UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of

Masters Pharmaceutical, Inc.  

Docket No. 13-39

DECLARATION OF
JENNIFER SEIPLE

John A. Gilbert, Jr.
Karla L. Palmer
Delia A. Stubbs
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, D.C. 20005
(202) 737-5600
(202) 737-9329 (fax)
jgilbert@hpm.com
kpalmer@hpm.com
dstubbs@hpm.com

Richard T. Lauer
Masters Pharmaceutical, Inc.
8695 Seward Road
Fairfield, Ohio 45011
(513) 619-8038
(513) 619-8039 (fax)
rlauer@mastersrx.com

Dated: December 31, 2013
STATE OF OHIO

COUNTY OF BUTLER

I, Jennifer Seiple, being duly cautioned and sworn, state the following:

BACKGROUND

1. My name is Jennifer Seiple. I am 44 years old and I have personal knowledge of the information contained in this affidavit.

2. I attended Lakota high school in Cincinnati, Ohio. I graduated in 1987 and then went to the University of Cincinnati. I received my Bachelor’s degree in African Studies in 1999. I received my Master’s degree in Urban Planning from the University of Cincinnati in 2001.

3. I began working in the pharmaceutical industry in October 2004 as a Sales Representative at KeySource Medical.

4. I began working at Masters Pharmaceutical, Inc. (“Masters” or “the Company”) in January 2006 as a Sales Representative. I was promoted to National Sales Manager four months later.

5. As a result of my work in pharmaceutical sales and through my interactions with hundreds of pharmacy customers, I learned about prescription drugs and medical devices. I also learned all the various families of controlled substances and the drugs within each family, and the ordering patterns and volume of numerous pharmacy customers who would order controlled substances. I also gained a general understanding of the medical conditions for which controlled substances were prescribed, typical monthly doses, and other information about controlled substances. I learned about 222 forms how they must be completed, and about CSOS, the electronic system for ordering controlled substances.
6. During my work in sales, I also gained a general understanding of DEA regulations, and the controlled substances that were most commonly diverted and abused.

7. In December 2008, I accepted the position as Compliance Manager at Masters. In that position, I worked closely with Matt Harmon, Wayne Corona and Dennis Smith to enhance my understanding of DEA regulations, the details of Masters’ Controlled Substance Handling Policies and Procedures, and, specifically, customer due diligence.

8. In approximately May 2010, I was promoted to Vice President of Compliance. I continue to hold that position today. I supervise Masters’ team of Compliance Analysts, and our Compliance Manager. I am responsible for all the day to day activities of Masters’ Compliance Department. I oversee and am directly involved in reviewing orders of interest that have been held by Masters’ electronic Suspicious Order Monitoring System (“SOMS”), regardless of whether those orders are placed by a customer of Masters or a customer of one of Masters’ third-party logistics (“TPL”) clients.

9. I am a member of Masters’ Compliance Committee and, as such, I am directly involved in setting compliance policies and procedures and making sure they are followed. I am also involved in maintaining Masters’ DEA registrations, as well as the Company’s numerous state licenses and permits. I report to Masters’ General Counsel.

10. In addition to the duties listed above, I am directly involved in investigating the loss or alleged theft of controlled substances. I complete and submit the DEA 106 forms when required. I am familiar with the physical security of Masters’
two DEA-registered facilities. I am also directly involved in helping some of Masters’ Third-party logistics clients complete the forms necessary to import the controlled substances they manufacture into the United States.

11. Since joining the Compliance Department, I have been a member of Masters’ Compliance Committee that reviews certain orders of interest held by Masters’ SOMS which, for various reasons, cannot be evaluated by the Company’s Compliance Analysts. The Compliance Committee meets regularly, usually at least once a week.

12. Since I began working at Masters, I have attended conferences, meetings and seminars relating to DEA compliance, suspicious order reporting, controlled drug handling and similar topics. Most recently, in May 2013, I attended a conference hosted by DEA in Washington, DC during which DEA provided guidance to the pharmaceutical industry about current trends in the abuse and diversion of controlled substances, ARCOS reporting, suspicious order reporting, customer due diligence and other related topics. I also subscribe to and routinely read industry newsletters, DEA publications, and other sources in order to stay abreast of current developments in the controlled substance compliance field.

13. As part of my duties, I have had regular contact with Masters’ local DEA representatives, with various state licensing boards, and with other governmental agencies that regulate the storage and distribution of prescription drugs.

14. Exhibit R3 is a true and accurate copy of a September 27, 2006 letter from Joseph Rannazzisi to Masters, which was then known as DBS Trading, Inc., which is maintained in Masters’ files relating to controlled substance compliance.
15. Exhibit R4 is a true and accurate copy of a December 27, 2007 letter from Joseph Rannazzisi to Masters which is maintained in Masters’ files relating to controlled substance compliance.

MASTERS’ CONTROLLED SUBSTANCE COMPLIANCE POLICIES AND PROCEDURES

16. In August 2009, in accordance with the Administrative Memorandum of Agreement dated April 1, 2009 between DEA and Masters (“the 2009 MOA”), Masters implemented its entirely new, proprietary, electronic SOMS. I was directly involved in implementing the new SOMS, reviewing orders of interest held by the system, and I am very familiar with the system and how it works. The Company also revised and enhanced its existing customer due diligence procedures, and implemented special policies for new customers in Florida and Houston, Texas.

17. Before Masters will deliver any controlled substances to any customer, the customer must go through a thorough due diligence evaluation. Among other things, Masters confirms that the customer has a valid state pharmacy license and a valid DEA registration.

18. In addition, the customer must complete a Due Diligence Assessment Form (“DD Survey”). A true and accurate copy of the DD Survey currently used by Masters has been identified as Respondent’s Exhibit 63.¹ This form has been changed several times over the years.

19. Among other things, the current DD Survey requires the customer to provide the following information: Company name, Company Owner(s), Pharmacist in charge, whether the pharmacy has any current or past ownership or affiliation with pain

¹ In this Declaration, Respondent’s Exhibits will be identified as “Exhibit R __.”
clinics, medical clinics or other pharmacies, whether the pharmacy has a website, its hours of operation, the date the pharmacy was opened, how many employees it has, its size, primary customer base, and whether it services any institutional or “closed door” customers.

20. Masters’ DD Survey also requires the pharmacy to provide information about its dispensing practices including the following: the pharmacy’s primary wholesaler, and whether it orders from other suppliers, whether it sells a full assortment of over-the-counter and sundry items, its daily prescription average and its daily ratio of controlled to non-controlled drugs dispensed, whether the pharmacy fills prescriptions for pain management physicians and, if so, the percentage of prescriptions being filled for pain management physicians or clinics, whether the pharmacy accepts insurance, Medicare or Medicaid and what percentage of prescriptions are paid for by those sources, and whether the pharmacy is located in a hospital, medical center or other similar facility.

21. Masters’ DD Survey also requires the pharmacy to disclose whether it fills prescriptions placed over the internet or via mail orders, whether it fills prescriptions for out-of-state patients or written by out-of-state physicians, and to describe the policies and procedures it uses to prevent “doctor shopping” and the diversion of controlled substances.

22. Masters’ Compliance Department reviews each survey and will contact the customer if it detects and discrepancies, has any questions or if it finds that material information is missing or incomplete. Masters will not do business with any pharmacy that discloses that it fills prescriptions placed over the internet.
23. All Masters' customers, including any that seek to purchase controlled substances, must complete a credit application. Exhibit R64 is a true and accurate copy of Masters' current credit application. To the best of my knowledge, Masters' Credit and Finance department obtains a Dun and Bradstreet or similar report on all potential customers which reveals how long the customer has been in business, the names of individuals associated with the customer, and other information relevant to the customer's credit worthiness. No customer is allowed to purchase any products from Masters, including controlled substances, unless it has sufficient credit worthiness as determined by the Company's Credit and Finance Department.

24. Masters subscribes to the NTIS Bibliographic Database maintained by the United States Department of Commerce. According to the NTIS website, the NTIS database is the only authorized official distributor of the DEA's Controlled Substance Act database on the internet. Before selling any controlled substances to any customer, Masters checks the NTIS database to confirm that the customer has a valid DEA registration. Masters reviews the NTIS database at least quarterly to confirm the registration status of each of its customers.

25. Masters also obtains a copy of the customers' state pharmacy license and, if applicable, its state controlled drug license. Masters also obtains a copy of the pharmacist's state license.

26. Only after a potential customer has provided all of the information listed above is it approved to place an order for controlled substances from Masters. The fact that the customer is approved to place an order, however, does not mean Masters has agreed to sell controlled substances to that customer.
27. Once a customer has completed Masters’ initial due diligence process and is approved to place an order for controlled substances, it is assigned to a specific “tier” based on the number of prescriptions the pharmacy dispenses each month, its so-called “script average.” Tier one customers dispense less than customers placed in tiers two or three. Within each tier, Masters limits the amount of any controlled drugs from any particular controlled drug family during any month. For example, a customer in tier one can order up to 1500 dosage units of drugs within the solid dose oxycodone family per month. Different drug families have different monthly limits in each tier. If a customer orders more than the amount permitted by the applicable tier, Masters’ SOMS automatically holds that order so it can be reviewed by Masters’ Compliance Department.

28. These tiers are used only until the customer has purchased controlled substances from within a particular drug family from Masters for six months. After the customer has established a six month ordering history, Masters’ SOMS system automatically establishes the controlled substance limit (“CSL”) for each controlled drug family that applies to that customer.

29. Masters’ SOMS automatically evaluates the size, pattern and frequency of each and every order for controlled substances (plus carisoprodol and tramadol) placed by any Masters’ customer, including customers who have not yet established six months of ordering history. Masters’ SOMS automatically holds and refers to the Compliance Department any order that deviates from the criteria established by SOMS. During the first six months the size criteria is based on the tier in which the customer is placed. SOMS begins evaluating the pattern criteria after two months of ordering history.
30. Masters’ SOMS also automatically holds each customer’s first order for any controlled substance from a controlled drug family; in other words, any time a customer seeks to order a drug from a controlled drug family that the customer has never ordered before, that order is automatically held for review by the Compliance Department.

31. Exhibit R65 is a true and accurate copy of a document that describes the various criteria used by Masters’ SOMS to evaluate controlled substance orders. This document was provided to Kyle Wright, James Arnold and Lewis Thomas in August 2009. The document is a summary, and does not describe all of the features of Masters’ SOMS.

32. An order for controlled substances that is held by Masters’ SOMS system will not be shipped to the customer unless and until a member of Masters’ Compliance Department reviews and approves the order. If the order contains more than one controlled substance, none of the controlled substances will be shipped until the order is reviewed and approved. Masters’ SOMS documents the date on which the order is reviewed and released for shipment to the customer, the name of the person who releases the order, and a “notes” section that permits Compliance Department personnel to include additional relevant information about the order or the account.

33. Compliance Department employees have the ability to “override” SOMS. In the vast majority of cases, the override is used to impose limits established by Masters’ Sales or Purchasing Departments, or so the Compliance Department can automatically review all orders placed by a particular customer for a specific controlled drug family.
34. To the best of my knowledge, the override feature has never been used as a means to disguise or hide suspicious orders. I know that I have never used it in that way. To the contrary, I have used the override feature at the request of Masters’ Sales or Purchasing Departments to protect limited inventory, or upon my own initiative to monitor certain accounts more closely.

35. Masters used the term “Release with Reservation” or “RWR” to identify controlled substance orders of interest that were reviewed by the Compliance Department, but about which we had not gathered enough information to confirm that the order was suspicious or that the products ordered were likely to be diverted. During the August 2009 “Compliance Review” conducted by DEA at Masters, Mr. Wright specifically instructed Masters to use that term in those circumstances. Mr. Wright instructed Masters to release such orders “with reservation” and continue its investigation until it had reached a firm conclusion. Mr. Wright compared this process to DEA’s practice of permitting a registrant to maintain its license while under investigation by DEA.

36. Masters also used the term when it had deemed an order to be not suspicious or that the products ordered were not likely to be diverted, but Masters’ Compliance Department wanted to obtain updated due diligence information from the customer.

37. To the best of my knowledge, Masters’ Compliance Department has never released a suspicious order “with reservation.” Suspicious orders are not released at all. Instead, all suspicious orders are reported to DEA.

38. Masters now uses the term “Release after Review” or “RAR” to describe orders that were previously marked “RWR.”
39. Masters' Compliance Department has the ability to edit or cancel customers' orders of controlled substances. Masters' Compliance Department edited or deleted orders for controlled substances primarily for two reasons: a. If the order was being held for review by Masters' Compliance Department and the product on the order (which Masters' inventory management system would remove from Masters' active inventory) was needed to fulfill orders placed by other customers, the original order would be cancelled thus returning that product to Masters' active inventory for sale; b. if Masters' SOMS held an order for controlled substances for review by Masters' Compliance Department, and the product being ordered was subject to a daily or monthly limit imposed by Masters' Purchasing or Sales Departments due to short supply or other factors, and if the Compliance Department's review determined that the order was not suspicious, then Masters would edit the order to reduce the amount shipped to the customer to no more than the applicable daily or monthly limit.

40. In my experience, these events are often related. Masters' customers often seek to increase the volume of controlled substances they purchase from Masters in response to market shortages or disruptions in the normal distribution channel. These same events also typically cause Masters' Sales and Purchasing Departments to impose daily or monthly purchasing limits on those products. Thus, customers order more than their typical volume, or order more frequently, and trigger a SOMS review by the Compliance Department. The subsequent due diligence review typically reveals that the reason for the higher than normal volume is the market shortage and is, thus, not suspicious. The order would nonetheless be edited so that Masters could maintain enough inventory for all customers.
41. On a few specific occasions, most notably after April 2009 and February 2011, Masters edited orders as part of a Company-wide compliance review of all customers that ordered controlled substances.

42. In addition, Masters’ SOMS system also automatically cancels or “deletes” any order that the Compliance Department determines to be suspicious. The system automatically prompts the Compliance Department to report such orders to DEA, and generates a report containing all the information relating to the order, before canceling it from Masters’ inventory control system. The system continues to prompt the Compliance Department until the order is actually reported to DEA.

