

THE ATTORNEY GENERAL OF THE STATE OF NEW YORK  
MEDICAID FRAUD CONTROL UNIT AND HEALTH CARE BUREAU

In the Matter of  
CARDINAL HEALTH INC.

**ASSURANCE OF DISCONTINUANCE  
PURSUANT TO EXECUTIVE LAW §63(15)**

In 2005, the Office of the Attorney General (the “OAG”) began an investigation focusing on trading in the Secondary Market for pharmaceuticals (the “Investigation”). The OAG issued subpoenas to parties, including Cardinal Health Inc. (“Cardinal”), under the authority of Executive Law §63(12) and the Martin Act (General Business Law §352-c). This Assurance of Discontinuance (the “Assurance”) contains the OAG’s findings with respect to Cardinal, and the relief to which Cardinal and the OAG have agreed.

**FINDINGS**

1. Over the past several years, prescription drug counterfeiters have become increasingly aggressive and sophisticated in their attempts to penetrate the pharmaceutical distribution network in the United States. The Attorney General has found that certain practices, including unfettered secondary-market trading in prescription pharmaceuticals, contribute to establishing substantial inventories of prescription pharmaceuticals in the Secondary Market, thereby providing opportunities for counterfeiters and price-diverters to introduce counterfeit, adulterated, mishandled, mislabeled, unreliable or price-diverted prescription pharmaceuticals into the mainstream distribution network. In particular, certain secondary-market trading practices are part of, or can facilitate, the Diversion Market, a sector of unscrupulous wholesalers buying and

selling real and sometimes counterfeit drugs in a variety of unlawful ways. As a Florida grand jury concluded on this subject in February 2003, the movement of drugs “up, down and sideways through the distribution system . . . creates opportunities for adulterated drugs that have been diverted from other sources” to enter that system.<sup>1</sup>

2. Cardinal is one of the three primary distributors of pharmaceuticals in the United States. Up until it ended the practice in December 2005, Cardinal, like other national full-line distributors, bought and sold drugs in the Secondary Market, buying from and selling to wholesalers known as “Alternate Source Vendors” or “ASVs.” As one Cardinal employee wrote in a 2001 e-mail to colleagues worried about the risks of the ASV market, the firm “must understand the need to not kill the goose (ASV) who is laying the golden eggs.” Through its conduct, Cardinal has violated Executive Law §63(12). Having previously undertaken significant voluntary reforms, Cardinal now enters into this Assurance.

3. Executive Law §63(12) forbids any person or business from engaging in repeated fraudulent or illegal acts, including any device, scheme or artifice to defraud, and any deception, misrepresentation, concealment, suppression, false pretense, false promise, or unconscionable contractual provisions. Conduct is actionable under Executive Law §63(12) if it violates any federal, state or local law or regulation.

4. Education Law §6811(9) makes it unlawful for any person to hold for sale, offer for sale, or sell any adulterated or misbranded drug, and §6811(11) makes it unlawful to receive an adulterated or misbranded drug and deliver or proffer delivery of it.

5. In a 2003 internal Cardinal e-mail to a compliance officer, one executive addressed the issue of “smaller vendors” which provided “unique opportunities” to Cardinal. Although acknowledging that the vendors are “high risk,” the writer concluded that “[s]ince we need the margin from these high risk vendors we will continue to buy from them.”

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<sup>1</sup> First Interim Report of the Seventeenth Statewide Grand Jury (Florida Case SC02-2645), available at <http://myfloridalegal.com/pages.nsf/0/09558F82389E020785256CDA006DB01A?OpenDocument>.

6. As late as 2004, internal Cardinal documents continued to discuss the risks inherent in the Secondary Market. A confidential draft policy paper, noting that “Cardinal Health is taking significant steps to make sure that the product distributed is authentic and safe,” also reported, “Cardinal Health has a vested interest in maintaining the secondary distribution market.” And as the same paper acknowledged, “It is believed by many that this market is the weakest [point in] the chain for the introduction of counterfeit product.”

7. One employee in 2002 wrote an e-mail discussing a newspaper article on a spate of recent counterfeit drug cases. The article quoted one commentator’s view that criminals are bright, rational people “doing the risk-benefit analysis,” and shifting their activities to diverting and counterfeiting prescription drugs. The Cardinal employee wrote, apparently referring to that observation regarding counterfeiters, “The article mentioned the risk reward ratio of price to penalty when caught.” He concluded: “We obviously need to earn money in this area, but have to manage risk.”

8. Cardinal purchased drugs on the Secondary Market that later turned out to be counterfeit. From May 2001 through May 2002, Cardinal unknowingly purchased and received over 10,000 units of counterfeit Procrit. These counterfeits were bought both by a business unit that was at the time part of Cardinal, and also by the Bindley Trading Company, which became part of Cardinal in a subsequent acquisition. Cardinal, still unaware that the product was counterfeit, sold some of this counterfeit Procrit to its customers. When alerted to the problem in May 2002, Cardinal took remedial steps including cooperation with the FDA in a voluntary recall of the product, and instituting a compliance program to screen and qualify distributors from whom it would purchase product.

