginia community with an estimated value in excess of $380 million. In 2017, he helped secure a $920 million DuPont C8 settlement.

Peter Mougey is a shareholder and the Chair of Levin Papantonio's Securities and Business Litigation department. Recognized as one of Florida's top 100 trial lawyers, a Florida Super Lawyer in securities litigation, Mr. Mougey has been rated AV Preeminent through Martindale-Hubbell and has served as the president of the international securities bar association PIABA ("Public Investors Arbitration Bar Association") and on the Board of Directors and Executive Committees thereof.

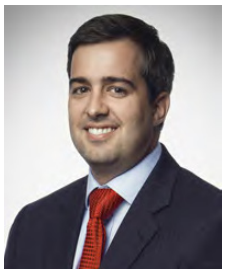
In Mr. Mougey's securities and complex litigation practice, over the last five years, Mr. Mougey has represented approximately 50 state, municipal, and institutional clients in litigation and arbitration, as well more than one thousand fraud victims in state and federal court and arbitrations across the country. He has recovered more than $250 million on behalf of his clients.

A founding member of the Business Torts section of Mass Torts Made Perfect, Mr. Mougey is a frequent national speaker regarding issues related to complex litigation. Mr. Mougey also serves in leadership positions in local community organizations and charities, including as President of the Association of Retarded Citizens ("ARC").

Mark Proctor is the president of Levin Papantonio, leading the firm in its large-scale, complex litigation. Under Mr. Proctor's leadership, Levin Papantonio has secured billions of dollars in recoveries for clients. Mr. Proctor's extensive experience includes serving as former Assistant General Counsel for the City of Jacksonville, and the former General Counsel for the State of Florida Department of Natural Resources.

Mr. Proctor has served as a member and in leadership roles in the Florida Bar Association, the Florida Justice Association, the American Association of Justice, and the National Trial Lawyers Association. He is a founding member of Mass Torts Made Perfect, is a member of the Board of Trustees of the Fredric G. Levin College of Law at the University of Florida, and also serves on the board of directors for several charitable organizations. An author of seminal environmental articles for the Center of Land Use Law, Mr. Proctor has also been an adjunct professor of Environmental Law at the University of Florida and the University of West Florida.

Laura Sherling Dunning is an attorney in the Securities and Business Litigation department of Levin Papantonio. Mrs. Dunning has been repeatedly recognized as an Alabama and MidSouth Super Lawyer Rising Star in securities litigation. In her practice, which focuses on complex business litigation, whistleblower, class action, and antitrust litigation, Mrs. Dunning has represented dozens of governmental entities and hundreds of fraud victims in arbitration and in state and federal court, and has helped secure more than one hundred million dollars in recoveries for clients. Mrs. Dunning also serves in leadership positions with local charitable boards, including the YWCA of Central Alabama.



Jeff Gaddy is an associate attorney with Levin Papantonio. A former Assistant State Attorney at the Office of the State Attorney of the First Judicial Circuit where he served as a special prosecutor in the Homicide and Major Crimes Division, Mr. Gaddy tried over one hundred jury trials to verdict. Mr. Gaddy has focused his civil practice on pharmaceutical and consumer protection litigation. As part of the C8 trial team, Mr. Gaddy helped to secure a $920 million settlement. He is also an active member of the Florida and Mississippi Bar, and the local Rotary Club.

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For 60 years, Greene, Ketchum, Farrell, Bailey & Tweel LLP has been committed to fighting for justice for their clients, and has been a highly esteemed pillar in the community. The firm's attorneys have served on numerous legal and educational boards in West Virginia, including West Virginia State Bar Board of Governors; the West Virginia Ethics Commission; West Virginia Law Institute's Governing Council; West Virginia Judicial Vacancy Advisory Commission; West Virginia Association for Justice Board of Governors; Marshall University Foundation, Inc.; The Society of Yeager Scholars at Marshall University; the Faculty Merit Foundation of West Virginia, Inc. (selects higher education's "Professor of the Year"); the Marshall University Graduate School Advisory Board; Hospice of Huntington; and the Cabell County American Cancer Society.

Greene Ketchum attorneys have successfully tried numerous civil cases to verdict in state and federal courts. Their skilled advocacy has returned millions of dollars in verdicts for their clients in both trial settings and settlements. The firm's attorneys have been recognized by legal organizations for excellence and included in The National Advocates Top 100 Trial Lawyers and West Virginia Super Lawyers®.

Paul Farrell, Jr. is a West Virginia trial lawyer and partner at Greene, Ketchum, Farrell, Bailey & Tweel, LLP in Huntington, West Virginia. Mr. Farrell is recognized as a premier trial lawyer in the field of medical malpractice and appellate advocacy, making some thirty (30) appearances before the West Virginia Supreme Court. He has been a frequent presenter at legal education seminars and since 2004 has served on the West Virginia Continuing Legal Education Commission.

