IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TERRY ASTON,
Baltimore, Maryland

and

JOHN FRATTI,
Hummelstown, Pennsylvania

and

LINDA MARTIN,
Phoenix, Arizona

and

DAVID MELVIN,
Chatsworth, Illinois

and

JENNIFER WILCOX,
Oroville, California

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.,

AMENDED 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 Amended Complaint sets forth allegations that involve a conspiracy by Defendants, each and every one of them, to reap large financial returns by failing to disclose to Plaintiffs and the public at large the full extent of the devastating, life-threatening, and deadly effects of a highly dangerous pharmaceutical drug named Levaquin. Specifically, on or about May of 2009, President Barack Obama nominated Dr. Margaret A. Hamburg as a political appointee to become

Commissioner of the U.S. Food and Drug Administration ("FDA"). On information and belief, Dr. Margaret A. Hamburg was nominated as a result of huge political and other gratuities to Hillary Clinton and The Clinton Foundation, and at Mrs. Clinton's recommendation. During the confirmation process before Congress, Dr. Margaret A. Hamburg, acting in concert with her husband, Peter F. Brown and the other Defendants named in this Amended Complaint, at all material times the Co-CEO of a hedge fund named Renaissance Technologies, L.L.C., failed to disclose to Congress and other relevant authorities, her and her husband's clear-cut conflict of interest –specifically, that Renaissance Technologies, L.L.C. held hundreds of millions of dollars of Johnson & Johnson stock, the manufacturer of the deadly drug, Levaquin.

Once confirmed as FDA Commissioner, Dr. Margaret A. Hamburg acted as the instrumentality that all Defendants used to perpetrate their conspiracy and racketeering enterprise by having her act illegally and outside the scope of her authority as FDA Commissioner to suppress material information to Plaintiffs and the public that Levaquin was inherently dangerous and in fact, deadly. Had this information been disclosed to Plaintiffs and the public at large, her and her husband's financial gain and net worth would have plummeted, since Dr. Margaret A. Hamburg's husband, Peter F. Brown, reaped and continues to reap huge financial gain as a result of Renaissance Technologies, L.L.C.'s holdings of Johnson & Johnson stock.

To further this conspiracy, Dr. Margaret A. Hamburg, acting in concert with each and every Defendant, jointly and severally, appointed officials of Johnson & Johnson to key FDA Advisory Committees and colluded with Johnson & Johnson and its officials and subsidiaries to suppress information about the dangerous and deadly effects of Levaquin. As a result, during Dr. Margaret A. Hamburg's tenure as FDA Commissioner from 2009 to 2015, over 5,000 people

died as a result of consuming Levaquin[1] and other dangerous drugs promoted, manufactured, marketed, distributed and sold by Johnson & Johnson, suffered debilitating, life-threatening, and deadly illnesses and effects.[2] This deadly harm is continuing as Plaintiffs and thousands of other people are suffering and dying from the highly dangerous effects of Levaquin.

Because of the Defendants' racketeering scheme and conspiracy to suppress warnings and other material information about the extent of the deadly effects of Levaquin, Plaintiffs were precluded from discovering the extent of their injuries until 2015, not coincidentally after Dr. Margaret A. Hamburg no longer held her position as FDA Commissioner in 2015 and material information about the full extent of the dangers of Levaquin were disclosed thereafter. Given these harmful effects, Plaintiffs, all of whom were previously gainfully employed, suffered financial and other loss and damage to their persons, business, and property in the form of significant lost income since they could no longer continue to work, as well as harmful physical effects at Plaintiffs' expense. Defendants, each and every one of them, profited handsomely from their racketeering conspiracy by their agreed-upon failure to disclose the harmful effects of Levaquin to Plaintiffs and the public at large. This case is thus of seminal importance not only for Plaintiffs, but also for the consuming public at large. It is a tragic testament to how corrupt companies like Johnson & Johnson and their officials bribe and illegally collude with government officials and line their pockets at the expense of persons such as Plaintiffs.

[1] This calculation is based on data from FDA's Adverse Event Reporting System ("FAERS"). During years that Margaret Hamburg was FDA Commissioner, there was approximately 500 reported deaths associated with Levaquin. However, the FDA estimates that only approximately 10% of adverse events are actually reported, which would bring the total to over 5,000 deaths.

[2] During the same period, there were approximately 8,000 reports of Levaquin related injury, which would bring the actual number of persons injured to approximately 80,000.

II. JURISDICTION AND VENUE

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

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 Pharmaceutical Research & Development, L.L.C, and Ortho-McNeil-Janssen Pharmaceuticals, Inc., market, distribute, and sell 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 state of Maryland.

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

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

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

8. Jennifer Wilcox is an individual, natural person who, at all material times, was and is a citizen of the state of California.

Defendants

9. 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.

10. Defendant Johnson & Johnson has transacted and conducted business and has derived substantial revenue from goods and products used within the District of Columbia.

11. 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.

12. 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 the drug Levaquin.

13. 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.

14. Defendant Johnson & Johnson PRD has transacted and conducted business and derived substantial revenue from goods and products used within the District of Columbia.

15. 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.

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

17. 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.

18. 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.

19. Defendant Janssen has transacted and conducted business and derived substantial revenue from goods and products used within the District of Columbia.

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

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

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

23. 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.

24. 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.

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

26. Defendant Dr. Margaret A. Hamburg ("Defendant Hamburg") is an individual, natural person who was employed as FDA Commissioner during May 2009 to March 2015. Defendant Hamburg is being sued in her individual and personal capacity, not her official capacity as FDA Commissioner, as all of the acts alleged herein were perpetrated illegally and outside of the scope of her official capacity and authority as FDA Commissioner. Defendant Hamburg's acts were and are patently illegal and part of a racketeering conspiracy to defraud Plaintiffs and the American people. At all material times, including from May 2009 to March 2015, Defendant Hamburg was and is the wife of Defendant Brown, co-CEO of Defendant Renaissance Technologies.

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

28. Defendant James H. Simons ("Defendant Simons") is an individual, natural person who founded Defendant Renaissance Technologies and who continues to this present day to reap benefit from and be involved in managing Defendant Renaissance Technologies' funds.

IV. STANDING

29. As set forth in the following paragraphs of this Amended Complaint, 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, Simons, Mercer, Brown, and Hamburg.

V. FACTS

Defendants

30. 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, promote for off-label use, 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, promoted for off-label use, marketed, distributed, and sold the pharmaceutical drug Levaquin.

31. Levaquin was approved by the FDA on December 20, 1996 for marketing, sale, and use in the United States, and is the brand name for the antibiotic levofloxacin.

32. Levaquin is – and was promoted, marketed, and sold through interstate commerce using the U.S. wires and mails 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.

33. Defendants, each and every one of them, jointly and severally, conspired to and fraudulently used the U.S. mails and wires to commit overt acts in furtherance of the racketeering enterprise and conspiracy to fraudulently cover up and/or fail to disclose the true extent of the devastating, life-threatening, and deadly side effects of Levaquin.

34. Despite having access to the FDA report, "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," from April 17, 2013 that directly links Defendant Johnson & Johnson's drug, Levaquin, to mitochondrial toxicity and

implicated neurodegenerative diseases, including ALS, Alzheimer's and Parkinson's diseases, Defendants willfully covered up and/or failed to warn the public about Levaquin's link to mitochondrial toxicity through the use of the U.S. mails and wires, in furtherance of their racketeering enterprise and conspiracy.

35. Defendants, each and every one of them, jointly and severally, fraudulently conspired to and used the U.S. mails and wires to commit overt acts in furtherance of a racketeering enterprise and conspiracy to fraudulently cover up and/or fail to warn the public about Levaquin's link to multi-system disability despite (1) having access to the FAERS data which clearly documents that, at least from 2009 to present, Levaquin consumption is associated with multi-system disability, and (2) the November 5, 2015 FDA Advisory Committee where the FDA coined the term Fluoroquinolone-Associated Disability ("FQAD"). Individuals with FQAD are defined by the FDA as patients who were reported to be previously healthy and prescribed an oral fluoroquinolone antibacterial drug, including Defendant Johnson & Johnson's drug, Levaquin, 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).

