

OFFICE OF THE ATTORNEY GENERAL
OF THE STATE OF NEW YORK

-----X

In the Matter of the

Assurance No. 09-162

Investigation by Andrew Cuomo,
Attorney General of the State of New York,
of O'Connor Hospital,

Respondent.

-----X

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

Pursuant to the provisions of Section 63 of the New York Executive Law, and Sections 5.86 and 6.5 of Volume 9 of the New York Codes, Rules, and Regulations, Andrew Cuomo, Attorney General of the State of New York, caused the Watershed Inspector General, an Assistant Attorney General within the Office of Attorney General ("OAG"), to perform an investigation ("the Investigation") of the pharmaceutical waste management practices of hospitals, nursing homes, and assisted living facilities within the New York City Watershed ("the Watershed").

Respondent O'Connor Hospital, a New York not-for-profit corporation, operates a hospital ("O'Connor" or "the Hospital") located within the Watershed. Respondent has agreed pursuant to this Assurance of Discontinuance ("Assurance") to resolve the part of the Investigation which concerns its management practices for pharmaceutical waste and other wastes by: (1) ceasing all discharges of pharmaceutical wastes into waterways that supply New York City's drinking water system;¹ (2) ensuring that the Hospital's pharmaceutical waste

¹ For purposes of this Assurance, "pharmaceutical" means any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a

management practices, and other waste management practices, comply fully with all New York laws and regulations implementing the federal Resource Conservation and Recovery Act (“RCRA”), 42 U.S.C. § 6901 et seq., and the federal Water Pollution Control Act (“Clean Water Act”), 33 U.S.C. § 1251 et seq., and are protective of the environment and public health, and (3) paying civil penalties for past violations of law and costs incurred by the State in the Investigation.

I. INVESTIGATION AND FINDINGS

Based on the Investigation, the Attorney General has made the following findings:

A. The New York City Watershed

1. The Watershed comprises areas within eight counties north of New York City both east and west of the Hudson River. Within the Watershed, water is collected by streams and reservoirs from precipitation, runoff from rain, melting of snow, and other sources. The water is disinfected, and distributed by a system of tunnels and pipes to over nine million State residents

chemical product, vaccine or allergenic), not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or injury in man or other animals; or any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended to affect the structure or function of the body in man or other animals. In this Assurance, “pharmaceutical” includes, without limitation, capsules, pills or tablets, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded solutions, chemotherapy drugs, vaccines, allergenics, medicinal shampoos, antiseptics and medicinal dermal patches, and any delivery devices with the primary purpose to deliver or dispense a chemical product, vaccine or allergenic. “Pharmaceutical” does not include sharps or other infectious or biohazardous waste, dental amalgams, medical devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated cleaning materials.

“Pharmaceutical waste” means any pharmaceutical that can no longer be used for its intended purpose. Such wastes include, without limitation, pharmaceuticals which are outdated, residue of compounding, discontinued or unused after dispensing, spoiled (e.g., from breakage or spillage), or found in partially used vials, IV bags, or other containers.

who drink the water, including nearly one million people who live outside of New York City. While comprising only 4.2% of the entire land mass of New York, the Watershed encompasses such precious natural resources as the Catskill Park and Mountains, the Great Swamp, and prized wild trout streams including the Esopus Creek and the West Branch of the Croton River.

2. The quality of New York City drinking water is generally good. However, as with all sources of drinking water, New York City water is threatened by numerous human activities which generate pollutants that may potentially impair the water's suitability for consumption and its healthfulness.

3. To safeguard the Watershed, in 1997 federal and state government agencies, New York City, Watershed communities, and environmental groups agreed to protect the Watershed in a "multiple barrier approach" to provide safe drinking water, by purchasing Watershed lands to serve as buffers for pollutant discharges, more strictly regulating human activities that generate pollution, and funding various programs to prevent pollution.² This approach to watershed protection reduces pollution by preventing direct discharges into wetlands, streams, and reservoirs in the first place, and by safeguarding the ecology of these waterbodies so that they can assimilate, and thus neutralize, pollutants that could potentially be introduced into them.

² See New York City Watershed Memorandum of Agreement, dated January 21, 1997; Watershed Management for Potable Water Supply: Assessing the New York City Strategy, National Research Council, National Academy Press (2000), p. 130. In addition to the Memorandum of Agreement, the Watershed is protected by a host of federal and state laws and regulations, such as the federal Safe Drinking Water Act (42 U.S.C. § 300f et seq.), the New York Public Health Law (Article 11), the Clean Water Act, and the New York Water Pollution Control Law (Environmental Conservation Law, Article 17).

