

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, :  
Plaintiff :  
 :  
v. : CIVIL ACTION NO.  
 :  
MERCK & CO., INC. :  
Defendant :

COMPLAINT

The United States of America ("United States), by the authority of the Attorney General of the United States and through its undersigned counsel, acting at the request and on behalf of the Administrator of the United States Environmental Protection Agency ("EPA"), files this Complaint and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action brought pursuant to Section 309(b) and (d) of the Federal Water Pollution Control Act, as amended by the Clean Water Act of 1977 and the Water Quality Act of 1987 (the "Clean Water Act" or "the Act"), 33 U.S.C. § 1319(b) and (d), for permanent injunctive relief and assessment of civil penalties against Merck & Co., Inc. ("Merck" or "Defendant") regarding the operation of a pharmaceutical research and manufacturing facility, located in West Point, Pennsylvania ("West Point Facility" or "Facility") that discharges sanitary and industrial wastewater containing pollutants from the facility to the Publicly Owned Treatment Works (POTW) owned and operated by Upper Gwynedd Township ("UGT"), also located in West Point, Pennsylvania. Merck's West Point Facility is a significant industrial user and source of "Indirect Discharge" of non-domestic wastewater and pollutants to the UGT POTW as regulated by EPA under Section 307 of the CWA, 33 U.S.C. § 1317. The United

States alleges that on several occasions between June 1, 2006 and August 31, 2006 as described further below, Merck discharged pollutants from its West Point Facility causing pass through and interference at UGT POTW, as well as violations of other requirements of the applicable pretreatment program.

#### JURISDICTION, VENUE, AUTHORITY AND NOTICE

2. This Court has jurisdiction over the subject matter of this action pursuant to Section 309(b) of the Act, 33 U.S.C. § 1319(b), and 28 U.S.C. §§ 1331, 1345, and 1355.

3. Venue lies in the Eastern District of Pennsylvania pursuant to Section 309(b) of the Act, 33 U.S.C. § 1319(b), and 28 U.S.C. § 1391(b) and (c) because Defendant conducts business in this district and because the violations alleged herein occurred in this judicial district.

4. The United States has authority to bring this action on behalf of the Administrator of EPA ("Administrator") under Section 506 of the Act, 33 U.S.C. § 1366, and under 28 U.S.C. §§ 516 and 519.

5. Notice of the commencement of this action has been given to the Commonwealth of Pennsylvania pursuant to Section 309(b) of the Act, 33 U.S.C. § 1319(b), which files a motion for intervention and complaint as co-plaintiff herewith.

6. Defendant Merck, a corporation, is a "person" within the meaning of Section 502 (5) of the Act, 33 U.S.C. § 1362(5), and an "industrial user" within the meaning of Section 502(18) of the Act, 33 U.S.C. § 1362(18).

7. Merck is regulated as a significant industrial user and source of "indirect discharge" of non-domestic wastewater and pollutants under Section 307 of the CWA and the implementing regulations covering the Pharmaceutical Manufacturing Point Source Category of

the National Categorical Pretreatment Standards as set forth in 40 C.F.R. Part 439, Subparts D and E.

### STATUTORY BACKGROUND

8. Section 301(a) of the Act, 33 U.S.C. § 1311(a), prohibits the discharge of pollutants into the waters of the United States by any person except in accordance with certain provisions, including Section 402 of the Act, 33 U.S.C. § 1342.

9. Section 307(d) of the Act, 33 U.S.C. § 1317(d), prohibits the owner or operator of any indirect source from discharging pollutants or otherwise operating that source in violation of any applicable pretreatment standard or prohibition as set forth in Section 307 of the Act, 33 U.S.C. § 1317, and the implementing regulations.