36. The November 5, 2015 report regarding fluoroquinolones, including Levaquin, stated, ". . . 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). On November 5, 2015, the FDA Advisory Committee "voted overwhelmingly that the benefits and risks for the systemic fluoroquinolone antibacterial drugs [including Levaquin] do not support the current labeled indications….",

Defendants Johnson & Johnson, Johnson & Johnson PRD and Janssen still have not, on information and belief, included warnings about FQAD on Levaquin labels.

37. Defendants, each and every one of them, jointly and severally, fraudulently conspired to and used the U.S. mails and wires to commit overt acts in furtherance of the racketeering enterprise and conspiracy to fraudulently cover up and/or fail to disclose warnings about the risk of Carbapenem-Resistant Enterobacteriaceae ("CRE") and Neuropsychiatric Adverse Events, despite having access to the FDA FAERS and Center for Disease Control information data which clearly documents that, at least from 2009 to present, Levaquin consumption is associated with significant neuropsychiatric adverse events and 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.

38. Defendants, each and every one of them, jointly and severally, used the U.S. mails and wires to fraudulently commit overt acts in furtherance of the racketeering enterprise and conspiracy to fraudulently promote Levaquin for uses not approved by the FDA—known as "off label use". 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.

39. Defendants Johnson & Johnson, Johnson & Johnson PRD and Janssen have a demonstrated a pattern of practice in colluding with and fraudulently and illegally conspiring with others, as evidenced by the fact that (1) 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 illegal bribes and kickbacks

in exchange for Omnicare increasing its sales of drugs, including Levaquin[3] and (2) Defendant Johnson & Johnson settled with the U.S. Justice Department and Securities and Exchange Commission in or around 2011 totaling $70 million for using bribery and kickbacks to expand foreign business.[4]

40. As part of and in furtherance of this conspiracy, Johnson & Johnson, Johnson & Johnson PRD, and Janssen, has conspired to commit a pattern and practice of failing to disclose material information about the harmful and deadly effects of its other products. For instance, in an article titled Johnson & Johnson Ordered to Pay 72 Million In Suit Linking Talcum Powder and Ovarian Cancer, The Washington Post reported on February 24, 2016 with regard to talcum powder:

> "A Missouri jury has ordered Johnson & Johnson to pay Fox's family $72 million in actual and punitive damages. One of Fox's lead attorneys, Jim Onder, told the St. Louis Post-Dispatch that $31 million will go to the Missouri Crime Victims' Compensation Fund . . . They tried to cover up and influence the boards that regulate cosmetics . . . They could have at least put a warning o the box but they didn't. They did nothing. One memo from a company medical consultant likened ignoring the risks associated with 'hygenic' talc use and ovarian cancer to denying the link between smoking cigarettes and cancer – in other words, 'denying the obvious in the fact of all evidence to the contrary . . . Another document noted that sales were declining as more people became aware of the health risks, and included strategies for making blacks and Hispanics the highest users of talcum power . . . Fox was African American. The New Jersey-based company faces many more lawsuits related to talcum products it has made household names.'"[5]

41. In the course of marketing Levaquin, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen fraudulently used the U.S. mails and wires to commit overt acts in furtherance of the racketeering enterprise and conspiracy to misrepresent the actual dangers

[3] https://www.justice.gov/opa/pr/us-files-suit-against-johnson-johnson-paying-kickbacks-nation-s-largest-nursing-home-pharmacy
[4] http://www.huffingtonpost.com/2011/04/08/johnson-johnson-settlement-bribery_n_846715.html
[5] https://www.washingtonpost.com/news/morning-mix/wp/2016/02/24/johnson-johnson-ordered-to-pay-72m-in-suit-linking-talcum-powder-to-ovarian-cancer/

associated with consumption of Levaquin by failing to include warnings of, and other material information about, its devastating and life-threatening effects. Defendants made these material misrepresentations with the intention of inducing reliance and encouraging the Plaintiffs and the general public to purchase and consume Levaquin without having the benefit of the knowledge of the full range of dangerous side effects caused by Levaquin.

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

43. Defendant Hamburg was a political appointee of President Barack Obama. On information and belief, Defendant Hamburg was recommended to and promoted to President Obama to fill the role of FDA Commissioner by Hillary Clinton, to whom Defendant Hamburg and Defendant Brown had provided, and continue to provide, significant political contributions and other gratuities.[6] For example, in 1993, Defendant Hamburg was President Bill Clinton's first choice for the newly created federal AIDS coordinator. In 1997 President Bill Clinton selected in to be assistant secretary for policy and evaluation at the U.S. Department of Health and Human Services.[7] In addition, in 2014 Defendant Hamburg spoke at an open town hall meeting on behalf of The Clinton Foundation.[8]

[6] https://www.opensecrets.org/pres16/contrib.php?id=N00000019. Defendant Renaissance Technologies has contributed over $2 million to Hillary Clinton in the current election cycle—the eleventh highest amount reported.
[7] https://www.nlm.nih.gov/changingthefaceofmedicine/physicians/biography_136.html
[8] https://www.clintonfoundation.org/press-releases/media-advisory-president-clinton-open-town-hall-prescription-drug-abuse-johns-hopkins

44. Defendant Hamburg, on behalf of all of the Defendants as part of this racketeering conspiracy, gave political contributions and gratuities to Hillary Clinton in 2005, 2006, 2007, and 2008 to induce Mrs. Clinton to recommend and push for Defendant Hamburg to be nominated by President Obama.

45. Defendant Hamburg, on behalf of all of the Defendants as part of this racketeering conspiracy, gave political contributions and gratuities to President Obama to induce him to nominate her to be appointed as FDA Commissioner.

46. Defendant Brown, on behalf of all of the Defendants as part of this racketeering conspiracy, gave political contributions and gratuities to Hillary Clinton in 2000 and 2007 in order for Mrs. Clinton to recommend and push for Defendant Hamburg to be nominated by President Obama as FDA Commissioner.

47. Defendant Simons, on behalf of all of the Defendants as part of this racketeering conspiracy, gave donations and gratuities to Hillary Clinton prior to the time Defendant Hamburg was nominated by President Obama in order to induce and cause this nomination of Defendant Hamburg as a quid pro quo for these contributions and gratuities.[9]

48. From May of 2009 to March of 2015, Defendant Mercer was an executive or co-CEO of Defendant Renaissance Technologies.

49. From May of 2009 to March of 2015, Defendant Simons was Chief Executive Officer or Board Chair of Defendant Renaissance Technologies. Although Defendant Simons retired as Chief Executive Officer in 2010, on information and belief, Defendant Simons still maintains an active role in Renaissance Technologies' decision-making and policies.

50. At all material times, Defendants Renaissance Technologies, Simons, and Mercer were aware that Defendant Brown was married to Defendant Hamburg.

[9] http://dealbook.nytimes.com/2008/04/22/obama-and-the-hedge-fund-factor/?_r=0

51. On November 27, 2007, Defendant Simons represented, "from managing directors to cleaning staff, everyone receives a percentage of the profits."[10] On February 1, 2011, at a speech at Massachusetts Institute of Technology, Defendant Simons represented, "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."[11]

52. In and around February 13, 2011, Defendant Renaissance Technologies held more than 2,700 stock holdings. The top 30 stock holdings from Renaissance Technologies in and around February 2011 included numerous drug companies, including Defendant Johnson & Johnson, which was Defendant Renaissance Technologies' third largest holding. The list is as follows[12]:

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

[10] http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aq33M3X795vQ
[11] http://www.distressedvolatility.com/2011/01/james-simons-speech-at-mit-renaissance.html
[12] http://www.businessinsider.com/jim-simons-and-renaissance-institutional-equities-funds-30-largest-holdings-2011-2

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

53. In and around May 26, 2009, Defendant 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. However, the conflict of interest herein was never resolved. Neither Defendant Hamburg nor Defendant Brown, nor any other Renaissance Technologies executive had fully disclosed to Congress and other authorities that Defendant Brown, Defendant Hamburg's husband at all material times, *still held shares in – and benefits financially from – all of the stocks of Renaissance*, *via Renaissance Technologies profit-sharing*, as explained in detail by Defendant Simons, (*see* paragraph 47) regardless of whether Defendant Brown divested himself of a particular hedge fund, in furtherance of the racketeering enterprise and conspiracy.

