

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS,	§	
INC. PINNACLE HIP IMPLANT	§	MDL Docket No.
PRODUCTS LIABILITY	§	
LITIGATION	§	3:11-MD-2244-K
	§	
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This Document Relates to all Cases	§	
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ORDER REGARDING DEPUY'S POST-MARKET SURVEILLANCE STUDY

The Court is advised by Defendant DePuy Orthopaedics, Inc. ("DePuy") that the United States Food and Drug Administration (the "FDA") has recently approved an explant study protocol to be conducted pursuant to Section 522 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 3601 *et seq.*, as part of the post-market surveillance study of the Pinnacle-brand product which is the subject matter of this litigation.

On August 9, 2012, this Court conducted a status conference where counsel for DePuy and counsel for Plaintiffs were instructed to confer, with the assistance of the Special Master, in an attempt to reach agreement on one letter DePuy can use in conjunction with the FDA-mandated Section 522 explant study to inform hospitals and surgeons who perform revision surgeries on patients with Pinnacle-brand products the importance of their cooperating to preserve the explanted devices. The Court has learned that, to date, the parties have been unable to reach agreement on the contents of the communication DePuy will send to the hospitals and surgeons.

IT IS THEREFORE ORDERED that the parties continue to confer, with the assistance of the Special Master, in an attempt to reach agreement on the contents of DePuy's correspondence with the hospitals and surgeons;

IT IS FURTHER ORDERED that Defendant DePuy Orthopaedics, Inc. must provide its list of hospitals and surgeons who will receive notification of the Section 522 post-market surveillance study to the Court by delivery to the Special Master within 20 days of this Order. The list provided by DePuy shall be reviewed by the Court *in camera* and shall not be disclosed to any party or its counsel; and,

IT IS FURTHER ORDERED that Defendant DePuy Orthopaedics, Inc. is prohibited from sending its proposed notification of the Section 522 post-market surveillance study to its list of hospitals and surgeons pending further Order from the Court.

SO ORDERED.

Signed August 27, 2012.



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UNITED STATES DISTRICT JUDGE