Distill Mass Tort Cases into Clear and Comprehensible CLNC® Work Product for Attorneys
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DISTILL MASS TORT CASES INTO CLEAR AND COMPREHENSIBLE CLNC® WORK PRODUCTS FOR ATTORNEYS

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I. INTRODUCTION

A. Class Action v Mass Tort

1. Class Action.
      (1) Certification of plaintiffs as a class.
         (a) Impractical for plaintiffs to sue individually.
         (b) Plaintiffs share a common complaint.
         (c) Defendants share a common defense.
      (2) Defining the class.
         (a) Scope of characteristics of the class.
      (3) Notification.
         (a) Potential plaintiffs notified of the litigation by mail, newspapers, billboards.
      (4) Plaintiffs may opt out.
      (5) Judge appoints counsel who is experienced in class action proceedings.
      (6) Distribution of damages.
      (1) Federal – claims exceed $5 million, plaintiffs or defendants are from many different states.
      (2) Judges investigate and approve all settlements.

   a. A single tort that results in injury to many people.
      (1) Significant number of plaintiffs who share a common, although not identical, injury.
      (2) Multiple defendants.
   b. Consolidated in multidistrict litigation groups (MDL) or Judicial Panel on Multidistrict Litigation (JPML).
      (1) Single judge oversees the litigation.
   c. No certification required.
II. ECONOMICS OF LITIGATION

A. Traditional Contingent Fee Tort Litigation
   1. Single plaintiff.
   2. Three to five years until resolution.
   3. Unique discovery and experts.
   4. Determination of damages and potential compensation.
   5. Plaintiff attorney absorbs cost of litigation.

B. Mass Tort Litigation
   1. Economies of scale with many plaintiffs.
      a. Standardized process for discovery.
      b. One expert for many cases.
   2. Increased probability of early settlement.
      a. Volume of cases mean it is cheaper for defendants to settle
         than fight in court.
   3. Judges developed procedural methods for quick resolution to
      decrease court case load.

III. MASS TORT LITIGATION PROCESS

A. Emergent Phase
   1. Food and Drug Administration (FDA) warning of injury.
      a. Manufacturer and User Facility Device Experience (MAUDE)
         database.
      b. Black box warning.
   2. Gathering plaintiffs.
      a. Marketing.
B. Immature Phase

1. Pretrial consolidation.
   a. Jurisdiction.
      (1) Federal MDL.
      (2) State.
   b. Transferee.

2. Road map.
   a. Discovery.
      (1) Sequenced.
         (a) Causation.
            i) Issue of general causation addressed early.
      (2) Fact.
         (a) Email.
         (b) Premarket trials.

3. Bellwether cases.
   a. Similar facts, claims and injuries to all plaintiffs.
   b. Tried as traditional product liability.
      (1) Outcome not binding to other plaintiffs.
      (2) Testing of trial theories.

4. Trial packages.
   a. Database of discovery documents, expert reports and depositions.

C. Mature Phase

   a. Matrix.
      (1) Categories that are rated by point system.
      (2) Product and litigation specific.
      (3) Higher score equals higher settlement amount.
         (a) Narrow and specific range of damages for each plaintiff.

2. Tolling agreements.
   a. Allows each side to file a case without being excluded by the statute of limitations.
IV. COMMON MASS TORT CASES

A. Toxic Tort

1. Causation.
   a. Toxin can cause injury.
   b. Toxin caused the plaintiff’s injuries.

2. Asbestos.
   a. Asbestosis, mesothelioma and lung cancer.
   b. Level of exposure.
      (1) Single fiber theory.
   c. Exposed to multiple asbestos containing products.

3. Talcum powder. (Exhibit A)
   a. Ovarian cancer.
      (1) Possible link studied since 1971.
      (2) Talc is mined in areas with naturally occurring asbestos.
   b. Johnson & Johnson baby powder.
      (1) Talc used in the U.S. has been asbestos free since 1976.
      (2) Cosmetic talc not included in recent studies.
      (3) Large prospective cohort study found no association with ovarian cancer.

