IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

JOHNSON & JOHNSON'S AND ETHICON'S MEMORANDUM IN SUPPORT OF MOTION TO REVISE CASE MANAGEMENT PROCEDURES AND FOR DISCOVERY RELATED TO PLAINTIFF SOLICITATION

During the last several years, the pelvic mesh litigation has continued to aggressively grow, with nearly one half the cases in this MDL involving only products within the TVT family. This is a perplexing statistic given the facts that these devices (a) are considered the "gold standard" for treatment for stress urinary incontinence, (b) have been endorsed by almost every relevant medical society, and (c) are among the most studied medical devices on the market.

What could account for this incongruity? Johnson & Johnson and Ethicon believe it is, in part, a direct relationship between the number of filings and the inappropriate, indeed illegal, solicitation of women by unscrupulous groups and individuals, compounded by ubiquitous attorney advertising. Numerous women have contacted Johnson & Johnson and Ethicon, upset about the disclosure of their private medical information and misled into believing Johnson & Johnson disseminated that information.

Johnson & Johnson and Ethicon feel compelled to inform the Court of these activities, which include the apparent misuse of women's private health information protected by HIPAA (Health Insurance Portability and Accountability Act), and encouraging women to file baseless lawsuits. These tactics and others detailed below not only threaten the integrity of the judicial system, but also put women's health at risk by interfering with the doctor-patient relationship.

I. Introduction

The following conversation sounds like it was lifted from a legal thriller. But it is not fiction.

> **Caller:** Ma'am, yeah, we are the -- yeah, because we have the criteria here to receive this medical compensation for the bladder sling surgery and for the mesh implant surgery, and I know you never have done this surgery before, but still as a good human being what I can do, I can provide information about the bladder sling surgery and you just have to share this information only two times on the call, I send to my counselor and then after to my attorney, that's it, ma'am, apart from that you doesn't have to do anything to receive your compensation. Okay?
>
> **Female Recipient of Call [FRC]:** But I've never had a bladder sling or mesh surgery.
>
> **Caller:** I know, [FRC] you never had done this surgery, but if you are interested to receive 30 up to 40 thousand dollars, you just have to tell my compensation officer that I had a bladder sling surgery and after that I had a complication.
>
> **[FRC]**: I know, but –
>
> **Caller**: So I will tell my ---
>
> **[FRC]:** That would be lying though.
>
> **Caller:** I do understand, but you have to tell a lie if you want to get the 30 up to 40 thousand dollars --
>
> **[FRC]**: No.
>
> **Caller:** No one will give you 30, 40 thousand dollars like that. You have to tell a lie for that.
>
> **[FRC]**: Right, but that's illegal.

Caller: Can you do this?

[FRC]: No, I will not do that.

Caller: Can you?

[FRC]: That is ridiculous, that is illegal.

Caller: Okay, [FRC] bye bye.

[FRC]: So you are – I mean this is fraud.

Caller: Hello?

[FRC]: Yes.

Caller: What happened, miss, you don't want to lie for the 30 to 40 thousand dollars?

[FRC]: No, I don't want to lie. I mean I have morals. This is fraud, this is illegal so ….[1]

Women across the nation are receiving unsolicited phone calls from strangers who are seeking – or, more disturbingly, already know – their very personal medical information. These individuals, who on some occasions may call as often as 50 times a month, try to entice each woman into filing a lawsuit, oftentimes disregarding whether she has an injury or even had a mesh implant at all. In an apparent effort to legitimize their message or engender the woman's trust, some callers have gone so far as to say that they are associated with the FDA or with Johnson & Johnson.

