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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA,
ex rel. STEVEN J. HARTPENCE,

Plaintiffs,

v.

KINETIC CONCEPTS, INC., and
KCI USA, INC.,

Defendants.

CASE: 2:08-cv-01885-BRO (AGRx)

**STIPULATED HIPAA QUALIFIED
PROTECTIVE ORDER**

**Judge: Hon. Beverly Reid O'Connell
Magistrate Judge: Alicia J. Rosenberg
Courtroom: First Street, Courtroom
7C**

1. INTRODUCTION

1.1 Purposes and Limitations. Discovery in this action is likely to involve production of confidential, proprietary, or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation may be warranted. Such information may include, among other information, protected health information within the meaning of 45 C.F.R. § 160.3. Accordingly, the parties hereby stipulate to and petition the Court to enter the following Stipulated HIPAA Qualified Protective Order. The parties acknowledge that this Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords from public disclosure and use extends only to the limited information or items that are entitled to confidential treatment under the applicable legal principles. The parties further acknowledge, as set forth in Section 12.3, below, that this Stipulated HIPAA Qualified Protective Order does not entitle them to file confidential information under seal; Civil Local Rule 79-5 sets forth the procedures that must be followed and the standards that will be applied when a party seeks permission from the court to file material under seal.

1.2 Good Cause Statement. This action is likely to involve third parties' individually identifiable health information within the meaning of 45 C.F.R. § 160.3, patient identifying information, and other confidential and proprietary medical information for which special protection from public disclosure and from use for any purpose other than prosecution of this action is warranted, both under federal law and for the proper safeguarding of the parties' business and legal interests. This action may also involve confidential and proprietary business information, which may consist of, among other things, trade secrets, confidential business or financial information, information regarding confidential business practices, or other confidential research, development, or commercial information (including information implicating privacy rights of third parties), information otherwise

1 generally unavailable to the public, or which may be privileged or otherwise
2 protected from disclosure under state or federal statutes, court rules, case decisions,
3 or common law. Accordingly, to expedite the flow of information, to facilitate the
4 prompt resolution of disputes over confidentiality of discovery materials, to
5 adequately protect information the parties are entitled to keep confidential or are
6 required to keep confidential by law, to ensure that the parties are permitted
7 reasonable necessary uses of such material in preparation for and in the conduct of
8 trial, to address their handling at the end of the litigation, and serve the ends of
9 justice, a protective order for such information is justified in this matter. It is the
10 intent of the parties that information will not be designated as protected under this
11 order for tactical reasons and that nothing be so designated without a good faith
12 belief that it has been maintained in a confidential, non-public manner, or that federal
13 or state law requires it to be so maintained, and there is good cause why it should not
14 be part of the public record of this case.

15
16 2. DEFINITIONS

17 2.1 Action: the above captioned action, *United States ex rel. Hartpence v.*
18 *Kinetic Concepts, Inc. et al.*, 2:08-cv-01885-BRO (AGRx) (C.D. Cal.).

19 2.2 Challenging Party: a Party or Non-Party that challenges the
20 designation of information or items under this Order.

21 2.3 “CONFIDENTIAL” Information or Items: information (regardless of
22 how it is generated, stored or maintained) or tangible things that qualify for
23 protection under Federal Rule of Civil Procedure 26(c), and as specified above in the
24 Good Cause Statement.

25 2.4 Counsel: Outside Counsel of Record and House Counsel (as well as
26 their support staff).

27 2.5 Designating Party: a Party or Non-Party that designates information or
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1 items that it produces in disclosures or in responses to discovery as
2 “CONFIDENTIAL.”

3 2.6 Disclosure or Discovery Material: all items or information, regardless of
4 the medium or manner in which it is generated, stored, or maintained (including,
5 among other things, testimony, transcripts, and tangible things), that are produced or
6 generated in disclosures or responses to discovery in this matter.

7 2.7 Expert: a person with specialized knowledge or experience in a matter
8 pertinent to the litigation who has been retained by a Party or its counsel to serve as
9 an expert witness or as a consultant in this Action.

