

4/22/13

RECEIVED
APR 22 2013

SUMMONS
(CITACION JUDICIAL) Law Department

ENDORSED

SUM-100

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):

Hung T. Luu, M.D.; Johnson & Johnson, a New Jersey Corporation; Ethicon, Inc., a New Jersey Corporation; and Does 1-60

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):

Coleen M. Perry and Patrick Perry

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)
FILED
SUPERIOR COURT, METROPOLITAN JUDICIAL DISTRICT
BY SUPERIOR COURT CLERK, COUNTY OF KERN, ON
APR - 11, 2013

APR 12 2013

TERRY McNALLY, CLERK
BY _____ DEPUTY

NOTICE) You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. NOTE: The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. **AVISO!** Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito a esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar al gravamen de la corte antes de que la corte pueda desear el caso.

The name and address of the court is:

(El nombre y dirección de la corte es):
Superior Court County of Kern
1415 Truxtun Avenue
1415 Truxtun Avenue
Bakersfield, California 93301

CASE NUMBER:

1300-CV 279123 LHB

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):
Stewart R. Albertson SBN 230841
Albertson & Davidson, LLP
3491 Concours, Suite 201 Ontario, California 91764

DATE:

APR 12 2013

Clerk, by

T. GLORIA

Deputy

(Fecha)

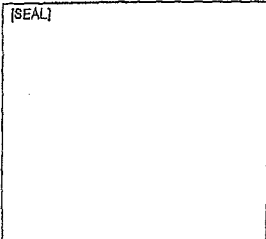
TERRY McNALLY

(Secretario)

(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).



NOTICE TO THE PERSON SERVED: You are served

- as an individual defendant.
- as the person sued under the fictitious name of (specify):
- on behalf of (specify): Johnson & Johnson, a New Jersey Corporation
under:

<input checked="" type="checkbox"/> CCP 416.10 (corporation)	<input type="checkbox"/> CCP 416.60 (minor)
<input type="checkbox"/> CCP 416.20 (defunct corporation)	<input type="checkbox"/> CCP 416.70 (conservatee)
<input type="checkbox"/> CCP 416.40 (association or partnership)	<input type="checkbox"/> CCP 416.90 (authorized person)
<input type="checkbox"/> other (specify):	
- by personal delivery on (date):

1 Stewart R. Albertson, SBN 230841
2 Albertson & Davidson, LLP
3 3491 Concours, Ste 201
4 Ontario, California 91764
5 (909) 466-1711
6 (909) 354-3460 fax
7 stewart@aldavlaw.com

8 Peter De La Cerda, SBN 249085
9 Edwards & De La Cerda, PLLC
10 3031 Allen St., Ste 100
11 Dallas, Texas 75204
12 (214) 550-5239
13 (214) 550-5223 fax
14 peter@edwardsdelacerda.com

15 Attorneys for Plaintiffs

16 Superior Court of the State of California
17 For the County of Kern

18 Coleen M. Perry and Patrick Perry,

19 Plaintiffs,

20 v.

21 Hung T. Luu, M.D.; Johnson & Johnson, a
22 New Jersey Corporation; Ethicon, Inc., a
23 New Jersey Corporation; and Does 1-60,

24 Defendants.

Case No. **1500-CV 279123 LHB**

Complaint for Damages and
Demand for Jury Trial

CASE MANAGEMENT CONFERENCE:

Hearing Date: 10-8-13

Time: 8:50am

Department: 17

See CRC Rule 3.720 Et. Seq.

25 Plaintiffs, for their cause of action against the Defendants, allege as follows:

Preliminary Allegations

26 1. Plaintiffs Coleen M. Perry and Patrick Perry are married citizens and
27 residents of the State of California.

28 2. On information and belief, Defendant Hung T. Luu, M.D. ("Dr.
29 Luu") is an individual and resident of the County of Kern, State of California.

30 3. Defendant Johnson & Johnson ("JNJ") is a foreign corporation
31 organized and existing under the laws of New Jersey, whose home office address is
32 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. All acts and

2:45pm 4/19/13

**SUMMONS
(CITACION JUDICIAL)**

SUM-100

**NOTICE TO DEFENDANT:
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Hung T. Luu, M.D.; Johnson & Johnson, a New Jersey Corporation; Ethicon, Inc., a New Jersey Corporation; and Does 1-60

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(LO ESTÁ DEMANDANDO EL DEMANDANTE):**

Coleen M. Perry and Patrick Perry

ENDORSED

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

FILED
SUPERIOR COURT METROPOLITAN DIVISION
COUNTY OF KERN, ON
BY SUPERIOR COURT CLERK
APR - 11, 2013

APR 12 2013

**TERRY McNALLY, CLERK
BY _____ DEPUTY**

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The name and address of the court is:

(El nombre y dirección de la corte es):

Superior Court County of Kern
1415 Truxtun Avenue
1415 Truxtun Avenue
Bakersfield, California 93301

CASE NUMBER:
(Número del Caso)
9-1500-CV 279123 LHB

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Stewart R. Albertson SBN 230841
Albertson & Davidson, LLP
3491 Concours, Suite 201 Ontario, California 91764

DATE:

(Fecha)

APR 12 2013

TERRY McNALLY

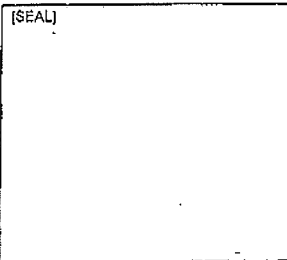
Clerk, by
(Secretario)

T. GLORIA

Deputy
(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).



NOTICE TO THE PERSON SERVED: You are served

- as an individual defendant.
- as the person sued under the fictitious name of (specify):
- on behalf of (specify): **Ethicon, Inc., a New Jersey Corporation**
under:

<input checked="" type="checkbox"/> CCP 416.10 (corporation)	<input type="checkbox"/> CCP 416.60 (minor)
<input type="checkbox"/> CCP 416.20 (defunct corporation)	<input type="checkbox"/> CCP 416.70 (conservatee)
<input type="checkbox"/> CCP 416.40 (association or partnership)	<input type="checkbox"/> CCP 416.90 (authorized person)
<input type="checkbox"/> other (specify):	
- by personal delivery on (date):

CM-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): Stewart R. Albertson (SBN 230841) Albertson & Davidson, LLP 3491 Concours, Suite 201 Ontario, California 91764 TELEPHONE NO.: (909) 466-1711 FAX NO.: (909) 354-3460 ATTORNEY FOR (Name): <u>stewart@aldavlaw.com</u>	FOR COURT USE ONLY FILED SUPERIOR COURT, METROPOLITAN DIVISION COUNTY OF KERN APR 11 2013 TERRY McNALLY, CLERK BY _____ DEPUTY
SUPERIOR COURT OF CALIFORNIA, COUNTY OF Kern STREET ADDRESS: 1415 Truxtun Avenue MAILING ADDRESS: 1415 Truxtun Avenue CITY AND ZIP CODE: Bakersfield, CA 93301 BRANCH NAME:	
CASE NAME: Perry v. Luu, et al	
CIVIL CASE COVER SHEET <input checked="" type="checkbox"/> Unlimited (Amount demanded exceeds \$25,000) <input type="checkbox"/> Limited (Amount demanded is \$25,000 or less)	Complex Case Designation <input type="checkbox"/> Counter <input type="checkbox"/> Joinder Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)
	CASE NUMBER: <u>S-1500-CV 279123 LHB</u> JUDGE: DEPT:

Items 1-6 below must be completed (see instructions on page 2).