9. At times, Cardinal purchased from sources despite indications that the vendors may have been unsuitable. For example, in January 2004, one employee examined the pedigrees that Cardinal was receiving, and noted suspicious sources in the chain of custody – in his words – firms “which could be bad.” The employee asked that a plan be put together to review those entities. A Cardinal compliance employee indicated that he had already verified that those entities were licensed as wholesalers. That

verification was one appropriate step but insufficient. It does not appear that there was any further response to the request for review, nor that the suspect vendors were excluded. The Investigation has shown that some of the entities the employee identified were, as he suspected, engaging in diversion. Cardinal subsequently discontinued its business relationships with these entities.

10. In March 2004, Cardinal realized that it possessed an anabolic steroid product that customers might perceive as high-risk, although in fact there was no specific evidence of any product integrity issues. It sought to avoid such customer concerns by transferring this product from its trading company, which was known for buying from ASVs, to its “divisions,” which customers perceived as selling pharmaceuticals purchased from manufacturers. A Cardinal employee sent an e-mail to the head of the Trading Company, noting a substantial inventory in “an anabolic steroid that is on the restricted list due to potential counterfeit. There is plenty of room to pass our inventory to the divisions. What are your thoughts on moving this product to the divisions?” The reply e-mail instructed simply: “Go ahead and move it.”

11. Cardinal repeatedly sold pharmaceuticals to customers that it knew or should have known were diverting pharmaceuticals. Prior to March 2005, Cardinal made numerous sales of pharmaceuticals to a Nevada company which purported to be a “closed-door” pharmacy that served only nursing homes. In a routine pattern, the Nevada company placed two orders at the same time. One was for products likely to be needed by its stated patient population of nursing home residents, typically in quantities of ones or twos, as would be expected for its needs. The other was for much higher quantities and included products unlikely to be needed by the nursing home residents. Despite this pattern, Cardinal continued to fill the company’s dual orders as described above. Investigation has shown that the company dispensed the products on the small-quantity orders to nursing home residents, and it transferred the products on the large-quantity orders to an affiliated wholesaler for resale on the Secondary Market. In March 2005, Cardinal discontinued doing business with this purported closed-door pharmacy.

12. Similarly, starting in January 2003, Cardinal was alerted that its customers in the Carrington network of closed-door pharmacies were diverting drugs. One warning

came from a Cardinal sales representative who reported visiting the Carrington pharmacies and finding the doors locked, an “Administrative Assistant” on site but no pharmacist, about thirty large boxes awaiting pickup by UPS and delivery to a wholesaler in Kentucky, and purchase orders from a Florida wholesaler with directions to ship to the Kentucky wholesaler. One of the Administrative Assistants explained in detail the process by which the closed-door pharmacy received drugs and sold them to the wholesalers. Cardinal took steps to determine whether the Carrington pharmacies were engaged in diversion, but continued its sales, though at a reduced level, until September 2003. The steps taken by Cardinal, such as seeking assurances from Carrington executives and accepting those assurances, were, in light of other evidence known to Cardinal, inadequate. In December 2003, Cardinal finally severed its business relationship with Carrington after learning from law enforcement that Carrington was under criminal investigation. Cardinal ultimately provided assistance in that investigation and helped law enforcement secure criminal convictions of Carrington personnel.

13. Cardinal also sold pharmaceuticals to wholesalers who were at the same time on Cardinal’s excluded vendor list – in other words, wholesalers that Cardinal itself deemed sufficiently high-risk that it adopted the policy of never buying product that had passed through their hands. The Trading Company president noted as to one wholesaler in June 2003 that “several things that have happened in the past are making us feel we need to very closely examine our buying” from the wholesaler, while simultaneously noting that “we are fine” with selling to that same wholesaler. In another example from December 2003, the president reported that “we now have been asked by compliance” to add a certain wholesaler to the excluded vendor list, but “We can still sell to them.”

14. Cardinal made “third party” returns to manufacturers on behalf of other wholesalers regardless of where the wholesaler had purchased the product. As a former Cardinal employee testified: “[I]t wasn’t worth our while to research whether we had [originally] sold it to the alternate source or to this third party or not.” Such practices can support the Diversion Market by giving unscrupulous customers an incentive to divert

drugs and then “return” them for full credit. In 2005, Cardinal adopted a policy eliminating third-party wholesaler returns.

15. Since the initiation of the OAG’s investigation, Cardinal has initiated a number of voluntary reforms. In the spring of 2005, Cardinal hired a Chief Ethics and Compliance Officer to further advance ethics and compliance efforts, and he has hired additional staff.

16. In the summer of 2005, Cardinal closed down its Pharmaceutical Trading Company. In December 2005, Cardinal stopped purchasing prescription pharmaceuticals on the Secondary Market for general distribution.

17. In February 2006, Cardinal promulgated an Anti-Diversion Compliance Policy, an Anti-Diversion Compliance Manual, and developed an Anti-Diversion Training Program. Cardinal also created the position of Anti-Diversion Compliance Coordinator. Since promulgating the Anti-Diversion Policy, over 400 employees have been trained, over 65 investigations have been launched, and over 30 accounts have been closed for suspected diversion.

18. In August 2006, Cardinal issued a revision of the employee code of conduct that addressed the diversion of prescription pharmaceuticals. The Chief Ethics and Compliance Officer has responsibility for reviewing anti-diversion investigative reports and, in conjunction with senior management, approving any corrective action.