54. Defendants Hamburg and Brown, acting in concert with each and every Defendant, fraudulently used the U.S. mails and wires to commit overt acts in furtherance of the racketeering enterprise and conspiracy by failing to fully disclose to Congress and other relevant authorities that, less than a year after Defendant Hamburg became FDA Commissioner, Defendant Brown at all material times was responsible for the overall financial success of Renaissance Technologies and for the overall profitability of stocks held by Renaissance Technologies, including drug stocks, including Defendant Johnson & Johnson stock, and

including stocks in other companies regulated by the FDA, regardless of whether Defendant Brown held or divested himself of a particular hedge fund.

55. From May of 2009 to March of 2015, Defendant Renaissance Technologies held the following amounts of Johnson & Johnson stock as documented on the U.S 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

56. While Defendant Hamburg was FDA Commissioner, her husband, Defendant Brown's annual income, not coincidentally, increased from a reported $10 million in 2008[13] to an estimated $125 million in 2011[14] and an estimated $90 million in 2012[15], due in whole or in

[13] http://www.wsj.com/articles/SB124328188115551961
[14] http://www.insidermonkey.com/blog/best-hedge-fund-managers-of-2011-11302/
[15] http://www.forbes.com/lists/2013/hedge-fund-managers-13_land.html

part to Defendants' racketeering conspiracy to withhold information about the devastating, life threatening, and deadly effects of Levaquin.

57. As part of Defendant Hamburg's pattern and practice of acting illegally outside of the scope of her authority as FDA Commissioner in furtherance of the racketeering enterprise and conspiracy, she counseled the FDA to also approved another highly dangerous pharmaceutical drug that Renaissance Technologies owns stock in, Zohydro,[16] despite the fact that on December 7, 2012, an FDA Advisory Committee voted 11 to 2 **against** its approval. In or around March 2013, Defendant Hamburg personally testified to members of Congress that she supported Zohydro's approval.[17]

58. From 2011 to May 2015, Defendant Renaissance Technologies, not coincidentally, held the following amounts of stock in Alkermes, the manufacturer of Zohydro.

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

[16] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm372287.htm
[17] http://news.yahoo.com/fda-chief-defends-zohydro-criticism-intensifies-220949363.html

59. From 2009 to March 2015, Defendants Brown, Mercer, and Simons shared in Defendant Renaissance Technologies' profits, made in part from stocks held in pharmaceutical companies and companies considered "significantly regulated" by the FDA, including Defendant Johnson & Johnson. Defendant Hamburg and the other Defendants, each and every one of them, jointly and severally, participated and profited personally and substantially in and from many matters in which she and her spouse, Defendant Renaissance Technologies' co-CEO, Defendant Brown, had a financial interest.

60. Defendant Hamburg, as part of her pattern and practice of illegally acting outside the scope of her authority as Commissioner of the FDA, fraudulently used the U.S. mails and wires to commit overt acts in furtherance of the racketeering enterprise and conspiracy by willfully and intentionally and illegally preventing the FDA from issuing warnings about the devastating and life-threatening effects of Levaquin.

61. On November 5, 2015, **after Defendant Hamburg had resigned**, an FDA employee, Debra Boxwell, finally exposed to Plaintiffs, and the public at large, that Defendant Hamburg and the FDA had been aware that Levaquin may result in multi-system disability since 2013, but that it did nothing to add this information to the Levaquin label and instead conspired with the other Defendants to fraudulently withhold it.

62. Defendants, each and every one of them, jointly and severally, fraudulently using the U.S. mails and wires to commit overt acts in furtherance of the racketeering enterprise and conspiracy, perpetrated this fraud to protect and further the financial interests and expected profits and gains that all Defendants had in Defendant Johnson & Johnson.

63. Defendant Hamburg and the other Defendants, each and every one of them, were aware of the extent of the devastating, life-threatening, and deadly effects of Levaquin.

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

65. 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.

66. 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.

67. 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.

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

69. 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.

70. 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.

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

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

73. On May 13, 2013, a House of Representatives panel questioned Defendant 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.

74. 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 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 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 Defendant Renaissance Technologies, specifically Johnson & Johnson.

75. In August of 2014, Defendant Hamburg received hundreds of emails from individuals who had severe Levaquin adverse affects, but Defendant 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 Defendant Renaissance Technologies, specifically Johnson & Johnson.

76. On September 8, 2014, Dr. Charles Bennett sent a second Citizen's Petition directly to Defendant Hamburg requesting that she put adequate information on the Levaquin label regarding serious psychiatric adverse events, but Defendant Hamburg, fraudulently using the U.S. mails and wires to commit overt acts in furtherance of the racketeering enterprise and conspiracy, did not order that adequate information be included on the Levaquin label because of each and every Defendant's enormous financial interest in Defendant Johnson & Johnson.

Plaintiffs

77. Each and every Plaintiff was prescribed brand-name Levaquin, purchased brand-name Levaquin, and ingested brand-name Levaquin, manufactured by Defendant Johnson & Johnson.

78. 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.

79. 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.

80. As a direct result of injuries suffered by Plaintiffs due to the purchase and ingestion of Levaquin, and due to Plaintiffs' inability to receive appropriate assessment, diagnosis, treatment planning, and treatment, Plaintiffs have been, and continue to be, unable to secure, maintain, and or perform the duties of employment and have therefore already, and will

continue to, suffer from loss of past, present, and future earnings and loss of earning capacity. As such, Defendants have intentionally and/or negligently interfered with, without limitation, Plaintiffs' contractual expectations, business expectations and, prospective economic advantage.[18]

81. Due to injuries suffered as a result of consumption of Levaquin, Plaintiff David Melvin has been, and will continue to be, unable to work as a law enforcement officer. At the time that Plaintiff David Melvin became unable to work on or around 2012, he was earning an approximate annual salary of $72,000, and therefore has suffered, and will continue to suffer financial loss, from loss of earnings. Plaintiff David Melvin has never ingested any fluoroquinolone other than brand-name Levaquin.

82. Due to injuries suffered as a result of consumption of Levaquin, Plaintiff Linda Martin has been, and will continue to be, unable to work as a healthcare manager. At the time that Plaintiff Linda Martin became unable to work on or around 2007, she was earning an approximate annual salary of $115,000, and therefore has suffered, and will continue to suffer financial loss, from loss of earnings. Plaintiff Linda Martin has never ingested any fluoroquinolone other than brand-name Levaquin.

83. Due to injuries suffered as a result of consumption of Levaquin, Plaintiff Jennifer Wilcox has been, and will continue to be, unable to work as a teacher. At the time that Plaintiff Jennifer Wilcox became unable to work on or around 2008, she was earning an approximate

[18] The Ninth Circuit held that a Plaintiff had standing to bring a RICO claim when Plaintiff claimed lost employment, employment opportunities, and wages and other compensation suffered as a result of a personal injury. *Diaz v. Gates*, 410 F.3d 897 (9th Cir. 2005). Importantly, the Court reasoned that Plaintiff had brought a viable claim because California state law dictated that Plaintiff's "particular interest amounts to property." *Id*. at 899 (internal quotations omitted). Looking to Washington D.C.'s law, courts have held that "…business expectancies, not grounded on present contractual relationships but which are commercially reasonably to anticipate, are considered to be property…." *Carr v. Brown*, 395 A.2d 79, 84 (D.C. 1978).

annual salary of $60,000, and therefore has suffered, and will continue to suffer financial loss, from loss of earnings.

84. Due to injuries suffered as a result of consumption of Levaquin, Plaintiff Terry Aston has been, and will continue to be, unable to work as a truck driver. At the time that Plaintiff Terry Aston became unable to work on or around 2008, she was earning an approximate annual salary of $50,000, and therefore has suffered, and will continue to suffer financial loss, from loss of earnings.

85. Due to injuries suffered as a result of consumption of Levaquin, Plaintiff John Fratti has been, and will continue to be, unable to work as a pharmaceutical sales representative. At the time that Plaintiff John Fratti became unable to work on or around 2005, he was earning an approximate annual salary of $67,000, and therefore has suffered, and will continue to suffer financial loss, from loss of earnings. Plaintiff John Fratti has never ingested any fluoroquinolone other than brand-name Levaquin.

86. Three of the Plaintiffs, Linda Martin, John Fratti, and Terry Aston, have been identified as disabled by the U.S. 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.

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

88. Each and every Plaintiff discovered his or her injury in the form of the Levaquin-related diagnosis of FQAD only in or around November of 2015.

89. Each and every Plaintiff discovered his or her injury in the form of Levaquin related Mitochondrial Toxicity only in or around May of 2014.