1. Check one box below for the case type that best describes this case:

Auto Tort <input type="checkbox"/> Auto (22) <input type="checkbox"/> Uninsured motorist (46) Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort <input type="checkbox"/> Asbestos (04) <input type="checkbox"/> Product liability (24) <input checked="" type="checkbox"/> Medical malpractice (45) <input type="checkbox"/> Other PI/PD/WD (23) Non-PI/PD/WD (Other) Tort <input type="checkbox"/> Business tort/unfair business practice (07) <input type="checkbox"/> Civil rights (08) <input type="checkbox"/> Defamation (13) <input type="checkbox"/> Fraud (16) <input type="checkbox"/> Intellectual property (19) <input type="checkbox"/> Professional negligence (25) <input type="checkbox"/> Other non-PI/PD/WD tort (35) Employment <input type="checkbox"/> Wrongful termination (36) <input type="checkbox"/> Other employment (15)	Contract <input type="checkbox"/> Breach of contract/warranty (06) <input type="checkbox"/> Rule 3.740 collections (09) <input type="checkbox"/> Other collections (09) <input type="checkbox"/> Insurance coverage (18) <input type="checkbox"/> Other contract (37) Real Property <input type="checkbox"/> Eminent domain/Inverse condemnation (14) <input type="checkbox"/> Wrongful eviction (33) <input type="checkbox"/> Other real property (26) Unlawful Detainer <input type="checkbox"/> Commercial (31) <input type="checkbox"/> Residential (32) <input type="checkbox"/> Drugs (38) Judicial Review <input type="checkbox"/> Asset forfeiture (05) <input type="checkbox"/> Petition re: arbitration award (11) <input type="checkbox"/> Writ of mandate (02) <input type="checkbox"/> Other judicial review (39)	Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400-3.403) <input type="checkbox"/> Antitrust/Trade regulation (03) <input type="checkbox"/> Construction defect (10) <input type="checkbox"/> Mass tort (40) <input type="checkbox"/> Securities litigation (28) <input type="checkbox"/> Environmental/Toxic tort (30) <input type="checkbox"/> Insurance coverage claims arising from the above listed provisionally complex case types (41) Enforcement of Judgment <input type="checkbox"/> Enforcement of judgment (20) Miscellaneous Civil Complaint <input type="checkbox"/> RICO (27) <input type="checkbox"/> Other complaint (not specified above) (42) Miscellaneous Civil Petition <input type="checkbox"/> Partnership and corporate governance (21) <input type="checkbox"/> Other petition (not specified above) (43)
---	--	---

2. This case is is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
- | | |
|--|--|
| a. <input type="checkbox"/> Large number of separately represented parties | d. <input type="checkbox"/> Large number of witnesses |
| b. <input type="checkbox"/> Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve | e. <input type="checkbox"/> Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court |
| c. <input type="checkbox"/> Substantial amount of documentary evidence. | f. <input type="checkbox"/> Substantial postjudgment judicial supervision. |

3. Remedies sought (check all that apply): a. monetary b. nonmonetary; declaratory or injunctive relief c. punitive

4. Number of causes of action (specify): Seven Causes of Action

5. This case is is not a class action suit.

6. If there are any known related cases, file and serve a notice of related case. (You may use form CM-015.)

Date: April 10, 2013

Stewart R. Albertson

Stewart R. Albertson
 (SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE

- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

Page 1 of 2

1 Stewart R. Albertson, SBN 230841
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15 Attorneys for Plaintiffs.

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17 For the County of Kern

18 Coleen M. Perry and Patrick Perry,
19 Plaintiffs,

20 v.

21 Hung T. Luu, M.D.; Johnson & Johnson, a
22 New Jersey Corporation; Ethicon, Inc., a
23 New Jersey Corporation; and Does 1-60,
24 Defendants.
25

Case No. **1500-CV 279123 LHB**

Complaint for Damages and
Demand for Jury Trial

CASE MANAGEMENT CONFERENCE:

Hearing Date: 10-8-13

Time: 8:50am

Department: 17

See CRC Rule 3.720 Et. Seq.

26 Plaintiffs, for their cause of action against the Defendants, allege as follows:

27 **Preliminary Allegations**

- 28 1. Plaintiffs Coleen M. Perry and Patrick Perry are married citizens and
29 residents of the State of California.
- 30 2. On information and belief, Defendant Hung T. Luu, M.D. ("Dr.
31 Luu") is an individual and resident of the County of Kern, State of California.
- 32 3. Defendant Johnson & Johnson ("JNJ") is a foreign corporation
33 organized and existing under the laws of New Jersey, whose home office address is
34 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. All acts and
35

FILED
SUPERIOR COURT, METROPOLITAN DIVISION
COUNTY OF KERN
APR 11 2013
TERRY McNALLY, CLERK
BY _____ DEPUTY

1 Stewart R. Albertson, SBN 230841
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15 Attorneys for Plaintiffs

16
17 Superior Court of the State of California
18 For the County of Kern

19 Coleen M. Perry and Patrick Perry,
20
21 Plaintiffs,

22 v.

23 Hung T. Luu, M.D.; Johnson & Johnson, a
24 New Jersey Corporation; Ethicon, Inc., a
25 New Jersey Corporation; and Does 1-60,

26 Defendants.
27
28

Case No.:

Complaint for Damages and
Demand for Jury Trial

29 Plaintiffs, for their cause of action against the Defendants, allege as follows:

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33 2. On information and belief, Defendant Hung T. Luu, M.D. ("Dr.
34 Luu") is an individual and resident of the County of Kern, State of California.

35 3. Defendant Johnson & Johnson ("JNJ") is a foreign corporation
36 organized and existing under the laws of New Jersey, whose home office address is
37 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. All acts and

1 omissions of Defendant JNJ as described herein were done by its agents, servants,
2 employees and/or owners, acting in the course and scope of their respective
3 agencies, services, employments, and/or ownerships.

4 4. Defendant Ethicon, Inc., ("Ethicon") is a foreign corporation
5 organized and existing under the laws of New Jersey, whose home office address is 1
6 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant Ethicon is
7 wholly owned subsidiary of JNJ. All acts and omissions of Defendant Ethicon as
8 described herein were done by its agents, servants, employees and/or owners, acting
9 in the course and scope of their respective agencies, services, employments, and/or
10 ownerships.