B. Environmental Problems Posed by Pharmaceutical Wastes Discharged to Waterways

4. Recently, as a result of ongoing advances in laboratory techniques, scientists have found small concentrations of numerous pharmaceutical wastes in the Nation's waterways.³ including within the New York City Watershed.⁴ The sources of pharmaceuticals in waterways include pharmaceutical manufacturing facilities, hospitals and other healthcare facilities, residences, landfills and other land disposal facilities, and farms, among others. Studies have found that waste streams from hospitals have a particularly high concentration of waste pharmaceuticals.⁵

5. When waste pharmaceuticals are flushed down toilets or sinks, they are conveyed to sewage treatment plants or septic systems which were not designed to treat such wastes or to neutralize their potential adverse effects. While wastewater treatment does provide some

³ See Nicholas D. Kristoff, "Its Time to Learn From Frogs," The New York Times, June 27, 2009, www.nytimes.com/2009/06/28/opinion/28kristof.html?_r=1; "46 Million Affected by Trace Drugs in Drinking Water," Associated Press, September 10, 2008, <http://www.cnn.com/2008/HEALTH/conditions/09/11/pharma.testing.water.ap/index.html>; "Prescription Drugs Found in Drinking Water Across U.S.," Associated Press, March 10, 2008, <http://www.cnn.com/2008/HEALTH/03/10/pharma.water1/index.html>.

⁴ See, e.g., EPA, Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) (August 2008) (hereinafter, "Interim EPA Study"), p. 3-1; Patrick M. Palmer, Lloyd R. Wilson, Patrick O'Keefe, Robert Sheridan, Thomas King, Chia-Yang Chen, "Sources of Pharmaceutical Pollution in the New York City Watershed," Science of the Total Environment 90-102, 2008; D. Koplun, E. Furlong, M. Meyer, M. Thurman, S. Zaugg, L. Barber, "Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance," 36(6) Environ. Sci. Technol. 1202-1211, March 2002.

⁵ Klaus Kummerer, "The Presence of Pharmaceuticals in the Environment Due to Human Use - Present Knowledge and Future Challenges," Journal of Environmental Management 1-13 (2009); Lin, et al., "Pharmaceutical Contamination in Residential, Industrial, and Agricultural Waste Streams: Risks to Aqueous Environments in Taiwan," 74 Chemosphere 131-141 (2008).

removal of pharmaceutical wastes, studies have shown that the effectiveness of such treatment varies widely depending the characteristics of the treatment plant and the particular pharmaceutical wastes; and some pharmaceuticals are not consistently removed from drinking water even with chlorination.⁶

6. Only small concentrations of some pharmaceuticals have been found in Watershed streams and even smaller concentrations of fewer pharmaceuticals have been found in reservoirs. Research concerning potential health impacts to humans who ingest, or are otherwise exposed to, pharmaceutical wastes in water is at a very early stage, and no showing of adverse health impacts to consumers of New York City water or other drinking water sources has been made at this point in time at current concentration levels. However, the results do suggest the need for further research,⁷ as well as the need for reasonable precautions to reduce concentrations of pharmaceuticals in waterbodies in the Watershed and other sources of drinking water.

7. Research concerning potential adverse effects of pharmaceutical wastes on the environment is also at an early stage. Nevertheless, as discussed below, a significant body of scientific literature has already found that discharges of pharmaceutical wastes in the effluent of sewage treatment plants may pose harm to aquatic organisms and thereby imperil the ecology of

⁶ See Interim EPA Study, pp. 6-2 to 6-3; “Sources of Pharmaceutical Pollution in the New York City Watershed,” Science of the Total Environment at 96; J. Gibs, P. Stackelberg, E. Furlong, M. Meyer, S. Zaugg, R. Lipincott, “Persistence of Pharmaceuticals and Other Organic Compounds in Chlorinated Drinking Water as a Function of Time,” 373 Science of the Total Environment 240-49 (2007).

⁷ See Francesco Pomati, “Effects of a Complex Mixture of Therapeutic Drugs at Environmental Levels on Human Embryonic Cells,” 40 Environmental Science and Technology 2442-2447 (2006). This laboratory study concluded that pharmaceuticals inhibited the growth of certain human embryonic cells. Because the study conditions did not replicate likely exposure patterns for consumers of water, it does not demonstrate a health risk.

streams.

8. Some pharmaceutical wastes, such as certain flu vaccines and insulin which contain hazardous preservatives, have long been classified as “hazardous waste,” or – in the case of the widely used blood thinning drug warfarin – as “acutely hazardous waste” under RCRA and New York regulations. See 40 C.F.R. Part 261, Appendix VIII; 6 NYCRR § 371.4(d)(5). Research has shown that other pharmaceutical wastes in concentrations found in discharges into streams from the effluent of sewage treatment plants can cause environmental harm. For example, “endocrine disruptors” are chemicals that may interfere with an organism’s endocrine system and produce adverse developmental, reproductive, neurological, and immune effects.⁸ Some pharmaceuticals are endocrine disruptors, such as forms of estrogen used for birth control or to treat menopause. Studies have shown that these pharmaceuticals cause the feminization of male fish⁹ and can so upset the ability of fish to reproduce as to result in the collapse of fish populations.¹⁰

⁸ “Endocrine Disruptors,” National Institute of Environmental Health Sciences. www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm.

⁹ Colin Richman and Staffan Castensson, “Impact of Waste Pharmaceuticals: An Environmental Hazard or ‘Greenwash,’” 280 The Pharmaceutical Journal 335-342 (2008); Hotchkiss et al., “Fifteen Years after “Wingspread” - Environmental Endocrine Disruptors and Human and Wildlife Health: Where We are Today and Where We Need to Go,” 104 Toxicological Sciences 235-259 (2008); Zeilinger et al., “Effects of Synthetic Gestagens on Fish Reproduction,” 28 (12) Environmental Toxicology and Chemistry (In Press 2009).