90. Each and every Plaintiff discovered his or her injury in the form of Levaquin related CRE only in or around February of 2015.

91. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and Plaintiffs' treating physicians the true risks and adverse events associated with Levaquin.

92. 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 was not named until November 5, 2015.

93. 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. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, lobbying, promoting, promoting for off-label use, and/or distributing and selling, 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.

VI. CAUSES OF ACTION

RICO Violations

94. Defendants acting in concert, jointly and severally, entered into and took action in furtherance of, a conspiracy fraudulently using the U.S. mails and wires to suppress information about the devastating and life-threatening effects of Levaquin.

95. Specifically, Defendants conspired to and committed two or more predicate acts by the fraudulent use of the U.S. mails and wires in furtherance of the racketeering enterprise by willfully suppressing warnings about the dangers of Levaquin on at least two instances, constituting fraudulent concealment: (1) Defendant Johnson & Johnson did not, as part of this racketeering conspiracy, include warnings and disclose other material information concerning the risk of mitochondrial toxicity on Levaquin labels, even in response to the April 17, 2013 FDA report which directly linked Levaquin to mitochondrial toxicity and implicated neurodegenerative diseases, and (2) Defendant Johnson & Johnson did not include warnings and disclose other material information concerning the risk of FQAD or other multi-system disability on Levaquin Labels, despite the November 5, 2015 testimony from Debra Boxwell, an FDA employee, that the FDA had been aware that Levaquin may result in multi-system disability since 2013. Defendant Hamburg, acting illegally and outside the scope of her authority as FDA Commissioner and as part of the racketeering conspiracy, willfully, intentionally, and fraudulently suppressed information regarding these devastating effects in order to promote each and every Defendants' financial interest in Defendant Johnson & Johnson.

96. Defendants, each and every one of them, operated a criminal conspiracy at least between the years 2009 to 2015 to fraudulently suppress warnings about the devastating effects of Levaquin.

(a) Defendant Hamburg engaged in a pattern and practice of illegally acting outside the scope of her legitimate authority as commissioner of the FDA to use the U.S. mails and wires in furtherance of the racketeering enterprise and conspiracy by willfully suppress material information about the effects of Levaquin in order to further the financial interest held by each and every Defendant in Defendant Johnson & Johnson.

(b) Defendant Hamburg engaged in a pattern and practice of illegally acting outside the scope of her legitimate authority as commissioner of the FDA to fraudulently use the U.S. mails and wires in furtherance of the racketeering enterprise and conspiracy to appoint Defendant Johnson & Johnson's employees to positions of influence, such as members of FDA Advisory Committees, in order to suppress material information about the dangerous effects of Levaquin. For instance, (1) on September 11, 2012, Dr. Samuel Maldonado, a paid Johnson & Johnson employee, was selected to be a member of the FDA Pediatric Advisory Committee during the time that pediatric Levaquin use was addressed by the committee[19] and (2) the FDA chose Dr. Samuel Maldonado, a paid Johnson & Johnson employee, to speak at the FDA's "First Annual Neonatal Scientific Workshop Roadmap for Applying Regulatory Science to Neonates."[20]

(c) Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen used the U.S. mails and wires in furtherance of the racketeering enterprise and conspiracy by provided gratuities to Defendant Hamburg during the time period including Defendant Hamburg's tenure as commissioner of the FDA from May 2009 to March 2015, as

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[19] http://www.fda.gov/advisorycommittees/committeesmeetingmaterials/pediatricadvisorycommittee/ucm318625.htm

[20] http://www.fda.gov/downloads/drugs/newsevents/ucm415813.pdf

evidenced by their pattern and practice of bribery as described in herein of this Amended Complaint.

(d) Defendant Hamburg and her husband, Defendant Brown, reaped financial benefit from the inflated Johnson & Johnson stock through Defendant Renaissance Technologies, for which Defendant Brown served in an executive capacity. Defendant Renaissance Technologies, held significant amounts of Defendant Johnson & Johnson stock, thereby incentivizing it to conspire to inflate Defendant Johnson & Johnson stock prices. Defendant Renaissance Technologies utilized a profit-sharing model whereby Defendants Renaissance Technology, Brown, Mercer, and Simons all benefitted financially from any profits gained.

(e) Defendants Mercer and Simons both served in an executive capacity at Renaissance Technologies during the relevant time period. On information and belief, where there was mutual sharing of information between Defendants Brown, Mercer, and Simons and Defendants Brown, Mercer, and Simons all directly managed the Renaissance Technologies hedge fund.

97. **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."

98. **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.

99. **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 . . ."

100. **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."

The Rico Enterprise

101. 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 Amended Complaint. Specifically, the purpose of Defendants' racketeering enterprise included, but was not limited to, reaping large financial gain by willfully and intentionally suppressing material information, through the fraudulent use of the U.S. mails and wires, about the devastating, life threatening, and deadly effects of Levaquin. 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. As described in the foregoing paragraphs of this Amended Complaint, Defendants, each and every one of them, maintained an ongoing relationship during the course of their ongoing criminal enterprise. Specifically, Defendant Hamburg was and remains married to Defendant Brown, who served in

an executive capacity at Defendant Renaissance Technologies, for which Defendants Mercer and Simons also served in an executive capacity. Renaissance Technologies held and continue to hold substantial stock in Defendant Johnson & Johnson. Defendant Johnson & Johnson, on information and belief, provided Defendant Hamburg with significant gratuities during Defendant Hamburg's tenure as FDA Commissioner. 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 are likely other members of the enterprise who are unknown as this time, but which will be uncovered during discovery. Defendants operated their criminal enterprise at least from 2009-2015, and continue to operate the same in the future.

102. As described in the foregoing paragraphs of this Amended Complaint, each and every Defendant participated in the operation or management of the enterprise.

103. 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

104. 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) -(5)

105. 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.

106. 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.

107. 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 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. Plaintiffs discovered the acts no earlier than 2015.

PREDICATE ACTS

Bribery in Violation of 18 U.S.C. § 201

108. *Predicate Act No. 1*: From May 2009 to March 2015, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen committed acts constituting indictable offenses under 18 U.S.C. § 201(b)(1)(A)-(C) in that they directly or indirectly, corruptly gave, and offered and promised things of valuable, such as money, to Defendant Hamburg, who for the purposes of this predicate act was a public official as FDA Commissioner, with the intent to influence Defendant Hamburg to suppress material information about the devastating, life-threatening, and deadly effects of Levaquin. This is evidenced by Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen's pattern and practice of using gratuities and bribery to secure favorable treatment for its products, as described in paragraph 40 of this Amended Complaint.

109. *Predicate Act No. 2*: On information and belief, from May 2009 to March 2015, Defendant Hamburg committed offenses illegally and outside the scope of her official duties,

constituting indictable offenses under 18 U.S.C. § 201(b)(2)(A)-(C) in that Defendant Hamburg, being a public official, directly or indirectly, corruptly demanded, sought, received, accepted, or agreed to receive things of value, such as money from Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen in return for suppressing material information about the devastating, life-threatening, and deadly effects of Levaquin.

Use of U.S Mails to Defraud in Violation of 18 U.S.C. § 1341.

110. As alleged above, 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, other relevant authorities, 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.

111. Defendants Johnson & Johnson, Johnson & Johnson PRD, Janssen, and Hamburg all had a duty to disclose the devastating, life-threatening, and deadly effects of Levaquin.

112. *Predicate Act No. 3*: From May 2009 to March 2015, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen fraudulently used the U.S. mails in furtherance of the racketeering enterprise and conspiracy in order to misbrand Levaquin without warnings of the extent of Levaquin's devastating, life-threatening, and deadly effects and withhold material information about Levaquin.

113. *Predicate Act No. 4*: From May 2009 to March 2015, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen used the U.S. mails in furtherance of the

racketeering enterprise and conspiracy in order to market, promote, distribute, and sell misbranded Levaquin to Plaintiffs and the public at large.

114. *Predicate Act No. 5*: On information and belief, from May 2009 to March 2015, Defendant Hamburg fraudulently used the U.S. mails in furtherance of the racketeering enterprise and conspiracy in order to solicit and accept gratuities and bribes from Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen in exchange for acting outside the scope of her legitimate authority as FDA Commissioner to fraudulently suppress material information about the dangers of Levaquin.