### **PURPOSE OF THIS ASSURANCE**

19. The State of New York is committed to a policy of ensuring the integrity of the pharmaceutical distribution chain. It is a central goal of that policy to prevent the introduction of any pharmaceuticals that are counterfeit, adulterated, misbranded, improperly stored or shipped, or otherwise unreliable. It is the OAG’s aim, in pursuing the Investigation and signing this Assurance, to help implement this state policy.

20. Cardinal has cooperated, and is continuing to cooperate, with the Investigation. It has been responsive in producing documents, information and witnesses

as requested. Moreover, Cardinal has worked over an extended period, both on its own and in conjunction with the OAG, to devise and implement innovative reforms to address the concerns raised by the Investigation.

21. Cardinal has already voluntarily undertaken and implemented a number of business reforms governing its conduct with respect to matters examined as part of the Investigation, some of which are described above. To the extent required by this Assurance, Cardinal will maintain those reforms. Cardinal will also adopt and implement such further reforms as are required by this Assurance.

22. Cardinal is willing to enter into this Assurance without admitting or denying the OAG's findings. Neither this Assurance, nor any acts performed or documents executed in furtherance of this Assurance, may be used as an admission of such findings.

23. The OAG finds the relief and agreements contained in this Assurance appropriate and in the public interest. The OAG is willing to accept this Assurance pursuant to Executive Law §63(15) in lieu of commencing a statutory proceeding with respect to Cardinal, and to discontinue its Investigation with respect to Cardinal.

24. This Assurance is entered into solely for the purpose of resolving issues raised by the Investigation with respect to Cardinal, and is not intended to be used for any other purpose.

### **RELIEF**

WHEREAS, the parties both believe that the obligations imposed by this Assurance are prudent and appropriate,

IT IS HEREBY UNDERSTOOD AND AGREED by and between the parties that Cardinal shall provide prospective and monetary relief as follows:

## **Business Reforms**

25. Cardinal agrees to comply with reforms with respect to its prescription pharmaceutical wholesale distribution business in the United States that, at a minimum, will contain the following elements.

26. Cardinal will ensure that it complies with this Agreement; with the Wholesaler Safe Product Practices in Appendix B; with the reforms previously adopted voluntarily as described above; and with all governing federal, state, and local laws and regulations.

27. Cardinal will have a Chief Ethics and Compliance Officer responsible for ensuring that Cardinal complies with its obligations under this Assurance. The Chief Ethics and Compliance Officer shall:

- a. Have direct reporting lines to the CEO and to the Audit Committee or similar oversight committee of the Board of Directors;
- b. Have available staffing resources that are sufficient both in quantity and variety of skill sets; and
- c. Report in writing, at least once every six months, to the relevant oversight committee of the Board of Directors as to his or her activities with respect to Cardinal's compliance efforts under this Assurance, including actual or suspected issues, steps taken to investigate and resolve issues, and any recommendations for changes in corporate practices.

28. Buy-side reforms. Cardinal will not purchase any prescription pharmaceutical from any source other than the Manufacturer of such pharmaceutical unless such purchase is within one of the following four exceptions.

- a. Cardinal may purchase prescription pharmaceuticals from a source other than the Manufacturer when directed to do so by an agency of the United States government that is entitled by contract to make such direction, provided that Cardinal distributes such pharmaceuticals only to that agency.



- b. Cardinal may purchase prescription pharmaceuticals from a Group Buying Cooperative solely for sale to members of such Cooperative and in accordance with paragraph 30(a) below.
- c. When a Manufacturer sells or distributes prescription pharmaceuticals exclusively through distributors other than Cardinal, then Cardinal may purchase such pharmaceuticals from an Authorized Distributor of that Manufacturer in accordance with paragraph 1 of the Wholesaler Safe Product Practices in Appendix B.
- d. Cardinal may purchase prescription pharmaceuticals from a source other than the Manufacturer when required by emergency medical needs reflected in any federal, state, or local government official's declaration, request, or statement, or upon specific request from a Final Dispenser to treat a patient's emergency medical condition.

29. Sell-side reforms. Starting 60 days after the Effective Date of this Assurance, Cardinal will not sell prescription pharmaceuticals to any customer that is not a Final Dispenser unless such sale is within one of the following three exceptions:

- a. Cardinal may sell prescription pharmaceuticals to units of federal, state, or local government, for use by such governmental units, including medical facilities owned by governmental or quasi-governmental agencies, instrumentalities, or authorities, or for intragovernmental transfer for such use.
- b. Cardinal may sell pharmaceuticals to a Wholesaler when required by emergency medical needs reflected in any federal, state, or local government official's declaration, request, or statement, or upon specific request from a Final Dispenser to treat a patient's emergency medical condition. Cardinal may make de minimis sales to a Wholesaler in the event of a manufacturer-recognized product shortage to satisfy legitimate Final Dispensers' needs.

