ER

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS. **SUPERIOR COURT**

CIVIL ACTION NO.:

TALIA SMITH
520 North Street
Walpole, MA 02081

Plaintiff,

v.

BAYER CORPORATION
100 Bayer Boulevard
Whippany, New Jersey 07981

And

BAYER HEALTHCARE PHARMACEUTICALS, INC.
100 Bayer Boulevard
Whippany, New Jersey 07981

And

BAYER PHARMACEUTICALS CORPORATION
6 West Belt Road
Wayne, NJ 07470

And

HIKMA PHARMACEUTICALS USA, INC.
200 Connell Drive, 4th Floor
Berkeley Heights, NJ 07922

And

HIKMA PHARMACEUTICALS PLC
1 New Burlington Place
London W1S 2HR
United Kingdom

JURY TRIAL DEMANDED

And

WEST-WARD PHARMACEUTICALS CORPORATION
200 Connell Drive
Berkeley Heights, NJ 07992

And

BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM, INC.
148 Chestnut Street
Needham, MA 02192

And

BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM CAMPUS, INC.
148 Chestnut Street
Needham, MA 02192

And

BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, INC.
330 Brookline Avenue
Boston, MA 02215

And

BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC
701 Edgewater Drive, Suite 420
Wakefield, MA 01880

And

BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC d/b/a BETH ISRAEL DEACONESS CARE ORGANIZATION LLC
701 Edgewater Drive, Suite 420
Wakefield, MA 01880

And

BETH ISRAEL LAHEY HEALTH PRIMARY CARE, INC.
20 University Road, Suite 700
Cambridge, MA 02138

And

BETH ISRAEL LAHEY HEALTH, INC.
20 University Road, Suite 700
Cambridge, MA 02138

And

LAHEY HEALTH SYSTEM, INC.
41 Mall Road
Burlington, MA 01805

And

AFFILIATED PHYSICIANS, INC.
1180 Beacon Street
Brookline, MA 02146

And

AFFILIATED PHYSICIANS, INC.
600 Unicorn Park Drive, 4th Floor
Woburn, MA 01801

And

HARVARD UNIVERSITY AND THE PRESIDENTS AND FELLOWS OF HARVARD COLLEGE
Massachusetts Hall
Cambridge, MA 02138

And

HEATHER BOXERMAN, M.D.
93 Pond Street
Sharon, MA 02067

And

ALISON BOYER, N.P.
700 Congress Street, Suite 103
Quincy, MA 02169

Defendants.

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CIVIL ACTION – COMPLAINT

I. BRIEF INTRODUCTION TO THE CASE

1. This action is about preserving the dignity and value of human life against pharmaceutical conglomerates that exploit individuals for corporate gain. For decades, the corporate pharmaceutical Defendants have designed, produced, and labeled a dangerous and defective drug known as ciprofloxacin, a fluoroquinolone antibiotic that has caused permanent and severe injuries, pain, and suffering to countless victims across the United States. Adding insult to injury, Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., (collectively referred to as "Bayer"), Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC (collectively referred to as "Hikma"), and West-Ward Pharmaceuticals Corporation ("West-Ward"), have concealed the dangerous effects of fluoroquinolones at the expense of consumer health and safety without providing adequate warnings—all while lining their corporate pockets with billions of dollars in estimated revenue. To be clear: it is well-established that fluoroquinolones, including ciprofloxacin, are dangerous and harmful to human beings. According to the U.S. Food and Drug Administration ("FDA"), both oral and injectable fluroquinolones are linked to crippling side effects that disable the tendons, muscles, joints, nerves, and central nervous system, and can leave permanent damage to the human body. Since the early 2000s, the FDA has enacted drastic responses to these dangerous effects by mandating multiple warnings, including Boxed Warnings, for fluroquinolones. With this filing, the Corporate Defendants must finally face accountability for their misconduct. They must answer to the thousands of victims their defective drugs have severely injured, including Plaintiff, Talia Smith.

Unfortunately, Talia further suffered permanent, lifelong injuries not only as a result of the misconduct of the producers of this drug, but also from her healthcare providers, who had a duty to warn of Cipro's dangerous effects. As a direct result of Heather Boxerman, M.D. ("Dr. Boxerman") and Alison Boyer, N.P.'s ("N.P. Boyer") inexcusable failure to properly prescribe and warn Plaintiff of Cipro's damaging effects prior to prescribing ciprofloxacin, Plaintiff tragically sustained severe, permanent disability, requiring hospice care and multiple hospitalizations.

II. PARTIES

2. Plaintiff, Talia Smith, is an adult citizen and resident of the Commonwealth of Massachusetts, residing therein at 520 North Street, Walpole, Massachusetts 02081.

3. Plaintiff, Talia Smith, developed mast cell activation disorder, paresthesias, achilles tendinitis, significant gut alteration, and disability as a direct result of the egregious, negligent, wrongful, and reckless conduct of the Defendants in their design, manufacture, sale, creation, distribution, and prescription of the dangerous and harmful effects of Cipro.

4. Defendant, Bayer Corporation, is a German corporation organized and existing under the laws of the State of Indiana with its principal place of business located at 100 Bayer Boulevard, Whippany, New Jersey 07981.

5. Defendant, Bayer Pharmaceuticals Corporation, is a German corporation organized and existing under the laws of Delaware with its principal place of business located at 6 West Belt Road, Wayne, New Jersey 07470.

6. Defendant, Bayer Healthcare Pharmaceuticals, Inc., is a German corporation organized and existing under the laws of Delaware with its principal place of business located at 100 Bayer Boulevard, Whippany, New Jersey 07981.

7. Defendant, Hikma Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 200 Connell Drive, Berkeley Heights, New Jersey 07992.

8. Hikma Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Hikma Pharmaceuticals PLC, a multinational generic pharmaceutical manufacturing company headquartered in London, United Kingdom.

9. Defendant, Hikma Pharmaceuticals PLC is a corporation organized and existing under the laws of the United Kingdom of Great Britain and Northern Ireland with its headquarters located at 1 Burlington Place, London W1S 2HR.

10. West-Ward Pharmaceuticals Corporation ("West-Ward") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 200 Connell Drive, Berkeley Heights, New Jersey 07992.

11. West-Ward was established in 1946 as a generic oral drug manufacturing company.

12. On January 1, 1991, Hikma Pharmaceuticals acquired West-Ward Pharmaceuticals Corporation by merger.

13. As of August 2, 2023, Hikma Pharmaceuticals PLC had a market capitalization of approximately $5.83 billion.

14. In 2023, Hikma Pharmaceuticals PLC acquired approximately $2.875 billion in core revenue, $1.407 billion in core gross profit, and $707 million in core operating profit.

15. Defendant, Beth Israel Deaconess Hospital—Needham, Inc., and Beth Israel Deaconess Hospital—Needham Campus, Inc. were at all times material hereto institutional healthcare providers, medical health care facilities, corporations, and/or other jural entities organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts,

with their principal place of business located at 148 Chestnut Street, Needham, Massachusetts 02192. The claims asserted against these Defendants are for the professional negligence of their agents, servants, and/or employees, including Heather Boxerman, M.D., and Alison Boyer, N.P., who rendered treatment and care to Talia Smith from on or about January 1, 2021, through September 9, 2021, as stated more fully, and with specificity, throughout this Complaint. Claims for direct corporate negligence are also asserted against these Defendants.

16. Defendant, Beth Israel Deaconess Physician Organization, Inc., was at all times material hereto an institutional healthcare provider, medical health care facility, corporation, hospital, and/or other jural entity, organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, with a principal place of business located at 330 Brookline Avenue, Boston, Massachusetts 02215, and owning, operating, maintaining, supporting, and/or staffing a hospital and/or physician practice groups at Beth Israel Deaconess Hospital—Needham. The claim asserted against this Defendant is for the professional negligence of its agents, ostensible agents, servants, and/or employees, including Heather Boxerman, M.D., and Alison Boyer, N.P., who rendered treatment and care to Talia Smith, from on or about January 1, 2021, through September 9, 2021, as stated more fully, and with specificity, throughout this Complaint. A claim for direct corporate negligence is also asserted against this Defendant.

17. Defendant, Beth Israel Deaconess Physician Organization, LLC, was at all times material hereto an institutional healthcare provider, medical health care facility, corporation, hospital, and/or other jural entity, organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, with a principal place of business located at 701 Edgewater Drive, Suite 420, Wakefield, Massachusetts 01880, and owning, operating, maintaining, supporting, and/or staffing a hospital and/or physician practice groups at Beth Israel Deaconess

Hospital—Needham. The claim asserted against this Defendant is for the professional negligence of its agents, ostensible agents, servants, and/or employees, including Heather Boxerman, M.D., and Alison Boyer, N.P., who rendered treatment and care to Talia Smith, from on or about January 1, 2021, through September 9, 2021, as stated more fully, and with specificity, throughout this Complaint. A claim for direct corporate negligence is also asserted against this Defendant.

18. Defendant, Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC, was at all times material hereto an institutional healthcare provider, medical health care facility, corporation, hospital, and/or other jural entity, organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, with a principal place of business located at 701 Edgewater Drive, Suite 420, Wakefield, Massachusetts 01880, and owning, operating, maintaining, supporting, and/or staffing a hospital and/or physician practice groups at Beth Israel Deaconess Hospital—Needham. The claim asserted against this Defendant is for the professional negligence of its agents, ostensible agents, servants, and/or employees, including Heather Boxerman, M.D., and Alison Boyer, N.P., who rendered treatment and care to Talia Smith, from on or about January 1, 2021, through September 9, 2021, as stated more fully, and with specificity, throughout this Complaint. A claim for direct corporate negligence is also asserted against this Defendant.

19. Defendant, Beth Israel Lahey Health Primary Care, Inc., was at all times material hereto an institutional healthcare provider, medical health care facility, corporation, hospital, and/or other jural entity, organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, with a principal place of business located at 20 University Road, Suite 700, Cambridge, Massachusetts 02138, and owning, operating, maintaining, supporting, and/or staffing a hospital and/or physician practice groups. The claim asserted against this

Defendant is for the professional negligence of its agents, ostensible agents, servants, and/or employees, including Heather Boxerman, M.D., and Alison Boyer, N.P., who rendered treatment and care to Talia Smith, from on or about January 1, 2021, through September 9, 2021, as stated more fully, and with specificity, throughout this Complaint. A claim for direct corporate negligence is also asserted against this Defendant.