115. *Predicate Act No. 6*: On information and belief, from May 2009 to March 2015, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen fraudulently used the U.S. mails in furtherance of the racketeering enterprise and conspiracy in order to provide gratuities and bribes to Defendant Hamburg in exchange for her fraudulently suppressing material information about the dangers of Levaquin.

116. *Predicate Act No. 7*: From May 2009 to March 2015, Defendants Hamburg and Brown fraudulently used the U.S. mails in furtherance of the racketeering enterprise and conspiracy in order to submit false and misleading conflicts of interest statements to Congress and other relevant authorities, and thus reap large financial gain from holdings of Defendant Johnson & Johnson's stock.

117. *Predicate Act No. 8*: From May 2009 to March 2015, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen fraudulently used the U.S. mails in furtherance of the racketeering enterprise and conspiracy in order to misrepresent to Plaintiffs and the public the true and inherently dangerous effects of Levaquin consumption.

118. *Predicate Act No. 9*: From May 2009 to March 2015, Defendant Hamburg fraudulently used U.S mails in furtherance of the racketeering enterprise and conspiracy by illegally acting outside the scope of her legitimate authority as FDA Commissioner in order to keep the American people and Plaintiffs in the dark about the dangers of Levaquin.

Use of U.S. Wires to Defraud in Violation of 18 U.S.C. § 1343.

119. Defendants, each and every one of them acting individually and in concert, committed acts constituting indictable offenses under 18 U.S.C. § 1343 in that they advised or intended to devise a scheme or artifice to defraud Plaintiffs, Congress, other relevant authorities, and the greater public by means of fraudulent pretenses, representations or promises. For the purpose of executing their scheme or artifice, Defendants fraudulently 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, other relevant authorities, and the greater public.

120. Defendants Johnson & Johnson, Johnson & Johnson PRD, Janssen, and Hamburg all had a duty to disclose the devastating, life-threatening, and deadly effects of Levaquin.

121. *Predicate Act No. 10*: From May 2009 to March 2015, Defendants Renaissance Technologies, Brown, Mercer, and Simons fraudulently used U.S wires in furtherance of the racketeering enterprise and conspiracy by transferring earnings from Defendant Renaissance Technologies' holdings of Defendant Johnson & Johnson's stock to each and every Defendant.

122. *Predicate Act No. 11*: From May 2009 to March 2015, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen fraudulently used the U.S. wires in furtherance of the racketeering enterprise and conspiracy in order to misbrand Levaquin without warnings of the extent of Levaquin's devastating, life-threatening, and deadly effects.

123. *Predicate Act No. 12*: From May 2009 to March 2015, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen fraudulently used the U.S. wires in furtherance of the racketeering enterprise and conspiracy in order to manufacture, promote, distribute and sell misbranded Levaquin to Plaintiffs and the public at large.

124. *Predicate Act No. 13*: On information and belief, from May 2009 to March 2015, Defendant Hamburg fraudulently used the U.S. wires in furtherance of the racketeering enterprise and conspiracy in order to solicit and accept gratuities and bribes from Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen in exchange for illegally acting outside the scope of her legitimate authority as FDA Commissioner to fraudulently suppress material information about the dangers of Levaquin.

125. *Predicate Act No. 14*: On information and belief, from May 2009 to March 2015, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen fraudulently used the U.S. wires in furtherance of the racketeering enterprise and conspiracy in order to provide gratuities and bribes to Defendant Hamburg in exchange for her fraudulently suppressing material information about the dangers of Levaquin.

126. *Predicate Act No. 15*: On information and belief, from May 2009 to March 2015, Defendants Hamburg and Brown fraudulently used the U.S. wires in furtherance of the racketeering enterprise and conspiracy by submitting false and misleading conflicts of interest statements to Congress and other relevant authorities in order to reap large financial gain from holdings of Defendant Johnson & Johnson's stock.

127. *Predicate Act No. 16*: From May 2009 to March 2015, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen fraudulently used the U.S. wires in furtherance

of the racketeering enterprise and conspiracy by misrepresenting to Plaintiffs and the public the true and inherently dangerous effects of Levaquin consumption.

128. *Predicate Act No. 17*: On information and belief, from May 2009 to March 2015, Defendant Hamburg fraudulently used U.S wires in furtherance of the racketeering enterprise and conspiracy by acting outside of the scope of her legitimate authority as FDA Commissioner in order to keep the American people and Plaintiffs in the dark about the dangers of Levaquin.

129. *Predicate Act No. 18*: From May 2009 to March 2015, Defendants Renaissance Technologies, Brown, Mercer, and Simons fraudulently used U.S wires in furtherance of the racketeering enterprise and conspiracy in order to accept and collect dividends from holdings of Defendant Johnson & Johnson's stock.

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

130. *Predicate Act No. 19*: From May 2009 to March 2015, Defendants Renaissance Technologies, Brown, Mercer, and Simons, in furtherance of the racketeering enterprise and conspiracy, transferred ill-gotten and illegal financial gains from Defendant Renaissance Technologies' holdings of Defendant Johnson & Johnson stock to Defendants in order to continue to carry out Defendants unlawful conspiracy to conceal material information about the devastating and life-threatening effects of Levaquin.

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

131. *Predicate Act No. 20*: From May 2009 to March 2015, Defendants Renaissance Technologies, Brown, Mercer, and Simons, in furtherance of the racketeering enterprise and conspiracy, transferred into interstate commerce money having value of $5,000 or more that Defendants Renaissance Technologies, Brown, Mercer, and Simons knew was acquired by

Defendants' fraudulent and unlawful conspiracy to conceal material information about the devastating and life-threatening effects of Levaquin.

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

132. *Predicate Act No. 21*: From May 2009 to March 2015, Defendants Renaissance Technologies, Brown, Mercer, and Simons, in furtherance of the racketeering enterprise and conspiracy, received, possessed, and/or concealed money having value of $5,000 or more that had crossed interstate and Defendants Renaissance Technologies, Brown, Mercer, and Simons knew was acquired by Defendants' fraudulent and unlawful conspiracy to conceal material information about the devastating and life-threatening effects of Levaquin.

Pattern of Racketeering Activity and Continuity of Conduct

133. 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

134. 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 Hamburg, her husband Defendant Brown, Renaissance Technologies, Defendant Simons and Defendant Mercer, since 2009, and for the other Defendants, for much longer than that.

135. As set forth previously, in every quarter except one, from May 2009 to March 2015, while Defendant Hamburg was FDA Commissioner, her husband, Defendant Brown's employer, Defendant Renaissance Technologies, held significant amounts of Defendant Johnson & Johnson stock, including as much as half a billion dollars in Defendant Johnson & Johnson stock.

136. These acts were all committed with the intent of furthering Defendants' illegal racketeering enterprise and conspiracy to cover up material information about the devastating, life-threatening, and deadly effects of Levaquin in order to protect and further each and every Defendants' significant financial interest in Defendant Johnson & Johnson' s stock. Therefore, violations were a part of a pattern of racketeering activity under 18 U.S.C. §§ 1961(1) and (5).

137. 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).

138. The unlawful actions of Defendants, each of them, have directly, illegally, and proximately caused and continue to cause injuries, including but not limited to financial loss, to Plaintiffs in their business and property.

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

139. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

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

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

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

143. 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).

144. As set forth in the preceding paragraphs of this Amended Complaint, each and every Defendant, fraudulently using the U.S. mails and wires in furtherance of the racketeering enterprise and conspiracy, participated in conducting and/or directing the affairs of the racketeering enterprise. Defendant Hamburg, acting outside of the scope of her legitimate authority as FDA Commissioner, willfully and fraudulently suppressed material information about the devastating, life-threatening, and deadly effects of Levaquin, which is manufactured by Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen. Defendants Renaissance Technologies', Brown, Mercer, and Simons, used the Renaissance Technologies hedge fund to ensure that Defendants, each and every one of them, profited handsomely from their pattern of racketeering activity and criminal enterprise. Thus, Defendants, each and every one of them, banded together to commit a pattern of racketeering, fraudulently using the U.S. mails and wires, that they could not possibly have accomplished individually.