B. Pharmaceuticals

1. Redux (Fen-Phen). (Exhibit B)
   a. Diet medication prescribed in the 1990s.
   b. Primary pulmonary hypertension.
      (1) Withdrawn from market in 1997.
   c. Over the counter (OTC) diet pills contain fenfluramine/phentermine.

2. Multaq. (Exhibit C)
   a. Antiarrhythmic used to treat atrial fibrillation.
   b. Cardiac arrest and liver failure.

3. Abilify. (Exhibit D)
   a. Antipsychotic also used to treat depression.
   b. Type 2 diabetes.
   c. Impulse control.
      (1) Gambling to excess.
      (2) Binge eating.
(3) Shopping to excess.
(4) Sex to excess.

4. Onglyza (Januvia, Janumet and Byetta).
   a. Treats diabetes type 2.
   b. Heart failure.

5. Risperdal.
   a. Gynecomastia.

C. Medical Devices

1. Transvaginal mesh. (Exhibit E)
   b. Pelvic organ prolapse.
      (1) Erosion.
      (2) Pain.
   c. Bellwether cases: $10-$13.5 million.
   d. Settlement amounts: $120-$200 million.
   e. Estimated number of plaintiffs: 80,000.

2. Hip implants. (Exhibit F)
   a. Metal-on-metal.
      (1) Metallosis.
      (2) Pain.
      (3) Hip instability.
      (4) Cardiomyopathy.
      (5) Neurologic impairment.
      (6) Renal function impairment.
   b. Zirconia ceramic femoral head.

D. Cosmetics

E. Food

V. COMMON PLAINTIFF ALLEGATIONS FOR MASS TORT CASES

A. The Company Knew They Manufactured and Sold a Faulty and Dangerous Product
B. The Company Failed to Warn Patients That the Device Could Fail Under Normal Usage

C. The Company Falsified Studies Used in the Approval Process

D. The Manufacturer Failed to Adequately Train Surgeons in the Proper Implant Technique Resulting in Catastrophic Injury

E. Strategies

1. Venue.
   a. File in plaintiff friendly jurisdiction.

2. Overwhelming number of plaintiffs injured.
   a. Company may come to rapid settlement when evaluating number of cases filed.

3. Future plaintiffs.
   a. Product may continue causing harm.
   b. Attorneys may continue to stretch the causation theories.

4. Latent injuries.
   a. Future medical treatments.

VI. COMMON DEFENSES FOR MASS TORT CASES

A. Plaintiff Knew of the Risks and Agreed or Continued to Use the Product

B. State-of-the-Art Product So the Injury Could Not Be Foreseen

C. The Product Does Not Cause the Alleged Injury

D. The Plaintiff Expert Is Relying on Junk Science to Support Claims of Injury
E. The Product Went Through Rigorous Testing for Safety and Obtained FDA Approval

F. This Is a Case of Medical Malpractice and Not Product Liability

G. Strategies
   1. Federal MDL.
      a. Speeds settlement.

VII. THE ROLE OF THE CERTIFIED LEGAL NURSE CONSULTANT\textsuperscript{CM} IN MASS TORT CASES

A. Understand Strict Liability Cases
   1. Duty.
      a. “Absolute duty on the part of the manufacturer to make nondefective products that are reasonably safe for their intended uses and for reasonably foreseeable misuses.” Vickie Milazzo, RN, MSN, JD.
   2. Breach of duty.
      a. Proof of fault is not required.
      b. Plaintiff only needs to prove that the product is defective.
   3. Damages.
      a. Injury resulted from the defective product.
   4. Causation.
      a. Must prove that injuries resulted from defect in product.

B. How Do I Fit In?
   1. Depends on the age of the litigation.
      a. Emergent.
         (1) Provide expert research using authoritative sources to discover adverse events and trends.
2. FDA pharmaceutical warnings.
   (a) Warning letters.
      i) Office of Prescription Drug Promotion (OPDP).
      ii) Office of Compliance/Immediate Office.
      iii) Office of Manufacturing Quality.
      iv) Office of Scientific Investigation and Research (OSIR).
      vi) Main FDA FOI Warning Letters Page.