¹⁰ See Kidd et. al., “Collapse of a Fish Population After Exposure to a Synthetic Estrogen,” 104 Proceedings of the National Academy of Sciences 8897-8901 (2007), finding that estrogen discharges into an experimental lake caused a collapse of the minnow population. Following that collapse, the abundance and condition of trout, whose diet included minnows, declined. K. H. Mills et. al., “A Whole-Lake Experiment to Assess the Impacts of an Endocrine Disruptor on a Lake Trout Community.” International Charr Symposium, Scotland, 2009 (slide

9. Studies have also found that some common pharmaceuticals, including pain killers, beta-blockers, antidepressants, and antiepileptic drugs pose harm to trout, carp, or other fish at concentrations found in wastewater discharging into streams.¹¹

10. Studies of other pharmaceuticals have not found environmental impacts at the small concentrations in which they are found discharging into streams.¹² However, many of these studies may understate the adverse environmental impacts of pharmaceuticals because they test for “acute” toxicity when exposure to pharmaceuticals in the environment is usually “chronic” or “persistent.”¹³

11. In light of the concerns regarding environmental impacts posed by waste

presentation).

¹¹ Triebkorn *et al.*, “Ultrastructural Effects of Pharmaceuticals (Carbamazepine, Clofibrilic Acid, Metoprolol, Diclofenac) in Rainbow Trout (*Oncorhynchus mykiss*) and Common Carp (*Cyprinus carpio*),” 387 *Analytical and Bioanalytical Chemistry* 1405-1416 (2007); Birgit Hoeger, *et al.*, “Water-borne Diclofenac Affects Kidney and Gill Integrity and Selected Immune Parameters in Brown Trout (*Salmo trutta f. fario*),” 75 *Aquatic Toxicology* 53-64 (2005); D.B. Huggett, *et al.*, “Toxicity of Select Beta Adrenergic Receptor-Blocking Pharmaceuticals (B-Blockers) on Aquatic Organisms,” 43 *Archives of Environmental Contamination and Toxicology* 229-235 (2002) (Beta Blocker reduces number of viable eggs of the Japanese medaka fish); C.M. Foran *et al.*, “Reproductive Assessment of Japanese medaka (*Oryzias latipes*) Following a Four-week Fluoxetine Exposure,” 46 *Archives of Environmental Contamination and Toxicology* 511-517 (2004); M.M. Painter *et al.*, “Antidepressants at Environmentally Relevant Concentrations Affect Predator Avoidance Behavior of Larval Fathead Minnows (*Pimephales promelas*),” 28 (12) *Environmental Toxicology and Chemistry* (In Press 2009).

¹² See, e.g., Fent, *et al.*, “Ecotoxicology of Human Pharmaceuticals,” 76 *Aquatic Toxicology* 122-159 (2006).

¹³ Ankley *et al.*, “Repeating History: Pharmaceuticals in the Environment,” 41 *Environmental Science and Technology* 8211-8217 (2007) (noting that pharmaceuticals “are introduced relatively continually to aquatic systems via wastewater effluents”).

pharmaceuticals raised in scientific studies, and the early stage of this research field, regulators, including EPA and DEC, recommend that common sense precautionary measures be taken to minimize discharges of pharmaceuticals into waterways by halting the flushing of pharmaceutical wastes down toilets and sinks.¹⁴

C. Investigation of O'Connor's Pharmaceutical Waste Management Practices

12. O'Connor is a 23-bed critical access hospital located within the Watershed at 460 Andes Road, Delhi, New York 13753.

13. On January 13, 2009, the Watershed Inspector General ("WIG" or "the WIG Office") within the Office of Attorney General Cuomo, wrote to fifteen hospitals, nursing homes, and assisted living facilities located within the Watershed, including O'Connor, providing notice of the Investigation and requesting information concerning their pharmaceutical waste management practices. A copy of this letter is attached to this Assurance as Exhibit A.

14. The findings set forth in this Assurance do not address whether O'Connor was negligent or engaged in any intentional misconduct and the Hospital does not, by signing it, admit any fault, negligence or intentional misconduct.

15. O'Connor has cooperated with the Investigation by making its management and patient care staff available for interviews, providing relevant documents, and consenting to an inspection of the Hospital. A copy of the WIG Office's inspection report concerning its inspection held on March 6, 2009, is attached to this Assurance as Exhibit B. During the

¹⁴ See "Proper Disposal of Prescription Drugs," Office of National Drug Control Policy 2009, www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf; "Proper Disposal of Household Prescriptions and Over-the-Counter Drugs," New York State Department of Environmental Conservation, <http://www.dec.ny.gov/chemical/45083.html>.

Investigation. O'Connor's management claimed that it did not flush any waste pharmaceuticals down sinks and toilets. However, these assertions were not correct, as contradicted by interviews of some of the nursing staff.

16. O'Connor disposes some waste pharmaceuticals down toilets and sinks, resulting in the discharge of such wastes into waterways within the Watershed. As discussed in detail below, some O'Connor practices concerning the management of pharmaceutical wastes, and other wastes, violate various State regulations, RCRA, and the Clean Water Act.