43. Masters’ inventory control system also automatically edits orders for non-controlled drugs, or orders which do not trigger a review by the Compliance Department, to comply with limits imposed by the Sales or Purchasing Departments. Again, these limits are imposed by Masters’ Sales Department in response to market disruptions or supply shortages.

44. Exhibit R18 is a true and accurate copy of an advertisement Masters received from Harvard Drug Group on or about December 8, 2009. In the advertisement, Harvard states that it “has learned that there is currently a shortage of generic Roxicodone tablets, manufactured by Mallinckrodt, in the market” and offers its customers the ability to buy oxycodone manufactured by its “partner” KVK Tech which was identical to the brand-name drug. Masters was aware of this market shortage before receiving this advertisement from Harvard.

45. Exhibit R29 is a true and accurate copy of an email dated July 12, 2010 which describes DEA’s recent enforcement actions against Harvard and Sunrise Wholesale. We had been aware of these actions prior to receiving this email. These
enforcement actions resulted in another market disruption. All of these events, and
others like them, impacted Masters’ customers’ ordering volume, pattern, and
frequency, and also resulted in new customers seeking to purchase controlled drugs
from Masters.

46. During the August 2009 “Compliance Review,” Mr. Wright instructed
Masters that orders of interest placed electronically via CSOS should not remain in the
system for an extended period of time. Accordingly, he instructed Masters to either
release such orders “with reservation” or delete the order until Masters could gather
more due diligence information from the customer. Masters followed this guidance.

47. To the best of my knowledge, Masters has never cancelled, deleted, or
edited orders to bring customers within their controlled substance limits as established
by Masters’ SOMS, to make suspicious orders appear non-suspicious, or to otherwise
thwart review by the Compliance Department.

48. At certain times, Masters’ Sales Department has required all customers to
order a certain dollar volume of non-controlled products in order to receive controlled
substances. These “ratios” were imposed exclusively by Masters’ Sales Department as a
way to increase sales, preserve inventory, and prevent “cherry-picking.” Masters’
Compliance Department has never considered the ratio of controlled to non-controlled
products on any order as a factor in determining whether the order was suspicious.
Likewise, Masters’ Compliance Department does not consider a customer’s overall ratio
of controlled to non-controlled products purchased from Masters as a factor in
determining whether to permit any customer to purchase controlled substances from
Masters.
49. Given Masters' business model, customers often turn to Masters to acquire products, including controlled substances, that are in short supply or which Masters offered at a below-market price. In order to increase sales and preserve Masters' inventory of such products, Masters' Sales Department would require the customer to purchase a certain dollar volume of other products in order to acquire the product in high demand. Oxycodone was often in short supply or available from Masters at below-market prices and, thus, customers who sought to purchase oxycodone were routinely subject to these requirements.

50. Exhibit R22 is a true and accurate copy of an email string dated March 22, 2010 in which a sales representative and sales manager request the assistance of the Compliance Department to enforce its policy requiring customers to purchase a certain volume of non-controlled products.

51. Exhibit R35 is a true and accurate copy of an email string dated August 16, 2010 describing Masters' Compliance Department efforts to assist the Sales Department in ensuring that two customers complied with the Sales Departments' policies.

52. Exhibit R45 is a true and accurate copy of an email string dated January 18 and 19, 2011 in which a Masters' sales representative, Alida Healy, discusses a customer that had "consistently maintained an average or [sic] 20-30 percent n/control ratio . . . " Despite this, Masters' Compliance Department terminated the account based on its own investigation.

53. Exhibits R22, R35 and R45 are just a few examples of the numerous times Masters' Compliance Department has been asked to help enforce the ratios imposed by the Sales Department. However, such ratios have never been established by the Compliance Department.
54. To the best of my knowledge, Masters’ Compliance Department never deemed an order for controlled substances that was otherwise suspicious to be not suspicious because it also included a quantity of non-controlled products. I know I have never done that.

55. As part of its customer due diligence procedures, Masters’ Compliance Department obtains and review Dispensing Reports or Utilization Reports (“UR’s”) provided by its pharmacy customers. Consistent with the policies and procedures described to DEA during the August 2009 “Compliance Review,” the UR’s are primarily used for three purposes: 1. To ensure that Masters is not selling the customer more than the customer was dispensing; 2. to determine whether the customer is dispensing a full-range of pharmaceutical products that would be expected of a legitimate pharmacy; and 3. to confirm that the customer’s dispensing patterns are consistent with its stated business model.

56. Prior to August 2009, DEA had advised Masters that rogue internet pharmacies would often purchase more hydrocodone or other controlled substances from a single distributor than the pharmacy’s UR indicated the pharmacy had dispensed. Beginning in August 2009, Masters began using UR’s to ensure that it was not providing any customer with more than 70% of the total quantity of any particular controlled substance the pharmacy was dispensing (assuming the order was deemed not suspicious, other factors justified the customer’s volume, the order was not subject to a sales limit, etc.). Masters’ policy did permit minor variations from this percentage in certain circumstances if approved by the Company’s Compliance Committee.

57. Prior to August 2009, DEA advised Masters that rogue internet pharmacies and other pharmacies operating illegally did not typically dispense a full
range of pharmaceutical products. Masters had reviewed UR’s provided by pharmacies alleged to be operating illegally and many of them showed a very limited selection of drugs being dispensed, and nearly all of those that were dispensed were specific controlled substances known to be abused. Based on DEA’s guidance to the Company, Masters’ enhanced policies were designed to identify such pharmacies by a review of their UR’s, in addition to other due diligence.

58. In addition to the uses set forth above, Masters’ Compliance Department routinely obtains UR’s from customers or potential customers in order to confirm information provided by the pharmacy about its dispensing volume, or to verify that its dispensing patterns are consistent with the customer’s stated business model. These factors are among many considered by Masters’ Compliance Department when determining whether a particular customer is permitted to purchase controlled substances.

59. Masters also uses UR’s, information gathered from our customers, and our knowledge of controlled substance prescribing patterns, to estimate the number of prescriptions for controlled substances, including oxycodone, certain pharmacy customers dispense each day. For example, if a pharmacy’s UR indicates that it dispenses 50,000 dosage units of oxycodone per month, and knowing that physicians will typically prescribe between 180 and 240 doses of oxycodone per month to a patient with chronic pain, Masters can determine that the pharmacy is filling between 208 and 277 oxycodone prescriptions per month. Masters also asks its pharmacy customers how many hours each day it is open. Most pharmacies are open six days a week, some with limited hours on Saturdays. Thus, the pharmacy in this example that dispenses 50,000
dosage units of oxycodone per month would be filling approximately eight to twelve prescriptions for oxycodone per day.

60. Masters’ Compliance Department has a critical role within the Company. The Compliance Department, which includes the Compliance Committee, makes the final determination about whether any customer will be permitted to purchase, or continue to purchase, controlled substances from Masters. There are often competing interests between Masters’ Sales and Compliance Departments. For this reason, the Compliance Department limits the information provided to the Sales Department and to customers in order to protect the integrity of the Compliance Department’s work and the Company’s SOMS.

61. The employees in Masters’ Compliance Department have significant experience administering Masters’ controlled substance policies and procedures. Of the four full-time employees who currently review orders held by SOMS or conduct customer due diligence, including myself, three have been working in these positions since before August 2009. In 2012, we hired a new Compliance Manager who has been involved in the pharmaceutical industry for over 20 years. In February 2013, Masters hired an in-house General Counsel to oversee the Compliance Department. The longevity of our Compliance Analysts and other employees helps ensure our policies and procedures are carried out effectively and uniformly.

62. Compliance Analysts receive training at the time they are hired and throughout their employment. I meet with them often to review trends in the pharmaceutical industry, DEA guidance, and other information relevant to their jobs. They are taught how to ask pharmacy customers relevant questions, to look for “red flags” that might be indicative of diversion, and how to analyze UR’s. Masters’
Compliance Analysts often work together as informal teams when they are faced with an increased workload. They are encouraged to consult with one another when they have unusual circumstances or have questions about an account.

63. My office is located within the Compliance Department suite which is separated from Masters' general offices by a glass wall and a controlled access door. Only certain people have access to the Compliance Department. All records are kept in locking cabinets, and all our computers are password protected. The Compliance Department stores its electronic data, including customer records, notes, etc., on a dedicated directory that only the Compliance Department and the IT Department can access.

64. I worked with Eric Schulze during the time he was employed in Masters' Compliance Department. He reported directly to me. Mr. Schulze was trained on Masters' Controlled Substance Compliance Policies and Procedures and taught how to review customer files. He had a general understanding of how Masters' SOMS worked, and when the system would hold orders. Mr. Schulze was taught how to conduct a site inspection, and what "red flags" to look for while inspecting a pharmacy.

65. Mr. Schulze never expressed to me that he felt uncomfortable working for Masters due to concerns about its controlled substance sales. He never told me that he felt pressure to not include derogatory information on site inspection reports. To the contrary, a number of Mr. Schulze's site inspection reports contain information about potential "red flags" and, to the best of my knowledge, Masters stopped selling controlled substances to several customers based on Mr. Schulze's site inspections.

66. Exhibit R17 is an email Mr. Schulze sent me on November 3, 2009 that outlines his concerns about site inspection reports that had been prepared by Jeff Chase,
including Mr. Chase’s failure to adequately describe potentially suspicious activity he observed during his inspections. I shared Mr. Schulze’s concerns, and brought those concerns to Wayne Corona via email. Sometime shortly thereafter, Mr. Corona informed Mr. Chase that he was no longer my direct supervisor.

67. Not long after he began working in the Compliance Department, Mr. Schulze indicated that he had found another position working for a different company. He explained to me that his wife did not like him working the evening hours that were required in the Compliance Department, and that he did not make enough money. In an effort to keep him at Masters, he was offered, and accepted a position with Masters’ third-party logistics division. Sometime later, he was laid off from that position due to lack of work. Mr. Schulze never told me that he wanted to leave the Compliance Department because he was uncomfortable with Masters’ sales of oxycodone, or objected to the Company’s business practices.

68. During his time at Masters, I worked with Jeff Chase. He was hired in January 2009, and I believe his position was Vice President of Loss Prevention. He was placed in charge of the Compliance Department at that time. As part of his duties, Mr. Chase performed site inspections of some of Masters’ pharmacy customers in Florida and other locations. Prior to traveling to Florida to perform inspections, Mr. Chase would receive a list of pharmacies that he was required to inspect during his trip.

69. I personally reviewed many of Mr. Chase’s site inspection reports, and I found some of them to be troubling for various reasons. Some of the reports seemed to have duplicate, missing or inconsistent information. Some of his reports contained derogatory or racist information about the pharmacy, its owners or its customers. Some of his reports included Mr. Chase’s own personal feelings about a pharmacy or the
pharmacist which were not consistent with Masters' policies. On a few of those occasions, Mr. Corona asked Mr. Chase to amend his reports to remove the objectionable information. Mr. Chase amended his reports when asked and never told me that he objected to doing so.

70. Mr. Chase did not submit his site inspection reports until several days or a week after he had returned from a trip. This concerned me because, not only did it delay the Compliance Committee's evaluation of many customers, it caused me to question whether Mr. Chase was preparing his reports at the time of his inspection or sometime after. Exhibit R21 is a true and accurate copy of an email in which I asked Mr. Chase directly whether he was preparing his reports while he was at the pharmacy, and he admitted that he was not. He told me he would prepare all his reports after returning to his hotel in the evening, or he would prepare them after returning home to Cincinnati following his trip. I reported this information to Mr. Corona.

71. Despite the concerns I had about Mr. Chase's site inspection reports, Masters' Compliance Committee considered the information he gathered as part of our due diligence on our pharmacy customers. In a number of cases, the Compliance Committee decided not to do business with, or discontinue doing business with, a pharmacy customer based on the information contained in Mr. Chase's site inspection reports.

72. Masters' Compliance Department has no role whatsoever in setting the prices Masters charged for any product, including controlled substances. The Compliance Department does not monitor the reimbursement rates paid by private insurers, Medicare or Medicaid for any product.
73. A small number of Masters’ pharmacy customers indicated that they did not accept insurance for certain products, including oxycodone, because the reimbursement rates on those products were less than the price they paid for the product. Other customers explained that their ratio of cash-paying customers was higher than normal for this same reason. We considered that information as part of our analysis of those customers, but did not consider it to be suspicious per se.

74. Exhibit R14 is a copy of an August 18, 2009 Memorandum from Matt Harmon to “Denny, Wayne” regarding “Compliance with DEA’s directives.” Mr. Harmon never discussed this Memorandum or its contents with me until 2011. He did not bring it to the attention of the Compliance Committee. He never suggested that Masters change its policies and procedures in the ways outlined in the Memorandum.

75. I discussed the Memorandum with Mr. Harmon only after Mr. Rafalski advised Masters of its existence in February 2011. I asked him why he had not shared it with me. Mr. Harmon told me that he could not recall writing the Memorandum, that he could not recall where the Memorandum was located on his computer, and that he did not recall giving a copy of the Memorandum to Mr. Chase. Mr. Harmon told me that he had not intended the Memorandum to be used to guide or impact Masters’ policies and procedures.

76. After Masters received the Order to Show Cause in 2013, I searched Masters’ computer network for Mr. Harmon’s Memorandum. It was not saved in Masters’ networked “Compliance Drive” with other documents – including other Memoranda written by Mr. Harmon – relating to the Compliance Department. Instead, I located the Memorandum on the hard drive of Mr. Harmon’s computer in the “Deleted Items” folder.
THE AUGUST 2009 “COMPLIANCE REVIEW” PERFORMED BY DEA

77. I was present during the entire “Compliance Review” conducted by James Arnold, Kyle Wright and Lewis Thomas of DEA which took place at Masters on August 17 and 18, 2009. At least five employees of Masters attended some or all of the review. During the review, these employees, myself included, explained in detail its newly enacted Controlled Substances Compliance Policies and Procedures and SOMS.