3. Drug Supply Chain.
   (a) Counterfeit medications.
   (b) Recalls.

4. Medical devices.
   (a) MAUDE.
      i) Adverse events.
      ii) Post approval studies.
      iii) Post market surveillance studies.
      iv) Recalls.

b. Provide analysis of studies published by experts.
   (1) Evaluate for junk journals.
   (2) Compare to studies in authoritative sources.

c. Review of medical records.
   (1) Review.
      (a) High quality systematic review and organization of records.

   (2) Analysis.
      (a) Causation.
          i) Are there commonalities among patients?
      (b) Comorbidities.
          i) Which ones lead to worse outcomes?

   (3) Development of Patient Profile Form (PPF). *(Exhibit G)*
      (a) Age group.
      (b) Date of injury.
      (c) Type of injury.
      (d) Relevant past medical history and comorbidities.

2. Bellwether cases.
   a. Attorneys must have some understanding of individual cases.
(1) Review of medical records
   (a) Detailed analysis of causation and comorbidities.
       i) Did the product cause the injury or was it medical malpractice?
   (b) Detailed chronologies.

b. Demonstrative evidence.
(1) Extract exhibits from medical records.

c. Research of opposing experts.
   (1) Literature review of published studies.
       (a) Evaluate quality of the journal and the study.

a. High volume record review for the matrix. (Exhibit H)
(1) Limited analysis.
    (a) Watch for strong cases as attorney may choose to pull from settlement.
(2) Extraction of specific facts.
(3) Develop systematic review process and report structure focusing on individual needs of attorney-clients.

VIII. INTERROGATORIES AND REQUESTS FOR PRODUCTION

A. Interrogatories Directed to the Defense

1. Please list the name, reference number and lot number of device removed from (Plaintiff) _________.

2. Please list the brand name, generic name, NDC number of (Medication) _________.

3. Please include all lot numbers for (Medication/Device) _________.
   from (Date) ___________ to (Date) ___________.

4. Please provide all reports, summaries or records of any kind relating to investigation of adverse events for (Medication/Device) _________.

5. Please list the name of all sales representatives, employed or contracted, who called on physicians or hospitals in (State) _________.
   during (Year) ___________ through (Year) ___________.
6. Please provide dates of all in-services or product demonstrations for (Device) __________ that occurred at (Facility) __________ from (Date) __________ to (Date) __________.

7. Please name all physicians and their specialties who spoke or presented at any physician meetings or conferences that occurred between (Date) __________ and (Date) __________.

8. Please identify all studies and clinical trials done to evaluate the safety and efficacy of (Medication/Device) __________.

9. Please identify each adverse event for (Medication/Device) __________ that was reported to the FDA.

10. Please describe in detail the internal adverse reporting system used for (Medication/Device) __________ by (Facility) __________ in effect on (Date) __________.

B. Interrogatories Directed to the Plaintiff

1. Please describe the specific nature of each alleged design, manufacturing or information defect of (Device) __________.

2. Please provide the name and address of any medical provider who attributes the alleged injury to (Medication/Device) __________.

3. Please list all the names and addresses of all treating providers for (Plaintiff) __________ from (Date) __________ to (Date) __________.

4. Please list the reason for any and all hospitalizations from (Date) __________ to (Date) __________.

5. Please list the dates of all hospitalizations from (Date) __________ to (Date) __________.

6. Please list the name and address of all hospitals visited by (Plaintiff) __________ from (Date) __________ to (Date) __________.

7. Please list the name and address of all urgent care clinics visited by (Plaintiff) __________ from (Date) __________ to (Date) __________.
8. Please list the name and address of all pharmacies used by (Plaintiff) __________ for purchase of prescription medications from (Date) __________ to (Date) __________.

9. Please provide the names of any and all journals where (Expert) __________ has published research.

10. Please identify each person who had custody of (Device) __________ from (Date of Occurrence) __________ to present.

C. Requests for Production Directed to the Defense

1. Please provide all product inserts for (Medication/Device) __________ from (Date) __________ to (Date) __________.

2. Please provide all printed patient handouts for (Medication/Device) __________ from (Date) __________ to (Date) __________.

3. Please provide all patient education videos for (Medication/Device) __________ made available on television, Internet or at physicians' offices from (Date) __________ to (Date) __________.