145. Defendants' racketeering enterprise and conspiracy, using the U.S. mails and wires, was conducted for the purpose of reaping large financial gains from Defendant Johnson & Johnson's drug, Levaquin. Critical to the conducting of Defendants' racketeering enterprise was the willful suppression of the true devastating, life-threatening, and deadly effects of Levaquin, in order to maximize the financial gain of each and every Defendant. Therefore, as a result of Defendants' conducting of this criminal enterprise, Plaintiffs were prescribed and subsequently

consumed Levaquin without knowledge of Levaquin's devastating effects. This directly resulted in financial injury to their business and/or property in the form of substantial loss of earnings.

146. 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, jointly and severally.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants for actual, compensatory damages including, but not limited to, loss of earnings in excess of $120,000,000, trebled pursuant to 18 U.S.C. § 1964(c), 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

147. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

148. Section 1962(a) prohibits a person or persons from using or investing any income derived from racketeering in the acquisition, establishment, or operation of any enterprise which is engaged in interstate commerce.

149. As described in the foregoing paragraphs of this Amended Complaint, Defendants, each and every one of them, fraudulently using the U.S. mails and wires in furtherance of the racketeering enterprise, used and invested income that was derived from a pattern of racketeering activity in an interstate enterprise. Specifically, on information and belief, Defendants Renaissance Technologies, Brown, Mercer, and Simons re-invested ill-gotten and illegal profits from Defendant Johnson & Johnson's stocks and from stocks in companies significantly regulated by the FDA, while Defendant Hamburg was FDA Commissioner, into

Defendant Johnson & Johnson and 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.

150. On information and belief, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen, fraudulently using the U.S. mails and wires in furtherance of the racketeering enterprise, used and invested the income derived from the pattern of racketeering activity in order to promote the use of Levaquin, thereby causing Plaintiffs to be prescribed and administered Levaquin during Plaintiffs' courses of treatment and ensuring the continued increase of the value of Defendants' personal and corporate interests in Johnson & Johnson stock.

151. Thus, as a direct and proximate result of each and every Defendants' use and investment of racketeering income, 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 person, business and/or property.

152. 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, jointly and severally.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants for actual, compensatory damages including, but not limited to, loss of earnings in excess of $120,000,000, trebled pursuant to 18 U.S.C. § 1964(c), 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

153. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

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

155. 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). Specifically,

156. As a result of Defendant's acquisition and maintenance of a criminal enterprise, whereby Defendants continually willfully failed to provide adequate warning as to the dangers of Levaquin, Plaintiffs ingested Levaquin and, as a result, suffer damages, including but not limited to significant financial loss in the form of loss of earnings and profits.

157. 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).

158. 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).

159. 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 person, 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.

160. 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, jointly and severally.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants for actual, compensatory damages including, but not limited to, loss of earnings in excess of $120,000,000, trebled pursuant to 18 U.S.C. § 1964(c), 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

161. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

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

163. As described in the foregoing paragraphs of this Amended Complaint, each and every Defendant has unlawfully, knowingly, and willfully combined, conspired, confederated and agreed together and with to participate in an endeavor(s) which would constitution a violation of the RICO statute and each and every Defendant has willfully conspired and agreed that Defendants would carry out each predicate act in furtherance of the racketeering enterprise and conspiracy.

164. Specifically, Defendant Hamburg, willfully and knowingly acted illegally outside of the scope of her legitimate authority as FDA commissioner to cover up the devastating effects of Levaquin, upon knowledge and agreement of all Defendants, in furtherance of this criminal conspiracy.

165. Specifically, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen manufactured, promoted, distributed, misbranded, distributed and sold an inherently dangerous drug, Levaquin, upon knowledge and agreement of all Defendants, in furtherance of this criminal conspiracy.

166. Specifically, Defendants Renaissance Technologies, Brown, Mercer, and Simons used their hedge fund, Renaissance Technologies, to reap enormous financial gain for all Defendants resulting from holdings of Defendant Johnson & Johnson stock and otherwise, upon knowledge and agreement of all Defendants, in furtherance of this criminal conspiracy.

167. 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(a)-(c), in violation of 18 U.S.C. § 1962(d).

168. Each and every Defendant had knowledge of and 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 (c).

169. As set forth in the preceding paragraphs of this Amended Complaint, 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.

170. As a direct and proximate result of each and every Defendants' conspiracy to reap huge financial gains by willfully suppressing the dangerous effects of Levaquin, each and every Plaintiff has been financially injured in their person, business and/or 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, jointly and severally.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants for actual, compensatory damages including, but not limited to, loss of earnings in excess of $120,000,000, trebled pursuant to 18 U.S.C. § 1964(c), 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
(Civil Racketeering - A.R.S. § 13-2314.04(A))
Against Defendants Hamburg, Brown, Mercer, Simons, Renaissance Technologies, Johnson & Johnson, Johnson & Johnson PRD, and Janssen

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

173. As described in the foregoing paragraphs of this Amended Complaint, Defendants formed a criminal enterprise and engaged in a pattern of racketeering activity through the

commission of predicate acts including, but not limited to, (1) bribery in violation of 18 U.S.C. § 201, (2) laundering of monetary instruments in violation of 18 U.S.C. §1956(a)(2), (3) use of U.S. mails to defraud in violation of 18. U.S.C. § 1341, (4) use of U.S wires to defraud in violation of 18 U.S.C. §1343, (5) transport and receipt of money in violation of 18 U.S.C. § 2314-15, and (6) engaging in a scheme or artifice to defraud.

174. As described in the foregoing paragraphs of this Amended Complaint, Defendants, each and every one of them, jointly and severally, engaged in a pattern of racketeering activity evidenced by (1) the continuity and threat of continuity of Defendants' predicate acts, (2) the relation between Defendants' predicate acts in furtherance of the common purpose of increasing each and every Defendant's financial interest in Defendant Johnson & Johnson's stock by willfully covering up the devastating and life-threatening effects of Levaquin, and (3) the last act of racketeering having occurred within five years of a prior act of racketeering.

175. Additionally, as described in the foregoing paragraphs of this Amended Complaint, Defendants engaged in a pattern of racketeering activity pursuant to § 13-2312(A)-(B) evidenced by (1) Defendants committing illegal control of a racketeering enterprise and (2) Defendants illegally conducting a racketeering enterprise.

176. 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 as pled herein, each and every Plaintiff has been financially injured in their person, 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, person, and/or property.

177. As a direct result of Defendants' criminal racketeering enterprise, through the use of the U.S. mails and wires, Plaintiffs have suffered, and will continue to suffer, reasonably foreseeable injuries as a result of Defendants' scheme to increase the value of Defendant Johnson & Johnson stock by willfully failing to provide adequate warnings about the dangers of Levaquin, insomuch as it is clearly foreseeable that willfully suppressing warnings and other material information about the true devastating, life-threatening, and deadly effects of Levaquin induced Plaintiffs to be prescribed and ingest Levaquin.

178. Pursuant to A.R.S. § 13-2314.04(A), Plaintiffs are entitled to recover treble damages plus costs and attorneys' fees from each and every Defendant, jointly and severally.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants in a for actual, compensatory damages including, but not limited to, loss of earnings and medical expenses in excess of $120,000,000, trebled pursuant to A.R.S. § 13-2314.04(A), for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

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

179. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

180. Defendants Brown, Mercer, Simons, Renaissance Technologies, Johnson & Johnson, Johnson & Johnson PRD, and Janssen schemed with each other to push, promote, distribute, and to distribute and sell 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.

181. Plaintiffs' purchases of Levaquin have enriched these Defendants, each and every one of them, jointly and severally, because, as described in the foregoing paragraphs of this Amended Complaint, all Defendants held a personal financial interest in Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen, and therefore all Defendants profited from the sales of Levaquin.

182. Retention of these benefits by the Defendants would be unjust and inequitable because Defendants engaged in a criminal conspiracy to willfully suppress material information about the true extent of the devastating, life-threatening, and deadly effects of Levaquin.

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

184. As a consequence of Defendants' actions and inactions, each and every one of them, jointly and severally, Plaintiffs have suffered enormous damage, including physical injury from the consumption of Levaquin, physical injury from the inability to receive adequate medical care as a result of Defendants' scheme and artifice, and damage to Plaintiffs' business and/or property such as loss of earnings and other damages.

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

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants for actual, compensatory damages in excess of $120,000,000, punitive damages in excess of $750,000,000, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

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

186. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

187. 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.