What is happening here is wrong. And the fallout includes a compromised judicial system, exploitation of women and their federally (HIPPA) protected private health information, and undermined doctor-patient relationships. Further, the influx of potentially baseless claims hampers Johnson & Johnson's and Ethicon's ability to accurately assess the true number and value of these cases. The effectiveness of the spurious direct solicitation likely is enhanced by

[1] Exhibit 1, Affidavit A with attached emails, certified transcript, and recording.

the steady stream of attorney advertising – an estimated $45 million in just television advertising for mesh litigation in 10 months of 2014 alone. Dickerson and Asbury, "*Mesh litigation on the rise, Hellhole report says*," The West Virginia Record (Dec. 18, 2014) (Exhibit 2). In the light of this "lead generating" and unfettered mass marketing, it is little wonder that the cases in MDL 2327 alone now number nearly 24,000. http://www.wvsd.uscourts.gov/mdl2327/caseviewlist.aspx (last viewed January 9, 2014).

It also is little wonder that Johnson & Johnson's and Ethicon's goal of efficiently addressing claims is being thwarted. Nearly 1,000 MDL plaintiffs have offered no evidence they even received an Ethicon mesh device, and almost one half of all MDL plaintiffs apparently still have the device implanted and have had no revision surgery. The specter of exaggerated and possibly fraudulent claims is very real. And the objective of those persons soliciting claimants is becoming clear – to achieve a settlement based solely on the sheer number of claims without regard to their merit. When that number is potentially artificially inflated by baseless claims that can "hide out" on the Court's docket unchallenged, the legal process is badly broken.

Johnson & Johnson and Ethicon are convinced that the burgeoning docket cannot be addressed effectively until illegal solicitation calls are stopped and their impact on this MDL assessed. To that end, Johnson & Johnson and Ethicon ask that the Court order every plaintiff to provide the basic information requested in the attached discovery (Ex. 3) within a reasonable timeframe set by the Court or agreed to by the parties.

Further, Johnson & Johnson and Ethicon also ask the Court to order plaintiffs' counsel to provide certain limited information (Ex. 4) under oath and *in camera* for the Court to determine who may be profiting from the unethical and illegal direct solicitation of women and whether further investigation of others is warranted.

With the Court's help, the parties can take steps to identify claims that should be dismissed because the plaintiff cannot demonstrate she ever had an injury or even had an Ethicon pelvic mesh device implanted at all. These steps also should help to curtail the tactics that have violated women's rights, put women at risk, and jeopardized the integrity of the judicial process. Additionally, Johnson & Johnson and Ethicon will separately brief the issues of estoppel and limitations as the resolution of those defenses likewise will help with an accurate evaluation of the cases.

Notwithstanding the potential fraud that may permeate this MDL, Johnson & Johnson and Ethicon have no intention of letting this inquiry slow down the MDL process and stand prepared to move forward with discovery and resolution of individual cases. Toward that end, we suggest that the Court randomly select 200 cases involving currently marketed products for discovery and establish a schedule for work up and trial. It is important that women bringing non-fraudulent claims have an opportunity to have their claims presented in court. At the same time, production of basic information supporting the claims is required to weed out fraudulent or unmeritorious suits. Discovery and trials can proceed in parallel with the fraud inquiry.

II. Direct Solicitation is a Problem.

A. Call Centers are Breaking the Law.

> *"Numerous callers have suggested that I lie to qualify for the money. They frequently say 'wouldn't you like to have $30-40,000.' When I tell them I have never had mesh, they say 'that's ok, wouldn't you like $30,000?'"*

See Exhibit 1, Affidavit B at ¶ 8. This woman had not had surgery with mesh, but the callers somehow knew she did have an unrelated surgery. The calls to this woman are alarming by themselves, but this is not an isolated incident.

> *"The callers claimed that they had information that a lady in my family had undergone a bladder sling surgery or a mesh implant surgery. They also asked if I had undergone mesh sling surgery."*

The wife of one of Johnson & Johnson's counsel received this solicitation. *See* Exhibit 1, Affidavit C at ¶ 7. The individuals then tried to cajole her into giving them private information so that she "could receive money from a 'class action lawsuit.'" *Id*. at ¶ 8.