78. Exhibit R11 is a true and accurate copy of an email dated August 11, 2009 from Kyle Wright to Matt Harmon in which Mr. Wright describes the agenda for the “Compliance Review” scheduled for August 17 and 18.

79. Exhibit R12 is a true and accurate the Power Point presentation Masters gave DEA during the Compliance Review. None of the representatives from DEA expressed any concerns or criticisms about the information Masters provided or make any suggestions about how the policies or procedures might be improved or enhanced.

80. During the morning of August 17, DEA (primarily Mr. Wright) presented information about ARCOS reporting, CSOS, controlled drug inventories, DEA C2 and 106 forms, and recordkeeping.

81. After we returned from lunch that afternoon, Mr. Wright asked us to run a report identifying, and to retrieve our compliance files relating to, the top ten customers by volume of controlled substances purchased from Masters during the first half of 2009. Mr. Wright also asked Masters to produce a report showing Masters’ total sales of certain controlled substances over the same period. Masters’ IT Department complied with DEA’s requests.
82. During the afternoon of August 17, Mr. Wright presented information about the increase in the volume of hydrocodone, oxycodone and other controlled substances dispensed in the United States since 2005. He described the “closed system of distribution” that exists within the United States. He stated that it was easier for DEA to monitor the relatively small number of pharmaceutical distributors than the millions of physicians and pharmacies that handle controlled substances. He admitted that DEA does not have the power or ability to determine whether any particular prescription is legitimate, and noted that physicians are often protected by the state medical boards. He also admitted that DEA did not have the resources it needed to investigate all of the unlawful diversion of controlled substances.

83. Mr. Wright told us that physicians in Florida prescribed more oxycodone than any other pain medication. He also discussed the different strengths of hydrocodone that were available on the market, and which were more likely to be abused.

84. On August 18, 2009, we spent the morning reviewing the files the customers Mr. Wright had asked us to retrieve the previous afternoon. We spent a few minutes looking at each file and looking at the volume of controlled substances we sold to each customer. The DEA representatives repeatedly stressed that no one factor, or “red flag,” necessarily indicated that a pharmacy was engaged in illegal diversion. To the contrary, DEA instructed Masters to evaluate all the facts and circumstances surrounding a pharmacy in order to determine if its orders were suspicious. They stated that the Compliance Department needed to “continue to ask questions” of Masters’ controlled substance customers, and “get the facts.”
85. Mr. Wright discussed the use of Memoranda for Records ("MFR's"), and advised us that our Compliance Department should continue to use them to keep notes about our customers, something we had done for many years.

86. Mr. Wright stated that Masters should use the term "Release with Reservation" to designate those orders that the Compliance Department had reviewed, and which it had found to be not suspicious based upon information Masters had available at that time. Often, Masters would use terms like "Release with Reservation – continue to monitor" or "Release with Reservation - pending site visit" to indicate that Masters was continuing to gather information about a customer.

87. DEA did not tell Masters that all orders for more than a certain quantity of controlled substances should be automatically considered suspicious. DEA did not tell Masters that any pharmacy that dispensed a certain ratio of controlled substances to non-controlled substances should be deemed to be operating illegally. However, Mr. Wright did tell us that pharmacies that were near hospitals, physicians' offices, pain clinics, or that specialized in filling prescriptions for nursing homes, hospice centers and other "closed door" facilities would likely dispense a higher ratio of controlled substances than other pharmacies. DEA did not tell Masters that any pharmacy that dispensed more than a specific quantity of controlled drugs was to be terminated. DEA did not instruct Masters to discontinue its sales of controlled substances to any of the pharmacies involved in the review (or any other pharmacy).

88. Mr. Wright instructed Masters to send a monthly email to DEA with a list of all the pharmacies the Company had determined would no longer be able to purchase controlled substances from the Company, or that had not passed Masters' initial due
diligence screening. We complied with that request, although we were subsequently requested to send the list only quarterly and we did so.

89. Of the eight pharmacies identified in DEA's Prehearing Statement, DEA reviewed four of them during the "Compliance Review:" Englewood Specialty Pharmacy, The Drug Shoppe, Lam's Pharmacy, and Morrison's Rx. During the review, DEA did not instruct Masters to stop selling controlled substances to any of these pharmacies.

90. DEA did not seek to review Masters' files relating to Tru-Valu Drugs, Inc., City View Pharmacy, Medical Plaza Pharmacy of Plantation, LLC, or Temple Terrace Pharmacy d/b/a Superior Pharmacy, despite the fact that, at that time, each of those pharmacies were ordering oxycodone from Masters.

91. DEA did not ask for copies of any of Masters' compliance files, and did not take any files or other documents with them when they left for further review or analysis.

92. Exhibit R13 is a document given to us by Mr. Wright during the Compliance Review. It is dated July 7, 2009 and is entitled "Suggested Questions a Distributor should ask prior to shipping controlled substances." During our due diligence process, we gather all the information listed on that document that is relevant to our particular business model. My handwritten notes are on the exhibit.

93. During the "Compliance Review" Mr. Wright specifically instructed Masters to not discontinue selling controlled substances to pharmacies about which Masters was requested by DEA to provide information. He explained that a pharmacy that was the subject of a DEA subpoena may or may not be the target of DEA's investigation. He also expressed concern that, if Masters stopped selling controlled
substances to a pharmacy identified on a DEA subpoena, it could interfere with DEA’s investigation.

94. Based on these instructions from Mr. Wright, Masters changed its prior policy of automatically discontinuing all sales of controlled drugs to any pharmacy that was the subject of a DEA subpoena or other request for information directed to Masters by DEA.

95. Exhibit R19 is a true and accurate copy of an email I sent to Jeff Chase and Wayne Corona on January 5, 2010 in which, among other things, I report that, like Mr. Wright, another DEA agent had requested that we not disclose to our customer the fact that DEA had requested information about the customer for fear that it would jeopardize DEA’s investigation.

96. In February 2011, DEA Diversion Investigator James Rafaski criticized Masters for continuing to sell controlled substances to certain pharmacies which had been named in DEA subpoenas. Following this criticism, Masters re-instated the policy we had prior to August 2009 under which we would automatically stop selling controlled substances to any pharmacy that was listed in a DEA subpoena.

97. DEA did not conduct an exit interview with Masters at the conclusion of the “Compliance Review.” However, following lunch on August 18, just before leaving, Mr. Wright stated that he “liked what [he] saw” and that Masters was “on the right track.”

98. Masters never received any written notice from DEA that any of its newly enacted policies and procedures or SOMS were inadequate.

99. Based on the lack of criticism from DEA during or after the “Compliance Review” and Mr. Wright’s comments, I believed that Masters’ new SOMS and enhanced
policies and procedures were acceptable to DEA, were sufficiently robust to identify suspicious orders, were reasonable measures to prevent the illegal diversion of controlled substances, and were in compliance with both DEA regulations and DEA’s expectations of registrants (which, in my experience, are not necessarily expressed in any regulation).

100. Exhibit R16 is a true and accurate copy of a document dated November 3, 2009 that I discovered in Masters’ files relating to controlled substance compliance. I assume the document was written by Matt Harmon, but it does not state to whom it was given. I had never seen this document until it was identified by DEA as a potential exhibit at the hearing of this matter. Mr. Harmon never discussed this document with me or, to my knowledge, Masters’ Compliance Committee, and the suggestions contained in the document were not adopted as part of Masters’ controlled drug handling policies and procedures.

THE EFFECTIVENESS OF MASTERS’ COMPLIANCE DEPARTMENT
IN DETECTING AND REPORTING SUSPICIOUS ORDERS
AND PREVENTING UNLAWFUL DIVERSION

101. I believe that Masters has been effective at identifying suspicious orders for controlled substances placed by its customers. I also believe that our due diligence process has identified DEA registrants that present an unreasonable risk of diverting controlled substances. Masters has been instrumental in helping various law enforcement and regulatory agencies identify and apprehend people who have broken the law.

102. Exhibit R6 is a true and accurate copy of a letter dated April 30, 2008 from Matt Harmon to Lewis Thomas of DEA’s Cincinnati Field Office. The letter encloses an email Masters received from United Parcel Service’s security department.
Mr. Harmon’s letter, which is maintained in Masters’ files relating to controlled substance compliance, advised DEA that the efforts of Masters and UPS had resulted in the apprehension of an individual who had been stealing packages containing prescription drugs for nearly a year.

103. Exhibit R10 is a true and accurate copy of a letter dated May 5, 2009 from Matt Harmon to Lewis Thomas relating to a customer that had placed a suspicious order with Masters in January 2009, which order was subsequently reported to DEA. In the letter, Mr. Harmon describes an incident that occurred on May 4, 2009 in which a customer stated “Tell your boss if he calls the DEA again, he is going to get hurt.” Mr. Harmon relayed Masters’ concern that DEA may have revealed to the customer that Masters had reported its order as suspicious. This letter is maintained in Masters’ files relating to controlled substance compliance.

104. Exhibit R23 is a true and accurate copy of a Memorandum from Matt Harmon dated April 1, 2010 in which he describes a meeting that occurred that day. In that meeting, which I attended along with other Masters’ employees, two DEA representatives requested Masters’ assistance with a criminal investigation they were conducting of a driver for a common carrier suspected of stealing packages contained controlled substances. This memorandum is maintained in Masters’ files relating to controlled substance compliance.

105. Exhibit R8 is a true and accurate copy of a letter from the California Board of Pharmacy to Matt Harmon dated September 7, 2010 relating to Bell Plaza Pharmacy. The letter states that the Board had issued a citation to the pharmacy following an investigation “initiated by your complaint regarding unauthorized activity at the
pharmacy.” This letter is maintained in Masters’ files relating to controlled substance compliance.

106. Exhibits R6, R10, R23 and R8 are just some of the examples of instances in which information provided by Masters has assisted law enforcement or regulatory agencies with their efforts to protect the public.

107. According to data compiled from Masters’ SOMS, since August 2009, Masters has reported to DEA more than 2,100 orders for controlled substances placed by more than 900 separate DEA registrants that Masters determined to be suspicious. Often customers do not realize that Masters has terminated their ability to order controlled substances, and will continue to place orders (often on Masters’ website) after being terminated. Thus, the number of suspicious orders reported exceeds the number of registrants placing those orders.

108. Except in exceedingly rare circumstances, once a customer places an order deemed suspicious, that customer never receives another order for controlled substances from Masters.

109. According to data compiled by Masters’ IT Department, since August 1, 2009, Masters has received orders containing controlled substances from nearly 7200 separate DEA registrants. Of those registrants, only approximately 6100 have actually received controlled substances from Masters. Thus, Masters has for various reasons, refused to ship nearly 15 percent of all the orders for controlled substances it has received since August 1, 2009.

110. Exhibit R61a is a true and accurate copy of all the suspicious order reports Masters submitted to DEA from August 1, 2009 to December 31, 2009. The exhibit is a compilation of all reports submitted during the period. Each page of the exhibit
represents a different report, and the date on which the report was generated is indicated on each page. Generally, reports were submitted to DEA via DEA’s website on the same day the report was generated. However, in some cases there may have been a delay of a day or two between the date the report was generated and the date it was submitted to DEA.

111. Exhibit R61b is a true and accurate copy of all the suspicious order reports Masters submitted to DEA from January 1, 2010 to December 31, 2010. The exhibit is a compilation of all reports submitted during the period. Each page of the exhibit represents a different report, and the date on which the report was generated is indicated on each page. Generally, reports were submitted to DEA via DEA’s website on the same day the report was generated. However, in some cases there may have been a delay of a day or two between the date the report was generated and the date it was submitted to DEA.

112. Exhibit R61c is a true and accurate copy of all the suspicious order reports Masters submitted to DEA from January 1, 2011 to December 31, 2011. The exhibit is a compilation of all reports submitted during the period. Each page of the exhibit represents a different report, and the date on which the report was generated is indicated on each page. Generally, reports were submitted to DEA via DEA’s website on the same day the report was generated. However, in some cases there may have been a delay of a day or two between the date the report was generated and the date it was submitted to DEA.

113. Exhibit R61d is a true and accurate copy of all the suspicious order reports Masters submitted to DEA from January 1, 2012 to December 31, 2012. The exhibit is a compilation of all reports submitted during the period. Each page of the exhibit
represents a different report, and the date on which the report was generated is indicated on each page. Generally, reports were submitted to DEA via DEA’s website on the same day the report was generated. However, in some cases there may have been a delay of a day or two between the date the report was generated and the date it was submitted to DEA.

114. Exhibit R61e is a true and accurate copy of all the suspicious order reports Masters submitted to DEA from January 1, 2013 to December 17, 2013. The exhibit is a compilation of all reports submitted during the period. Each page of the exhibit represents a different report, and the date on which the report was generated is indicated on each page. Generally, reports were submitted to DEA via DEA’s website on the same day the report was generated. However, in some cases there may have been a delay of a day or two between the date the report was generated and the date it was submitted to DEA.

115. Masters continues to submit suspicious order reports to DEA immediately upon receipt of any order the Company deems to be suspicious.

116. Exhibits R62a through R62nn are true and accurate copies of the “Termination Lists” Masters sent to DEA between August 27, 2009 and September 4, 2013 identifying the names and DEA registration numbers of the pharmacies to which Masters has decided that it will no longer sell controlled substances. The exhibit also includes some correspondence between me and DEA relating to these reports. Masters continues to periodically submit these termination lists to DEA today despite the fact that, to the best of my knowledge, we are not required by law or regulation to do so.
117. I do not know what DEA has done with the information Masters has provided, if anything. I do not know whether DEA has investigated any of the pharmacies Masters has reported.

118. I believe the loss of Masters' DEA registration would not be in the public interest because, among many other things, Masters continues to provide DEA with valuable information about pharmacies that may be engaged in unlawful diversion.

**MASTERS' EFFORTS TO COMBAT UNLAWFUL DIVERSION IN FLORIDA AND HOUSTON, TEXAS**

119. Masters used enhanced measures, in addition to its standard policies and procedures, to combat unlawful diversion by customers in Florida and the Houston, Texas areas. For example, in early 2009, Masters voluntarily ceased the direct sale of controlled substances to all physicians and pain clinics in Florida. In addition, Masters required all of its distributor customers to execute an affidavit stating that they would not sell controlled substances purchased from Masters to physicians or pain clinics located in Florida.

