

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

In Re: COOK MEDICAL, INC., IVC FILTERS
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

Case No. 1:14-ml-2570-RLY-TAB
MDL No. 2570

This Document Relates to ALL ACTIONS

CASE MANAGEMENT ORDER #7

**(AGREED QUALIFIED PROTECTIVE ORDER REGARDING
PROTECTED HEALTH INFORMATION)**

This Order shall govern (1) all cases transferred to this court by the Judicial Panel on Multidistrict Litigation, including those cases identified in the original Transfer Order and those subsequently transferred as tag-along actions; and (2) all cases directly filed in or removed to this MDL. It is ORDERED as follows:

1. Defendants Cook Incorporated, Cook Medical LLC, *formerly known as* Cook Medical Incorporated, and William Cook Europe ApS (collectively referred to as the “Cook Defendants”) and Plaintiffs (individually, a “Party” or collectively, the “Parties”), through their respective attorneys, hereby stipulate and agree to the entry of this Qualified Protective Order Regarding Protected Health Information (“Order”) in the above-captioned action. This Order is entered pursuant to Federal Rule of Civil Procedure 26(c) and the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

2. For purposes of this Order, Protected Health Information (“PHI”) has the meaning set forth at 45 C.F.R. § 160.103 and shall refer only to PHI disclosed to a Party or its representatives in the course of and for purposes of litigation of the above-captioned matter.

3. The Parties anticipate that the claims and defenses in this matter will require disclosure and/or use of recollected and/or recorded PHI, the privacy of which is protected under HIPAA. By way of example, but not by way of limitation, the Parties anticipate disclosure of and possibly the use of (a) PHI related to the implantation and removal of Cook's medical device in non-parties; (b) PHI related to treatment of non-parties who have had the Cook medical device implanted in them; and (c) PHI related to clinical trial participants. The Parties also anticipate disclosure of Parties' PHI that is not related to the Cook medical device but is incidentally produced by way of the Parties' medical records.

4. This Order is intended to protect the privacy of the non-party patients and/or clinical trial participants whose recollected and/or recorded PHI is disclosed and/or used. This Order also is intended to protect the privacy of Party patients whose recorded PHI unrelated to their claims in this litigation is disclosed.

5. This Order is tailored to allow the Parties to pursue their claims and defenses without disclosing PHI to the public. This Order covers only PHI that is objectively identifiable.

6. The need for the Parties and their attorneys to disclose/use recollected and/or recorded PHI and the goal of protecting the privacy of patients constitute good cause for the entry of this Order.

7. This Order shall govern the disclosure and use of PHI during discovery, whether such PHI is used, discussed and/or disclosed by way of requests for admission and responses thereto, interrogatories and responses thereto, requests for documents and responses thereto, deposition testimony, expert reports, negotiations, court filings or in any other manner associated with this litigation.

8. This Order is not intended to govern the use of PHI at the trial of this action.

Procedures governing the use of PHI at trial shall be established by separate order, pursuant to application to the Court by one or both Parties.

9. By agreeing to this Order, the Parties are not waiving any objections to disclosure and/or production of any PHI during discovery.

10. Nothing in this Order shall prevent or prohibit either Party from seeking such additional or further protection as it deems necessary to protect PHI subject to discovery in this action.

11. The Parties agree:

a. PHI may be disclosed only to the following persons, and only on the condition that the PHI not be further disclosed or used in a manner that violates this Order:

1. The Court and the Court staff;

2. Attorneys employed by the Parties' law firms of record and the employees of those law firms who are assisting those attorneys in this action, including but not necessarily limited to employees working in secretarial, clerical or paralegal capacities, as well as outside vendors retained to provide litigation support services to those attorneys;

3. Court reporters and videographers taking testimony involving PHI and necessary stenographic and clerical personnel thereof; and/or

4. Consultants, trial consultants or experts employed by the Parties.

b. Consultants, trial consultants and experts identified in subparagraph 4 of paragraph 11.a. shall not review any PHI until he or she has been provided with a copy of this Order and has executed the Agreement of Confidentiality in the form attached hereto as Exhibit A.

c. At no time shall either Party, or any other individual to whom PHI properly is disclosed pursuant to this Order, disclose any PHI to anyone not authorized by this Order to receive PHI, except as otherwise authorized to do so under HIPAA (with regard to PHI) or other applicable law.

d. Recorded, as opposed to merely recollecting, PHI that is disclosed under this Order clearly shall be marked or stamped with the legend "CONFIDENTIAL." Such legend shall be placed on every page of a multi-page document. Such legend need not be placed on the original document of the producing Party, but instead may be placed upon copies produced or exchanged. Subject to the exceptions set forth in this Order, as to each document so marked, the receiving Party shall not use or disclose such document, or the contents thereof, to others unless by specific order of this Court.

e. Interrogatories and the answers thereto, requests for admissions and responses thereto, requests for documents and responses thereto, motions, briefs, memoranda, correspondence and other documents prepared, produced, and served and/or filed in connection with this action, containing or referencing PHI, may be similarly designated as "CONFIDENTIAL" in accordance with the provisions of this Order.