- c. Cardinal may sell prescription pharmaceuticals to a Wholesaler that has executed a certification, still in force, of its compliance with Wholesaler Safe Product Practices in accordance with Appendix C. Cardinal will pass appropriate pedigrees or pedigree information to all such Wholesalers when and as required by any federal or state law.
30. Requirements applicable to above buy-side and sell-side business reforms.
- a. Cardinal will adopt procedures to ensure that all sales from a Group Buying Cooperative to Cardinal are limited to prescription pharmaceuticals that the Cooperative has purchased directly from the Manufacturer. These procedures will include annual site visits to all Cooperative warehouses from which Cardinal purchases, and random audit of the Cooperative's purchase orders for prescription pharmaceuticals sold to Cardinal. Cardinal will distribute such prescription pharmaceuticals only to members of that Cooperative, and to that end will maintain processes for keeping prescription pharmaceuticals purchased from a Cooperative separate from prescription pharmaceuticals intended for general distribution.
  - b. If Cardinal buys or sells prescription pharmaceuticals on the basis of emergency medical needs and in transactions that would otherwise be prohibited by paragraph 28 or 29 above, it shall report such circumstances to its Chief Ethics and Compliance Officer, and also to the OAG in one report four months after the Effective Date of this Assurance, and subsequently, in reports to accompany the audit reports described in paragraph 32 below. Reports under this paragraph shall include details of the nature of the medical emergency, the transactions that would otherwise have been prohibited by paragraph 28 or 29, and the reasons that such emergency necessitated such transactions.
31. Mechanisms to enforce sell-side reforms. Mechanisms to enforce sell-side reforms shall include, at a minimum:

- a. Employees. Cardinal will:
- i. Maintain an employee code of conduct focused on developing a culture of compliance that fosters integrity and responsibility, including a corporate commitment to diligent and effective prevention and detection of the diversion of prescription pharmaceuticals and other practices that could impair the integrity of the pharmaceutical distribution chain. Policies and procedures issued pursuant to the code of conduct will address diversion of prescription pharmaceuticals sold to Closed-Door Pharmacies at contract pricing, as well as other forms of diversion. The code of conduct will make clear that any violations of policies and procedures issued pursuant to the code will subject the employee to discipline, up to and including termination.
  - ii. Maintain a comprehensive compliance manual addressing means to prevent and detect diversion and assure the safety and integrity of prescription pharmaceuticals, including “know your customer” provisions as described in paragraph 31(b)(i). All appropriate employees, including all those who engage in, supervise, or oversee the selling of prescription pharmaceuticals, must annually certify that they have received the compliance manual, read it, and have abided by and will abide by its terms.
  - iii. Annually train all employees who engage in, supervise, or oversee the selling of prescription pharmaceuticals about indicia of diversion. Such training shall be tailored to employees’ different roles and functions.
  - iv. Maintain means for employees to report suspected instances of diversion to the compliance department, including means for anonymous reporting; publicize such reporting channels to all

employees; and mandate employee reporting of suspicious transactions.

- v. Terminate (or when appropriate, discipline) employees who fail to adhere to the promulgated procedures or standards, or who violate the law or this Assurance.

b. Customers. Cardinal will:

- i. Create firmwide “know your customer” mechanisms to detect customers who are reselling prescription pharmaceuticals into the Secondary Market. Such mechanisms shall, at a minimum, require that:

1. Cardinal will require from new Closed-Door Pharmacy customers, and from existing Closed-Door Pharmacy customers no later than the first annual inspection, data such as the basis for claiming contract eligibility, the GPOs of which the pharmacy is a member if applicable, affiliated retail pharmacies or wholesalers, other names under which it has operated, patient and bed count information, expected purchases, and, when possible, the previous three to 12 month history of prescription pharmaceutical purchases.
2. Cardinal will obtain from new Wholesaler customers, and from existing Wholesaler customers no later than the first annual inspection, information such as any affiliated pharmacies or wholesalers, other names under which the Wholesaler has operated, general information about its customers and expected purchases, and, when possible, the previous three to 12 month history of prescription pharmaceutical purchases.
3. Cardinal will exercise due diligence to determine that each of its Chain Pharmacy Warehouse customers supplies

prescription pharmaceuticals only to affiliated retail pharmacies and/or individuals with prescriptions. Such due diligence shall include, at a minimum, obtaining usage information from any new Chain Pharmacy Warehouse customer; monitoring purchases by existing Chain Pharmacy Warehouse customers; and obtaining information about the business of such customers from publicly available sources or commercially available third-party sources.

- ii. Require that Closed-Door Pharmacy customers sign a contract-pricing declaration certifying that prescription pharmaceuticals purchased at contract pricing will be dispensed only to patients in such pharmacy's intended populations, and will not be sold or transferred to any other entities.
- iii. Require certifications by other customers as follows:
  1. Each customer, except those within the exceptions to paragraph 29 above and Chain Pharmacy Warehouses, shall certify to Cardinal that it is a Final Dispenser as defined in Appendix A, and that it does not and will not redistribute prescription pharmaceuticals purchased from Cardinal into the Secondary Market. Cardinal may comply with this requirement by adding such certifications with reasonable promptness to electronic ordering interfaces and paper documents relating to the purchase of prescription pharmaceutical products on a going-forward basis, including customer agreements, credit applications, and purchase order documents.
  2. Wholesalers purchasing prescription pharmaceuticals from Cardinal pursuant to paragraph 29(c) above shall agree to

the Wholesaler Safe Product Practices set forth in Appendix B, make certification of their compliance with those Practices in the form of Appendix C, and agree to a right-to-audit clause in Cardinal's favor that is sufficient for Cardinal to verify the accuracy of the certification, within 60 days of the Effective Date of this Assurance.

