STATE OF TEXAS
OFFICE OF THE ATTORNEY GENERAL
CONSUMER PROTECTION DIVISION

CIVIL INVESTIGATIVE DEMAND

Johnson & Johnson
Ethicon Inc.
c/o Steve Brody
O'Melveny & Meyers LLP
1625 Eye Street, NW
Washington, D.C. 2006-4001

Via Email

Pursuant to the authority granted to the Office of the Attorney General under the provisions of § 17.61 of the TEXAS DECEPTIVE TRADE PRACTICES--CONSUMER PROTECTION ACT (DTPA), § 17.41, *et seq.*, TEX. BUS. & COM. CODE, you are hereby directed to produce the documentary material specified in Exhibit A.

You are to make available the documentary material described in Exhibt A below on or before April 10, 2013. You may forward the responsive material via courier or certified mail to the Office of Attorney General, 1412 Main Street, Suite 810, Dallas, Texas 75202. The Civil Investigative Demand is relevant to the subject matter of an investigation of Johnson & Johnson and Ethicon Inc. for possible violations of §§ 17.46(a) and (b) of the DTPA for issues related to the advertising, marketing, promotion, sale and distribution of surgical mesh products to treat hernia, stress incontinence, and pelvic organ prolapse.

Please be advised that pursuant to § 17.62, TEX. BUS. & COM. CODE, any person who attempts to avoid, evade, or prevent compliance, in whole or in part, with this directive by removing, concealing, withholding, destroying, mutilating, altering or by any other means falsifying any documentary material may be guilty of a misdemeanor that, upon conviction, is punishable by a fine of not more than $5,000.00 or by confinement in the county jail for not more than one year, or both.

ISSUED THIS 27th day of March, 2013

Designated Persons:
Joyce Wein Iliya
Patricia Stein
Jhoslyn Hood

Patricia Stein
Assistant Attorney General
Consumer Protection Division, Health Team

DEFINITIONS

As used in this Civil Investigative Demand:

3.1 "SALES NOTES" shall mean notes taken by SALES REPRESENTATIVES that memorialize, describe, or document the SALES REPRESENTATIVES' visits or other interactions with HEALTH CARE PROVIDERS and/or contain information gleaned from these visits or other interactions, including but not limited to what may be referred to as "call notes."

3.2 "COMMUNICATION" means every disclosure, transfer, exchange, or transmission of information, whether oral, written, or electronic, and whether face-to-face, by telecommunications, computer, mail, telecopier, facsimile (fax) machine, or otherwise.

3.3 "COMPLICATIONS" means any and all complications, injuries, side effects, risks, contraindications, adverse reactions and/or adverse events associated with and/or caused by the use of SURGICAL MESH devices.

3.4 "DOCUMENT" means, without limitation, any "writing," and includes originals or duplicates of or copies of the writings, and non-identical copies bearing or having any attachments, notes or marks which distinguish them from the originals, and any electronic records, including, without limitation, electronic mail, spreadsheets, word processing files, and records saved as .pdf or other electronic files. Electronic mail subject to this subpoena includes messages and/or attachments now only available on backup or archive tapes or disks. Also, if a print-out of an electronic record is a non-identical copy of the electronic version (for example, because the print-out has a signature, handwritten notation, or other mark or attachment not included in the computer DOCUMENT), both the electronic version in which the DOCUMENT was created and the original print-out must be produced.

3.5 "DETAIL" means to provide a HEALTH CARE PROVIDER and/or CONSUMERS with information regarding YOUR medical devices.

3.6 "FDA" means the United States Food and Drug Administration.

3.7 "HEALTH CARE PROVIDER" means any individual or entity engaged in the business of providing health care services, including hospitals, medical facilities, clinics, licensed

physicians, doctors, and/ or specialists, who purchase, prescribe and/or implant medical devices or who may potentially prescribe and/or implant medical devices. This includes individuals who influence or potentially influence the decision to purchase, prescribe and/or implant medical devices and/or the selection of which medical devices to prescribe and/or implant.

3.8 "MESH" or "SURGICAL MESH" means a medical device intended to be implanted to reinforce soft tissue or bone where weakness exists that is used to treat hernia, stress urinary incontinence, and pelvic organ prolapse.

3.9 "MAUDE" means the Manufacturers And User Facility Device Experience database operated and maintained by the FDA.

3.10 "RELATING TO" means constituting, containing, concerning, discussing, describing, analyzing, identifying, referring to, or stating.

3.11 "SALES REPRESENTATIVES" means any of YOUR employees, independent contractors, or distributors, who received PAYMENT from YOU to sell or market YOUR SURGICAL MESH products.

3.12 "SPONSOR" means to pay for in whole or in part, provide financial support for, subsidize, and/or provide goods or materials in support.

3.13 "YOU," "YOUR," and "COMPANY" mean Johnson & Johnson, Ethicon ,Inc., and any parent, affiliate, sister, subsidiary, predecessor, successor or assignee of it, and its principals, operating divisions, present or former owners, employees, servants, officers, directors, agents, representatives, attorneys, accountants, independent contractors, distributors, and any other persons or entities acting on behalf of or under the direction, authorization or control of Johnson & Johnson.

3.14 "And" means and/or. "Or" means and/or.

INSTRUCTIONS

4.1 For each response that requires a response in several parts, provide YOUR response **in a searchable, spreadsheet format such as Excel or Access.**

4.2 At the date, time and location for production of the DOCUMENTS requested, YOU shall provide verified responses to the rquests and a certification regarding the DOCUMENTS produced. This certification must state that a diligent search for all requested DOCUMENTS has been conducted and that the signor was in charge of the search or otherwise monitored and reviewed the search sufficiently to be able to represent under oath that such a search was conducted. It must be signed under oath by the person most knowledgeable about the DOCUMENTS being produced and YOUR efforts to comply with the Civil Investigative Demand. If different persons are the most knowledgeable about various portions of the search, then each such person shall sign a certification identifying the numbered requests for DOCUMENTS for which that person is the most knowledgeable.

