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UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
WESTERN DIVISION

UNITED STATES OF AMERICA,  
*ex rel.* GERALDINE GODECKE,  
  
Plaintiff,  
  
v.  
  
KINETIC CONCEPTS, INC. and  
KCI USA, INC.,  
  
Defendants.

NO.: 2:08-cv-06403-CAS-AGR  
~~PROPOSED~~ STIPULATED  
PROTECTIVE ORDER FOR  
PRODUCTION BY NON-PARTIES  
THE CENTERS FOR MEDICARE &  
MEDICAID SERVICES; NORIDIAN  
HEALTHCARE SOLUTIONS, LLC;  
AND CGS ADMINISTRATORS, LLC  
  
Judge: Hon. Christina A. Snyder  
Courtroom: 8D

STIPULATED PROTECTIVE ORDER FOR PRODUCTION BY CMS AND DME MACS

1 ~~PROPOSED~~ **STIPULATED PROTECTIVE ORDER FOR PRODUCTION**  
2 **BY NON-PARTIES THE CENTERS FOR MEDICARE & MEDICAID**  
3 **SERVICES (“CMS”); NORIDIAN HEALTHCARE SOLUTIONS, LLC**  
4 **(“NORIDIAN”); AND CGS ADMINISTRATORS, LLC (“CGS”)**

5 Relator Geraldine Godecke (“Relator”) and defendants Kinetic Concepts, Inc.  
6 and KCI USA, Inc. (collectively defendants are “KCI”) (Relator and KCI are the  
7 “Parties” and each is a “Party”) file this Stipulated Protective Order and Exhibits for  
8 Production by non-party the Department of Health & Human Services (“HHS”),  
9 Centers for Medicare & Medicaid Services (“CMS”; HHS and CMS are agencies of  
10 the United States), and on CMS’s Durable Medical Equipment Medicare  
11 Administrative Contractors (“DME MACs”), Noridian Healthcare Solutions, LLC  
12 (“Noridian”) and CGS Administrators, LLC (“CGS”) (the “Protective Order”) to  
13 preserve the confidentiality of Protected Health Information (“PHI”), privileged, and  
14 financial, commercial, and trade secret information that may be produced in discovery  
15 in this action. The Parties agree that a protective order concerning such information  
16 is necessary to protect the confidentiality and integrity of the information, waiver of  
17 privilege, and to prevent injury (including without limitation financial and competitive  
18 injury) that the Producing Party or the person who is the subject of the information  
19 might incur from public disclosure. All headings and subheadings used in this  
20 Protective Order are used for convenience only and are not to be considered in  
21 construing or interpreting this Protective Order. The Parties have agreed to the  
22 following terms of confidentiality, and the court has found that good cause exists for  
23 issuance of an appropriately-tailored Protective Order governing all phases of this  
24 action. It is therefore ORDERED:

- 25 1. **Definitions.** As used in this Protective Order,  
26 (a) “Commercially Sensitive Information” means information that the  
27 Producing Party believes would result in competitive, commercial, or  
28 financial harm, including pricing information, reimbursement rates, rebate

1 terms, minimum guarantee payments, sales reports, sales margins, and  
2 contracts or agreements between pharmaceutical companies and pharmacy  
3 benefit managers.

4 (b) “Conclusion” means the end time for any records retention requirement and  
5 statute of limitations applicable to a Party or a Party’s counsel.

6 (c) “Covered Entity or Entities” means “covered entity” as defined in 45 C.F.R.  
7 § 160.103.

8 (d) “Discovery Material” is intended to be comprehensive and includes any and  
9 all CMS/Noridian/CGS produced materials, including documents,  
10 information, electronically-stored information (“ESI”) and tangible things in  
11 the broadest sense contemplated under Federal Rules of Civil Procedure 34,  
12 and includes all written, oral, recorded, electronic, or graphic material,  
13 however produced or reproduced, including, but not limited to all written or  
14 printed matter of any kind, computer data of any kind, graphic or manual  
15 records or representations of any kind, and electronic, mechanical, or electric  
16 records furnished in the course of discovery under this Protective Order by  
17 the signatories to this Protective Order, and other persons or entities subject  
18 to this Protective Order, including deposition testimony and exhibits,  
19 answers to interrogatories, and responses to discovery requests and  
20 subpoenas issued under this Protective Order.

21 (e) “Litigation” or “this case” means the case entitled *United States ex rel.*  
22 *Geraldine Godecke v. Kinetic Concepts, Inc. and KCI USA, Inc.*, Central  
23 District of California no. 2:08-cv-06403-CAS-AGR as well as all related  
24 appellate proceedings.