- iv. Create and execute a customer audit program sufficient to verify the accuracy of certifications by its Wholesaler customers, and by other customers when Cardinal obtains information calling such certifications into question.
  - v. Terminate (or when appropriate, sanction) customers that are redistributing pharmaceuticals into the Secondary Market, are noncompliant with their required certifications, or as to whom Cardinal obtains information indicative of unlawful activity.
- c. Ongoing data analysis. Cardinal will gather, monitor, and analyze sales data to detect instances of possible diversion of prescription pharmaceuticals. Cardinal will develop this monitoring program in a way that effectively utilizes the range of appropriate information including sales volume, volume changes over time or other significant changes in purchasing patterns, purchases of frequently diverted products, consistency with the customers' business (including, in the case of Closed-Door Pharmacies, comparison between drug sale profiles and expected patient profiles), and any other available relevant information.

32. External Review. Within 60 days of the Effective Date of this Assurance, Cardinal shall retain, at its own expense, an auditor. The auditor retained shall have been previously provided with a copy of this Assurance. The auditor shall conduct annual agreed-upon procedures tests, including tests to assess Cardinal's compliance with the procedures outlined in this Assurance, and shall create a report summarizing the results of those tests. The agreed-upon procedures tests shall include all those to which Cardinal

and the OAG have separately agreed. The OAG may at any time request the inclusion of additional agreed-upon procedure tests in future reports, and Cardinal will not unreasonably withhold approval of such requests. The audit reports shall be issued by January 1, 2008, January 1, 2009, and January 1, 2010, and will be provided to Cardinal and to the OAG.

33. Term. Cardinal will adhere to the business reforms set forth above at least until January 1, 2010. If the OAG, in the course of its investigation into Secondary Market trading of prescription pharmaceuticals, obtains a court order against, or settlement agreement with, any other national full-line distributor of such pharmaceuticals, then the OAG shall provide Cardinal with a copy of such order or agreement. If such order or agreement includes any terms more permissive than those contained in this Assurance, then Cardinal may, at its option, provide notice to the OAG that it will invoke the benefit of those more permissive terms, rather than the corresponding terms in this Assurance, and this Assurance shall be deemed amended accordingly.

### **Monetary Relief**

34. Within thirty days after the Effective Date of this Assurance and in a manner directed by the OAG, Cardinal will pay three million dollars to the State of New York, one million dollars to the OAG to cover costs of investigation pursuant to Executive Law §63(15), and seven million dollars to Health Research, Inc., a New York not-for-profit corporation affiliated with the New York State Department of Health and the Roswell Park Cancer Institute, that assists those entities through financial support and technology transfers.

### **COOPERATION WITH THE ATTORNEY GENERAL**

35. Cardinal shall fully and promptly cooperate with the OAG with respect to the OAG's investigation of any other person, corporation or entity, not excluding

Cardinal's current and former employees, officers, directors, or agents, concerning the pharmaceutical wholesaling industry, and any related proceedings or actions.

36. Cardinal shall fully and promptly cooperate with the OAG with respect to the OAG's efforts to verify the extent to which Cardinal has complied with this Assurance.

37. Cardinal shall use its best efforts to ensure that all its employees, officers, directors, and agents also fully and promptly cooperate with the OAG in the respects set forth in paragraphs 35 and 36 above.

38. Cooperation as required by the above paragraphs shall not require service of subpoenas, and shall include without limitation: (a) voluntarily producing any information and all documents or other tangible evidence reasonably requested by the OAG, and any compilations or summaries of information or data that the OAG reasonably requests be prepared; (b) attending any meetings or proceedings as requested by the OAG; (c) fully, fairly, and truthfully answering any and all inquiries by the OAG; and (d) in the event any document is withheld or redacted on grounds of privilege or work-product or other legal doctrine, providing a comprehensive and detailed privilege schedule, with the understanding that the OAG may challenge such claim in any forum of its choice.

39. Cardinal shall maintain custody of, or make arrangements to have maintained, all documents and records of Cardinal related to this matter for a period of not less than six years.

40. Cardinal shall not jeopardize the safety of any investigator or the confidentiality of any aspect of the OAG's Investigation, including sharing or disclosing evidence, documents, or other information with others during the course of the Investigation, without the consent of the OAG. Nothing herein shall prevent Cardinal from providing such evidence to other regulators, or as otherwise required by law.



## **GENERAL PROVISIONS**

41. Terms in this Assurance are to be interpreted in accordance with the Definitions in Appendix A.

42. Cardinal shall comply fully with the terms of this Assurance. If Cardinal violates the terms of any paragraph of this Assurance in any material respect, as determined solely by the OAG: (a) the OAG may pursue any action, criminal or civil, against any entity for any crime committed, as authorized by law, without limitation; and (b) as to any criminal prosecution brought by the OAG for violation of law committed within six years prior to the date of this Assurance or for any violation committed on or after the date of this Assurance, Cardinal shall waive any claim that such prosecution is barred by the statute of limitations or speedy trial or arraignment requirements or is otherwise time-barred.

43. If Cardinal fully complies with this Assurance, the OAG will not initiate any case against Cardinal related to the matters uncovered to date within the subject matter and theory of this Assurance and Investigation. That subject matter and theory, as described more fully above, is that certain practices, including general purchases from, general sales to, and returns from the Secondary Market provide opportunities for counterfeiters and price-diverters to introduce counterfeit, adulterated, mishandled, mislabeled, or otherwise unreliable prescription pharmaceuticals into the mainstream distribution network and to obtain benefit from such activities.