188. 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 and sold through interstate commerce, and/or labeled Levaquin, and were otherwise negligent:

(a) In the design, development, research, manufacture, testing, packaging, promotion and sale for off-label use, marketing, distribution, and/or sale 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, distributing, and selling 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 effects 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.

189. 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 because all Plaintiffs actually ingested "name brand" Levaquin, and are informed and believe, and thereon allege, that Plaintiff's injuries were caused by the ingestion of Levaquin.

190. 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 assessment, diagnosis, treatment planning, and treatment.

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

192. 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.

193. 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, 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 but not limited to, incurring significant expenses for medical care and treatment and loss of earnings. 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 and damages against Defendants for actual, compensatory damages in excess of $120,000,000, punitive damages in excess of $750,000,000, 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
(Product Defect)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

194. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

195. 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.

196. At all material times mentioned, the product Levaquin was defective and unsafe in design 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. At all

material times, the product Levaquin was defective in that it failed to warn of the hidden, dangerous risks posed by Levaquin. As described in the foregoing paragraphs of this Amended Complaint, at all material times, Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen knew, or reasonably should have known, of the inherently dangerous nature of Levaquin and its devastating and life-threatening effects.

197. Levaquin was defective in that warnings, instructions and directions accompanying Levaquin failed to warn of the hidden 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. Had Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen used an alternative warning which fully disclosed the hidden deadly risks posed by Levaquin, Plaintiffs would not have ingested Levaquin and Plaintiffs physicians, on information and belief, would not have prescribed Levaquin to Plaintiffs.

198. 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. 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.

199. 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, on information and belief, been obtained by the use of other designs that do not cause the devastating, life-threatening, and deadly effects that Levaquin does.

200. An ordinary consumer would not have expected Levaquin to cause the devastating, life-threatening, and deadly effects that it does, even when used in the intended or reasonably foreseeable manner. 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.

201. 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.

202. Plaintiffs ingested Levaquin, and as a result of Levaquin's defective condition, Plaintiffs suffered the injuries and damages alleged herein including 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 but not limited to, incurring significant expenses for medical care and treatment and loss of earnings.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants for actual, compensatory damages in excess of $120,000,000, punitive damages in excess of $750,000,000, 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
(Negligent Misrepresentation)

Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

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

204. 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.

205. 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.

206. 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 and failed to provide warning of numerous devastating and life-threatening effects caused by Levaquin, such as mitochondrial toxicity, certain neuropsychiatric adverse events, increased risk of acquiring potentially fatal Carbapenem-Resistant Enterobacteriaceae, FQAD, and other chronic, degenerative illness.

207. 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, but covered up, 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.

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

209. Defendants knew or should have known under the circumstances and through the exercise of due care, that those representations were false and misleading, 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.

210. Defendants made these false and misleading 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.

211. 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 these facts, Plaintiff's prescribing physicians would not have prescribed Levaquin and Plaintiff would not have utilized the defective product.

212. 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.

213. Defendants, each and every one of them, jointly and severally, had a pecuniary interest in making these false and misleading 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.

214. 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.

215. 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.

216. 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.

217. 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.

218. 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, Plaintiffs' prescribing physicians, Plaintiffs' healthcare providers, and the healthcare industry justifiably relied on the misrepresentations and concealments.

219. As a direct and proximate result of Defendants negligent or reckless conduct, Plaintiffs relied on Defendants' misrepresentations and subsequently ingested Levaquin. Plaintiffs suffered and will continue to suffer severe and permanent physical and emotional and other 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.

220. Plaintiffs have endured and will continue to endure pain, suffering, emotional distress, and loss of enjoyment of life; and have suffered and will continue to suffer economic

loss, including incurring lost earnings and 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 and damages against Defendants for actual, compensatory damages in excess of $120,000,000, punitive damages in excess of $750,000,000, 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 Express Warranty)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

221. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

222. 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.

223. 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.

224. Levaquin did not conform to these express representations because Levaquin was falsely represented and 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.

225. As a direct and proximate result of this wrongful conduct, Plaintiffs were injured in the form of pain, suffering, emotional distress and loss of enjoyment of life; and have suffered

and will continue to suffer economic loss, including, but not limited to, incurring significant expenses for medical care and treatment and loss of earnings. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

226. Plaintiffs have provided notice to Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen, through counsel, of the breach of express warranty.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants in a for actual, compensatory damages in excess of $120,000,000, punitive damages in excess of $750,000,000, 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
(Breach of Implied Warranty)
Against Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen

227. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

228. 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.

229. 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.

230. 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.

231. As a direct and proximate result of Plaintiffs' ingestion of Levaquin and the acts and failures to act by these Defendants, Plaintiffs were injured in the form of pain, suffering, emotional distress and loss of enjoyment of life; and have suffered and will continue to suffer economic loss, including but not limited to, incurring significant expenses for medical care and treatment and loss of earnings. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

232. Plaintiffs have provided notice to Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen, through counsel, of the breach of implied warranty.

233. 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 and damages against Defendants in a for actual, compensatory damages in excess of $120,000,000, punitive damages in excess of $750,000,000, 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
(Fraud)
Against Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen

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

235. 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.

236. 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 and illegally 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.

237. These misrepresentations and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants. Defendants only disclosed some of the effects of Levaquin and omitted many of the devastating and life threatening effects, including but not

limited to, mitochondrial toxicity and FQAD, which Plaintiffs suffer from.

238. 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.

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

240. 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, Plaintiffs' prescribing physicians would not have prescribed and Plaintiff would not have utilized the subject product, Levaquin, and Plaintiffs would have been able to receive appropriate treatment.

241. 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.

242. 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.

243. 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.

244. 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.

245. 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.

246. 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 and damages against Defendants for actual, compensatory damages in excess of $120,000,000,

punitive damages in excess of $750,000,000, 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
(Fraudulent Concealment/Constructive Fraud)
Against Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen

247. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

248. Defendants committed actual fraud by making material representations that were false, knowing that such material representations were false and misleading, 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. Specifically, Defendants actively and illegally concealed from Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, the health care industry, and the consuming public that:

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

(f) There had been insufficient studies by Defendants and/or their predecessors regarding the safety of Levaquin before and after its product launch;

(g) 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

(h) 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.

249. 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.

250. Additionally, Defendants knowingly omitted material information and remained silent regarding these misrepresentations despite the fact that they had a duty to inform Plaintiffs, Plaintiff's healthcare providers, and the general public of the inaccuracy of these misrepresentations. Defendants' omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiffs and Plaintiff's prescribing physicians, healthcare providers, the healthcare industry, and the consuming public 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.

251. 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.

252. Defendants only disclosed some of the effects of Levaquin and omitted many of its devastating and life threatening effects, including but not limited to, mitochondrial toxicity

and FQAD, which Plaintiffs suffer from.

253. 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.

254. 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 for actual, compensatory damages in excess of $120,000,000, punitive damages in excess of $750,000,000, 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
(Strict Liability)
Johnson & Johnson, Johnson & Johnson PRD, and Janssen

255. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

256. Defendants Johnson & Johnson, Johnson & Johnson PRD, and Janssen, were at all material times, engaged in the business of manufacturing and selling pharmaceutical drugs, such as Levaquin.

257. 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.

258. 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.

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

260. 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, on information and belief, been obtained by the use of other designs that do not cause the devastating and life-threatening effects that Levaquin does.

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

262. 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.

263. Plaintiffs ingested Levaquin, and as a result of Levaquin's defective condition, Plaintiffs suffered the injuries and damages alleged herein including 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 but not limited to, incurring significant expenses for medical care and treatment and loss of earnings.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants for actual, compensatory damages in excess of $120,000,000, punitive damages in excess of $750,000,000, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

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

264. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

265. 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."

266. As set forth in the preceding paragraphs of this Amended Complaint, Defendants made false and/or misleading statements of fact in commercial advertisements, productions, and reports about Levaquin.

267. The false and/or misleading statements deceived and/or had the capacity to deceive consumers such as Plaintiffs, who in fact purchased and consumed Levaquin.

268. 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.

269. The product of Levaquin is in interstate commerce.

270. 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 and damages against Defendants in a sum to be determined by a jury, trebled pursuant to 15 U.S.C. § 1117(a), for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

SIXTEENTH CAUSE OF ACTION
(Violation of D.C. Code § 28-3904)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

271. Plaintiffs re-allege and incorporate herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

272. As set forth in the preceding paragraphs of this Amended Complaint, Defendants made false and/or misleading statements of fact in commercial advertisements, productions, and reports about Levaquin and the associated risks and dangers of ingestion. Defendants also failed to state material facts, specifically the risks and dangers of Levaquin, in a manner that had a tendency to mislead, with, on information and belief, the intent of inducing reliance from Plaintiffs and the general public at large, to purchase and consume Levaquin.