25 (f) “Parties” means Relator Geraldine Godecke and defendants Kinetic  
26 Concepts, Inc. and KCI USA, Inc., and each is a “Party.”

27 (g) “Producing Party” means CMS or any CMS contractor or CMS agent that  
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1 produces Discovery Material pursuant to this Protective Order (specifically  
2 including Noridian and CGS).

3 (h) “Proprietary Information” means trade secret or other confidential research,  
4 development, or commercial information entitled to protection under Federal  
5 Rules of Civil Procedure 26(c)(1)(G).

6 (i) “Protected Health Information” or “PHI” means “protected health  
7 information” as defined in 45 C.F.R. § 160.103.

8 (j) “Service Providers” means any court reporter service, videographer service,  
9 translation service, photocopy service, document management service,  
10 records management service, graphics service, or other such litigation  
11 service designated by a Party or a Party’s legal counsel in this case.

12 **2. CONFIDENTIAL Information.** Information designated as  
13 “CONFIDENTIAL” pursuant to this Protective Order (hereinafter “CONFIDENTIAL  
14 Information”) means Discovery Material that contains PHI and any Discovery  
15 Material that would be protected by the Privacy Act of 1974, 5 U.S.C. § 552a, and/or  
16 45 C.F.R. Part 5b in the hands of CMS.

17 **3. HIGHLY CONFIDENTIAL Information.** Information designated as  
18 “HIGHLY CONFIDENTIAL” pursuant to this Protective Order (hereinafter  
19 “HIGHLY CONFIDENTIAL Information”) means Discovery Material that contains  
20 Proprietary Information or Commercially Sensitive Information. “HIGHLY  
21 CONFIDENTIAL” information is also documents that are marked as Deliberative  
22 Process Privileged (“DPP”) but produced under the separate STIPULATED  
23 PROTECTIVE ORDER GOVERNING NON-WAIVER OF UNITED STATES OF  
24 AMERICA’S PRIVILEGE AND PROTECTED MATERIAL that is attached as  
25 Exhibit A to this Protective Order.

26 **4. Designation of Material as CONFIDENTIAL.** Upon producing  
27 Discovery Material to the Parties pursuant to a subpoena or other lawful process, the  
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1 Producing Party should designate the Discovery Material as “CONFIDENTIAL.” The  
2 Producing Party shall, if practical, designate “CONFIDENTIAL” on every page of the  
3 Discovery Material in the same manner in which every page is Bates stamped. If it is  
4 not practical to designate “CONFIDENTIAL” on the Discovery Material, then the  
5 Producing Party shall designate the Discovery Material as “CONFIDENTIAL” in  
6 correspondence or in some other manner reasonably giving notice of the designation,  
7 including (but not limited to) affixing a label marked “CONFIDENTIAL” on the cover  
8 of or surface of any electronic media. It is practical to designate “CONFIDENTIAL”  
9 on every page of the Discovery Material if it is produced with a Bates stamp on every  
10 page. It is not practical to designate “CONFIDENTIAL” on every page of the  
11 Discovery Material if it is a spreadsheet or presentation file produced in native format  
12 (e.g., Microsoft Excel, PowerPoint, or Access).

13       **5. Designation of Material as HIGHLY CONFIDENTIAL.** Upon  
14 producing Discovery Material containing Proprietary Information or Commercially  
15 Sensitive Information to the Parties pursuant to a subpoena or other lawful process,  
16 the Producing Party should designate the Discovery Material as “HIGHLY  
17 CONFIDENTIAL.” The Producing Party shall, if practical, designate “HIGHLY  
18 CONFIDENTIAL” on every page of the Discovery Material in the same manner in  
19 which every page is Bates stamped. If it is not practical to designate “HIGHLY  
20 CONFIDENTIAL” on the Discovery Material, then the Producing Party shall  
21 designate the Discovery Material as “HIGHLY CONFIDENTIAL” in correspondence  
22 or in some other manner reasonably giving notice of the designation, including (but  
23 not limited to) affixing a label marked “HIGHLY CONFIDENTIAL” on the cover of  
24 or surface of any electronic media. It is practical to designate “HIGHLY  
25 CONFIDENTIAL” on every page of the Discovery Material if it is produced with a  
26 Bates stamp on every page. It is not practical to designate “HIGHLY  
27 CONFIDENTIAL” on every page of the Discovery Material if it is a spreadsheet or  
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1 presentation file produced in native format (*e.g.*, Microsoft Excel, PowerPoint, or  
2 Access). Moreover, as noted above, “HIGHLY CONFIDENTIAL” information is  
3 also documents that are marked as Deliberative Process Privileged (“DPP”) but  
4 produced under the separate STIPULATED PROTECTIVE ORDER GOVERNING  
5 NON-WAIVER OF UNITED STATES OF AMERICA’S PRIVILEGE AND  
6 PROTECTED MATERIAL that is attached as Exhibit A to this Protective Order.