17. O'Connor generates numerous pharmaceutical wastes. Some pharmaceutical wastes are returned to EXP Pharmaceutical Services Corp. ("EXP") for potential credit, but O'Connor does not consistently receive credit for all its returns. O'Connor therefore sends wastes to EXP for it to dispose of even though EXP is not a RCRA-authorized treatment, storage, or disposal facility. Some pharmaceutical wastes, including injectable wastes (e.g., waste medications in IV bags), capsules, tablets, and controlled substances are flushed down toilets and sinks at the Hospital. Some waste capsules and tablets and/or controlled substances are also disposed of in sharps containers or the municipal trash.

18. Some of the Hospital's pharmaceutical wastes are classified as "hazardous waste" under RCRA and State implementing regulations. Wastes from the following drugs generated by O'Connor are deemed "hazardous" under those laws: warfarin (coumadin), nicotine, and physostigmine salicylate (all classified as acutely hazardous waste), insulin. O'Connor's formulary includes other drugs whose wastes are hazardous under RCRA, which can be generated at the Hospital: nitroglycerin, alcohol, lindane, silver nitrate, silver sulfadizine, propylthiouracil, oxymetazoline, flurbiprofen, acetic acid, trypan blue, chloral hydrate, amyl

nitrate, and aromatic spirits of ammonia. Other pharmaceutical wastes generated by O'Connor, while not classified as "hazardous waste," pose risk of harm to aquatic organisms if such wastes are discharged into waterways. These include, among other drugs, endocrine disruptors such as estrogens, anti-depressants, pain medications, and beta blockers.

19. O'Connor's laboratory and endoscopy departments generate RCRA hazardous wastes as well. The laboratory wastes include stains (chemistry and blood analyzers) which are flushed down drains or are otherwise collected and placed in a sharps container for disposal along with waste solvents. Peracetic acid wastes are generated by the endoscopy unit and are disposed down drains.

20. The Hospital also generates "universal wastes," including used batteries and burned out fluorescent light bulbs. These wastes frequently constitute "hazardous waste" because they contain heavy metals, such as mercury or cadmium, and/or corrosive electrolyte solutions. O'Connor does not have a formal policy for managing or disposing of these wastes. While it states that it recycles some used batteries, it does not recycle alkaline batteries and does not recycle burned out bulbs.

D. O'Connor is In Violation of State Laws and Regulations, RCRA, and the Clean Water Act

1. Statutory and Regulatory Background

21. RCRA regulates the treatment, storage and disposal of solid and hazardous wastes. Under RCRA, states are authorized to administer and enforce their own hazardous waste programs subject to approval of the Administrator of the United States Environmental Protection Agency ("EPA"). 42 U.S.C. §6926(b). EPA has granted such approval to New York State,

enabling DEC to administer the State's hazardous waste program pursuant to Article 27, Title 9, of the New York Environmental Conservation Law, entitled "the Industrial Hazardous Waste Management Act of 1978" ("the Act"). See 74 Fed. Reg. 31380 (July 1, 2009). Pursuant to the Act, DEC has promulgated, at 6 New York Codes Rules and Regulations ("NYCRR") Parts 370-374 and 376, regulations governing the management of hazardous wastes, including hazardous pharmaceutical wastes, in New York State.

22. The Clean Water Act seeks to eliminate discharges of pollutants into the Nation's waters, primarily through implementation of the National Pollutant Discharge Elimination System, a permitting program administered by EPA and the States under Section 402 of that statute. Arkansas v. Oklahoma, 503 U.S. 91, 101 (1992); 33 U.S.C. §§ 1251(a)(1), 1342. As with RCRA, under the Clean Water Act, states may operate their own programs subject to EPA approval. In 1975, EPA approved New York's application for DEC to administer and enforce within New York the State Pollutant Discharge Elimination System ("SPDES"), which DEC implements pursuant to Article 17, Title 8 of the New York Environmental Conservation Law. As required by EPA, the State has promulgated SPDES regulations to comply with federal standards for the "pretreatment" of wastes discharged by facilities to publicly owned wastewater treatment plants to ensure that the waste is properly treated. 6 NYCRR § 750-2.9; 40 U.S.C. §§ 403.4, 403.5, 403.10.

2. Hazardous Waste Generation Violations

23. In violation of 6 NYCRR § 372.2(a)(2), O'Connor fails to make "hazardous waste determinations" to determine which of its pharmaceutical wastes and other wastes are "hazardous" wastes.

24. The Hospital has been, and is, a “generator” of hazardous wastes as defined in 6 NYCRR § 370.2(b)(83).

25. In violation of 6 NYCRR §§ 372.2(a)(1) and 372.2(a)(3)(i), the Hospital has failed to obtain an identification number from EPA and failed to notify DEC that it generates hazardous wastes.

26. In violation of 6 NYCRR § 372.2(c), O’Connor fails to keep records and prepare reports concerning its hazardous waste management activities.

27. In violation of 6 NYCRR §§ 372.2(a)(4), (5), (6), (8), the Hospital fails to package, label, and properly mark hazardous waste placed by O’Connor into containers before such waste is transported away from the facility.

28. In violation of 6 NYCRR §§ 372.2(b)(5) and 372.2(a)(3)(ii), O’Connor sends its hazardous wastes away from the Hospital: (i) using transporters which are not authorized by EPA and DEC to transport such wastes, and (ii) to facilities which are not authorized by EPA and DEC to accept such wastes, such as EXP and recipients of hazardous pharmaceutical in sharps containers.