f. Any documents filed in the Court containing PHI related to non-party patients must be filed under seal for the Court's review and a redacted version of such documents excluding any PHI must be filed for public access in accordance with 45 C.F.R. § 164.514(b)(2). Any documents filed in this Court containing PHI related to any Party need not be filed under seal *except* to the extent those filed documents contain PHI about the Party that is unrelated to the Party's claim (e.g., a page of a Party's medical record contains relevant PHI and also

contains PHI about, for example, an irrelevant sexually transmitted disease). A redacted version of such documents excluding the unrelated PHI must be filed for public access.

g. At a deposition, the Parties may disclose PHI governed by this Order (a) to any officer, director, employee, attorney or agent of the producing Party, and (b) to any former officer, director, employee, attorney or agent of the producing Party provided that (i) the document or thing includes indicia that the former officer, director, employee, attorney or agent had authored or received it, or (ii) a foundation first is laid that the person likely would have had access to the PHI in the course of the person's employment or agency, or (iii) all information identifying the individual associated with the PHI is fully redacted and the deponent has executed the Acknowledgment of Protective Order adopted by the Court. Counsel for the producing Party shall have the right to exclude from oral depositions any person, other than the deponent, who is not authorized by this Order to receive PHI, but such right or exclusion shall be applicable only during periods of examination or testimony directed to or referencing PHI.

h. Any oral or written deposition testimony may be designated confidential either at the time the testimony is given, or within thirty (30) days following receipt of a transcript, by written notice to the court reporter with a copy of the notice to opposing counsel of the specific pages and lines of the transcript that contain PHI or references thereto. Such written notification then shall be attached by the reporter and/or Party receiving the notice to the transcript and each copy thereof in its possession, custody or control. All deposition transcripts shall be treated as confidential in their entirety until thirty (30) days following receipt of the transcript unless confidentiality designations are received earlier. Deposition exhibits previously designated "CONFIDENTIAL" need not be re-designated to retain their status as confidential.

i. Within thirty (30) days after the conclusion of this litigation whether by settlement, dispositive motion or trial, including any appeal, all recorded PHI subject to this Order, including any copies or extracts or summaries thereof, or documents containing or derived from PHI, shall be returned to counsel for the producing Party or destroyed, at the option of the producing Party. Should the producing Party request destruction, the receiving Party shall certify in writing to the disclosing Party the destruction thereof.

12. Should any PHI be disclosed inadvertently by either Party to any person not entitled to receive the PHI, the inadvertently disclosing Party immediately shall inform counsel for the producing Party of the inadvertent disclosure and shall provide all known relevant information concerning the nature and circumstances of the disclosure. When recorded or recollected PHI inadvertently has been disclosed, the disclosing Party shall exercise all reasonable efforts to ensure that no further or greater unauthorized disclosure and/or use thereof is made, and when recorded PHI inadvertently has been disclosed, the inadvertently disclosing Party shall exercise all reasonable efforts to retrieve any such PHI from persons not authorized to receive the PHI under this Order.

13. The terms of this Order shall survive the conclusion of this litigation.

14. For the purpose of enforcing the terms of this Order, the Parties and their counsel hereby submit to the jurisdiction of this Court, with such jurisdiction continuing for purposes of enforcing or resolving disputes concerning this Order.

15. Each person or entity who receives any PHI agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any proceeding relating to the performance under, compliance with, or violation of this Order.

16. Until such time that the Court enters this Order, the Parties agree that upon execution by the Parties, this document will be treated as though it has been "So Ordered."

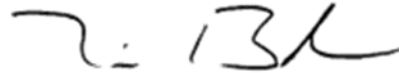
17. Any Party to this litigation or any interested member of the public may challenge the secreting of particular PHI under this Order by application to the Court.

The Court DIRECTS the Clerk to file a copy of this order in 1:14-ml-2570 and it shall be spread to each related case previously transferred to, removed to, or filed in this district. It shall be the responsibility of the parties to review and abide by all Orders previously entered by the Court, including case management orders. The orders may be accessed through the CM/ECF system.

So Ordered.

6/5/2015

Date



Tim A. Baker, Magistrate Judge
U. S. District Court
Southern District of Indiana

Copies to all registered counsel of record via the Court's ECF system.
All non-registered counsel of record will be served by Plaintiffs' Lead Counsel.

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EXHIBIT A TO AGREED QUALIFIED PROTECTIVE ORDER

Agreement of Confidentiality

The undersigned hereby acknowledges that he/she has reviewed the Agreed Qualified Protective Order (the "Order") dated _____, 2015 and entered in the United States District Court for the Southern District of Indiana in the action entitled Cook Medical, Inc., IVC Filters Marketing, Sales Practices and Product Liability Litigation, Case Number 1:14-ml-2570-RLY-TAB, MDL No. 2570, that he/she understands the terms thereof, and that he/she agrees to be bound by such terms. The undersigned hereby acknowledges that the United States District Court for the Southern District of Indiana, Indianapolis Division, has subject matter jurisdiction over any matters concerning the Order including, but not limited to, disputes concerning, and enforcement and violations of, the Order. The undersigned submits to personal jurisdiction in the United States District Court for the Southern District of Indiana, Indianapolis Division with respect to any and all matters concerning the Order. The undersigned also understands that any PHI transmitted to him/her for purposes of this litigation is confidential

and shall remain in his/her custody until he/she have completed his/her assigned duties, whereupon the PHI will be returned to counsel who provided him/her with the PHI.

Signature

Date

Printed