4.3 For each audio or video recording produced in response to this subpoena, provide both the recording and a transcript.

4.4 The relevant time period covered by this Civil Investigative Demand ("CID") is from **January 1, 2005,** up to five days before YOUR full compliance with this CID.

Any DOCUMENTS applicable during or relating to this time period are to be produced, regardless of whether the DOCUMENTS came into existence before, after, or during this period.

4.5 DOCUMENTS provided shall be complete and, unless privileged, unredacted, submitted as found in YOUR files (e.g., a DOCUMENT that in its original condition was stapled, clipped, attached as a "post-it," or otherwise fastened together shall be produced in a manner that indicates that it is a single DOCUMENT). The following procedures shall apply to the electronic format of production in one of the following forms and formats. Currently supported electronic data formats are listed below (in order of preference):

In a Summation file structure in appropriate document formats, together with all .dii files needed to load produced documents into a Summation database.

1. Adobe files (.pdf) – OCR Enriched (searchable PDF).
2. Microsoft Word files (.doc), Microsoft Excel files (.xls), Microsoft PowerPoint files (.ppt), Text files (.txt), Tagged Image Format files (.tiff). Supported data formats for

word-processing files include Microsoft Word 2007 or prior versions. Supported data formats for spreadsheet files include Microsoft Excel 2007 or prior .xls files.

3. You shall submit electronically-stored data on a generally supported storage medium. Currently supported storage media include the following: CD-readable disks formatted to ISO 9660 specifications and DVD-ROMs.
4. Responsive documents produced in electronic format must (1) be properly identified; (2) be produced in a format that accurately captures each version of the document, including handwritten notes, signatures, etc.; (3) include all associated electronically-searchable text files for the document (4) include all metadata associated with the document; (e) include all attachments; and (5) otherwise comply with other provisions of these instructions.

4.6 If YOU contend that YOU are unable to comply with any of the Demands for Document Requests included in this CID, provide a declaration or affidavit signed under penalty of perjury that includes a representation of YOUR inability to comply with the particular demand for inspection, and affirms that a diligent search and a reasonable inquiry has been made in an effort to comply with that demand. This declaration or affidavit shall also specify whether YOUR inability to comply is because the particular item or category has never existed, has been destroyed, has been lost, misplaced, or stolen, or has never been, or is no longer, in YOUR possession, custody, or control. The declaration or affidavit shall set forth the name and address of any natural person or organization known or believed by YOU to have possession, custody, or control of that item or category of item.

4.7 Please mark each page of a paper DOCUMENT and each tangible thing containing audio, video, computer or other electronic DOCUMENT (e.g., cassette, disk, tape or CD) with corporate identification and consecutive DOCUMENT control numbers (e.g., J&J 001, J&J CD 001, J&J audio tape 001). Number each box of DOCUMENTS produced and mark each with the name(s) of the person(s) whose files are contained therein, the request(s) to which they are responsive, and the DOCUMENT control numbers contained therein.

4.8 For each DOCUMENT produced in response to this CID, identify the demand to which the DOCUMENT is responsive.

4.9 If any DOCUMENTS are withheld from production based on a claim of privilege, YOU must provide a privilege log.

4.10 In answering each Document Request, you are requested to furnish all information which is in your possession, custody, or control.

4.11 If the information requested in any Document Request is not known at the time of the answer but is or may be available from a third party not subject to Instruction Number 4.6 above, you are requested to so state and identify the person believed to have such information.

DO NOT DESTROY ANY DOCUMENTS RELATING TO OR REQUESTED IN ANY OF THESE DOCUMENT REQUESTS.

DOCUMENT REQUEST PART A

REQUEST NO. 1A: Produce all documents sufficient to identify each business entity (e.g., parent, affiliate, sister, subsidiary) that collectively comprise the COMPANY. Included in the response, produce all documents sufficient to indicate which of the above business entities are engaged in the research, development, manufacturing, marketing, sale and/or distribution of SURGICAL MESH products.

RESPONSE:

REQUEST NO. 2A: Produce all documents sufficient to identify all investigations of YOU or YOUR business practices RELATING TO SURGICAL MESH conducted by any local, state or federal governmental entity. This request also includes but is not limited to documents sufficient to identify inquiries from any Congressional office or committee RELATING TO SURGICAL MESH.

RESPONSE:

REQUEST NO. 3A: Produce all documents sufficient to identify each SURGICAL MESH device that YOU manufactured or sold in the United States during the relevant time frame. For

each medical device, produce all documents sufficient to identify the following: (1) the name and model number under which it received "predicate substantial equivalent determination" prior to marketing from the FDA; (2) the name(s) under which it was marketed and the dates it was marketed; (3) the name and model number associated with the device in FDA databases, including the MAUDE database; (4) the type of mesh material (e.g. synthetic or porcine, absorbable or non-absorbable, collagen infused, etc.); (5) all indications requested by YOU for which the device is to be used; (6) the type of FDA market determination that YOU obtained for the device; (7) if the device was "determined substantially equivalent to predicates prior to marketing" under the 510(k) process, the predicate devices upon which the clearance as based; (8) the date of FDA determination as substantially equivalent to predicates prior to marketing for the MESH device; (9) the indications for which the device was determined substantially equivalent to predicates prior to marketing; and (10) any FDA requirements specifically pertaining to the MESH device upon which determination prior to marketing was contingent (e.g. regarding labeling, performance, and safety, including special controls, performance standards, and post-market surveillance requirements).

RESPONSE:

REQUEST NO. 4A: Produce all documents sufficient to identify by name, title, last known address and telephone number all of YOUR current and former officers, directors, employees and contractors who had responsibility for and oversight over (1) obtaining FDA determination for marketing for YOUR MESH DEVICES; and (2) complying with post-market FDA requirements for MESH DEVICES. For former employees, please produce all documents sufficient to identify the last date of employment with YOU.