Another woman received harassing phone calls for more than six months. *See* Exhibit 1, Affidavit D. The callers knew her name and told her that she "could receive money from a lawsuit over vaginal mesh surgery." *Id*. at 2. Even after she told them she had never had surgery using mesh, the callers continued their attempts to entice her to join the litigation, often identifying themselves with government-sounding names like "Federal Medical Department." *Id.* at 5. One especially bold caller falsely stated that he worked for Johnson & Johnson. *Id*. at 6.

Yet another woman received more than 50 calls in less than a month. *See* Exhibit 1, Affidavit E at ¶ 3.

> *"They have been continually harassing me to either file a lawsuit about the mesh or join an already-existing lawsuit."*

Id. at ¶ 9. Again, most alarmingly, the callers already knew her personal medical information. When put on the spot to explain how they had that information, the callers said that Johnson & Johnson provided it – a blatant lie. *Id*. at ¶ 7.

The tactics are almost unbelievable – but numerous women have made surprisingly similar reports to Johnson & Johnson.[2] Johnson & Johnson's concern is how many other women have endured this invasion of privacy and been similarly harassed, but have remained silent.

[2] The majority of the information reported here was obtained when the victimized women have voluntarily called or emailed Johnson & Johnson or Ethicon to complain about receiving harassing phone calls or to protest when falsely advised that Johnson & Johnson had disseminated their personal information.

> *"Beginning around February of 2014, I began receiving unsolicited phone calls on both my landline and cellular telephones soliciting my participation in a class action lawsuit related to TVT surgery I had in 2003. The caller asked for me by name and knew I had undergone the surgery…. The caller insisted that I join the class action lawsuit."*

See Exhibit 1, Affidavit F at ¶¶ 2, 6.

Callers have claimed to be associated with the FDA and with Johnson & Johnson. *See* Exhibit 1, Affidavit G at ¶ 2. Some have sent documents with a fake FDA logo, advising that the "company is ready to pay you $25,000." *Id*. at ¶ 12.

The women who have contacted Johnson & Johnson and Ethicon are by no means alone. Members of the American Urogynecologic Society (AUGS) have seen a significant number of their patients contacted regarding mesh litigation. As Dr. Charles Nager, former AUGS President, reported in his Final Presidential Blog:

> Throughout this past year and during the annual meeting in July, AUGS members have expressed their concern for their patients who are being contacted (usually by phone) by individuals unknown to them asking them personal questions about their gynecologic surgery. **Many patients have been appalled that some person has information about a very intimate personal health matter and details about their vaginal surgery.** In many instances they have believed their physician, the physician's office, or their local hospital released privacy information about them to some third party….

http://www.augs.org/p/bl/et/blogid=16&blogaid=209 (last viewed January 9, 2015) (emphasis added) (Exhibit 5).

AUGS subsequently conducted its own survey of the members and, out of 202 responses, 92% reported they were aware of at least one patient who had been contacted and encouraged to file a lawsuit. "The majority (90%) were contacted by phone after their surgery (96%). The caller knew the patient's name and procedure-specific information." *Id.* And this captures only those patients who reported the experience to their physicians.

Due to the seriousness of these allegations, the breach of confidential medical information, the false claims to be federal employees, the risk to women's healthcare, and the threat to the legitimacy of this MDL, every MDL plaintiff should be required to demonstrate the viability of her claim **now**. This request is neither onerous nor inappropriate as it is the very type of "inquiry reasonable under the circumstances" that the federal rules require counsel to do prior to filing suit. Fed. R. Civ. P. 11. Based on the information Johnson & Johnson and Ethicon have obtained to date – with no action on their part other than to simply follow up a lead when it was presented – this improper solicitation appears to be pervasive.