7       6.     **Access to CONFIDENTIAL Information.** As needed to pursue the  
8 Litigation, and subject to paragraph 8, the Parties shall permit only the following  
9 persons to have access to CONFIDENTIAL Information:

- 10       (a) The Parties’ outside legal counsel and their employees and agents;
- 11       (b) The Parties’ in-house legal counsel, employees, and agents;
- 12       (c) Any Service Providers,;
- 13       (d) The Parties’ experts and consultants and their employees and agents;
- 14       (e) Individuals who any Party or Party’s legal counsel interviews or deposes;
- 15       (f) The court and court-related personnel; and
- 16       (g) Such other persons if this court so orders.

17       7.     **Access to HIGHLY CONFIDENTIAL Information.** As needed to  
18 pursue the Litigation, and subject to paragraph 8, the Parties shall permit only the  
19 following persons to have access to HIGHLY CONFIDENTIAL Information:

- 20       (a) The Parties’ outside legal counsel, and outside legal counsel’s employees  
21       and agents;
- 22       (b) Any Service Providers;
- 23       (c) The Parties’ experts and consultants and their employees and agents;
- 24       (d) Individuals who any Party or Party’s legal counsel interviews or deposes;
- 25       (e) The court and court-related personnel; and
- 26       (f) Such other persons if this court so orders.

27       8.     **Except for the individuals designated under paragraphs 6(f) and 7(e).**

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1 Except for the individuals designated under paragraphs 6(f) and 7(e), the Parties shall  
2 ensure that each individual designated in paragraphs 6 and 7 who reviews or is given  
3 access to Discovery Materials reads, agrees to, and signs a copy of the attached  
4 Acknowledgement of Protective Order (attached at Exhibit B), except that entry of this  
5 Protective Order by the court will constitute Acknowledgement by the Parties and their  
6 legal counsel. Where an entity is designated in paragraphs 6 and 7, an officer or  
7 manager of the entity may sign the Acknowledgement of Protective Order on behalf  
8 of the entire entity. Each Party's legal counsel shall maintain the copy of the  
9 Acknowledgement of Protective Order as signed by each individual or entity  
10 designated in paragraphs 6 and 7 and shall permit the opposing Party's legal counsel  
11 and U.S. Department of Health and Human Services (HHS) Office of the General  
12 Counsel, CMS Division to inspect said copy or copies upon request. Individuals and  
13 entities designated in paragraphs 6 and 7, except for the individuals designated under  
14 paragraphs 6(f) and 7(e), who do not sign the attached Acknowledgement of Protective  
15 Order must not be given access to Discovery Materials.

16 **9. Destruction of CONFIDENTIAL Information and HIGHLY**  
17 **CONFIDENTIAL Information at the Conclusion of the Litigation.** No later than  
18 90 days following the Conclusion of the Litigation, the Parties and the individuals and  
19 entities designated in paragraphs 6 and 7 shall destroy all CONFIDENTIAL  
20 Information and HIGHLY CONFIDENTIAL Information (including all copies made).

21 All counsel of record shall certify compliance with paragraph 9 on behalf  
22 of themselves, the Parties they represent, and the Parties' employees and agents  
23 (including, but not limited to, the individuals and entities designated in paragraphs 6  
24 and 7, as applicable) and shall deliver this certification to HHS Office of the General  
25 Counsel, CMS Division not more than 90 days after the Conclusion of the Litigation.