10. EPA established pretreatment requirements for the Pharmaceutical Manufacturing Point Source Category of the National Categorical Pretreatment Standards as set forth in 40 C.F.R. Part 439, Subparts D and E. These requirements prohibit a categorical pretreatment facility from causing "pass through" or "interference" at the POTW to which the pretreatment facility waste is discharged. Section 307(d) of the CWA; 33 U.S.C. § 1317, and implementing regulations at 40 C.F.R. §§ 403.5(a)(1) & 439.3.

11. As required by Section 307 of the Act, 33 U.S.C. § 1317, EPA promulgated the General Pretreatment Regulations for Existing and New Sources of Pollution at 40 C.F.R. Part 403, which establish the "responsibilities of Federal, State, and local government, industry and the public to implement National Pretreatment Standards to control pollutants which pass through or interfere with treatment processes [in POTWs]." 40 C.F.R. § 403.1(a).

12. Under those regulations, an industrial user may not introduce into a POTW any

pollutant that causes pass through or interference. Id. § 403.5(a). Those regulations define “pass through” as a discharge of pollutants from an industrial user that passes through and exits the POTW in concentrations that, alone or in conjunction with a discharge or discharges from other sources, cause a violation of “any requirement of the POTW’s NPDES permit.” 40 C.F.R. § 403.3(n). “Interference” is defined as a discharge of pollutants from the pretreatment facility that, alone or in conjunction with a discharge(s) from other sources, causes both (1) an inhibition or disruption at the POTW (including any treatment processes or operation, or its sludge processes, use or disposal); and (2) a violation of any requirement of the POTW NPDES permit. 40 C.F.R. § 403.3(h).

13. Section 402(b) of the Act, 33 U.S.C. § 1342(b), provides authority for the EPA Administrator to authorize a state to operate its own NPDES permit program, provided that the state program meets certain specific criteria.

14. By Memorandum of Agreement dated July 5, 1978, and renewed on May 15, 1991, the EPA Administrator authorized the Commonwealth of Pennsylvania to administer an NPDES program pursuant to these statutory and regulatory provisions.

15. EPA retains concurrent enforcement authority pursuant to Section 402(I) of the Act, 33 U.S.C. § 1342(I).

16. Sections 309(b) and (d) of the Act, 33 U.S.C. § 1319(b) and (d), authorize the United States to commence actions for injunctive relief and/or civil penalties for violation of Section 307 of the Act, 33 U.S.C. § 1317.

17. Section 309(b) of the Act, 33 U.S.C. § 1319(b), provides for civil penalties of up to \$25,000 per day for each violation occurring prior to January 30, 1997. Pursuant to the

Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 and 40 C.F.R. Parts 19 and 27, the Clean Water Act provides civil penalties of up to \$32,500 per day for each violation committed after March 15, 2004.

### FACTUAL ALLEGATIONS

18. Merck owns and operates the West Point Facility located in West Point, Montgomery County, Pennsylvania. The West Point Facility conducts pharmaceutical and vaccine research and manufactures pharmaceutical products and vaccines. The West Point Facility consists of approximately 400 acres, and 110 buildings, and currently employs approximately 8500 employees.

19. Merck discharges sanitary and non-domestic pollutants from its West Point Facility to the UGT POTW located in West Point, Pennsylvania, but is not authorized to discharge potassium thiocyanate (“KSCN”) to the UGT POTW.

20. The UGT POTW is authorized to discharge certain pollutants pursuant to the terms and conditions set forth in National Pollutant Discharge Elimination System (NPDES) Permit No. PA0023256 (Permit) issued pursuant to Section 402 of the CWA, 33 U.S.C. § 1342. The Permit does not authorize UGT to discharge KSCN or dissolved cyanogen gas in any amount. The Permit does not authorize UGT to discharge large amounts of foam.

21. The treated effluent is discharged from Upper Gwynedd POTW into the Wissahickon Creek, which is a water of the United States as that term is defined in Section 502(7) of the Act, 33 U.S.C. § 1362(7), and is a tributary of the Schuylkill River.