44. This Assurance is not intended to interfere with Cardinal's registration, licensure, or eligibility to do business consistent with the terms of this Assurance, in New York or in any other jurisdiction. Nothing in this Assurance shall relieve Cardinal of any obligations imposed by any applicable law or regulations of New York or any other jurisdiction.

45. Other than as provided herein, the acceptance of this Assurance shall not be deemed approval by the OAG of any of Cardinal's practices or procedures, and Cardinal shall make no representation to the contrary.

46. This Assurance shall not confer any rights upon any persons or entities other than the OAG and Cardinal.

47. Cardinal agrees not to take any action or to make or permit to be made any public statement denying, directly or indirectly, any of the OAG's findings in this Assurance or tending to create the impression that the findings are without factual basis. Nothing in this paragraph affects Cardinal's (a) testimonial obligations or (b) right to take legal or factual positions in defense of litigation or in defense of other legal proceedings in which the OAG is not a party.

48. The OAG may make such application as appropriate to enforce or interpret the provisions of this Assurance, or in the alternative, maintain any action, either civil or criminal, for such other and further relief as the OAG may determine is proper and necessary for the enforcement of this Assurance. Evidence of violation of this Assurance shall constitute prima facie proof of violation of the applicable law in any civil action or proceeding thereafter commenced by the OAG. Should it be determined that Cardinal has breached or otherwise violated this Assurance, Cardinal shall pay to the OAG the costs of such determination and of enforcing this Assurance, including, without limitation, legal fees, expenses, and costs.

49. If compliance with any aspect of this Assurance proves impracticable or unwarranted in light of changed circumstances (including an inconsistent court order or the imposition of inconsistent state or federal regulatory requirements), Cardinal reserves the right to request that the parties modify the Assurance accordingly. The OAG agrees to consider, in good faith, any written submissions or oral presentations requesting such a modification, and in the case of inconsistent legal obligations, its consent to such requests shall not be unreasonably withheld.

50. All notices, reports, requests, and other communications pursuant to this Assurance shall be in writing. Facsimile transmission or delivery to the addresses set forth below shall suffice unless a party provides otherwise by designating, in a writing to the other party, another person authorized to receive service by facsimile transmission. Such communications from the OAG to Cardinal may be directed to:

Cardinal Health Inc.  
Attn: Ivan K. Fong  
7000 Cardinal Place  
Dublin, Ohio 43017  
Fax: (614) 752-7325

Wachtell, Lipton, Rosen & Katz  
Attn: John F. Savarese  
51 West 52nd Street  
New York, New York 10019-6150  
Fax: (212) 403-2000

and from Cardinal to the OAG may be directed to:

Office of the Attorney General  
Medicaid Fraud Control Unit  
Attn: Albany Regional Director  
The Capitol  
Albany, New York 12224  
Fax: (518) 474-4951

51. This Assurance shall be governed by the laws of the State of New York without regard to conflict of laws principles.
52. In the event that one or more of the provisions contained in this Assurance shall for any reason be held to be invalid, illegal, or unenforceable in any respect, no party shall assert that such circumstance affects any other provision of this Assurance.
53. This Assurance constitutes the entire agreement between the parties with respect to its subject matter, and supersedes any other written or oral agreements or understandings between them with respect to that subject matter. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Assurance has been made or relied upon by any party to this Assurance.
54. This Assurance may not be amended except by an instrument in writing signed on behalf of both parties to this Assurance.
55. This Assurance shall be binding upon and extend to Cardinal, all affiliated companies, their employees, officers, directors, and any other entity or person whose acts, practices, or policies are controlled by Cardinal.
56. This Assurance may be executed in counterparts.

57. The Effective Date of this Assurance shall be the latest date of the four signatures below.


IN WITNESS WHEREOF, this Assurance is executed by the parties hereto on the dates indicated below.

ELIOT SPITZER  
Attorney General of the State of New York  
120 Broadway  
New York, New York

By: \_\_\_\_\_ Date: December \_\_, 2006  
William J. Comiskey  
Deputy Attorney General  
Medicaid Fraud Control Unit

\_\_\_\_\_ Date: December \_\_, 2006  
Joseph R. Baker, III  
Assistant Attorney General in Charge  
Health Care Bureau

CARDINAL HEALTH INC.  
7000 Cardinal Place  
Dublin, Ohio

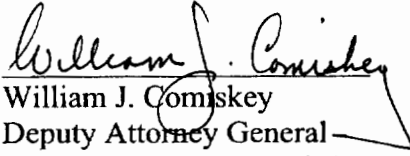
By:  \_\_\_\_\_ Date: December 24, 2006  
Ivan K. Fong  
~~Executive Vice President &~~  
Chief Legal Officer

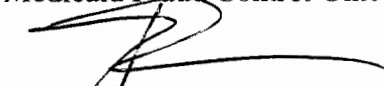
\_\_\_\_\_ Date: December \_\_, 2006  
John F. Savarese  
Wachtell, Lipton, Rosen & Katz  
Attorneys for Cardinal Health, Inc.