11 5. At all times alleged herein, Defendants include any and all parents,
12 subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and
13 organizational units of any kind, their predecessors, successors and assigns and their
14 officers, directors, employees, agents, representatives, and any and all other persons
15 acting on their behalf.

16 6. At all times alleged herein, Defendants were each the agent, servant,
17 partner, aider and abettor, co-conspirator and joint venturer of each other and were
18 at all times operating and acting within the purpose and scope of said agency, service,
19 employment, partnership, conspiracy and joint venture and rendered substantial
20 assistance and encouragement to each other, knowing that their conduct constituted
21 a breach of duty owed to Plaintiffs.

22 7. There exists, and at all times herein alleged, there existed, a unity of
23 interest in ownership between certain Defendants and other certain Defendants such
24 that any individuality and separateness between the certain Defendants has ceased
25 and these Defendants are the alter-ego of the other certain Defendants and exerted
26 control over those Defendants. Adherence to the fiction of the separate existence of
27 these certain Defendants as an entity distinct from other certain Defendants will
28 permit an abuse of the corporate privilege and would sanction fraud and would
29 promote injustice.

30 8. The true names or capacities, whether individual, corporate, or
31 otherwise, of Defendants Does 1-60, inclusive, are unknown to Plaintiffs, who
32 therefore sue said Defendants by such fictitious names. Plaintiffs believe and allege
33 that each of the Defendants designated herein by fictitious names is in some manner
34 legally responsible for the events and happenings herein referred to and caused
35 damages proximately and foreseeably to Plaintiffs as alleged herein.

36 **No Federal Claims Pleaded**

37 9. Plaintiffs' claims in this action are brought solely under state law.

1 Plaintiffs do not herein bring, assert, or allege, either expressly or impliedly, any
2 causes of action arising under any federal law, statute, regulation, or provision. Thus,
3 there is no federal jurisdiction in this action on the basis of a federal question
4 under 28 U.S.C. § 1331.

5 10. Furthermore, federal diversity jurisdiction is lacking in this action.
6 Complete diversity does not exist between the parties and therefore the federal
7 courts lack jurisdiction under 28 U.S.C. §1332.

8 **JNJ's and Ethicon's Gynecare TVT Abbrevo Sling System**

9 11. At all times relevant herein, Defendants JNJ and Ethicon engaged in
10 the business of placing medical devices into the stream of commerce by designing,
11 manufacturing, packaging, labeling, marketing, selling, and distributing such devices,
12 including the Gynecare TVT Abbrevo ("Sling System"). The Sling System is a
13 product targeted at women who suffer from pain, discomfort, and stress urinary
14 incontinence as a result of weakening or damage to the walls of the vagina. The Sling
15 System is represented by Defendants JNJ and Ethicon to correct and restore normal
16 vaginal structure by implantation of polypropylene mesh in the vaginal region. The
17 Sling System is specifically promoted to physicians and patients as part of an
18 innovative, minimally invasive procedure with minimal local tissue reactions, minimal
19 tissue trauma, and minimal pain while correcting stress urinary incontinence.

20 12. Prior the implantation of the Sling System at issue in this Complaint,
21 Defendants JNJ and Ethicon sought and obtained Food and Drug Administration
22 ("FDA") approval to market the Sling System under Section 510(k) of the Medical
23 Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows
24 marketing of medical devices if the device is deemed substantially equivalent to other
25 legally marketed predicate devices marketed prior to May 28, 1976. No formal review
26 for safety or efficacy is required.

27 13. Despite claims that the monofilament polypropylene mesh in the
28 Sling System is inert, the scientific evidence shows that this material is biologically
29 incompatible with human tissue and promotes an immune response. This immune
30 response promotes degradation of the pelvic tissue and can contribute to the
31 formation of severe adverse reactions to the mesh.

32 14. The Sling System has been and continues to be marketed to the
33 medical community and to patients as safe, effective, and a reliable medical device
34 that can be implanted by safe, effective, and minimally invasive surgical techniques.

35 15. Defendants JNJ and Ethicon marketed and sold the Sling System
36 through carefully planned, multifaceted marketing campaigns and strategies. These
37 campaigns and strategies include, but are not limited to, aggressive marketing and the

1 provision of valuable cash and non-cash benefits to healthcare providers. Defendant
2 JNJ and Ethicon also utilized documents, patient brochures, and websites, offering
3 exaggerated and misleading expectations as to the safety and utility of these products.

4 16. Contrary to Defendant JNJ and Ethicon's representations and
5 marketing, the Sling System has high failure, injury, and complication rates, fails to
6 perform as intended, requires frequent and often debilitating revision surgeries, and
7 has caused severe and irreversible injuries, conditions, and damage to a significant
8 number of women, including Plaintiff. The defects stem from many issues, including:

- 9 A. The use of polypropylene material in the Sling System and the
10 immune reaction that results;
- 11 B. The design of the Sling System to be inserted transvaginally into an
12 area of the body with high levels of pathogens that adhere to the
13 mesh, which can cause immune reactions and subsequent tissue
14 breakdown;
- 15 C. The contraction or shrinkage of the mesh;
- 16 D. Biomechanical issues with the design of the mesh that create strong
17 amounts of friction between the mesh and the underlying tissue that
18 subsequently cause that tissue to degrade;
- 19 E. The use and design of anchors in the Sling System that when placed
20 correctly are likely to pass through and injure major nerve routes in
21 the pelvic region;
- 22 F. Degradation of the mesh itself over time which causes the internal
23 tissue to degrade;
- 24 G. The welding of the mesh itself during production, which creates a
25 toxic substance that contributes to the degradation of the mesh and
26 host tissue; and
- 27 H. The design used to insert the Sling System into the vagina requires
28 tissue penetration in nerve-rich environments, which results
29 frequently in the destruction of nerve endings.

30 17. Upon information and belief, Defendants JNJ and Ethicon have
31 consistently underreported and withheld information about the propensity of its
32 Sling System to fail and cause injury and complications, and have misrepresented the
33 efficacy and safety of these products, through various means and media, actively and
34 intentionally misleading the public.

35 18. Despite the chronic underreporting of adverse events associated with
36 the Sling System, enough complaints were recorded for the FDA to issue a public
37 health notification regarding the dangers of these devices.

1 19. On October 20, 2008, the FDA issued a Public Health Notification
2 that described over a thousand (1,000) complaints (otherwise known as “adverse
3 events”) that had been reported over a three-year period relating to the Sling System
4 and other similar products. Although the FDA notice did not identify the
5 transvaginal mesh manufacturers by name, a review of the FDA’s MAUDE database
6 indicates that Defendants JNJ and Ethicon manufacturers of some of the products
7 that are the subject of the notification.