26 **10. Use of CONFIDENTIAL Information or HIGHLY**  
27 **CONFIDENTIAL Information in documents filed with the court.** In the event any  
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1 Party wishes to use CONFIDENTIAL Information or HIGHLY CONFIDENTIAL  
2 Information in any affidavits, briefs, memoranda, exhibits, motions, or other papers  
3 filed in court in this action, such Party shall take appropriate steps to safeguard  
4 CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information, including  
5 ensuring compliance with all applicable local rules and district court rules. Where the  
6 papers to be filed contain CONFIDENTIAL Information or HIGHLY  
7 CONFIDENTIAL Information not pertinent to the issue before the court, the Parties  
8 should redact such CONFIDENTIAL Information or HIGHLY CONFIDENTIAL  
9 Information. Where the filing Party wishes the court to review the CONFIDENTIAL  
10 Information or HIGHLY CONFIDENTIAL Information filed with the court, and all  
11 portions of pleadings, motions or other papers filed with the court that disclose such  
12 CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information, the filing  
13 Party must make the filing under seal with the clerk of the court and the filing should  
14 remain under seal until further order of the court. The Parties will use their best efforts  
15 to minimize such sealing.

16 **11. Exercise of Restraint and Care in Designating Material for**  
17 **Protection.** The Producing Party will take care to limit any such CONFIDENTIAL  
18 or HIGHLY CONFIDENTIAL designation to specific material that qualifies under the  
19 appropriate standards. The Producing Party must designate for protection only those  
20 parts of material, documents, items, or oral or written communications that qualify –  
21 so that other portions of the material, documents, items, or communications for which  
22 protection is not warranted are not swept unjustifiably within the ambit of this  
23 Protective Order.

24 Mass, indiscriminate, or routinized designations are prohibited. If it  
25 comes to the Producing Party's attention that information or items that it designated  
26 for CONFIDENTIAL or HIGHLY CONFIDENTIAL protection do not qualify for  
27 protection, the Producing Party must promptly notify all Parties that it is withdrawing  
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1 the mistaken designation.

2           The Parties recognize that the Local Rules of the Central District of  
3 California and controlling case law require that the party or nonparty who seeks to  
4 designate material as confidential bears the burden of showing why such documents  
5 are confidential and require filing under seal. Civil Local Rule 79 sets forth the  
6 procedures that must be followed and the standards that will be applied when a party  
7 seeks permission from the court to file material under seal.

8           Should any Party seek, or contemplate, filing with the Court a document  
9 designated as privileged or otherwise protectable under the law, that Party should  
10 notify the Producing Party five-business days in advance of such filing. If the  
11 Producing Party still desires that the document be filed under seal, it shall be so filed  
12 pursuant to applicable rules and a Court determination, based on the Parties' legal  
13 burdens, of any claim of privilege or other protection.

14           **12. Filing Protected Material.** Without written permission from the  
15 Producing Party or a court order secured after appropriate notice to all interested  
16 persons, a Party may not file in the public Court record any CONFIDENTIAL or  
17 HIGHLY CONFIDENTIAL material. And a Party seeking to file under seal any  
18 CONFIDENTIAL or HIGHLY CONFIDENTIAL material must comply with  
19 applicable Civil Local Rules including Local Rule 79. CONFIDENTIAL or HIGHLY  
20 CONFIDENTIAL material may only be filed under seal pursuant to a court order  
21 authorizing the sealing of the specific CONFIDENTIAL or HIGHLY  
22 CONFIDENTIAL material at issue with the Party seeking such under seal filing  
23 bearing the burden as to why the sealing of such documents should be authorized or  
24 continue. Pursuant to Civil Local Rule 79 a sealing order will issue only upon a  
25 request establishing that the CONFIDENTIAL or HIGHLY CONFIDENTIAL  
26 material at issue is privileged, protectable as a trade secret, or otherwise entitled to  
27 protection under the law. The Parties shall also give notice to the Producing Party of  
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1 any requests to file CONFIDENTIAL or HIGHLY CONFIDENTIAL materials under  
2 seal, and of any oppositions to such requests, so that the Producing Party may assert  
3 any interest it has in keeping the CONFIDENTIAL or HIGHLY CONFIDENTIAL  
4 material under seal. If a Party's request to file CONFIDENTIAL or HIGHLY  
5 CONFIDENTIAL material under seal pursuant to Civil Local Rule 79 is denied by the  
6 court, then the Party may file the information.

7 **Paragraphs 13–16—Terms Specific to PHI.**

8 13. Pursuant to 45 C.F.R. § 164.512(e)(1) and for purposes of compliance  
9 with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the  
10 Parties’ legal counsel in this Litigation, the employees and agents of each Party, and  
11 all non-Party Covered Entities are expressly and specifically authorized to use or  
12 disclose PHI in accordance with this order to:

- 13 (a) Respond to interrogatories, requests for admission, or requests for  
14 production of documents, including ESI, served pursuant to the Federal  
15 Rules of Civil Procedure in this case seeking PHI;
- 16 (b) Request interviews or depositions and interview, depose, or respond in  
17 interviews or depositions in which PHI might be disclosed;
- 18 (c) Prepare briefs and other materials for the court so long as such materials are  
19 treated in accordance with paragraph 10 of this Protective Order; and
- 20 (d) Disclose PHI to a Party’s expert regardless of whether the expert is a  
21 consulting or testifying expert.

