UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA

LANA C. KEETON, Plaintiff Pro Se

CIVIL ACTION NO._____

15-CV-20442-King/Torres

vs.

Johnson & Johnson,
a New Jersey Corporation with
Worldwide Headquarters in Middlesex County
1 Johnson and Johnson Plaza
New Brunswick, N.J. 08933

Ethicon, Inc., a wholly owned Subsidiary of Johnson & Johnson,
A New Jersey Corporation
Route 22 West, Box 151, Somerville, NJ 08876

Gynecare Worldwide,
now known as Ethicon's Women's Health and Urology,
a division of Ethicon, Inc.,
a wholly owned Subsidiary of Johnson & Johnson,
A New Jersey Corporation
Route 22 West, Box 151
Somerville, NJ 08876

Ethicon Sarl,
a wholly owned international subsidiary of Johnson & Johnson
Rue du Puits-Godet 20
CH-2000 Neuchatel, Switzerland

Mr. Peter Cecchini
Fellow, Regulatory Affairs
Ethicon Inc.
Route 22 West, P.O. Box 151
Somerville, NJ 08876

G. Willy Davila MD, FACOG
Chairman of the Dept of Gynecology
Cleveland Clinic Florida
2950 Cleveland Clinic Boulevard
Weston, FL 33331

Delos Cosgrove, MD
CEO and President
Cleveland Clinic Main Campus, Mail Code NA4
9500 Euclid Avenue, Cleveland, OH 44195

Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44106

Jeffrey B. Shapiro, Attorney
Arnstein & Lehr LLP
200 S. Biscayne Boulevard, Suite 3600
Miami, FL 33131

Neville M. Leslie, Attorney
Arnstein & Lehr LLP
200 S. Biscayne Boulevard, Suite 3600
Miami, FL 33131

Arnstein & Lehr LLP
200 S. Biscayne Boulevard, Suite 3600
Miami, FL 33131

David Krause
Branch Chief, General Plastic Surgery Devices
Center for Devices and Radiological Health (CDRH)
10903 New Hampshire Avenue
Silver Springs, MD 20993

and

The U.S. Food and Drug Administration's
Center for Devices and Radiological Health (FDA's CDRH)
10903 New Hampshire Avenue
Silver Springs, MD 20993

DEFENDANTS
_____/

LANA C. KEETON ORIGINAL COMPLAINT
PURSUANT TO THE FEDERAL RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (RICO), 18 U.S.C. §1961, MAIL OR WIRE FRAUD, 18 U.S.C. §§ 1341 and 1343 and an OBSTRUCTION OF JUSTICE18 U.S.C. § 1503, FRAUD BY OMISSION and/or FRAUD BY CONCEALMENT under DIVERSITY JURISDICTION 28:1332ri

Defendants have engaged, and are engaged, in a fraudulent scheme in violation of the

Federal Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §1961.

Defendants have committed mail fraud, wire fraud, perjury and a massive cover up to influence doctors and surgeons worldwide through professional societies, the International Urogynecological Association (IUGA), the International Continence Society (ICS), the American Urogynecological Society (AUGS) to implant millions of women over the last 20 years with a petroleum waste byproduct, the Ethcion/Johnson and Johnson trademark Prolene polypropylene synthetic surgical mesh for surgical treatment of incontinence and pelvic organ prolapse.

NATURE OF THE PRODUCT

The trademark Ethicon Prolene mesh is a thermoplastic polymer which shrinks, degrades, hardens and moves within the human body causing a myriad number of serious complications: organ perforation, inability to have sex, urinate, defecate, to sit, to walk and even death to name a few. The complications have been known by the company since at least 1999, almost 16 years.

Inherent defects in the manufacturing process for Prolene, including the use of Santonox as an additive, are the cause of autoimmune disease. Recurring infections are reported frequently by these women implanted with Prolene mesh and long term mesh infection has been shown to lead to cancer.

COVER UP OF RISKS VS. BENEFITS: THE FRAUDULENT SCHEME

The cover up of the real risks vs. benefits of a medical device, the Gynecare TVT System, by the Defendants are part of predicate acts constituting mail or wire fraud, 18 U.S.C. §§ 1341 and 1343,and/or an obstruction of justice, 18 U.S.C. § 1503, fraud by omission and/or fraud by concealment.