29. In violation of 6 NYCRR § 372.2(b), the Hospital fails to prepare manifests for hazardous wastes which it places in municipal trash containers and sharps containers or shipments to EXP for transportation away from the facility.

30. In violation of 6 NYCRR § 374-3.2(i), O’Connor fails to send its universal wastes, including some batteries and burned out fluorescent bulbs, to an appropriate destination facility for treatment, disposal, or recycling.

31. In violation of 6 NYCRR § 374-3.2(e), the Hospital fails to properly label and

mark its universal wastes.

32. In violation of 6 NYCRR § 374-3.2(g), O'Connor fails to provide its employees training concerning the proper management of its universal wastes.

3. Hazardous Waste Management Facility Violations

33. The Hospital has been engaged in the "storage" of hazardous wastes within the meaning of ECL § 27-0901(8) and 6 NYCRR § 370.2(b)(183), and therefore has been a "hazardous waste management facility" as defined in 6 NYCRR § 370.2(b)(89).

34. In violation of ECL § 27-0913(1)(a) and 6 NYCRR §§ 373-1.2(a), 373-2.2(c), O'Connor has operated a hazardous waste management facility without obtaining a permit to do so from DEC and an EPA identification number.

35. In violation of 6 NYCRR § 373-2.2(e), O'Connor failed to perform general waste analyses required of hazardous waste management facilities prior to storing hazardous wastes.

36. In violation of 6 NYCRR § 373-2.2(g), the Hospital failed to perform, schedule, and keep records of inspections of its hazardous waste management facility.

37. In violation of 6 NYCRR § 373-2.2(h), O'Connor failed to train its employees to ensure its compliance with State requirements concerning the management of hazardous wastes, and failed to maintain records documenting such training.

38. In violation of 6 NYCRR § 373-2.4, the Hospital has failed to prepare and implement a contingency plan, including measures to prevent and remedy spills, and failed to comply with required emergency procedures.

39. In violation of 6 NYCRR §§ 373-2.9(d) and (e), O'Connor failed to properly manage containers holding hazardous waste by not marking such containers with the words

“Hazardous Waste” and by not conducting weekly inspections of areas where containers are stored.

40. The findings contained in paragraphs 31 through 39 herein apply to O’Connor’s past conduct. In the event that the Hospital establishes its exemption as a conditionally exempt small quantity generator in the future, 6 NYCRR § 371.1(f), entitled “Specified Requirements for Hazardous Waste Generated By Conditionally Exempt Small Quantity Generators,” will apply to its future obligations.

4. Illegal Discharges of Ignitable Hazardous Wastes to a Publicly Owned Treatment Works

41. Pharmaceutical wastes and other wastes flushed down sinks and toilets at the Hospital are discharged to the Delhi wastewater treatment plant, a “publicly owned treatment works” in the Village of Walton.

42. In violation of 6 NYCRR § 750-2.9(b)(1) and 40 CFR § 403.5(b)(1), the Hospital routinely discharges ignitable hazardous waste (classified as D001) to the Delhi plant, including laboratory department stains and pharmaceuticals.

II. REMEDIAL PROGRAM

A. Compliance with Environmental Laws

43. O’Connor shall comply with all provisions of ECL Articles 17 and 27, and the regulations promulgated pursuant to those statutes. Within 90 days of the Effective Date of the Assurance, the Hospital shall cure and eliminate all violations of law found by the Attorney General in paragraphs 23 through 42 above, and shall submit a certification to OAG, signed by its Chief Executive Officer/Administrator, that it has done so.

B. Prohibition Against Discharges of Pharmaceutical Wastes

44. O'Connor is permanently enjoined from dumping, discharging, disposing, spilling or placing any pharmaceutical wastes:

a. down toilets, sinks, or drains – whether or not such structures are connected by pipe or other conveyance to a wastewater treatment plant, septic system, or storm sewer; and

b. into or upon any surface waters, groundwaters, or lands.

45. The Hospital is permanently enjoined from (i) dumping, discharging, disposing, spilling or placing, and (ii) transporting to, or arranging for the dumping, discharging, disposing, spilling or placing of, any pharmaceutical wastes into or upon any landfill, land application facility, surface impoundment, land treatment facility, impoundment, injection well, or waste pile.¹⁵

C. Incineration of Pharmaceutical Wastes¹⁶

46. The Hospital shall ensure that its pharmaceutical wastes containing “hazardous waste”¹⁷ generated by the facility are transported to a hazardous waste incinerator for incineration. The incinerator must be permitted and operate pursuant to Subpart O of 40 C.F.R.

¹⁵ For applicable definitions of these terms, see 6 NYCRR §§ 360-1.2(b)(93), (b)(95), and (b)(165); 6 NYCRR §§ 370.2(b)(101), (b)(111), (b)(113), and (b)(185); 40 C.F.R §§ 260.10.

¹⁶ “The major benefit of incineration over disposal to landfills and sewers is that the incineration process destroys the pharmaceutical waste, rather than storing it or transferring it to another medium.” EPA Interim Study, p. 6-1; see also Hospitals for a Healthy Environment, Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States (April 15, 2006), p. 32. Accordingly, incineration ensures that pharmaceutical waste will not contaminate streams and other bodies of water.