120. In addition, Masters enacted a policy under which new controlled substance customers in Florida, Houston, Texas, and Las Vegas, Nevada were required to undergo a site inspection prior to receiving controlled substances from Masters. Masters has conducted hundreds of site inspections in those areas; far more than in any other areas of the country.

121. In July 2011, Dennis Smith, Matt Harmon and I voluntarily attended two days of hearings that took place in the Federal District Court for the Southern District of Ohio at which KeySource Medical, Inc. ("KeySource") challenged an Immediate
Suspension Order issued by DEA. Rick Lauer, our attorney, also attended. Mr. Smith was not there the entire time, but he was there for at least the first day.

122. Mr. Smith instructed me to attend the hearing so we could learn about DEA’s position and enforcement criteria, and gather more information about controlled substance diversion in Florida. Based upon the testimony given and exhibits introduced at the hearing, it was clear that Masters’ policies and procedures were far more robust than those utilized by KeySource, and that KeySource was selling a far greater volume of oxycodone and other controlled substances to customers in Florida than was Masters. However, Masters also determined that it would have to enact even more stringent due diligence measures in order to keep up with the ever-changing tactics employed by unscrupulous pharmacists, doctors and others who were diverting oxycodone.

123. Following the KeySource hearing, Mr. Smith decided that Masters would discontinue all sales of controlled substances to independent, retail pharmacies in Florida. Since July 2011, Masters has not sold any controlled substances to any independent, retail pharmacy customer located in Florida.

THE EXTENT OF MASTERS’ BUSINESS IN FLORIDA

124. Based on information I received from Masters’ IT Department, it is my understanding that, during its entire existence, Masters has had approximately 2100 customers located in Florida. Of those customers, only approximately 1100 have purchased at least one controlled substance from Masters. Masters has never had “3000 to 5000” Florida customers.

MASTERS’ RELATIONSHIP WITH MALLINCKRODT

125. I am familiar with the Masters’ efforts to assist our vendor, Mallinckrodt Pharmaceuticals, to comply with its obligations under the Controlled Substance Act.
126. Exhibit R57d is a true and accurate copy of an email string dated June 22 and June 28, 2010 relating to DEA enforcement action against two pharmacies located in Kentucky.

127. Beginning in approximately November 2010, Karen Harper of Mallinckrodt began sending Masters periodic letters identifying certain pharmacies for which Mallinckrodt would no longer accept "charge backs." This meant that Mallinckrodt would not give Masters an agreed-upon rebate or discount on sales of Mallinckrodt to those pharmacies. I understood this to mean that Mallinckrodt had concerns about the account’s

128. Exhibit R57e is a true and accurate copy of a letter dated November 10, 2010 from Ms. Harper to Wayne Corona relating to Masters’ compliance policies and procedures and identifying four Florida pharmacies about which Mallinckrodt had concerns.

129. Exhibit R57f is a true and accurate copy of a letter dated November 11, 2010 I sent to Ms. Harper along with a copy of Masters’ Compliance File relating to Tru-Valu Drugs, Inc.

130. Exhibit R57g is a true and accurate copy of an email string dated November 15, 2010 relating to an upcoming audit of Masters’ compliance policies and procedures to be performed by Mallinckrodt. This audit occurred at Masters on December 8, 2010.

131. Exhibit R57h is a true and accurate copy of an email string dated December 9, 2010 from Ms. Harper in which she acknowledges receiving the Tru-Valu Compliance file I had sent her, and thanks me for the "very productive" meeting that had occurred the prior day.
132. Exhibit R57i is a true and accurate copy of an email string which I received from Ms. Harper on December 9, 2010 relating to DEA enforcement actions.

133. Exhibit R57k is a true and accurate copy of a letter from Ms. Harper dated February 4, 2011 in which she states that Mallinckrodt will no longer process charge backs from “distributor sales of Mallinckrodt’s Oxycodone 15 mg and 30 mg tablets” to Tru-Valu.

134. Exhibit R57l is a true and accurate copy of an email I sent Ms. Harper on February 7, 2010 relating to Tru-Valu.

135. Exhibit R57o is a true and accurate copy of a letter from Ms. Harper dated September 16, 2011 in which she states that Mallinckrodt will no longer process charge backs from sales to four pharmacies located in Florida.

136. Exhibit R57p is a true and accurate copy of a letter from Ms. Harper dated September 21, 2011 in which she states that Mallinckrodt will no longer process charge backs from sales to five pharmacies located in Florida.

137. Exhibit R57r is a true and accurate copy of a letter I sent to Ms. Harper dated September 28, 2011 in which I informed Mallinckrodt that Masters had ceased all sales of controlled substances to the four Florida pharmacies identified in her September 16, 2011 letter based on its own investigations, well before receiving Ms. Harper’s letter.

138. Exhibit R57s is a true and accurate copy of a letter from Ms. Harper dated October 17, 2011 in which she states that Mallinckrodt will no longer process charge backs from sales to 17 pharmacies in various states.

139. Exhibit R57t is a true and accurate copy of a letter from Ms. Harper dated October 17, 2011 in which she states that Mallinckrodt will resume processing charge
backs from two pharmacies located in Florida previously identified in her September 16, 2011 letter. Despite Mallinckrodt’s change of position relative to these two pharmacies, Masters did not resume the sale of controlled substances to them.

140. Exhibit R57u is a true and accurate copy of an email string dated October 20, 2011 in which Mr. Corona advised Ms. Harper that Masters had ceased all sales of controlled substances to 13 of the 17 pharmacies identified in her October 17, 2011 letter based on its own investigations, well before receiving Ms. Harper’s letter. Masters had no record of receiving any orders from the other four pharmacies identified in her letter.

141. Exhibits R57v, R57z and R57aa are true and accurate copies of letters from Ms. Harper dated between November 14, 2011 and March 27, 2012 in which she states that Mallinckrodt will no longer process charge backs from sales to various pharmacies in a number of states. When I received these letters, I would check the status of the account with Masters and, if the Company was selling controlled substances to any of the identified pharmacies, I would terminate the account. However, I stopped reporting this information to Ms. Harper.

142. Exhibit R57w is a true and accurate copy of a letter from Ms. Harper dated November 22, 2011 in which she states that Mallinckrodt will resume processing charge backs from one pharmacy located in Florida previously identified in her November 14, 2011 letter. Despite Mallinckrodt’s change of position relative to this pharmacy, Masters did not resume the sale of controlled substances to it.

143. Exhibit R57bb is a true and accurate copy of a letter from Ms. Harper dated May 4, 2012 in which she describes the steps Masters could take to request that Mallinckrodt resume processing charge backs from sales to a pharmacy that
Mallinckrodt had previously identified. Masters never took advantage of this procedure offered by Mallinckrodt.

144. Exhibit R57dd is a true and accurate copy of a letter from Ms. Harper dated June 13, 2012 in which she states that Mallinckrodt will resume processing charge backs from seven pharmacies located in Florida previously identified in her letters of November 17, 2011 and March 27, 2012 letters. Despite Mallinckrodt’s change of position relative to these seven pharmacies, Masters did not resume the sale of controlled substances to them.

145. I found it troubling that Mallinckrodt would inform Masters that it would not process charge backs for an account, thereby effectively instructing Masters to discontinue sales of controlled substances to that account, only to change its position relative to that account, often a very short time later.

**MASTERS’ INTERACTIONS WITH PHARMACIES IDENTIFIED IN THE OTSC**

**TRU-VALU DRUGS, INC.**

146. I am familiar with Masters’ account relating to Tru-Valu Drugs, Inc. (“Tru-Valu”), and the contents of the documents maintained by Masters relative to the account. Exhibit R2a includes the “Compliance File” maintained by Masters relating to Tru-Valu. I provided this Compliance File to Mr. Rafalski in response to a subpoena he served on Masters dated February 11, 2011. In addition to the complete Compliance File, I also provided Mr. Rafalski with a report showing all of Masters’ sales of controlled and non-controlled substances to Tru-Valu between May 9, 2008 and March 7, 2011. However, this report is not part of Masters’ Compliance File relating to Tru-Valu.
147. A customer’s Compliance File does not contain all the documents Masters maintains relating to that customer. Masters’ Accounting Department also maintains files relating to the Company’s customers. Those files typically contain the customer’s Credit Application, payment information, Dun & Bradstreet report, and other documents relating to the credit-worthiness of the customer. In addition, the Compliance Department is able to create notes in SOMS about each customer; these notes are maintained electronically, not in the paper Compliance File. Finally, Masters’ inventory control software permits various personnel, including Compliance Department personnel, to create “ship-to notes.” The ship-to notes are maintained electronically and are not contained within the Compliance File. The Compliance Department has access to the information maintained by Masters’ Accounting Department, the SOMS notes and the ship-to notes, and will routinely refer to that information while performing customer due diligence.

148. Tru-Valu established its account with Masters in May 2008. Prior to receiving its first shipment of controlled substances from Masters, Tru-Valu provided information necessary for Masters to complete its then-current DD Survey. In addition, Masters obtained a Dun & Bradstreet report about Tru-Valu, and a completed credit application.

149. Tru-Valu also provided Masters with a copy of a report of an inspection performed by the State of Florida Department of Health in September 2007.

150. The Pharmacist in Charge at Tru-Valu, Ken Jenkins, provided a written description of the policies and procedures Tru-Valu used to prevent the diversion of controlled substances. Masters’ Compliance Department believed that Tru-Valu
understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.

151. Before shipping any pharmaceutical products to Tru-Valu, Masters verified that its Florida pharmacy license and DEA registration were valid, current, and in good standing.

152. On May 28, 2008, Louis Fisher performed a site inspection of Tru-Valu on behalf of Masters. The Compliance File for Tru-Valu contains a copy of the written report completed by Mr. Fisher.

153. The DD Survey and Mr. Fisher's inspection report confirmed that Tru-Valu had been in business for 45 years, and had been owned and operated by Mr. Jenkins (and his wife) for more than 30 years. The pharmacy carried an extensive quantity of “front of the store” items typically found in neighborhood pharmacies. Mr. Fisher did not observe any suspicious activity during his inspection.

154. The pharmacist, Ken Jerkins, explained that Tru-Valu's business model included active marketing to various nearby pain clinics. Tru-Valu provided the names and DEA registration numbers of the doctors writing prescriptions for patients of those clinics. These marketing efforts accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.

155. After Tru-Valu's account was approved, Masters' SOMS system identified and held any order for controlled substances placed by Tru-Valu that deviated from its typical volume, pattern or frequency. All such orders were released only after review by Masters' Compliance Department. On some occasions, the Compliance Department would request Tru-Valu to provide a UR as part of its review of orders that had been held by SOMS.
156. Tru-Valu provided Masters with UR’s showing the prescription drugs
dispensed by the pharmacy during the following periods: April 1 to April 30, 2008;
December 1 to December 31, 2008; October 1 to October 31, 2009; February 1 to
February 28, 2010; July 1 to July 31, 2010; and September 1 to September 30, 2010.
These UR’s were provided in response to requests for information from Masters’
Compliance Department, and are included within Masters’ Compliance File.

157. To the best of my recollection, Masters’ Compliance Committee discussed
the Tru-Valu account and the information provided by the customer.

158. As a result of our ongoing due diligence, Masters was aware of the volume
of oxycodone and other controlled drugs being dispensed by Tru-Valu, and the
percentage of controlled drugs dispensed relative to other drugs. Masters specifically
investigated the reasons why Tru-Valu’s ordering and dispensing patterns were as
indicated on the UR’s.

159. The UR’s and other information provided by Tru-Valu were consistent
with the pharmacy’s business model as explained by Mr. Jenkins and confirmed in the
May 2008 site inspection. Tru-Valu appeared to be a full line pharmacy that was
dispensing a large variety of both controlled and non-controlled drugs, and that serviced
the patients of several nearby pain management physicians.

160. Masters was aware that Tru-Valu was ordering many of its products,
including oxycodone, from distributors other than Masters. Given Masters’ business
model, this is not unusual or considered suspicious. Given the numerous and frequent
interruptions in the supply and distribution of oxycodone in particular, as well as
significant price fluctuations of the product, Masters did not consider it suspicious that
Tru-Valu ordered the product from suppliers other than Masters.
161. Based on Masters' extensive investigation, it determined that the orders it shipped to Tru-Valu were not suspicious.

162. On August 6, 2010, Matt Harmon performed a site inspection of Tru-Valu on behalf of Masters. The Compliance File for Tru-Valu, Exhibit R2a, contains a copy of the written report completed by Mr. Harmon.

163. Mr. Harmon's site inspection raised some concerns about the Tru-Valu account. In particular, I was concerned that during his inspection Mr. Harmon had observed a sign in the pharmacy stating that Tru-Valu did not accept insurance for Oxycontin, oxycodone solution, or oxycodone manufactured by Mallinckrodt or Actavis.

164. On or about September 1, 2010, I asked Mr. Jenkins about this policy. He stated that, despite what the sign said, Tru-Valu did accept insurance on the listed products from its regular customers. Mr. Jenkins explained that Tru-Valu had received insurance cards from some customers who did not, in fact, have current valid insurance coverage. Mr. Jenkins was concerned that if Tru-Valu submitted invalid claims for payment it would jeopardize the pharmacy's relationship with insurers. Thus, he placed the sign to try and limit the number of new patients who attempted to use insurance to pay for the listed products. He continued to accept insurance for those items from patients who he knew had valid insurance coverage.

165. Consistent with our policies and procedures, Masters continued to sell oxycodone and other controlled drugs to Tru-Valu until November 2010, at which time the account was placed on "non-controlled status" due to concerns expressed about Tru-Valu by Mallinckrodt as well as other information gathered by Masters' Compliance Department since August 2010. Because there was no order pending at that time, Masters did not report any suspicious order placed by the pharmacy to DEA. Masters
did, however, advise DEA that the account had been terminated. Masters took this action on its own initiative, almost a year before Tru-Valu surrendered its DEA registration in October 2011.