10 2.8 House Counsel: attorneys who are employees of a party to this Action.
11 House Counsel does not include Outside Counsel of Record or any other outside
12 counsel.

13 2.9 Non-Party: any natural person, partnership, corporation, association, or
14 other legal entity not named as a Party to this action.

15 2.10 Outside Counsel of Record: attorneys who are not employees of a party
16 to this Action but are retained to represent or advise a party to this Action and have
17 appeared in this Action on behalf of that party or are affiliated with a law firm which
18 has appeared on behalf of that party, and includes support staff.

19 2.11 Party: any party to this Action, including all of its officers, directors,
20 employees, consultants, retained experts, and Outside Counsel of Record (and their
21 support staffs).

22 2.12 Producing Party: a Party or Non-Party that produces Disclosure or
23 Discovery Material in this Action.

24 2.13 Professional Vendors: persons or entities that provide litigation support
25 services (e.g., photocopying, videotaping, translating, preparing exhibits or
26 demonstrations, and organizing, storing, or retrieving data in any form or medium)
27 and their employees and subcontractors.

1 2.14 Protected Health Information (“PHI”): information as defined in 45
2 C.F.R. § 160.103 and as described in 45 C.F.R. § 164.514(b)(2).

3 2.15 Protected Material: any Disclosure or Discovery Material that is
4 designated as “CONFIDENTIAL” or “PHI.”

5 2.16 Receiving Party: a Party that receives Disclosure or Discovery Material
6 from a Producing Party.

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8 3. SCOPE

9 The protections conferred by this Stipulation and Order cover not only
10 Protected Material (as defined above), but also (1) any information copied or
11 extracted from Protected Material; (2) all copies, excerpts, summaries, or
12 compilations of Protected Material; and (3) any testimony, conversations, or
13 presentations by Parties or their Counsel that might reveal Protected Material.
14 Any use of Protected Material at trial shall be governed by the orders of the trial
15 judge. This Order does not govern the use of Protected Material at trial.

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17 4. DURATION

18 Even after final disposition of this litigation, the confidentiality obligations
19 imposed by this Order shall remain in effect, as to material designated as
20 CONFIDENTIAL, until a Designating Party agrees otherwise in writing or a court
21 order otherwise directs, and as to material designated as PROTECTED HEALTH
22 INFORMATION, until a court order otherwise directs. Final disposition shall be
23 deemed to be the later of (1) dismissal of all claims and defenses in this Action, with
24 or without prejudice; and (2) final judgment herein after the completion and
25 exhaustion of all appeals, rehearings, remands, trials, or reviews of this Action,
26 including the time limits for filing any motions or applications for extension of time
27 pursuant to applicable law.

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2 5. DESIGNATING PROTECTED MATERIAL

3 5.1 Exercise of Restraint and Care in Designating Material for Protection.

4 Each Party or Non-Party that designates information or items for protection under
5 this Order must take care to limit any such designation to specific material that
6 qualifies under the appropriate standards. The Designating Party must designate for
7 protection only those parts of material, documents, items, or oral or written
8 communications that qualify so that other portions of the material, documents, items,
9 or communications for which protection is not warranted are not swept unjustifiably
10 within the ambit of this Order.

11 Mass, indiscriminate, or routinized designations are prohibited. Designations
12 that are shown to be clearly unjustified or that have been made for an improper
13 purpose (e.g., to unnecessarily encumber the case development process or to impose
14 unnecessary expenses and burdens on other parties) may expose the Designating
15 Party to sanctions.

16 If it comes to a Designating Party's attention that information or items that it
17 designated for protection do not qualify for protection, that Designating Party must
18 promptly notify all other Parties that it is withdrawing the inapplicable designation.

19 5.2 Manner and Timing of Designations. Except as otherwise provided in
20 this Order (see, e.g., second paragraph of section 5.2(a) below), or as otherwise
21 stipulated or ordered, Disclosure or Discovery Material that qualifies for protection
22 under this Order must be clearly so designated before the material is disclosed or
23 produced.