¹⁷ For the applicable definition of “hazardous waste,” see 40 C.F.R. §§ 260.10 and 261.3 and 6 NYCRR § 370.2(b)(86) and 6 NYCRR Part 371.

Part 264 or Subpart O of Part 265, and if it is located within the State, pursuant to 6 NYCRR § 373-2.15.

47. O'Connor shall ensure that its pharmaceutical wastes not containing "hazardous waste" generated by the facility are transported to a "solid waste" incinerator or "regulated medical waste" incinerator for incineration or, if the Hospital chooses, it may overclassify such waste as "hazardous waste" and ensure that the waste is transported to a hazardous waste incinerator for incineration (as in paragraph 46 above).

48. If any of O'Connor's pharmaceutical wastes not containing hazardous wastes are incinerated by a solid waste incinerator or regulated medical waste incinerator located within the State, such incinerator must be permitted and operate pursuant to 6 NYCRR Subpart 360-3 or Subpart 360-17, as applicable.

49. This Assurance does not prevent the Hospital from returning any pharmaceutical wastes to obtain credit from the manufacturer. However, O'Connor is liable under this Assurance for ensuring that such wastes are incinerated in accordance with this Assurance and shall obtain manifests evidencing such incineration in accordance with paragraph 53 below.

D. Controlled Substances

50. Nothing in this Assurance may be construed as requiring or permitting the Hospital to dispose of any pharmaceutical wastes which are "controlled substances" under Federal or State law, in violation of 10 NYCRR § 80.51.

51. If the Hospital wishes to destroy controlled substances on its premises consisting of single-unit doses or partial doses remaining after the administration or attempted administration of a portion of a liquid or solid unit dose of a pharmaceutical in accordance with

10 NYCRR § 80.51(b), it shall render such wastes “totally unrecoverable and beyond reclamation” as required by 10 NYCRR § 80.51(a) by using methods other than flushing wastes down toilets, sinks, and drains subject to prior approval from the Bureau of Narcotics Enforcement of the State Department of Health (“BNE”).¹⁸ O’Connor shall subsequently ensure that such wastes are incinerated in accordance with paragraphs 46 through 49 above.

52. If O’Connor decides to destroy pharmaceutical wastes, which are controlled substances under Federal and State law, pursuant to 10 NYCRR § 80.51(c), it shall propose in its application to the BNE methods which would render the wastes “totally unrecoverable and beyond reclamation” other than flushing the substances down toilets, sinks, and drains.”¹⁹ After obtaining BNE approval, O’Connor shall subsequently ensure that such wastes are incinerated in accordance with paragraphs 46 through 49 above.

E. Recordkeeping, Training, and Compliance Assistance

53. O’Connor shall obtain and keep copies of manifests evidencing incineration of its pharmaceutical wastes, including the EPA Uniform Manifest (for hazardous waste incineration) and regulated medical waste manifest (for regulated medical waste incineration). For pharmaceutical wastes being sent to a solid waste incinerator, the Hospital shall create a manifest containing the following information: the name, address, telephone number and contact person for O’Connor; a signed certification that the wastes are non-hazardous in nature; the name,

¹⁸ BNE has, in the past, approved destruction of pharmaceuticals under 10 NYCRR § 80.51(b) by methods other than flushing. See description of these methods, in Exhibit C attached.

¹⁹ BNE has previously granted approval for the destruction of controlled substances, pursuant to 10 NYCRR § 80.51(c), by mixing them with chemical wastes. See description of this method in Exhibit C attached.

address, telephone number, permit number, contact person and signed certification of receipt by the broker or treatment facility and the size, type, number of containers and their general contents.

54. The Hospital shall keep records of all pharmaceutical wastes returned for credit and the credit obtained. These records shall include: (i) date of return; (ii) name, form, quantity of the wastes returned; and (iii) name and address of the facility making the return; (iv) name and address of the party to whom the pharmaceuticals are returned.

55. The Hospital shall keep the following records of the destruction of controlled substances at O'Connor: copies of all Department of Health forms 2340 and 166, and other correspondence between O'Connor and the BNE concerning destruction of such substances.

56. Consistent with 6 NYCRR § 373-2.2(h), the Hospital shall train its employees to ensure compliance with: (i) all State requirements concerning the management of hazardous wastes, and (ii) all additional requirements concerning management of pharmaceutical wastes (whether or not such wastes are "hazardous") set forth in this Remedial Program, and shall maintain records documenting such training.

57. It is strongly recommended, but not required, that O'Connor hire, or obtain the consulting services of, a professional with expertise in the management of hazardous waste and pharmaceutical waste in healthcare facilities to assist the Hospital in complying with the Remedial Program set forth in this Assurance.

F. Compliance Report and Certification

58. One year after the Effective Date of this Assurance, O'Connor shall submit to OAG a report demonstrating its compliance with the Hospital's obligations under paragraphs 43

through 57 above (Remedial Program) and paragraph 60 below (Take Back Program). The report shall provide a narrative discussion of the Hospital's efforts, activities, and results obtained in implementing the Remedial Program and Take Back Program, and shall include relevant documents and records as attachments. The report shall also include a certification by O'Connor's President/Chief Executive Officer that the Hospital has complied with its obligations under these programs.