22 14. Pursuant to 45 C.F.R. § 164.512(e)(1) and for purposes of HIPAA  
23 compliance, each deponent noticed for deposition in this case, including but not  
24 limited to a Party, a fact witness, a records custodian, an expert, or a Covered Entity  
25 of any type, is expressly and specifically authorized to use or to disclose to the Parties’  
26 legal counsel in this case and the employees and agents of each Party and each Party’s  
27 legal counsel in this case, the PHI that is responsive to deposition questions or a valid  
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1 subpoena *duces tecum*.

2 15. Pursuant to 45 C.F.R. § 164.512(e)(1) and for purposes of HIPAA  
3 compliance, any person or entity authorized or ordered under paragraphs 11 or 12  
4 above to use or disclose PHI is expressly and specifically authorized to do so with, to,  
5 or before any Service Providers designated by a Party or a Party's legal counsel in this  
6 case. The protections and requirements of paragraphs 16 and 19 of this Protective  
7 Order must be imposed on Service Providers as a condition of any Service Provider's  
8 receipt of PHI. Each Party or the Party's legal counsel is charged with obtaining  
9 advance consent of such Service Provider to comply with this paragraph. Upon such  
10 consent, the Service Provider will be deemed to have voluntarily submitted to this  
11 court's jurisdiction during the pendency of this case for purposes of enforcement of  
12 this paragraph, including but not limited to the imposition of such sanctions as may be  
13 appropriate for any non-compliance.

14 16. The intent of this Protective Order is to authorize the use and disclosure  
15 of PHI in accordance with 45 C.F.R. § 164.512(e) and the terms of this Protective  
16 Order. To the extent that the uses and disclosures of PHI authorized under this  
17 Protective Order may be permitted under other provisions of the HIPAA Privacy Rule,  
18 such uses and disclosures are made pursuant to and in accordance with 45 C.F.R. §  
19 164.512(e). This paragraph does not apply to uses and disclosures of PHI that are not  
20 authorized under this Protective Order.

21 **17. Terms Specific to Proprietary Information and Commercially**  
22 **Sensitive Information.** For Discovery Materials containing Proprietary Information  
23 or Commercially Sensitive Information designated as HIGHLY CONFIDENTIAL,  
24 the Producing Party's production of HIGHLY CONFIDENTIAL Information in this  
25 case is not to be construed as waiving or diminishing the Producing Party's interests  
26 in and rights to the confidentiality of Proprietary Information or Commercially  
27 Sensitive Information, unless otherwise ordered by the court.

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1 18. Discovery Material may not be disclosed or used by any Party or any  
2 individual or entity designated in paragraphs 6 or 7 for any purpose other than the  
3 Litigation.

4 19. Subject to paragraph 19, all CONFIDENTIAL Information and HIGHLY  
5 CONFIDENTIAL Information produced, transmitted, or otherwise received  
6 electronically must be maintained in a reasonably secure manner and guarded against  
7 re-disclosure for the life of the record.

8 20. **Inadvertent production by the Producing Party.** If at any time prior  
9 to the trial of this action, the Producing Party realizes that:

10 (a) Some portion(s) of Discovery Material was produced without a designation  
11 of CONFIDENTIAL or HIGHLY CONFIDENTIAL, the Producing Party  
12 may add either designation to those Discovery Materials without limitation  
13 by apprising the Parties in writing of such designation. Such Discovery  
14 Material will thereafter be treated as CONFIDENTIAL Information or  
15 HIGHLY CONFIDENTIAL Information under the terms of this Protective  
16 Order. Any failure of the Producing Party to designate Discovery Material  
17 as CONFIDENTIAL or HIGHLY CONFIDENTIAL does not constitute a  
18 waiver of any claim of privilege or work product protection with respect to  
19 the Discovery Material.