24 Designation in conformity with this Order requires:

25 (a) for information in documentary form (e.g., paper or electronic
26 documents, but excluding transcripts of depositions or other pretrial or trial
27 proceedings), that the Producing Party affix at a minimum, the legend
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1 “CONFIDENTIAL” (in the case of CONFIDENTIAL Information or Items)
2 or the legend “PROTECTED HEALTH INFORMATION” (in the case of
3 PHI; collectively, the “CONFIDENTIAL or PHI legend”), to each page that
4 contains protected material. Where appropriate, the Producing Party may affix
5 both legends. If only a portion or portions of the material on a page qualifies
6 for protection as CONFIDENTIAL Information or Items or as PHI, the
7 Producing Party also must clearly identify the portion(s) protected under each
8 classification (e.g., by making appropriate markings in the margins).

9 A Party or Non-Party that makes original documents available for
10 inspection need not designate them for protection until after the inspecting
11 Party has indicated which documents it would like copied and produced.
12 During the inspection and before the designation, all of the material made
13 available for inspection shall be deemed “CONFIDENTIAL.” After the
14 inspecting Party has identified the documents it wants copied and produced,
15 the Producing Party must determine which documents, or portions thereof,
16 qualify for protection under this Order, either as CONFIDENTIAL
17 Information or Items or as PHI. Then, before producing the specified
18 documents, the Producing Party must affix the CONFIDENTIAL or PHI
19 legend to each page that contains Protected Material. If only a portion or
20 portions of the material on a page qualifies for protection as CONFIDENTIAL
21 Information or Items or as PHI, the Producing Party also must clearly identify
22 the portion(s) protected under each classification (e.g., by making appropriate
23 markings in the margins).

24 (b) for testimony given in depositions that the Designating Party
25 identify the Disclosure or Discovery Material on the record, before the close of
26 the deposition all protected testimony.

27 (c) for information produced in some form other than documentary and
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1 for any other tangible items, that the Producing Party affix in a prominent
2 place on the exterior of the container or containers in which the information is
3 stored, as applicable, either or both of the legends “CONFIDENTIAL” or
4 “PROTECTED HEALTH INFORMATION.” If only a portion or portions of
5 the information warrants protection as CONFIDENTIAL Information or Items
6 or as PHI, the Producing Party, to the extent practicable, shall identify the
7 portion(s) protected under each classification.

8 5.3 Inadvertent Failures to Designate. If timely corrected, an inadvertent
9 failure to designate qualified information or items does not, standing alone, waive
10 the Designating Party’s right to secure protection under this Order for such material.
11 Upon timely correction of a designation, the Receiving Party must make reasonable
12 efforts to assure that the material is treated in accordance with the provisions of this
13 Order.

14 15 6. CHALLENGING CONFIDENTIALITY DESIGNATIONS

16 6.1 Timing of Challenges. Any Party or Non-Party may challenge a
17 designation of protection at any time that is consistent with the Court’s Scheduling
18 Order.

19 6.2 Meet and Confer. The Challenging Party shall initiate the dispute
20 resolution process under Local Rule 37.1 et seq.

21 6.3 The burden of persuasion in any such challenge proceeding shall be on
22 the Designating Party. Frivolous challenges, and those made for an improper purpose
23 (e.g., to harass or impose unnecessary expenses and burdens on other parties) may
24 expose the Challenging Party to sanctions. Unless the Designating Party has waived
25 or withdrawn the confidentiality designation, all parties shall continue to afford the
26 material in question the level of protection to which it is entitled under the Producing
27 Party’s designation until the Court rules on the challenge.

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2 7. ACCESS TO AND USE OF PROTECTED MATERIAL

3 7.1 Basic Principles. A Receiving Party may use Protected Material that is
4 disclosed or produced by another Party or by a Non-Party in connection with this
5 Action only for prosecuting, defending, or attempting to settle this Action. Such
6 Protected Material may be disclosed only to the categories of persons and under the
7 conditions described in this Order. When the Action has been terminated, a
8 Receiving Party must comply with the provisions of section 13 below (FINAL
9 DISPOSITION).