B. Fraud Should Not Be Rewarded.

Solicitation of plaintiffs in pharmaceutical litigation has "spawned a now well-understood business model that rewards attorneys who can recruit the most claimants in the most limited period of time." Daniel M. Schaffzin, *Warning: Lawyer Advertising May Be Hazardous To Your Health! A Call To Fairly Balance Solicitation Of Clients In Pharmaceutical Litigation*, 8 Charleston L. Rev. 319, 330 (Winter 2013-14) (Exhibit 6). Solicitation for mass tort litigation by third parties provides "access to large batches of potential clients" which purportedly "provides leverage in settlement negotiations with the corporate defendant." http://www.businessweek.com/articles/2013-12-12/mass-tort-lawsuit-lead-generator-jesse-levine-has-victims-for-sale (last viewed January 9, 2015) (Exhibit 7). As noted by Ted Frank, then-director of the Legal Center for the Public Interest at the American Enterprise Institute, "[t]hese lawyers don't really litigate cases — they settle cases. And they need a big inventory of cases. The only job of the attorney is to come up with the clients." A. Liptak, "*Competing for Clients, and Paying by the Click*," N.Y. Times (Oct. 15, 2007)

http://www.nytimes.com/2007/10/15/us/15bar.html?_r=1& (last viewed January 9, 2015) (Exhibit 8).

But the ABA Model Rules of Professional Conduct prohibit direct telephone solicitation by attorneys, and the vast majority of states also have adopted similar rules. *See* ABA Model Rule 7.3(a); Schaffzin, 8 Charleston L. Rev. 319 at 353-56. It is clear, however, that "call centers" have been contacting women over and over, discussing their personal and federally protected medical information, and attempting to browbeat them into filing lawsuits. Even worse, some of these women are directly being encouraged to lie in order to receive a cash award even if they are not truly injured.

Johnson & Johnson and Ethicon do not suggest that any specific plaintiffs' counsel involved in this MDL is knowingly participating in this scheme. In fact, it appears that the callers on occasion may be coaching women about what to say to lawyers. Nevertheless, plaintiffs' counsel have an obligation under the federal rules to make a preliminary inquiry – before filing suit – into whether there is evidence to support the claims being made. The pecuniary gain for lining up more lawsuits is more money when those cases are resolved, most likely through settlement, because most mass tort settlements are based on a "per capita" calculation with no real testing of the validity of the vast majority of the claims. But "[f]ew problems are more disruptive to the efficient negotiation and operation of comprehensive mass tort settlements than oversubscription, which at times, appears to be fueled primarily by specious claims. … [P]ayment of specious claims is merely another cost of settlement and the 'bad apples' who submit them clearly recognize that it will cost … more to uncover than it will to simply pay the claims." Brown, Todd, "*Specious Claims and Global Settlements*," 42 U. Mem. L. Rev. 559, 560-61 (Spring 2012) (Exhibit 9).

The evidence of fraud makes uncovering any specious claims now a requirement. Regardless of who the perpetrators of the fraud are, this practice is unlawful and unethical, and threatens the integrity of the judicial system generally and this MDL specifically. It must be stopped and those responsible for illegal direct solicitation must be held accountable.

These activities extend beyond the parties to any one case and are a fraud on the Court, constituting a "corruption of the judicial process itself." *See Cleveland Demolition Co. v. Azcon Scrap Corp*., 827 F.2d 984, 986 (4th Cir. 1986). Any attempt by Johnson & Johnson and Ethicon to number and value the cases accurately is futile without some mechanism to separate potentially legitimate claims from illegitimate ones now. And without answers by plaintiffs and their counsel, stopping the perpetrators remains a prohibitively challenging task.

III. Indirect Solicitation Likely Compounds the Problem.

Johnson & Johnson and Ethicon do not question the right of plaintiff lawyers to advertise for potential clients within the bounds of governing rules of ethics. But, in an environment such as this one, potentially riddled with fraud, the effect of blanketing the airwaves with calls to litigate cannot be viewed in a vacuum. For the past several years, the American public has been bombarded with hyperbolic advertising and other forms of indirect solicitation relating to transvaginal mesh lawsuits. For instance, one Facebook advertisement masquerading as a news source recently indicated that the "latest settlement" of transvaginal cases was $18.5 Million and, in "BREAKING NEWS," reported that Your Honor "has urged manufacturers to settle the cases to avoid billions in jury-awarded damages."