III. CIVIL PENALTIES, FEES, AND COSTS

59. In consideration of the making and execution of this Assurance, and within 30 calendar days thereafter, O'Connor agrees that it will pay by wire transfer, certified or bank check payable to the State of New York \$3500 in penalties, fees, and costs. Such payment and all correspondence related to this Assurance must reference Assurance # 09-162.

IV. PHARMACEUTICALS TAKE BACK PROGRAM

60. The Hospital shall use its best efforts, working with local, county, and state agencies and others, to implement a pharmaceuticals take back program ("Take Back Program") to facilitate the proper disposal of household pharmaceutical wastes. The Take Back Program will designate several collection days each year in which the public will have the opportunity to bring their outdated or otherwise unused pharmaceuticals for proper disposal by incineration in the manner set forth in paragraphs 46 through 49 above. O'Connor's role in this program will include providing nursing or pharmacist staff to assist in the collection, making its facility available to serve as the collection site, and/or taking financial and management responsibility for

ensuring that the wastes are incinerated.²⁰

**V. OAG DETERMINATIONS, ENFORCEMENT,
DISPUTE RESOLUTION, FORCE MAJEURE, COSTS**

61. OAG may issue a written determination (“OAG Determination”) approving or disapproving any submittal required by this Assurance; assessing stipulated penalties in accordance with paragraphs 62 and 63 below; seeking reimbursement for costs, fees, and expenses in accordance with paragraphs 64, 66, and 70 below; denying a request by O’Connor for additional time to perform its obligations based on a claim of force majeure; modifying the Remedial Program in light of changes in applicable laws, regulations, guidelines, or technology, or the development of new scientific evidence relating to pharmaceutical wastes; or otherwise relating to the Remedial Program. An OAG Determination is final and binding upon the Hospital subject to its right to dispute such Determination under paragraphs 65, 66 and 70 below.

62. To ensure the Hospital’s prompt compliance with this Assurance and subject to provisions concerning dispute resolution described below, in the event that O’Connor fails to perform any obligation required under this Assurance, it will be liable and pay penalties to the State in the amounts set forth in paragraph 63 below for each day that elapses after such failure to perform the obligation until the failure is cured. A failure to perform an obligation required under this Assurance is defined to include a failure to make a timely submittal to OAG (by failing to make a submittal to OAG in accordance with any schedule set forth in this Assurance, in a submittal approved by OAG, or in an OAG Determination), or a failure to take any action (or

²⁰ See T. Lauro and S. Gerry, “Removing Unused Drugs from the Environment: Westchester County’s ‘Take Back’ Pilot Program,” ClearWaters (New York Water Environment Association Inc. Fall 2008).

to refrain from taking any action) required by this Assurance or required by any submittal approved by OAG or by an OAG Determination.

63. For each failure to perform an obligation, O'Connor shall be liable to the State for penalties as follows:

<u>Length of Violation</u>	<u>Stipulated Penalty</u>
Day 1 through 30	\$100/day
Day 31 through 60	\$500/day
Day 61 and thereafter	\$1,000/day

64. Should OAG sue the Hospital to enforce an OAG Determination or other provisions of this Assurance and prevail, the Hospital shall pay to the State the cost of enforcing this Assurance, including without limitation legal fees, expenses, and court costs.

65. The Hospital may seek to dispute any OAG Determination by serving upon the OAG, and filing with New York State Supreme Court, Albany County, in a timely fashion, a petition or complaint to void, annul or modify such OAG Determination on the ground that the OAG Determination breaches the Assurance. To be timely, a petition/complaint must be served and filed within 45 days of service of the OAG Determination being challenged. If O'Connor fails to timely serve and file such petition/complaint following an OAG Determination, such Determination shall be final and binding upon the Hospital.

66. An OAG Determination will be deemed in breach of the Assurance only if such Determination is arbitrary, capricious, contrary to law, or inconsistent with the Assurance. The procedures and standards applicable to a proceeding under Article 78 of the CPLR shall apply to any petition/complaint by O'Connor seeking dispute resolution. The Hospital shall have the

burden of proof in any petition/complaint challenging an OAG Determination. If OAG prevails in such litigation, O'Connor shall pay to OAG its legal fees, expenses, fees, and court costs.

67. Nothing herein may be construed to affect in any way OAG's obtaining additional or alternative legal or equitable remedies relating to any violations of this Assurance, and the Hospital may assert any defenses, rights, or remedies with respect to such additional or alternative remedies to the extent permitted by law.

68. If any event arising from causes beyond the reasonable control and best efforts of O'Connor or its agents delays or prevents the performance of any of the Hospital's obligations under this Assurance despite its best efforts and due diligence to fulfill the obligation (hereinafter, a "Force Majeure Event"), then any such obligations will be suspended for the duration of the Force Majeure Event; provided, however, that O'Connor: (a) notifies OAG of the Force Majeure Event in full compliance with paragraph 69 below, and (b) undertakes best efforts and due diligence to minimize the duration and impact of the Force Majeure Event.