RESPONSE:

REQUEST NO. 5A: Produce all documents sufficient to identify all COMPLICATIONS associated with each of your SURGICAL MESH PRODUCTS. For each COMPLICATION,

produce all documents sufficient to: (1) identify the date or approximate dates by which YOU became aware of this COMPLICATION; (2) identify all data that YOU have regarding the rates, frequency, and seriousness of this COMPLICATION; and (3) identify all sources of information that YOU have regarding the COMPLICATION.

RESPONSE:

REQUEST NO. 6A: Produce all documents sufficient to identify all HEALTH CARE PROVIDERS by name, name of practice or affiliated hospital, address and phone number, who have communicated with YOU regarding the COMPLICATIONS associated with the use of YOUR SURGICAL MESH devices. Produce all documents sufficient to identify the MESH device(s) that was the subject of each communication.

RESPONSE:

REQUEST NO. 7A: Produce all documents sufficient to describe YOUR policies, procedures and practices RELATING TO receiving, tracking, evaluating, responding to, and/or reporting to the FDA any COMPLICATIONS, adverse events or other complaints regarding YOUR SURGICAL MESH DEVICES. Include in your response all documents sufficient to describe YOUR use and formulation of any formulas, matrices or decision tree(s) to determine which COMPLICATIONS to report to the FDA as adverse events.

RESPONSE:

REQUEST NO. 8A: Produce all documents sufficient to describe YOUR policies, procedures and practices RELATING TO the determination of whether complaints and reports of COMPLICATIONS regarding SURGICAL MESH are reported to the FDA and the criteria YOU use to make this determination.

RESPONSE:

REQUEST NO. 9A: Produce all documents sufficient to identify any studies or research RELATED TO the safety and efficacy of SURGICAL MESH and the date of publication. For each study or research, produce all documents sufficient to identify (1) whether YOU SPONSORED that study in whole or in part; (2) whether the study was submitted by YOU in the FDA determination process; (3) whether YOU refer to that study or provide a copy of that study in marketing or selling YOUR MESH PRODUCTS; and (4) whether YOU have circulated that study to HEALTH CARE PROVIDERS. Included in your response, produce all documents sufficient to identify whether you used any outside consultants in determining the safety and efficacy of MESH. Produce all documents sufficient to identify the outside consultants, including the information YOU received from the outside consultant. Produce all documents sufficient to identify the name and contact information for each outside consultant.

RESPONSE:

REQUEST NO. 10A: Produce all documents sufficient to describe any disclosures, reassurances or warnings regarding MESH COMPLICATIONS that YOU have made to HEALTH CARE PROVIDERS at any time who prescribe and/or implant YOUR SURGICAL MESH devices.

RESPONSE:

REQUEST NO. 11A: Produce all documents sufficient to identify by name, title, address and telephone number all persons responsible for adverse event reporting to the FDA RELATING TO SURGICAL MESH.

RESPONSE:

REQUEST NO. 12A: Produce all documents sufficient to identify by name, title, address and telephone number the person(s) most knowledgeable about FDA adverse event reporting RELATING TO YOUR SURGICAL MESH.

RESPONSE:

REQUEST NO. 13A: Produce all documents sufficient to identify all internal and external databases used by YOU or YOUR employees to track or maintain information RELATING to adverse events reports.

RESPONSE:

REQUEST NO. 14A: Produce all documents sufficient to identify all "Dear Doctor" letters, "Dear Health Care Provider" letters, and other similar COMMUNICATIONS RELATED TO YOUR SURGICAL MESH devices that YOU disseminated. For each such letter, produce all documents sufficient to identify the date you initially disseminated the letter and the date(s) you modified or stopped disseminating the letter. Also produce all documents sufficient to identify all doctors and other health care providers who were sent the letter and indicate by month and year the total number of the above letters that YOU disseminated.

RESPONSE:

REQUEST NO. 15A: Produce all documents sufficient to identify all of YOUR SURGICAL MESH devices, by the FDA name, model number and name under which it was marketed, that were either recalled by the FDA, voluntarily recalled by YOU, or voluntarily withdrawn from the market by YOU. For each such product, produce all documents sufficient to identify the reason for removing the MESH device from the market and the date of such action. If the removal of the device from the market was temporary, produce all documents sufficient to identify the date and reason the product was put back on the market.

RESPONSE:

REQUEST NO. 16A: Produce all documents sufficient to identify all of YOUR SURGICAL MESH devices that have been the subject of a personal injury or other lawsuit. For each

SURGICAL MESH device, produce all documents sufficient to identify the total number of legal actions, case names, case numbers and the courts and the alleged defect.

RESPONSE:

REQEST NO. 17A: Produce all documents sufficient to identify the total number of each of the SURGICAL MESH devices that YOU have sold in the United States during the relevant time frame and the total monetary value of these sales. Produce all documents sufficient to identify a yearly and quarterly breakdown of these sales and revenue figures for each specific MESH device (by FDA name and model number) that you sell.

RESPONSE:

REQUEST NO.18A: Produce all documents sufficient to identify by name, title, last known address and telephone number of all of YOUR current and former officers, directors, employees and contractors who had responsibility for and oversight over the marketing and sale of YOUR MESH DEVICES. For former employees, please provide all documents sufficient to identify the last date of employment with YOU.

RESPONSE:

REQUEST NO. 19A: For each year within the relevant time period, provide all documents sufficient to identify YOUR sales regions within the United States for the sale of each of your MESH DEVICES, and provide all documents sufficient to describe which geographical areas are encompassed in the sales regions identified.

RESPONSE:

REQUEST NO. 20A: For each year within the relevant time period, provide all documents sufficient to identify the total number of sales representatives and supervisors within each sales region in the United States who were authorized to sell each MESH DEVICE.