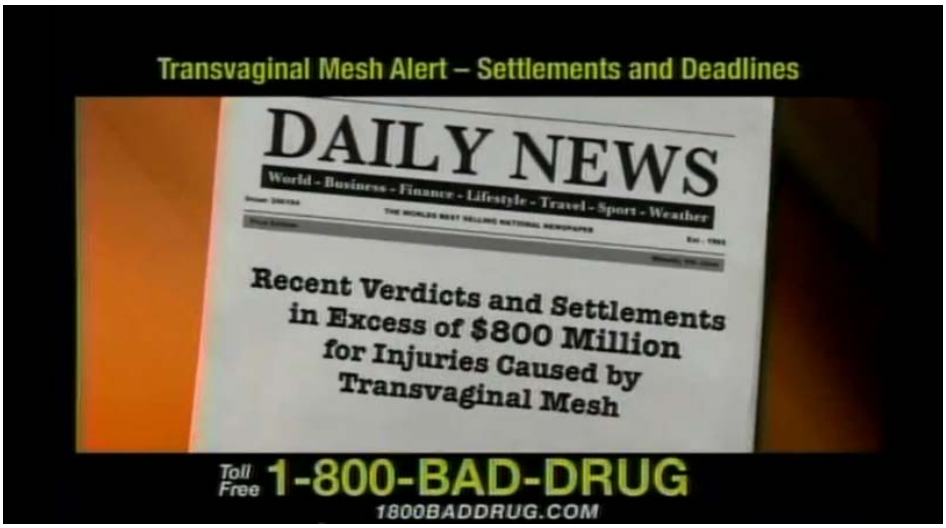
Vaginal mesh products were in the top three products targeted in plaintiff attorney advertising for eleven consecutive months in 2013 and 2014. The Silverstein Group, *Relentless advertising suggest no end in sight for pelvic mesh litigation*, April 28, 2014, http://www.silversteingroup.net/mass-tort-ad-watch-blog/archives/04-2014 (last viewed January 9, 2015) (Exhibit 10).

Advertising spending has increased dramatically in the last year. In March 2014, the spend was $2 million. *Id.* According to a recent report, "[t]he trial bar spent more than $2.5 million on mesh litigation advertising in April, $5.5 million in May, nearly $7.9 million in June and $8.2 million in July." Dickerson and Asbury, "*Mesh litigation on the rise, Hellhole report says*," The West Virginia Record (Dec. 18, 2014) (Exhibit 2). In a single month, plaintiff lawyers paid to air 8,000 television ads. *Id.* And there appears to be no end in sight. The December 2014 Mass Tort Advertising Report by the Silverstein Group noted that pelvic mesh advertising spending increased by 27% from October to November. (Exhibit 11). The result is that the size of the federal mesh litigation has surpassed all other mass torts except asbestos. http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-September-15-2014.pdf. This magnitude of advertising has potentially provoked the number of questionable lawsuits.

This enormous docket, however, reflects neither the viability of the claims nor the current medical knowledge regarding the safety of the products. Midurethral slings have been extensively studied - the subject of more than 2,000 published articles - and have been endorsed as a safe and effective treatment for stress urinary incontinence by the American Urological Society, the American Urogynecologic Society, the American College of Obstetricians and Gynecologists, the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, the European Association of Urology, and the National Institute for Health and Care Excellence. More than three million midurethral slings have been used worldwide, and the procedure is used by more than 99 percent of polled members of the American Urogynecologic Society. AUGS, *Frequently Asked Questions by Providers* (March 2014) (Exhibit 12); *Position*

Statement on Mesh Midurethral Slings for Stress Urinary Incontinence (Jan. 3, 2014) (http://www.augs.org/p/cm/ld/fid=599) (last viewed January 9, 2015) (Exhibit 13).

The ubiquitous lawyer advertisements, however, have pummeled viewers with repeated labeling of these products as "defective" or a "bad drug," causing some women to seek unnecessary medical treatment.