4. Please provide all printed materials created for clinical education about (Medication/Device) __________ from (Date) __________ to (Date) __________.

5. Please provide the actual (Device) __________ used during any in-services or demonstrations at (Facility) __________ from (Date) __________ to (Date) __________.

6. Please provide a copy of each patent or patent application for (Device) __________.

7. Please provide the most recent resume or CV on each expert you expect to call as an expert witness at trial.

8. Please provide all written reports of each person whom you expect to call as an expert witness at trial.

9. Please provide all documents relied upon by any expert witness you intend to call at trial.

10. Please provide any and all policies and procedures for (Medication/Device) __________ sales representatives from (Date) __________ to (Date) __________.
D. Requests for Production Directed to the Plaintiff

1. Please provide all pharmacy records from (Pharmacy) ______ from (Date) ______ to (Date) ______.

2. Please provide all medical records from (Facility) ______ from (Date) ______ to (Date) ______.

3. Please provide all medical records from (Clinic/Physician’s Office) ______ from (Date) ______ to (Date) ______.

4. Please provide all hospital billing records from (Facility) ______ from (Date) ______ to (Date) ______.

5. Please provide any and all photographs or videos made of (Plaintiff) ______ surgery on (Date) ______.

6. Please provide actual device removed from Plaintiff ______ at (Facility) ______ on (Date) ______.

7. Please provide all written reports of each person whom you expect to call as an expert witness at trial.

8. Please provide all documents relied upon by any expert witness you intend to call at trial.

9. Please provide the most recent resume or CV on each expert you expect to call as an expert witness at trial.

10. Please provide all studies published by (Expert) ______.

IX. FORMS

A. Patient Profile Form (Exhibit G)

B. Settlement Screening Report (Exhibit H)
X. RESOURCES

A. Associations and Organizations

1. American Association for Justice. justice.org
2. American Bar Association. americanbar.org
3. DRI-The Voice of the Defense Bar. dri.org
4. Federal Drug Administration. FDA.gov
5. Mass Torts Made Perfect®. mtmp.com

B. Authoritative Textbooks


C. Internet Resources

D. Journal Articles


Exhibit A
Talc Litigation Bellwether Case

Firm: Beasley Allen Law Firm
Expert: Dr. Daniel W. Crammer
Plaintiff: Jackie Fox
Defendant: Johnson & Johnson

Verdict: $72 million
   $10 million actual damages
   $62 million punitive damages

Jurisdiction: St. Louis, MO

Summary of Claims: Ms. Fox used Johnson & Johnson Baby Powder daily for decades. Johnson & Johnson intentionally refused to warn women who used J&J Baby Powder and Shower to Shower of the cancer risk.

Future Plaintiffs:
- 1,500 die per year as the result of talc products.
- Media outlets.
  - Change.org petition.
  - CBS This Morning.
  - CBS Evening News.
  - Internet.

Johnson & Johnson Baby Powder
- One of the company’s oldest products for babies and adults.
  - Contains only pharmaceutical grade talc.
  - Meets highest purity standards.
  - Decades of safety.
  - Cosmetic talc not included in recent report on carcinogens.
- Talc required to be asbestos free since 1976.
- Dose exposure is determined solely on self-reporting.

FDA
- Cosmetics do not undergo FDA review or approval prior to going to market.
- Sound scientific data required before taking action against a cosmetic.

Talc
- Naturally occurring mineral that may be found in close proximity to asbestos.
- Published studies from 1960 have suggested a possible association between the use of powders and the incidence of ovarian cancer.
o These studies have not conclusively demonstrated such a link exists.

- Relies on AMA laboratory surveys of company sites to assess for asbestos.
  - Survey found no asbestos fibers or structures in any cosmetic grade raw material talc or cosmetic products.
  - Does not prove that all or most products marketed in the U.S. are free from asbestos.
Exhibit B
Redux Litigation

FDA Approval for Short Term Appetite Suppression
- 1959 Phentermine.
- 1973 Fenfluramine (Pondimin).
  - Manufacturer – American Home Products (AHP).
  - Known risk – Primary pulmonary hypertension.
- 1996 Dexafluramine (Redux).
  - Manufacturer – Wyeth.
  - Label stated safety not shown for longer than one year of use.