THE DRUG SHOPPE, INC.

166. I am familiar with Masters' account relating to The Drug Shoppe, Inc. ("Drug Shoppe"), and the contents of the documents maintained by Masters relative to the account. Exhibit R2b includes the "Compliance File" maintained by Masters relating to Drug Shoppe. I provided this Compliance File to Mr. Rafalski in response to a subpoena he served on Masters dated February 11, 2011. In addition to the complete Compliance File, I also provided Mr. Rafalski with a report showing all of the invoices Masters issued to Drug Shoppe between March 18, 2008 and February 25, 2011. This report does not show the products that were sold to the Drug Shoppe. This report is not part of Masters' Compliance File relating to the Drug Shoppe.

167. Drug Shoppe established its account with Masters in March 2008. Prior to receiving its first shipment of controlled substances from Masters, Drug Shoppe provided information necessary for Masters to complete its then-current DD Survey. In addition, Masters obtained a Dun & Bradstreet report about Drug Shoppe and a completed credit application.

168. Drug Shoppe also provided Masters with a copy of a report of an inspection performed by the State of Florida Department of Health in August 2007.

169. The Pharmacist in Charge at Drug Shoppe, Bhupendra Agrawat, provided a written description of the policies and procedures Drug Shoppe used to prevent the diversion of controlled substances. Masters' Compliance Department believed that
Drug Shoppe understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.

170. Before shipping any pharmaceutical products to Drug Shoppe, Masters verified that its Florida pharmacy license and DEA registration were valid, current, and in good standing.

171. On April 28, 2008, Louis Fisher performed a site inspection of Drug Shoppe on behalf of Masters. The Compliance File for Drug Shoppe, Exhibit R2b, contains a copy of the written report completed by Mr. Fisher.

172. The DD Survey and Mr. Fisher's inspection report confirmed that Drug Shoppe had been in business since 2003, and had been owned and operated by the same pharmacist since that time. The pharmacist, Mr. Agravat, explained that Drug Shoppe's business model included filling prescriptions for a number patients suffering from the disease state of HIV/AIDS. This accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs. That fact, along with its location near a less affluent residential neighborhood, also accounted for the relatively large percentage of cash-paying customers. Drug Shoppe carried "front of the store" items typically found in neighborhood pharmacies. Mr. Fisher did not observe any suspicious activity during his inspection.

173. Temple Bradford, one of Masters' Sales Managers, and Tina Prather, one of Masters' Sales Representatives, were personally acquainted with Mr. Agravat (they referred to him as "Boo") and vouched for his character and that of the pharmacy.

174. After Drug Shoppe's account was approved, Masters' SOMS system identified and held any order for controlled substances placed by Drug Shoppe that deviated from its typical volume, pattern or frequency. All such orders were released
only after review by Masters’ Compliance Department. On some occasions, the Compliance Department would request Drug Shoppe to provide a UR as part of its review of orders that had been held by SOMS.

175. Drug Shoppe provided Masters with UR’s showing the prescription drugs dispensed by the pharmacy during the following periods: February 1 to February 29, 2008; May 14 to July 14, 2009; October 1 to October 31, 2009; May 1 to May 31, 2010; and October 1 to October 31, 2010. These UR’s were provided in response to requests for information from Masters’ Compliance Department, and are included within Masters’ Compliance File.

176. To the best of my recollection, Masters’ Compliance Committee discussed the Drug Shoppe account and the information provided by the customer.

177. As a result of our ongoing due diligence, Masters was aware of the volume of oxycodone and other controlled drugs being dispensed by Drug Shoppe, and the percentage of controlled drugs dispensed relative to other drugs. Masters specifically investigated the reasons why Drug Shoppe’s ordering and dispensing patterns were as indicated on the UR’s.

178. The UR’s and other information provided by Drug Shoppe were consistent with the pharmacy’s business model as explained by Mr. Agrawat and confirmed in the April 2008 site inspection. Drug Shoppe appeared to be a full line pharmacy that was dispensing a large variety of both controlled and non-controlled drugs, and that serviced patients who were suffering from the disease state of HIV/AIDS.

179. Masters was aware that Drug Shoppe was ordering many of its products, including oxycodone, from distributors other than Masters. Given Masters’ business model, this is not unusual or considered suspicious. Given the numerous and frequent
interruptions in the supply and distribution of oxycodone in particular, as well as significant price fluctuations of the product, Masters did not consider it suspicious that Drug Shoppe ordered the product from suppliers other than Masters.

180. Based on Masters’ extensive investigation, it determined that the orders it shipped to Drug Shoppe were not suspicious.

181. On January 13, 2010, Jeff Chase performed a site inspection of Drug Shoppe on behalf of Masters. The Compliance File for Drug Shoppe, Exhibit R2b, contains a copy of the written report completed by Mr. Chase.

182. Mr. Chase’s site inspection stated that 40 percent of the prescriptions filled by Drug Shoppe were for controlled substances. Mr. Chase stated that he felt this percentage was “a little high.” However, Masters’ Controlled Drug Handling Policies and Procedures do not specify any particular percentage of controlled drugs to non-controlled drugs that the Company considers “high” or “a little high.”

183. Masters recognizes that a pharmacy’s business model, location, and other factors will have a significant impact on the ratio of controlled substances to non-controlled substances being dispensed by that pharmacy. Mr. Chase did not recommend that Masters stop selling controlled drugs to Drug Shoppe following his inspection in January 2010.

184. On November 18, 2010, Eric Schulze performed a site inspection of Drug Shoppe on behalf of Masters. The Compliance File for Drug Shoppe contains a copy of the written report completed by Mr. Schulze. In his report, Mr. Schulze noted that a “Pain MD” was located in the office next to Drug Shoppe. The presence of this physician had not been noted during either of the previous site inspections. To the contrary, Mr.
Chase’s inspection report from January 2010 had noted that there were no doctors’ offices located in the same shopping plaza as Drug Shoppe.

185. On or about December 9, 2010, Masters’ Compliance Department requested Drug Shoppe to provide an updated UR. We received the updated UR on December 15, 2010. On December 16, 2010, I discussed the Drug Shoppe account with Mr. Harmon. The UR provided on December 15 did not differ significantly from a UR provided by the pharmacy from May 2010; in fact, the Drug Shoppe’s dispensing of oxycodone 30mg had decreased significantly over the intervening months.

186. I attempted to contact Mr. Agravat several times during December 2010 to discuss the Drug Shoppe account, and to determine if the pharmacy’s business model had changed. I was told that Mr. Agravat was traveling out of the country, and was having “visa problems” preventing his return to the United States.

187. On December 19, 2010, Tina Prather, the Masters’ Sales Representative who had vouched for Mr. Agravat’s credibility, received an email from Mr. Agravat’s wife that referred to immigration issues he was having and requested assistance. However, the email did not mention any drug-related criminal issues, and was not forwarded to Masters’ Compliance Department.

188. Masters’ Compliance Committee reviewed the Drug Shoppe account and determined that Masters could continue to sell controlled substances to the Drug Shoppe, but should closely monitor its ordering patterns and volume. Accordingly, Masters’ Compliance Department continued to monitor the account closely, and released several orders for controlled substances “with reservation.”

189. Consistent with our policies and procedures, Masters continued to sell oxycodone and other controlled drugs to Drug Shoppe until February, 2011. At that
time, the account was placed on “non-controlled status” when Mr. Agravat disclosed that he believed that he may be the target of a DEA investigation. He claimed that the investigation related to his involvement in the sale of controlled substances via the internet in 2004 and 2005, and that he had not known he was under investigation previously.

190. On or about February 23, 2011, Masters reported to DEA as suspicious an order placed by Drug Shoppe. Masters advised DEA that the account had been terminated.

191. Since at least April 2008, Masters had been aware that Mr. Agravat had been the subject of disciplinary proceedings initiated by the Florida Board of Pharmacy in 2006. Mr. Agravat admitted, and Masters confirmed, that he had received a Letter of Concern, paid a small fine, and agreed to attend a continuing education course to settle claims that he had dispensed two tablets of prescription medications to a physician without an accompanying prescription. Mr. Agravat freely admitted being subject to these disciplinary proceedings, but until February 2011 never informed Masters’ Compliance Department of any other criminal, regulatory, or disciplinary actions taken against him or Drug Shoppe. It was at that time that he first advised Masters that he was under investigation for issues relating to pharmaceutical sales on the internet that occurred in 2004 or 2005. When Mr. Agravat made that admission, the Drug Shoppe was immediately placed on “non-controlled status.”

192. Mr. Agravat never informed Masters that DEA had issued an Order to Show Cause, or that Drug Shoppe entered into a MOA and, to the best of my knowledge, DEA no longer publishes that type of information to the pharmaceutical industry.
193. To the best of my knowledge, Drug Shoppe currently retains a DEA registration and remains in business, although I believe the pharmacy is now owned by Mr. Agravat’s wife. To the best of my knowledge, Mr. Agravat remains a pharmacist in good standing with the State of Florida.

**ENGLEWOOD SPECIALTY PHARMACY, INC.**

194. I am familiar with Masters’ account relating to Englewood Specialty Pharmacy, Inc. ("Englewood"), and the contents of the documents maintained by Masters relative to the account. Exhibit R2c includes the “Compliance File” maintained by Masters relating to Englewood. I provided this Compliance File to Mr. Rafalski in response to a subpoena he served on Masters dated February 11, 2011. In addition to the complete Compliance File, I also provided Mr. Rafalski with a report showing all of the invoices Masters issued to Englewood between June 27, 2008 and March 31, 2011. This report does not show the products that were sold to Englewood. This report is not part of Masters’ Compliance File relating to Englewood.

195. Englewood established its account with Masters in March 2008. Prior to receiving its first shipment of controlled substances from Masters, Englewood provided information necessary for Masters to complete its then-current DD Survey. In addition, Masters obtained a Dun & Bradstreet report about Englewood and a completed credit application.

196. Englewood also provided Masters with a copy of a report of an inspection performed by the State of Florida Department of Health in August 2007.

197. The Pharmacist in Charge at Englewood, Dan Farris, provided copies of the written policies and procedures Englewood used to prevent the diversion of controlled substances, and described those policies and procedures to Masters. Masters’
Compliance Department believed that Englewood understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.

198. Before shipping any pharmaceutical products to Englewood, Masters verified that its Florida pharmacy license and DEA registration were valid, current, and in good standing.

199. On November 3, 2008, Louis Fisher performed a site inspection of Englewood on behalf of Masters. The Compliance File for Englewood, Exhibit R2e, contains a copy of the written report completed by Mr. Fisher.

200. The DD Survey and Mr. Fisher’s inspection report confirmed that Englewood had been in business since 2004. The Pharmacist in Charge, Mr. Farris, explained that Englewood’s business model included servicing patients from two large hospitals and a number of physicians’ offices that were located in the area immediately surrounding the pharmacy. Englewood also informed Masters that it filled prescriptions for patients from several nearby pain clinics, and identified the physicians who wrote prescriptions for those patients. This accounted for the volume of pain medications and other controlled substances, including oxycodone, being dispensed relative to other drugs.

201. After Englewood’s account was approved, Masters’ SOMS system identified and held any order for controlled substances placed by Englewood that deviated from its typical volume, pattern or frequency. All such orders were released only after review by Masters’ Compliance Department. On some occasions, the Compliance Department would request Englewood to provide a UR as part of its review of orders that had been held by SOMS.
202. Englewood provided Masters with UR's showing the prescription drugs dispensed by the pharmacy during the following periods: January 1 to January 31, 2008; March 1, 2008 to September 22, 2008; September 1 to September 30, 2009; and July 1, 2010 to July 31, 2010. These UR's were provided in response to requests for information from Masters' Compliance Department, and are included within Masters' Compliance File.

203. To the best of my recollection, Masters' Compliance Committee discussed the Englewood account and the information provided by the customer.

204. As a result of our ongoing due diligence, Masters was aware of the volume of oxycodone and other controlled drugs being dispensed by Englewood, and the percentage of controlled drugs dispensed relative to other drugs. Masters specifically investigated the reasons why Englewood's ordering and dispensing patterns were as indicated on the UR's.

205. The UR's and other information provided by Englewood were consistent with the pharmacy's business model as explained by Mr. Farris and confirmed in the November 2008 site inspection. Englewood appeared to be a full line pharmacy that was dispensing a large variety of both controlled and non-controlled drugs, and that serviced patients from two large hospitals, a number of physicians' offices and several pain clinics that were located in the area immediately surrounding the pharmacy.

206. Masters was aware that Englewood was ordering many of its products, including oxycodone, from distributors other than Masters. Given Masters' business model, this is not unusual or considered suspicious. Given the numerous and frequent interruptions in the supply and distribution of oxycodone in particular, as well as
significant price fluctuations of the product, Masters did not consider it suspicious that Englewood ordered the product from suppliers other than Masters.

207. Based on Masters’ extensive investigation, it determined that the orders it shipped to Englewood were not suspicious.

208. On January 12, 2010, Jeff Chase performed a site inspection of Englewood on behalf of Masters. The Compliance File for Englewood, Exhibit R2c, contains a copy of the written report completed by Mr. Chase.

209. Mr. Chase’s site inspection stated that 40 percent of the prescriptions filled by Englewood were for controlled substances. Mr. Chase stated that he felt this percentage was “a little high.” However, Masters’ Controlled Drug Handling Policies and Procedures do not specify any particular percentage of controlled drugs to non-controlled drugs that the Company considers “high” or “a little high.”

210. Masters recognizes that a pharmacy’s business model, location, and other factors will have a significant impact on the ratio of controlled substances to non-controlled substances being dispensed by that pharmacy. Mr. Chase did not recommend that Masters stop selling controlled drugs to Englewood following his inspection in January 2010.

211. On October 6, 2010, Allen Hovis performed a site inspection of Englewood on behalf of Masters. The Compliance File for Englewood, Exhibit R2c contains a copy of the written report completed by Mr. Hovis. In his report, Mr. Hovis noted that he observed out-of-state vehicles in Englewood’s parking lot, and saw several young men acting suspiciously outside of the pharmacy.