8 20. On July 13, 2011, the FDA issued a Safety Communication entitled,
9 “UPDATE on Serious Complications Associated with Transvaginal Placement of
10 Surgical Mesh for Pelvic Organ Prolapse.” Therein, the FDA advised that it had
11 conducted an updated analysis of adverse events reported to the FDA and
12 complications reported in the scientific literature and concluded that surgical mesh
13 used in transvaginal repair of pelvic organ prolapse was an area of “**continuing**
14 **serious concern.**” (Emphasis supplied.) The FDA concluded that serious
15 complications associated with surgical mesh for transvaginal repair of pelvic organ
16 prolapse were “not rare.” These serious complications include, but are not limited
17 to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems.
18 Many of the serious complications required medical and surgical treatment and
19 hospitalization. The FDA concluded that it was not clear that transvaginal repair of
20 pelvic organ prolapse and stress urinary incontinence with mesh kits was more
21 effective than traditional non-mesh repair of these conditions. The FDA conducted a
22 systematic review of the published scientific literature from 1996 to 2011 and
23 concluded that transvaginal pelvic organ prolapse repair with mesh “does not
24 improve symptomatic results or quality of life over traditional non-mesh repair.” In
25 the July 13, 2011 Safety Communication, the FDA concluded that “a mesh
26 procedure may put the patient at risk for requiring additional surgery or for the
27 development new complications. Removal of the mesh due to mesh complications
28 may involve multiple surgeries and significantly impair the patient’s quality of life.
29 Complete removal of mesh may not be possible.” The information contained in the
30 FDA’s Public Health Notification of October 2008 and the FDA Safety
31 Communication of July 13, 2011 was known or knowable to Defendants JNJ and
32 Ethicon and was not disclosed in any manner.

33 21. Defendants JNJ and Ethicon have further known the following:
34 A. That some of the predicate devices for the Sling System had high
35 failure and complication rates, resulting in the recall of some of these
36 predicate devices;
37 B. That there were and are significant differences between the Sling

1 System and some or all of the predicate devices, rendering them
2 unsuitable for designation as predicate devices;

3 C. That these significant differences render the disclosures to the FDA
4 incomplete and misleading; and

5 D. That the Sling System was and is causing numerous patients severe
6 injuries and complications.

7 22. Defendants JNJ and Ethicon suppressed this information and failed
8 to accurately and completely disseminate or share this and other critical information
9 with others, including Plaintiff. As a result, Defendants JNJ and Ethicon actively and
10 intentionally misled and continue to mislead the public into believing that the Sling
11 System and the procedures for implantation were and are safe and effective.

12 23. Defendants JNJ and Ethicon failed to perform or rely on proper and
13 adequate testing and research in order to determine and evaluate the risks and
14 benefits of its Sling System.

15 24. Defendants JNJ and Ethicon failed to design and establish a safe,
16 effective procedure for removal of the Sling System; thus, in the event of a failure,
17 injury, or complications, it is impossible to easily and safely remove the Sling System.

18 25. Feasible and suitable alternative designs as well as suitable alternative
19 procedures and instruments for repair of stress urinary incontinence have existed at
20 all times relevant to this matter.

21 26. The Sling System was at all times utilized and implanted in a manner
22 foreseeable to Defendants JNJ and Ethicon, as Defendants JNJ and Ethicon
23 generated the instructions for use, created the procedures for implanting the device,
24 and trained the implanting physicians.

25 27. Defendants JNJ and Ethicon provided incomplete, insufficient, and
26 misleading training and information to physicians to increase the number of
27 physicians utilizing the Sling System, and thus increase the sales of these products.

28 28. The Sling System implanted into Plaintiff Coleen M. Perry
29 ("Plaintiff") was in the same or substantially similar condition as it was when they
30 left the possession of Defendants JNJ and Ethicon, as well as being in the condition
31 directed by and expected by Defendants JNJ and Ethicon.

32 29. Plaintiff and her physicians foreseeably used and implanted the Sling
33 System, and did not misuse or alter these products in an unforeseeable manner.

34 30. The injuries, conditions, and complications suffered by women who
35 have been implanted with Defendants JNJ and Ethicon's Sling System include, but
36 are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation,
37 scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood

1 loss, acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor
2 damage, chronic pelvic pain, urinary and fecal incontinence, and prolapse of organs.
3 In many cases, these women have been forced to undergo intensive medical
4 treatment, including, but not limited to, the use of pain control and other
5 medications, injections into various areas of the pelvis, spine, and the vagina, and
6 surgeries to remove portions of the female genitalia, to locate and remove mesh, and
7 to attempt to repair pelvic organs, tissue, and nerve damage.

8 31. The medical and scientific literature studying the effects of
9 polypropylene pelvic mesh (like the material used in the Sling System) have examined
10 each of these injuries, conditions, and complications and determined that they are in
11 fact casually related to the mesh itself and do not often implicate errors related to the
12 implantation of the devices.

13 32. Defendants JNJ and Ethicon knew and had reason to know that the
14 Sling System could and would cause severe and grievous personal injury to the users
15 of the Sling System, and that they were inherently dangerous in a manner that
16 exceeded any purported, inaccurate, or otherwise downplayed warnings.

17 33. At all relevant times herein, Defendants JNJ and Ethicon continued
18 to promote the Sling System as safe and effective even when no clinical trials had
19 been done supporting long or short-term efficacy.

20 34. At all relevant times herein, Defendants JNJ and Ethicon failed to
21 provide sufficient warnings and instructions that would have put Plaintiff and the
22 public on notice of the dangers and adverse effects caused by implantation of the
23 Sling System.

24 35. The Sling System was defective as marketed due to inadequate
25 warnings, instructions, labeling, and/or inadequate testing.

26 **Medical Care at Issue**

27 36. Defendant Luu is an individual licensed to practice medicine in the
28 State of California.

29 37. Upon information and belief, prior to March 23, 2011, Defendant
30 Luu knew, or should have known, the Sling System had high failure, injury, and
31 complication rates, failed to perform as intended, required frequent and often
32 debilitating additional surgeries, and has caused severe and irreversible injuries,
33 conditions, and damage to a significant number of women.

34 38. Prior to March 23, 2011, Plaintiff presented to Defendant Luu for
35 consultation regarding her stress urinary incontinence. During this consultation,
36 Defendant Luu recommended implantation of the Sling System but failed to fully
37 disclose to Plaintiff all risks he knew, or should have known, were associated with

1 implantation.

2 39. Upon information and belief, Defendant Luu recommended the Sling
3 System to Plaintiff as appropriate and safe for the treatment of stress urinary
4 incontinence. Consequently, Plaintiff consented to the implantation of the Sling
5 System.

6 40. On March 23, 2011, Defendant Luu implanted Plaintiff with the
7 Sling System at San Joaquin Community Hospital, in Bakersfield, California with the
8 intention of treating her for stress urinary incontinence, the use for which
9 Defendants JNJ and Ethicon marketed and sold the Sling System.

10 41. On or about January 17, 2012, a revision surgery was performed on
11 Plaintiff, which surgically explanted the Sling System.

