IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TERRY ASTON,

and

JOHN FRATTI,

and

LINDA MARTIN,

and

DAVID MELVIN,

and

ESTER SCHULKIN,

and

JENNIFER WILCOX,

Plaintiffs,

v.

JOHNSON & JOHNSON,
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

and

JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C.,
920 Route 202 South
P.O. Box 300 Mail Stop 2628
Raritan, New Jersey 08869

and

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.,

COMPLAINT

1000 Route 202 South
P.O. Box 300
Raritan, New Jersey 08869

and

RENAISSANCE TECHNOLOGIES, L.L.C.,
800 Third Avenue
New York, New York 10022

and

PETER F. BROWN,
Georgetown, Washington, D.C.

and

ROBERT L. MERCER,
800 Third Avenue
New York, New York 10022

and

JAMES H. SIMONS,
800 Third Avenue
New York, New York 10022

and

DR. MARGARET A. HAMBURG
Georgetown, Washington, D.C.

Defendants.

I. INTRODUCTION

This is a cause of action alleging violations of the federal Racketeer Influenced Corrupt Organizations Act ("RICO") on behalf of Plaintiffs, Terry Aston, John Fratti, Linda Martin, David Melvin, Ester Schulkin, and Jennifer Wilcox, who were directly and proximately injured by the intentional, willful, and negligent actions and inactions of each and every Defendant, including Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development,

L.L.C., Ortho-McNeil-Janssen Pharmaceuticals, INC., Renaissance Technologies, L.L.C., Peter F. Brown, Dr. Margaret A. Hamburg, Robert L. Mercer, and James Simons. Defendants, each and every one of them, acting in concert jointly and severally, through the use of the interstate mail and wires, entered into and furthered a conspiracy to illegally and criminally influence the Commissioner of the Food & Drug Administration and the Food & Drug Administration to mislabel and misbrand a drug in order to make and sell an inherently dangerous drug by defrauding consumers such as Plaintiffs in order to acquire and reap financial gain, including but not limited to: 1) driving up or maintaining the price of shares of Defendant Johnson & Johnson stock; 2) increasing the financial holdings and value of Defendant Johnson & Johnson stock held by Defendant Renaissance Technologies, L.L.C.; 3) increasing Defendant Renaissance Technologies, L.L.C.'s corporate income thereby increasing financial remuneration and gain to Defendants Peter F. Brown, Robert L. Mercer, and James H. Simons by virtue of Dr. Margaret A. Hamburg's marriage to Peter F. Brown; 4) increasing corporate income of the officers of Defendant Johnson & Johnson, Defendant Johnson & Johnson Pharmaceutical Research & Development, L.L.C, and Ortho-McNeil-Janssen Pharmaceuticals, INC.; 5) avoiding potential lawsuits against Defendant Johnson & Johnson, Defendant Johnson & Johnson Pharmaceutical Research & Development, L.L.C, and Ortho-McNeil-Janssen Pharmaceuticals, INC.; and 6) increasing the combined wealth of Defendants Dr. Margaret A. Hamburg and her husband, Defendant Peter F. Brown, by virtue of the above.

This is also an action for damages suffered by Plaintiffs as a direct and proximate result of Defendant Johnson & Johnson's, Johnson & Johnson Pharmaceutical Research & Development, L.L.C.'s, and Ortho-McNeil-Janssen Pharmaceuticals, INC.'s willful and/or negligent and wrongful conduct, and false advertising in violation of the Lanham Act, 15 U.S.C.

§ 1125, in connection with the design, development, manufacture, testing, packaging, promoting of off-label use, marketing, advertising, distribution, misbranding, and/or sale of the pharmaceutical drug Levaquin (also known as Levofloxacin). Levaquin in any of its forms will be referred to herein as "Levaquin." Plaintiffs maintain that Levaquin is defective, dangerous to human health, unfit and unsuitable to be marketed as labeled and sold, misbranded, falsely advertised, promoted for off-label use, and introduced into interstate commerce.

II. JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1332 (Diversity of Citizenship Jurisdiction), 18 U.S.C. § 1964 (Civil Remedies for RICO), and 18 U.S.C. § 1125 (The Lanham Act).

2. This Court has supplemental jurisdiction over this case pursuant to 28 U.S.C. § 1367.

3. Venue is proper pursuant to 18 U.S.C. § 1965 and 28 U.S.C. § 1391(b)(2), (3) in that Defendants either conduct significant business here or reside here and are subject to personal jurisdiction in this District. Furthermore, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen, market, and/or distribute Levaquin in the District of Columbia and this District.

III. PARTIES

Plaintiffs

4. Terry Aston is an individual, natural person who, at all material times, was and is a citizen of the United States.

5. John Fratti is an individual, natural person who, at all material times, was and is a citizen of the United States.

6. Linda Martin is an individual, natural person who, at all material times, was and is a citizen of the United States.

7. David Melvin is an individual, natural person who, at all material times, was and is a citizen of the United States.

8. Ester Schulkin is an individual, natural person who, at all material times, was and is a citizen of the United States.

9. Jennifer Wilcox is an individual, natural person who, at all material times, was and is a citizen of the United States.

Defendants

10. Defendant Johnson & Johnson is a New Jersey corporation that has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

11. Defendant Johnson & Johnson has transacted and conducted business within the District of Columbia.

12. Defendant Johnson & Johnson has derived substantial revenue from goods and products used in the District of Columbia.

13. Defendant Johnson & Johnson expected or should have expected its acts to have consequences within the District of Columbia, and derived substantial revenue from interstate commerce.

14. At all material times, Defendant Johnson & Johnson was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, lobbying, marketing, distributing, labeling, and/or selling Levaquin.

15. Defendant Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ("Johnson & Johnson PRD") is a limited liability company organized under the laws of New

Jersey, which has its principal place of business at 920 Route 202 South, P.O. Box 300, Mail Stop 2628, Raritan, New Jersey 08869.

16. Defendant Johnson & Johnson PRD has transacted and conducted business within the District of Columbia.

17. Defendant Johnson & Johnson PRD has derived substantial revenue from goods and products used in the District of Columbia.

18. Defendant Johnson & Johnson PRD expected or should have expected its acts to have consequences within the District of Columbia, and derived substantial revenue from interstate commerce.

19. Defendant Johnson & Johnson PRD is part of the Defendant Johnson & Johnson's "Family of Companies."

20. At all material times, Johnson & Johnson PRD was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

21. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen"), is a corporation with its principal place of business at 1000 Route 202 South, P.O. Box 300, Raritan, New Jersey 08869.

22. Defendant Janssen has transacted and conducted business within the District of Columbia.

23. Defendant Janssen has derived substantial revenue from goods and products used in the District of Columbia.

24. Defendant Janssen expected or should have expected its acts to have consequences within the District of Columbia, and derived substantial revenue from interstate commerce.

25. On information and belief, Janssen is a wholly owned subsidiary of Defendant Johnson & Johnson.

26. At all material times, Janssen was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

27. Defendant Renaissance Technologies, L.L.C. ("Renaissance Technologies"), is an investment management company with its principal place of business at 800 Third Avenue, New York, New York 10022.

28. Defendant Renaissance Technologies has transacted and conducted business within the District of Columbia and expected or should have expected to be haled into court in the District of Columbia.

29. Defendant Peter F. Brown ("Defendant Brown") is an individual, natural person who was employed as an executive or co-CEO of Renaissance Technologies during May 2009 to March 2015.

30. Defendant Dr. Margaret A. Hamburg ("Defendant Dr. Hamburg") is an individual, natural person who was employed as FDA Commissioner during May 2009 to March 2015. Dr. Hamburg is being sued in her individual and personal capacity, not her official capacity as FDA Commissioner. At all material times, including from May 2009 to March 2015, Dr. Hamburg was and is the wife of Peter F. Brown, co-CEO of Renaissance Technologies.

31. Defendant Robert L. Mercer ("Defendant Mercer") is an individual, natural person who was employed as an executive or co-CEO of Renaissance Technologies during May 2009 to March 2015.

32. Defendant James H. Simons ("Defendant Simons") is an individual, natural person who founded Renaissance Technologies and who continues to this present day to play a role at – and benefit from – Renaissance Technologies' funds.

33. Each and every Defendant acted in concert with one another in the District of Columbia and throughout the United States to violate RICO through a pattern of racketeering activity because of personal, financial gain, to fraudulently convey false and misleading information concerning the safety of Levaquin, and to conceal from the Plaintiffs, the public, physicians, and healthcare providers, the risks of serious adverse events, including mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, Fluoroquinolone-Associated Disability ("FQAD"), and other chronic, degenerative illnesses directly associated with Levaquin. The pattern of racketeering was perpetrated by each and every Defendant. These concerted efforts resulted in significant harm and/or death to consumers of Levaquin, including Plaintiffs. But for the actions and inactions of Defendants, individually, jointly, and in concert with one another, Plaintiffs would not have ingested, or permitted injection of, Levaquin, and they would have received appropriate treatment for their harm and debilitating illnesses after consuming Levaquin. Defendants' actions and inactions make them each individually liable and responsible for Plaintiffs' injuries and damages as described herein.[1]

[1] Defendants, as alleged herein, have acted as enumerated in each relevant count below, individually and in concert, jointly and severally, in furtherance of the violative acts and practices as alleged in that count.

IV. STANDING

34. Plaintiffs have standing to bring this action because they have been directly affected and victimized by the unlawful conduct complained herein. Their injuries are proximately related to the illegal conduct of Defendants Johnson & Johnson, Johnson & Johnson PRD, Janssen, Renaissance Technologies, James Simon, Robert Mercer, Peter Brown, and Dr. Hamburg.

V. FACTS

Defendant Johnson & Johnson, Defendant Johnson & Johnson PRD, and Defendant Janssen

35. At all relevant times, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen were in the business of and did design, research, manufacture, test, advertise, promote, lobby, market, sell, distribute, introduce into interstate commerce, and/or have acquired and are responsible for Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the pharmaceutical drug Levaquin through interstate commerce and through a pattern of racketeering.

36. Levaquin was approved by the United States Food and Drug Administration ("FDA") on December 20, 1996 for use in the United States, and is the brand name for the antibiotic levofloxacin.

37. Levaquin is – and was marketed through interstate commerce as – a broad-spectrum fluoroquinolone antibiotic used to treat a range of infections, including lung, sinus, skin and urinary tract infections caused by certain strains of bacteria.

38. As part of Defendants Johnson & Johnson's, Johnson & Johnson PRD's and Janssen's pattern of practice in colluding with and conspiring with others, in January of 2010, the U.S. Department of Justice filed a complaint alleging that Johnson & Johnson illegally paid

Omnicare, one of the largest pharmacies supplying nursing home patients, millions of dollars in kickbacks in exchange for Omnicare increasing its sales of drugs, including Levaquin. Sales of Levaquin increased over other fluoroquinolones over the five-year period from 1999 to 2004. Sales of Levaquin dramatically increased despite the increasing number of reports of the severe adverse reactions in elderly patients.

39. Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen have a significant history of manufacturing, advertising, promoting, lobbying for, marketing, selling, and distributing, and introducing into interstate commerce, defective and/or dangerous drugs and devices, including but not limited to Tylenol, Motrin, Zyrtec, Benadryl, Risperdal, Invega, DePuy hip implants, Transvaginal Mesh, Xarelto, and Invokana.

40. On April 17, 2013, the FDA wrote, "Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology," with the subject line, "Disabling Peripheral Neuropathy Associated with Systemic Fluoroquinolone Exposure," that directly link Defendant Johnson & Johnson's drug, Levaquin, to mitochondrial toxicity and implicated neurodegenerative diseases, including ALS, Alzheimer's and Parkinson's diseases.

41. On August 14, 2014 the FDA wrote, "Pediatric Postmarketing Pharmacovigilance and Drug Utilization Review," which documents that 100% of pediatric prescriptions for Defendant Johnson & Johnson's drug, Levaquin, from April 1, 2011 to March 31, 2014, were for purposes not approved by the FDA, equating to 100% off-label use.

42. On November 5, 2015, the FDA convened an Advisory Committee to consider "The Benefits and Risks of Systemic Fluoroquinolone Antibacterial Drugs." For this meeting,

the FDA wrote the "FDA Briefing Document, Joint Meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee."

43. At the November 5, 2015 Advisory Committee meeting, an FDA employee, Debra Boxwell, stated that the FDA has been aware that Levaquin may result in multi-system disability since 2013, but did nothing to add this information to the Levaquin label, and indeed did not add this critical information to the Levaquin label.

44. Indeed, this multi-system disability is named Fluoroquinolone-Associated Disability ("FQAD"), and is an FDA formal review identification for a constellation of symptoms that have been identified in the FDA's Adverse Event Reporting System in review of data in the fluoroquinolone safety reports. These adverse reactions have been identified as leading to disabilities involving the following body systems: neuromuscular, neuropsychiatric, peripheral neuropathy, senses, skin, and cardiovascular.

45. The term FQAD did not exist until November 5, 2015 when the FDA coined it.

46. Plaintiffs suffer from a constellation of medical issues related to the following body systems: neuromuscular, neuropsychiatric, peripheral neuropathy, senses, skin, cardiovascular, plus, endocrine, nutritional, metabolic and immunity; blood and blood forming organs; circulatory system; respiratory system; digestive system; genitourinary system; and connective tissue.

47. Three of the Plaintiffs, Linda Martin, John Fratti, and Terry Aston, have been identified as disabled by the federal government's Social Security Administration; two Plaintiffs did not contact Social Security disability determination; and one Plaintiff was over the age of 65 and not eligible for Social Security disability.

48. Individuals with FQAD, as determined by the Advisory Committee on November 5, 2015, are defined by the FDA as patients who were reported to be previously healthy and prescribed an oral fluoroquinolone antibacterial drug, who experienced disabling adverse events, lasting more than a month, in two or more of the following body systems: neuromuscular, neuropsychiatric, peripheral neuropathy, senses, skin, cardiovascular. (FDA, November 5, 2015).

49. On November 5, 2015, in the report discussing FQAD, the FDA used the regulatory definition of disability as a "substantial disruption of a person's ability to conduct normal life functions" 21 C.F.R. 314.80.

50. On November 5, 2015, the FDA Advisory Committee "voted overwhelmingly that the benefits and risks for the systemic fluoroquinolone antibacterial drugs do not support the current labeled indications . . ."

51. The Levaquin label does not include warnings regarding the following:

(a) Carbapenem-Resistant Enterobacteriaceae ("CRE"): "Infections caused by these organisms are associated with high mortality rates, up to 50% in some studies. Which patients are at increased risk for CRE acquisition? . . . Antimicrobials have been associated with CRE acquisition including . . . fluoroquinolones . . ." http://www.cdc.gov/hai/organisms/cre/cre-clinicianFAQ.html.

(b) Mitochondrial Toxicity: "Mitochondrial conditions that are due to an insufficiency of ATP [adenosine triphosphate], especially in organs that rely on mitochondria for their energy source, include developmental disorders of the brain, optic neuropathy, neuropathic pain, hearing loss, muscle weakness, cardiomyopathy, and lactic acidosis. Neurodegenerative diseases, like

Parkinson's, Alzheimer's, and amyotrophic lateral sclerosis ("ALS") have been associated with the loss of neurons due to oxidative stress." (FDA, April 17, 2013, page 12).

(c) Neuropsychiatric Adverse Events: "Feeling abnormal, loss of consciousness, disorientation, agitation, delirium, depressed level of consciousness, amnesia, coma, disturbance in attention, panic attack, memory impairment, and nervousness are adverse events significantly reported in the FDA Adverse Event Reporting System ("FAERS") data from November 1997 to June 2012 which are not on the Levaquin label." (Bennett, Citizen Petition, September 8, 2014).

(d) FQAD: "In conclusion, we find an association between oral fluoroquinolone use . . . and the development of FQAD. While the individual components are included in fluoroquinolone labels, a description of the constellation of disabling adverse events is not currently described in the fluoroquinolone labels." (FDA, November 5, 2015, page 28).

52. Defendant Johnson & Johnson, Defendant Johnson & Johnson PRD, and Janssen had, or had access to, the FDA website, which contains documents indicating that the FDA concluded that some of Defendant Johnson & Johnson's Levaquin clinical trials had "significant flaws in protocol design and implementation."

53. Defendant Johnson & Johnson, Defendant Johnson & Johnson PRD, and Janssen had, or had access to, the April 17, 2013, FDA report titled, "Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Drug Evaluation and

Research, Office of Surveillance and Epidemiology," with the subject line, "Disabling Peripheral Neuropathy Associated with Systemic Fluoroquinolone Exposure."

54. Defendant Johnson & Johnson, Defendant Johnson & Johnson PRD, and Janssen had, or had access to, the August 14, 2014, FDA report titled, "Pediatric Postmarketing Pharmacovigilance and Drug Utilization Review."

55. Defendant Johnson & Johnson, Defendant Johnson & Johnson PRD, and Janssen had, or had access to, the "FDA Briefing Document, Joint Meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee."

56. Defendant Johnson & Johnson, Defendant Johnson & Johnson PRD, and Janssen had, or had access to, the FDA FAERS data which documents that from 2009 through 2015, there were approximately 500 reported deaths associated with consuming Levaquin. The FDA assumes only approximately ten percent (10%) of adverse events are reported to the FDA meaning that the estimated number of deaths associated with Levaquin from 2009 through 2015 was approximately 5,000.

57. Defendant Johnson & Johnson, Defendant Johnson & Johnson PRD, and Janssen had, or had access to, the FDA FAERS data which documents that from 2009 through 2015, there were approximately 8,000 individuals who reported damage associated with consuming Levaquin. The FDA assumes only approximately ten percent (10%) of adverse events are reported to the FDA meaning that the estimated number of individuals with damage associated with Levaquin from 2009 through 2015 was approximately 80,000.

58. Defendant Johnson & Johnson, Defendant Johnson & Johnson PRD, and Janssen had, or had access to, the FDA FAERS data which clearly documents that, at least from 2009 to present, Levaquin consumption is associated with multi-system disability.

59. Defendant Johnson & Johnson, Defendant Johnson & Johnson PRD, and Janssen had, or had access to, the FDA FAERS data which clearly documents that, at least from 2009 to present, Levaquin consumption is associated with significant neuropsychiatric adverse events for which there are no warning on the Levaquin label.

60. Defendant Johnson & Johnson, Defendant Johnson & Johnson PRD, and Janssen had, or had access to, the Centers for Disease Control ("CDC") website that clearly indicates there is an increased risk for acquiring Carbapenem-Resistant Enterobacteriaceae for those who consume Levaquin and that CRE is fatal an estimated 50% of the time.

Defendants Renaissance Technologies, Peter Brown, Robert Mercer, Dr. Hamburg, and James Simons

61. From May of 2009 to March of 2015, Defendant Dr. Hamburg was employed as the FDA Commissioner. During the time Defendant Dr. Hamburg was FDA Commissioner, she was married to Defendant Peter Brown, who at all material times was employed as an executive or co-CEO of the hedge fund, Renaissance Technologies, during and throughout Dr. Margaret Hamburg's tenure as FDA Commissioner.

62. From May of 2009 to March of 2015, Defendant Robert Mercer was employed as an executive or co-CEO of the hedge fund, Renaissance Technologies.

63. From May of 2009 to March of 2015, Defendant James Simons was employed as Chief Executive Officer or Board Chair of the hedge fund, Renaissance Technologies. While Defendant Simons retired as Chief Executive Officer in 2010, from 2010 to the present, Defendant Simons maintains an active role in Renaissance Technologies' decision-making and policies.

64. On November 27, 2007, Defendant James Simons stated, "from managing directors to cleaning staff, everyone receives a percentage of the profits." http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aq33M3X795vQ.

65. On February 1, 2011, at a speech at Massachusetts Institute of Technology, Defendant James Simons stated, "people get paid based on the profits of the entire firm. You don't get paid just on your work. You get paid based on the profits of the firm. So everyone gets paid based on the firm's success." http://www.distressedvolatility.com/2011/01/james-simons-speech-at-mit-renaissance.html.

66. In and around February 13, 2011, Defendant Renaissance Technologies had more than 2,700 securities. The top 30 stock holdings from Renaissance Technologies in and around February 2011 were as follows:

Company	Ticker	Return	Value (in Millions)
APPLE INC	AAPL	10.6%	438
LORILLARD INC	LO	-4.7%	360
JOHNSON & JOHNSON	**JNJ**	**-1.9%**	**342**
DIRECTV	DTV	8.9%	184
BOEING CO	BA	11.2%	169
SALESFORCE COM INC	CRM	7.2%	163
GOOGLE INC	GOOG	5.1%	161
ABBOTT LABS	ABT	-4.0%	160
TEVA PHARMACEUTICAL INDS LTD	TEVA	-1.7%	156
NOVO-NORDISK A S	NVO	5.5%	156
COCA COLA CO	KO	-3.3%	148
COLGATE PALMOLIVE CO	CL	-1.1%	145
ALCON INC	ACL	0.4%	145
HUMANA INC	HUM	6.5%	137
CHIPOTLE MEXICAN GRILL INC	CMG	26.4%	133
HEWLETT PACKARD CO	HPQ	15.5%	129
ALTERA CORP	ALTR	16.5%	125
MCDONALDS CORP	MCD	-0.8%	125
INTEL CORP	INTC	4.4%	123
PEPSICO INC	PEP	-2.2%	120
FAMILY DLR STORES INC	FDO	-11.2%	118
CF INDS HLDGS INC	CF	11.3%	117
VERISIGN INC	VRSN	12.4%	108

LOCKHEED MARTIN CORP	LMT	16.9%	108
PHILIPPINE LONG DISTANCE TEL	PHI	-6.8%	107
PRUDENTIAL FINL INC	PRU	11.0%	102
GILEAD SCIENCES INC	GILD	5.9%	102
NEWMONT MINING CORP	NEM	-7.4%	102
POTASH CORP SASK INC	POT	21.7%	100
FRANKLIN RES INC	BEN	15.6%	100

http://www.businessinsider.com/jim-simons-and-renaissance-institutional-equities-funds-30-largest-holdings-2011-2.