212. Following this site inspection, I spoke with Mr. Farris about the suspicious activity Mr. Hovis had observed at Englewood. During that conversation, I expressed
concern that Englewood was filling prescriptions for controlled substances for patients who were not residents of Florida. Mr. Farris explained that out-of-state residents tended to come to Florida between October and March.

213. Consistent with our policies and procedures, Masters continued to sell oxycodone and other controlled drugs to Englewood until October 2010. At that time, the account was placed on “non-controlled status.” Masters took this action in response to Mr. Hovis’ site inspection report dated October 6, 2010, and my subsequent conversation with Mr. Farris during which he admitted filling prescriptions for out of state residents.

214. Masters did not report to DEA any suspicious orders placed by Englewood because at the time the account was terminated there was no order pending. Masters did, however, report to DEA that it had terminated Englewood’s account. Masters took this action on its own initiative, long before Englewood surrendered its DEA registration in July 2013.

CITY VIEW PHARMACY

215. I am familiar with Masters’ account relating to City View Pharmacy (“City View”), and the contents of the documents maintained by Masters relative to the account. Exhibit R2d includes the “Compliance File” maintained by Masters relating to City View. I provided this Compliance File to Mr. Rafalski in response to a subpoena he served on Masters dated February 11, 2011. In addition to the complete Compliance File, I also provided Mr. Rafalski with a report showing all of the invoices Masters issued to City View between June 18, 2008 and March 31, 2011. This report does not show the products that were sold to City View. This report is not part of Masters’ Compliance File relating to the City View.
216. City View established its account with Masters in March 2008. Prior to receiving its first shipment of controlled substances from Masters, City View provided information necessary for Masters to complete its then-current DD Survey. In addition, Masters obtained a Dun & Bradstreet report about City View, and a completed credit application.

217. City View also provided Masters with a copy of a report of an inspection performed by the State of Florida Department of Health in November 2006.

218. Mr. Agbelusi provided an explanation of the policies and procedures City View used to prevent the diversion of controlled substances. Masters' Compliance Department believed that City View understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.

219. Before shipping any pharmaceutical products to City View Masters verified that its Florida pharmacy license and DEA registration were valid, current, and in good standing.

220. On June 25, 2008, Louis Fisher performed a site inspection of City View on behalf of Masters. The Compliance File for City View, Exhibit R2d, contains a copy of the written report completed by Mr. Fisher.

221. The DD Survey and Mr. Fisher’s inspection report confirmed that that City View had been in business since 2005. The Pharmacist-in-Charge, Mr. Agbelusi, explained that City View's business model included marketing to “closed-door” facilities such as nursing homes, hospice programs, and in-patient medical facilities. The pharmacy was located in an urban area of Orlando, Florida within two blocks of two hospitals. City View was also located next door to a police station. City View also informed Masters that it filled prescriptions for patients from several pain clinics, and
identified the physicians who wrote the prescriptions for those patients. These factors accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.

222. After City View's account was approved, Masters' SOMS system identified and held any order for controlled substances placed by City View that deviated from its typical volume, pattern or frequency. All such orders were released only after review by Masters' Compliance Department. On some occasions, the Compliance Department would request City View to provide a UR as part of its review of orders that had been held by SOMS.

223. City View provided Masters with UR's showing the prescription drugs dispensed by the pharmacy during the following periods: February 1 to February 29, 2008; September 1 to September 30, 2009; March 1 to March 30, 2010; October 1 to October 30, 2010; and November 1 to November 31, 2010. These UR's were provided in response to requests for information from Masters' Compliance Department, and are included within Masters' Compliance File.

224. To the best of my recollection, Masters' Compliance Committee discussed the City View account and the information provided by the customer.

225. As a result of our ongoing due diligence, Masters was aware of the volume of oxycodone and other controlled drugs being dispensed by City View, and the percentage of controlled drugs dispensed relative to other drugs. Masters specifically investigated the reasons why City View's ordering and dispensing patterns were as indicated on the UR's.

226. The UR's and other information provided by City View were consistent with the pharmacy's business model as explained by Mr. Agbelusi and confirmed in the
June 2008 site inspection. City View appeared to be a full-line pharmacy that was dispensing a large variety of both controlled and non-controlled drugs, and appeared to be servicing patients of nearby hospitals, closed-door facilities, and pain management physicians.

227. Masters was aware that City View was ordering many of its products, including oxycodone, from distributors other than Masters. Given Masters’ business model, this is not unusual or considered suspicious. Given the numerous and frequent interruptions in the supply and distribution of oxycodone in particular, as well as significant price fluctuations of the product, Masters did not consider it suspicious that City View ordered the product from suppliers other than Masters.

228. Based on Masters’ extensive investigation, it determined that the orders it shipped to City View were not suspicious.

229. On February 17, 2010, Jeff Chase performed a site inspection of City View on behalf of Masters. The Compliance File for City View, Exhibit R2d, contains a copy of the written report completed by Mr. Chase. Mr. Chase did not note any suspicious activity during his inspection, and determined that the site inspection was acceptable.

230. On June 20, 2010, Matt Harmon performed a site inspection of City View on behalf of Masters. The Compliance File for City View, Exhibit R2d, contains a copy of the written report completed by Mr. Harmon.

231. Consistent with its policies and procedures, Masters continued to sell oxycodone and other controlled drugs to City View until December 6, 2010, at which time the account was placed on “non-controlled status.” At that time, Masters developed concerns following its review of UR’s Masters obtained from City View. During a discussion of City View’s dispensing patterns and volume I had with Mr.
Agbelusi on or about December 6, 2010, I became concerned because of discrepancies in the information he provided to me and the dispensing history set forth on the UR. As a result, Masters terminated the account’s ability to purchase controlled drugs as of that date.

232. Masters did not report to DEA a suspicious order placed by City View because the pharmacy did not have an order pending at the time the account was terminated. Masters did, however, report to DEA that it had terminated City View’s account.

233. To the best of my knowledge, City View retains its DEA registration and remains in business today.

**LAM’S PHARMACY**

234. I am familiar with Masters’ account relating to Lam’s Pharmacy (“Lam’s”), and the contents of the documents maintained by Masters relative to the account. Exhibit R2e includes the “Compliance File” maintained by Masters relating to Lam’s. I provided this Compliance File to Mr. Rafalski in response to a subpoena he served on Masters dated February 11, 2011. In addition to the complete Compliance File, I also provided Mr. Rafalski with a report showing all of the products Masters sold to Lam’s between June 8, 2005 and February 25, 2011. The report shows the prescription drugs, “over-the-counter” items, and other products Masters sold to Lam’s during that time. This report is not part of Masters’ Compliance File relating to the Lam’s.

235. Lam’s established its account with Masters in June 2005. It first ordered controlled substances from Masters in April 2008. Prior to receiving its first shipment of controlled substances from Masters, Lam’s completed a credit application, and was inspected by Wayne Corona. Exhibit R5 is a true and accurate copy of a report Mr.
Corona submitted following his inspection of Lam's on March 1, 2008. In addition, Masters obtained a Dun & Bradstreet report about Lam's and a completed credit application.

236. Lam's provided Masters with a copy of a report of an inspection performed by the State of Nevada Board of Pharmacy dated July 18, 2008.

237. Lam's provided Masters with a copy of its written policies and procedures it used to prevent the illegal diversion of controlled substances. Masters' Compliance Department believed that Lam's understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.

238. Before shipping any pharmaceutical products to Lam's, Masters verified that its Nevada pharmacy license and DEA registration were valid, current, and in good standing.

239. On August 11, 2008, Louis Fisher performed a site inspection of Lam's on behalf of Masters. The Compliance File for Lam's contains a copy of the written report completed by Mr. Fisher. Lam's also provided a current UR and a list of the pain management physicians for whom it was filling prescriptions.

240. Mr. Corona's report confirmed that, among other customers, Lam's serviced 11 pain separate pain management medical practices located across the street from the pharmacy at University Medical Center. Mr. Fisher's inspection report confirmed that that Lam's had been in business since 1986. The Pharmacist in Charge, Jason Smith, explained that Lam's business model included servicing patients from several nearby hospitals, medical centers, and pain clinics as well as an in-patient juvenile detention facility. Lam's provided the names of the pain management physicians for whom it was filling prescriptions. These factors accounted for the volume
of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.

241. After Lam’s account was approved, Masters’ SOMS system identified and held any order for controlled substances placed by Lam’s that deviated from its typical volume, pattern or frequency. All such orders were released only after review by Masters’ Compliance Department. On some occasions, the Compliance Department would request Lam’s to provide a UR as part of its review of orders that had been held by SOMS.

242. Lam’s provided Masters with UR’s showing the prescription drugs dispensed by the pharmacy during the following periods: November 1, 2007 to January 31, 2008; July 1 to July 31, 2008; April 1 to June 30, 2009; January 1 to July 6, 2010; May 1 to July 31, 2010; June 1 to June 30, 2010; and January 1 to January 31, 2011. These UR’s were provided in response to requests for information from Masters’ Compliance Department, and are included within Masters’ Compliance File.

243. To the best of my recollection, Masters’ Compliance Committee discussed the Lam’s account and the information provided by the customer.

244. As a result of our ongoing due diligence, Masters was aware of the volume of oxycodone and other controlled drugs being dispensed by Lam’s, and the percentage of controlled drugs dispensed relative to other drugs. Masters specifically investigated the reasons why Lam’s ordering and dispensing patterns were as indicated on the UR’s.

245. The UR’s and other information provided by Lam’s were consistent with the pharmacy’s business model as explained by Jason Smith and confirmed in the August 2008 site inspection. Lam’s appeared to be a high-volume pharmacy that was dispensing a wide variety of both controlled and non-controlled products, that serviced
patients from numerous hospitals, medical facilities, and pain clinics located nearby and an in-patient juvenile detention facility.

246. Masters was aware that Lam’s was ordering many of its products, including oxycodone, from distributors other than Masters. Given Masters’ business model, this is not unusual or considered suspicious. Given the numerous and frequent interruptions in the supply and distribution of oxycodone in particular, as well as significant price fluctuations of the product, Masters did not consider it suspicious that Lam’s ordered the product from suppliers other than Masters.

247. Based on Masters’ extensive investigation, it determined that the orders it shipped to Lam’s were not suspicious.

248. Exhibit R7 is a true and accurate copy of an email concerning Lam’s from Lieutenant Clinton Nichols of the Las Vegas Police Department to Jeff Chase dated January 20, 2009. In the email, Lieutenant Nichols describes his department’s review of Lam’s and that of the Nevada Bureau of Investigations. Among other things, the email confirmed that Lam’s was “the largest in the State of Nevada for Oxycontin sales and is able to sell this product at ‘cut rate prices’ due to their sales volume.” The email also states that Lam’s was not suspected of any wrong doing at that time.

249. On September 4, 2009, Wayne Corona performed another site inspection of Lam’s on behalf of Masters. The Compliance File for Lam’s, Exhibit R2e, contains a copy of an email from Mr. Corona describing his observations during the inspection. Mr. Corona did not note any suspicious activity during his inspection, and determined that Masters should continue filling orders for controlled substances placed by Lam’s.
250. On August 3, 2010 Masters was served with an administrative subpoena requesting information and documents about Lam’s. The subpoena was served by a DEA representative in Las Vegas. I provided the documents requested by DEA.

251. The DEA subpoena instructed Masters to “not disclose the existence of this request or investigation for an indefinite time period. Any such disclosure could impede the criminal investigation being conducted and interfere with the enforcement of the Controlled Substances Act.” During the August 2009 “Compliance Review,” Mr. Wright had instructed Masters that it should not automatically terminate its relationship with a pharmacy about which DEA had sought information because the pharmacy may not be the subject of DEA’s investigation.

252. Nonetheless, in August 2010, Masters suspended sales of controlled substances to Lam’s in order to conduct additional due diligence on the account.

253. On August 5, 2010, I inspected Lam’s with Mr. Corona, Mr. Smith, and Diane Garvey. Exhibit R2e contains a copy of the inspection report I completed. We were in Las Vegas to attend an industry conference at which DEA was presenting, but wanted to see Lam’s as part of our ongoing due diligence on the account. My inspection of Lam’s revealed that it appeared to be a pharmacy that primarily serviced “closed door” facilities, including hospice centers, and patients from nearby medical centers. I did not observe anything unusual or suspicious during my inspection of Lam’s. Although Lam’s carried only a small selection of “front of the store” items, that was consistent with our understanding of the pharmacy’s business model.

254. As part of our ongoing due diligence investigation of Lam’s, Dennis Smith and Wayne Corona visited a CVS Pharmacy located in the same shopping center as Lam’s. A true and accurate copy of Mr. Smith’s notes from that visit is included in
Exhibit R2e. According to Mr. Smith's notes, the pharmacist in charge at CVS knew the pharmacists at Lam's and did not think that they were involved in any illegal activity. He stated that the high volume of controlled substances Lam's dispensed was consistent with his CVS pharmacy. According to the CVS pharmacist, his CVS store next to Lam's dispensed three or four times more controlled substances than other high-volume CVS pharmacies. He attributed the high volume of controlled substances dispensed by Lam's and his own pharmacy to the prevalence of hospitals and medical offices in the immediate area. This information was all consistent with the information provided to us by Lam's itself.

255. As part of our ongoing due diligence investigation of Lam's, Dennis Smith and Wayne Corona also visited a different CVS Pharmacy located near Lam's. According to Mr. Smith's notes, a true and accurate copy of which are included in Exhibit R2e, that pharmacist also stated that she did not believe Lam's was operating illegally. She confirmed that her CVS pharmacy filled a far greater volume of prescriptions for controlled drugs than most other CVS pharmacies. She attributed this dispensing pattern to the surrounding hospitals and medical centers.

256. The information Mr. Smith and Mr. Corona gathered from the CVS pharmacists was consistent with the information provided to us by Lam's itself.

