BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: POWER MORCELLATOR LITIGATION	)))	MDL No. 2652

GYRUS ACMI, LP AND GYRUS ACMI, LLC'S RESPONSE TO MOTION OF CERTAIN PLAINTIFFS FOR TRANSFER OF ACTIONS TO THE U.S. DISTRICT COURT FOR THE DISTRICT OF KANSAS, PURSUANT TO 28 U.S.C. § 1407, AND JPML RULE 7.2, FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

Gyrus ACMI, LP and Gyrus ACMI, LLC (collectively "Gyrus"), defendants in the matter of *Lisa Nielsen and Kurt Nielsen v. Gyrus ACMI, LP and Gyrus ACMI, LLC*, Case No. 2:14-cv-02375-GEB-DAD in the U.S. District Court for the Eastern District of California, file this response to certain plaintiffs' motion to establish a multidistrict litigation ("MDL") for several matters, including *Nielsen*, respectfully showing the Judicial Panel as follows:

INTRODUCTION

Plaintiffs seek to create an MDL for 22 cases – although there are now (or soon will be) only 20 such cases -- alleging "the use of a Power Morcellator device" during a hysterectomy or similar procedure spread cancerous cells from the uterus elsewhere in the body, worsening plaintiffs' hopes for recovery. Plaintiffs describe the morcellator device as "electronically powered medical tools with spinning blades that shred, grind, and core tissue into smaller pieces or fragments" that "can disperse cellular particles from the shredded tissue throughout the abdomen during surgery." Even though morcellators are made by a half-dozen different defendants, plaintiffs suggest the products are so similar discovery can easily be consolidated.

Plaintiffs are wrong, at least as to Gyrus. The Gyrus PlasmaSORD morcellator at issue in *Nielsen* does not contain "spinning blades" that shred and scatter tissue. Instead, Gyrus's product is a single-use device that uses superheated plasma energy to cut apart and cauterize uterine tissue. Indeed, the device is promoted as "The First Completely Bladeless SORD" (solid organ removal device), designed to reduce the number of tissue fragments remaining after the procedure. Because of this fundamental difference, evidence that a typical bladed morcellator could cause plaintiffs' claimed injuries would not implicate a plasma morcellator at all. Of the 20 cases at issue here, *Nielsen* is the only one to involve a plasma rather than a bladed morcellator.

Because the PlasmaSORD has little in common with a bladed morcellator, *Nielsen* is unlikely to have sufficient factual commonality with other morcellator cases. Design, warnings, causation, and notice evidence applicable to bladed morcellators will not apply to the Gyrus PlasmaSORD, which means the expert and fact discovery conducted in the MDL, should this Panel approve the transfer, will be largely irrelevant to *Nielsen*, while the same discovery in *Nielsen* will not be germane to the larger group of cases. Instead of promoting efficiency, transfer of *Nielsen* to an MDL will require the parties (and perhaps the transferee court) to duplicate efforts, not streamline them.

With only 20 cases and a large number of different defendants, Gyrus does not believe an MDL would be useful or warranted in any event. But even if one is established for bladed morcellators, Gyrus lacks the commonality plaintiffs contend exists between those other cases. Regardless of this Panel's ultimate decision on plaintiffs' motion, Gyrus respectfully requests the *Nielsen* case remain where it is, so the parties can focus on the unique fact questions it raises.

ARGUMENT AND CITATION TO AUTHORITY

A. THIS PANEL MUST CONSIDER WHETHER INCLUDING *NIELSEN* IN AN MDL WOULD BE EFFICIENT BASED ON COMMON ISSUES.

Cases pending in federal court with "one or more common questions of fact" can be transferred to an MDL if transfer "will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). These questions must be considered individually for each case being considered for transfer. *See In re: DePuy Orthopaedics, Inc., ASR Hip Implant Prods. Liab. Litg.,* 753 F. Supp. 2d 1378, 1379-80 (J.P.M.L. 2010) ("[W]e find that *seven of these eight* actions involve common questions of fact, and … will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation.") (emphasis added).