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

274. 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.

275. 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 D.C. Code § 28-3905(k)(2)(A).

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, trebled pursuant to D.C. Code § 28-3905(k)(2)(A), for punitive damages in excess of $750,000,000, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

SEVENTEENTH CAUSE OF ACTION
(Violation of 815 ILCS 510/2)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

276. Plaintiff David Melvin re-alleges and incorporates herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

277. As set forth in the preceding paragraphs of this Amended Complaint, Defendants have engaged in deceptive trade practices including, but not limited to, (1) representing that goods have characteristics that they do not have, (2) advertising goods with intent not to sell them as advertised, and (3) engaging in conduct which creates a likelihood of confusion or misunderstanding. Specifically, Defendants advertised and represented Levaquin without providing warning of the risks and dangers of ingesting Levaquin.

278. As set forth in the preceding paragraphs of this Amended Complaint, Defendants made false and/or misleading statements of fact in commercial advertisements, productions, and reports about Levaquin, with, on information and belief, the intent of inducing reliance from Plaintiffs and the general public at large to purchase and consume Levaquin.

279. The false and/or misleading statements deceived and/or had the capacity to deceive physicians and consumers such as Plaintiffs, who in fact purchased and consumed Levaquin.

280. 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.

281. Plaintiff David Melvin is a resident of Illinois and purchased and consumed Levaquin in the state of Illinois.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants in a sum to be determined by a jury, for punitive damages in excess of $750,000,000, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

EIGHTEENTH CAUSE OF ACTION
(Violation of Md. Com. Law Code § 13-301)

Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

282. Plaintiff Terry Aston re-alleges and incorporates herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

283. As set forth in the preceding paragraphs of this Amended Complaint, Defendants made false and/or misleading statements of fact in commercial advertisements, productions, and reports about Levaquin and the associated risks and dangers of ingestion. Defendants also failed to state material facts, specifically the risks and dangers of Levaquin, in a manner that had a tendency to mislead.

284. Defendants made false and/or misleading statements with, on information and belief, the intent of inducing reliance from Plaintiffs and the general public at large to purchase and consume Levaquin.

285. The false and/or misleading statements deceived and/or had the capacity to deceive physicians and consumers such as Plaintiffs, who in fact purchased and consumed Levaquin.

286. 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.

287. Plaintiff Terry Aston is a resident of Maryland and purchased and consumed Levaquin in the state of Maryland.

288. Plaintiff Terry Aston has 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.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants in a sum to be determined by a jury, for punitive damages in excess of $750,000,000, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

NINETEENTH CAUSE OF ACTION
(Violation of 73 P.S. §201-9.2)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

289. Plaintiff John Fratti re-alleges and incorporates herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

290. As set forth in the preceding paragraphs of this Amended Complaint, Defendants have engaged in deceptive trade practices including, but not limited to, (1) representing that goods have characteristics that they do not have, (2) advertising goods with intent not to sell them as advertised, and (3) engaging in conduct which creates a likelihood of confusion or misunderstanding. Specifically, Defendants advertised Levaquin without providing warnings of the risks and dangers of ingesting Levaquin.

291. Defendants made false and/or misleading statements with, on information and belief, the intent of inducing reliance from Plaintiffs and the general public at large to purchase and consume Levaquin.

292. The false and/or misleading statements deceived and/or had the capacity to deceive physicians and consumers such as Plaintiffs, who in fact purchased and consumed Levaquin.

293. 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.

294. Plaintiff John Fratti is a resident of Pennsylvania and purchased and consumed Levaquin in the state of Pennsylvania.

295. Plaintiff John Fratti 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 73 P.S. §201-9.2

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants in a sum to be determined by a jury, trebled pursuant to 73 P.S. §201-9.2, for punitive damages in excess of $750,000,000, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

TWENTIETH CAUSE OF ACTION
(Violation of Cal Bus. & Prof. Code § 17500)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

296. Plaintiff Jennifer Wilcox re-alleges and incorporates herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

297. As set forth in the preceding paragraphs of this Amended Complaint, Defendants made false and/or misleading statements of fact in commercial advertisements, productions, and reports about Levaquin and the associated risks and dangers of ingestion. Defendants also failed to state material facts, specifically the risks and dangers of Levaquin, in a manner that had a tendency to mislead.

298. Defendants made false and/or misleading statements with, on information and belief, the intent of inducing reliance from Plaintiffs and the general public at large to purchase and consume Levaquin.

299. The false and/or misleading statements deceived and/or had the capacity to deceive physicians and consumers such as Plaintiffs, who in fact purchased and consumed Levaquin.

300. 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.

301. As set forth previously in this Amended Complaint, Defendants knew, or should have known with the exercise of reasonable care, that its statements were untrue or misleading.

302. Plaintiff Jennifer Wilcox is a resident of California and purchased and consumed Levaquin in the state of California.

303. Plaintiff Jennifer Wilcox has been injured as a result of the false and/or misleading statements as a result of the false advertising set forth above.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages 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.

TWENTY-FIRST CAUSE OF ACTION
(Violation of A.R.S. § 44-1522)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

304. Plaintiff Linda Martin re-alleges and incorporates herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

305. As set forth in the preceding paragraphs of this Amended Complaint, Defendants made false and/or misleading statements of fact in commercial advertisements, productions, and reports about Levaquin and the associated risks and dangers of ingestion. Defendants also failed

to state material facts, specifically the risks and dangers of Levaquin, in a manner that had a tendency to mislead.

306. The false and/or misleading statements deceived and/or had the capacity to deceive physicians and consumers such as Plaintiffs, who in fact purchased and consumed Levaquin.

307. 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.

308. As set forth previously in this Amended Complaint, Defendants knew, or should have known with the exercise of reasonable care, that its statements were untrue or misleading.

309. In making false and/or misleading statements and omitting material facts, Defendants intended to induce reliance of the general public, including Plaintiffs, and encourage the purchase and consumption of Levaquin.

310. Plaintiff Linda Martin is a resident of Arizona and purchased and consumed Levaquin in the state of Arizona.

311. Plaintiff Linda Martin have been injured as a result of the false and/or misleading statements as a result of the false advertising set forth above.

312. Plaintiff Linda Martin only discovered the false nature of Defendants' statements in or around November 2015, when the FDA coined the term FQAD.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants in a sum to be determined by a jury, for punitive damages in excess of $750,000,000, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

TWENTY-SECOND CAUSE OF ACTION
(Violation of N.Y. CLS Gen. Bus. § 349)
Against Johnson & Johnson, Johnson & Johnson PRD, and Janssen

313. Plaintiffs re-alleges and incorporates herein by reference each and every foregoing paragraph of this Amended Complaint as if set forth in full.

314. As set forth in the preceding paragraphs of this Amended Complaint, Defendants made false and/or misleading statements of fact in commercial advertisements, productions, and reports about Levaquin and the associated risks and dangers of ingestion. Defendants also failed to state material facts, specifically the risks and dangers of Levaquin, in a manner that had a tendency to mislead.

315. Defendants made false and/or misleading statements with, on information and belief, the intent of inducing reliance from Plaintiffs and the general public at large to purchase and consume Levaquin.

316. The false and/or misleading statements deceived and/or had the capacity to deceive physicians and consumers such as Plaintiffs, who in fact purchased and consumed Levaquin.

317. 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.

318. 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 N.Y CLS Gen. Bus. § 349(h).

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment and damages against Defendants in a sum to be determined by a jury, trebled pursuant to N.Y CLS

Gen. Bus. § 349(h), for punitive damages in excess of $750,000,000, for costs herein incurred, for attorneys' fees, and for such other and further relief as this Court deems just and proper.

VII. 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 damage to person, business, and/or property, including but not limited to, past, present, and future financial loss such as lost earnings and loss of earning capacity, medical, hospital, and incidental expenses, emotional distress and pain and suffering damages 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: April 11, 2016

Respectfully submitted,

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Attorney for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2016, the foregoing Amended Complaint was served and filed on this Court's ECF system and delivered to the following persons:

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