

# BUTLER | SNOW

June 4, 2012

VIA EMAIL

Kate Fife (kate\_fife@wvsc.uscourts.gov)

The Honorable Joseph R. Goodwin, Chief Judge  
United States District Court  
Southern District of West Virginia  
7009 Robert C. Byrd United States Courthouse  
300 Virginia Street East  
Charleston, West Virginia 25301

The Honorable Mary E. Stanley, Magistrate Judge  
United States District Court  
Southern District of West Virginia  
7009 Robert C. Byrd United States Courthouse  
300 Virginia Street East  
Charleston, West Virginia 25301

Re: *In re: Ethicon, Inc. Pelvic Repair System Products Liability Litigation*  
MDL No. 2327

Dear Judge Goodwin/Judge Stanley:

The purpose of this letter is to notify the Court that Ethicon has advised FDA that it will stop commercializing the GYNECARE TVT SECUR™ system, GYNECARE PROSIMA™ Pelvic Floor Repair System, GYNECARE PROLIFT™ Pelvic Floor Repair System, and GYNECARE PROLIFT+M™ Pelvic Floor Repair System in the United States.

Ethicon has no present intention to commercialize these products in the future, but it has requested that FDA allow it 120 days to cease commercialization. This time period would permit Ethicon to notify its customers, and provide those hospitals and surgeons with sufficient time to select alternative treatment options for their patients. Ethicon will also discontinue or revise, as appropriate, all marketing materials during this time. Ethicon will continue to report adverse events and provide medical communications for these products, consistent with applicable regulations; however, Ethicon has requested that FDA's Office of Surveillance and Biometrics place the existing 522 orders requiring additional studies for these products on hold. Ethicon is awaiting written confirmation of that plan.

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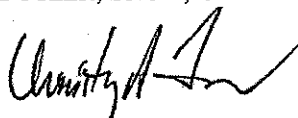
Ethicon also plans to update the product labeling for GYNECARE GYNEMESH® PS, including the Indication for Use, to restrict the indication for use to the abdominal sacrocolpopexy procedure for the treatment of pelvic organ prolapse. In order to allow customers continued access to this product for patient treatment, Ethicon has requested that it be allowed to continue the sale of GYNECARE GYNEMESH® PS using the current Instructions for Use until FDA responds to this proposed plan.

Although FDA has not yet responded to these proposals, we thought it appropriate to advise the Court and counsel of these decisions. In light of the Public Health Notifications previously issued by FDA, the publicity surrounding the FDA Advisory Committee Meeting last year, and the pending litigation before this Court and New Jersey, we anticipate that there may be publicity about these decisions. By copy of this letter, we are simultaneously advising Lead Plaintiffs' Counsel as well as Liaison Counsel of these decisions.

As always, we very much appreciate your time and consideration in this litigation. We will be happy to answer any questions or furnish any additional information that you may require, and we will be prepared to discuss these issues at the next conference in July.

Respectfully yours,

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC



Christy D. Jones

CDJ/lhd

Enclosures

cc: Bryan F. Aylstock  
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