Mr. Farrell filed some of the first transvaginal mesh (TVM) cases in the country and served as liaison counsel on the executive committee for the 7 Pelvic Repair System Products Liability MDLs in Charleston, West Virginia. These MDLs consolidated 80,000 cases and resulted in several multi-million dollar jury verdicts. Mr. Farrell served as trial counsel for the TVM litigation, successfully trying 2 bellwether cases to verdicts in excess of $20 million.

Mr. Farrell recently filed the first cases in the country on behalf of public entities against the wholesale distributors of prescription opiates in southern West Virginia and is focusing his efforts to abate the nationwide opioid epidemic.

Mr. Farrell is a graduate of the University of Notre Dame (1994) and West Virginia University College of Law (1997) and licensed to practice law in West Virginia, Ohio and Kentucky. He was named West Virginia Association for Justice Trial Lawyer of the Year (2002) and served as the President of the West Virginia Association for Justice (2011-2012).

The Law Firm of Hill, Peterson, Carper, Bee & Deitzler, PLLC, began in 1980, when senior partner, R. Edison Hill, departed a large corporate and insurance defense firm to begin a small personal injury practice. The firm's attorneys represent individuals and families in many diverse areas of complex litigation including water contamination, personal injury, pharmaceutical and defective medical devices, and medical malpractice. The firm's attorneys were awarded the prestigious Trial Lawyer of the Year award by Public Justice in 2005 for their work on the successful class action litigation *Leach, et al. v. E. I. du Pont de Nemours and Company* involving representation of plaintiffs who suffered various cancers and other illnesses due to exposure through drinking water to the chemical ammonium perfluorooctanoate ("PFOA" or "C-8"), a chemical utilized in the manufacture of Teflon. The firm's attorneys also served on the Plaintiffs Steering Committee for *In re: E. I. Dupont de Nemours and Company C-8 Personal Injury Litigation*, which has reached a global settlement of close to $1 billion. Hill, Peterson, Carper, Bee & Deitzler, PLLC, has been designated by "Benchmark Plaintiff" (The Definitive Guide To American Leading Plaintiff Firms & Attorneys) as one of West Virginia's three top and "highly recommended" litigation law firms.

R. Edison (Ed) Hill is a trial attorney and the founder and a member/partner of Hill, Peterson, Carper, Bee & Deitzler, PLLC. Mr. Hill has served as class action counsel for numerous certified class actions, including *Burch, et al. v. American Home Products Corp, et al.* (Fen-Phen Diet Drug Litigation), the largest pharmaceutical class action in the history of West Virginia, and *Leach, et al. v. E. I. du Pont de Nemours and Company.* He also serves on the Plaintiffs Steering Committee for *In re: E. I. Dupont de Nemours and Company C-8 Personal Injury Litigation*, which recently reached a settlement valued at nearly $1 billion. Mr. Hill was named as one of "America's 100 Most Influential Trial Lawyers" by *The Trial Lawyer*'s RoundTable in 2017 and has been designated as one of West Virginia's twelve "Litigation Stars" by *Benchmark Plaintiff* (The Definitive Guide To American Leading Plaintiff Firms & Attorneys). He has also been named as a Fellow of the West Virginia Bar Foundation, awarded to "lawyers whose professional, public and private careers have demonstrated outstanding dedication to the welfare of their communities and honorable service to the legal profession with the individuals selected reflecting the diverse nature of the legal profession in West Virginia." Mr. Hill is involved in many legal professional organizations, including American Association for Justice (Life Member), National Trial Lawyers Association (Executive Committee Member), West Virginia Trial Lawyers Association (Past-President and current Board of Governors member), Public Justice Foundation, Lawyer-Pilots Bar Association, Southern Trial Lawyers Association and the Consumer Attorneys of West Virginia. He has been named a *West Virginia Super Lawyer*® each year from 2009 the present. He also serves as Chairman for the Central West Virginia Regional Airport Authority, which is the governing board for Yeager Airport, located in Charleston, West Virginia. He has served on the Yeager Airport Board of Directors since 1993.