Plaintiff Lana C. Keeton was the specific intended target of the fraudulent RICO scheme. Plaintiff was unable to recover her losses from bankruptcy of more than $1 million dollars

($1,000,000.00) because of the conspiracy between and among the Defendants, fraud by Omission and fraudulent concealment, because the product liability lawsuit filed by Keeton, Case No. 1:06-cv-21116, U.S.D.CT. for the S.D. of Florida exposed the product defects and the fraudulent scheme.

The cover up, fraud and conspiracy started in the mid 1990's with a multi-million dollar Contract paid to Dr. Ulf Ulmsten, Medscand Medical AB, Uppsala Sweden to provide favorable outcomes in a "clinical trial" of the Ethicon/Johnson and Johnson Prolene polypropylene surgical mesh. The fraudulent scheme continues today.

HISTORY AND FACTS

Plaintiff Keeton filed a lawsuit against Gynecare Worldwide, Ethicon, Inc and Johnson & Johnson in Florida state court, December 2005. It was removed to United States District Court of the Southern District of Florida in May 2006, Case No. 1:06-cv-21116. Attorneys Jeffrey Shapiro and Neville Leslie of Arnstein & Lehr, LLP, Miami, FL represented Defendants, Gynecare Worldwide, Ethicon, Inc., Johnson and Johnson.

Plaintiff Keeton was unduly harmed because of unnecessary surgeries from 2002 through 2009 by Dr. G.Willy Davila, Cleveland Clinic Florida. Dr. Davila's treatment plan for Plaintiff Keeton's complications of the Gynecare TVT System and its Prolene polypropylene bladder sling protected the product itself, not Keeton.

Rather than perform a surgery in the hospital under anesthesia to remove the entire bladder sling implanted in Keeton, Dr. Davila repeatedly removed the mesh from inside the bladder of Keeton in his office. For years, the Gynecare TVT bladder sling cut into Keeton's bladder because of a "roping" effect. Dr. Davila thus supported the fraudulent medical marketing of the success of the TVT trial by Ulmsten in 1995-1996 by Ethicon.

In sworn deposition testimony in the fall of 2005 and at trial in December 9, 2009 in a medical negligence case filed by Bankruptcy Trustee Drew M. Dillworth against Dr. Bernard Cantor and Mt Sinai Hospital in Miami Beach, FL, Dr. G. Willy Davila never revealed his financial connections with Johnson and Johnson, Ethicon, Inc. or Gynecare Worldwide.

Unknown to Plaintiff Keeton, the entire time Davila treated her, he was under contract with co-conspirator Defendants Johnson and Johnson, Ethicon, Inc. and Gynecare Worldwide for $50,000.00 and $25,000.00 acknowledged by a letter mailed to Dr. Davila from Gynecare in November 7, 2001 by Zenobia Walji, Worldwide Director of Marketing for Gynecare at that time before her 1st consult with him in November 2002.

During the 7 years he treated Keeton, Dr. Davila never mentioned receipt in 2004 of a $40,000.00 check as an education grant for the IUGA speaker fees. Ethicon mailed the $40,000.00 check dated November 3, 2004 to him at his office in Cleveland Clinic in Weston, FL, not to the home office of IUGA. These are just two of the predicate acts of Defendants under the RICO act, U.S.C. 1961

Arnstein & Lehr, LLP sent over 4,000 pages to Plaintiff Keeton through the use of the United States Postal Service in approximately May 2007. The 4,000 pages were unresponsive discovery. Keeton Request for Production of Documents included Quality Control Reports for Sterilization. The documents mailed were Quality Control Reports for Manufacturing. In a hearing before Judge John O'Sullivan, attorneys Shapiro and Leslie testified the reports requested were not available.

In a letter dated September 28, 2009, in a mass tort lawsuit in New Jersey, the sterilization records were to be supplied by Anne M. Patterson, Riker, Danzig, Scherer, Hyland, Perretti LLP, an attorney for Defendants, Gynecare, Ethicon, Inc. and Johnson and Johnson, to a

different plaintiff. The records existed but were not provide to Keeton in her product liability lawsuit in 2007 as part of the fraudulent scheme.

Attorneys Shapiro and Leslie then conspired with Defendants to win summary judgment in August 2007 through mail fraud, perjury in court and continued the cover up to protect the launch of another Ethicon product, the Prolift pelvic mesh kit launched in 2004/2005. The Prolift had a raw material cost of $13.00 and sold for approximately $1,800 initially and dropped to approximately $1,000.00 generating an 88-90% profit on each kit sold generating millions of dollars in profit to Gynecare Worldwide, Ethicon, Inc and Johnson and Johnson.