RESPONSE:

REQUEST NO. 21A: Provide all documents sufficient to identify by name, title, last known address and telephone number, every current or former SALES REPRESENTATIVE employed or authorized by YOU to promote, market, and/or sell YOUR SURGICAL MESH devices in the following States: Washington, California, South Carolina, Ohio, Pennsylvania, Florida, Texas, Illinois, Colorado and Maryland. For each SALES REPRESENTATIVE, provide all documents sufficient to identify his/her direct supervisor by name, title, last known address and telephone number and the state/regional supervisor by name, title, last known address and telephone number. Provide all documents sufficient to identify the types or models of SURGICAL MESH products sold by each SALES REPRESENTATIVE. For former employees, please provide all documents sufficient to identify the last date of employment with YOU.

RESPONSE:

REQUEST NO. 22A: Provide all documents sufficient to describe all methods by which YOU advertise, market, promote, sell, and/or distribute information regarding YOUR SURGICAL MESH devices to HEALTH CARE PROVIDERS and consumers.

RESPONSE:

REQUEST NO. 23A: For each of YOUR SURGICAL MESH PRODUCTS, provide documents sufficient to identify by name, title, address and telephone number all persons who drafted or assisted in drafting marketing materials, including but not limited to website materials. For former employees, please provide all documents sufficient to identify the last date of employment with YOU.

RESPONSE:

REQUEST NO. 24A: Provide all documents sufficient to identify by name, title, address and telephone number the person(s) most knowledgeable about the drafting and approval of marketing materials RELATING TO SURGICAL MESH. If the person most knowledgeable about the above varies by MESH product, provide all documents sufficient to identify each of the persons most knowledgeable about the drafting and approval of marketing materials RELATING TO each specific SURGICAL MESH device that YOU market and sell.

RESPONSE:

REQUEST NO. 25A: Provide all documents sufficient to describe the role played by YOUR SALES REPRESENTATIVES in advertising, marketing, promoting, selling, and/or distributing information regarding YOUR medical devices.

RESPONSE:

REQUEST NO. 26A: Provide all documents sufficient to identify all databases used by YOU or YOUR employees to track or maintain information regarding SALES NOTES and/or information concerning YOUR DETAILS to HEALTH CARE PROVIDERS regarding MESH products.

RESPONSE:

REQUEST NO. 27A: Provide all documents sufficient to identify by name, date and location all continuing medical education (CME) events regarding SURGICAL MESH SPONSORED by YOU in whole or in part. Include in this response provide all documents sufficient to identify all events at which YOU provide training, certification and credentialing to HEALTH CARE PROVIDERS with regard to MESH.

RESONSE:

REQUEST NO. 28A: Provide all documents sufficient to describe all methods by which YOU have solicited or encouraged HEALTH CARE PROVIDERS to perform MESH implantations or to become trained to perform MESH implantations, including but not limited to whether you target certain specialties for such solicitations.

RESPONSE:

REQUEST NO. 29A: Provide all documents sufficient to identify by name, title, last known address and telephone number of each HEALTH CARE PROVIDER that has received payments and other incentives to promote and market MESH products for YOUR COMPANY. Include in YOUR response, documents sufficient to identify the amounts of payments and, if known, provide provide documents sufficient to identify the MESH device that was promoted and marketed by the HEALTH CARE PROVIDER.

RESPONSE:

REQUEST NO. 30A: Provide all documents sufficient to identify any studies or research RELATED TO the use of SURGICAL MESH rather than non-MESH surgical repair for hernia.

RESPONSE:

REQUEST NO. 31A: For each study or research identified in Request No. 30A, provide all documents sufficient to identify (1) whether YOU SPONSORED that study in whole or in part; (2) whether the study was submitted by YOU in the FDA clearance process; (3) whether YOU use that study in marketing or selling YOUR MESH products; and (4) whether YOU have circulated that study to HEALTH CARE PROVIDERS.

RESPOSNE:

REQUEST NO. 32A: Provide all documents sufficient to identify any studies or research RELATED TO the use of SURGICAL MESH rather than NON-MESH surgical repair for stress urinary incontinence.

RESPONSE:

REQUEST NO. 33A: For each study or research identified in response to Request No. 32A, provide all documents sufficient to identify (1) whether YOU SPONSORED that study in whole or in part; (2) whether the study was submitted by YOU in the FDA clearance process; (3) whether YOU use or have used that study in marketing or selling YOUR MESH products; and (4) whether YOU have circulated that study to HEALTH CARE PROVIDERS.

RESPONSE:

REQUEST NO. 34A: Provide all documents sufficient to identify any studies or research RELATED TO the use of SURGICAL MESH rather than NON-MESH surgical repair for pelvic organ prolapse.

RESPONSE:

REQUEST NO. 35A: Provide all documents sufficient to identify each study or research identified in the documents Response No. 34A. Produce all documents sufficient to identify: (1) whether YOU SPONSORED that study in whole or in part; (2) whether the study was submitted by YOU in the FDA clearance process; (3) whether YOU use or have used that study in marketing or selling YOUR MESH products; and (4) whether YOU have circulated that study to HEALTH CARE PROVIDERS.

RESPONSE:

REQIEST NO. 36A: Provide all documents sufficient to identify each of YOUR mesh products that YOU submitted to the FDA that had a 510(k) application showing a substantial equivalence to Boston Scientific's ProteGen product.

RESPONSE:

RESPONSE NO. 37A: Provide all documents sufficient to identify every one of YOUR MESH products that YOU submitted to the FDA that had a 510(k) application showing a substantial equivalence to another mesh product that had a substantial equivalence based on Boston Scientific's ProteGen surgical mesh product. Include in YOUR response, all documents sufficient to identify every MESH product YOU manufactured that relates to or references a MESH product with a substantial equivalence based on Boston Scientific's ProtoGen surgical mesh product.

RESPONSE:

REQUEST NO. 38A: Provide all documents sufficient to describe YOUR position with regard to the definition of MESH erosion, the frequency and severity with which it occurs in patients implanted with MESH, and whether this occurrence constitutes an adverse event. Include in YOUR response all documents sufficient to identify how YOU evaluate, track and react to reports or complaints of MESH erosion.

RESPONSE:

REQUEST NO. 39A: Provide all documents sufficient to identify all persons involved in responding to the inquiries from any Congressional office or committee RELATING TO SURGICAL MESH information from YOU.