20. Defendant, Beth Israel Lahey Health, Inc., was at all times material hereto an institutional healthcare provider, medical health care facility, corporation, hospital, and/or other jural entity, organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, with a principal place of business located at 20 University Road, Suite 700, Cambridge, Massachusetts 02138, and owning, operating, maintaining, supporting, and/or staffing a hospital and/or physician practice groups. The claim asserted against this Defendant is for the professional negligence of its agents, ostensible agents, servants, and/or employees, including Heather Boxerman, M.D., and Alison Boyer, N.P., who rendered treatment and care to Talia Smith, from on or about January 1, 2021, through September 9, 2021, as stated more fully, and with specificity, throughout this Complaint. A claim for direct corporate negligence is also asserted against this Defendant.

21. Defendant, Lahey Health System, Inc., was at all times material hereto an institutional healthcare provider, medical health care facility, corporation, hospital, and/or other jural entity, organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, with a principal place of business located at 41 Mall Road, Burlington, Massachusetts 01805, and owning, operating, maintaining, supporting, and/or staffing a hospital and/or physician practice groups. The claim asserted against this Defendant is for the professional negligence of its agents, ostensible agents, servants, and/or employees, including Heather

Boxerman, M.D., and Alison Boyer, N.P., who rendered treatment and care to Talia Smith, from on or about January 1, 2021, through September 9, 2021, as stated more fully, and with specificity, throughout this Complaint. A claim for direct corporate negligence is also asserted against this Defendant.

22. Defendant, Affiliated Physicians, Inc., was at all times material hereto an institutional healthcare provider, medical health care facility, corporation, hospital, and/or other jural entity, organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, with a principal place of business located at 1180 Beacon Street, Brookline, Massachusetts 02146, and owning, operating, maintaining, supporting, and/or staffing a hospital and/or physician practice groups. The claim asserted against this Defendant is for the professional negligence of its agents, ostensible agents, servants, and/or employees, including Heather Boxerman, M.D., and Alison Boyer, N.P., who rendered treatment and care to Talia Smith, from on or about January 1, 2021, through September 9, 2021, as stated more fully, and with specificity, throughout this Complaint. A claim for direct corporate negligence is also asserted against this Defendant.

23. Defendant, Affiliated Physicians, Inc., was at all times material hereto an institutional healthcare provider, medical health care facility, corporation, hospital, and/or other jural entity, organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, with a principal place of business located at 600 Unicorn Park Drive, 4th Floor, Woburn, Massachusetts 01801, and owning, operating, maintaining, supporting, and/or staffing a hospital and/or physician practice groups. The claim asserted against this Defendant is for the professional negligence of its agents, ostensible agents, servants, and/or employees, including Heather Boxerman, M.D., and Alison Boyer, N.P., who rendered treatment and care to Talia Smith,

from on or about January 1, 2021, through September 9, 2021, as stated more fully, and with specificity, throughout this Complaint. A claim for direct corporate negligence is also asserted against this Defendant.

24. Defendant Harvard University and the President and Fellows of Harvard College is a non-profit corporation organized and existing under the laws of the Commonwealth of Massachusetts that maintains its principal place of business at Massachusetts Hall, Cambridge, Massachusetts, 02138, and owning, operating, maintaining, supporting, and/or staffing a hospital and/or physician practice groups at Beth Israel Deaconess Hospital—Needham. This Defendant also owns and operates Harvard Medical School—Beth Israel, a nonprofit corporation organized and existing under the laws of the Commonwealth of Massachusetts that is affiliated with Beth Israel Deaconess Hospital—Needham. The claim asserted against this Defendant is for the professional negligence of its agents, ostensible agents, servants, and/or employees, including Heather Boxerman, M.D., and Alison Boyer, N.P., who rendered treatment and care to Talia Smith, from on or about January 1, 2021, through September 9, 2021, as stated more fully, and with specificity, throughout this Complaint. A claim for direct corporate negligence is also asserted against this Defendant.

25. Defendants, Beth Israel Deaconess Hospital—Needham, Inc.; Beth Israel Deaconess Hospital—Needham Campus, Inc.; Beth Israel Deaconess Physician Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Defendant, Lahey Health System, Inc.; Affiliated Physicians, Inc.; Affiliated Physicians, Inc.; and Harvard University and the President and Fellows of Harvard College, were acting by and through their employees, agents, ostensible

agents, apparent agents, shareholders, partners, officers, directors and/or managing agents, who were acting within the scope of their employment or agency and rendering care to Talia Smith, specifically but not limited to Heather Boxerman, M.D., and Alison Boyer, N.P., and any physicians, residents, interns, fellows, technicians, medical students, nurses, and staff, who attended to, provided care to, or were responsible for providing care to Talia Smith, who are known to Defendants and unknown to Plaintiffs.

26. At all times material hereto, the physicians, residents, interns, fellows, technicians, medical students, nurses, and staff describes and identified in paragraph 23 of this Complaint, who are known to Defendants, were actual agents, ostensible agents, servants, and/or employees of Defendants, Beth Israel Deaconess Hospital—Needham, Inc.; Beth Israel Deaconess Hospital—Needham Campus, Inc.; Beth Israel Deaconess Physician Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Defendant, Lahey Health System, Inc.; Affiliated Physicians, Inc.; Affiliated Physicians, Inc.; and Harvard University and the President and Fellows of Harvard College, acting within the course and scope of their employment and/or agency relationship with Defendants, Beth Israel Deaconess Hospital—Needham, Inc.; Beth Israel Deaconess Hospital—Needham Campus, Inc.; Beth Israel Deaconess Physician Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Defendant, Lahey Health System, Inc.; Affiliated Physicians, Inc.; and Affiliated Physicians, Inc.; and Harvard University and the President and Fellows of Harvard College, over whom Defendants, Beth Israel Deaconess Hospital—Needham, Inc.; Beth Israel

Deaconess Hospital—Needham Campus, Inc.; Beth Israel Deaconess Physician Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Defendant, Lahey Health System, Inc.; Affiliated Physicians, Inc.; Affiliated Physicians, Inc.; and Harvard University and the President and Fellows of Harvard College, had control and right of control.

27. Defendant, Heather Boxerman, M.D. ("Dr. Boxerman") is and was at all times material hereto, a physician duly licensed to practice in the Commonwealth of Massachusetts, specializing in the field of internal medicine and primary care, with an office, medical practice, and place of business at Beth Israel Lahey Heath Primary Care, Inc., 93 Pond Street, Sharon, Massachusetts 02067. Plaintiff is asserting a professional liability claim against this healthcare provider.

28. At all times material hereto, Dr. Boxerman provided medical evaluation, care, and treatment to Talia Smith, while acting within the course and scope of her employment, master-servant, and/or agency relationship with Defendants, Beth Israel Deaconess Hospital—Needham, Inc.; Beth Israel Deaconess Hospital—Needham Campus, Inc.; Beth Israel Deaconess Physician Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Defendant, Lahey Health System, Inc.; Affiliated Physicians, Inc.; and Affiliated Physicians, Inc.; and Harvard University and the President and Fellows of Harvard College.

29. Defendant, Alison Boyer, N.P., was at all times material hereto, a nurse practitioner duly licensed to practice in the Commonwealth of Massachusetts, with an office, medical practice,

and place of business at Beth Israel Lahey Heath Primary Care, Inc., 93 Pond Street, Sharon, Massachusetts 02067. Plaintiff is asserting a professional liability claim against this healthcare provider.

30. At all times material hereto, Nurse Practitioner Boyer provided medical evaluation, care, and treatment to Talia Smith, while acting within the course and scope of her employment, master-servant, and/or agency relationship with Defendants, Beth Israel Deaconess Hospital—Needham, Inc.; Beth Israel Deaconess Hospital—Needham Campus, Inc.; Beth Israel Deaconess Physician Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Defendant, Lahey Health System, Inc.; Affiliated Physicians, Inc.; and Affiliated Physicians, Inc.; and Harvard University and the President and Fellows of Harvard College.

III. VENUE AND JURISDICTION

31. Venue is proper in Suffolk County because Defendants, Beth Israel Deaconess Physician Organization, Inc., Beth Israel Deaconess Physician Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Lahey Health System, Inc.; Affiliated Physicians, Inc.; and Affiliated Physicians, Inc., each have regularly conducted business in Suffolk County, have maintained a regular place of business located in Suffolk County, and/or might sue or be sued in Suffolk County.

32. Venue is proper in Suffolk County also because Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma

Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, have regularly conducted business in Suffolk County through their sale, distribution, shipment, direction, and placement of their products, including Ciprofloxacin and other fluroquinolones, into and throughout Suffolk County.

33. This Court has jurisdiction over Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, because: (1) these Defendants have transacted business and transact business in the Commonwealth of Massachusetts specifically in relation to the sale, distribution, procurement, shipment, use, discarding, research into, assessment of risks, assessment of dangers, related to Defendants' Ciprofloxacin products; (2) these Defendants have contracted to supply services or things in the Commonwealth of Massachusetts, including Ciprofloxacin and other fluoroquinolones; (3) these Defendants have caused tortious injury by acts and omissions in the Commonwealth of Massachusetts, including the improper, negligent, reckless, and wrongful design, sale, shipment, and warning of Ciprofloxacin to consumers in the Commonwealth of Massachusetts; and (4) these Defendants have caused tortious injury in the Commonwealth of Massachusetts by actions or omissions outside of Massachusetts where the Defendants have regularly done and solicited business in the Commonwealth of Massachusetts.

34. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, have engaged in a persistent course of conduct in the Commonwealth of Massachusetts through their ongoing use, distribution, sale, and shipment of Ciprofloxacin and other fluroquinolones in the Commonwealth of Massachusetts.

35. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, derived substantial amounts of revenue in the Commonwealth of Massachusetts through their persistent use, distribution, sale, and shipment of Ciprofloxacin and other fluoroquinolones in the Commonwealth of Massachusetts.