1996.
- Mass marketing of diet medications.
  - Diet centers and Internet.
  - Mass prescribing by physicians.

1997.
- Physicians begin prescribing fenfluramine and dexafluramine in combination with phentermine.
  - Medications given for extended period of time.
    - Off label use.
  - Mayo Clinic.
    - 24 patients developed heart valve disease after taking “fen-phen.”
      - 40% mortality rate within four years.
  - Soon 100 cases were reported with combined medications.
    - No cases involved phentermine alone.
  - Redux and Pondamin pulled from market.

1999.
- $23 million verdict against AHP.
  - Claimant had history of mitral valve prolapse.

2002.
- Abuses by medical experts.
  - Cardiologist earns $3 million in one year supervising and interpreting more than 10,000 echocardiograms (EKGs).
    - Acknowledged she spent only a few minutes evaluating EKGs.
    - 60-70% noted to have “moderate to severe” mitral regurgitation.
    - 5x greater rate of severity.
  - Judge suspended settlement payout due to abuses.
2006.
- 175,000 pending cases against Wyeth.
  - Heart valve damage and primary pulmonary hypertension.
  - Claim illegal marketing of off-label use.

2013.
- Major plaintiff attorney disbarred by Kentucky Supreme Court.
  - Violated rules regarding excessive fees.
2009
- Multaq approved for persistent or paroxysmal atrial fibrillation.
- Contraindicated in patients with Class IV CHF or Class II-III CHF with recent hospitalization for decompensation.

2011
- FDA safety review determined that Multaq increased the risk of:
  - Serious cardiovascular events, including death, when used by patients in permanent atrial fibrillation.
    - Should not be prescribed in patients who fail cardioversion.
    - Should immediately stop Multaq if the patient is found to be in atrial fibrillation.
  - Two post-market reports of liver injury including acute liver failure requiring liver transplant were reported 4.5 and 6 months after initiating treatment.
    - Consider periodic monitoring of liver enzymes during the first 6 months of treatment.
    - Should immediately stop Multaq if the patient shows any signs or symptoms of liver injury.
- Risk of liver injury was added in warning and precautions.

2012
- Black box warning stating increased risk of death, stroke or heart failure was added to the label.

Defense of Allegations
- Alcohol abuse.
- Medical malpractice.
- Amiodarone.
  - Pulmonary toxicity.
  - Liver injury.
Exhibit D
Abilify Litigation

2004
• FDA warning of hyperglycemia and risk of diabetes.

2006
• FDA warning of risk of death in patients with dementia-related psychosis.

2007
• $515 million settlement with Department of Justice over improperly marketing to children.

2014
• Plaintiff claims she developed diabetes due to weight gain after being prescribed Abilify as a child.

2016
• FDA warning of compulsive behavior, including excessive gambling, sexual acts, shopping and binge eating.
• Several lawsuits filed alleging severe financial hardship due to excessive gambling.
Exhibit E
Transvaginal Mesh Litigation

2005 – 2008
• FDA received 1,000 reports from nine manufacturers of complications associated with mesh repair of stress urinary incontinence (SUI) and pelvic organ prolapse (POP).
  o Erosion.
  o Pain.
  o Recurrent SUI and recurrent POP.

2011
• FDA warns that “serious complications associated with surgical mesh for transvaginal repair of POP are not rare.”

2016
• FDA warns that nonabsorbable surgical mesh remains in the body indefinitely and is considered a permanent implant.
• Manufacturers must address serious safety concerns of severe pelvic pain and organ perforation.
• Boston Scientific mesh found to contain counterfeit materials.

Verdicts
• As of 2016.
  o 18 plaintiff verdicts.
  o 6 defense verdicts.
• Bard: $5.5 million.
• Johnson & Johnson Ethicon: $12.5 million.
• Boston Scientific: $100 million.

Settlement Amounts
• AMS: $830 million for unspecified number of claims.
• Coloplast: $16 million to settle 400 claims.
Exhibit F
Metal-on-Metal Hip Implant Litigation

Metal-on-Metal Implant
- Consist of ball, stem and shell all made of metal.
  - Designed for less wear and tear.
  - Decreased chance of dislocation.
  - Decreased chance of device fracture
- Types.
  - Traditional.
  - Resurfacing.