20 (b) If Discovery Materials subject to a claim of attorney-client privilege or  
21 attorney work product protection (“Inadvertently Disclosed Information”)  
22 were inadvertently produced, the Producing Party will be entitled to  
23 “clawback” this Inadvertently Disclosed Information and to have all copies  
24 of it either returned to the Producing Party or destroyed. If the Producing  
25 Party seeks to clawback Inadvertently Disclosed Information, it is entitled to  
26 do so, regardless of the Producing Party’s diligence in initially attempting to  
27 prevent such an inadvertent disclosure. To the extent possible, the Producing  
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1 Party will clawback only the portions of Discovery Materials containing  
2 information subject to a claim of attorney-client privilege or attorney work  
3 product protection. Any Inadvertent Disclosure by the Producing Party does  
4 not constitute and shall not be deemed a waiver or forfeiture of any claim of  
5 privilege or work product protection with respect to the Inadvertently  
6 Disclosed Information itself and/or its subject matter with respect to this  
7 Litigation or in any other federal, state, or local proceeding, regardless of the  
8 Producing Party's diligence in initially attempting to prevent such  
9 disclosure. If the Producing Party makes a claim of inadvertent disclosure,  
10 the Parties shall, within five business days, return or destroy all copies of the  
11 Inadvertently Disclosed Information, and provide a certification of counsel  
12 that all such information has been returned or destroyed. Within five  
13 business days of the notification that such Inadvertently Disclosed  
14 Information has been returned or destroyed, the Producing Party shall  
15 produce a privilege log with respect to the Inadvertently Disclosed  
16 Information. The Parties may move the court for an order compelling  
17 production of the Inadvertently Disclosed Information. The motion must be  
18 filed under seal, and may not assert as a ground for entering such an order  
19 the fact or circumstances of the inadvertent production. The Producing Party  
20 retains the burden of establishing the privileged or protected nature of any  
21 Inadvertently Disclosed Information contained in Discovery Materials.  
22 Nothing in this Protective Order limits the right of any Party to request an in  
23 camera review of the Inadvertently Disclosed Information.

24 **21. Inadvertent production or re-disclosure by a Party or an individual**  
25 **or entity designated in paragraphs 6 or 7.** If a Party or an individual or entity  
26 designated in paragraphs 6 or 7 (the "Responsible Party") produces or discloses  
27 Discovery Material designated as CONFIDENTIAL Information or HIGHLY  
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1 CONFIDENTIAL Information to a person or entity not authorized to receive such  
2 disclosure under this Protective Order, such Responsible Party shall, upon becoming  
3 aware of such disclosure, immediately inform the Producing Party. The Responsible  
4 Party also shall take all reasonable measures to cure the improper disclosure and to  
5 promptly ensure that no further or greater unauthorized disclosure of the Discovery  
6 Material designated as CONFIDENTIAL Information or HIGHLY CONFIDENTIAL  
7 Information.

8 **Miscellaneous Provisions**

9 22. Any and all Medicare Part D Prescription Drug Event (PDE) data  
10 produced by the Producing Party in this action is considered CONFIDENTIAL  
11 Information and/or HIGHLY CONFIDENTIAL Information (depending on which  
12 data fields are included or excluded) as that term is used throughout this Protective  
13 Order.

14 23. Pursuant to 5 U.S.C. § 552a(b)(11), this Protective Order authorizes CMS  
15 to release Privacy Act-protected information covered by this Protective Order, without  
16 the consent of the subject individual.

17 24. The production of any Discovery Material by CMS in the course of this  
18 action, pursuant to and in compliance with the terms of this Protective Order, which  
19 might otherwise be prohibited by the Trade Secrets Act, 18 U.S.C. § 1905, constitutes  
20 a disclosure “authorized by law” under the terms of the Act.

21 25. Should any Party bound by this Protective Order receive a subpoena, civil  
22 investigative demand, or other process from a third Party seeking, requesting, or  
23 requiring disclosure of Discovery Materials produced in this Litigation designated as  
24 CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information, such  
25 person shall give notice to HHS Office of the General Counsel, CMS Division so that  
26 CMS may seek appropriate relief, if any. Notice must be made by the sooner date of  
27 ten days from the date the Party received the request for production or seven days prior  
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1 to the deadline for responding to the request for production, and must be in writing.

2 26. Notwithstanding any provisions of this Protective Order to the contrary,  
3 in accordance with any applicable federal, state, or local laws that afford heightened  
4 protection to certain categories of confidential health information, including but not  
5 limited to, records or diagnosis or treatment for alcohol or substance abuse, certain  
6 sexually transmitted diseases such as HIV/AIDS, mental health, and research  
7 pertaining to genetic testing, the Party in receipt of such information shall comply with  
8 the applicable federal, state, or local law that affords heightened protection to such  
9 information.