12 42. As a result of the implantation of the Sling System, Plaintiff suffered
13 and will continue to suffer serious bodily injuries, including pain, discomfort,
14 pressure, difficulty voiding urine, continued incontinence, discharge, scarring,
15 infection, odor, and bleeding.

16 43. As a result of Plaintiff's injuries from the Sling System, Plaintiff
17 Patrick Perry suffered a loss of consortium.

18 **First Cause of Action: Medical Malpractice**
19 **(Against Defendant Luu and Does 1-10)**

20 44. Plaintiffs reallege and incorporate herein by reference each of the
21 foregoing paragraphs of this Complaint as though fully set forth herein.

22 45. At all relevant times herein, Defendant Luu and Does 1-10, inclusive,
23 were healthcare providers, physicians, surgeons, and other hospital personnel and
24 facilities duly licensed to practice medicine and surgery, operate hospitals and other
25 medical facilities, and provide other related medical services in the State of
26 California. Defendant Luu and Does 1-10, inclusive, have held themselves out to
27 possess that degree of skill, ability, and learning, common to medical personnel in
28 said community.

29 46. At all relevant times herein, Defendant Luu and Does 1-10, inclusive,
30 were agents and employees, each of the other, and in doing the things hereinafter
31 mentioned were acting within the scope of their authority as such agents and
32 employees and with the consent of their Co-Defendants.

33 47. Upon information and belief, Defendant Luu and Does 1-10,
34 inclusive, were doing business in the State of California, in the County of Kern.

35 48. Plaintiff retained the services of Defendant Luu and Does 1-10 to
36 treat her for stress urinary incontinence, a medical condition for which these
37 Defendants implanted the Sling System in Plaintiff.

1 49. Defendants Yeo and Does 1-10, inclusive, carelessly and negligently
2 treated, operated on, and cared for Plaintiff, and so negligently failed to conform to
3 the standards of care required of them as medical practitioners, surgeons, nurses, and
4 physicians, and that by reason thereof, Plaintiff was caused to and did suffer
5 irreparable, serious personal injuries and damages as described herein.

6 50. More specifically, the injuries and damages sustained by Plaintiff were
7 proximately caused by the negligence of Defendant Luu and Does 1-10 in at least the
8 following particulars:

- 9 A. In failing to select and implant the proper medical device to treat
10 Plaintiff's stress-urinary incontinence;
- 11 B. In failing to select and perform the proper medical procedure for
12 treating Plaintiff's stress urinary incontinence;
- 13 C. In improperly selecting Plaintiff as an appropriate candidate for
14 implantation of the Sling System; and
- 15 D. In implanting the Sling System in Plaintiff despite the fact that these
16 products have high failure, injury, and complication rates, fail to
17 perform as intended, require frequent and often debilitating
18 additional surgeries, and have caused severe and irreversible injuries,
19 conditions, and damage to a significant number of women

20 51. Plaintiff had no knowledge of these Defendants' negligence until less
21 than one year from the date of the filing of this Complaint.

22 52. As a direct result of said negligence of Defendants Yeo and Does 1-
23 10, inclusive, Plaintiff suffered and will continue to suffer serious, debilitating and
24 permanent injuries and damages, including great mental and physical pain and
25 permanent disability, medical and related expenses, and lost earnings, all to her
26 general and special damage in a sum in excess of the jurisdictional minimum of this
27 Court. Plaintiff will seek leave of court to insert said sum when known to her or
28 upon proof thereof at the time of trial.

29 **Second Cause of Action: Strict Liability in Tort – Failure To Warn**
30 **(Against Defendants JNJ, Ethicon, and Does 11-60)**

31 53. Plaintiffs reallege and incorporate herein by reference each of the
32 foregoing paragraphs of this Complaint as though fully set forth herein.

33 54. The Sling System was defective at the time of its manufacture,
34 development, production, testing, inspection, endorsement, prescription, sale and
35 distribution in that, and not by way of limitation, the Sling System's warnings,
36 instructions, and directions failed to warn of the dangerous risks posed by the Sling
37 System, including increased dangerous propensities as compared to other similar and

1 comparable alternatives, which risks were known or reasonably scientifically
2 knowable to Defendants JNJ, Ethicon, and Does 11-60. These Defendants, and each
3 of them, knew or should have known of the defective condition, characteristics and
4 risks associated with the Sling System, as previously set forth herein.

5 55. At all times alleged herein, the Sling System was defective and
6 Defendants JNJ, Ethicon, and Does 11-60, and each of them, knew that the Sling
7 System was to be used by consumers without inspection for defects therein.
8 Moreover, Plaintiff, her prescribing physicians, and healthcare providers, neither
9 knew, at the time of their use of the Sling System of the existence of all the
10 aforementioned defects. Ordinary consumers would not have recognized the
11 potential risks or side effects for which these Defendants failed to include
12 appropriate warnings.

13 56. At all times mentioned herein, the Sling System was being used as
14 intended by these Defendants and in a manner reasonably foreseeable to these
15 Defendants.

16 57. As a result of the defective condition of the Sling System, namely the
17 lack of sufficient warnings, Plaintiff suffered and will continue to suffer serious,
18 debilitating and permanent injuries and damages, including great mental and physical
19 pain and permanent disability, medical and related expenses, and lost earnings, all to
20 her general and special damage in a sum in excess of the jurisdictional minimum of
21 this Court. Plaintiff will seek leave of court to insert said sum when known to her or
22 upon proof thereof at the time of trial.

23 58. Defendants JNJ, Ethicon, and Does 11-60 acted with malice,
24 oppression, and a conscious disregard for Plaintiff and the general public's safety,
25 who accordingly request that the trier of fact, in the exercise of sound discretion,
26 award additional damages for the sake of example and for the purpose of punishing
27 these Defendants for their conduct, in an amount sufficiently large to be an example
28 to others and deter these Defendants and others from engaging in similar conduct in
29 the future. Furthermore, the aforesaid wrongful conduct was done with the advance
30 knowledge, authorization, and/or ratification of an officer, director, and/or
31 managing agent of these Defendants.

32 59. Defendants JNJ, Ethicon, and Does 11-60 had a duty to warn of
33 known or reasonably knowable side effects of the Sling System. On information and
34 belief, Defendants JNJ, Ethicon, and Does 11-60 failed to warn Defendant Luu and
35 Does 1-10, of all known and reasonably knowable side effects of the Sling System.

36 60. Defendants JNJ, Ethicon, and Does 11-60 had a duty to adequately
37 warn the medical profession, including Defendant Luu and Does 1-10, of the Sling

1 System's dangerous properties or of facts which make it likely to be dangerous. On
2 information and belief, Defendants JNJ, Ethicon, and Does 11-60 did not adequately
3 warn the medical profession, including Defendant Luu and Does 1-10, of the Sling
4 System's dangerous properties or of facts that make it likely to be dangerous.

5 61. On information and belief, Defendants JNJ, Ethicon, and Does 11-
6 60 created a vigorous sales program that persuaded the prescribing medical
7 providers, including Defendant Luu and Does 1-10, to disregard any warnings given
8 pertaining to the Sling System.