RESPONSE:

REQUEST NO. 40A: Provide all documents sufficient to describe YOUR training program for SALES REPRESENTATIVES. Include in YOUR response (1) all documents sufficient to identify of all persons responsible for training SALES REPRESENTATIVES by their names, title and contact information, including speakers at training events; and (2) all documents sufficient to identify whether there were national or regional conferences or training schools for the purpose of training SALES REPRESENTATIVES.

ANSWER:

REQUEST NO. 41A: Provide all documents sufficient to identify all persons involved in responding to Document Requests Parts A and B on your behalf.

RESPONSE:

REQUEST NO. 42A: Provide all documents sufficient to identify all of YOUR MESH products, by name and model number, that are or that YOU claim to be "tension-free".

RESPONSE:

REQUEST NO. 43A: For any such product identified in response to Request No. 42A, provide all documents sufficient to describe how the MESH stays in place immediately after placement. Provide all documents sufficient to describe any changes expected in the six months following placement.

RESPONSE:

DOCUMENT REQUEST PART B

REQUEST NO. 1B: Provide organizational charts showing the relationship among business entities identified in the documents produced in response to Request No. 1A.

RESPONSE:

REQUEST NO. 2B: Provide copies of all DOCUMENTS from any investigations of YOU or YOUR company conducted by any local, state or federal government entity. Provide copies of any responses made by YOU or YOUR company in response to all investigations identified in the documents produced in response to Request No. 2A.

RESPONSE:

REQUEST NO. 3B: For each of YOUR SURGICAL MESH devices marketed and sold to HEALTH CARE PROVIDERS, provide all DOCUMENTS that YOU submitted to the FDA for clearance. Include all COMMUNICATIONS with the FDA RELATING TO the clearance process, including all 510(k) application product updates, Special 510(k) applications, requests from the FDA for further information, and YOUR responses to the FDA's requests.

RESPONSE:

REQUEST NO. 4B: For each of the SURGICAL MESH devices identified by you in the documents produced in response to Request No. 3A, provide all DOCUMENTS RELATING TO the FDA's rejection of any indication that YOU applied for in any New Device Approval (NDA), Premarket Approval (PMA), and/or 501(k) applications for YOUR SURGICAL MESH devices. Include all COMMUNICATIONS with the FDA that refer to the rejection of any indication that was requested in the NDA, PMA, and/or 501(k), as well as internal COMPANY DOCUMENTS that discuss that rejection.

RESPONSE:

REQUEST NO. 5B: For the employees listed in the documents in response to Request No. 4A, provide an organizational chart(s) of these individuals.

RESPONSE:

REQUEST NO. 6B: Provide all COMMUNICATIONS between YOU and the FDA RELATED TO any failure(s) by YOU to comply with FDA requirements with regard to any SURGICAL MESH products.

RESPONSE:

REQUEST NO. 7B: Provide all COMMUNICATIONS between YOU and the FDA RELATED TO adverse event reporting RELATING TO SURGICAL MESH products.

RESPONSE:

REQUEST NO. 8B: Provide all COMMUNICATIONS RELATING TO the October 20, 2008 FDA Public Health Notification attached hereto as **Exhibit A**. Include in YOUR response all internal COMMUNICATIONS and COMMUNICATIONS to the FDA, HEALTH CARE PROVIDERS, consumers and on YOUR websites.

RESPONSE:

REQUEST NO, 9B: Provide all COMMUNICATIONS RELATING TO the July 13, 2011 FDA Safety Communication attached hereto as **Exhibit B.**

RESPONSE:

REQUEST NO. 10B: Provide all internal COMMUNICATIONS within YOUR COMPANY regarding COMPLICATIONS associated with MESH.

RESPONSE:

REQUEST NO. 11B: Provide all COMMUNICATIONS between YOU and HEALTH CARE PROVIDERS RELATING to the COMPLICATIONS associated with SURGICAL MESH.

RESPONSE:

REQUEST NO. 12B: For any studies identified in the documents produced in response to Request No. 9A, provide a copy of all such studies and research. If YOU identified in the documents produced in response to Request No. 9A, provide copies of all COMMUNICATIONS between YOU and each outside consultant.

RESPONSE:

REQUEST NO. 13B: For any disclosures, reassurances or warnings regarding COMPLICATIONS that YOU have made to HEALTH CARE PROVIDERS identified in documents responsive to Request No. 10A, provide representative copies of all such disclosures and warnings, including but not limited to the packaging of YOUR devices.

RESPONSE:

REQUEST NO. 14B: Produce copies of any decision trees, formulas, matrices, or other criteria formulated and used by YOU as identified in documents produced in response to Request No. 7A. Provide draft versions of any of the above DOCUMENTS.

RESPONSE:

REQUEST NO. 15B: Produce copies of all "Dear Doctor" letters, "Dear Health Care Provider" letters and similar COMMUNICATIONS as identified in documents produced by YOU in response to Request No. 14A.

RESPONSE:

REQUEST NO. 16B: For any products withdrawn from the market as identified in documents produced in response to Request No. 15A, provide all DOCUMENTS RELATING TO YOUR the response to the request.. Include in YOUR response all responses YOU provided to the FDA in response to its request for 522 Postmarket Surveillance Studies relating to MESH.

RESPONSE:

REQUEST NO. 17B: Provide DOCUMENTS that evidence or support YOUR response to Request No. 17A regarding the total number of MESH devices sold; the total monetary value of these sales; and the yearly and quarterly breakdown of these sales and revenue figures for each MESH device.

RESPONSE:

REQUEST NO. 18B: For individuals identified in the documents produced in response to Request No. 18A, provide an organizational chart(s) of these individuals.

RESPONSE:

REQUEST NO. 19B: For individuals indentified in the documents produced in response to Request No. 21A, provide an organizational chart(s) of these individuals.