Thus, the goals of this Panel as to the *Nielsen* case are to determine (a) if there are common fact questions between *Nielsen* and the other cases at issue; (b) if consolidating *Nielsen*'s discovery and pretrial activities with the other cases would be more convenient for those involved in all 20 actions; and (c) if consolidation with *Nielsen* will be more efficient than allowing it to proceed independently in its home district. Regardless of whether there are some or even several common facts, transfer should be denied where "the inherent disadvantages" do not "outweigh the benefits" of a transfer. *In re G.D. Searle & Co. "Copper 7" IUD Prods. Liab. Litig.*, 483 F. Supp. 1343, 1345 (J.P.M.L. 1980).

B. THERE ARE FEW, IF ANY, COMMON FACT QUESTIONS BETWEEN *NIELSEN* AND THE BLADED MORCELLATOR CASES.

1. Traditional morcellators have spinning metal blades.

Plaintiffs' motion and brief in support describe the "substantial overlap of factual issues" they claim undergird their request for transfer into an MDL. (Pls' Brief at 7.) All

power morcellators, they contend, "are electronically powered medical tools **with spinning blades** that shred, grind, and core tissue into smaller pieces or fragments so the tissue can be removed through small incisions or extraction 'ports' in the abdomen." (*Id.* at 3 (emphasis added).) "The morcellator's **spinning blade** shreds the tissue masses at a high velocity and can disperse cellular particles from the shredded tissue throughout the abdomen during surgery." (*Id.* (emphasis added).)

2. <u>The *Nielsen* morcellator uses superheated plasma, not blades.</u>

None of this, however, describes the PlasmaSORD morcellator at issue in the *Nielsen* matter. That device has no "spinning blades," or even blades of any kind. Instead, the PlasmaSORD uses energized plasma – in effect, superheating gas around the tip of the morcellator to cut, coagulate, and incinerate unwanted tissue. This is a key feature of the PlasmaSORD: on its web page (reproduced in part below), the product is described as "The first bladeless SORD" and notes as its top benefit that it morcellates tissue without "sharp, spinning blades."

(Ex. A, http://acmicorp.com/acmi/user/display.cfm?display=product&pid=9854&catid=-60&maincat=Gynecology&catname=PK™%20Technology%20Laparoscopic%20Devices.) Unlike many bladed morcellators, the PlasmaSORD is used once and then discarded.

This is not a meaningless distinction, because the superheated plasma involved in the PlasmaSORD does not act the same way as do the blades of a traditional power morcellator. A bladed morcellator spins and whirs, allegedly stirring up tissue fragments as it cuts (envision the way a gardener's edger scatters bits of grass). Plaintiffs' claims hinge on the theory that those dispersed bits of tissue allegedly spread throughout the abdomen, distributing any malignancies (including cancerous cells) they contain. (Pls' Brief at 3-4.) The PlasmaSORD, however, contains no spinning parts, and the tissue it

contacts is burned away, with the edges of the surrounding tissue cauterized from the searing heat. Gyrus even promotes the product with the claim that it "leaves fewer tissue fragments to clean up." (Ex. A.)

3. The PlasmaSORD is operated differently from bladed morcellators.

There are other differences between the products. Bladed morcellators contain graspers that pull the tissue toward the blade so it can be cut; while the PlasmaSORD has a grasper, it is used only to collect and remove severed tissue. (Ex. B, Instructions for Use, at 8.) Bladed morcellators can be used with a tissue collection bag – indeed, whether the use of these bags can prevent the very injuries plaintiffs allege is a key question in the 19 bladed morcellator cases. But collection bags *cannot* be used with the PlasmaSORD and are contraindicated in the instructions for use. (*Id.* at 7.)

4. Causation evidence as to bladed morcellators has no bearing on whether a plasma morcellator can cause plaintiffs' injuries.

The *Nielsen* plaintiffs no doubt contend that despite this difference, a PlasmaSORD can spread cancerous cells in much the same way as bladed morcellators do, and that issue will be litigated thoroughly. Regardless of its validity, however, the evidence for either position will be very different from that presented in a traditional morcellator case. Both sides will need to rely on experts with specialized knowledge about the mechanics and use of plasma medical devices (a much smaller share of the market) who will offer causation opinions focusing on these devices in particular. The bases for those opinions will be unique to *Nielsen*, as none of the studies relied upon by the U.S. Food and Drug Administration ("FDA") in evaluating the safety of morcellators considered plasma morcellation events.