Not only has this unfettered advertising potentially originated some number of questionable lawsuits, as noted above, but the "[s]ensational news coverage and ads by law firms

have spread fear among women about vaginal mesh."[3] *The Truth About Vaginal Mesh*, health.clevelandclinic.org/ 2013/06/the-truth-about-vaginal-mesh/ (Exhibit 14). "Women need to know that they can't believe everything they hear on the news." *Id.* The Cleveland Clinic is not the only voice echoing this sentiment.

Layer the evidence of fraudulent direct solicitation on top of the tremendous outlay of advertising that touts the award of hundreds of millions – or billions – of dollars, and the propensity of these activities to encourage (even unintentionally) unmeritorious or fraudulent claims is clear.

IV. We Can and Should Take Steps to Begin to Fix the Problem.

The Court has expressed its interest in the resolution of these claims. Plaintiffs certainly are interested. And Johnson & Johnson and Ethicon would like to be in a position to properly evaluate the claims. On the other hand, everyone involved in the litigation should have genuine concerns about the legitimacy of these cases because the evidence that women have been solicited to file fraudulent claims taints the entire MDL.

A. The Court Can and Should Take Proactive Steps to Bring Back Balance.

One professor who analyzed mass torts wrote, "If you build a super-highway, there will be a traffic jam." McGovern, Francis, "*An Analysis of Mass Torts for Judges*," 73 Tex. L.Rev. 1821, 1840 (1995) (Exhibit 15). In this instance, though, the persons who may be helping to create the congestion appear to be doing so illegally. Johnson & Johnson and Ethicon are not quibbling about the steps taken to manage this litigation or attempting to delay the proceedings.

[3] The advertising also appears to have spawned a telephone scam operation. These scammers represent themselves as employees of the FDA and/or Johnson & Johnson and ask that money be sent via Green Dot Moneypak in exchange for receipt of a $25,000 settlement. *See* Exhibit 1, Affidavit G. According to the affiant in Affidavit G, the caller also claimed an association with a particular lawyer. *Id*. at ¶ 3.

As in all litigated cases, the parties have an obvious disagreement over the merits of the plaintiffs' claims. Johnson & Johnson and Ethicon maintain that their pelvic mesh products are safe and effective. Plaintiffs assert they are not. But the obstacle to meaningful resolution faced by the parties in this MDL goes far beyond a difference of opinion about the adequacy of the warnings or the designs of the products. Evidence of outright fraud is blocking the way forward.

The only way to advance the MDL other than trying every case is by evaluating them to separate the non-fraudulent from the fraudulent cases and to identify and dispense with those otherwise legally unmeritorious cases. Plaintiffs with non-fraudulent claims are entitled to their day in court. In order to help effectuate that goal, Johnson & Johnson and Ethicon proposed mechanisms last year to cull the docket. The dramatically different landscape now underscores the need to implement such procedures. The number of cases in the Ethicon MDL is nearly 24,000. All mesh MDLs together have over 70,000 cases. Plaintiffs' counsel have ratcheted up their advertising spend – quadrupled it, in fact. And we have significant evidence of overt fraud.

Couple that with the percentage of plaintiffs who have chosen to dismiss their claims when faced with individual discovery and the requirement to participate in the litigation, and the need for relief cannot be overstated. For example, in this MDL only 40 plaintiffs have been chosen for individual discovery. Of those, twenty percent (8) chose to dismiss their claims rather than proceed through discovery or have their cases set for trial.[4]

[4] Five plaintiffs of the original 30 selected for the Discovery Pool dismissed their claims rather than be deposed or engage in other case-specific discovery. One of the five Prolift discovery cases selected by Johnson & Johnson and Ethicon dismissed with prejudice rather than go through discovery. One of the TVT bellwether plaintiffs nominated by the defense dismissed once she was selected as the "back up" case for trial. And the "back up" Prolift trial plaintiff, also a defense nominee, likewise voluntarily dismissed.