67. On information and belief, Congress intends to avoid all real and apparent conflicts of interest with regard to government employees, like Defendant Dr. Hamburg from 2009 to 2015.

68. In and around May 26, 2009, Defendant Dr. Hamburg was forced to divest herself of several hedge fund holdings, as was her husband, Defendant Brown. This was done in order for her to take the position as the top food and drug regulator without any real or apparent conflicts of interest.

69. Defendant Dr. Hamburg and Defendant Brown were allowed to retain their interest in Renaissance Technologies' Medallion fund because, on information and belief, Renaissance Technologies' Medallion fund "computerized quantitative model trades rapidly and holds shares only briefly, creating the equivalent of 'a very blind trust.' Its programming does not allow for human tracking or input except in rare instances, meaning that neither Dr. Hamburg nor her husband would be in a position to direct their Medallion account to companies or areas affected by the FDA . . ." http://www.wsj.com/articles/SB124328188115551961.

70. On information and belief, neither Defendant Dr. Hamburg nor Defendant Brown, nor any other Defendant Renaissance Technologies' executive fully confessed or described to Congress that Defendant Brown, Defendant Dr. Hamburg's husband at all material times, *still*

shares in – and benefits financially from – all of the stocks of Renaissance, via Renaissance Technologies profit-sharing, as explained in detail by Defendant James Simons, regardless of whether Defendant Brown divested himself of a particular hedge fund(s).

71. Many of Renaissance Technologies' profits are from drug companies and from companies considered "significantly regulated" by the FDA.

72. From May of 2009 to March of 2015, Renaissance Technologies held the following amounts of Johnson & Johnson stock as documented on the Securities and Exchange website, 13F filings for Renaissance Technologies.

Period of Report	Johnson & Johnson	
31-Mar-15	$	87,240,000
31-Dec-14	$	244,349,000
30-Sep-14	$	281,717,000
30-Jun-14	$	329,082,000
31-Mar-14	$	261,213,000
31-Dec-13	$	503,598,000
30-Sep-13	$	283,936,000
30-Jun-13	$	62,455,000
31-Mar-13	$	133,807,000
31-Dec-12	$	14,153,000
30-Sep-12	$	3,211,000
30-Jun-12	$	454,213,000
31-Mar-12	$	207,352,000
31-Dec-11	$	10,965,000
30-Sep-11	$	904,000
30-Jun-11	$	80,795,000
31-Mar-11	$	396,572,000
31-Dec-10	$	342,395,000
30-Sep-10	$	23,991,000
30-Jun-10	$	50,231,000
31-Mar-10	$	83,300,000
31-Dec-09	$	-
30-Sep-09	$	10,948,000
30-Jun-09	$	25,134,000

73. Defendant Brown's annual income increased from a reported $10 million in 2008 (WSJ, http://www.wsj.com/articles/SB124328188115551961) to an estimated $125 million in

2011 (Insider Monkey, http://www.insidermonkey.com/blog/best-hedge-fund-managers-of-2011-11302/) and an estimated $90 million in 2012 (Forbes, http://www.forbes.com/lists/2013/hedge-fund-managers-13_land.html), while his wife, Defendant Dr. Hamburg, was FDA Commissioner.

74. At some point from May 2009 to March 2015, Renaissance Technologies held stock in the majority of companies with drugs given "breakthrough" status with priority FDA review, and the potential for a fast-tract to market.

75. On December 7, 2012, an FDA Advisory Committee voted 11 to 2 against the approval of the painkiller drug, Zohydro, manufactured by Alkermes. However, as described on the FDA website, on October 25, 2013, the FDA approved Zohydro anyway. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm372287.htm.

76. From 2011 to May 2015, Defendant Renaissance Technologies held the following amounts of stock in Alkermes, the manufacturer of Zohydro, the drug the FDA Advisory Committee voted against approving, but which the FDA approved anyway.

Date	Value
03/31/2015	$ 12,114,000
12/31/2014	$ 3,747,000
09/30/2014	$ 6,679,000
06/30/2014	$ 10,805,000
03/31/2014	$ 2,350,000
12/31/2013	$ 20,557,000
09/30/2013	$ 22,246,000
06/30/2013	$ 22,792,000
03/31/2013	$ 2,792,000
12/31/2012	$ 829,000
09/30/2012	$ 2,955,000
06/30/2012	$ 6,603,000
03/31/2012	$ 0
12/31/2011	$ 0
09/30/2011	$ 3,765,000
06/30/2011	$ 2,561,000

03/31/2011	$ 0

77. From 2009 to March 2015, Defendants Peter Brown, Robert Mercer, and James Simons shared in Renaissance Technologies' profits, made in part from stocks held in pharmaceutical companies and companies considered "significantly regulated" by the FDA.

78. Defendant Dr. Hamburg participated and profited personally and substantially in and from many matters in which she and her spouse, Renaissance Technologies' co-CEO, Defendant Peter F. Brown, had a financial interest, e.g., Johnson & Johnson stock, other pharmaceutical company stocks, and stock in other companies considered "significantly regulated" by the FDA.

79. In and around 2010, Plaintiff John Fratti, FDA-designated Patient Representative for Drug Safety, presented information about the dangers of Levaquin at an FDA meeting, but Defendant Dr. Hamburg failed to order adequate information to be put on the Levaquin label by omitting facts, because of her personal, financial interest in maintaining Levaquin's branding as "status quo" because of her husband's stock interests in Renaissance Technologies, specifically Johnson & Johnson, among other nefarious factors and reasons.

80. In and around 2010, Plaintiff John Fratti, FDA-designated Patient Representative for Drug Safety, again presented information about the dangers of Levaquin at a second FDA drug safety meeting, but Defendant Hamburg failed to order adequate information to be put on the Levaquin label by omitting facts, because of her personal, financial interest in maintaining Levaquin's branding as "status quo" because of her husband's stock interests in Renaissance Technologies, specifically Johnson & Johnson.

81. In and around 2011, Plaintiff John Fratti wrote to Defendant Dr. Hamburg directly several months after the second presentation, describing devastating, severe affects of Levaquin.

Still, Defendant Dr. Hamburg failed to order adequate information to be put on the Levaquin label by omitting facts, because of her personal, financial interest in maintaining Levaquin's branding as "status quo" because of her husband's stock interests in Renaissance Technologies, specifically Jonson & Johnson.

82. On March 11, 2010, Senator Robert Casey sent a letter to the FDA requesting a hearing to address Levaquin safety concerns.

83. On November 16, 2010, Pennsylvania State Representative Mike Folmer sent a letter to the FDA requesting that the FDA add additional safety warnings for Levaquin.

84. On November 16, 2010, Pennsylvania State Representative John Payne sent a letter to the FDA requesting that the FDA add additional safety warnings for Levaquin.

85. On November 16, 2010, Pennsylvania State Representative Jeffrey Piccola sent a letter to the FDA requesting that the FDA add additional safety warnings for Levaquin.

86. On December 6, 2010, Congressman Tim Holden sent a letter to the FDA requesting that the FDA add additional safety warnings for Levaquin.

87. On December 20, 2010, Pennsylvania State Representative Maureen Gingrich sent a letter to the FDA requesting that the FDA add additional safety warnings for Levaquin.

88. On December 29, 2010, Pennsylvania State Representative Susan Helm sent a letter to the FDA requesting that the FDA add additional safety warnings for Levaquin.

89. On March 29, 2011, Senator Pat Toomey sent a letter to the FDA requesting that the FDA add additional safety warnings for Levaquin.

90. In and around 2012, Dr. Karen Weiss, FDA Director for the Office of Drug Evaluation and Director of the FDA's Safe Use Initiative, who reported directly to Defendant Dr.

Hamburg, left the FDA and, not coincidentally, went to work for Johnson & Johnson as the Vice President for Regulatory Affairs.

91. On May 13, 2013, a House of Representatives panel questioned Defendant Dr. Hamburg about Dr. Leona Brenner-Gati, a former Johnson & Johnson executive who Defendant Hamburg hired and who resigned from the FDA on May 3, 2013.

92. On June 18, 2014, Dr. Charles Bennett, from the Center for Medication Safety and Efficacy Southern Network on Adverse Reactions ("SONAR"), sent a Citizen's Petition directly to Defendant Dr. Hamburg requesting her to order adequate information be included on the Levaquin label regarding mitochondrial toxicity and implicated neurodegenerative diseases, including but not limited to ALS, Alzheimer's and Parkinson's diseases, but Defendant Dr. Margaret Hamburg still refused to place adequate information on the Levaquin label because of her personal, financial interest in maintaining Levaquin's branding as "status quo" because of her husband's stock interests in Renaissance Technologies, specifically Johnson & Johnson.

93. In August of 2014, Defendant Dr. Hamburg received hundreds of emails from individuals who had severe Levaquin adverse affects, but Defendant Dr. Hamburg did not order that adequate information be included on the Levaquin label because of her personal, financial interest in maintaining Levaquin's branding as "status quo" because of her husband's stock interests in Renaissance Technologies, specifically Johnson & Johnson.

94. On September 8, 2014, Dr. Charles Bennett sent a second Citizen's Petition directly to Defendant Dr. Hamburg requesting that she put adequate information on the Levaquin label regarding serious psychiatric adverse events, but Defendant Dr. Hamburg did not order that adequate information be included on the Levaquin label because of her personal, financial interest in maintaining Levaquin's branding as "status quo" because of her husband's stock

interests in Renaissance Technologies, specifically Johnson & Johnson, among other nefarious factors and reasons.

95. On September 23, 2014, Defendant Dr. Hamburg or her designee not coincidentally chose Dr. Samuel Maldonado, a paid Johnson & Johnson employee, to be a member of the FDA Pediatric Advisory Committee during the time that pediatric Levaquin use was addressed by the Committee.

96. From May 2009 to March 2015, Plaintiffs suffered mitochondrial toxicity, neuropsychiatric adverse events, and multi-system disability related to their consumption of Levaquin, including a constellation of medical issues related to the following body systems: neuromuscular, neuropsychiatric, peripheral neuropathy, senses, skin, cardiovascular, plus, endocrine, nutritional, metabolic and immunity; blood and blood forming organs; circulatory system; respiratory system; digestive system; genitourinary system; and connective tissue.

97. Specifically, Plaintiffs suffer from a constellation of medical issues, including but not limited to widespread bodily pain, fatigue, muscle weakness, muscle twitching, muscle wasting, gait disturbances, severe balance issues, stiffness, spasms, joint pain, tendon issues, seizures, tremors, numbness, burning, tingling, fasciculation, spasticity, nerve damage, autonomic issues, voice issues, exercise intolerance, difficulty swallowing, slow digestive motility, abdominal pain, acid reflux, gastritis, nausea, constipation, diarrhea, colitis, cognitive impairment, memory impairment, cardiac issues, urinary issues, kidney damage, liver damage, pancreatic damage, thyroid abnormalities, hair loss, glucose issues, respiratory issues, emotional issues, depression, psychosis, depersonalization, dissociation, anxiety, insomnia, abnormal dreams, suicidal thoughts, thought alterations, agitation, fatigue, dizziness, inability to concentrate, panic attacks, difficulty communicating, forgetfulness, bruising, vision issues,

hearing issues, tinnitus, dental issues, gum issues, skin issues, rashes, multiple chemical sensitivity, sexual dysfunction, reproductive issues, and DNA damage.