James C. Peterson has been a member/partner at Hill, Peterson, Carper, Bee & Deitzler, PLLC since 1983, focusing his legal practice on litigation of severe personal injury, medical/legal malpractice, product liability, insurance bad faith, mass tort/class action involving defective products, pharmaceuticals and insurance issues. He served as co-lead counsel for the settlement of the largest pharmaceutical class action litigation in the history of the State of West Virginia, involving the diet drug Fen-Phen (*Burch, et al. v. American Home Products Corporation, et al.*). Settlements and verdicts handled on behalf of Hill & Peterson or on a co-counsel basis exceeds $1.6 billion. Representative mass tort/class action in addition to *Burch* includes *McCallister, et al., v. Purdue-Pharma, Inc., et al.* (Oxycontin - potent pain killer drug); *VIOXX Products Liability Litigation*, MDL 1657 (osteo-arthritic pain medication); *In Re: E. I. Dupont de Nemours and Company C-8 Personal Injury Litigation*, MDL 2433 (involving representation of 3,500 plaintiffs who suffered various cancers and other illnesses due to exposure to C-8, a chemical used in the manufacture of Teflon, in public drinking water; global settlement reached in 2017 for close to $1 billion.); and *Good v. American Water Works Company, Inc.*, et al., Case No. 2:14-CV-01374 (putative class alleging economic and personal injury loss due to water contamination, tentative settlement reached Fall 2016, for over 250,000 residents and businesses in the 9-county area). Mr. Peterson has been board-certified as a civil trial specialist by the National Board of Trial Advocacy (NBTA) since 1990; named member of the year by the West Virginia Trial Lawyers Association in both 1988 and 1993; served in a variety of positions with both state and national trial lawyer organizations, including president of the West Virginia Trial Lawyers' Association (1996-1997); and admitted to practice in the states of Minnesota, Ohio, and West Virginia. Since 1987, Mr. Peterson has presented over 40 papers and articles nationwide on various legal topics in over two dozen states. He authored a chapter for a National Brain Injury Association publication involving hedonic damages, and an article on the same for TRIAL Magazine (published by American Association for Justice). Mr. Peterson is recognized as a life member of American Association for Justice (AAJ), an honor bestowed on approximately 50 lawyers for that nationwide trial organization. He was selected in 2005, along with two of his partners Ed Hill and Harry Deitzler, as Trial Lawyers of the Year by Public Justice.

McHUGH FULLER LAW GROUP

McHugh Fuller Law Group is a trial firm based out of Hattiesburg, Mississippi that specializes in complex litigation and trials in the health and medical fields. With only eight members, the firm functions as an elite trial team made up of experienced litigators and legal writers. The attorneys at McHugh Fuller are admitted to practice law in eighteen states including Mississippi, Florida, Texas, Alabama, Arkansas, Georgia, Illinois, Kentucky, Michigan, Missouri, New Hampshire, New York, Ohio, Oklahoma, Pennsylvania, Tennessee, West Virginia, Wisconsin, and the District of Columbia. Our lawyers have tried over one hundred cases, obtaining multi-million dollar verdicts in courts throughout the country. The attorneys at McHugh Fuller have amassed over three-hundred million dollars in jury verdicts alone, and have successfully handled appeals before State Supreme Courts and Courts of Appeal in seven states, numerous Federal District Courts, the 4th, 5th and 11th Circuit Courts of Appeal and the United States Supreme Court.

Mike Fuller has extensive experience in nursing home, medical malpractice and criminal prosecutions and trials. He has worked with a top national law firm and the Hillsborough County State Attorney's Office in Florida, and he has litigated and tried numerous cases to verdict in jurisdictions nationwide.

Mr. Fuller obtained his undergraduate degree from the University of Central Florida, where he graduated Summa Cum Laude, and his Juris Doctorate from the University of Florida, where he graduated with high honors. Part of his educational process was spent working in the White House as an intern involved with Presidential Correspondence, providing a wealth of experience with citizens, legislators and diplomats across the United States.

Mr. Fuller is licensed to practice law in the District of Columbia, Florida, Georgia, Kentucky, Michigan, Mississippi, Missouri, New York, Ohio, Pennsylvania, Tennessee, West Virginia and Wisconsin.

Amy Quezon received her undergraduate degree from Furman University in 1989. She received her Juris Doctorate degree from Stetson University, College of Law, cum laude, in 1992.

Prior to joining McHugh Fuller Law Group, Ms. Quezon was an associate with the law firm of Jacobs & Goodman. Prior to that she was with the law firm of Wilkes & McHugh, P.A. where she practiced nursing home abuse and neglect litigation. Ms. Quezon also spent part of her career as a prosecutor with the Hillsborough County State Attorney's Office. While there, Ms. Quezon was the lead trial attorney focusing on violent felony cases. During her career, she has tried over 100 civil and criminal jury trials.

Ms. Quezon is licensed to practice law in Florida, Georgia, Kentucky, Mississippi, Missouri, New Hampshire, Ohio, Tennessee, Texas, West Virginia and Wisconsin. She is a member of the Florida Bar, the Hillsborough County Bar Association, The Florida Justice Association (f/k/a The Academy of Florida Trial Lawyers), the American Bar Association, the American Association for Justice (f/k/a the American Trial Lawyers Association), the Mississippi Bar Association, the State Bar of Texas, and the Southern Trial Lawyers Association.

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