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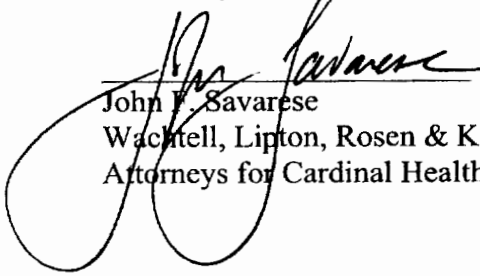
ELIOT SPITZER  
Attorney General of the State of New York  
120 Broadway  
New York, New York

By:  Date: December 26, 2006  
William J. Comiskey  
Deputy Attorney General  
Medicaid Fraud Control Unit

 Date: December 26, 2006  
Joseph E. Baker, III  
Assistant Attorney General in Charge  
Health Care Bureau

CARDINAL HEALTH INC.  
7000 Cardinal Place  
Dublin, Ohio

By: \_\_\_\_\_ Date: December 26, 2006  
Ivan K. Fong  
Executive Vice President &  
Chief Legal Officer

 Date: December 26, 2006  
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## APPENDIX A

1. “Authorized distributor” means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer’s products, as established by a written agreement under which the distributor is authorized to distribute the manufacturer’s products for a period of time or for a number of shipments.

2. “Chain Pharmacy Warehouse” means a warehouse operation that is owned or controlled by a group of affiliated pharmacies, or their parent companies, that sells exclusively to members of such group of retail pharmacies, and that does not sell or transfer prescription pharmaceuticals to any entity other than retail pharmacies within that group or people with prescriptions.

3. “Closed-Door Pharmacy” means any pharmacy other than a retail pharmacy, and any pharmacy that is limited by contract or otherwise from reselling, in the retail market, prescription pharmaceuticals it has purchased from Cardinal. Closed-door pharmacies thus include a pharmacy that purchases pharmaceuticals under a Manufacturer’s contract in order to service non-retail customers such as nursing homes, hospitals, home care, or long-term care facilities.

4. “Final Dispenser” means (i) entities and individuals, such as pharmacies, hospitals, physicians, and other authorized prescribers, whose practice with respect to prescription pharmaceuticals is devoted to selling, dispensing, or administering such pharmaceuticals to individual patients or patients’ agents, (ii) Chain Pharmacy Warehouses that exclusively supply affiliated retail pharmacies and/or individuals with prescriptions, and (iii) entities that use prescription pharmaceuticals for research and development or clinical trials. A Final Dispenser may make other de minimis transfers to satisfy legitimate needs of another Final Dispenser, but no transfer will be considered de minimis if it violates any terms of licensure or registration for Final Dispensers in the state in question.

5. “Group Buying Cooperative” means an organization of retail pharmacies not under common ownership and control that negotiates discounted pricing with Manufacturers for sales to the Cooperative and/or its members. The pharmacies that are

part of a Group Buying Cooperative are considered members of that cooperative for purposes of this Assurance whether or not they participate in its profits.

6. “HDMA Recommended Guidelines” means the Healthcare Distribution Management Association’s “Recommended Guidelines for Pharmaceutical Distribution Integrity” dated November 6, 2003, and available at [www.healthcaredistribution.org](http://www.healthcaredistribution.org), except that the guidelines shall be deemed to require vendor inspections on an annual basis.

7. “Manufacturer” means an establishment authorized to engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, as reflected in a registration with the United States Food and Drug Administration, or an establishment that submits listing information directly to the Food and Drug Administration and obtains a Labeler Code.

8. “PDMA” means the Prescription Drug Marketing Act, Public Law No. 100-293, 102 Stat. 95 (Apr. 22, 1988), as subsequently amended and codified.

9. “Purchase” of prescription pharmaceuticals by a Wholesaler, for purposes of paragraph 28, does not include bona fide arrangements in which a customer of the Wholesaler transfers title of prescription pharmaceuticals to such Wholesaler, whether or not the pharmaceuticals are transferred to the actual possession of the Wholesaler, if (a) the arrangement is one designed to allow the Wholesaler to provide warehousing or financing services to the customer; and (b) there are procedures ensuring that such pharmaceuticals are not distributed to any customer other than the one that transferred title to the Wholesaler. A prescription pharmaceutical is “sold” each time it is the subject of any sale or transfer, except that (a) a bona fide intracompany transfer does not constitute a sale, and (b) when one party sells the pharmaceutical to a second party, and the second then returns it to the first in full compliance with federal and state law, then neither such return, nor the prior transfer from the first to the second party, shall be considered a sale.

10. “Retail pharmacy” means a pharmacy that does not limit the classes of persons to which it dispenses or sells pharmaceuticals, but rather is open to members of the general public.

11. “Secondary Market” means the market for purchases, sales, or trades between Wholesalers.

12. “Wholesaler” means an entity that engages in the business of distributing prescription drugs to persons other than those with prescriptions or their agents, but does not include Manufacturers or Final Dispensers.



## APPENDIX B

### Wholesaler Safe Product Practices

To help thwart the counterfeiting and adulteration of pharmaceutical products and to suppress the illicit traffic in such products, [name of company] adopts the following practices:

#### 1. Distribution Chain

[Name of company] will not trade any prescription pharmaceutical product that is sold more than three times in the supply chain from the Manufacturer to the Final Dispenser.