RESPONSE:

REQUEST NO. 20B: Provide representative copies of all DOCUMENTS used by YOU in advertising, marketing, promoting, selling, and/or distributing information regarding YOUR SURGICAL MESH devices marketed and sold to HEALTH CARE PROVIDERS and the general public.

RESPONSE:

REQUEST NO. 21B: Provide all policies, practices, guidelines, or guidance RELATING TO the marketing of SURGICAL MESH.

RESPONSE:

REQUEST NO. 22B: Provide all marketing reports RELATING to YOUR SURGICAL MESH.

RESPONSE:

REQUEST NO. 23B: Provide all DOCUMENTS used by YOU in training YOUR SALES REPRESENTATIVES. Also provide all DOCUMENTS that you have given to YOUR SALES REPRESENTATIVES to be used by them in advertising, marketing, promoting, selling, and/or distributing any representations or information regarding YOUR SURGICAL MESH devices.

RESPONSE:

REQUEST NO. 24B: Provide all SALES NOTES or other notes made by SALES REPRESENTATIVES RELATING TO SURGICAL MESH or sales of SURGICAL MESH, including those generated on or sent to SALES REPRESENTATIVES' personal computers and electronic devices.

RESPONSE:

REQUEST NO. 25B: Provide any and all databases referred to in your response to Request No.26A.

RESPONSE:

REQUEST NO. 26B: Provide all periodic reviews of SALES REPRESENTATIVES including but not limited to their sales goals, failures and achievements in marketing MESH products. Provide DOCUMENTS regarding the qualifications of SALES REPRESENTATIVES, pay structures, bonus programs and all incentives.

RESPONSE:

REQUEST NO. 27B: For any CME or other events at which YOU provide training, certification, or credentialing to HEALTH CARE PROVIDERS regarding MESH devices,

identified in the documents produced in response to Request No. 27, provide all materials prepared and used at these events, and all recordings and/or transcript of these events. Include representative copies of certifications issued to HEALTH CARE PROVIDERS at these events.

RESPONSE:

REQUEST NO. 28B: Provide all DOCUMENTS that you have provided to HEALTH CARE PROVIDERS for use during medical conferences and other continuing medical education events including, but not limited to, educational materials, talking points, outlines, slide decks, and/or Power Point presentations RELATING TO the use of and implanting of surgical mesh.

RESPONSE:

REQUEST NO. 29B: Provide all DOCUMENTS that YOU have provided to HEALTH CARE PROVIDERS for use during medical conferences and other continuing medical education events including, but not limited to, educational materials, talking points, outlines, slide decks, and/or Power Point presentations relating to the removal of SURGICAL MESH.

RESPONSE:

REQUEST NO. 30B: Produce copies of YOUR budgets and other financial DOCUMENTS reflecting the amounts YOU spend in marketing or promotion of SURGICAL MESH, including but not limited to, financial and other incentives for doctors to promote the use of SURGICAL MESH and bonuses, commissions, or financial incentives of any kind paid to SALES REPRESENTATIVES for selling YOUR MESH products.

RESPONSE:

REQUEST NO. 31B: Provide copies of all FDA Form 483 that YOU have received RELATING TO SURGICAL MESH products.

RESPONSE:

REQUEST NO. 32B: Provide copies of all responses and other correspondence YOU have provided to the FDA in response to any Form 483 that YOU have received RELATING TO SURGICAL MESH products.

RESPONSE:

REQUEST NO. 33B: Provide all studies or research RELATED TO the use of SURGICAL MESH rather than non-MESH surgical repair for hernia.

RESPONSE:

REQUEST NO. 34B: Provide all studies or research RELATED TO the use of SURGICAL MESH rather than non-MESH surgical repair for stress urinary incontinence.

RESPONSE:

REQUEST NO. 35B: Provide all studies or research RELATED TO the use of SURGICAL MESH rather than non-MESH surgical repair for pelvic organ prolapse.

RESPONSE:

REQUEST NO. 36B: Provide all studies relied on by YOU to support any 510(k) application.

RESPONSE:

REQUEST NO. 37B: Provide all studies used or disseminated by YOUR SALES REPRESENTATIVES in promoting YOUR MESH products.

RESPONSE:

REQUEST NO. 38B: Provide all studies and research YOU were requested to conduct by the FDA. Include any studies on the rates of organ damage and COMPLICATIONS linked to vaginal MESH implants.

RESPONSE:

REQUEST NO. 39B: Provide all studies and research YOU funded in any way RELATING TO SURGICAL MESH.

RESPONSE:

REQUEST NO. 40B: For each MESH product that you identified in the documents produced in response to Requests Nos. 36A and 37A produce the FDA applications you submitted to the FDA.

RESPONSE:

REQUEST NO. 41B: Produce copies of all DOCUMENTS and COMMUNICATIONS RELATING TO YOUR efforts to sell MESH or solicit HEALTH CARE PROVIDERS to implant MESH, including but not limited to, efforts to target certain specialties in the course of marketing MESH. Include all promotional training manuals and training directives.

RESPONSE:

REQUEST NO. 42B: Produce all internal and external COMMUNICATIONS from July 2007 to the present RELATING TO FDA market clearance for the Gynecare Prolift device, including but not limited to COMMUNICATIONS regarding the need for obtaining clearance and the decision to obtain or not obtain FDA market clearance.

RESPONSE:

REQUEST NO. 43B: Provide all DOCUMENTS YOU have RELATING TO Prolene suture, N 16-374.

RESPONSE:

REQUEST NO. 44B: Provide all DOCUMENTS you submitted to the FDA RELATING TO Prolene suture, N 16-374.

RESPONSE:

REQUEST NO. 45B: Provide all DOCUMENTS YOU have RELATING TO NDA 17-804.

RESPONSE:

REQUEST NO. 46B: Provide all DOCUMENTS YOU have RELATING TO the NDA 16-374.

RESPONSE:

REQUEST NO. 47B: Produce copies of all DOCUMENTS YOU have RELATING TO the voluntarily cessation of marketing activities for any of YOUR SURGICAL MESH products.