9 62. On information and belief, Defendants JNJ, Ethicon, and Does 11-
10 60 unfairly and unreasonably promoted the Sling System's to the medical profession,
11 including Defendant Luu and Does 1-10, while at the same time failing to adequately
12 inform of the risks associated with the Sling System, essentially promoting the Sling
13 System's safety and effectiveness but minimizing its dangers.

14 63. On information and belief, Defendants JNJ, Ethicon, and Does 11-
15 60 unfairly and unreasonably instructed its sales force to counter the medical
16 professions concerns, including Defendant Luu's and Does 1-10's concerns, about
17 the safety and effectiveness of the Sling System.

18 64. On information and belief, Defendants JNJ, Ethicon, and Does 11-
19 60 zealously worked to influence the medical profession, including Defendant Luu
20 and Does 1-10, with a combination of deceptive advertisements and high-pressure
21 sales techniques, including written promotions and aggressive in-person promotions,
22 causing Defendant Luu and Does 1-10 to disregard the meager warnings given by
23 Defendants JNJ, Ethicon, and Does 11-60 pertaining to the Sling System.

24 65. On information and belief, Defendant Luu and Does 1-10 would not
25 have surgically implanted the Sling System had Defendants JNJ, Ethicon, and Does
26 11-60 adequately warned them of the needless and high-risk dangers associated with
27 the Sling System.

28 **Third Cause Of Action: Strict Liability In Tort -- Design Defect**
29 **(Against Defendants JNJ, Ethicon, and Does 11-60)**

30 66. Plaintiffs reallege and incorporate herein by reference each of the
31 foregoing paragraphs of this Complaint as though fully set forth herein.

32 67. Defendants JNJ, Ethicon, and Does 11-60 designed, engineered,
33 developed, manufactured, fabricated, assembled, equipped, tested or failed to test,
34 inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied,
35 distributed, wholesaled, and sold the Sling System.

36 68. The Sling System manufactured, supplied, and/or placed into the
37 stream of commerce by Defendants JNJ, Ethicon, and Does 11-60 was defective and

1 unreasonably dangerous in that:

2 A. The foreseeable risks exceeded the benefits associated with their
3 design or formulation;

4 B. They contained inadequate warnings or instructions; and

5 C. They contained inadequate post-marketing warnings or instructions.

6 69. The Sling System manufactured, supplied, and/or placed into the
7 stream of commerce by Defendants JNJ, Ethicon, and Does 11-60 was more
8 dangerous than an ordinary consumer would expect, and more dangerous than other
9 products or procedures available to treat stress urinary incontinence.

10 70. Defendants JNJ, Ethicon, and Does 11-60 knew that the Sling
11 System was to be purchased and used without inspection for defects.

12 71. The Sling System was and continues to be unsafe for its intended use
13 by reason of defects in its design so that it does not safely serve its purpose, but
14 would instead expose its users to serious injuries.

15 72. Plaintiff used the Sling System in a reasonably foreseeable manner.

16 73. Defendants JNJ, Ethicon, and Does 11-60 designed the Sling System
17 defectively, causing it to fail to perform as safely as an ordinary consumer would
18 expect when used in an intended or reasonably foreseeable manner.

19 74. As a legal and proximate result of the aforementioned defects in the
20 design of the Sling System, Plaintiff suffered and will continue to suffer serious,
21 debilitating and permanent injuries and damages, including great mental and physical
22 pain and permanent disability, medical and related expenses, and lost earnings, all to
23 her general and special damage in a sum in excess of the jurisdictional minimum of
24 this Court. Plaintiff will seek leave of court to insert said sum when known to her or
25 upon proof thereof at the time of trial.

26 75. Defendants JNJ, Ethicon, and Does 11-60 acted with malice,
27 oppression, and a conscious disregard for Plaintiff and the general public's safety,
28 who accordingly request that the trier of fact, in the exercise of sound discretion,
29 award additional damages for the sake of example and for the purpose of punishing
30 these Defendants for their conduct, in an amount sufficiently large to be an example
31 to others and deter these Defendants and others from engaging in similar conduct in
32 the future. Furthermore, the aforesaid wrongful conduct was done with the advance
33 knowledge, authorization, and/or ratification of an officer, director, and/or
34 managing agent of these Defendants.

35 76. Defendants JNJ, Ethicon, and Does 11-60 had a duty to warn of all
36 known or reasonably knowable side effects of the Sling System. On information and
37 belief, Defendants JNJ, Ethicon, and Does 11-60 failed to warn Defendant Eüü and

1 Does 1-10, of the known and reasonably knowable side effects of the Sling System.

2 77. Defendants JNJ, Ethicon, and Does 11-60 had a duty to adequately
3 warn the medical profession, including Defendant Luu and Does 1-10, of the Sling
4 System's dangerous properties or of facts which make it likely to be dangerous. On
5 information and belief, Defendants JNJ, Ethicon, and Does 11-60 did not adequately
6 warn the medical profession, including Defendant Luu and Does 1-10, of the Sling
7 System's dangerous properties or of facts that make it likely to be dangerous.

8 78. On information and belief, Defendants JNJ, Ethicon, and Does 11-
9 60 created a vigorous sales program that persuaded the prescribing medical
10 providers, including Defendant Luu and Does 1-10, to disregard any warnings given
11 pertaining to the Sling System.

12 79. On information and belief, Defendants JNJ, Ethicon, and Does 11-
13 60 unfairly and unreasonably promoted the Sling System's to the medical profession,
14 including Defendant Luu and Does 1-10, while at the same time failing to adequately
15 inform of the risks associated with the Sling System, essentially promoting the Sling
16 System's safety and effectiveness but minimizing its dangers.

17 80. On information and belief, Defendants JNJ, Ethicon, and Does 11-
18 60 unfairly and unreasonably instructed its sales force to counter the medical
19 professions concerns, including Defendant Luu's and Does 1-10's concerns, about
20 the safety and effectiveness of the Sling System.

21 81. On information and belief, Defendants JNJ, Ethicon, and Does 11-
22 60 zealously worked to influence the medical profession, including Defendant Luu
23 and Does 1-10, with a combination of deceptive advertisements and high-pressure
24 sales techniques, including written promotions and aggressive in-person
25 promotions, causing Defendant Luu and Does 1-10 to disregard the meager
26 warnings given by Defendants JNJ, Ethicon, and Does 11-60 pertaining to the Sling
27 System.

28 82. On information and belief, Defendant Luu and Does 1-10 would not
29 have surgically implanted the Sling System had Defendants JNJ, Ethicon, and Does
30 11-60 adequately warned them of the needless and high-risk dangers associated with
31 the Sling System.

32 **Fourth Cause of Action: Negligence**

33 **(Against Defendants JNJ, Ethicon, and Does 11-60)**

34 83. Plaintiffs reallege and incorporate herein by reference each of the
35 foregoing paragraphs of this Complaint as though fully set forth herein.