36. This Court has jurisdiction over Defendants, Beth Israel Deaconess Hospital—Needham, Inc.; Beth Israel Deaconess Hospital—Needham Campus, Inc.; Beth Israel Deaconess Physician Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Defendant, Lahey Health System, Inc.; Affiliated Physicians, Inc.; Affiliated Physicians, Inc.; and Harvard University and the President and Fellows of Harvard College, in the Commonwealth of Massachusetts because (1) these Defendants have transacted business and transact business in the Commonwealth of Massachusetts specifically in relation to the sale, procurement, and rendering of healthcare services; (2) these Defendants have contracted to supply services or things in the Commonwealth of Massachusetts, including medical care; (3) these Defendants have caused tortious injury by acts and omissions in the Commonwealth of Massachusetts, including failing to warn about the dangerous effects of Ciprofloxacin and to properly prescribe this drug for patients; and (4) these Defendants are at home in Massachusetts and have their principal place of business in Massachusetts.

37. This Court has jurisdiction over Defendants, Heather Boxerman, M.D., and Alison Boyer, N.P., because: (1) these Defendants are domiciled in the Commonwealth of Massachusetts; (2) regularly transact business in Massachusetts in rendering healthcare services or care to patients;

(3) have contracted to supply healthcare services in Massachusetts; and (4) have caused tortious injury to Plaintiff in Massachusetts.

IV. CIPROFLOXACIN DANGERS AND TOXICITY

38. Ciprofloxacin is dangerous.

39. Ciprofloxacin is disabling.

40. Ciprofloxacin causes permanent, debilitating side effects and attacks the tendons, muscles, joints, nerves, and central nervous system.

41. Ciprofloxacin is a fluoroquinolone antibiotic prescription drug that is used to treat bacterial infections, including urinary tract infections, pneumonia, gastrointestinal infections, prostatitis, sexually transmitted infections, skin and skin structure infections, bone and joint infections, complicated intra-abdominal infections, typhoid fever, and infectious diarrhea.

42. As a fluoroquinolone, Ciprofloxacin prevents DNA replication in bacterial agents that enter the human body by restricting bacterial DNA topoisomerase and DNA-gyrase.

43. DNA topoisomerases are enzymes that provide proper functioning for genetic processes in bacterial cells.

44. By restricting the DNA topoisomerase and DNA-gyrase in bacterial cells, fluoroquinolones, including Ciprofloxacin, prevent the growth of bacterial agents that infect the human body.

45. Fluoroquinolones aid the human body in resisting complicated bacterial infections.

46. Scientists discovered fluoroquinolones in the 1960s as a derivative of chloroquine, an antimalarial drug.

47. In the 1980s, scientists at Bayer Pharmaceuticals discovered Ciprofloxacin after substituting the ethyl group of norfloxacin with a cyclopropyl group increased Gram-negative activity.

48. Cipro was initially patented in 1983 by Bayer A.G.

49. In 1987, Bayer received approval for a United States patent on ciprofloxacin hydrochloride, the active ingredient in Cipro.

50. The patent Bayer received expired in December 2003.

51. Between 1987 and 2003, Bayer designed, produced, manufactured, and sold Cipro on the market for prescription use.

52. During this time, Bayer sold Cipro exclusively in the United States, acquiring over $6 billion in gross sales.

53. Although Bayer's patent for Cipro expired in December 2003, other pharmaceutical corporations subsequently manufactured and sold generic versions known as Ciprofloxacin.

54. West-Ward Pharmaceuticals Corporation, designed, manufactured, produced, distributed, and sold Ciprofloxacin throughout the United States.

55. On January 1, 1991, Hikma Pharmaceuticals acquired West-Ward Pharmaceuticals, and rebranded this wholly-owned subsidiary as "Hikma Pharmaceuticals USA, Inc.," on June 26, 2018.

56. At all relevant times, Defendants, Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, West-Ward Pharmaceuticals Corporation, Bayer Corporation, Bayer Pharmaceuticals Corporation, and Bayer Healthcare Pharmaceuticals, Inc., designed, manufactured, sold, distributed, created, marketed, and advertised Ciprofloxacin throughout the United States.

57. In October 1996, the FDA issued a statement in its Medical Bulletin to all manufacturers of fluoroquinolones requesting that drug packaging include new language in the "Warnings" section acknowledging the risk of tendonitis and tendon rupture in fluoroquinolones.

58. On May 28, 2005, the Illinois Attorney General submitted a Citizen Petition to the FDA, petitioning the FDA to warn consumers about the risk of tendon rupture associated with fluoroquinolone use.

59. In its petition to the FDA, the Illinois Attorney General urged the administration to (1) "revise drug labeling to strengthen warnings of the potential for the serious adverse event of tendinopathy and tendon rupture," (2) "create a 'Black Box' warning to reflect the risk and severity of this adverse side effect," (3) "require manufacturers of fluoroquinolone antibiotics to issue a 'Dear Health Care Professional' letter to inform health care providers about this significant hazard to health and announce the changes in drug package labeling," (4) "supplement information provided to patients with bolded warnings about the risk of tendinopathy and tendon rupture," and (5) submit the class of fluoroquinolone drugs for review to the FDA's Drug Safety Oversight Board."

60. The May 2005 petition warned the FDA that based on data from the FDA Adverse Event database, fluoroquinolones were "implicated significantly more often in tendon ruptures than any other class of drugs (38 percent of all tendon ruptures were thought due to fluoroquinolones)."

61. According to data from the FDA Adverse Event database, twenty-three percent of fluoroquinolone-associated tendon ruptures were specifically linked to Ciprofloxacin.

62. Arnold Widen, M.D., Medical Director with the Illinois Attorney General's Office and Babs Waldman, M.D., Medical Director at the Illinois Health Care Bureau, drafted a petition

to the FDA entitled "Illinois Attorney General's Office Citizen Petition, Docket No. 2005P-0205 Fluoroquinolone-Induced Tendinopathies," requesting action to enact proper and robust warnings regarding the risk of tendon rupture and tendinopathy associated with fluoroquinolone use.

63. When the FDA failed to take appropriate action, the Illinois Attorney General filed suit against the administration in January 2007.

64. On July 8, 2008, the FDA, for the first time, announced a Boxed Warning to fluoroquinolones for increased risk of tendinitis and tendon rupture.

65. In February 2011, the FDA added warnings to the original 2008 Boxed Warning concerning the risk of worsening symptoms for consumers with myasthenia gravis.

66. In August 2013, the FDA mandated updates to fluoroquinolone warning labels to "describe the potential for irreversible peripheral neuropathy" which is associated with critical nerve damage.

67. In November 2015, the FDA held a public advisory committee to discuss the risks and benefits of fluoroquinolone antibacterial medicines for the treatment of uncomplicated urinary tract infections, acute bacterial sinusitis, and acute bacterial exacerbation of chronic bronchitis in patients with chronic obstructive pulmonary disease.

68. The FDA committee concluded that the "serious risks associated with the use of fluoroquinolones for these types of uncomplicated infections generally outweighed the benefits for patients with other treatment options."

69. On May 12, 2016, the FDA published a safety announcement entitled "FDA Drug Safety Communication: FDA advises restricting fluoroquinolone antibiotic use for certain uncomplicated infections; warns about disabling side effects that can occur together."

70. In this public safety announcement, the FDA advised patients and healthcare professionals that "the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options" and further warned that patients with these conditions should refrain from using fluoroquinolones when other treatment options are available.

71. The FDA further warned that systematic use of fluoroquinolones is linked to "disabling and potentially permanent serious side effects that can occur together," including side effects that impact the tendons, muscles, joints, nerves, and central nervous system.

72. The FDA mandated enhanced label warnings, requiring fluoroquinolone drug labels and Medication guides to include updated warnings disclosing the impact of systematic use of fluoroquinolones on the human body.

73. Notably, in its May 2016 statement, the FDA warned healthcare professionals that they should suspend fluoroquinolone treatment when a patient reports "serious side effects" and switch the patient to a non-fluoroquinolone antibacterial drug.

74. On July 26, 2016, the FDA announced enhanced warning labeling changes, including an updated Boxed Warning and revisions to the Warnings and Precautions section of labels concerning the risk of "disabling and potentially irreversible adverse reactions that can occur together."

75. In accordance with these enhanced warnings, the FDA also mandated new "limitation-of-use statements to reserve fluoroquinolones for patients who do not have other available treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis and uncomplicated urinary tract infections."

76. The FDA also determined that fluoroquinolones should be reserved for use in patients where "no alternative treatment options" are available for patients with acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections.

77. On July 10, 2018, the FDA again announced new safety label changes for fluoroquinolones to warn patients concerning the risks of mental health side effects and serious blood sugar disturbances.

78. On December 20, 2018, the FDA issued a Drug Safety Communication, which found that fluoroquinolones "can increase the occurrence of rare but serious events of ruptures or tears" in the aorta that can cause "dangerous bleeding or even death."

79. As a result of this finding, the FDA issued yet another warning about the increased risk of aortic dissections or ruptures of aortic aneurysms in fluoroquinolone use.

80. In connection with this updated warning, the FDA warned healthcare providers that professionals should not prescribe fluoroquinolone antibiotics to patients with aortic aneurysms or who are at risk of such conditions.

81. The Ciprofloxacin drug product and packaging produced by Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, fails to specify, delineate, provide, or notify potential patients, healthcare providers, consumers, and buyers that the drug is reserved for use in patients with no alternative treatment options for urinary tract infections.

82. The Ciprofloxacin drug product and packaging produced by Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma

Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, fails to provide any warnings that Ciprofloxacin is unsafe or may cause harm to adult patients, consumers, and buyers with urinary tract infections.

83. At the time of their design, manufacture, advertising, and creation of Ciprofloxacin, Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, knew or should have known of the dangerous risks, including permanent disability and severe bodily harm, associated with the consumption of Ciprofloxacin based on the warnings and statistics published by the FDA between 2008 and 2021.

84. At the time of their design, manufacture, advertising, and creation of Ciprofloxacin, Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, knew or should have known that placing Ciprofloxacin on the market for sale to consumers created an imminent risk of serious bodily harm to patients with urinary tract infections, including patients with Escherichia Coli infections and low bacteria counts.

85. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, knew, prior to and during the design, manufacture, creation, and sale of their Ciprofloxacin drug products that, if they included a warning about the use of Ciprofloxacin in adult patients with urinary tract infections, their sales of Ciprofloxacin would likely be less than if the Ciprofloxacin drug labels and packaging did not contain a warning about such use.

86. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, consciously decided to disregard the known risk of disabling and irreversible serious adverse reactions to consumers posed by their Ciprofloxacin drug product because Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation wanted to maximize profits as much as humanly possible with respect to the Ciprofloxacin despite knowing that Ciprofloxacin posed a clear danger and risk to consumers due to the product's defective, negligent, reckless, and dangerous design.

87. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, knew or should have known that placing the dangerous Ciprofloxacin product on the market for sale would result in severe and permanent harm to patients with urinary tract infections, including but not limited to Plaintiff Talia Smith.

88. At the time of Plaintiff Talia Smith's ingestion of the Ciprofloxacin produced by Defendants, the drug was not in the condition expected by the ordinary consumer due to the excessively hazardous effects of the drug on the human body, including mast cell activation disorder, paresthesias, achilles tendinitis, significant gut alteration, and severe disability and the lack of any warning labels regarding the dangers of Ciprofloxacin in patients with urinary tract infections, low bacteria counts, and other alternative treatment options.

89. The severe and irreversible harm posed by Ciprofloxacin was not generally known and recognized by ordinary consumers, including Plaintiff, Talia Smith, due to the lack of any

warning labels on the Ciprofloxacin warning packet specifying the dangers of Ciprofloxacin consumption in patients with urinary tract infections and/or delineating that the drug should not be consumed by patients with other alternative treatment options.

90. At the time the Defendants sold the Ciprofloxacin that injured Plaintiff, the Ciprofloxacin was in a defective condition because the drug was in an unreasonably dangerous condition for all the reasons outlined throughout this Complaint, including the product's design, makeup, and ingredients.

91. At the time Defendants' Ciprofloxacin that injured Plaintiff was placed on the market, the drug was in a defective condition because it was unreasonably dangerous for all the reasons outlined throughout this Complaint, including the product's design, makeup, and ingredients.

92. The dangers and hazards of Ciprofloxacin, including the product's design, makeup, and ingredients, were at all times unknowable and unacceptable to the average or ordinary consumer, including Plaintiff Talia Smith.

93. At all times material hereto, based on the hazards and dangers of Ciprofloxacin, a reasonable person would conclude that the probability and seriousness of harm caused by the Ciprofloxacin outweighed the burden or costs of taking precautions, including but not limited to ensuring adequate warnings about the devastating and irreversible side effects posed by the drug and/or changing the drug's design, makeup, and ingredients to eliminate the hazards and dangers of the product.

V. MEDICAL MALPRACTICE

94. On or about April 14, 2021, Plaintiff Talia Smith was suspicious of a urinary tract infection and contacted her primary care physician, Heather Boxerman, M.D., at Affiliated Physicians Group.

95. Plaintiff had a urinalysis taken, which yielded a negative result.

96. On or about April 14, 2021, at 7:44 p.m., a urine culture sample was ordered by Dr. Boxerman and sent to the laboratory at Beth Israel Deaconess Hospital Needham for analysis.

97. On April 16, 2021, the results of the urine culture sample indicated a positive result for Escherichia Coli.

98. In a note entered April 16, 2021, by Dr. Boxerman, Plaintiff's "urine test showed a small amount of bacteria," and Plaintiff took Macrobid.

99. On April 17, 2021, Plaintiff called Dr. Boxerman's office, and her call was returned by Nurse Practitioner Alison Boyer.

100. Nurse Practitioner Boyer informed Plaintiff that Escherichia Coli is "gram negative" and that Macrobid does not treat Escherichia Coli because Macrobid is an antibiotic that exclusively treats gram-positive infections.

101. Despite being an effective antibiotic to treat gram-negative infections such as Escherichia Coli, Nurse Practitioner Boyer informed Plaintiff that she needed to switch to Cipro to treat her infection.

102. Plaintiff expressed concern regarding the prescription of Cipro and plainly communicated that she had previously experienced adverse reactions to antibiotics, including clostridium difficile (C. Diff) while prescribed Keflex.

103. Plaintiff also expressed concern and questioned the strength of Cipro because of the "small" bacteria count noted by Dr. Boxerman in her urine sample.

104. Remarkably, Plaintiff specifically asked Nurse Practitioner Boyer whether there was anything she needed to be aware of prior to being prescribed Cipro.

105. Nurse Practitioner Boyer downplayed and ignored Plaintiff's concerns, assuring Plaintiff that there was nothing she needed to know, and that Cipro was "very safe and effective for UTIs."

106. Unbeknownst to Plaintiff and as alleged in this Complaint, the FDA had issued multiple updated Boxed Warnings between 2008 and 2018, also known informally as "black box" warnings, regarding the adverse and potentially irreversible side effects linked to Ciprofloxacin.

107. Boxed Warnings are the highest safety-related warnings that medications are assigned by the FDA and warn consumers about significant risks associated with ingestion of the drug.

108. On May 12, 2016, the FDA published a safety announcement, advising patients and healthcare professionals that the harmful side effects associated with Ciprofloxacin generally "outweighed the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options."

109. The May 2016 FDA warning also advised that patients should refrain from using fluoroquinolones when alternative treatment options are available.

110. Despite multiple Boxed Warnings publicly available and published to healthcare providers through the FDA, Dr. Boxerman and Nurse Practitioner Boyer failed to provide and disclose any existing warnings regarding the use, consumption, and prescription of Ciprofloxacin for patients.

111. At all relevant times, Dr. Boxerman and Nurse Practitioner Boyer were licensed professionals in the Commonwealth of Massachusetts and learned intermediaries regarding fluoroquinolones, including ciprofloxacin.

112. Adding insult to injury, neither Nurse Practitioner Boyer nor Dr. Boxerman disclosed any of the potential adverse effects associated with Ciprofloxacin—even though Plaintiff directly asked whether she needed to know anything about her prescription of this harmful drug.

113. On April 17, 2021, Nurse Practitioner Boyer and/or Dr. Boxerman provided Plaintiff with a prescription for fourteen (14) Ciprofloxacin 500 milligram oral tablets.

114. The manufacturer listed on Plaintiff's pharmacy prescription was Defendant, "West-Ward," a wholly-owned subsidiary of Hikma Pharmaceuticals USA, Inc. and designer and producer of Ciprofloxacin.

115. After ingesting the first two dosages of her Ciprofloxacin prescription, Plaintiff experienced worsening pain in her lower extremities on April 18, 2021.

116. By 5:00 p.m., on April 18, 2021, Plaintiff sustained severe heel pain and difficulty standing due to pain in her lower extremities.

117. On April 19, 2021, Plaintiff experienced diarrhea and gastrointestinal complications in the morning hours and attempted to contact Dr. Boxerman's office.

118. Plaintiff continued to experience persistent pain in her feet and ankles, which were self-described as similar to "pins and needles."

119. On April 20, 2021, Plaintiff presented to the emergency department at Beth Israel Deaconess Hospital Needham with severe pain on her left leg with difficulty standing.

120. While in the emergency department, Plaintiff received an ultrasound venous duplex of the left lower extremities, which demonstrated "no evidence of deep venous thrombosis in the left lower extremity veins."

121. Plaintiff was assessed by Jason J. Lewis, M.D. ("Dr. Lewis"), who noted that Plaintiff may have sustained "inflammation from the ciprofloxacin" and that Plaintiff's "lab tests are reassuring."

122. Plaintiff was diagnosed with "achilles tendinopathy from cipro."

123. Plaintiff discontinued Ciprofloxacin and was discharged with instructions to "take ibuprofen 400 mg every 6 hours and/or Tylenol 650 mg every 6 hours as needed for pain control."

124. On May 3, 2021, Plaintiff presented to the emergency department at Beth Israel Deaconess Needham with a "headache and neuro symptoms."

125. Plaintiff received an MRI of her head, neck, brain, and cervical spine.

126. The brain and cervical spine MRI demonstrated "no acute intracranial pathology, infarction, or demyelinating disease."

127. Plaintiff was started on 100 mg of gabapentin and referred to a neurology urgent care clinic following discharge.

128. On May 4, 2021, Plaintiff had a telehealth visit with Dr. Boxerman, who noted concern for "persistent symptoms and elevated CRP and worry this could be side effect from cipro."

129. Dr. Boxerman diagnosed Plaintiff with paresthesia of upper limb and further noted that "staff will facilitate getting an urgent referral to neurology."

130. Throughout Plaintiff's treatment, Dr. Boxerman continued to downplay, ignore, and delay proper diagnosis of Plaintiff's adverse effects to Ciprofloxacin, resulting in approximately six (6) months of hospice care and recurrent hospitalizations for Plaintiff.

131. On December 28, 2023, the FDA announced that it would withdraw its approval of Ciprofloxacin hydrochloride oral tablet, equivalent to 100 mg base under new drug application 019537 and five generic ciprofloxacin HCL, oral tablet, EQ 100 mg base products. The holders of these applications purportedly requested withdrawal of the 100 mg strength products applications to the FDA and waived their opportunity to a hearing.

132. As a direct and proximate result of the negligence of the Defendants and their agents, as detailed throughout this Complaint, Plaintiff Talia Smith suffered severe and permanent injuries and disability.

133. As a direct and proximate cause of the negligence of Defendants and their agents, as stated throughout this Complaint, Plaintiff Talia Smith has suffered the following avoidable injuries and damages, the full extent of which is not yet known:

a) Mast cell activation disorder;

b) Paresthesias;

c) Achilles tendinitis;

d) Hospice;

e) Myalgias;

f) Weight loss;

g) Malnutrition;

h) Chronic pain syndrome;

i) Ulcers;

j) Abnormal skin tone;

k) Paresthesia of upper limb;

l) Paresthesia of skin;

m) Neuropathic pain;

n) Muscle weakness;

o) Dysphagia;

p) Significant gut alteration;

q) Permanent or semi-permanent disability;

r) Nausea;

s) Fevers;

t) Impaired strength;

u) Impaired endurance;

v) Loss of consciousness;

w) Migraines;

x) Headaches;

y) Nightmares;

z) Insomnia;

aa) Depression;

bb) Limited range of motion;

cc) Impaired balance;

dd) Impaired locomotion;

ee) Impaired gait;

ff) Impaired activities of daily living;

gg) Impaired manual dexterity;

hh) Impaired coordination;

ii) Impaired skin integrity;

jj) Need for MRIs;

kk) Occupational therapy;

ll) Physical therapy;

mm) Past and future pain and suffering;

nn) Past and future medical bills and expenses;

oo) Past and future loss of income and earning capacity;

pp) Past and future loss of life's pleasures;

qq) Past and future emotional distress;

rr) Past and future embarrassment;

ss) Past and future disfigurement;

tt) Past and future humiliation;

uu) Incidental expenses; and

vv) All damages allowable under the law.