Thousands of Prolift pelvic mesh kits were implanted between 2005 and 2008 without clearance by the FDA/CDRH. When Ethicon sought clearance of its next generation pelvic mesh kit, the Prolift M, it listed the Prolift as a predicate device and alerted the FDA/CDRH to the fact that it had never sought clearance from the agency and was selling an adulterated and misbranded product. The FDA/CDRH cleared the Prolift despite the clear violations by Gynecare Worldwide, Ethicon/Johnson & Johnson. No doctors, hospitals or patients were alerted to this by the FDA/CDRH. Thus the agency became a co-conspirator to the fraud of the companies.

Plaintiff Keeton was, and is, the intended target of the cover up and fraud. Keeton's focus on removing the mesh kit products from the market started in 2008 with conference calls with the CDRH Director Daniel Schulz and multiple other senior officials. Keeton provided documents to the FDA/CDRH of the fraud in July 2008 and was then told not to call the agency anymore.

While acting as if they were addressing the complaints brought forth by Keeton, in reality the FDA/CDRH protected the products and the companies and not the patients harmed by the

products and the companies. Keeton is the mesh injured patient. FDA/CDRH continues to ask her to do their job as a means of placating her so she will go away.

Keeton presented scientific evidence of the inherent defects in the pelvic mesh kits for bladder suspension and for pelvic organ prolapse repair to the FDA/CDRH. Out of 5 different meetings with the FDA/CDRH, on 3 occasions top personnel at the agency ask Keeton to provide them with more studies or to present them with the scientific info in a different format, or for her organization, Truth in Medicine Incorporated, to pay someone to do it. Meeting dates: March 2, 2010, November 3, 2010, May 17, 2011, November, 2011 and August 22, 2014.

Plaintiff Pro Se Keeton is the injured patient, supposedly protected by the FDA/CDRH. She is not, and was not, protected from the harm of a dangerous 510(k) medical device, the Gynecare TVT System, catalog/model number 810041, FDA 510(k) 974098, cleared for sale by the FDA/CDRH but never proven safe or effective.

Further, David Krause, Branch Chief, General Plastic Surgery Devices at the FDA's Center for Devices and Radiological Health (CDRH), interacted with Peter Cecchini, Fellow, Regulatory Affairs, Ethicon, Inc. disclosing Keeton's activities at the FDA in 2010. Krause alerted Cecchini to the existence of damning information in a video, "The Benefits of Light Weight Mesh" funded by Ethicon, Inc. in collaboration with one of Ethicon's experts, Dr. B. Todd Heniford at the Carolinas Medical Center in 2007. Krause was concerned that it was being shown to Dr. Jeffrey Shuren, Director of the CDRH in a meeting in November 2010.

The cover up continues. Presented with this interaction in December 2014, the CDRH took no action, rather having an ombudsman contact Keeton saying they took seriously the actions of their employees. No actions have been taken against David Krause by the CDRH.

Plaintiff Pro Se Lana C. Keeton has full documentation and proof of all allegations in this Original Complaint. An excel document will be filed with this Honorable Court by February 11, 2015 with dates, predicate acts and which U.S.C. code has been violated in the commission of This fraudulent scheme in violation of the Federal Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §1961. Exhibits will be attached.

IN CONCLUSION

Accordingly Plaintiff Keeton asks for damages, costs, and attorney's fees (if there are any) because she will successfully establish the elements of a RICO violation by a preponderance of the evidence showing standing and proximate cause for this civil RICO claim.

> *"Sedima, S.P.R.L.v. Imrex Co.,* 473 U.S. 479, 491-93, 105 S.Ct. 3275, 3282-83, 87 L.Ed.2d 346 (1985). A pattern of racketeering activity consists of at least two predicate acts of racketeering committed within a ten-year period.18 U.S.C. § 1961(5). Predicate acts are acts indictable under a specified list of criminal laws, 18 U.S.C. § 1961(1)(B), including mail fraud under 18 U.S.C. § 1341, and wire fraud under 18 U.S.C. § 1343."