- a. Whenever [name of company] purchases any prescription pharmaceutical product from an entity other than a Manufacturer, it will:
  - i. purchase only from an Authorized Distributor of that Manufacturer or a wholesaler that has adopted these Wholesaler Safe Product Practices,
  - ii. if purchasing from an Authorized Distributor that has not adopted these Wholesaler Safe Product Practices, obtain a written certification from that Authorized Distributor that said product was purchased directly from the Manufacturer, and
  - iii. sell that product only to a Final Dispenser.
- b. If [name of company] purchases a prescription pharmaceutical product from a Manufacturer, it will sell that product only to a Final Dispenser or to a wholesaler that has adopted these Wholesaler Safe Product Practices and within the last 12 months certified its compliance as required by paragraph 3.
- c. [Name of company] will provide purchasers with pedigrees or pedigree information when and as required by any federal or state law.

#### 2. Compliance

- a. [Name of company] will have compliance measures, subject to audit by its trading partners or third parties, designed to detect and prevent (i) the purchase or sale of any prescription pharmaceutical that will be sold more than three times in the supply chain from the Manufacturer to the Final Dispenser; (ii) diversion of prescription pharmaceuticals, including sales by Closed-Door Pharmacies into the Secondary Market; and (iii) other practices impairing the integrity of the pharmaceutical distribution chain. The compliance measures shall include mechanisms for punishing or terminating employees and excluding trading partners who engage in such practices.
- b. [Name of company] will comply with the PDMA, any regulations in force thereunder, and any other applicable federal and state law governing wholesaling of prescription pharmaceuticals.

- c. [Name of company] will comply with HDMA Recommended Guidelines.

### **3. Certification**

- a. Upon adoption of these Wholesaler Safe Product Practices and at the end of each year thereafter, [name of company] will designate one of its officers who will certify the company's compliance with such Practices in the form annexed.
- b. Upon request, [name of company] will provide the certification, via United States mail, to any federal, state or local governmental entity for retention in that entity's files, and for any use as such entity sees fit.

### **4. Verification**

[Name of company] will include an audit of its compliance provisions under paragraph 2 above in its annual audit plan.

### **5. Exceptions**

- a. If emergency medical needs require in particular instances that a prescription pharmaceutical be purchased from or sold to an entity other than as provided above, such purchase or sale does not violate these Wholesaler Safe Product Practices. Nor does it violate these Wholesaler Safe Product Practices to make de minimis sales to a wholesaler in the event of a manufacturer-recognized product shortage to satisfy legitimate Final Dispensers' needs.
- b. If an agency of the United States government directs that particular prescription pharmaceuticals be purchased from an entity other than as provided above, then such purchase, for distribution only to such agency, does not violate these Wholesaler Safe Product Practices.
- c. Sale of prescription pharmaceutical products to units of federal, state, or local government, for use by such governmental units, including medical facilities owned by governmental or quasi-governmental agencies, instrumentalities, or authorities, or for intragovernmental transfer for such use, does not violate these Wholesaler Safe Product Practices.

### **6. Definitions**

The following definitions apply to terms used in these Wholesaler Safe Product Practices:

- a. "Manufacturer" means an establishment authorized to engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, as reflected in a registration with the United States Food and Drug Administration, or an establishment that submits listing information directly to the Food and Drug Administration and obtains a Labeler Code.
- b. "Authorized distributor" means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, as

established by a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments.

- c. "Final Dispenser" means (i) entities and individuals, such as retail pharmacies, hospitals, physicians, and other authorized prescribers, whose practice with respect to prescription pharmaceuticals is devoted to dispensing or administering such pharmaceuticals to individual patients or patients' agents; (ii) chain pharmacy warehouses that exclusively supply retail pharmacies in their chains and/or individual patients with prescriptions; and (iii) entities that use prescription pharmaceuticals for research and development or clinical trials. Accordingly, an entity is not a Final Dispenser if its business includes the sale of prescription pharmaceuticals to wholesalers.
- d. A prescription pharmaceutical is "sold" each time it is the subject of any sale or transfer, except for transactions in which the purchaser or transferee, rather than subsequently dispensing or reselling the pharmaceutical, subsequently returns it in full compliance with federal and state law.
- e. "PDMA" means the Prescription Drug Marketing Act, Public Law No. 100-293, 102 Stat. 95 (Apr. 22, 1988), as subsequently amended and codified.
- f. "HDMA Recommended Guidelines" means the Healthcare Distribution Management Association's "Recommended Guidelines for Pharmaceutical Distribution Integrity" dated November 6, 2003, and available at [www.healthcaredistribution.org](http://www.healthcaredistribution.org), except that the guidelines shall be deemed to require vendor inspections on an annual basis.

APPENDIX C

Certification of Compliance with Wholesaler Safe Product Practices

*Signature of this certification constitutes a representation that your Company complies with the annexed Wholesaler Safe Product Practices, as set forth more fully in the next paragraph. Any violation of those practices will constitute cause for immediate termination of your accounts with any vendors or customers.*

I hereby certify that (i) the [name of company] has adopted these Wholesaler Safe Product Practices and fully complied with them during the past 12 calendar months (or since the firm adopted these Wholesaler Safe Product Practices, if that period is shorter); (ii) that [name of company] will continue to comply with the Wholesale Safe Product Practices; (iii) that [name of company] makes this certification to induce entities to sell and/or to purchase prescription pharmaceutical products to and from it; and (iv) that I have made sufficient inquiry to be able to make the certification truthfully and accurately and without material omissions. I understand that any false statements herein may violate federal or state laws and result in liability thereunder.

Your name:

Title:

Company Name:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_