98. From May 2009 to March 2015, personal enrichment and greed, illegal actions and inactions by each and every Defendant, jointly and severally, resulted in inadequate information and warnings on the Levaquin label and Plaintiffs were *unable to receive appropriate, accurate clinical assessment,* and were financially damaged in their business and/or property.

99. From May 2009 to March 2015, personal enrichment and greed, illegal actions and inactions by each and every Defendant, jointly and severally, resulted in inadequate information and warnings on the Levaquin label and Plaintiffs were *unable to receive an accurate treatment plan* and were financially damaged in their business and/or property.

100. From May 2009 to March 2015, personal enrichment and greed, illegal actions and inactions by each and every Defendant, jointly and severally, resulted in inadequate information and warnings on the Levaquin label and Plaintiffs were *unable to receive an appropriate treatment* and were financially damaged in their business and/or property.

101. From May 2009 to March 2015, personal enrichment and greed, illegal actions and inactions by each and every Defendant, jointly and severally, resulted in inadequate information and warnings on the Levaquin label and Plaintiffs were *subjected to unnecessary and inappropriate medical tests, including radiation exposure* and were financially damaged in their business and/or property.

FDA's Support for Plaintiffs' Claims

102. As indicated on the FDA website, the FDA concluded that some of the Levaquin clinical trials submitted in an application for Levaquin's approval in 1996, had "significant flaws in protocol design and implementation."

103. On April 17, 2013, the FDA wrote a report which it suppressed from the public as a result of the actions and non-actions of the Defendants, each and every one of them, jointly and severally, titled, "Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology," with the subject line, "Disabling Peripheral Neuropathy Associated with Systemic Fluoroquinolone Exposure," that directly linked Levaquin to mitochondrial toxicity and implicated neurodegenerative diseases, including ALS, Alzheimer's and Parkinson's diseases.

104. This April 17, 2013 FDA report includes twenty-one "References" to Levaquin and other fluoroquinolone published research studies that document Levaquin and other fluoroquinolone adverse events, safety concerns, and other applicable information.

105. An August 14, 2014, FDA report titled, "Pediatric Postmarketing Pharmacovigilance and Drug Utilization Review," documents that 100% of pediatric Levaquin use from April 1, 2011 to March 31, 2014 was for purposes not approved by the FDA, equating to 100% off-label use.

106. As discussed above, on November 5, 2015, an FDA Advisory Committee voted overwhelmingly that the information on the Levaquin label was inadequate and did not provide appropriate warnings of the dangerous of the drug.

107. As discussed above, on November 5, 2015, an FDA employee, Debra Boxwell, stated that the FDA has been aware that Levaquin may result in multi-system disability since 2013, but did nothing to add this information to the Levaquin label.

108. The FDA FAERS data documents that from 2009 through 2015, there were approximately 500 reported deaths associated with consuming Levaquin. The FDA assumes only approximately ten percent (10%) of adverse events are reported to the FDA meaning that the estimated number of deaths associated with Levaquin from 2009 through 2015 was approximately 5,000.

109. The FDA FAERS data documents that from 2009 through 2015, there were approximately 8,000 individuals who reported damage associated with consuming Levaquin. The FDA assumes only approximately ten percent (10%) of adverse events are reported to the FDA meaning that the estimated number of individuals who were damaged associated with Levaquin from 2009 through 2015 was approximately 80,000.

110. The FDA FAERS data clearly documents that, at least from 2009 to present, Levaquin consumption is associated with multi-system disability.

111. The FDA FAERS data clearly documents that, at least from 2009 to present, Levaquin consumption is associated with significant neuropsychiatric adverse events for which there are no warnings on the Levaquin label.

112. On January 6, 2016, the FDA asked Plaintiff Aston to speak about Levaquin adverse events and FQAD at an April 2016 symposium.

Equitable Tolling of Applicable Statute of Limitations

113. Plaintiffs reallage and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

114. Each and every Plaintiff discovered the racketeering activity perpetrated by each and every Defendant with the collusion and conspiracy of Renaissance Technologies, Dr. Hamburg, her husband and co-CEO of Renaissance Technologies Peter Brown, James Simons, and Robert Mercer only in or around January of 2015.

115. The running of any statute of limitations has been tolled by reason of each and every Defendant's fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and Plaintiffs' treating physicians the true risks and adverse events associated with Levaquin.

116. As a result of Defendants' actions, Plaintiffs and Plaintiffs' treating physicians and healthcare managers were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions, particularly since FQAD did not exist until November 5, 2015.

117. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Levaquin. Defendants were under a duty to disclose the true character, quality, and nature of Levaquin because this was non-public information over which Defendants had and continues to have exclusive control, and because Defendants, each and every one of them, knew that this information was not available to the Plaintiffs, medical providers and/or to their facilities. In addition, Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

118. The Plaintiffs had no knowledge that Defendants, each and every one of them, were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment

of wrongdoing by Defendants, the Plaintiffs could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, lobbying, promoting and/or distributing, through interstate commerce and a pattern of racketeering, a profitable drug, notwithstanding the known or reasonably known substantial risks. Plaintiffs and their physicians could not have afforded and could not have possibly have been expected to conduct studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations.

119. Accordingly, Defendants are precluded by the discovery rule and/or the doctrine of fraudulent concealment from relying upon any statute of limitations.

Rico Violations

120. **18 U.S.C. § 1962(a)**: Section 1962(a) of RICO provides that "it shall be unlawful for any person who has received any income derived, directly or indirectly, from a pattern of racketeering activity . . . in which such person has participated as a principal within the meaning of § 2, title 18, United States Code, to use or invest, directly or indirectly, any part of such income, or the proceeds of such income, in acquisition of any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect interstate or foreign commerce."

121. Defendants receive income from their participation as principals in a conspiracy with overt acts in concert, evidencing an extensive pattern of racketeering activity.

122. That income was and is used to finance future racketeering activity.

123. **18 U.S.C. § 1962(b)**: Section 1962(b) of RICO provides that it "shall be unlawful for any person through a pattern of racketeering activity or through collection of an unlawful

debt to acquire or maintain, directly or indirectly, any interest in or control of any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce.

124. **18 U.S.C. § 1962(c)**: Section 1962(c) of RICO provides that it "shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . ."

125. **18 U.S.C. § 1962(d)**: Section 1962(d) of RICO makes it unlawful "for any person to conspire to violate any of the provisions of subjection (a), (b), or (c), of this section."

VI. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF
(Violations of RICO, 18 U.S.C. § 1962(c))
Against All Defendants

126. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

127. Section 1962(c) prohibits a person from conducting the affairs of an enterprise through a pattern of racketeering.

128. At all relevant times, each Defendant is a person within the meaning of 18 U.S.C. §§ 1961(3) and 1962(c).

129. Each Plaintiff is a person within the meaning of 18 U.S.C. § 1964(c).

130. Each and every Defendant is a person capable of holding legal or beneficial interest in property within the meaning of 18 U.S.C. § 1961(3).

131. Because of each and every Defendants' violations of RICO, Plaintiffs were financially injured as a result to their business and/or property.

132. Each and every Defendant violated 18 U.S.C. § 1962(c) by the acts described in the prior paragraphs, and as further described below.

The Rico Enterprise

133. The Defendants and their co-conspirators are a group of "persons" associated together in fact for the common purpose of carrying out an ongoing criminal enterprise, as described in the foregoing paragraphs of this Complaint. These Defendants form this association in fact for the common and continuing purpose described herein and constitute an enterprise within the meaning of 18 U.S.C. § 1961(4) engaged in the conduct of their affairs through a continuing pattern of racketeering activity. Each of the Defendants participated in the operation of or management of the enterprise. The members of the enterprise functioned as a continuing unit with an ascertainable structure separate and distinct from that of the conduct of the pattern of racketeering activity. There may be other members of the enterprise who are unknown as this time, but which will be uncovered during discovery.

134. At all material times, the enterprise has engaged in, and their activities have affected, interstate and foreign commerce within the meaning of 18 U.S.C. § 1962(c).

Pattern of Racketeering Activity In General

135. Defendants, each of whom are persons associated with, or employed by, the enterprise, did knowingly, willfully and unlawfully conduct or participate, directly or indirectly, in the affairs of the enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1), 1961(5), and 1962(c).

136. The racketeering activity, through the use of the interstate mails and wires, was made possible by Defendants' regular and repeated use of the services of the enterprise. Defendants had the specific intent to engage in the substantive RICO violations alleged herein.

137. Predicate acts of racketeering activity are acts which are indictable under provisions of U.S.C. § 1961(1)(B). Defendants each committed at least two such acts or else aided and abetted such acts.

138. The acts of racketeering were not isolated, but rather the acts of Defendants were related in that they had the same or similar purpose and result, participants, victims and method of commission. Further, the acts of racketeering by Defendants have been continuous. There was repeated conduct during a period of time beginning in approximately 2009, for Defendants Brown and Dr. Hamburg, and several years before that, but within the last ten years, for the other Defendants, and continuing to the present, and there is a continued threat of repetition of such conduct.

Pattern of Racketeering Activity: Violation of 21 U.S.C. § 331(a)(1) (Introduction of a Misbranded Drug into Interstate Commerce)

139. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §331 *et seq.*, assures, among other things, that drugs intended for human use are safe and effective for their intended uses and that the labeling of such drugs bear true, complete, and accurate information.

140. The FDCA, among other purposes, governs the interstate distribution of drugs for human use, including Levaquin.

141. The FDCA and its implementing regulations, with exception not applicable here, prohibit the distribution of any drug in interstate commerce unless and until the FDA has approved the drug for the purposes indicated on the drug label. This applies to Levaquin.

142. The FDCA prohibits a drug from being introduced into interstate commerce until the FDA has approved the drug for the intended uses and until the drug's label accurately reflects the drugs approved uses and accurately reflects warnings of possible adverse events. This applies to Levaquin.

143. Under the FDCA, a drug is "misbranded" if its labeling does not bear "adequate directions for use." 21 U.S.C. §352(f)(1).

144. A prescription drug, including Levaquin, that is intended for non-FDA approved, off-label use, is misbranded.

145. The FDCA prohibits introducing, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce, any drug that is misbranded.

146. Defendants, each and every one of them, have a history of lobbying for, introducing, delivering for introduction, or causing the introduction or delivery for introduction into interstate commerce, misbranded drugs by providing inadequate, inaccurate label information and by promoting drugs for non-FDA approved uses, such as Risperdal.