Metallosis
- Metal debris in blood stream.
  - Elevated cobalt levels.
  - Early failure of device.
  - Pseudotumors.
    - Reaction to cobalt levels.
  - Aseptic fibrosis and local necrosis.
  - Other symptoms.
    - Rash.
    - Cardiomyopathy.
    - Visual or auditory changes.
    - Impaired renal function.
- No medical treatment.
- Surgery always required.
  - Complete debridement.
  - Replacement of all components.

Recalls
- 2010 Johnson & Johnson DePuy Acetabular System.
  - Possible $4 billion settlement.
  - 7,000-12,000 claims.
  - Possible $350,000 per claimant.
## I. CASE INFORMATION

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<th>Ms. Doe, et al. v Johnson &amp; Johnson</th>
<th>Date: 04/02/0000</th>
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<td>Docket No. 2:15-cv-1579</td>
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<tr>
<td>Plaintiff’s Attorney and Contact Information:</td>
<td>Dewy, Cheatum &amp; How</td>
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## II. PLAINTIFF INFORMATION

<table>
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<tr>
<th>Name: Mary Doe</th>
<th>Loss of Consortium?</th>
<th>Yes</th>
<th>No</th>
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<tr>
<td>Spouse: John Doe</td>
<td>Address:</td>
<td>Anywhere USA</td>
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<tr>
<td>Date of Birth: 01/01/0000</td>
<td>Social Security Number: 000-00-0000</td>
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## III. DEVICE INFORMATION

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<tr>
<th>Date of Implant: 05/01/0000</th>
<th>Reason for Implant: Cystocele</th>
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<tr>
<td>Brand: Gynecare</td>
<td>Manufacturer: Johnson &amp; Johnson Ethicon</td>
</tr>
<tr>
<td>Lot Number: 902245</td>
<td>Implanting Surgeon: Dr. Obgyn</td>
</tr>
<tr>
<td>Medical Facility: Anytown Hospital</td>
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## IV. REMOVAL/REVISION SURGERY INFORMATION

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<th>Date of Surgery: 03/01/0000</th>
<th>Type of Surgery: Partial vaginectomy with excision of vaginal mesh exposure</th>
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<tr>
<td>Explanting Surgeon: Dr. Urogyn</td>
<td>Medical Facility: Best Place Medical Center</td>
</tr>
<tr>
<td>Reason for Explant: Vaginal mesh exposure</td>
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## V. OUTCOME ATTRIBUTED TO DEVICE

- [x] Pain
- [ ] Erosion
- [ ] Extrusion
- [ ] Exposure
- [ ] Urinary Problems
- [x] Bowel Problems
- [ ] Organ Perforation
- [ ] Fistulae
- [ ] Infection
- [ ] Bleeding
- [ ] Dyspareunia
- [ ] Neuromuscular Problems
- [ ] Vaginal Scarring
- [ ] Excision (partial or total)
VI. PAST MEDICAL HISTORY

<table>
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<tr>
<th>Number of Pregnancies: 3</th>
<th>Number of Live Births: 3</th>
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<td>Date of Hysterectomy: 0000</td>
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Prior to Implant, Have You Ever Had:

- [ ] Lupus
- [x] Diabetes
- [ ] Autoimmune disorder
- [ ] Endometriosis
- [ ] Pelvic pain disorder
- [x] Fibroids
- [x] Adhesive disorder

- Are You Claiming Damages for Lost Wages: [ ] Yes [x] No
- Have You Ever Filed Bankruptcy? [ ] Yes [x] No
- Do You Have a Computer? [x] Yes [ ] No
- Are You a Member of Facebook, LinkedIn or Other Social Media? [x] Yes [ ] No

VII. LIST ALL TREATING PHYSICIANS

For the period of 10 years prior to the first implant, including all primary care physicians, OB-Gyn, urologist, endocrinologist, rheumatologist, psychiatrist or any other specialist.
## Exhibit H
### Settlement Screening Report