In short, discovery regarding whether a bladed morcellator can spread cancer has no bearing on whether a plasma morcellator can, and thus is not relevant to a claim involving the use of a plasma morcellator. Indeed, the FDA itself has noted this potential difference, directing an expert panel to explore "whether the mode of morcellation, i.e., electromechanical versus radiofrequency … [may] increase tissue fragmentation and dissemination into the peritoneal cavity." FDA, *Executive Summary: Laparoscopic Power Morcellation* (July 2014) at 5-6, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM404148.pdf.

C. INCLUDING AN INCOMPATIBLE CASE LIKE *NIELSEN* WOULD MAKE LITIGATION LESS EFFICIENT, NOT MORE.

Because the relevant facts in *Nielsen* will have little if any overlap with those in the bladed morcellator cases, consolidation with the other cases in Kansas or elsewhere will only make litigation less efficient, not more. Instead of reducing costs, travel, and effort for the parties, witnesses, and counsel involved in *Nielsen* – as well as those in the other cases – it will only add to the burden, for the following reasons:

- The two defendants in *Nielsen* are not named in any of the other cases, so no discovery conducted by or from them will be relevant to any other matter. And the actual manufacturer of the PlasmaSORD morcellator is located in Wales, an expensive and inconvenient location. The ultimate corporate parent is in Japan, an even more inconvenient and expensive place.
- Because the PlasmaSORD is fundamentally different from the bladed morcellators involved in the other matters, design, manufacturing, and warnings

evidence collected from Gyrus will likely have no impact on the remaining cases. There is little discovery in *Nielsen* that will be duplicative of that in the other matters. *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 844 F. Supp. 1553, 1554 (J.P.M.L. 1994).

- Similarly, the fundamental differences between the PlasmaSORD and bladed morcellators mean that experts opining on ostensibly common issues like causation and alternative design cannot be shared.
- Regardless of whether morcellators are bladed or use plasma, they are complicated, cutting-edge medical devices requiring state-of-the-art engineering and manufacturing techniques and subject to a complex regulatory scheme. Requiring counsel and experts to gain proficiency and facility in the design, manufacture, and use of just *one* of these devices is time-consuming: two is doubly so – especially where one type of device has no relevance to the issues in their case.
- Once discovery is complete, the Court will have to contend with numerous additional motions: *Daubert* challenges to added experts, dispositive motions related to unique design issues, and so on – all because the products are so different.
- Because the issues – and the evidence and experts involved – will be different in *Nielsen* from the other cases, there is no risk of inconsistent rulings, if the cases remain unconsolidated. *In re TMJ Implants*, 844 F. Supp. at 1554.

Even if counsel for the parties limit their attendance and participation only to discovery and motion practice relevant to them – that is, if *Nielsen* counsel only travels to

depositions involving plasma morcellators and do not focus on documents and discovery responses related to bladed devices, a forced consolidation with the 21 other cases still imposes costs in money and time, even in cursory document and transcript review. Simply put, there are no efficiencies to be gained, and only extra burdens to shoulder, should *Nielsen* be included in an MDL.

D. THERE ARE NO CONVENIENCES TO BE GAINED BY INCLUDING NIELSEN IN AN MDL.

For the reasons stated above, including *Nielsen* in an MDL will not make litigation more convenient for any party. Plaintiffs' motion does not actually argue consolidation will be more convenient for counsel, parties, or the Court, instead only suggesting an MDL will not make litigation any *less* convenient. Even accepting as true plaintiffs' statements about the number of flights to Kansas City and the availability of hotel rooms near the courthouse, none of that will make litigation more convenient for counsel in California and Georgia or defendants in Minnesota and Massachusetts. At best, it only alleviates the *in*convenience inclusion into an MDL will undoubtedly cause.