Fortunately, a federal district court has broad power to manage litigation, especially complex litigation, for the purpose of affording the parties a "just, speedy, and inexpensive" disposition of the action. *See* Fed. R. Civ. P. 1, 16, 26, 37, 42, 53 and 83; *see generally* Manual for Complex Litigation, Fourth §§ 10.1, 11, 20, 22, and 23. Among other things, the Court has the inherent authority and duty to identify, define, and resolve issues. *See, e.g.*, Fed. R. Civ. P. 16(c)(2) (authorizing "special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems").

B. There are Blatant Deficiencies in Proof.

Some of the issues that need immediate resolution are blatant deficiencies in the basic information necessary to support filing a claim. Despite the fact that this MDL has been pending for over three years, almost 1,500 plaintiffs have not produced *any* medical records to date – not even a product code sticker. That number includes roughly 900 plaintiffs who claim an injury from an Ethicon device,[5] but have yet to provide *any* evidence they were in fact implanted with an Ethicon medical device. Additionally, based upon the information provided by plaintiffs about their claims, nearly 50% of plaintiffs have had no surgical revision and thus still have the product, intact – some for more than 10 years. These statistics are troubling, especially when viewed through the prism of skepticism created by the "encouragement" to pursue money for injuries one has not experienced or for a device one never had implanted.

C. Prove Implantation with Ethicon Device

The most basic piece of evidence that every plaintiff ought to have prior to filing suit (except in an exceptional case) is proof that she has been implanted with an Ethicon pelvic mesh

[5] More than 400 plaintiffs in the Ethicon MDL have failed to specify with which device they were implanted.

device. To that end, we ask the Court to implement new case management procedures to require each plaintiff to provide the complete surgical operative report for the implantation of the Ethicon device within a reasonable timeframe as set by the Court. In addition, if the operative report does not include the product identifier code showing the particular Ethicon device implanted, the plaintiff must also provide the specific medical record or hospital invoice that does contain the product code. Any plaintiff who joins this MDL after the date of the Order should provide the same records within a reasonable number of days of being assigned an MDL case number. This is not an additional burden that Johnson & Johnson and Ethicon are seeking to place on plaintiffs or their counsel, but instead is the "evidentiary support" that should have been in hand before filing their lawsuit. The Court should dismiss with prejudice every plaintiff who fails to timely comply.

D. Prove Compensable Injury

Another area where information has been woefully lacking, but that plaintiffs' counsel should have reviewed before filing suit, is evidence of a compensable injury. If more than 10,000 plaintiffs have had no surgical revision, as is indicated by Ethicon's data, then it may well be that a substantial number of MDL participants may not be able to prove an injury at all. As an initial matter, we ask the Court to require every plaintiff to provide within a reasonable timeframe all physician office notes addressing the indications for the implant, going back at least 1 year prior to the surgery, and physician notes one year following the implant, as well as all medical records reflecting any complaint to a physician of the injuries allegedly caused by the device, including but not limited to records evidencing excision, revision or explant of the mesh product (either in a physician's office or under regional or general anesthesia).

This is not an additional burden on plaintiffs. Indeed, Pretrial Order #17 already requires each plaintiff to produce the medical records in their possession. This basic evidence will enable the Court and the parties to identify those cases that should properly be dismissed, allowing potentially legitimate claims to be reviewed in a more expedient manner. Additionally, it will help the parties to become more informed concerning the best cases to move forward for complete discovery and for trial. Dismissal with prejudice should quickly follow all failures to timely comply and provide proof of a compensable injury.

E. Some Suits Appear Presumptively Barred by Limitations or by Estoppel.

In a further effort to expedite the consideration of potentially valid claims, the Court could consider implementing certain tools to evaluate quickly limitations and estoppel defenses. Relying almost exclusively upon information in the PPFs, Johnson & Johnson and Ethicon believe as many as half the pending claims may be time-barred. Additionally, while more than 6,000 plaintiffs indicated on the PPF that they have filed for bankruptcy protection, most provided little or no information beyond that affirmative response and may lack standing to pursue the claims. Johnson & Johnson and Ethicon will separately brief these issues and provide suggestions to the Court for determining the application of these defenses in a fair and efficient manner.