147. Defendants, each and every one of them, lobbied for, introduced, delivered for introduction, or caused the introduction or delivery for introduction into interstate commerce, misbranded Levaquin through the use of interstate wires and mails, including but not limited to, by providing inadequate, inaccurate label information and by promoting Levaquin for non-FDA approved uses.

148. Defendants, each and every one of them, promoted the "off-label" use of Levaquin for purposes not approved by the FDA, including-but-not-limited-to:

(a) For pediatric use in cases other than those with the inhalational anthrax (post-exposure) and plague; and

(b) For prevention purposes in both pediatric individuals and adults.

149. The FDA has only approved pediatric Levaquin use for anthrax and the plague as described in the August 14, 2014, FDA report titled, "Pediatric Postmarketing

Pharmacovigilance and Drug Utilization Review," "Pediatrics…. Risk-benefit appropriate only for the treatment of inhalational anthrax (post-exposure) and plague." (FDA, page 7)

150. Although this report indicated that 100% of the estimated 100,000 Levaquin prescriptions for pediatric patients were for off-label use and although Dr. Samuel Maldonado had a copy of the August 14, 2014 report, the Defendants took no action to condemn past off-label use or to prevent future off-label use. The Defendants silence equated to support of and promotion of off-label use in pediatric patients for non-FDA approved purposes.

151. The FDA has not approved Levaquin for prevention purposes for adults or children.

152. Dr. E.P. Dillenger, Johnson & Johnson Advisory Board Member, used undue and illegal undue influence to promote Levaquin for off-label use, as documented on the Department of Health and Human Services website, which resulted in off-label use Guidelines being accepted for both adults and children by the following clinical specialties: Anesthesiology, Colon and Rectal Surgery, Gastroenterology, Internal Medicine, Nephrology, Neurological Surgery, Obstetrics and Gynecology, Ophthalmology, Orthopedic Surgery, Otolaryngology, Pediatrics, Pharmacology, Plastic Surgery, Preventive Medicine, Surgery, Thoracic Surgery, and Urology.

153. Because an estimated 60 million prescriptions were written for Levaquin while it was misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that its labeling lacked adequate directions for use and with inaccurate and inadequate warnings and label information, from May 2009 to March 2015, Defendants violated 21 U.S.C. §331(a)(1), Introduction of a Misbranded Drug into Interstate Commerce, *an estimated 60 million times* in a clear and undeniable pattern of racketeering.

154. As a direct and proximate result of each and every Defendants' RICO violations, the acts of racketeering activity of the enterprise, the overt acts taken in furtherance of those violations, and violations of 18 U.S.C. § 1962(a), (b), (c), and (d), each and every Plaintiff has been injured financially and individually in their business and property, including damage to Plaintiffs' reputations and good will; the impairment of Plaintiffs' interest in obtaining work, enormous medical expenses, jointly and severally, and other damage to their business and/or property.

155. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs are entitled to recover treble damages plus costs and attorneys' fees from each and every Defendant.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

Pattern of Racketeering Activity: Violation of 18 U.S.C. § 208, Conflict of Interest

156. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

157. Each and every Defendant, jointly and severally, has unlawfully, knowingly, and willfully combined, conspired, confederated and agreed together and with others to violate 18 U.S.C. § 208, a statute that "bars a Federal employee from participating personally and substantially as a Government employee in any particular matter in which the employee has a financial interest. These restrictions also apply regarding the interests of an employee's spouse . . ." (FDA website, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm197511.htm)

158. As discussed above, Defendant Renaissance Technologies held significant amounts of Defendant Johnson & Johnson stock while Defendant Hamburg was FDA Commissioner and participated personally and substantially in matters pertaining to Defendant Johnson & Johnson.

159. On information and belief, each and every Defendant knew that they were engaged in violations to commit the predicate acts, as set forth above and herein, and they knew that the predicate acts were part of such racketeering activity, and the participation and agreement of each of them was necessary to allow the commission of this pattern of racketeering activity. This conduct constitutes violations and conspiracy to violate 18 U.S.C. § 1962(a), (b), (c), and (d).

160. On information and belief, each and every Defendant agreed to conduct or participate, directly or indirectly, in the conduct, management, or operation of the enterprise's affairs through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(b), and (c).

161. Each and every Defendant knew about and agreed to facilitate the enterprise's scheme to violate 18 U.S.C. § 208. It was part of the conspiracy that each and every Defendant and their co-conspirators would commit a pattern of racketeering activity in the conduct of the affairs of the enterprise, including the acts of racketeering set forth in herein.

162. As a direct and proximate result of each and every Defendants' RICO violations, the acts of racketeering activity of the enterprise, the overt acts taken in furtherance of those violations, and violations of 18 U.S.C. § 1962(a), (b), (c), and (d), each and every Plaintiff has been financially injured in their business and property, including financial damage to Plaintiffs' reputations and good will; the impairment of Plaintiffs' interest in obtaining work, enormous medical expenses, and other damage to their business and/or property.

163. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs are entitled to recover treble damages plus costs and attorneys' fees from each and every Defendant.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

Pattern of Racketeering Activity: Violation of 21 U.S.C. § 393 of the Food, Drug, and Cosmetic Act ("FDCA")

164. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

165. Each and every Defendant has unlawfully, knowingly, and willfully combined, conspired, confederated and agreed together and with others to violate 21 U.S.C. § 393 of the Food, Drug, and Cosmetic Act ("FDCA"), ensuring safe drugs.

166. As discussed above, Defendant Renaissance Technologies held significant amounts of Defendant Johnson & Johnson stock while Defendant Hamburg was FDA Commissioner and participated personally and substantially in matters pertaining to Defendant Johnson & Johnson.

167. On information and belief, each and every Defendant, jointly and severally, knew that they were engaged in violations to commit the predicate acts, and they knew that the predicate acts were part of such racketeering activity, and the participation and agreement of each of them was necessary to allow the commission of this pattern of racketeering activity. This conduct constitutes violations and conspiracy to violate 18 U.S.C. § 1962(a), (b), (c), and (d).

168. On information and belief, each and every Defendant agreed to conduct or participate, directly or indirectly, in the conduct, management, or operation of the Enterprise's affairs through a pattern of racketeering activity in violation of 18 U.S.C. 1962(b), and (c).

169. Each and every Defendant, jointly and severally, knew about and agreed to facilitate the Enterprise's scheme to violate 21 U.S.C. § 393 of the FDCA. It was part of the conspiracy that each and every Defendant and their co-conspirators would commit a pattern of racketeering activity in the conduct of the affairs of the Enterprise, including the acts of racketeering set forth herein.

170. As a direct and proximate result of each and every Defendants' RICO violations, the acts of racketeering activity of the enterprise, the overt acts taken in furtherance of those violations, and violations of 18 U.S.C. § 1962(a), (b), (c), and (d), each and every Plaintiff has been financially injured in their business and property, including damage to Plaintiffs' reputations and good will; the impairment of Plaintiffs' interest in obtaining work, enormous medical expenses, and other damage to their business and/or property.

171. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs are entitled to recover treble damages plus costs and attorneys' fees from each and every Defendant.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

Pattern of Racketeering Activity: Violation of 18 U.S.C. § 1001 Statements of Entries Generally

172. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

173. Each and every Defendant has unlawfully, knowingly, and willfully combined, conspired, confederated and agreed together and with others to violate 18 U.S.C. § 1001 which states that: "[e]xcept as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United

States, knowingly and willfully – (1) falsifies, conceals, or covers up by any trick, scheme, or device of a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation . . .”

174. On information and belief, each and every Defendant, acting individually and in concert, knew that they were engaged in violations to commit the predicate acts, and they knew that the predicate acts were part of such racketeering activity, and the participation and agreement of each of them was necessary to allow the commission of this pattern of racketeering activity. This conduct constitutes violations and conspiracy to violate 18 U.S.C. § 1962(a), (b), (c), and (d).

175. On information and belief, each and every Defendant agreed to conduct or participate, directly or indirectly, in the conduct, management, or operation of the enterprise’s affairs through a pattern of racketeering activity in violation of U.S.C. § 1962(b) and (c).

176. Each and every Defendant knew about and agreed, acting individually and in concert, to facilitate the enterprise’s scheme to violate 18 U.S.C. § 1001. It was part of the conspiracy to each and every Defendant and their co-conspirators would commit a pattern of racketeering activity in the conduct of the affairs of the enterprise, including the acts of racketeering as set forth herein.

177. As a direct and proximate result of each and every Defendants’ RICO violations, the acts of racketeering activity of the enterprise, the overt acts taken in furtherance of those violations, and violations of 18 U.S.C. § 1962(a), (b), (c), and (d), each and every Plaintiff has been financially injured in their business and property, including damage to Plaintiffs’ reputations and good will; the impairment of Plaintiffs’ interest in obtaining work, enormous medical expenses, and other damage to their business and/or property.

178. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs are entitled to recover treble damages plus costs and attorneys' fees from each and every Defendant.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

PREDICATE ACTS

Predicate Act: Bribery in Violation of 18 U.S.C. § 201.

179. Defendants committed acts constituting indictable offenses under 18 U.S.C. § 201 in that they directly or indirectly, corruptly gave, and offered and promised things of valuable, such as money, to Defendant Dr. Hamburg, who for the purposes of this predicate act was a public official as FDA Commissioner, with the intent to influence Defendant Dr. Hamburg to commit or aid in committing, or collude in, or allow, fraud, or the opportunity for the commission of any fraud and to induce Defendant Dr. Hamburg to do or omit acts in violation of her lawful duty as FDA Commissioner within the meaning of 18 U.S.C. § 201(b)(1)(B), (C).

180. Defendant Dr. Hamburg, being a public official for the purposes of this predicate act, directly or indirectly, corruptly demanded, sought, received, accepted or agreed to receive and/or accepted things of value personally for herself, her husband and her husband's hedge fund Renaissance Technologies, in return for being influenced to commit or aid in committing, or collude in, or allow, fraud or the opportunity for the commission of fraud against the United States and was induced to do or omit acts in violation of her official duty as FDA Commissioner within the meaning of 18 U.S.C. § 201 (b)(2)(B), (C).

Predicate Act: Use of Mail Fraud to Defraud in Violation of 18 U.S.C. § 1341.

181. Defendants, each and every one of them acting individually and in concert, committed acts constituting indictable offenses under 18 U.S.C. § 1341 in that they advised or intended to devise a scheme or artifice to defraud Plaintiffs, Congress, and the greater public by means of false or fraudulent pretenses, representations or promises. Defendants did place in an authorized depository for mail, or did deposit or cause to be deposited with private commercial interstate carriers and knowingly caused to be delivered by the U.S. postal service, letters, memoranda, and other matters, in violation of 18 U.S.C. § 1341, or aided and abetted in such criminal acts.