**Claimant:** Doe, Jane  
**Date:** 4/21/2015  
**Category:** UTD

### SUMMARY

<table>
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<tr>
<th>Nature of initial complaint</th>
<th>SUI, Cystourethrocele</th>
<th>PLTF 000005 JDOE</th>
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<tr>
<td>Date of other corrective surgery SUI/POP</td>
<td>See additional records needed – prior bladder surgery noted on AAA preoperative history</td>
<td>PLTF 000003 JDOE</td>
</tr>
</tbody>
</table>
| Product name, lot number and manufacturer       | 08/25/0000 AAA transobturator  
  o Lot # 1934220  
  o Ref # 93-4400  
  o XYC | PLTF 000004 JDOE |
| Date and nature of adverse event                | 12/28/0000 Microscopic hematuria | PLTF 000007 JDOE |
| Corrective measure                              | Cystoscopy under MAC | PLTF 000007 JDOE |

### Date

<table>
<thead>
<tr>
<th>Date</th>
<th>Description of Important Events</th>
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<tbody>
<tr>
<td>08/25/2009</td>
<td>Claimant underwent AAA sling implant for SUI and grade II cystourethrocele under general anesthesia.</td>
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<tr>
<td>12/28/2010</td>
<td>Cystoscopy performed under MAC for microscopic hematuria. No abnormalities noted in urethra or bladder. Additional records needed to evaluate any claimed adverse events.</td>
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### Risk Factor Assessment

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<tr>
<th>Risk factors contributing to SU, POP and poor healing</th>
<th>Parity</th>
<th>Large baby size</th>
<th>C-section</th>
<th>Vaginal delivery</th>
<th>Forceps used</th>
<th>Advanced age</th>
<th>Obesity</th>
<th>Hx of UTIs</th>
<th>Diabetic</th>
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**INCONTINENCE ASSESSMENT**

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<tbody>
<tr>
<td>08/25/0000</td>
<td>SUI</td>
<td>“This is a 49-year-old white female seen with stress urinary incontinence,</td>
<td>PLTF 000005</td>
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<td>cystourethrocele, hypermobility of the anterior vaginal wall.” (Sammy</td>
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<td>Surgeon, MD, Urology)</td>
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<td>Urge</td>
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**POP ASSESSMENT**

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<tr>
<th>Date</th>
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<td>Sammy Surgeon, MD, Urology 0000 Woodland Dr. Anytown, USA 45678</td>
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<td><strong>Revision Surgeon</strong>&lt;br&gt;• See additional records needed</td>
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<td>□ Erosion&lt;br&gt;□ Mesh exposure&lt;br&gt;□ Exposure at midline incision site&lt;br&gt;□ Other location ______________&lt;br&gt;□ Mesh shrinkage&lt;br&gt;□ Infection&lt;br&gt;□ Fever noted&lt;br&gt;□ Alternative causes for infection noted&lt;br&gt;□ Tension modification&lt;br&gt;□ Pain&lt;br&gt;□ Pain documented “intractable”&lt;br&gt;□ Incontinence/dysuria&lt;br&gt;□ Scarring&lt;br&gt;□ Nerve damage&lt;br&gt;□ Fistula&lt;br&gt;□ In area where trocar was passed&lt;br&gt;□ In incisional area&lt;br&gt;• Bleeding&lt;br&gt;• “This 50-year-old white female was seen with microscopic hematuria.” <em>(Sammy Surgeon, MD, Urology)</em>&lt;br&gt;□ Dyspareunia&lt;br&gt;□ Secondary prolapse&lt;br&gt;□ Other:&lt;br&gt;• See additional records needed</td>
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<td>12/28/0000</td>
<td><strong>Treatment of adverse event</strong>&lt;br&gt;<strong>Cystoscopy, bilateral retrograde under MAC</strong>&lt;br&gt;• Sammy Surgeon, MD, Urology&lt;br&gt;• See additional records needed</td>
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<td><strong>Treating providers for mesh issues</strong>&lt;br&gt;• Sammy Surgeon, MD, Urology&lt;br&gt;0000 Woodland Dr.&lt;br&gt;Anytown, USA 45678&lt;br&gt;• Surgical Center of Anytown&lt;br&gt;111 Financial Dr.&lt;br&gt;Anytown, USA 45678</td>
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