V. The Court Should Order Responses to Discovery.

Johnson & Johnson and Ethicon became aware of the direct solicitation of potential plaintiffs only because individual women receiving the calls contacted them. Their ability to investigate these solicitations is quite limited. Discovery from plaintiffs and counsel in this litigation is necessary to further develop facts that might allow the Court or the appropriate investigating agencies to uncover the identities of those involved and, most importantly, put a

stop to it. Johnson & Johnson and Ethicon have a substantial interest in stopping these unlawful solicitations because some callers are falsely claiming to work for Johnson & Johnson or misrepresenting that Johnson & Johnson released confidential information about women who received their devices. Some callers also on occasion appear to be misrepresenting a connection to plaintiff lawyers and law firms. Thus, all parties and the Court should be concerned about the potential harm to individual reputations and to the entire judicial process.

Plaintiffs may have information identifying the company that contacted them or intake sheets or other documents from those call centers. Counsel may have intake questionnaires or other documents that could help identify the offenders at these call centers. That information should be produced.

Because this fraud needs to be investigated, the Court should order all plaintiffs with a case pending on the date of the Order to respond to the basic discovery attached as Exhibit 3 within a reasonable timeframe to be set by the Court. The Court likewise should order all counsel of record (and all lawyers or law firms who otherwise have an interest in the resolution of these cases) to respond under oath and *in camera* to the few questions and document requests attached as Exhibit 4. Each plaintiff who files a new case directly in this MDL or whose case is transferred should respond to the same discovery. Similarly, any attorney who did not represent a plaintiff in a suit pending on the date of the Order but who later files a case in the MDL or has a case transferred to the MDL should likewise provide the necessary information within a reasonable number of days of joining the MDL.

The way forward likely cannot be established without the requested information. The abuses occurring here threaten to undermine both the perception and the reality of our legal system. More importantly, left unchecked, these tactics eventually will jeopardize our healthcare

system and the availability of products that patients need. If the Court desires additional study before addressing these matters, then Johnson & Johnson and Ethicon alternatively request a referral to Magistrate Judge Eifert to study and fashion a plan to address the early identification and dismissal of baseless claims as well as the investigation of improper or illegal solicitation.

VI. Set 200 TVT or TVT-O Cases for Discovery

Even if the Court does not implement new case management procedures or allow discovery directed to solicitation and fraudulent claims, Johnson & Johnson and Ethicon want to move this litigation forward and are prepared to do so. Nearly half of the cases pending in MDL 2327 involve only the TVT or TVT-O devices. Johnson & Johnson and Ethicon propose the Court randomly select 200 TVT and/or TVT-O cases where the plaintiff has submitted a substantially complete Plaintiff Profile Form (PPF) with medical records and authorizations, a requirement already found in PTO #17, and allow case-specific discovery of those claims. Defendants and Plaintiffs' Liaison Counsel can meet and confer and submit a proposed agreed docket control order governing the 200 cases selected by the Court and/or submit to the Court unresolved issues related to the conduct and timing of discovery. The cases could be selected and a docket control order entered in less than two months.

VII. Conclusion

The parties and the Court can no longer ignore the mounting evidence that fraud is being perpetrated in the pelvic mesh litigation. The effects of the fraud are potentially far-reaching and violate women's rights. If left unchecked, it could alter not just the integrity of this litigation, but the legal and healthcare systems, too. The judicial process becomes a mockery if plaintiffs without valid claims are harassed into filing baseless suits and allowed to flood the system, with the weight of their numbers then used as a hammer to force settlement without ever having to

demonstrate the merit of their claims. The Supreme Court presciently captured this situation when it noted that uninjured claimants get a "free ride" where the tort system encourages the "parasitic fusion of strong and weak cases." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 628-29 (1999).

Respectfully submitted,

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AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I certify that on January 14, 2015, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)