36 84. At all times relevant herein, Defendants JNJ, Ethicon, and Does 11-
37 60, and each of them, had a duty to properly manufacture, design, formulate,

1 distribute, compound, produce, process, assemble, test, inspect, research, market,
2 label, package, prepare for use, issue warnings with respect to, promote, advertise,
3 sell, and monitor the use of the Sling System, and to adequately test and warn of the
4 risks and dangers of the Sling System, both before and after sale.

5 85. At all times relevant herein, Defendants JNJ, Ethicon, and Does 11-
6 60, and each of them, breached their duties in that they negligently and carelessly
7 manufactured, designed, formulated, distributed, compounded, produced, processed,
8 assembled, tested, inspected, researched, marketed, labeled, packaged, prepared for
9 use, issued warnings with respect to, promoted, advertised, sold, and monitored the
10 use of the Sling System, and failed to adequately test and warn of the risks and
11 dangers of the Sling System, both before and after their sale.

12 86. As a result of the breach of these Defendants' duties with respect to
13 the Sling System, Plaintiff suffered and will continue to suffer serious, debilitating
14 and permanent injuries and damages, including great mental and physical pain and
15 permanent disability, medical and related expenses, and lost earnings, all to her
16 general and special damage in a sum in excess of the jurisdictional minimum of this
17 Court. Plaintiff will seek leave of court to insert said sum when known to her or
18 upon proof thereof at the time of trial.

19 **Fifth Cause of Action: Negligent Failure to Recall**
20 **(Against Defendants JNJ, Ethicon, and Does 11-60)**

21 87. Plaintiffs reallege and incorporate herein by reference each of the
22 foregoing paragraphs of this Complaint as though fully set forth herein.

23 88. Defendants JNJ, Ethicon, and Does 11-60 designed, engineered,
24 developed, manufactured, fabricated, assembled, equipped, tested or failed to test,
25 inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied,
26 distributed, wholesaled, and sold the Sling System.

27 89. Defendants JNJ, Ethicon, and Does 11-60 knew or reasonably
28 should have known that the Sling System was dangerous or was likely to be
29 dangerous when used in a reasonably foreseeable manner.

30 90. Defendants JNJ, Ethicon, and Does 11-60 became aware of these
31 defects after the Sling System was sold. Yet, these Defendants failed to recall,
32 retrofit, and/or warn of the danger of the Sling System when a reasonable
33 manufacturer, distributor, or seller under the same or similar circumstances would
34 have recalled, retrofitted, and/or warned of the dangers of these products.

35 91. As a result of the breach of these Defendants' duties with respect to
36 the Sling System, Plaintiff suffered and will continue to suffer serious, debilitating
37 and permanent injuries and damages, including great mental and physical pain and

1 permanent disability, medical and related expenses, and lost earnings, all to her
2 general and special damage in a sum in excess of the jurisdictional minimum of this
3 Court. Plaintiff will seek leave of court to insert said sum when known to her or
4 upon proof thereof at the time of trial.

5 **Sixth Cause of Action: Negligent Misrepresentation**
6 **(Against Defendants JNJ, Ethicon, and Does 11-60)**

7 92. Plaintiffs reallege and incorporate herein by reference each of the
8 foregoing paragraphs of this Complaint as though fully set forth herein.

9 93. Defendants JNJ, Ethicon, and Does 11-60, and each of them, from
10 the time that the Sling System was first tested, studied, researched, manufactured,
11 marketed and distributed, and up to the present, made false representations, as
12 previously set forth herein, to Plaintiff, her prescribing physicians, and healthcare
13 providers, including, but not limited to, the misrepresentation that the Sling System
14 was safe, fit, and effective for the treatment of stress urinary incontinence.

15 94. At all times relevant hereto, Defendants JNJ, Ethicon, and Does 11-
16 60, and each of them, conducted a sales and marketing campaign to promote the sale
17 of the Sling System and willfully deceived Plaintiff, her prescribing physicians, and
18 healthcare providers as to the health risks and consequences of the use of the Sling
19 System.

20 95. Defendants JNJ, Ethicon, and Does 11-60 made the foregoing
21 misrepresentations without any reasonable ground for believing them to be true.
22 These misrepresentations were made directly by these Defendants, by sales
23 representatives, detail persons, and other authorized agents of these Defendants, and
24 in publications and other written materials directed to Plaintiff, her prescribing
25 physicians, and healthcare providers, with the intention of inducing reliance and the
26 purchase and implantation of the Sling System.

27 96. The foregoing representations by Defendants JNJ, Ethicon, and
28 Does 11-60, and each of them, were in fact false, in that the Sling System are not,
29 and at all relevant times alleged herein, were not safe, fit, and effective for the
30 treatment of stress urinary incontinence, the use of the Sling System is hazardous to
31 health, and the Sling System has a significant propensity to cause serious injuries to
32 users including, but not limited to, the injuries suffered described herein. The
33 foregoing misrepresentations by Defendants JNJ, Ethicon, and Does 11-60, and each
34 of them, were made with the intention of inducing reliance and inducing the
35 purchase and implantation of the Sling System.

36 97. In reliance on the misrepresentations by the Sling System, and each
37 of them, Plaintiff, her prescribing physicians, and healthcare providers were induced

1 to purchase and use the Sling System. If they had known of the true facts and the
2 facts concealed by Defendants JNJ, Ethicon, and Does 11-60, they would not have
3 used the Sling System. Furthermore, their reliance upon these Defendants'
4 misrepresentations was justified because such misrepresentations were made and
5 conducted by individuals and entities that were in a position to know the true facts.

6 98. As a result of the foregoing negligent misrepresentations by these
7 Defendants, and each of them, Plaintiff suffered and will continue to suffer serious,
8 debilitating and permanent injuries and damages, including great mental and physical
9 pain and permanent disability, medical and related expenses, and lost earnings, all to
10 her general and special damage in a sum in excess of the jurisdictional minimum of
11 this Court. Plaintiff will seek leave of court to insert said sum when known to her or
12 upon proof thereof at the time of trial.

13 **Seventh Cause of Action: Loss of Consortium**
14 **(Against All Defendants)**

15 99. Plaintiffs reallege and incorporate herein by reference each of the
16 foregoing paragraphs of this Complaint as though fully set forth herein.

17 100. By reason of the injuries sustained by his spouse, Plaintiff Patrick
18 Perry has been and will continue to be deprived of the loss of love, companionship,
19 comfort, care, assistance, protection, affection, society, and moral support of his
20 spouse.