69. Initial notification of the Force Majeure Event must be provided to OAG orally as soon as possible (but by no later than 10 business days after O'Connor or any of its agents becomes aware that circumstances constituting the Force Majeure event have occurred or will occur) by contacting the WIG at (518) 474-7178. Written notice shall be provided no later than 20 business days after the Hospital or any of its agents becomes aware that circumstances constituting the Force Majeure event have occurred or will occur. Written notice shall be accompanied by all available documentation and shall contain the following: (a) a description of the circumstances constituting the Force Majeure Event; (b) the actions (including pertinent dates) that O'Connor has taken and plans to take to minimize the delay, and (c) the date the

Hospital expects to complete the delayed obligation. O'Connor's failure to comply with these notification requirements will deprive it of an extension of time to perform its obligations and foreclose a defense based upon force majeure to an OAG Determination assessing penalties.

70. O'Connor shall reimburse the State within 60 days of a written demand made by OAG for reasonable incurred and customary out-of-pocket costs paid by OAG to outside contractors for any future inspection, surveying, sampling, and laboratory analysis work concerning the Remedial Program except for costs that the Hospital disputes by timely serving and filing a petition/complaint disputing such costs pursuant to paragraphs 65 and 66 above. In the event and to the extent that O'Connor does not succeed in its petition/complaint, it shall reimburse the State for disputed costs plus interest in accordance with CPLR § 5004 within 30 days of entry of final judgment concerning the petition. Interest shall be applied beginning 60 days from OAG's written demand through the date of payment of costs by the Hospital to the State.

VI. MISCELLANEOUS

71. The Effective Date of this Assurance is November 2, 2009.

72. O'Connor shall allow OAG, its employees, agents, and other State employees reasonable access to its facility at 460 Andes Road, Delhi, New York 13753, to inspect such facility, monitor the Hospital's compliance with this Assurance, and to conduct further investigations relating to the Remedial Program and Take Back Program. O'Connor shall provide to OAG all information and documentation relating to the Remedial Program and Take Back Program or its obligations under the Assurance upon request by OAG.

73. OAG has agreed to the terms of this Assurance based on, among other things, the

representations made to OAG by the Hospital and its representatives and OAG's Investigation as set forth in the findings (see paragraphs 1 through 42) above. To the extent that any material representations are later found to be inaccurate or misleading, this Assurance is voidable by OAG in its sole discretion.

74. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Assurance has been made to or relied upon by O'Connor in agreeing to this Assurance.

75. Respondent represents and warrants, through its signature below, that the terms and conditions of this Assurance are duly approved, and execution of this Assurance is duly authorized. Respondent shall not take any action or make any statement denying, directly or indirectly, the propriety of this Assurance or expressing the view that this Assurance is without factual or legal basis. Nothing in this paragraph affects Respondent's (i) testimonial obligations or (ii) right to take legal or factual positions in defense of litigation or other legal or administrative proceedings to which OAG, the State, or the Federal Government are not parties.

76. This Assurance may not be amended except by an instrument in writing signed on behalf of all the parties to the Assurance.

77. This Assurance shall be binding on and inure to the benefit of the parties to this Assurance and their respective successors and assigns, provided that no party, other than OAG, may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without the prior written consent of OAG.

78. In the event that any 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, in the sole

discretion of OAG, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Assurance.

79. All notices, requests, reports, or other documents from O'Connor to OAG (other than a petition or complaint brought under paragraphs 65 and 66) shall be served upon Philip Bein, WIG, Office of the Attorney General, Environmental Protection Bureau, The Capitol, Albany, New York 12224 (fax: 518-473-2534; e-mail: philip.bein@oag.state.ny.us). All notices, requests, reports, or other documents from OAG to the Hospital shall be served upon Dan Ayres, Chief Executive Officer/Administrator, O'Connor Hospital, 460 Andes Road, Delhi, New York 13753 (fax: (607) 746-0326; e-mail: dan.ayres@oconnorhosp.org). Service may be made by facsimile transmission or by e-mail, but must be followed in hard copy by mail.

80. Acceptance of this Assurance by OAG shall not be deemed approval by OAG of any of the practices or procedures referenced in the findings (see paragraphs 1 through 42 above), and the Hospital shall make no representation to the contrary.

81. Pursuant to New York Executive Law Section 63(15), evidence of a violation of this Assurance shall constitute prima facie proof of violation of the applicable law in any action or proceeding thereafter commenced by OAG.

82. OAG finds the relief and agreements contained in this Assurance appropriate and in the public interest. OAG is willing to accept this Assurance pursuant to New York Executive Law Section 63(15), in lieu of commencing a statutory proceeding. This Assurance shall be governed by the laws of the State of New York without regard to any conflict of laws principles.

IN WITNESS WHEREOF, this Assurance is executed by the parties hereto on
January 11, 2010
~~December 1, 2009~~

ANDREW M. CUOMO
Attorney General of the State of New York

By: Philip Bein Date: 1/11/10
Philip Bein

Watershed Inspector General
Assistant Attorney General
New York State Department of Law
The Capitol
Albany, NY 12224
tel: (518) 474-7178
fax: (518) 473-2534
e-mail: philip.bcin@oag.state.ny.us

O'Connor Hospital

By: Dan Ayres Date: 12/4/09
Dan Ayres
DANIEL M. AYRES

Chief Executive Officer/Administrator
O'Connor Hospital
460 Andes Road
Delhi, New York 13753
tel: (607) 746-0326
fax: (607) 746-0326
e-mail: dan.ayres@oconnorhosp.org