257. Following our visit to Las Vegas, I contacted several of the hospice centers for which Lam's claimed to fill prescriptions. I investigated public filings relating to those hospice centers, and spoke with representatives of each hospice. Each hospice confirmed that they sent their patients' prescriptions to Lam's to be filled, and that Lam's delivered the prescribed drugs directly to the patients. This was consistent with the information that had been provided by Lam's.
258. After we returned from Las Vegas, we learned that Lam's had been served with a search warrant by DEA.

259. Exhibit R37 is a true and accurate copy of an email from Mr. Corona to myself, Mr. Smith and Diane Garvey dated August 17, 2010 in which he confirms that Cardinal Health, Lam's primary supplier, was continuing to ship controlled substances to Lam's.

260. Exhibit R38 is a true and accurate copy of an email string dated August 18, 2010 in which Mr. Corona relates information he obtained from Jason Smith, the pharmacist in charge at Lam's. According to the email, Mr. Smith claimed that the search warrant related to Dr. Thalgott. Upon receiving this email, I conducted a search for information on the internet and learned that Dr. Thalgott and other Las Vegas physicians, attorneys, and insurance agents known as the "Medical Mafia of Las Vegas" had been the subject of an ongoing fraud investigation by the FBI. During my search, I did not find any evidence that Lam's or Mr. Smith was the subject of the FBI's investigation.

261. Exhibit R39 is a true and accurate copy of an email dated August 19, 2010 from Wayne Corona to myself and others. In the email, Mr. Corona describes a conversation he had with Mr. Wright of DEA regarding Lam's. According to the email, Mr. Wright told Mr. Corona that DEA had taken no action against Lam's, and that he, Mr. Wright, was aware of the voluminous amount of due diligence Masters had conducted on Lam's. Mr. Wright told Mr. Corona that "the ball was in [Masters'] court."

262. Exhibit R40 is a true and accurate copy of an email dated August 23, 2010 from Mr. Corona to myself and others. In the email, Mr. Corona describes a conversation he had with Mike Monet of Cardinal Health, Lam's primary supplier.
According to the email, Mr. Monet told Mr. Corona that Cardinal was continuing to ship controlled substances to Lam's, that DEA was not currently taking any action against Lam's, that Cardinal had conducted extremely thorough due diligence on the account and verified the fact that the pharmacy serviced several hospice centers (as I had done).

263. Exhibit R41 is a true and accurate copy of an email string dated August 23, 2010 which followed Mr. Corona's email of earlier that day, Exhibit R40. In the emails, both Diane Garvey, Dennis Smith and I all expressed concern about continuing to sell controlled substances to Lam's. I confirmed that the account remained on “non-controlled status” at that time. Mr. Corona believed we should continue selling controlled substances to Lam's based on our own due diligence and the information provided by Cardinal.

264. Between August 23 and August 30, 2010, we continued to discuss the Lam's account informally and in Masters' Compliance Committee. Although I remained concerned about the fact that we had received an administrative subpoena about Lam's from DEA, others within the Company felt that we had no reason to believe that Lam's itself was involved in the diversion of controlled substances. During my inspection of the pharmacy, I did not observe anything suspicious, and it appeared that Lam's took great care to verify the legitimacy of the prescriptions it filled. I had also confirmed that Lam's serviced the hospice centers it identified as customers.

265. Based on all the facts and circumstances known to us at the time, Masters' Compliance Department decided to resume the sale of controlled substances to Lam's.

266. Exhibit R42 is a true and accurate copy of an email string dated August 31, 2010 between myself, Mr. Smith, Mr. Corona and others. In my initial email, I describe a conversation I had with Kristen, a pharmacist at Lam's, during which I confirmed that
Lam's was again able to order controlled substances from Masters. In response, Mr. Corona sent an email in which he describes a conversation he had with Teri Carter, another pharmacist at Lam's, during which Ms. Carter informed him that the records that had been produced in response to the search warrant had begun to be returned to Lam's. Mr. Corona viewed this as a "very positive signal." I believed that the return of the records to Lam's was consistent with our understanding that the "Medical Mafia of Las Vegas," not Lam's, was the target of the ongoing investigation.

267. Sometime in early 2011, I learned that Jason Smith was no longer associated with Lam's. Exhibit R47 is a true and accurate copy of an email string dated April 28, 2011 in which Wayne Corona describes a conversation he had with Teri Carter, the "owner-consultant" at Lam's relating to Jason Smith's departure from the pharmacy. According to Mr. Corona's email, Mr. Smith had left Lam's on "good terms" due to "major personal issues with [his] marriage." The email advised me that Kristin would be the pharmacist in charge at Lam's.

268. Exhibit R2e1 is a true and accurate copy of a spreadsheet showing Masters' sales of controlled substances to Lam's between June 1, 2009 and August 17, 2010. The spreadsheet was produced in response to a subpoena served on Masters by DEA Diversion Investigator Julio Alejo of the Las Vegas Field Office. I also provided Mr. Rafalski with a copy of this spreadsheet.

269. Exhibit R2e2 is a true and accurate copy of a spreadsheet showing Masters' sales of carisoprodol to Lam's between June 1, 2009 and August 17, 2010. The spreadsheet was produced in response to a subpoena served on Masters by DEA Diversion Investigator Julio Alejo of the Las Vegas Field Office. I also provided Mr. Rafalski with a copy of this spreadsheet.
270. Consistent with its policies and procedures, Masters continued to sell oxycodone and other controlled drugs to Lam’s until July 6, 2011, at which time the account was placed on “non-controlled status” after Masters learned that Lam’s was apparently the subject of a DEA investigation.

271. Masters reported to DEA suspicious orders placed by Lam’s on July 14, 2011, September 21, 2011 and October 12, 2011. Masters stopped selling any controlled substances to Lam’s after July 6, 2011. Masters took this action on its own initiative, long before Lam’s surrendered its DEA registration in February 2012.

272. Exhibit R50 is a true and accurate copy of an email string dated October 5, 2011 relating to the indictment of Jason Smith on charges arising from the unlawful distribution of controlled substances. Lam’s is not mentioned in the news report. I responded to Mr. Corona’s email by stating that Masters had terminated Lam’s account on July 7, 2011.

273. Masters’ Sales Representatives, including Adam Sloan, had no ability to influence whether any order for controlled substances placed by Lam’s (or any other customer) would be approved for shipping by Masters’ Compliance Department.

MEDICAL PLAZA PHARMACY OF PLANTATION, LLC

274. I am familiar with Masters’ account relating to Medical Plaza Pharmacy of Plantation, LLC (“Medical Plaza”), and the contents of the documents maintained by Masters relative to the account. Exhibit R2f includes the “Compliance File” maintained by Masters relating to Medical Plaza. I provided this Compliance File to Mr. Rafalski in response to a subpoena he served on Masters dated April 22, 2011. In addition to the complete Compliance File, I also provided Mr. Rafalski with a report showing all of the
products Masters sold to Medical Plaza. This report is not part of Masters’ Compliance File relating to the Medical Plaza.

275. Medical Plaza established its account with Masters in March 2009. Prior to receiving its first shipment of controlled substances from Masters, Medical Plaza provided information necessary for Masters to complete its then-current DD Survey. In addition, Masters obtained a Dun & Bradstreet report about Medical Plaza and a completed credit application.

276. Medical Plaza also provided Masters with a copy of a report of an inspection performed by the State of Florida Department of Health in December 2008.

277. The pharmacist in charge at Medical Plaza, Mr. Meroeh Rabiefar, described the policies and procedures Medical Plaza used to prevent the diversion of controlled substances. Masters’ Compliance Department believed that Medical Plaza understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.

278. Before shipping any pharmaceutical products to Medical Plaza Masters verified that its Florida pharmacy license and DEA registration were valid, current, and in good standing.

279. On or about June 18, 2009, Jeff Chase performed a site inspection of Medical Plaza on behalf of Masters. The Compliance File for Medical Plaza, Exhibit R2f, contains a copy of the written report completed by Mr. Chase.

280. The DD Survey and Mr. Chase’s inspection report confirmed that Medical Plaza had been in business since 1974, although the pharmacy changed ownership in late 2008 or early 2009. Mr. Rabiefar explained that Medical Plaza was located in a medical center with 60 physicians, and the pharmacy serviced patients from that
medical center and an adjacent hospital. This accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.

281. After Medical Plaza's account was approved, Masters' SOMS system identified and held any order for controlled substances placed by Medical Plaza that deviated from its typical volume, pattern or frequency. All such orders were released only after review by Masters' Compliance Department. On some occasions, the Compliance Department would request Medical Plaza to provide a UR as part of its review of orders that had been held by SOMS.

282. Medical Plaza provided Masters with UR's showing the prescription drugs dispensed by the pharmacy during the following periods: July 1 to July 31, 2009; November 1 to November 30, 2009; July 1 to July 31, 2010; and December 1 to December 31, 2010. These UR's were provided in response to requests for information from Masters' Compliance Department, and are included within Masters' Compliance File.

283. To the best of my recollection, Masters' Compliance Committee discussed the Medical Plaza account and the information provided by the customer.

284. As a result of our ongoing due diligence, Masters was aware of the volume of oxycodone and other controlled drugs being dispensed by Medical Plaza and the percentage of controlled drugs dispensed relative to other drugs. Masters specifically investigated the reasons why Medical Plaza's ordering and dispensing patterns were as indicated on the UR's.

285. The UR's and other information provided by Medical Plaza were consistent with the pharmacy's business model as explained by Mr. Rabiefar and
confirmed in the June 2009 site inspection. Medical Plaza appeared to be a full line pharmacy that was dispensing a large variety of both controlled and non-controlled drugs, and that serviced patients from an adjacent medical center and hospital.

286. Masters was aware that Medical Plaza was ordering many of its products, including oxycodone, from distributors other than Masters. Given Masters’ business model, this is not unusual or considered suspicious. Given the numerous and frequent interruptions in the supply and distribution of oxycodone in particular, as well as significant price fluctuations of the product, Masters did not consider it suspicious that Medical Plaza ordered the product from suppliers other than Masters.

287. Based on Masters’ extensive investigation, it determined that the orders it shipped to Medical Plaza were not suspicious.

288. Consistent with our policies and procedures, Masters continued to sell oxycodone and other controlled drugs to Medical Plaza until March 2011, at which time the account was placed on “non-controlled status” because Medical Plaza refused to provide Masters with a detailed list of the physicians for whom the pharmacy was filling prescriptions for controlled substances. Although Masters had not previously required our pharmacy customers to provide this information, we began requesting a detailed physicians’ list from certain customers in approximately February 2011 after Mr. Rafalski criticized us for not doing so. Masters did not ship any controlled substances to Medical Plaza after March 4, 2011.

289. Masters did not report to DEA a suspicious order placed by Medical Plaza because no order was pending at the time the account was terminated. However, Masters did report to DEA that Medical Plaza’s ability to purchase controlled substances had been suspended indefinitely.
290. To the best of my knowledge, Medical Plaza remains in business today.

MORRISON'S RX, INC.

291. I am familiar with Masters’ account relating to Morrison’s Rx, Inc. (“Morrison’s”), and the contents of the documents maintained by Masters relative to the account. Exhibit R2g includes the “Compliance File” maintained by Masters relating to Morrison’s. I provided this Compliance File to Mr. Rafalski in response to a subpoena he served on Masters dated February 11, 2011. In addition to the complete Compliance File, I also provided Mr. Rafalski with a report showing Masters’ sales to Morrison’s between October 10, 2007 and February 25, 2011. This report is not part of Masters’ Compliance File relating to Morrison’s.

292. Exhibit R2g1 is true and accurate copy of the original DD Survey relating to Morrison’s completed by Matt Harmon on November 28, 2007.

293. Exhibit R2g2 is a true and accurate copy of the completed credit application and other documents provided to Masters by Morrison’s on or about September 27, 2007.

294. Morrison’s established its account with Masters in September 2007. Prior to receiving its first shipment of controlled substances from Masters, Morrison’s provided information necessary for Masters to complete its then-current DD Survey. In addition, Masters obtained a Dun & Bradstreet report about Morrison’s and a completed credit application.

295. Morrison’s also provided Masters with a copy of a report of an inspection performed by the State of Florida Department of Health in September 2007.

296. Morrison’s provided copies of the written policies and procedures Morrison’s employed to prevent the diversion of controlled substances. Masters’
Compliance Department believed that Morrison's understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.

297. Before shipping any pharmaceutical products to Morrison's, Masters verified that its Florida pharmacy license and DEA registration were valid, current, and in good standing.

298. On April 24, 2008, Louis Fisher performed a site inspection of Morrison's on behalf of Masters. The Compliance File for Morrison's, Exhibit R2g, contains a copy of the written report completed by Mr. Fisher.

299. The DD Survey and Mr. Fisher's inspection report confirmed that Morrison's had been in business since 2003. The Pharmacist in Charge, Marilyn Morrison-Padilla, explained that Morrison's business model included servicing a nearby nursing home and an in-patient facility, and filling prescriptions for a large number of elderly patients who lived in a nearby residential area. The pharmacy also filled prescriptions for patients of pain management clinics, and identified the physicians who were writing the prescriptions for those patients. These factors accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.

300. After Morrison's account was approved, Masters' SOMS system identified and held any order for controlled substances placed by Morrison's that deviated from its typical volume, pattern or frequency. All such orders were released only after review by Masters' Compliance Department. On some occasions, the Compliance Department would request Morrison's to provide a UR as part of its review of orders that had been held by SOMS.
301. Morrison’s provided Masters with UR’s showing the prescription drugs dispensed by the pharmacy during the following periods: September 1 to November 27, 2007; January 1 to April 1, 2008; November 1, 2008 to January 1, 2009; January 1 to May 6, 2009; and July 1 to July 31, 2009. These UR’s were provided in response to requests for information from Masters’ Compliance Department, and are included within Masters’ Compliance File.

302. To the best of my recollection, Masters’ Compliance Committee discussed the Morrison’s account and the information provided by the customer.

303. As a result of our ongoing due diligence, Masters was aware of the volume of oxycodone and other controlled drugs being dispensed by Morrison’s and the percentage of controlled drugs dispensed relative to other drugs. Masters specifically investigated the reasons why Morrison’s ordering and dispensing patterns were as indicated on the UR’s.