22. The Wissahickon Creek supports an aquatic life habitat and recreational uses including seasonal trout fishing. Immediately downstream of the confluence of the Wissahickon

and the Schuylkill River the City of Philadelphia has a major drinking water intake at Queen Lane Station. Pennsylvania has adopted water quality standards designed to protect the beneficial waters uses including aquatic life, recreation, and drinking water uses for the Wissahickon Creek by Pennsylvania. 92 Pa. Code § 93.9.

23. The Merck West Point Facility is subject to EPA regulations under the Pharmaceutical Manufacturing Point Source Category of the National Categorical Pretreatment Standards as set forth in 40 C.F.R. Part 439, Subparts D and E.

24. As a facility subject to the Pharmaceutical Manufacturing Point Source Category, Merck is prohibited from causing “pass through” or “interference” at the UGT POTW, or from introducing any pollutant into the UGT POTW which results in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems. 40 C.F.R. §§ 403.5(a)(1); 403.5(b)(7) & 439.3.

26. On June 13, 2006 Merck discharged KSCN into the Upper Gwynedd POTW.

27. The KSCN discharged by Merck on June 13, 2006 moved through the UGT POTW treatment system undetected until the last stage of the process, disinfection of the effluent through chlorination, at which point the KSCN reacted with the chlorinated compounds producing cyanogen chloride gas, a highly toxic substance. The UGT POTW then discharged those pollutants on June 14 and 15.

28. The discharge of wastewater from UGT POTW containing dissolved cyanogen gas killed hundreds of fish in the Wissahickon Creek, which were discovered on June 14 and June 15, 2006.

29. As a direct result discharge of wastewater from UGT POTW containing dissolved

cyanogen gas, the City of Philadelphia Water Department closed the drinking water intake at Queen Lane on the Schuylkill River (immediately downstream of the confluence of the Wissahickon Creek and Schuylkill River) on June 14 and June 15, 2006, and also closed the Belmont drinking water intake, located approximately two miles further down on the Schuylkill River on June 15<sup>th</sup>, 2006. For the period from June 14, 2006 until July 10, 2006, PADEP and the Montgomery County Health Department issued an advisory to ban all recreational uses of the Wissahickon Creek.

30. On August 8 and 9, 2006 Merck discharged a large quantity of spent vaccine substrate with a high protein content, a foam producing pollutant, to UGT POTW.

31. The discharge of the spent vaccine substrate on August 8 and 9, 2006, to UGT POTW, caused UGT POTW to discharge foam into the Wissahickon Creek. The UGT POTW NPDES permit does not authorize the discharge of such foam.

32. On August 16, 2006, Merck again discharged foam-producing pollutants to UGT POTW, causing a disruption at UGT POTW.

#### FIRST CLAIM FOR RELIEF

(Violation of Prohibition of Pass Through for June 13, 2006 Discharge of KSCN)

33. Paragraphs 1-31 are realleged and incorporated by reference.

34. Because Merck's discharge of KSCN on June 13, 2006, into UGT POTW passed through and caused a fish kill in the Wissahickon Creek, a closure of drinking water intakes on the Schuylkill River, and a ban on recreational uses in the Wissahickon Creek, Merck caused pass through in violation of Section 307(d) of the CWA, 33 U.S.C. § 1317(d), and the

implementing regulations at 40 C.F.R. §§ 403.5(a)(1) & 439.3.

35. Pursuant to 33 U.S.C. § 1319(b) and (d), Merck is liable for permanent injunctive relief and civil penalties of up to \$32,500 per day for each violation.

### SECOND CLAIM FOR RELIEF

(Violation of Prohibition of Interference for June 13, 2006 Discharge of KSCN)

36. Paragraphs 1-31 are realleged and incorporated by reference.

37. As a direct result of the Merck discharge of KSCN on June 13, 2006, UGT POTW stopped using chlorination and thus ceased disinfecting the effluent, thereby causing UGT POTW to exceed its NPDES monthly effluent limit for fecal coliform , 200 colony units per 100 mL, and also to exceed the instantaneous maximum limit for fecal coliform of not greater than 1,000/100mL in more than 10 percent of the samples tested. Merck therefore caused interference with the UGT POTW in violation of Section 307(d) of the CWA, 33 U.S.C. § 1317(d) and the implementing regulations at 40 C.F.R. §§ 403.5(a)(1) and 439.3.