134. Plaintiff's injuries and damages were caused solely by the negligence, recklessness, breach of warranty, fraud, and wrongful conduct of the Defendants and their agents and employees, as set forth throughout this Complaint.

VI. CLAIMS AND CAUSES OF ACTION

COUNT I—STRICT PRODUCTS LIABILITY (DESIGN DEFECT)
PLAINTIFF v. BAYER CORPORATION, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., HIKMA PHARMACEUTICALS USA, INC., HIKMA PHARMACEUTICALS PLC, AND WEST-WARD PHARMACEUTICALS CORPORATION

135. The preceding paragraphs of this Complaint are incorporated as though fully set forth herein.

136. At all relevant times, Defendants, Bayer, Hikma, and West-Ward were the manufacturers of ciprofloxacin.

137. These Defendants defectively designed ciprofloxacin because the gravity of physical harm and danger from severe adverse side effects is substantial, including tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis.

138. The likelihood of damaging and irreparable harm occurring due to the numerous hazardous and dangerous effects on patients posed by ciprofloxacin is and was at all times a guaranteed certainty, and Defendants, Bayer, Hikma, and West-Ward, at all times knew this and have known this based on data, statistics, and multiple warnings published by the FDA.

139. At all times, Defendants, Bayer, Hikma, and West-Ward had at their disposal feasible alternative chemicals, medicine, methods, and solutions other than toxic fluoroquinolones that were safer to patients than fluoroquinolones. At all times, Defendants Bayer, Hikma, and West-Ward had an available design modification through use of these alternative chemicals, medicine, methods, and solutions that would have reduced the risks posed by fluoroquinolones, including ciprofloxacin, without undue cost or interference with the performance of the products.

140. At all times, ciprofloxacin, including fluoroquinolones, were unreasonably dangerous because fluoroquinolones, due to their severe adverse effects, including tendinitis and tendon rupture, peripheral neuropathy, central nervous system effects, and disabling properties, are dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

141. At all times, ciprofloxacin was unreasonably dangerous due to the defects in the design of the drug.

142. At all times, ciprofloxacin was unreasonably dangerous because the fluoroquinolones manufactured, distributed, promoted, and sold by Defendants lacked adequate warnings to communicate the nature, gravity, and severity of the many harmful effects of ciprofloxacin on the human body.

143. As a direct and proximate cause of the defective design of ciprofloxacin that was manufactured by Defendants, Bayer, Hikma, and West-Ward, Plaintiff was caused to suffer injuries and damages set forth throughout this Complaint.

WHEREFORE, Plaintiff, Talia Smith, respectfully demands judgment against Defendants, including punitive damages, individually, jointly and severally, for sums including interest, prejudgment interest, and costs.

COUNT II—STRICT PRODUCTS LIABILITY (FAILURE TO WARN) PLAINTIFF v. BAYER CORPORATION, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., HIKMA PHARMACEUTICALS USA, INC., HIKMA PHARMACEUTICALS PLC, AND WEST-WARD PHARMACEUTICALS CORPORATION

144. Plaintiff hereby incorporates by reference all the averments and allegations previously averred and alleged throughout this Complaint.

145. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals

PLC, and West-Ward Pharmaceuticals Corporation, are strictly liable for failure to warn in or more of the following ways with respect to these Defendants' ciprofloxacin drugs:

a) Failure to warn that ciprofloxacin, or other fluoroquinolones, are unsafe for use when alternative treatment options are available in patients with urinary tract infections caused by Escherichia coli;

b) Failure to specify any minimal bacterial infection count that would allow patients with urinary tract infections to understand when ciprofloxacin is safe to use;

c) Failure to warn that ciprofloxacin is unsafe and hazardous for patients with urinary tract infections;

d) Failure to warn that ciprofloxacin use may cause mast cell activation disorder;

e) Failure to warn that ciprofloxacin use may cause significant gut alteration;

f) Failure to warn that patients should refrain from using ciprofloxacin, including other fluoroquinolones, when any other treatment alternative is available; and

g) Failure to warn that patients should refrain from using ciprofloxacin, including other fluoroquinolones, when urinary tract infections caused specifically by Escherichia coli are low in bacteria count;

146. As a direct factual and proximate result and cause of the Defendants' foregoing failures to warn regarding the hazards and dangers of ciprofloxacin, Plaintiff suffered and sustained injuries as damages as alleged throughout this Complaint.

WHEREFORE, Plaintiff, Talia Smith, demands damages against all Defendants, jointly and severally, including punitive damages, prejudgment interest, delay damages, and costs on all counts.

COUNT III—STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT)
PLAINTIFF v. BAYER CORPORATION, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., HIKMA PHARMACEUTICALS USA, INC., HIKMA PHARMACEUTICALS PLC, AND WEST-WARD PHARMACEUTICALS CORPORATION

147. Plaintiffs hereby incorporate by reference all the averments and allegations previously averred and alleged throughout this Complaint.

148. At all relevant times, Defendants Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, manufactured, distributed, and/or sold the ciprofloxacin prescribed and ingested by Plaintiff.

149. At the time the ciprofloxacin that Plaintiff ingested left the possession of Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, the ciprofloxacin contained a number of manufacturing defects, which made the product defective and unreasonably dangerous in one or more of the following ways:

a) The drug failed to contain the correct proportion of active ingredients to make the product absorb within the body properly when ingested;

b) The drug failed to contain ingredients sufficient to ensure patients did not sustain excruciating pain within twenty-four (24) hours of ingestion;

c) Improper makeup of ingredients, including but not limited to, the chemical composition used and or the composition of the capsule;

d) The product failed to contain essential ingredients and/or contained improper ingredients to make it so that the product did not trigger headaches and nausea;

e) The product failed to contain essential ingredients and/or contained improper ingredients to make it so that the product did not trigger headaches and nausea;

f) The product failed to contain essential ingredients and/or contained improper ingredients to make it so that the product did not cause paresthesia;

g) The product failed to contain essential ingredients and/or contained improper ingredients to make it so that the product did not cause insomnia, nightmares, depression, and anxiety;

h) The product failed to contain essential ingredients and/or contained improper ingredients to make it so that the product did not cause insomnia, nightmares, depression, and anxiety; and

i) The product failed to contain essential ingredients and/or contained improper ingredients to make it so that the product did not cause achilles tendinopathy, muscle weakness, and neuropathic pain.

150. As a direct and proximate result and cause of the Defendants' manufacturing defect(s) in the ciprofloxacin produced and ingested, Plaintiff, Talia Smith, suffered and sustained the injuries and damages as alleged throughout this Complaint.

WHEREFORE, Plaintiff, Talia Smith, demands damages against Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Hikma Pharmaceuticals USA, Inc., Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, jointly and severally, including punitive damages, prejudgment interest, delay damages, and costs on all counts.

COUNT IV—NEGLIGENT DESIGN
PLAINTIFF v. BAYER CORPORATION, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., HIKMA PHARMACEUTICALS USA, INC., HIKMA PHARMACEUTICALS PLC, AND WEST-WARD PHARMACEUTICALS CORPORATION

151. Plaintiff hereby incorporates by reference all of the averments and allegations previously averred and alleged throughout this Complaint.

152. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals

PLC, and West-Ward Pharmaceuticals Corporation, were negligent and reckless in their design of ciprofloxacin in one or more of the following ways:

a) Failure to properly and adequately perform safety testing on ciprofloxacin prior to placing the drug on the market;

b) Improper balancing of the molecules and chemical compounds used in ciprofloxacin;

c) Failure to design the product to include adequate warnings regarding the risks and hazards of ingesting ciprofloxacin;

d) Failure to design the product to include warnings that conformed with FDA regulations and Boxed Warnings for fluoroquinolones;

e) Designing the product that poses an unreasonably dangerous risk of tendinopathy, paresthesia, and myalgia;

f) Improper composing the design of the product to include an unsafe mixture of materials and ingredients;

g) Designing the product in such a way that poses an unreasonably dangerous risk of permanent, irreversible damage to the body and central nervous system;

h) Designing the product in such a way that poses an unreasonably dangerous risk of permanent disability; Failure to warn that ciprofloxacin, or other fluoroquinolones, are unsafe for use when alternative treatment options are available in patients with urinary tract infections caused by Escherichia coli;

i) Failure to specify any minimal bacterial infection count that would allow patients with urinary tract infections to understand when ciprofloxacin is safe to use;

j) Failure to warn that ciprofloxacin is unsafe and hazardous for patients with urinary tract infections;

k) Failure to warn that ciprofloxacin use may cause mast cell activation disorder;

l) Failure to warn that ciprofloxacin use may cause significant gut alteration;

m) Failure to warn that patients should refrain from using ciprofloxacin, including other fluoroquinolones, when any other treatment alternative is available; and

n) Failure to warn that patients should refrain from using ciprofloxacin, including other fluoroquinolones, when urinary tract infections caused specifically by Escherichia coli are low in bacteria count;

153. As a direct factual and proximate result and cause of the Defendants' negligent design of ciprofloxacin, Plaintiff, Talia Smith, suffered and sustained injuries and damages as alleged throughout this Complaint.

WHEREFORE, Plaintiff, Talia Smith, demands damages against the Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, jointly and severally, including punitive damages, prejudgment interest, delay damages, and costs on all counts.

COUNT V—NEGLIGENT FAILURE TO WARN
PLAINTIFF v. BAYER CORPORATION, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., HIKMA PHARMACEUTICALS USA, INC., HIKMA PHARMACEUTICALS PLC, AND WEST-WARD PHARMACEUTICALS CORPORATION

154. Plaintiff hereby incorporates by reference all of the averments and allegations previously averred and alleged throughout this Complaint.

155. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, were negligent and reckless in their design of ciprofloxacin in one or more of the following ways:

a) Failure to warn that ciprofloxacin, or other fluoroquinolones, are unsafe for use when alternative treatment options are available in patients with urinary tract infections caused by Escherichia coli;

b) Failure to specify any minimal bacterial infection count that would allow patients with urinary tract infections to understand when ciprofloxacin is safe to use;

c) Failure to warn that ciprofloxacin is unsafe and hazardous for patients with urinary tract infections;

d) Failure to warn that ciprofloxacin use may cause mast cell activation disorder;

e) Failure to warn that ciprofloxacin use may cause significant gut alteration;

f) Failure to warn that patients should refrain from using ciprofloxacin, including other fluoroquinolones, when any other treatment alternative is available; and

g) Failure to warn that patients should refrain from using ciprofloxacin, including other fluoroquinolones, when urinary tract infections caused specifically by Escherichia coli are low in bacteria count;

156. As a direct factual and proximate result and cause of the Defendants' negligent failure to warn of ciprofloxacin, Plaintiff, Talia Smith, suffered and sustained injuries and damages as alleged throughout this Complaint.