An MDL is intended to make litigation more efficient and convenient by allowing counsel to "combine their forces and apportion the workload." *In re Baldwin-United Corp. Litig.*, 581 F. Supp. 739, 740-41 (J.P.M.L. 1984). But that is only possible where the issues applicable to many are applicable to all. Because the product in *Nielsen* is fundamentally different from those in the other cases, *Nielsen* counsel cannot simply designate another party to represent it at depositions or conduct discovery on their behalf, because the information sought is not the same and the parties' interests may not align. Including *Nielsen* in an MDL will only add to its counsel's burden while offering absolutely no relief.

E. EVEN DISCOUNTING THE DIFFERENCES BETWEEN *NIELSEN* AND THE OTHER CASES, AN MDL IS NOT WARRANTED HERE.

The discussion above explained why the *Nielsen* case, with its wholly different product, should not be included in an MDL with the 21 other morcellator cases. In fact, this Panel should not create an MDL at all, for several reasons[1]:

- This litigation is too small for an MDL. Even if *Nielsen* were included, there are only 20 cases at issue – and no promise that number will grow much larger. Indeed, it is unlikely many more claims will surface, as it has been more than 14 months since the FDA issued its safety communication about the potential link between morcellators and cancer. The number of cases here is far smaller than in many prior medical device MDLs. *See, e.g., In re TMJ Implants*, 844 F. Supp. 1553 (involving 173 cases); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 793 F. Supp. 1098 (J.P.M.L. 1992) (78 cases); *In re A. H. Robins Co. "Dalkon Shield" IUD Prods. Liab. Litig.*, 406 F. Supp. 540 (J.P.M.L. 1975) (57 cases).
- This litigation involves multiple defendants. There are at least six independent defendants in these actions, all of whom will be required to provide separate discovery responses and witnesses and each of whom will have individualized defenses about causation, notice, and other key issues. The duplicative discovery avoided when several claims are asserted against a single defendant (or set of defendants), as in *In re DePuy,* 753 F. Supp. 2d at 1379, cannot be prevented here. Even plaintiffs' motion noted that an MDL is appropriate only when the cases "raise similar questions regarding ***a Defendant's*** development, design, and

[1] In support of its position no MDL is warranted here regardless of whether *Nielsen* is included, Gyrus joins in the arguments raised in the briefs its fellow defendants have filed opposing transfer under Section 1407.

testing of a particular prescription medication or device." (Pls' Mot. at 8 (emphasis added).) For this reason, the J.P.M.L. is "typically hesitant to centralize litigation against multiple, competing defendants," *In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350, 1351 (J.P.M.L. 2012). The record bears this out: Of the seven cases plaintiffs cited in support of this proposition, only one involved more than two separate manufacturers, and that case concerned silicone breast implants, with plaintiffs who sued all manufacturers because they could not identify their particular product. *In re Silicone Gel Breast Implants*, 793 F. Supp. 1098.

- Plaintiffs' plan is not efficient or convenient. Because the cases involve a number of different defendants, there is little convenience to be gained by consolidating them. As noted above, the defendants in *Nielsen* are located in Massachusetts and Minnesota, with the device manufactured in Wales and the corporate parent in Japan. Other defendants likewise manufacture morcellators in Europe and have domestic locations all over the United States. Counsel for these defendants already must travel to the district court in which their case is pending, the residence of the plaintiffs, and the location of the surgery at issue – adding parties through consolidation only increases the burden.

CONCLUSION

The PlasmaSORD plasma morcellator in *Nielsen* is fundamentally different from the bladed morcellators involved in the other cases, and the *Nielsen* defendants do not appear in any other case. Consolidating *Nielsen* with the other matters in an MDL would only make litigation less efficient, forcing the parties to contend with discovery and

motions that have nothing to do with their respective cases. An MDL is unwarranted here; but even if one is formed, the *Nielsen* matter has no place in it.

Respectfully submitted, this 10th day of July, 2015.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on July 10, 2015, I served the foregoing on all parties of record by filing via the CM/ECF system of the Judicial Panel on Multidistrict Litigation.

/s/ Michael Weiss

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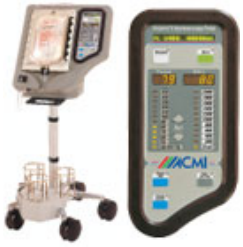

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