38. Pursuant to 33 U.S.C. § 1319(b) and (d), Merck is liable for permanent injunctive relief and civil penalties of up to \$32,500 per day for each violation.

### THIRD CLAIM FOR RELIEF

(Violation of Prohibition of Pass Through for August 8-9, 2006 Discharge of Foam causing substances)

39. Paragraphs 1-31 are realleged and incorporated by reference.

40. Because Merck's discharge of spent substrate used in vaccine production on August 8 and 9, 2006 into the UGT POTW passed through and caused foam in violation of the

UGT NPDES permit conditions, Merck caused pass through in violation of Section 307(d) of the CWA, 33 U.S.C. § 1317(d) and the implementing regulations at 40 C.F.R. §§ 403.5(a)(1) and 439.3.

41. Pursuant to 33 U.S.C. § 1319(b) and (d), Merck is liable for permanent injunctive relief and civil penalties of up to \$32,500 per day for each violation.

#### FOURTH CLAIM FOR RELIEF

(Violation of Prohibition of Interference at UGT POTW for August 16, 2006 Discharge of Foam causing substances)

42. Paragraphs 1-31 are realleged and incorporated by reference.

43. Because Merck's discharge of foam-producing pollutants on August 16, 2006 into the UGT POTW disrupted and otherwise interfered with the operations at UGT POTW, Merck caused interference in violation of Section 307(d) of the CWA, 33 U.S.C. § 1317(d) and the implementing regulations at 40 C.F.R. §§ 403.5(a)(1) and 439.3.

44. Pursuant to 33 U.S.C. § 1319(b) and (d), Merck is liable for permanent injunctive relief and civil penalties of up to \$32,500 per day for each violation.

#### PRAYER FOR RELIEF

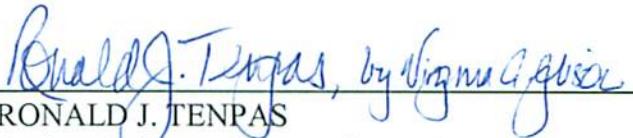
WHEREFORE, Plaintiff, the United States of America, respectfully prays that this Court:

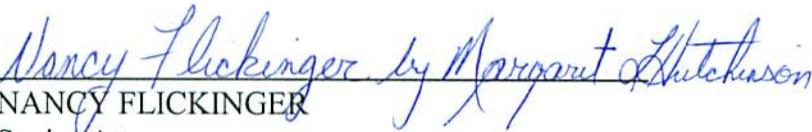
1. Permanently enjoin Defendant Merck from indirectly discharging pollutants except as expressly authorized by the Act, the Pretreatment Program, and the limitations and conditions of any applicable local pretreatment permit.
2. Order Merck to take all steps necessary to comply with the Act,

Pretreatment Program, and the limitations and conditions of any applicable local pretreatment permit.

3. Order Merck to take all steps necessary to redress or mitigate the impact of its discharges into the Wissahickon Creek in violation of the Act.
4. Assess civil penalties against the City up to \$32,500 per day for each violation described in this Complaint.
5. Award the United States its costs for this action.
6. Grant such other and further relief as the Court may deem appropriate.

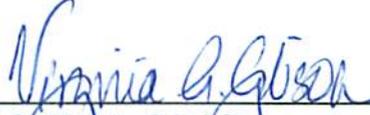
Respectfully submitted,

  
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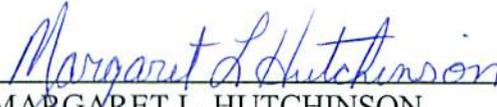
  
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