10 Protected Material must be stored and maintained by a Receiving Party at a
11 location and in a secure manner that ensures that access is limited to the persons
12 authorized under this Order and, for PHI, otherwise complies with federal law and
13 regulations concerning the storage, security, and disclosure of personal health
14 information.

15 7.2 Disclosure of “CONFIDENTIAL” Information or Items and PHI.

16 Unless otherwise ordered by the court or permitted in writing by the Designating
17 Party, a Receiving Party may disclose any information or item designated
18 “CONFIDENTIAL” or “PROTECTED HEALTH INFORMATION” only to:

19 (a) the Receiving Party’s Outside Counsel of Record in this Action, as
20 well as employees of said Outside Counsel of Record to whom it is reasonably
21 necessary to disclose the information for this Action;

22 (b) the officers, directors, and employees (including House Counsel) of
23 the Receiving Party to whom disclosure is reasonably necessary for this
24 Action;

25 (c) Experts (as defined in this Order) of the Receiving Party to whom
26 disclosure is reasonably necessary for this Action and who have signed the
27 “Acknowledgment and Agreement to Be Bound” (Exhibit A);
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1 (d) the court and its personnel;

2 (e) court reporters and their staff;

3 (f) professional jury or trial consultants, mock jurors, and Professional
4 Vendors to whom disclosure is reasonably necessary for this Action and who
5 have signed the “Acknowledgment and Agreement to Be Bound” (Exhibit A);

6 (g) the author or recipient of a document containing the information or a
7 custodian or other person who otherwise possessed or knew the information;

8 (h) during their depositions, witnesses, and attorneys for witnesses, in
9 the Action to whom disclosure is reasonably necessary provided: (1) the
10 deposing party requests that the witness sign the form attached as Exhibit A
11 hereto; and (2) they will not be permitted to keep any confidential information
12 unless they sign the “Acknowledgment and Agreement to Be Bound” (Exhibit
13 A), unless otherwise agreed by the Designating Party or ordered by the court.
14 Pages of transcribed deposition testimony or exhibits to depositions that reveal
15 Protected Material may be separately bound by the court reporter and may not
16 be disclosed to anyone except as permitted under this Stipulated Protective
17 Order; and

18 (i) any mediator or settlement officer, and their supporting personnel,
19 mutually agreed upon by any of the parties engaged in settlement discussions.

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21 8. PROTECTED MATERIAL SUBPOENAED OR ORDERED PRODUCED IN
22 OTHER LITIGATION

23 If a Party is served with a subpoena or a court order issued in other litigation
24 that compels disclosure of any information or items designated in this Action as
25 “CONFIDENTIAL” or “PROTECTED HEALTH INFORMATION,” that Party
26 must:

27 (a) promptly notify in writing the Designating Party. Such notification
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1 shall include a copy of the subpoena or court order;

2 (b) promptly notify in writing the party who caused the subpoena or
3 order to issue in the other litigation that some or all of the material covered by
4 the subpoena or order is subject to this Protective Order. Such notification
5 shall include a copy of this Stipulated Protective Order; and

6 (c) cooperate with respect to all reasonable procedures sought to be
7 pursued by the Designating Party whose Protected Material may be affected.
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9 If the Designating Party timely seeks a protective order, the Party served with
10 the subpoena or court order shall not produce any information designated in this
11 action as “CONFIDENTIAL” or “PROTECTED HEALTH INFORMATION”
12 before a determination by the court from which the subpoena or order issued, unless
13 the Party has obtained the Designating Party’s permission. The Designating Party
14 shall bear the burden and expense of seeking protection in that court of its
15 confidential material and nothing in these provisions should be construed as
16 authorizing or encouraging a Receiving Party in this Action to disobey a lawful
17 directive from another court.
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19 9. A NON-PARTY’S PROTECTED MATERIAL SOUGHT TO BE
20 PRODUCED IN THIS LITIGATION

21 9.1 The terms of this Order are applicable to information produced by a
22 Non-Party in this Action and designated as “CONFIDENTIAL” or “PROTECTED
23 HEALTH INFORMATION.” Such information produced by Non-Parties in
24 connection with this litigation is protected by the remedies and relief provided by
25 this Order. Nothing in these provisions should be construed as prohibiting a Non-
26 Party from seeking additional protections.