WHEREFORE, Plaintiff, Talia Smith, demands damages against these Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, jointly and severally, including punitive damages, prejudgment interest, delay damages, and costs on all counts.

COUNT VI—NEGLIGENCE
PLAINTIFF v. BAYER CORPORATION, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., HIKMA PHARMACEUTICALS USA, INC., HIKMA PHARMACEUTICALS PLC, AND WEST-WARD PHARMACEUTICALS CORPORATION

157. Plaintiffs hereby incorporate by reference all the averments and allegations previously averred and alleged throughout this Complaint.

158. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals

PLC, and West-Ward Pharmaceuticals Corporation, were negligent and reckless in their design of ciprofloxacin in or more of the following ways:

a) Improper oversight and supervision over the manufacturing process to ensure that the product was made in a method and manner that did not produce unreasonable hazards and dangers to the human body, including the unreasonable risk of tendinitis, tendinopathy, and tendon rupture; peripheral neuropathy; central nervous system damage, and muscle weakness;

b) Improper oversight and supervision over the design process to ensure that the product was made in a method and manner that did not produce unreasonable hazards and dangers, including the unreasonable risk of tendinitis, tendinopathy, and tendon rupture; peripheral neuropathy; central nervous system damage, and muscle weakness;

c) Improper oversight and supervision over the process and decision making regarding what warnings, if any, should accompany ciprofloxacin;

d) Failure to perform adequate and proper testing to ensure that ciprofloxacin did not contain unreasonable hazards and dangers, including the unreasonable risk of tendinitis, tendinopathy, and tendon rupture; peripheral neuropathy; central nervous system damage, and muscle weakness;

h) Failure to properly and adequately perform safety testing on ciprofloxacin prior to placing the drug on the market;

i) Improper balancing of the molecules and chemical compounds used in ciprofloxacin;

j) Failure to design the product to include adequate warnings regarding the risks and hazards of ingesting ciprofloxacin;

k) Failure to design the product to include warnings that conformed with FDA regulations and Boxed Warnings for fluoroquinolones;

l) Designing the product that poses an unreasonably dangerous risk of tendinopathy, paresthesia, and myalgia;

m) Improper composing the design of the product to include an unsafe mixture of materials and ingredients;

n) Designing the product in such a way that poses an unreasonably dangerous risk of permanent, irreversible damage to the body and central nervous system;

o) Designing the product in such a way that poses an unreasonably dangerous risk of permanent disability; Failure to warn that ciprofloxacin, or other fluoroquinolones, are unsafe for use when alternative treatment options are available in patients with urinary tract infections caused by Escherichia coli;

p) Failure to specify any minimal bacterial infection count that would allow patients with urinary tract infections to understand when ciprofloxacin is safe to use;

q) Failure to warn that ciprofloxacin is unsafe and hazardous for patients with urinary tract infections;

r) Failure to warn that ciprofloxacin use may cause mast cell activation disorder;

s) Failure to warn that ciprofloxacin use may cause significant gut alteration;

t) Failure to warn that patients should refrain from using ciprofloxacin, including other fluoroquinolones, when any other treatment alternative is available; and

u) Failure to warn that patients should refrain from using ciprofloxacin, including other fluoroquinolones, when urinary tract infections caused specifically by Escherichia coli are low in bacteria count;

159. As a direct factual and proximate result and cause of the Defendants' negligence and recklessness, Plaintiff, Talia Smith, suffered and sustained injuries and damages as alleged throughout this Complaint.

WHEREFORE, Plaintiff, Talia Smith, demands damages against these Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, jointly and severally, including punitive damages, prejudgment interest, delay damages, and costs on all counts.

COUNT VII—BREACH OF IMPLIED WARRANTY
PLAINTIFF v. BAYER CORPORATION, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., HIKMA PHARMACEUTICALS USA, INC., HIKMA PHARMACEUTICALS PLC, AND WEST-WARD PHARMACEUTICALS CORPORATION

160. Plaintiffs hereby incorporate by reference all the averments and allegations previously averred and alleged throughout this Complaint.

161. At all relevant times, Defendants manufactured, distributed, advertised, promoted, and sold ciprofloxacin.

162. At all relevant times, Defendants intended that ciprofloxacin would be prescribed to and ingested by patients with urinary tract infections and other health complications, including Talia Smith, at the time that Talia Smith ingested ciprofloxacin.

163. At all relevant times, Defendants impliedly warranted that ciprofloxacin was safe, of merchantable quality, fit for its intended use, and had been adequately tested.

164. Defendants were aware and knew that consumers, including Plaintiff, Talia Smith, would purchase and ingest ciprofloxacin without any instruction, direction, or notice of the harmful and damaging side effects associated with ciprofloxacin.

165. Plaintiff was at all times in privity with each Defendant.

166. The Defendants' ciprofloxacin was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by the Defendants.

167. The Defendants represented in their packaging, labeling, advertising, and marketing of ciprofloxacin—including but not limited to the product's inadequate warnings—that ciprofloxacin was safe to be ingested by patients, including individuals with a urinary tract infection.

168. In reliance upon the implied warranties of the Defendants, Plaintiff did in fact use and consume ciprofloxacin in compliance with any instructions, directions, or warnings in the foreseeable manner normally intended, recommended, promoted, marketed, and expected by the Defendants.

169. Defendants breached their implied warranties to Plaintiff in that ciprofloxacin was not of merchantable quality, safe, or fit for its intended use, and was not adequately tested.

170. As a direct factual and proximate result and cause of the Defendants' breach of implied warranty, Plaintiff, Talia Smith, suffered and sustained injuries and damages as alleged throughout this Complaint.

WHEREFORE, Plaintiff, Talia Smith, demands damages against these Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, jointly and severally, including punitive damages, prejudgment interest, delay damages, and costs on all counts.

COUNT VIII—BREACH OF EXPRESS WARRANTY
PLAINTIFF v. BAYER CORPORATION, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., HIKMA PHARMACEUTICALS USA, INC., HIKMA PHARMACEUTICALS PLC, AND WEST-WARD PHARMACEUTICALS CORPORATION

171. Plaintiffs hereby incorporate by reference all of the averments and allegations previously averred and alleged throughout this Complaint.

172. At all relevant times, Defendants manufactured, distributed, advertised, promoted, and sold ciprofloxacin.

173. At all relevant times, Defendants intended that ciprofloxacin would be prescribed to and ingested by patients with urinary tract infections and other health complications, including Talia Smith, at the time that Talia Smith ingested ciprofloxacin.

174. At all relevant times, Defendants impliedly warranted that ciprofloxacin was safe, of merchantable quality, fit for its intended use, and had been adequately tested.

175. Defendants were aware and knew that consumers, including Plaintiff, Talia Smith, would purchase and ingest ciprofloxacin without any instruction, direction, or notice of the harmful and damaging side effects associated with ciprofloxacin.

176. Plaintiff was at all times in privity with each Defendant.

177. The Defendants' ciprofloxacin was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by the Defendants.

178. The Defendants represented in their packaging, labeling, advertising, and marketing of ciprofloxacin—including but not limited to the product's inadequate warnings—that ciprofloxacin was safe to be ingested by patients, including individuals with a urinary tract infection.

179. In reliance upon the implied warranties of the Defendants, Plaintiff did in fact use and consume ciprofloxacin in compliance with any instructions, directions, or warnings in the foreseeable manner normally intended, recommended, promoted, marketed, and expected by the Defendants.

180. Defendants breached their warranties to Plaintiff in that ciprofloxacin was not of merchantable quality, safe, or fit for its intended use, and was not adequately tested.

181. As a direct factual and proximate result and cause of the Defendants' breach of implied warranty, Plaintiff, Talia Smith, suffered and sustained injuries and damages as alleged throughout this Complaint.

WHEREFORE, Plaintiff, Talia Smith, demands damages against these Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, jointly and severally, including punitive damages, prejudgment interest, delay damages, and costs on all counts.

COUNT IX—FRAUD
PLAINTIFF v. BAYER CORPORATION, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., HIKMA PHARMACEUTICALS USA, INC., HIKMA PHARMACEUTICALS PLC, AND WEST-WARD PHARMACEUTICALS CORPORATION

182. The preceding paragraphs of the Complaint are incorporated as though fully set forth herein.

183. For years, Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, have fraudulently misrepresented the dangers and harm posed by fluoroquinolones, including iprofloxacin to the public and community.

184. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, by and through their agents and representatives, have repeatedly stated to the public that fluoroquinolones, including ciprofloxacin, are safe despite knowing this is not true.

185. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, by and through their agents and representatives, have repeatedly misrepresented, hidden, manipulated, and misstated the import and meaning of scientific and medical literature and data regarding the risks and dangers linked to fluoroquinolones, including ciprofloxacin.

186. These statements made by Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, constitute false representations of material facts with Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation's knowledge of the falsity of the statements.

187. Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, have persistently, routinely, and fraudulently concealed material facts regarding the risks, dangers, and toxicity of fluoroquinolones, including ciprofloxacin.

188. These fraudulent statements made by Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, were made for the purpose of inducing members of the public, including Plaintiff, to act thereon.

189. These fraudulent statements made by Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, were made for the purpose of inducing members of the public, including Plaintiff, to refrain from acting and refrain from investigating or discovering the true nature and extent of the dangers of fluoroquinolones and the misconduct of the Defendants, as published and reported by the FDA.

190. Plaintiff has relied on these fraudulent statements and misrepresentations made by Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, and has acted upon them to her own detriment, harm, and damage.

191. As a direct and proximate cause of the fraud of Defendants, Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Hikma Pharmaceuticals USA, Inc., Hikma Pharmaceuticals PLC, and West-Ward Pharmaceuticals Corporation, Plaintiff was caused to suffer the injuries and damages set forth throughout this Complaint.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants, including punitive damages, individually, jointly and severally, for sums including all interest, prejudgment interest and costs.