182. Each and every Defendant had a duty to disclose omitted facts with respect to the dangers of Levaquin.

183. For the purpose of devising, executing, and carrying on their schemes or artifice by means of false and fraudulent pretenses, Defendants caused delivery of various documents and things by the U.S. mails or by private or commercial interstate carriers, or received such therefrom. These predicate acts include, but are not limited to the following:

(a) From May 2009 to March 2015, using the mail system and the wires to misbrand Levaquin;

(b) From May 2009 to March 2015, using the mail system and the wires to sell Levaquin;

(c) From May 2009 to March 2015, using the mail system and the wires to solicit and accept contributions;

(d) From May 2009 to March 2015, using the mail system and the wires to unduly influence the FDA and Defendant Dr. Hamburg;

(e) From May 2009 to March 2015, using the mail system and the wires to submit false and misleading conflicts of interest statements to Congress;

(f) From May 2009 to March 2015, using the mail system and the wires to pay bribes, on information and belief;

(g) From May 2009 to March 2015, using the mail system and the wires to bestow perks, dinners, entertainment, and other perks or benefits;

(h) From May 2009 to March 2015, using the mail system and the wires to fail to report liability on SEC filings;

(i) From May 2009 to March 2015, using the mail system and the wires to keep the American people and Plaintiffs in the dark about the dangers of Levaquin.

Predicate Act: Use of Wire Fraud to Defraud in Violation of 18 U.S.C. § 1343.

184. Defendants, each and every one of them acting individually and in concert, committed acts constituting indictable offenses under 18 U.S.C. § 1342 in that they advised or intended to devise a scheme or artifice to defraud Plaintiffs, Congress, and the greater public by means of fraudulent pretenses, representations or promises. For the purpose of executing their scheme or artifice, Defendants transmitted, or caused to be transmitted, by means of wire communication in interstate or foreign commerce, writings, signs, signals, pictures, sounds, in order to defraud Plaintiffs', Congress, and the greater public.

185. Each and every Defendant had a duty to disclose omitted facts with respect to the dangers of Levaquin.

186. These predicate acts include, but are not limited, to the following:

(a) From May 2009 to March 2015, using the mail system and the wires to transfer funds from various Renaissance Technologies' stocks to offices nationally and internationally;

(b) From May 2009 to March 2015, using the mail system and the wires to misbrand Levaquin;

(c) From May 2009 to March 2015, using the mail system and the wires to sell Levaquin;

(d) From May 2009 to March 2015, using the mail system and the wires to solicit and accept contributions and/or illegal gratuities;

(e) From May 2009 to March 2015, using the wires to unduly influence the FDA and Defendant Dr. Hamburg;

(f) From May 2009 to March 2015, using the wires to submit false and misleading conflicts of interest statements to Congress;

(g) From May 2009 to March 2015, using the wires to pay bribes, on information and belief;

(h) From May 2009 to March 2015, using the wires to bestow perks, dinners, entertainment, etc.

(i) From May 2009 to March 2015, using the wires to fail to report liability on SEC filings;

(j) From May 2009 to March 2015, using the wires to keep the American people and Plaintiffs in the dark about the dangers of Levaquin;

(k) From May 2009 to March 2015, using the wires to accept and collect dividends to and from Renaissance Technologies;

(l) From May 2009 to March 2015, using the wires to accept, collect, and transfer funds to and from the Medallion Fund, with its principal place of business in Hamilton, Bermuda;

(m) From May 2009 to March 2015, emails incorporating false and misleading statements regarding Levaquin, on information and belief;

(n) In and around May 2009, wirings by and between the Defendants concerning the preparation of Defendant Dr. Hamburg's statement before Congress;

(o) In and around May 2009, communications by wire directed toward the U.S. state and federal government officials and regulators, including Congress, incorporating false and misleading statements regarding Levaquin.

Predicate Act: Laundering of Monetary Instruments in Violation of 18 U.S.C. § 1956(a)(2).

187. Defendants, each and every one of them acting individually and in concert, have on multiple occasions, acting in their individual capacities and as agents for Renaissance Technologies, Johnson & Johnson, Johnson & Johnson PRD, and Janssen, knowingly caused the transportation, transmission, and/or transfer of funds to or from the United States to themselves and to others with the intent that those funds be used to promote the carrying on of unlawful activity, including but not limited to violations of 18 U.S.C. §§ 201, 1341, 1343, 2314, 2315.

Predicate Act: Transport and Receipt of Money in Violation of 18 U.S.C. § 2314

188. Defendants, each and every one of them acting individually and in concert, committed acts constituting indictable offense under 18 U.S.C. § 2314 in that having devised or intended to devise a scheme or artifice to defraud Plaintiffs, Congress and the general public and/or to obtain money from Plaintiffs by means of false or fraudulent pretenses, representations

or promises, Defendants transported or caused to be transported in interstate or foreign commerce money having a value of $5,000 or more, which was converted or taken by fraud as alleged herein.

Predicate Act: Transport and Receipt of Money in Violation of 18 U.S.C. § 2315

189. Defendants, each and every one of them acting individually and in concert, committed acts constituting indictable offenses under 18 U.S.C.§ 2315 in that they received money in excess of $5,000, which crossed State or United States boundary after being unlawfully converted or taken. The acts of Defendants were done willfully and with the knowledge that the money was converted or taken by fraud. These acts were done intentionally and knowingly with the specific intent to advance Defendants' scheme or artifice.

Pattern of Racketeering Activity and Continuity of Conduct

190. Defendants' violations of 18 U.S.C. §§ 1962(a), (b), (c), (d), 18 U.S.C. §§ 1341, 1343, 1956(a)(2), 2314, and 2315 constitute a "pattern of racketeering activity," as that term is defined in Section 1961(1) and (5) of RICO, because the acts were related to each other and had continuity. As alleged herein, Defendants' violations of these statutes had the same or similar purposes, results, participants, victims, or methods of commission; they were interrelated and not isolated events.

Continuity of Conduct

191. Defendants' violations of these laws as set forth herein, each of which directly and proximately injured Plaintiffs and others, constituted a continuous course of conduct spanning a period, for Defendant Dr. Hamburg, her husband Defendant Peter Brown, Renaissance Technologies, James Simon and Robert Mercer, since 2009, and for the other Defendants, for much longer than that.

192. These acts were intended to obtain money through false representations, fraud, deceit, and other improper and unlawful means. Therefore, violations were a part of a pattern of racketeering activity under 18 U.S.C. §§ 1961(1) and (5).

193. On information and belief, Defendants have conducted and/or participated, directly and/or indirectly, in the conduct of the affairs of the alleged enterprises through a pattern of racketeering activity as defined herein in violation of 18 U.S.C. § 1962(c).

194. The unlawful actions of Defendants, each of them, have directly, illegally, and proximately caused and continue to cause injuries to Plaintiffs in their business and property.

195. As a direct and proximate result of each and every Defendants' RICO violations, the acts of racketeering activity of the enterprise, the overt acts taken in furtherance of those violations, and violations of 18 U.S.C. § 1962(a), (b), (c), and (d), each and every Plaintiff has been financially injured in their business and property, including damage to Plaintiffs' reputations and good will; the impairment of Plaintiffs' interest in obtaining work, enormous medical expenses, and other damage to their business and/or property.

196. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs are entitled to recover treble damages plus costs and attorneys' fees from each and every Defendant.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

SECOND CLAIM FOR RELIEF
(Violations of RICO, 18 U.S.C. § 1962(a))
Against All Defendants

197. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

198. Section 1962(a) prohibits a person or persons from acquiring an interest in an enterprise with racketeering income.

199. The Defendants and their co-conspirators make up an enterprise that engages in and whose activities affect interstate commerce.

200. These Defendants used and invested income that was derived from a pattern of racketeering activity in an interstate enterprise. Specifically, Defendants Brown, Mercer, and Simons invested profits made from drug company stocks and from stocks in companies significantly regulated by the FDA, while Defendant Hamburg was FDA Commissioner, in more drug company stocks and from stocks in companies significantly regulated by the FDA, as evidenced by the changes in drug stock holdings and holdings in stocks in companies significantly regulated by the FDA, listed each quarter for Defendant Renaissance Technologies on the Securities and Exchange website.

201. As a direct and proximate result of each and every Defendants' RICO violations, the acts of racketeering activity of the enterprise, the overt acts taken in furtherance of those violations, and violations of 18 U.S.C. § 1962(a), (b), (c), and (d), each and every Plaintiff has been financially injured in their business and property, including damage to Plaintiffs' reputations and good will; the impairment of Plaintiffs' interest in obtaining work, enormous medical expenses, and other damage to their business and/or property.

202. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs are entitled to recover treble damages plus costs and attorneys' fees from each and every Defendant.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

THIRD CLAIM FOR RELIEF
(Violations of RICO 18 U.S.C. § 1962(b))
Against All Defendants

203. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

204. Section 1962(b) prohibits a person or persons from using a pattern of racketeering activity to acquire or maintain control over an enterprise.

205. Defendants did acquire and/or maintain, directly or indirectly, an interest in or control of a RICO enterprise of individuals who were associated in fact and who did engage in, and whose activities did affect, interstate and foreign commerce, in violation of 18 U.S.C. § 1962(b).

206. Each and every Defendant did cooperate jointly and severally in the commission of two or more of the RICO predicate acts that are itemized above, and did so in violation of 18 U.S.C. § 1962(b).

207. Defendants did commit two or more of the offenses in a manner which they calculated and premeditated intentionally to threaten continuity, i.e. a continuing threat of their respective racketeering activities, in violation of 18 U.S.C. § 1962(b).

208. As a direct and proximate result of each and every Defendants' RICO violations, the acts of racketeering activity of the enterprise, the overt acts taken in furtherance of those violations, and violations of 18 U.S.C. § 1962(a), (b), (c), and (d), each and every Plaintiff has been financially injured in their business and property, including damage to Plaintiffs' reputations and good will; the impairment of Plaintiffs' interest in obtaining work, enormous medical expenses, and other damage to their business and/or property.

209. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs are entitled to recover treble damages plus costs and attorneys' fees from each and every Defendant.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

FOURTH CLAIM FOR RELIEF
(Violations of RICO, 18 U.S.C. § 1962(d))
Against All Defendants

210. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

211. Section 1962(d) prohibits a person from conspiring to violate 18 U.S.C. §§ 1962(b), and (c).

212. Each and every Defendant has unlawfully, knowingly, and willfully combined, conspired, confederated and agreed together and with others to violate 18 U.S.C. § 1962(b) and (c) as described above, in violation of 18 U.S.C. § 1962(d).

213. Upon information and belief, each and every Defendant knew that they were engaged in a conspiracy to commit the predicate acts, and they knew that the predicate acts were part of such racketeering activity, and the participation and agreement of each of them was necessary to allow the commission of this pattern of racketeering activity. This conduct constitutes a conspiracy to violate 18 U.S.C. § 1962(b), and (c), in violation of 18 U.S.C. § 1962(d).

214. Upon information and belief, each and every Defendant agreed to conduct or participate, directly or indirectly, in the conduct, management, or operation of the enterprise's affairs through a pattern of racketeering activity in violation of 18 U.S.C. 1962(b), and (c).