27 9.2 In the event that a Party is required, by a valid discovery request, to
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1 produce a Non-Party's confidential information or PHI in its possession, and the
2 Party is subject to an agreement with the Non-Party not to produce the Non-Party's
3 confidential information or PHI, then the Party shall:

4 (a) promptly notify in writing the Requesting Party and the Non-Party
5 that some or all of the information requested is subject to a confidentiality
6 agreement with a Non-Party;

7 (b) promptly provide the Non-Party with a copy of the Stipulated
8 Protective Order in this Action, the relevant discovery request(s), and a
9 reasonably specific description of the information requested; and

10 (c) make the information requested available for inspection by the Non-
11 Party, if requested.

12 9.3 If the Non-Party fails to seek a protective order from this court within
13 14 days of receiving the notice and accompanying information, the Receiving Party
14 may produce the Non-Party's confidential information responsive to the discovery
15 request, and may produce the Non-Party's PHI responsive to the discovery request to
16 the extent and in the manner required by federal and state laws and regulations. If the
17 Non-Party timely seeks a protective order, the Receiving Party shall not produce any
18 information in its possession or control that is subject to the confidentiality
19 agreement with the Non-Party before a determination by the court. Absent a court
20 order to the contrary, the Non-Party shall bear the burden and expense of seeking
21 protection in this court of its Protected Material.

22 23 10. UNAUTHORIZED DISCLOSURE OF PROTECTED MATERIAL

24 If a Receiving Party learns that, by inadvertence or otherwise, it has disclosed
25 Protected Material to any person or in any circumstance not authorized under this
26 Stipulated Protective Order, the Receiving Party must immediately (a) notify in
27 writing the Designating Party of the unauthorized disclosures, (b) use its best efforts
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1 to retrieve all unauthorized copies of the Protected Material, (c) inform the person or
2 persons to whom unauthorized disclosures were made of all the terms of this Order,
3 and (d) request such person or persons to execute the “Acknowledgment and
4 Agreement to Be Bound” that is attached hereto as Exhibit A.

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6 11. INADVERTENT PRODUCTION OF PRIVILEGED OR OTHERWISE
7 PROTECTED MATERIAL

8 When a Producing Party gives notice to Receiving Parties that certain
9 inadvertently produced material is subject to a claim of privilege or other protection,
10 the obligations of the Receiving Parties are those set forth in Federal Rule of Civil
11 Procedure 26(b)(5)(B). This provision is not intended to modify whatever procedure
12 may be established in an e-discovery order that provides for production without prior
13 privilege review. Pursuant to Federal Rule of Evidence 502(d) and (e), insofar as the
14 parties reach an agreement on the effect of disclosure of a communication or
15 information covered by the attorney-client privilege or work product protection, the
16 parties may incorporate their agreement in the stipulated protective order submitted
17 to the court.

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19 12. MISCELLANEOUS

20 12.1 Right to Further Relief. Nothing in this Order abridges the right of any
21 person to seek its modification by the Court in the future.

22 12.2 Right to Assert Other Objections. By stipulating to the entry of this
23 Protective Order no Party waives any right it otherwise would have to object to
24 disclosing or producing any information or item on any ground not addressed in this
25 Stipulated Protective Order. Similarly, no Party waives any right to object on any
26 ground to use in evidence any of the material covered by this Protective Order.