COUNT X—MEDICAL PROFESSIONAL NEGLIGENCE
PLAINTIFF v. HEATHER BOXERMAN, M.D., AND VICARIOUSLY AND DERIVATIVELY, BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM, INC.; BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM CAMPUS, INC.; BETH ISRAEL DEADONESS PHYSICIAN ORGANIZATION, INC.; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC, D/B/A BETH ISRAEL DEACONESS CARE ORGANIZATION LLC; BETH ISRAEL LAHEY HEALTH

PRIMARY CARE, INC.; BETH ISRAEL LAHEY HEALTH, INC.; DEFENDANT, LAHEY SYSTEM, INC.; AFFILIATED PHYSICIANS, INC.; AND HARVARD UNIVERSITY AND THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

192. The preceding paragraphs of this Complaint are incorporated as though fully set forth herein.

193. The negligent acts and omissions of Dr. Boxerman consisted of one or more of the following:

a) Failure to timely disclose all warnings as a learned intermediary, including the warning label and Boxed Warnings issued and published by the FDA, to Plaintiff regarding the harmful and dangerous effects of fluoroquinolones prior to prescribing ciprofloxacin;

b) Failure to timely disclose, as a learned intermediary, all potential harmful effects of fluoroquinolones, including the possibility of serious adverse reactions such as tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis, prior to prescribing the drug to Plaintiff;

c) Failure to inform Plaintiff of alternative, safe antibiotics or medication when such alternatives were available to treat Plaintiff's urinary tract infection;

d) Failure to prescribe a safe alternative antibiotic to Plaintiff to timely treat the urinary tract infection;

e) Failure to timely discontinue Plaintiff's ciprofloxacin prescription when Plaintiff began demonstrating early and clear symptoms of adverse side effects linked to fluoroquinolones;

f) Failure to follow the FDA's July 26, 2016, enhanced warning mandates by not prescribing an alternative treatment option for Plaintiff's uncomplicated urinary tract infection when such alternative treatment option was available;

g) Failure to follow the FDA's July 26, 2016, enhanced warning mandates by not prescribing an alternative treatment option for Plaintiff's uncomplicated urinary tract infection when Plaintiff's bacterial count was "small;"

h) Failure to fully, accurately, and timely answer Plaintiff's questions regarding the safety and administration of ciprofloxacin before prescribing this powerful antibiotic;

i) Failure to intervene in a timely manner to Plaintiff's tendinopathy and myalgia;

j) Failure to ensure Plaintiff was timely examined and assessed by a neurologist following the observation and notation of Plaintiff's tendinopathy, myalgia, and paresthesia;

k) Failure to oversee all persons rendering care to Plaintiff, including but not limited to Alison Boyer, N.P.

l) Failure to promptly and adequately evaluate and monitor Plaintiff, given the circumstances described above;

m) Failure to timely and properly communicate with the other healthcare providers caring for Plaintiff, including Alison Boyer, N.P.;

n) Failure to stay informed as to updates in medical and scientific literature and FDA regulations and guidelines concerning fluoroquinolones, including ciprofloxacin;

o) Failure to prevent the permanent or semi-permanent disability, myalgia, mast cell activation disorder, tendinitis, and other harm sustained by Plaintiff as a result of not intervening to timely correct blatantly false medical advice and misrepresentations rendered to Plaintiff by Nurse Practitioner Boyer concerning the safety of ciprofloxacin; and

p) Failure to timely perform and complete a thorough physical examination and assessment of Plaintiff at Affiliated Physicians, Inc.

194. As a direct and proximate cause of the negligence of Dr. Boxerman, Plaintiff, Talia Smith, sustained the injuries and damages set forth throughout the Complaint.

WHEREFORE, Plaintiff, Talia Smith, respectfully demands judgment against Defendants, including punitive damages, individually, jointly and severally, for sums including all interest, prejudgment interest and costs.

COUNT XI—MEDICAL PROFESSIONAL NEGLIGENCE

PLAINTIFF v. ALISON BOYER, N.P., AND VICARIOUSLY AND DERIVATIVELY, BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM, INC.; BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM CAMPUS, INC.; BETH ISRAEL DEADONESS PHYSICIAN ORGANIZATION, INC.; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC, D/B/A BETH ISRAEL

DEACONESS CARE ORGANIZATION LLC; BETH ISRAEL LAHEY HEALTH PRIMARY CARE, INC.; BETH ISRAEL LAHEY HEALTH, INC.; DEFENDANT, LAHEY SYSTEM, INC.; AFFILIATED PHYSICIANS, INC.; AND HARVARD UNIVERSITY AND THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

195. The preceding paragraphs of this Complaint are incorporated as though fully set forth herein.

196. The negligent acts and omissions of Nurse Practitioner Boyer consisted of one or more of the following:

a) Failure to timely disclose all warnings, including the warning label and Boxed Warnings issued and published by the FDA, to Plaintiff regarding the harmful and dangerous effects of fluoroquinolones prior to prescribing ciprofloxacin;

b) Failure to timely disclose all potential harmful effects of fluoroquinolones, including the possibility of serious adverse reactions such as tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis, prior to prescribing the drug to Plaintiff;

c) Failure to inform Plaintiff of alternative, safe antibiotics or medication when such alternatives were available to treat Plaintiff's urinary tract infection;

d) Failure to prescribe a safe alternative antibiotic to Plaintiff to timely treat the urinary tract infection;

e) Failure to timely discontinue Plaintiff's ciprofloxacin prescription when Plaintiff began demonstrating early and clear symptoms of adverse side effects linked to fluoroquinolones;

f) Failure to follow the FDA's July 26, 2016, enhanced warning mandates by not prescribing an alternative treatment option for Plaintiff's uncomplicated urinary tract infection when such alternative treatment option was available;

g) Failure to follow the FDA's July 26, 2016, enhanced warning mandates by not prescribing an alternative treatment option for Plaintiff's uncomplicated urinary tract infection when Plaintiff's bacterial count was "small;"

h) Failure to fully, accurately, and timely answer Plaintiff's questions regarding the safety and administration of ciprofloxacin before prescribing this powerful antibiotic;

i) Failure to intervene in a timely manner to Plaintiff's tendinopathy and myalgia;

j) Failure to ensure Plaintiff was timely examined and assessed by a neurologist following the observation and notation of Plaintiff's tendinopathy, myalgia, and paresthesia;

k) Failure to oversee all persons rendering care to Plaintiff, including but not limited to Alison Boyer, N.P.

l) Failure to promptly and adequately evaluate and monitor Plaintiff, given the circumstances described above;

m) Failure to timely and properly communicate with the other healthcare providers caring for Plaintiff, including Heather Boxerman, M.D.;

n) Failure to stay informed as to updates in medical and scientific literature and FDA regulations and guidelines concerning fluoroquinolones, including ciprofloxacin;

o) Failure to prevent the permanent or semi-permanent disability, myalgia, mast cell activation disorder, tendinitis, and other harm sustained by Plaintiff as a result of not intervening to timely correct blatantly false medical advice and misrepresentations rendered to Plaintiff by Nurse Practitioner Boyer concerning the safety of ciprofloxacin; and

p) Failure to timely perform and complete a thorough physical examination and assessment of Plaintiff at Affiliated Physicians, Inc.

197. As a direct and proximate cause of the negligence of Alison Boyer, N.P., Plaintiff, Talia Smith, sustained the injuries and damages set forth throughout the Complaint.

WHEREFORE, Plaintiff, Talia Smith, respectfully demands judgment against Defendants, including punitive damages, individually, jointly and severally, for sums including all interest, prejudgment interest and costs.

COUNT XII—MEDICAL PROFESSIONAL NEGLIGENCE/VICARIOUS LIABILITY
PLAINTIFF v. BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM, INC.; BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM CAMPUS, INC.; BETH ISRAEL DEADONESS PHYSICIAN ORGANIZATION, INC.; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC, D/B/A BETH ISRAEL DEACONESS CARE ORGANIZATION LLC; BETH ISRAEL LAHEY HEALTH PRIMARY CARE, INC.; BETH ISRAEL LAHEY HEALTH, INC.; DEFENDANT, LAHEY SYSTEM, INC.; AFFILIATED PHYSICIANS, INC.; AND HARVARD

UNIVERSITY AND THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

198. The preceding paragraphs of this Complaint are incorporated as though fully set forth herein.

199. The negligent acts and omissions of the employees, agents ostensible agents, apparent agents, shareholders, partners, officers, directors and/or managing agents, of Defendants, Beth Israel Deaconess Hospital—Needham, Inc.; Beth Israel Deaconess Hospital—Needham Campus, Inc.; Beth Israel Deaconess Physician Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Lahey Health System, Inc.; Affiliated Physicians, Inc.; Affiliated Physicians, Inc.; and Harvard University and the President and Fellows of Harvard College, and rendering care to Talia Smith, specifically including but not limited to, Heather Boxerman, M.D., Alison Boyer, N.P., and/or any physicians, residents, nurses, interns, fellows, technicians, medical students, nurses, and/or staff, who attended to, provided care to, or were responsible for providing care to Talia Smith, who are known to Defendants and unknown to Plaintiffs, consisted of one or more of the following:

a) Failure to timely disclose all warnings, including the warning label and Boxed Warnings issued and published by the FDA, to Plaintiff regarding the harmful and dangerous effects of fluoroquinolones prior to prescribing ciprofloxacin;

b) Failure to timely disclose all potential harmful effects of fluoroquinolones, including the possibility of serious adverse reactions such as tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis, prior to prescribing the drug to Plaintiff;

c) Failure to inform Plaintiff of alternative, safe antibiotics or medication when such alternatives were available to treat Plaintiff's urinary tract infection;

d) Failure to prescribe a safe alternative antibiotic to Plaintiff to timely treat the urinary tract infection;

e) Failure to timely discontinue Plaintiff's ciprofloxacin prescription when Plaintiff began demonstrating early and clear symptoms of adverse side effects linked to fluoroquinolones;

f) Failure to follow the FDA's July 26, 2016, enhanced warning mandates by not prescribing an alternative treatment option for Plaintiff's uncomplicated urinary tract infection when such alternative treatment option was available;

g) Failure to follow the FDA's July 26, 2016, enhanced warning mandates by not prescribing an alternative treatment option for Plaintiff's uncomplicated urinary tract infection when Plaintiff's bacterial count was "small;"

h) Failure to fully, accurately, and timely answer Plaintiff's questions regarding the safety and administration of ciprofloxacin before prescribing this powerful antibiotic;

i) Failure to intervene in a timely manner to Plaintiff's tendinopathy and myalgia;

j) Failure to ensure Plaintiff was timely examined and assessed by a neurologist following the observation and notation of Plaintiff's tendinopathy, myalgia, and paresthesia;

k) Failure to oversee all persons rendering care to Plaintiff, including but not limited to Alison Boyer, N.P.

l) Failure to promptly and adequately evaluate and monitor Plaintiff, given the circumstances described above;

m) Failure to timely and properly communicate with the other healthcare providers caring for Plaintiff, including Heather Boxerman, M.D.;

n) Failure to stay informed as to updates in medical and scientific literature and FDA regulations and guidelines concerning fluoroquinolones, including ciprofloxacin;

o) Failure to prevent the permanent or semi-permanent disability, myalgia, mast cell activation disorder, tendinitis, and other harm sustained by Plaintiff as a result of not intervening to timely correct blatantly false medical advice and misrepresentations rendered to Plaintiff by Nurse Practitioner Boyer concerning the safety of ciprofloxacin; and

p) Failure to timely perform and complete a thorough physical examination and assessment of Plaintiff at Affiliated Physicians, Inc.