10 27. Nothing in this Protective Order affects the rights of the Parties,  
11 Producing Party, or third-Parties to object to discovery on grounds other than those  
12 related to the protection of CONFIDENTIAL Information or HIGHLY  
13 CONFIDENTIAL Information, nor does it preclude any Party or third-Party from  
14 seeking further relief or protective orders from this court as may be appropriate under  
15 the Federal Rules of Civil Procedure.

16 28. Any person requiring further protection of CONFIDENTIAL  
17 Information or HIGHLY CONFIDENTIAL Information may petition this court for a  
18 separate order governing the disclosure of its information.

19 29. The provisions of this Protective Order survive the Conclusion of this  
20 Litigation.

21 30. This court retains jurisdiction over all persons subject to this Protective  
22 Order to the extent necessary to enforce any obligations arising hereunder or to impose  
23 sanctions for any contempt therefore.

24 31. This Protective Order does not dictate the use of CONFIDENTIAL  
25 Information or HIGHLY CONFIDENTIAL designated information by a Party at trial.  
26 Such use must be determined by appropriate order of the court upon noticed motion.

27 32. To the extent that inconsistencies exist between this Protective Order and  
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1 any CMS Data Use Agreement executed by the Party in receipt of applicable  
2 Discovery Materials, the provisions of this Protective Order control.

3 33. This Protective Order may be amended for good cause shown.

4 34. This Protective Order for Production by non-Party CMS (including its  
5 DME MACs Noridian and CGS) is intended solely to supplement any existing  
6 Protective Order in the case. It governs only Discovery Materials produced by the  
7 Producing Party as defined in this Protective Order.

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1 IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.

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3 DATED: August 3, 2021

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1 DATED: August 3, 2021

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25 *Attorneys for Kinetic Concepts, Inc. & KCI, USA, Inc.*

26 FOR GOOD CAUSE SHOWN, IT IS SO ORDERED.

27 DATED: August 16, 2021

28 

Honorable Alicia G. Rosenberg  
United States Magistrate Judge

1 **EXHIBIT A**

2 **STIPULATED PROTECTIVE ORDER GOVERNING NON-WAIVER OF**  
3 **UNITED STATES OF AMERICA’S PRIVILEGE AND PROTECTED**  
4 **MATERIAL**

5 **Good Cause Statement**

6 This Action is a *qui tam* False Claims Act case. The United States of America  
7 declined to intervene in this Action in April 2011.

8 Defendants Kinetic Concepts, Inc. and KCI USA, Inc. (collectively “KCI” or  
9 defendants), and relator Geraldine Godecke (“Relator”) have each served Rule 45  
10 subpoenas on non-parties (1) the Department of Health & Human Services (“HHS”),  
11 Centers for Medicare & Medicaid Services (“CMS”; HHS and CMS are agencies of  
12 the United States), and on CMS’s Durable Medical Equipment Medicare  
13 Administrative Contractors (“DME MACs”), (2) Noridian Healthcare Solutions, LLC  
14 (“Noridian”) and (3) CGS Administrators, LLC (“CGS”).

15 CMS, Noridian, and CGS contend that CMS may claim the deliberative process  
16 privilege for documents in the possession of Noridian and CGS (as well as for CMS’  
17 own documents).

18 KCI disputes that CMS may claim the deliberative process privilege for  
19 Medicare records in the possession of Noridian and CGS; and further contends that  
20 even if it does apply to such documents in the possession of Noridian, CGS, and CMS,  
21 the privilege is a qualified one that may be overridden in appropriate circumstances,  
22 which KCI contends exist in this case.

23 CMS, Noridian, and CGS wish to produce responsive documents to KCI and  
24 Relator as soon as reasonably possible.

25 In order to potentially avoid litigating the issue of deliberative process privilege,  
26 KCI, Relator, and CMS/Noridian/CGS desire that discovery proceed in an expeditious  
27 and efficient manner without waiver of any potential privilege or protection afforded  
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1 to the CMS, Noridian, and CGS materials.