27 12.3 Filing Protected Material. Before filing any pleadings or other
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documents of any nature, including any brief, memorandum, motion, letter, or other document, all or part of which contain material designated “CONFIDENTIAL” or “PROTECTED HEALTH INFORMATION,” the Parties shall confer and seek in good faith to agree on redactions or other accommodations that would permit the filing of such documents in the public record. To the extent that any part of such documents must be redacted or filed under seal, the Party that seeks to file the Protected Material must comply with Civil Local Rule 79-5.2.2(b). No un-redacted pleadings or other documents which contain material designated “CONFIDENTIAL” or “PROTECTED HEALTH INFORMATION” shall be filed in the public record prior to the Court’s ruling on that Party’s application under Local Rule 79-5. If a Party's request to file Protected Material under seal is denied by the court, then the Receiving Party may file the information in the public record unless otherwise instructed by the court.

13. FINAL DISPOSITION

If this Action proceeds to final disposition without trial, then after the final disposition of this Action, as defined in paragraph 4, within 60 days of a written request by the Designating Party, each Receiving Party must return all Protected Material to the Producing Party or destroy such material. As used in this subdivision, “all Protected Material” includes all copies, abstracts, compilations, summaries, and any other format reproducing or capturing any of the Protected Material. Whether the Protected Material is returned or destroyed, the Receiving Party must submit a written certification to the Producing Party (and, if not the same person or entity, to the Designating Party) by the 60 day deadline that (1) identifies (by category, where appropriate) all the Protected Material that was returned or destroyed and (2) affirms that the Receiving Party has not retained any copies, abstracts, compilations, summaries or any other format reproducing or capturing any of the Protected

1 Material. Notwithstanding this provision, Counsel are entitled to retain an archival
2 copy of all pleadings, motion papers, trial, deposition, and hearing transcripts, legal
3 memoranda, correspondence, deposition and trial exhibits, expert reports, attorney
4 work product, and consultant and expert work product, even if such materials contain
5 Protected Material, insofar as Counsel retaining PHI under this provision observe all
6 requirements for, restrictions on, and specifications governing retention of PHI under
7 federal and state law and regulations. Any such archival copies that contain or
8 constitute Protected Material remain subject to this Protective Order as set forth in
9 Section 4 (DURATION).

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11 14. VIOLATIONS

12 Any violation of this Order may be punished by any and all appropriate
13 measures including, without limitation, contempt proceedings and/or monetary
14 sanctions.

1 IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.

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3 DATED: October 11, 2017_____

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27 DATED: October 11, 2017_____

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

1 FOR GOOD CAUSE SHOWN, IT IS SO ORDERED.

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3 DATED: 10/16/2017

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Alicia G. Rosenberg

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Honorable Alicia G. Rosenberg
United States Magistrate Judge

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1 EXHIBIT A

2 ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND

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4 I, _____ [print or type full name], of
5 _____ [print or type full address], declare under penalty of perjury
6 that I have read in its entirety and understand the Stipulated HIPAA Qualified
7 Protective Order that was issued by the United States District Court for the Central
8 District of California on [date] in the case of _____ *United States ex rel.*
9 *Hartpence v. Kinetic Concepts, Inc. et al.*, 2:08-cv-01885-BRO (AGRx). I agree to
10 comply with and to be bound by all the terms of this Stipulated HIPAA Qualified
11 Protective Order and I understand and acknowledge that failure to so comply could
12 expose me to sanctions and punishment in the nature of contempt. I solemnly
13 promise that I will not disclose in any manner any information or item that is subject
14 to this Stipulated HIPAA Qualified Protective Order to any person or entity except in
15 strict compliance with the provisions of this Order.

16 I further agree to submit to the jurisdiction of the United States District Court for the
17 Central District of California for the purpose of enforcing the terms of this Stipulated
18 Protective Order, even if such enforcement proceedings occur after termination of
19 this action. I hereby appoint _____ [print or type full
20 name] of _____ [print or type full address
21 and telephone number] as my California agent for service of process in connection
22 with this action or any proceedings related to enforcement of this Stipulated HIPAA
23 Qualified Protective Order.

24 Date: _____

25 City and State where sworn and signed: _____

26 Printed name: _____

27 Signature: _____