304. The UR’s and other information provided by Morrison’s were consistent with the pharmacy’s business model as explained by Ms. Morrison-Padilla and confirmed in the April 2008 site inspection. Morrison’s appeared to be pharmacy that serviced patients of pain management physicians, elderly patients, nursing home patients, and patients from an in-patient medical facility.

305. Masters was aware that Morrison’s was ordering many of its products, including oxycodone, from distributors other than Masters. Given Masters’ business model, this is not unusual or considered suspicious. Given the numerous and frequent interruptions in the supply and distribution of oxycodone in particular, as well as significant price fluctuations of the product, Masters did not consider it suspicious that Morrison’s ordered the product from suppliers other than Masters.
306. Based on Masters’ extensive investigation, it determined that the orders it shipped to Morrison’s were not suspicious.

307. Consistent with our policies and procedures, Masters continued to sell oxycodone and other controlled drugs to Morrison’s until Mr. Wright and Mr. Arnold inadvertently revealed during the August 2009 “Compliance Review” that DEA was investigating Morrison’s, after which the account was placed on “non-controlled” status. Masters did not report a suspicious order placed by Morrison’s because no order was pending at that time. However, Masters did report to DEA that it had terminated Morrison’s account.

308. To the best of my knowledge, Morrison’s remains registered with DEA and in business today.

**TEMPLE TERRACE PHARMACY d/b/a SUPERIOR PHARMACY**

309. I am familiar with Masters’ account relating to Temple Terrace Pharmacy d/b/a Superior Pharmacy ("Superior"), and the contents of the documents maintained by Masters relative to the account. Exhibit R2h includes the “Compliance File” maintained by Masters relating to Superior. I provided this Compliance File to Mr. Rafalski in response to a subpoena he served on Masters dated April 22, 2011. In addition to the complete Compliance File, I also provided Mr. Rafalski with a report showing all of Masters’ sales of controlled substances to Superior. This report is not part of Masters’ Compliance File relating to Superior.

310. Superior established its account with Masters in January 2008. Prior to receiving its first shipment of controlled substances from Masters, Superior provided information necessary for Masters to complete its then-current DD Survey. In addition,
Masters obtained a Dun & Bradstreet report about Superior and a completed credit application.

311. Superior also provided Masters with a copy of a report of an inspection performed by the State of Florida Department of Health in October 2007.

312. Superior described the policies and procedures it employed to prevent the diversion of controlled substances. Masters’ Compliance Department believed that Superior understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.

313. Before shipping any pharmaceutical products to Superior, Masters verified that its Florida pharmacy license and DEA registration were valid, current, and in good standing.

314. On June 24, 2008, Louis Fisher performed a site inspection of Superior on behalf of Masters. The Compliance File for Superior, Exhibit R2h, contains a copy of the written report completed by Mr. Fisher.

315. The DD Survey and Mr. Fisher’s inspection report confirmed that Superior had been in business since 2004. The pharmacist, Ike Okeke, explained that Superior’s business model included filling prescriptions for a juvenile in-patient facility, and a weight-loss and pain management facility located in an adjacent office. Superior provided Masters with the names of the physicians associated with that weight loss and pain clinic. These factors accounted for the volume of controlled substances being dispensed, and the percentage of oxycodone dispensed relative to other drugs.

316. After Superior’s account was approved, Masters’ SOMS system identified and held any order for controlled substances placed by Superior that deviated from its typical volume, pattern or frequency. All such orders were released only after review by
Masters' Compliance Department. On some occasions, the Compliance Department would request Superior to provide a UR as part of its review of orders that had been held by SOMS.

317. Superior provided Masters with UR's showing the prescription drugs dispensed by the pharmacy during the following periods: January 1 to June 10, 2008; May 1 to May 31, 2009; and August 1 to August 31, 2009. These UR's were provided in response to requests for information from Masters' Compliance Department, and are included within Masters' Compliance File.

318. To the best of my recollection, Masters' Compliance Committee discussed the Superior account and the information provided by the customer.

319. As a result of our ongoing due diligence, Masters was aware of the volume of oxycodone and other controlled drugs being dispensed by Superior and the percentage of controlled drugs dispensed relative to other drugs. Masters specifically investigated the reasons why Superior ordering and dispensing patterns were as indicated on the UR's.

320. The UR's and other information provided by Superior were consistent with the pharmacy's business model as explained by the customer. The UR's and other information obtained by Masters confirmed that Superior appeared to be a full-line pharmacy that serviced an in-patient facility and an adjacent pain management and weight loss clinic.

321. Masters was aware that Superior was ordering many of its products, including oxycodone, from distributors other than Masters. Given Masters' business model, this is not unusual or considered suspicious. Given the numerous and frequent interruptions in the supply and distribution of oxycodone in particular, as well as
significant price fluctuations of the product, Masters did not consider it suspicious that Superior ordered the product from suppliers other than Masters.

322. Based on Masters' extensive investigation, it determined that the orders it shipped to Superior were not suspicious.

323. Consistent with our policies and procedures, Masters continued to sell oxycodone and other controlled drugs to Superior until December 2009 when the account was placed on "compliance hold" pending a site visit. At that time, Masters learned that Superior and the adjacent pain clinic had common ownership. On January 11, 2010, Mr. Chase performed a site inspection of Superior and observed suspicious activity occurring inside the pharmacy. Superior's account with Masters was immediately terminated.

324. Masters did not report to DEA a suspicious order placed by Superior because there was no order pending at the time the account was terminated. Masters did, however, report to DEA that it had terminated Superior's account.

325. To the best of my knowledge, Superior retains its DEA registration and remains in business today.

**DISCUSSIONS AND MEETINGS WITH DEA REPRESENTATIVES**

326. Since joining Masters' Compliance Department in 2009, I have had numerous interactions and meetings with Masters' local DEA agents, and Diversion Investigator James Rafalski. I also routinely communicate with officials from the US Food and Drug Administration, various state boards of pharmacy, and other regulatory agencies about issues relating to Masters.

327. I was present during the inspection of Masters performed by Lewis Thomas of DEA's Cincinnati office on November 23, 2010. To the best of my
knowledge, Mr. Thomas observed no deficiencies during his inspection. He did not instruct Masters to make any changes to its policies or procedures, he was not critical of our SOMS, and he did not question any of our controlled substance sales to any of our customers.

328. On February 8 and February 9, 2011 Wayne Corona, Matt Harmon and I met with Mr. Thomas and Mr. Rafalski and Scott Kurtz from DEA’s Detroit field office. The meetings took place at Masters’ facility in Forest Park, and the Company’s new TPL facility in Fairfield, Ohio. I attended all of the meetings that took place over those two days.

329. During the February 2011 meetings, Mr. Rafalski was critical of Masters’ compliance efforts and recommended several changes to our policies and procedures. For example, Mr. Rafalski was critical of the scope of Masters’ investigation into the physicians for whom our pharmacy customers were filling prescriptions. He told me that Masters should have been getting written “physicians lists” from our pharmacy customers that identified the name, DEA registration number, and address of the physicians that were writing prescriptions for controlled substances that were being filled by our pharmacy customers. He stated that we should be determining how far from the pharmacy each physician’s office was, and that Masters should consider it suspicious if the physician’s office was more than ten miles away from the pharmacy.

330. During these meeting, Mr. Rafalski also criticized Masters’ use of the term “release with reservation” or “RWR” to designate controlled substance orders that had been investigated and determined not to be suspicious, but which, for various reasons, required further scrutiny.
331. Despite these criticisms, Mr. Rafalski told me he "could tell [we] were trying" to comply with DEA regulations. He told me he could tell we were "not turning a blind eye" toward our customers. He told me that Masters did not act quickly enough to terminate its relationship with certain unnamed pharmacies; however, he did not name any particular pharmacy.

332. Mr. Rafalski's February 2011 criticisms were directly contrary to guidance we had received from DEA in August 2009. After the August 2009 "Compliance Review," DEA did not inform Masters that our policies and procedures were inadequate even though we did not, at that time, investigate the physicians for whom our pharmacy customers were filling prescriptions.

333. Additionally, it was Mr. Wright of DEA who had specifically instructed Masters to use the term "release with reservation" to designate accounts that required further investigation.

334. Despite the fact that Mr. Rafalski's guidance to us was in conflict with the guidance we had received from DEA in August 2009, we immediately implemented his suggestions, and continue to follow them today.

335. At no time has Mr. Rafalski ever told Masters that the Company should not sell to any pharmacy that dispenses a certain volume of controlled substances, or a certain ratio of controlled substances to non-controlled substances. Indeed, I am aware of no DEA guidance at all on this subject. To the contrary, it is my understanding that numerous factors, including the pharmacy's location and business model will have a significant impact on its dispensing patterns.

336. Prior to the meetings in February 2011, I had never met Mr. Rafalski. To the best of my knowledge, he has never inspected our Forest Park warehouse or its
physical security. He has never inspected the controlled substances vault or cage at the Forest Park facility. Mr. Rafalski has never asked me to produce minutes from our Compliance Committee meetings.

337. Following the February 2011 meetings, Mr. Rafalski told me that he would be returning to Masters late in February or early March to interview at least two sales representatives and one sales manager. To the best of my knowledge, those meetings never occurred.

338. Exhibit R46 is a true and accurate copy of an email string dated February 9, 2011 in which I summarized the meetings with DEA.

339. Exhibit R46a is a true and accurate copy of an email I sent to Leonard Levin of DEA, and on which I copied Mr. Rafalski. The email attached Masters’ updated Pharmacy Evaluation Form. The form is completed by Masters’ personnel when performing a pharmacy site inspection. Neither Mr. Levin nor Mr. Rafalski ever contacted me to discuss the form or suggest Masters make additional changes to it.

340. Mr. Rafalski has never asked me any questions about my working relationship with Jeff Chase, Eric Schulze or Temple Bradford, and he never asked me whether any of them might have a bias against Masters. He never revealed to me that they had provided information or documents to him, and he never gave me an opportunity to review or respond to any of the statements they have apparently made about Masters. Based on my review of DEA’s Prehearing Statement, I believe that Mr. Chase, Mr. Schulze and Ms. Bradford have either given incomplete or inaccurate information to DEA about Masters, or DEA has misinterpreted or misstated the information they provided.
341. After the meeting in February 2011, I had a telephone conversation with Mr. Thomas during which I asked him why the Detroit office, rather than the Cincinnati office, was involved with Masters. Mr. Thomas told me only that it was “out of [his] hands.”

342. Mr. Rafalski served three administrative subpoenas dated February 11, 2011, April 22, 2011, and January 6, 2012 on Masters. I had several discussions with him about the scope of the documents he wanted us to produce. He instructed me to provide Masters’ entire Compliance File relative to the named pharmacies. The subpoenas also requested copies of all “correspondences” relative to the named pharmacies. I explained to Mr. Rafalski that if I produced all the emails sent to or received from the named pharmacies, it would include thousands of automated system emails relating to each customer’s orders. He told me that he did not want me to produce all the emails we may have had in our possession relating to the named pharmacies; instead, he only wanted emails that specifically mentioned controlled substances. I explained that we did not have an automated way to identify all such emails, and that Masters did not begin archiving emails until the spring of 2010, but that I would attempt to locate all emails that were responsive to his request. He told me that would be fine, and I used my best efforts to provide all the documents he requested.

343. The only times I have ever met Mr. Rafalski in person were the meetings in February 2011, and a meeting that occurred in August 2013 relating to Masters’ DEA import registration.

344. Throughout my career at Masters, I feel that Masters has maintained a very good relationship with our local DEA agents, including Mr. Thomas, Chris Krasnek, and Erik Collins, our current agent. I feel that Masters has worked hard to comply with
DEA regulations and directives, and we have always tried to communicate with our local office openly. We take very seriously our obligation to assist DEA with its law enforcement mission.

**RECENT IMPROVEMENTS AND ENHANCEMENTS TO MASTERS' CONTROLLED SUBSTANCE COMPLIANCE PROGRAM**

345. Since August 2009, Masters has continued to improve and enhance its due diligence policies and procedures. In addition to a greater focus on prescribing physicians as described above, Masters has subscribed to a newly-offered online database that allows Masters to quickly gather a great deal of information about its pharmacy customers and the physicians for whom those pharmacies fill prescriptions. The database also alerts Masters in the event new derogatory information about its customers becomes available.

346. Since February 2011, Masters has used UR’s to calculate and more closely monitor the percentage of controlled to non-controlled substances being dispensed by its customers. The Company now refuses to sell controlled substances to any pharmacy that dispenses more controlled substances than non-controlled substances.

347. Masters continually re-evaluates, refines and updates its Controlled Substance Compliance program in light of new trends in the pharmaceutical industry, law enforcement updates and priorities, and other relevant information. Masters does not consider these improvements to be remedial in nature because they are not intended to correct prior deficiencies in Masters’ policies and procedures.

348. Exhibit R51 is a true and accurate copy of an email I sent to Mr. Thomas, Mr. Rafalski and Leonard Levin of DEA on December 5, 2011 advising them of updates
to Masters' due diligence policies and procedures. I never received any response from DEA to this email.

349. I know that Masters had done everything within its power to identify pharmacies and other DEA registrants that may be engaged in the illegal diversion of controlled substances during my tenure in the Compliance Department. We have reported the names and DEA registration numbers of those registrants to DEA, and we have provided DEA and countless other law enforcement agencies with information in support of their investigations. To the extent DEA is now critical of my efforts and those of the other dedicated employees in my Department, I believe that the criticism is based on flawed statistics, a lack of understanding of the customers we serve, the misinterpretation of our Compliance Files, and, perhaps, false information provided by people who are biased against Masters. The public would suffer if Masters were no longer able to sell controlled substances because I do not believe that any other distributor does a better job of enforcing the laws and DEA regulations than Masters.

FURTHER AFFIANT SAYETH NAUGHT

Jennifer Seiple

Sworn to and subscribed in my presence this 20th day of December 2013 by Jennifer Seiple.

Notary Public