2 Good cause existing for entry of this Protective Order, it is, pursuant to the  
3 Court's authority and with the consent of KCI, Relator, CMS, Noridian, and CGS,  
4 ORDERED as follows:

5 **Terms:**

- 6 1. Documents produced by CMS, Noridian, and CGS to KCI and Relator in this  
7 Action will be held *not* to have waived any applicable protections or privileges,  
8 including the deliberative process privilege. The production of materials by  
9 CMS, Noridian, and CGS to KCI and Relator does not constitute a waiver of  
10 any privilege or protection in this Action or any other federal or state  
11 proceeding. This Order shall be interpreted to provide the maximum protection  
12 allowed by Rule 502(d) of the Federal Rules of Evidence.
- 13 2. KCI and Relator retain their rights to later challenge the applicability of any  
14 privilege or protection to the produced documents, including any challenges to  
15 the applicability of the deliberative process privilege.
- 16 3. CMS, Noridian, and/or CGS retain their rights to later assert any privilege or  
17 protection applicable to the produced documents, including the deliberative  
18 process privilege.
- 19 4. Experts for KCI and Relator may review any material produced by CMS,  
20 Noridian, and CGS; but experts shall be bound by this Order to the same extent  
21 as KCI and Relator.
- 22 5. Nothing in this Order prohibits CMS, Noridian, or CGS from withholding from  
23 production any material covered by any privilege or other protection properly  
24 claimed, including any deliberative process privileged materials (for instance,  
25 including, but not limited to: (a) draft LCDs, LMRPs, articles and related  
26 communications; and (b) draft proposed and final rules and related  
27 communications). As noted, KCI and Relator retain their rights to challenge  
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1 any such assertions of privilege or protection.

2 6. KCI, Relator, CMS, Noridian, or CGS may seek modification of this Order for  
3 good cause – including but not limited to any circumstance created or  
4 exacerbated by the terms of this Order that may result in an unreasonable burden  
5 being imposed on KCI, Relator, CMS, Noridian, or CGS – at any time; but the  
6 provisions of this Order shall continue to be binding after the termination of this  
7 Action, whether by settlement, judgment, or other disposition or conclusion and  
8 all appeals therefrom, unless otherwise ordered. KCI, Relator, CMS, Noridian,  
9 and CGS agree to promptly meet and discuss joint modification of this Order  
10 should any specific provision become overly burdensome upon implementation.  
11

12 IT IS SO STIPULATED, THROUGH COUNSEL.

13  
14 DATED: August 3, 2021

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1 DATED: August 3, 2021

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26 FOR GOOD CAUSE SHOWN, IT IS SO ORDERED.

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Honorable Alicia G. Rosenberg  
United States Magistrate Judge

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**EXHIBIT B**

**ACKNOWLEDGEMENT OF PROTECTIVE ORDER**

I, \_\_\_\_\_, [in my individual capacity] OR [as \_\_\_\_\_ (title) of \_\_\_\_\_ (entity name), on behalf of \_\_\_\_\_ (entity name)], acknowledge that I have read, understand and agree to be bound by the Stipulated Protective Order for Production by Non-Parties the Centers for Medicare & Medicaid Services (“CMS”); Noridian Healthcare Solutions, LLC (“Noridian”); and CGS Administrators, LLC (“CGS”), including CMS’s Durable Medical Equipment Medicare Administrative Contractors (“DME MACs”), Noridian and CGS (the “Protective Order”) in this action governing the non-disclosure of those portions of Discovery Material that have been designated as CONFIDENTIAL Information and/or HIGHLY CONFIDENTIAL Information. I agree that I will disclose such CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information only as expressly permitted by this Protective Order and only for purposes of the Litigation (as defined in the Protective Order), that I will not use, or cause to be used, the CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information for the commercial or competitive benefit of any Party or competitor to any Party in this Litigation, and that I will take all reasonable measures to protect the confidentiality of all such Discovery Material. No later than 90 days following the Conclusion of the Litigation, I will destroy or return to HHS Office of the General Counsel, CMS Division all CONFIDENTIAL Information and HIGHLY CONFIDENTIAL Information in my possession (including all copies made). If I am counsel of record in the Litigation, I will certify compliance with paragraph 9 of the Protective Order and deliver this certification to HHS Office of the General Counsel, CMS Division not more than 90 days after the Conclusion of the Litigation.

By acknowledging these obligations under the Protective Order, I understand

1 that I am submitting myself to the jurisdiction of the United States District Court for  
2 the \_\_\_\_ District of \_\_\_\_\_ for the purpose of any issue or dispute arising  
3 hereunder and that my willful violation of any term of the Protective Order could  
4 subject me to punishment for contempt of court.

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6 Date: \_\_\_\_\_

7 City and State where sworn and signed: \_\_\_\_\_

8 Printed name: \_\_\_\_\_

9 Signature: \_\_\_\_\_

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