200. As a direct and proximate cause of the negligence of the employees, agents, ostensible agents, apparent agents, shareholders, partners, officers, directors and/or managing agents, of Defendants, Beth Israel Deaconess Hospital—Needham, Inc.; Beth Israel Deaconess Hospital—Needham Campus, Inc.; Beth Israel Deaconess Physician Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Lahey Health System, Inc.; Affiliated Physicians, Inc.; Affiliated Physicians, Inc.; and Harvard University and the President and Fellows of Harvard College, as set forth above and throughout this Complaint, Plaintiff, Talia Smith, was caused to suffer the injuries and damages set forth throughout this Complaint.

WHEREFORE, Plaintiff, Talia Smith, respectfully demands judgment against Defendants, including punitive damages, individually, jointly and severally, for sums including all interest, prejudgment interest and costs.

COUNT XIII—CORPORATE NEGLIGENCE
PLAINTIFF v. BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM, INC.; BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM CAMPUS, INC.; BETH ISRAEL DEADONESS PHYSICIAN ORGANIZATION, INC.; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC, D/B/A BETH ISRAEL DEACONESS CARE ORGANIZATION LLC; BETH ISRAEL LAHEY HEALTH PRIMARY CARE, INC.; BETH ISRAEL LAHEY HEALTH, INC.; DEFENDANT, LAHEY SYSTEM, INC.; AFFILIATED PHYSICIANS, INC.; AND HARVARD UNIVERSITY AND THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

201. The preceding paragraphs of this Complaint are incorporated as though fully set forth herein.

202. The actions of Defendants, Beth Israel Deaconess Hospital—Needham, Inc.; Beth Israel Deaconess Hospital—Needham Campus, Inc.; Beth Israel Deaconess Physician

Organization, Inc.; Beth Israel Deaconess Physician Organization, LLC; Beth Israel Deaconess Physician Organization, LLC, d/b/a Beth Israel Deaconess Care Organization LLC; Beth Israel Lahey Health Primary Care, Inc.; Beth Israel Lahey Health, Inc.; Lahey Health System, Inc.; Affiliated Physicians, Inc.; Affiliated Physicians, Inc.; and Harvard University and the President and Fellows of Harvard College, constitute negligence in one or more of the following ways and about which they each had actual and/or constructive knowledge:

a) Failing to select and retain physicians and healthcare providers competent in the field of internal medicine, family medicine, and/or primary care;

b) Failing to select and retain physicians with the necessary skill, knowledge, and/or training to properly recognize and respond to adverse reactions caused by fluoroquinolone use, including ciprofloxacin;

c) Failing to select and retain physicians with the necessary skill, knowledge, and/or training to properly prescribe fluoroquinolones, including ciprofloxacin;

d) Failure to properly oversee and supervise the care provided by physicians and nurse practitioners at the Affiliated Physicians, Inc.;

e) Failing to create, implement, and/or enforce appropriate policies, procedures, and protocols to ensure physicians and nurse practitioners were reasonably informed about warnings from drug manufacturers regarding the proper use, adverse effects, and prescription of fluoroquinolones, including ciprofloxacin;

f) Failure to create, implement, and/or enforce appropriate policies, procedures, and protocols, to ensure a proper communication between physicians and other healthcare providers;

g) Failure to create, implement, and/or enforce appropriate policies, procedures, and protocols, to refer, recommend, or order patients with urinary tract infections to be prescribed with safe alternative treatment to fluoroquinolones, including ciprofloxacin;

203. As a direct and proximate cause of the corporate negligence set forth below, Plaintiff, Talia Smith, sustained the injuries and damages set forth throughout the Complaint.

WHEREFORE, Plaintiff, Talia Smith, respectfully demands judgment against Defendants, including punitive damages, individually, jointly and severally, for sums including all interest, prejudgment interest and costs.

COUNT XIV: BATTERY/LACK OF INFORMED CONSENT
PLAINTIFF v. DEFENDANT HEATHER BOXERMAN, M.D., AND VICARIOUSLY AND DERIVATIVELY, BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM, INC.; BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM CAMPUS, INC.; BETH ISRAEL DEADONESS PHYSICIAN ORGANIZATION, INC.; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC, D/B/A BETH ISRAEL DEACONESS CARE ORGANIZATION LLC; BETH ISRAEL LAHEY HEALTH PRIMARY CARE, INC.; BETH ISRAEL LAHEY HEALTH, INC.; DEFENDANT, LAHEY SYSTEM, INC.; AFFILIATED PHYSICIANS, INC.; AND HARVARD UNIVERSITY AND THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

204. The preceding paragraphs of this Complaint are incorporated as though fully set forth below.

205. Dr. Boxerman failed to disclose all material facts about ciprofloxacin prior to prescribing the drug for Plaintiff's urinary tract infection.

206. Dr. Boxerman failed to disclose to Plaintiff that ciprofloxacin had multiple Boxed Warnings and that the FDA had issued warnings to healthcare providers to prescribe the drug for urinary tract infections only when no safe alternative treatment option was available.

207. Dr. Boxerman failed to disclose to Plaintiff that ciprofloxacin can cause paresthesia, tendinitis, peripheral neuropathy, and irreversible adverse reactions.

208. Dr. Boxerman failed to disclose to Plaintiff whether safe alternative antibiotic prescription drugs were available to treat Plaintiff's urinary tract infection.

209. Dr. Boxerman failed to disclose the rate or percentage of risk fluoroquinolones, including ciprofloxacin, can cause harmful, debilitating reactions, such as paresthesia, tendinitis,

tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis, prior to prescribing the ciprofloxacin to Plaintiff;

210. The undisclosed information Dr. Boxerman failed to disclose to Plaintiff prior to the prescription of ciprofloxacin would have been a substantial factor in Plaintiff's decision whether to ingest ciprofloxacin as a fluoroquinolone to treat her urinary tract infection.

WHEREFORE, Plaintiff, Talia Smith, respectfully demands judgment against Defendants, including punitive damages, individually, jointly and severally, for sums including all interest, prejudgment interest and costs.

COUNT XV: BATTERY/LACK OF INFORMED CONSENT
PLAINTIFF v. DEFENDANT ALISON BOYER, N.P. AND VICARIOUSLY AND DERIVATIVELY, BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM, INC.; BETH ISRAEL DEACONESS HOSPITAL—NEEDHAM CAMPUS, INC.; BETH ISRAEL DEADONESS PHYSICIAN ORGANIZATION, INC.; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC; BETH ISRAEL DEACONESS PHYSICIAN ORGANIZATION, LLC, D/B/A BETH ISRAEL DEACONESS CARE ORGANIZATION LLC; BETH ISRAEL LAHEY HEALTH PRIMARY CARE, INC.; BETH ISRAEL LAHEY HEALTH, INC.; DEFENDANT, LAHEY SYSTEM, INC.; AFFILIATED PHYSICIANS, INC.; AND HARVARD UNIVERSITY AND THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

211. The preceding paragraphs of this Complaint are incorporated as though fully set forth below.

212. Nurse Practitioner Boyer failed to disclose all material facts about ciprofloxacin prior to prescribing the drug for Plaintiff's urinary tract infection.

213. Nurse Practitioner Boyer failed to disclose to Plaintiff that ciprofloxacin had multiple Boxed Warnings and that the FDA had issued warnings to healthcare providers to prescribe the drug for urinary tract infections only when no safe alternative treatment option was available.

214. Nurse Practitioner Boyer failed to disclose to Plaintiff that ciprofloxacin can cause paresthesia, tendinitis, peripheral neuropathy, and irreversible adverse reactions.

215. Nurse Practitioner Boyer failed to disclose to Plaintiff whether safe alternative antibiotic prescription drugs were available to treat Plaintiff's urinary tract infection.

216. Nurse Practitioner Boyer failed to disclose the rate or percentage of risk fluoroquinolones, including ciprofloxacin, can cause harmful, debilitating reactions, such as paresthesia, tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis, prior to prescribing the ciprofloxacin to Plaintiff;

217. The undisclosed information Nurse Practitioner Boyer failed to disclose to Plaintiff prior to the prescription of ciprofloxacin would have been a substantial factor in Plaintiff's decision whether to ingest ciprofloxacin as a fluoroquinolone to treat her urinary tract infection.

WHEREFORE, Plaintiff, Talia Smith, respectfully demands judgment against Defendants, including punitive damages, individually, jointly and severally, for sums including all interest, prejudgment interest and costs.

PRAYER FOR RELIEF

For the above reasons, Plaintiff demands the following relief against Defendants, jointly and severally:

1. Judgment for Plaintiff on all counts in the Complaint;

2. Compensatory damages in an amount to be proven at trial, plus all applicable and available prejudgment interest and post-judgment interest;

3. Punitive damages in an amount to be proven at trial, plus all applicable and available prejudgment interest and post-judgment interest;

4. Attorney's fees and expenses;

5. Costs of suit;

6. Any other and further relief that the Court deems just, proper, and appropriate.

JURY DEMAND

Plaintiff demands a jury trial on all issues so triable.

Respectfully submitted,

By: _____
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(Admission *pro hac vice forthcoming*)

Date: April 16, 2024