Plaintiff Pro Se Lana C. Keeton asks for a jury trial in this matter. Plaintiff Keeton is seeking compensatory damages in the amount of $7 million dollars ($7,000,000.00) and punitive damages in the amount of $21 million dollars ($21,000,000.00) for the egregious behavior and massive fraud of all the named Defendants which is a menace not only to Plaintiff Keeton but to millions of women worldwide and to society as a whole.

Dated: February 4, 2015
Miami Beach, Florida 33139

Lana C. Keeton

LANA C. KEETON
Plaintiff Pro Se
Lana@LanaKeeton.com
1602 Alton Road, #423
Miami Beach, FL 33139
305-671-9331 phone; 800-509-9917 fax

By: Lana C. Keeton
Lana C. Keeton, Plaintiff Pro Se

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served via e-mail and fax this 4 day of February 2015 on all counsel or parties of record on the attached service list and also filed on the Court's CM/ECF system by filing it with the Clerk of the Court.

Lana C. Keeton
LANA C. KEETON
Plaintiff Pro Se
Lana@LanaKeeton.com
1602 Alton Road, #423
Miami Beach, FL 33139
305-671-9331 phone; 800-509-9917 fax

By: Lana C. Keeton
Lana C. Keeton, Plaintiff Pro Se

SERVICE LIST

Christy D. Jones
Christy.Jones@butlersnow.com
Butler Snow LLP
1020 Highland Colony Pkwy, Ste 1400
Ridgeland, MS 39157
601-985-4523 phone 601-985-4500 fax

David B. Thomas
dthomas@tcspllc.com
Thomas Combs & Spann, PLLC
P.O. Box 3824
Charleston, WV 25338
304-414-1800 phone 304-414-1807 direct 304-414-1801 fax

Johnson & Johnson,
a New Jersey Corporation,
with Worldwide Headquarters in Middlesex County
1 Johnson And Johnson Plaza
New Brunswick, NJ 08933
Phone 732-524-0400

Ethicon, Inc.,
a wholly owned Subsidiary of Johnson & Johnson,
a New Jersey Corporation
Route 22 West, Box 151
Somerville, NJ 08876
Phone 908-218-0707; 800-255-5050 fax 908-218 2471

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now known as Ethicon's Women's Health and Urology,
a division of Ethicon, Inc.,
a wholly owned Subsidiary of Johnson & Johnson,
a New Jersey Corporation
Route 22 West, Box 151
Somerville, NJ 08876
Phone 800-873-3636

Ethicon Sarl,
a wholly owned international subsidiary of Johnson & Johnson
Rue du Puits-Godet 20
CH-2000 Neuchatel, Switzerland

SERVICE LIST CONT'D

Mr. Peter Cecchini
Fellow, Regulatory Affairs
Ethicon, Inc.
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

G. Willy Davila MD, FACOG
Chairman of the Dept of Gynecology
Cleveland Clinic Florida
2950 Cleveland Clinic Boulevard
Weston, FL 33331
davilag@ccf.org
Phone 954-659-5559

Delos Cosgrove, MD
CEO and President
Cleveland Clinic Main Campus, Mail Code NA4
9500 Euclid Avenue
Cleveland, OH 44195
Phone 216-444-6733

Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44106
216-444-2300

Jeffrey B. Shapiro, Attorney
Arnstein & Lehr LLP
200 S. Biscayne Boulevard, Suite 3600
Miami, FL 33131
E-Mail: jbshapiro@arnstein.com
Phone 305-374-3330 Fax 305-374-4744

Neville M. Leslie, Attorney
Arnstein & Lehr LLP
200 S. Biscayne Boulevard, Suite 3600
Miami, FL 33131
E-Mail: nmleslie@arnstein.com
Phone 305-374-3330 Fax 305-374-4744

Arnstein & Lehr LLP
200 S. Biscayne Boulevard, Suite 3600
Miami, FL 33131
Phone 305-374-3330 Fax 305-374-4744

SERVICE LIST CONT'D

David Krause
Branch Chief, General Plastic Surgery Devices
Center for Devices and Radiological Health (CDRH)
10903 New Hampshire Avenue
Silver Springs, MD 20993
David.Krause@fda.hhs.gov
Phone 888-463-6332

and

The U.S. Food and Drug Administration's
Center for Devices and Radiological Health (FDA's CDRH)
10903 New Hampshire Avenue
Silver Springs, MD 20993
Phone 888-463-6332