215. This intentional conduct, through a pattern of racketeering activity, includes:

(a) Multiple instances of bribery in violation of 18 U.S.C. § 201

(b) Multiple instances of mail fraud in violation of 18 U.S.C. § 1341

(c) Multiple instances of wire fraud in violation of 18 U.S.C. § 1343

(d) Multiple instances of money laundering in violation of 18 U.S.C. § 1956

(e) Multiple instances of transporting and receiving money in violation of 18 U.S.C. §§ 2314 and 2315.

216. Each and every Defendant knew about and agreed to facilitate the enterprise's scheme to defraud the American public, Plaintiffs, and Congress. It was part of the conspiracy that each and every Defendant and their co-conspirators would commit a pattern of racketeering activity in the conduct of the affairs of the Enterprise, including the acts of racketeering set forth herein.

217. As a direct and proximate result of each and every Defendants' conspiracy, the acts of racketeering activity of the enterprise, the overt acts taken in furtherance of that conspiracy, and violations of 18 U.S.C. § 1962(d), each and every Plaintiff has been financially injured in their business and property, including damage to Plaintiffs' reputations and good will; the impairment of Plaintiffs' interest in obtaining work, enormous medical expenses, and other damage to their business and/or property.

218. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs are entitled to recover treble damages plus costs and attorneys' fees from each and every Defendant.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

FIFTH CLAIM FOR RELIEF
(Unjust Enrichment)
Against Defendants Brown, Mercer, Simons, Renaissance Technologies, Johnson & Johnson, Johnson & Johnson PRD, and Janssen

219. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

220. Defendants Brown, Mercer, Simons, Renaissance Technologies, Johnson & Johnson, Johnson & Johnson PRD, and Janssen schemed with each other to push, promote, and to promote for off-label use, a misbranded drug that is unsafe for consumption and received improper benefits that they would otherwise not have secured, including monies paid by Plaintiffs for the unsafe drug, Levaquin.

221. As a consequence of Defendants' actions and inactions, Plaintiffs have been denied adequate medical care in connection with their failing health, because of their consumption of Levaquin.

222. Plaintiffs' ingesting Levaquin has enriched these Defendants.

223. Retention of these benefits by the Defendants would be unjust and inequitable.

224. The Defendants are guilty of malice, oppression, and fraud, through their willful and conscious disregard for the rights of Plaintiffs through manipulation, in order to directly enrich themselves. The Defendants willful and conscious disregard for the rights of Plaintiffs created an unjust hardship for Plaintiffs.

225. The circumstances are such that equity and good conscience require the Defendants to make restitution in an amount to be proven at trial.

SIXTH CLAIM FOR RELIEF
(Negligence)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

226. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

227. At all material times, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen had a duty to exercise reasonable care, and to comply with existing standards of care, in the design, development, manufacture, testing, inspecting, packaging, promotion, marketing, distribution, labeling, and/or sale of Levaquin through interstate commerce.

228. Defendants breached their duty of reasonable care to Plaintiffs, Plaintiffs' physicians, and Plaintiffs' healthcare providers, and failed to comply with existing standards of care, in that they negligently promoted for off-label use, marketed, misbranded, distributed through interstate commerce, and/or labeled Levaquin, and were otherwise negligent:

(a) In the design, development, research, manufacture, testing, packaging, promotion for off-label use, marketing, sale, and/or distribution of Levaquin through interstate commerce;

(b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the dangerous product, including Plaintiffs, of Levaquin's dangerous and defective characteristics;

(c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the product;

(d) In promoting the product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal

Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness;

(e) In representing that the product was safe for its intended use when, in fact, the product was unsafe for its intended use;

(f) In failing to perform appropriate pre-market testing of the product through clinical trials that, some of which, the FDA concluded had "significant flaws in protocol design and implementation";

(g) In failing to perform appropriate post-market surveillance of the subject product;

(h) In failing to adequately and properly test Levaquin before and after placing it on the market;

(i) In failing to conduct sufficient testing on Levaquin which, if properly performed, would have shown that Levaquin had the serious side effect of causing mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness;

(j) In failing to adequately warn Plaintiffs, Plaintiffs' physicians healthcare providers that the use of Levaquin carried a risk of developing mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness;

(k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of

mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness associated with the use of Levaquin; and

(l) In failing to adequately and timely inform Plaintiffs, Plaintiffs physicians and Plaintiffs' healthcare providers, and the healthcare industry of the risk of serious personal injury from Levaquin ingestion as described herein.

229. Plaintiffs' injuries and damages as alleged herein were and are the direct and proximate result of Defendants' failure to comport with their obligations of due care.

230. Defendants' actions were a substantial factor in bringing about the injuries and damages suffered by Plaintiffs, as well as the Plaintiffs' subsequent inability to receive appropriate treatment.

231. If Defendants exercised ordinary care, and complied with standards of care, Plaintiffs would not have been injured and would have received appropriate treatment.

232. Defendants knew or should have known that consumers, such as Plaintiffs, would foreseeable suffer injury and would not receive appropriate treatment as a result of Defendants' failure to exercise reasonable and ordinary care.

233. As a direct and proximate result of Defendants' carelessness and negligence, their failure to exercise reasonable care and their deviation from accepted standards of care, Plaintiffs Linda Martin, Terry Aston, Ester Schulkin, David Melvin, Jennifer Wilcox, and John Fratti suffered and will continue to suffer severe and permanent physical and emotional injuries, including, but not limited to mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness. Plaintiffs have endured and will continue to endure pain,

suffering, and loss of enjoyment of life; and have suffered and will continue to suffer economic loss, including incurring significant expenses for medical care and treatment. Plaintiffs seek actual and punitive damages from Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen as alleged.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

SEVENTH CAUSE OF ACTION
(Negligent Design Defect)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

234. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

235. At all material times, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings, and take such steps to assure that Levaquin did not cause users to suffer from unreasonable and dangerous side effects.

236. At all material times mentioned, the product Levaquin was defective and unsafe in design and manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen and ingested by Plaintiffs and when Plaintiffs did not receive appropriate treatment.

237. Levaquin was defective at the time of its design, manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Levaquin failed to warn of the dangerous risks posed by Levaquin, including the risk of developing mitochondrial toxicity, certain neuropsychiatric

adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness, such as those the Plaintiffs have endured because of this dangerous product.

238. At all material times, Levaquin was defective and Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen knew that it was to be used by consumers without inspection for defects, indeed because these Defendants marketed it as such. Moreover, Plaintiffs, Plaintiffs' prescribing physicians, Plaintiffs healthcare providers, and the healthcare industry neither knew nor had reason to know at the time of Plaintiffs' use and reliance on Levaquin of the substantial and dangerous defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include in the appropriate warnings.

239. At all material times, Levaquin was prescribed to and used by Plaintiffs as intended by Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen in a manner reasonably foreseeable to these Defendants.

240. The design of Levaquin was defective in that the risks associated with using Levaquin outweighed any benefits of the design. Any benefits associated with the use of Levaquin could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results.

241. This defect in design existed when the defective product left the Defendants' possession.

242. At the time Levaquin left the control of Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen Defendants knew or should have known of the risks associated with ingesting Levaquin.

243. As a result of Levaquin's defective condition, Plaintiffs suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

EIGHTH CAUSE OF ACTION
(Negligent Misrepresentation)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

244. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

245. At all material times, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Levaquin, and through that conduct have knowingly and intentionally misbranded Levaquin and placed Levaquin into the stream of interstate commerce with full knowledge that it reaches consumers such as Plaintiffs here who ingested it.

246. Defendants, in the course of their business, negligently and/or recklessly misrepresented to Plaintiffs, Plaintiffs' prescribing physicians, and the healthcare industry, the safety of Levaquin and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, and dangers posed by Levaquin.

247. Defendants made representations that Levaquin was safe to Plaintiffs, Plaintiffs' prescribing physicians, Plaintiffs' healthcare providers, and the healthcare industry when it marketed its product to them but failed to provide any warning that Levaquin causes mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic,

degenerative illness.

248. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that Levaquin had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiffs, Plaintiffs' physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiffs, Plaintiffs' prescribing physicians, the health care industry, and the consuming public that:

(a) Since at least 1996, Defendant Johnson & Johnson was in possession of data demonstrating that Levaquin has significant safety issues;

(b) There had been insufficient studies by Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen regarding the safety of Levaquin before and after its produce launch;

(c) Levaquin was not fully and adequately tested by Defendants for the risk of developing mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness;

(d) Testing and studies by other entities in scientific literature has shown that the use of Levaquin increases the risk of mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness.

249. These negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by these Defendants.

250. Defendants knew or should have known under the circumstances and through the exercise of due care, that those representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiffs, Plaintiffs' prescribing physicians, Plaintiffs' healthcare providers, and the healthcare industry.

251. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiffs, Plaintiffs' prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiffs as well as the general public.

252. At all times material times, neither Plaintiffs nor Plaintiffs' physicians, or Plaintiffs' healthcare providers were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, Plaintiff's prescribing physicians would not have prescribed Levaquin and Plaintiff would not have utilized the defective product.

253. Plaintiffs, Plaintiffs' prescribing physicians, and Plaintiffs' healthcare providers justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Levaquin and relied on the absence of information regarding the dangers of Levaquin which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiffs' detriment.

254. Defendants had a pecuniary interest in making these statements about Levaquin to Plaintiffs, Plaintiffs' prescribing physicians, Plaintiffs' healthcare providers, and the healthcare industry as Defendants stood to lose a significant amount in sales and revenue and stood to be served with a significant number of lawsuits if consumers and medical providers discovered there were safety issues with Levaquin.

255. Defendants had a post-sale duty to warn Plaintiffs, Plaintiffs' prescribing physicians, Plaintiffs' healthcare providers and the general public about the potential risks and complications associated with Levaquin in a timely manner.

256. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin with the absence of due care such that Plaintiffs' prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Levaquin as a treatment.

257. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin with the absence of due care such that Plaintiffs' treating physicians would rely on such information, or the absence of information, in selecting appropriate treatment for Plaintiffs post-Levaquin consumption.

258. The false information supplied by Defendants to Plaintiffs, Plaintiffs' prescribing physicians, Plaintiffs' healthcare providers, and the healthcare industry was that Levaquin was safe, and would not harm or adversely affect patients' health, including Plaintiffs, when used as directed.

259. The representations and false information communicated by Defendants to Plaintiffs, Plaintiff's prescribing physicians, Plaintiffs' healthcare providers, and the healthcare industry were material and Plaintiffs, Plaintiff's prescribing physicians, Plaintiffs' healthcare providers, and the healthcare industry justifiably relied on the misrepresentations and concealments.

260. As a direct and proximate result of Defendants negligent or reckless conduct, Plaintiffs ingested Levaquin and suffered and will continue to suffer severe and permanent physical and emotional injuries, including, but not limited to mitochondrial toxicity, certain

neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness.

261. Plaintiffs have endured and will continue to endure pain, suffering, and loss of enjoyment of life; and have suffered and will continue to suffer economic loss, including incurring significant expenses for medical care and treatment. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

NINTH CAUSE OF ACTION
(Breach of Express Warranty)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

262. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

263. Before Plaintiffs were first prescribed Levaquin, during the period in which Plaintiffs used Levaquin, and after the time Plaintiffs used Levaquin and sought treatment, Defendants expressly warranted that Levaquin was safe.