RESPONSE:

REQUEST NO. 48B: Produce copies of all DOCUMENTS you have RELATING TO the withdrawing or removing from the market any of YOUR SURGICAL MESH products.

RESPONSE:

REQUEST NO. 49B: Provide copies of all training videos, animations and audio/ visual materials RELATING TO MESH that were created by YOU or disseminated by YOU.

RESPONSE:

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence

For updated information about Surgical Mesh for Pelvic Organ Prolapse, see: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse, released July 13, 2011.

Issued: October 20, 2008

Dear Healthcare Practitioner:

This is to alert you to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). Although rare, these complications can have serious consequences. Following is information regarding the adverse events that have been reported to the FDA and recommendations to reduce the risks.

Nature of the Problem

Over the past three years, FDA has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI. These mesh devices are usually placed transvaginally utilizing tools for minimally invasive placement.

The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia.

Treatment of the various types of complications included additional surgical procedures (some of them to remove the mesh), IV therapy, blood transfusions, and drainage of hematomas or abscesses.

Specific characteristics of patients at increased risk for complications have not been determined. Contributing factors may include the overall health of the patient, the mesh material, the size and shape of the mesh, the surgical technique used, concomitant procedures undertaken (e.g. hysterectomy), and possibly estrogen status.

Recommendations

Physicians should:

- Obtain specialized training for each mesh placement technique, and be aware of its risks.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
- Provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if available.

Additional patient information can be found on the following FDA Consumer website.

Reporting Adverse Events to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of surgical mesh, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to surgical mesh that do not meet the requirements for mandatory reporting. You can report directly to MedWatch, the FDA Safety Information and Adverse Event Reporting program online, by phone at 1-800-FDA-1088, or obtain the fillable form online, print it out and fax to 1-800-FDA-0178 or mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

Getting More Information

FDA Medical Device Public Health Notifications are available on the Internet. You can also be notified through email each time a new Public Health Notification is added to our web page. To subscribe, visit: http://service.govdelivery.com/service/subscribe.html?code=USFDA_39.

Sincerely,

EXHIBIT A

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

If you have questions about this Notification, please contact FDA's Division of of Small Manufacturers, International and Consumer Assistance (DSMICA) by e-mail at dsmica@fda.hhs.gov or by phone at 1-800-638-2041 or 301-796-7100

Page Last Updated: 03/09/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

EXHIBIT A

Medical Devices

Medical Device Safety
- Safety Communications
- Information About Heparin
- Medical Device Safety Archive
- Tubing and Luer Misconnections: Preventing Dangerous Medical Errors

FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse

Date Issued: July 13, 2011

Audience:

- Health care providers who implant surgical mesh to repair pelvic organ prolapse and/or stress urinary incontinence
- Health care providers involved in the care of patients with surgical mesh implanted to repair pelvic organ prolapse and/or stress urinary incontinence
- Patients who are considering or have received a surgical mesh implant to repair pelvic organ prolapse and/or stress urinary incontinence

Medical Specialties: gynecology, urogynecology, urology, general surgery, internal medicine, family practice, emergency medicine

Device:
Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence.

Background:
Pelvic Organ Prolapse
Pelvic organ prolapse (POP) occurs when the tissues that hold the pelvic organs in place become weak or stretched. Thirty to fifty percent of women may experience POP in their lifetime with 2 percent developing symptoms. When POP happens, the organs bulge (prolapse) into the vagina and sometimes prolapse past the vaginal opening. More than one pelvic organ can prolapse at the same time. Organs that can be involved in POP include the bladder, the uterus, the rectum, the top of the vagina (vaginal apex) after a hysterectomy, and the bowel.

Stress Urinary Incontinence
Stress urinary incontinence (SUI) is a leakage of urine during moments of physical activity, such as coughing, sneezing, laughing, or exercise.

Purpose:
On Oct. 20, 2008, the FDA issued a Public Health Notification and Additional Patient Information on serious complications associated with surgical mesh placed through the vagina (transvaginal placement) to treat POP and SUI.

Based on an updated analysis of adverse events reported to the FDA and complications described in the scientific literature, the FDA identified surgical mesh for transvaginal repair of POP as an area of continuing serious concern.

The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**. This is a change from what the FDA previously reported on Oct. 20, 2008. Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk. This Safety Communication provides updated recommendations for health care providers and patients and updates the FDA's activities involving surgical mesh for the transvaginal repair of POP.

The FDA continues to evaluate the effects of using surgical mesh to repair SUI and will communicate these findings at a later date.

For detailed information, please see: Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse.

Summary of Problem and Scope:
In the Oct. 20, 2008 FDA Public Health Notification, the number of adverse events reported to the FDA for surgical mesh devices used to repair POP and SUI for the previous 3-year period (2005 – 2007) was "over 1,000." Since then, from Jan. 01, 2008 through Dec. 31, 2010, the FDA received 2,874 additional reports of complications associated with surgical mesh devices used to repair POP and SUI, with 1,503 reports associated with POP repairs and 1,371 associated with SUI repairs. Although it is common for adverse event reporting to increase following an FDA safety communication, we are concerned that the number of adverse event reports remains high.

From 2008 – 2010, the most frequent complications reported to the FDA for surgical mesh devices for POP repair include mesh erosion through the vagina (also called exposure, extrusion or protrusion), pain, infection,

EXHIBIT B

bleeding, pain during sexual intercourse (dyspareunia), organ perforation, and urinary problems. There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage, and emotional problems. Many of these complications require additional intervention, including medical or surgical treatment and hospitalization.

In order to better understand the use of surgical mesh for POP and SUI, the FDA conducted a systematic review of the published scientific literature from 1996 – 2011 to evaluate its safety and effectiveness. The review showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair. The FDA continues to evaluate the literature for SUI surgeries using surgical mesh and will report about that usage at a later date.