21 **Discovery Rule**

22 101. Plaintiffs file this Complaint within the applicable limitations period
23 of first suspecting that the Sling System was the cause of any appreciable harm
24 sustained by Plaintiffs, within the applicable limitations period of first suspecting or
25 having reason to suspect any wrongdoing, and within the applicable limitations
26 period of first discovering the injuries. Plaintiffs could not by the exercise of
27 reasonable diligence have discovered any wrongdoing, nor could Plaintiffs have
28 discovered the causes of the injuries at an earlier time because the injuries occurred
29 without initial perceptible trauma or harm, and when the injuries were discovered,
30 their causes were not immediately known. Plaintiffs did not suspect, nor did they
31 have reason to suspect, that wrongdoing had caused the injuries, or the tortious
32 nature of the conduct causing the injuries, until less than the applicable statute of
33 limitations period prior to the filing of this Complaint. Plaintiffs had no knowledge
34 of the defects in the Sling System or of the wrongful conduct of Defendants as set
35 forth herein, nor did they have access to the information regarding other injuries and
36 complaints in the possession of Defendants. Additionally, Plaintiffs were prevented
37 from discovering this information sooner because Defendants herein misrepresented

1 and continue to misrepresent to the public and to the medical profession that the
2 Sling System is and was safe and free from serious side effects.

3 **Relief Requested**

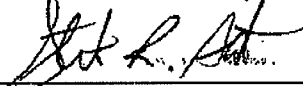
4 102. Wherefore, Plaintiffs pray for judgment against Defendants Luu,
5 Johnson & Johnson and Ethicon, Inc., and Does 1-60, jointly and severally, and as
6 appropriate to each cause of action alleged, as follows:

- 7 A. Past and future general damages, the exact amount of which has yet
8 to be ascertained, in an amount which will conform to proof at time
9 of trial;
- 10 ~~B. Past and future economic and special damages according to proof at~~
11 ~~the time of trial;~~
- 12 C. Loss of earnings and impaired earning capacity according to proof at
13 the time of trial;
- 14 D. Medical expenses, past and future, according to proof at the time of
15 trial;
- 16 E. Past and future mental and emotional distress, according to proof at
17 the time of trial;
- 18 F. Loss of consortium as to Plaintiff Patrick Perry;
- 19 G. Punitive or exemplary damages according to proof at the time of trial;
- 20 H. Costs of suit incurred herein;
- 21 I. For pre-judgment interest as provided by law; and
- 22 J. For such other and further relief as the Court may deem just and
23 proper.

24 Dated: April 11, 2013

Respectfully submitted,

Albertson & Davidson, LLP

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Attorneys for Plaintiffs

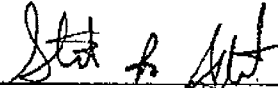
Demand for Jury Trial

Plaintiffs hereby demand a jury trial on all counts in this Complaint.

Dated: April 11, 2013

Respectfully submitted,

Albertson & Davidson, LLP

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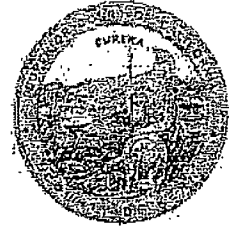
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SUPERIOR COURT OF CALIFORNIA, COUNTY OF KERN
ALTERNATIVE DISPUTE RESOLUTION (ADR)
INFORMATION PACKAGE



Most civil disputes are resolved without filing a lawsuit and most civil lawsuits are resolved without the necessity of a trial. The courts, community organizations and private providers offer a variety of ADR processes to help people resolve disputes without a trial. Kern County Superior Court encourages, and under certain circumstances may require, parties to try ADR before trial. Courts have also found ADR to be beneficial when used early in the case process.

Below is some information about the potential advantages and disadvantages of ADR, the most common types of ADR, and how to find a local ADR program or neutral. You may find more information about these ADR processes at <http://www.courts.ca.gov/programs/adr.htm>.

Possible Advantages and Disadvantages

ADR may have a variety of advantages or disadvantages over a trial, depending on the type of ADR process used as well as the particular type of case involved:

Possible Advantages: Saves time; saves money; gives the parties more control over the dispute resolution process and outcome; helps to preserve and/or improve party relationships.

Possible Disadvantages: May add additional cost to the litigation if ADR does not resolve the dispute; procedures such as discovery, jury trial, appeals, and other protections may be limited or unavailable.

Most Common Types of ADR

Mediation: A neutral person, or "mediator," helps the parties communicate in an effective and constructive manner so the parties can try to resolve their dispute. The mediator does not decide the outcome, but helps the parties to do so. Mediation is generally confidential, and may be particularly useful where on going relationships are involved, such as between family members, neighbors, employers/employees or business partners.

Settlement Conferences: A judge or another neutral person assigned by the court helps the parties to understand the strengths and weaknesses of their case and to discuss settlement. The judge or settlement conference neutral does not make a decision in the case but helps the parties to negotiate a settlement. Settlement conferences may be particularly helpful when the parties have very different views about the likely outcome of a trial in their case.

Neutral Evaluation: The parties briefly and informally present their facts and arguments to a neutral person who is often an expert in the subject matter of the dispute. The neutral does not decide the outcome of the dispute, but helps the parties to do so by providing them with a non-binding opinion about the strengths, weaknesses and likely outcome of their case. Depending on the neutral evaluation process and the parties' consent, the neutral may then help the parties try to negotiate a settlement. Neutral evaluation may be appropriate if the parties desire a neutral's opinion about how the case might be resolved at trial, if the primary dispute is about the amount of damages, or if there are technical issues the parties would like a neutral expert to resolve.

Arbitration: The parties present evidence and arguments to a neutral person, or "arbitrator," who then decides the outcome of the dispute. Arbitration is less formal than a trial, and the rules of evidence are generally more

ATTORNEY OR PARTY WITHOUT ATTORNEY (NAME AND ADDRESS); TELEPHONE NO. ATTORNEY FOR (NAME)	FOR COURT USE ONLY
SUPERIOR COURT OF CALIFORNIA, COUNTY OF KERN STREET ADDRESS: CITY AND ZIP CODE: BRANCH NAME:	
PLAINTIFF;	
DEFENDANT;	
ADR STIPULATION AND ORDER FORM	CASE NUMBER:

Pursuant to California Rule of Court 3.221(a)(4), the parties and their attorneys stipulate that all claims in this action will be submitted to the following alternative dispute resolution (ADR) process:

- Court-connected mediation pursuant to Local Rules (no fee or order required when filed within 10 days of Case Management Conference)
- Private Mediation
- Neutral Evaluation
- Binding Arbitration
- Referee/Special Master
- Settlement Conference with Private Neutral
- Non-binding Judicial Arbitration pursuant to CCP 1141.10 et seq., and applicable Rules of Court
- Discovery will remain open until 30 days before trial
- Other _____

It is also stipulated that _____ (name of individual neutral, not organization) has consented to and will serve as _____ (neutral function/process) and that the session will take place on _____ (enter a FIRM date) and that all persons necessary to effect a settlement and having full authority to resolve the dispute will appear at such session.

Date: _____

On behalf of Plaintiffs

(Type or print name)

(Signature)

On behalf of Defendants

(Type or print name)

(Signature)

Attach additional signature pages if needed

KC ADR-101 (Mandatory)

Page 1 of 2

(Rev. 2/2012)