264. Plaintiffs either directly or indirectly through Plaintiffs' prescribing physicians did in fact see and hear these representations and justifiably relied on these representations that Levaquin was safe for the treatment of Plaintiffs' medical issues.

265. Levaquin did not conform to these express representations because Levaquin was misbranded and was not safe and had an increased risk of serious side effects, including mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic,

degenerative illness.

266. As a direct and proximate result of this wrongful conduct, Plaintiffs were injured as described above.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

TENTH CAUSE OF ACTION
(Breach of Implied Warranty)
Against Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen

267. Plaintiffs reallage and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

268. At the time Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen marketed, sold, and distributed, Levaquin, through interstate commerce, for use by Plaintiffs and the consuming population, these Defendants knew of the use for which Levaquin was intended and impliedly warranted Levaquin to be of merchantable quality and safe and fit for such use.

269. Plaintiffs reasonably relied upon the skill and judgment of these Defendants as to whether Levaquin was of merchantable quality and safe and fit for its intended use.

270. Contrary to such implied warranty, Levaquin was not of merchantable quality or safe or fit for its intended use, because Levaquin was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used as described above.

271. As a direct and proximate result of Plaintiffs' ingestion of Levaquin and the acts and failures to act by these Defendants, Plaintiffs were caused to suffer injuries and damages.

272. The Defendants' conduct is outrageous because of their reckless indifference to the health and safety of the Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

ELEVENTH CAUSE OF ACTION
(Fraud)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

273. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

274. Defendants misrepresented to Plaintiffs, Plaintiffs' prescribing physicians, Plaintiffs' healthcare providers, and the healthcare industry that Levaquin was safe and effective. Defendants fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety of Levaquin.

275. Defendants made misrepresentations and actively concealed adverse information when Defendants knew, or should have known, that Levaquin had defects, dangers, and characteristics that were different than what Defendants had represented to Plaintiffs, Plaintiffs' physicians, Plaintiffs' healthcare providers, and the healthcare industry generally. Specifically, Defendants actively concealed from Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, the health care industry, and the consuming public that:

(a) Since at least 1996, Defendant Johnson & Johnson and/or its predecessors were in possession of data demonstrating that Levaquin has significant safety issues;

(b) There had been insufficient studies by Defendants and/or their predecessors

regarding the safety of Levaquin before and after its product launch;

(c) Levaquin was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness; and

(d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Levaquin increases the risk of mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness.

276. These misrepresentations and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

277. Defendants knew and/or showed reckless disregard for the truth and should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiffs, Plaintiffs' prescribing physicians, Plaintiffs' healthcare providers, and the healthcare industry.

278. Defendants made these false representations with the intent or purpose that Plaintiffs, Plaintiff's prescribing physicians, Plaintiffs' healthcare providers, and the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well as the general public.

279. At all times herein mentioned, neither Plaintiffs nor Plaintiffs' prescribing

physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, Plaintiff's prescribing physicians would not have prescribed and Plaintiff would not have utilized the subject product, and Plaintiffs would have been able to receive appropriate treatment.

280. Plaintiffs relied on and/or was induced by Defendant's representations and/or active concealment and relied on the absence of safety information which Defendant did suppress, conceal, or fail to disclose in purchasing and using Levaquin.

281. Plaintiffs, Plaintiffs' prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of Levaquin that Defendants did suppress, conceal, or fail to disclose to Plaintiffs' detriment. Plaintiffs justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of Levaquin. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiffs would indirectly rely on Defendants' misrepresentations and/or active concealment.

282. Plaintiffs, Plaintiffs' prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry, justifiably relied on Defendants representations that Levaquin was safe as it is reasonable that Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry would rely on the statements of Defendants whether Levaquin was safe because as the manufacturer of Levaquin, they are held to the level of knowledge of an expert in the field.

283. Defendants had a post-sale duty to warn Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the general public about the potential risks and

complications associated with Levaquin in a timely manner.

284. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin with the intent and specific desire that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Levaquin as a treatment, as well as in selecting subsequent appropriate treatment.

285. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested Levaquin and suffered severe and permanent physical and emotional injures, as set forth herein, and Plaintiffs were subsequently unable to receive appropriate treatment.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

TWELFTH CAUSE OF ACTION
(Fraudulent Concealment/Constructive Fraud)
Against Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen

286. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

287. Defendants committed actual fraud by making material representations that were false, knowing that such material representations were false, and/or with reckless disregard for the truth or falsity of such material representations with the intent that Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, the healthcare industry, and the consuming public would rely on such material representations.

288. Plaintiffs, Plaintiffs' prescribing physicians, and Plaintiffs' healthcare providers

were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material representations, and Plaintiffs were injured as a direct and proximate result.

289. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiffs, Plaintiff's healthcare providers, and the general public of the inaccuracy of said misrepresentations. Defendants' omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiffs and Plaintiff's prescribing physicians would rely on Defendants' misrepresentations. Plaintiffs, Plaintiffs' prescribing physicians, and Plaintiffs' healthcare providers did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiffs were injured as a result.

290. At all times herein mentioned, Defendants had a duty to Plaintiffs, Plaintiffs' prescribing physicians, Plaintiffs' healthcare providers, and the general public to accurately inform them of risks associated with Levaquin because Defendants, as the manufacturer and/or distributor of the subject product, were in a position of superior knowledge and judgment regarding any potential risks associated with Levaquin.

291. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiffs relating to the Levaquin at issue in this lawsuit, said breach or breaches constituting fraud because of his propensity to deceive others or constitute an injury to public interests or public policy.

292. In breaching their duties to Plaintiffs, Defendants used their position of trust as the manufacturer and/or distributor of Levaquin to increase sales of the drug and to avoid potential lawsuits at the expense of informing Plaintiffs that, by ingesting Levaquin, they were placing themselves at a significantly- increased risk of developing mitochondrial toxicity, certain

neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

THIRTEENTH CAUSE OF ACTION
(Strict Liability)
Johnson & Johnson, Johnson & Johnson PRD, and Janssen

293. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

294. Levaquin was defective at the time of its manufacture, development, production, testing, inspection endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Levaquin failed to warn of the dangerous risks posed by Levaquin, including the risk of developing mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness.

295. At all material times alleged, Levaquin was defective and Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen knew that Levaquin was to be used by consumers without inspection for defects. Moreover, Plaintiffs, their prescribing physicians, and their healthcare providers neither knew nor had reason to know at the time of Plaintiffs' use of Levaquin of these defects. Ordinary customers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

296. At all material times, Levaquin was prescribed to and used by Plaintiffs as intended by Defendants in a manner reasonably foreseeable to Defendants.

297. The design of Levaquin was defective in that the risks associated with using Levaquin outweighed any benefits of the design. Any benefits associated with the use of Levaquin were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results.

298. The defect in design existed when the product left Defendants' possession.

299. At the time Levaquin left the control of the Defendants' they knew or should have known the risks associated with ingesting Levaquin and that Plaintiffs would not receive appropriate treatment without adequate warnings.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

FOURTEENTH CAUSE OF ACTION
(Violation of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B))
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

300. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

301. Defendants violated 15 U.S.C. § 1125(a)(1)(B), which provides, "[a]ny person who, on or in connection with any good or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods,

services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act."

302. As set forth above, the Defendants made false and/or misleading statements of fact in commercial advertisements, productions, and reports about Levaquin.

303. The false and/or misleading statements deceived and/or had the capacity to deceive consumers such as Plaintiffs.

304. This deception is material in that it influences the physician's, consumer's and Plaintiffs' purchasing decision by relying on the false and/or misleading representations by Defendants.

305. The product of Levaquin is in interstate commerce.

306. Plaintiffs have been injured as a result of the false and/or misleading statements as a result of the false advertising set forth above in an amount equal to Defendants' gross sales, trebled, and attorneys' fees and costs pursuant to 15 U.S.C. § 1117(a).

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

VII. PUNITIVE DAMAGES

307. Plaintiffs reallege and incorporate herein by reference each and every foregoing paragraph of this Complaint as if set forth in full.

308. At all material times, Defendants, each and every one of them, knew or should have known that Levaquin was inherently dangerous with respect to the risk of mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal

Carbapenem-Resistant Enterobacteriaceae ("CRE"), FQAD, and other chronic, degenerative illness, among other significant risks as discussed above.

309. At all material times, Defendants, each and every one of them, attempted to misrepresent and did misrepresent facts concerning the safety of Levaquin.

310. Defendants' misrepresentations including knowingly withholding material information from the medical community and the public, including Plaintiffs and Plaintiffs' prescribing physicians, and Plaintiffs' treating physicians concerning the safety of Levaquin. Defendants' conduct was outrageous so as to be malicious, willful, wanton, or oppressive and shows a reckless indifference to the interests of others.

311. At all material times, Defendants knew and recklessly disregarded the fact that Levaquin causes chronic, mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness.

312. Notwithstanding the foregoing, Defendants continued to aggressively market the misbranded product to consumers, including Plaintiffs, without disclosing the deadly side effects.

313. Defendants knew of the product's lack of warnings regarding the risk of irreversible FQAD, but they intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and/or sell Levaquin through interstate commerce and through a pattern of racketeering, without warnings so as to maximize sales and profits and to avoid potential lawsuits at the expense of the health and safety of the public, including the Plaintiffs here, in conscious and/or negligent disregard of the foreseeable harm caused by the dangerous drug, Levaquin.

314. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using Levaquin against its benefits and this willful and wanton conduct created an unreasonable risk of physical harm to Plaintiffs and other users of the dangerous product and deprived Plaintiffs' of receiving appropriate treatment for adverse events after consuming Levaquin.

315. As a direct and proximate result of Defendants' outrageous, malicious, willful, wanton, oppressive conduct so as to know a reckless indifference to the interests of others, Plaintiffs suffered severe and permanent physical and emotional injuries, including, but not limited to, mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness;

316. Plaintiffs have endured pain and suffering, have suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiffs' injuries and damages are permanent and will continue in the future.

317. Defendants' conduct was committed with knowing, malicious, willful, wanton, oppressive, reckless, careless and deliberate disregard for the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish Defendants and to deter them from similar conduct in the future.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment against all named Defendants as follows:

(a) For general (non-economic), special (economic), actual and compensatory damages in excess of $120,000,000;

(b) For damages trebled in the amount of Johnson & Johnson's gross sales pursuant to 15 U.S.C. § 1117 of the Lanham Act.

(c) With regard to the RICO counts, trebled damages with attorneys' fees and costs;

(d) For medical, incidental, and hospital expenses according to proof;

(e) For consequential damages in a sum reasonable to a jury;

(f) For punitive damages in excess of $750,000,000 to impress upon Defendants the seriousness of their egregious conduct and to deter similar conduct in the future;

(g) For attorneys' fees, treble damages, expenses, and costs of this action; and

(h) For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts as to all issues so triable.

Dated: January 18, 2016

Respectfully submitted,

/s/ Larry Klayman

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