In particular, the literature review revealed that:

- Mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair.
- Mesh placed abdominally for POP repair appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
- There is no evidence that transvaginal repair to support the top of the vagina (apical repair) or the back wall of the vagina (posterior repair) with mesh provides any added benefit compared to traditional surgery without mesh.
- While transvaginal surgical repair to correct weakened tissue between the bladder and vagina (anterior repair) with mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh, this anatomic benefit may not result in better symptomatic results.

The FDA's literature review found that *erosion* of mesh through the vagina is the *most common and consistently reported mesh-related complication* from transvaginal POP surgeries using mesh. Mesh erosion can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complication.

Mesh contraction (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the Oct. 20, 2008 *FDA Public Health Notification*. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain.

Both mesh erosion and mesh contraction may lead to severe pelvic pain, painful sexual intercourse or an inability to engage in sexual intercourse. Also, men may experience irritation and pain to the penis during sexual intercourse when the mesh is exposed in mesh erosion.

The complications associated with the use of surgical mesh for POP repair have not been linked to a single brand of mesh.

Recommendations for Health Care Providers:

As stated in the Oct. 20, 2008 Public Health Notification, the FDA continues to recommend that health care providers should:

- Obtain specialized training for each mesh placement technique, and be aware of the risks of surgical mesh.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall in POP repair using surgical mesh.
- Provide patients with a copy of the patient labeling from the surgical mesh manufacturer if available.

In addition, the FDA also recommends that health care providers:

- Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.
- Choose mesh surgery only after weighing the risks and benefits of surgery with mesh versus all surgical and non-surgical alternatives.
- Consider these factors before placing surgical mesh:
  - Surgical mesh is a permanent implant that may make future surgical repair more challenging.
  - A mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications.
  - Removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain.
  - Mesh placed abdominally for POP repair may result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
- Inform the patient about the benefits and risks of non-surgical options, non-mesh surgery, surgical mesh placed abdominally and the likely success of these alternatives compared to transvaginal surgery with mesh.
- Notify the patient if mesh will be used in her POP surgery and provide the patient with information about the specific product used.
- Ensure that the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data.

Recommendations for Patients:
Before Surgery

Be aware of the risks associated with surgical mesh for transvaginal repair of POP. Know that having a mesh surgery may put you at risk for needing additional surgery due to mesh-related complications. In a small number of patients, repeat surgery may not resolve complications.

Ask your surgeon about all POP treatment options, including surgical repair with or without mesh and non-surgical options, and understand why your surgeon may be recommending treatment of POP with mesh.

EXHIBIT B

In addition, ask your surgeon these questions before you agree to have surgery in which surgical mesh will be used:

- Are you planning to use mesh in my surgery?
- Why do you think I am a good candidate for surgical mesh?
- Why is surgical mesh being chosen for my repair?
- What are the alternatives to transvaginal surgical mesh repair for POP, including non-surgical options?
- What are the pros and cons of using surgical mesh in my particular case? How likely is it that my repair could be successfully performed without using surgical mesh?
- Will my partner be able to feel the surgical mesh during sexual intercourse? What if the surgical mesh erodes through my vaginal wall?
- If surgical mesh is to be used, how often have you implanted this particular product? What results have your other patients had with this product?
- What can I expect to feel after surgery and for how long?
- Which specific side effects should I report to you after the surgery?
- What if the mesh surgery doesn't correct my problem?
- If I develop a complication, will you treat it or will I be referred to a specialist experienced with surgical mesh complications?
- If I have a complication related to the surgical mesh, how likely is it that the surgical mesh could be removed and what could be the consequences?
- If a surgical mesh is to be used, is there patient information that comes with the product, and can I have a copy?

After Surgery

- Continue with your annual and other routine check-ups and follow-up care. There is no need to take additional action if you are satisfied with your surgery and are not having complications or symptoms.
- Notify your health care provider if you have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after your follow-up appointment.
- Let your health care provider know you have surgical mesh, especially if you plan to have another surgery or other medical procedures.
- Talk to your health care provider about any questions you may have.

If you had POP surgery, but do not know whether your surgeon used mesh, ask your health care provider at your next scheduled visit.

FDA Activities:
The FDA is working in several areas to assess and improve the safety and effectiveness of urogynecologic mesh products. The FDA will:

- Convene the Obstetrics-Gynecology Devices Panel of the Medical Device Advisory Committee, on September 8-9, 2011.The panel will discuss and make recommendations regarding the safety and effectiveness of transvaginal surgical mesh for POP and SUI.
- Explore regulatory solutions to answer questions about the safety and effectiveness of urogynecologic mesh products that are now being marketed and those that will be reviewed for marketing in the future.
- Continue to monitor adverse events reported to FDA associated with surgical mesh used to repair POP and SUI, as well as assessing any and all data as it becomes available.

Reporting Problems to the FDA:
Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with surgical mesh, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. Device manufacturers must comply with the Medical Device Reporting (MDR) regulations.

To help us learn as much as possible about the adverse events associated with surgical mesh to repair POP and SUI, please include the following information in your reports, if available:

- Manufacturer's name
- Product name (brand name)
- Catalog number
- Lot number
- Size
- Date of implant
- Date of explant (if mesh was removed)
- Details of the adverse event and medical and/or surgical interventions (if required)
- Type of procedure (e.g., anterior or posterior repair, sacral colpopexy, sling procedure for SUI)
- Surgical approach: (e.g., vaginal, abdominal, laparoscopic)
- Reason for mesh implantation: (e.g., POP of the uterus, bladder, rectum, vaginal apex or bowel, SUI)
- Specific postoperative symptoms experienced by the patient with time of onset and follow-up treatment

Contact Information:
If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

This document reflects the FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.

Additional Information

- **Urogynecologic Surgical Mesh Implants**
- **Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of**

EXHIBIT B

Transvaginal Placement for Pelvic Organ Prolapse (July 2011) (PDF - 243KB)

- **Press Release: Surgical placement of mesh to repair pelvic organ prolapse poses risks**
- **Federal Register Notice: Urogynecologic Surgical Mesh**
- **Federal Register Notice Ammendment: Urogynecologic Surgical Mesh**

Page Last Updated: 11/20/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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