2nd Civil No. **B241684**

IN THE
Court of Appeal
STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT
DIVISION FIVE

POMONA VALLEY HOSPITAL MEDICAL CENTER,

Defendant and Petitioner,

vs.

SUPERIOR COURT OF THE COUNTY OF LOS ANGELES,

Respondent,

APRIL CHRISTINE CABANA,

Real Party in Interest.

Appeal from the Superior Court for the County of Los Angeles
Honorable Michael P. Linfield, Presiding
Superior Court Case No. BC465313

REAL PARTY IN INTEREST'S RETURN TO PETITION FOR WRIT OF MANDATE

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INTRODUCTION

Much blood has been shed by unscrupulous scientists under the guise of "the greater good." Whether scientists from ancient Greece who saw fit to perform fatal experimentations on prisoners; the scientists who deliberately inflicted healthy individuals in Guatemala with syphilis so as to study its effects; or the scientists in Tuskegee, Alabama who neglected to inform African-American patients infected with syphilis of the availability of penicillin so they could continue research on the effects of syphilis - scientists have for centuries engaged in non-consensual experimentation. Despite safeguards instituted to protect patients from such undisclosed scientific experimentation, abuses sometimes still occur. Petitioner Pomona Hospital recently added its own chapter to this dark history when it initiated a secret "research project" to test an investigational/humanitarian medical device, yet, in violation of state and federal laws, it never bothered to inform the test subjects that they were part of a research project. Patients went to the hospital expecting to receive routine surgical treatment and left as unwitting guinea pigs in an uncontrolled clinical trial.

Plaintiff, April C. Cabana, was one of Pomona Hospital's guinea pigs, who suffered debilitating injuries following her experimental procedure. Once Cabana learned about the experimental nature of the product implanted in her (and the criminal action initiated against the device manufacturer), she filed the instant action against Pomona Hospital, the device manufacturers, Stryker Biotech, LLC and Stryker, Inc. (collectively "Stryker"), and the surgeon who performed the surgery, Ali Mesiwala, M.D.

Under federal law, institutions that engage in human experimentation must establish an Institutional Review Board "IRB" whose membership must include *unaffiliated* members from the public and non-scientists. The duty of an IRB is to review research protocols and ensure human subjects are provided with informed consent regarding the experiment and the risks associated with the experimental procedures. The United States Congress mandated IRBs following reports of numerous non-consensual experiments performed on patients by scientists, including the public outcry that ensued following revelation of the Tuskegee Syphilis Study.[1] The

[1] http://en.wikipedia.org/wiki/Tuskegee_syphilis_experiment

purpose of IRBs was to create transparency in human experimentation and to protect the safety and *free-will* of test-subjects.

Cabana served discovery on Pomona Hospital (and other defendants), seeking, *inter alia,* information regarding the hospital's IRB. In response to Special Interrogatories, Pomona Hospital *falsely* stated that its IRB had *not* approved the use of the experimental device at issue. In addition, the hospital refused to produce any of its IRB records claiming all of the records are privileged from discovery by the "peer review" and "medical staff committee" privilege as espoused by Evidence Code Section 1157.

In compelling Pomona Hospital to produce the requested information, including the IRB records, the trial court observed that Section 1157 does not reference IRBs, that no California court has ever extended Section 1157 to cover IRBs, that IRBs are not "peer review" committees since they do not review peers and are not "medical staff committees" because, under federal law, its membership must include non-scientists and at least one person who is "not-affiliated" with the hospital. The court found that the case law that Pomona Hospital had marshaled in its support was distinguishable. The court further observed that case law from other jurisdictions

with similar privilege statutes, including Minnesota, have persuasively held that the records of federally mandated IRBs are not protected by such state medical committee privileges. The trial court thus held that "Evidence Code §1157 does not apply to IRBs" and compelled Pomona Hospital to provide further responses to Plaintiff's discovery.

Pomona Hospital, thereafter, filed the instant petition for a writ of mandamus arguing that the trial court abused its discretion in compelling production of the IRB records. As outlined herein, Pomona Hospital's reliance upon Section 1157 is misplaced and demonstrates a fundamental misunderstanding regarding the history, purpose and policy of the regulations and statutes at issue. Moreover, Pomona Hospital's reliance upon *Santa Rosa Mem'l Hosp. v. Superior Court,* 174 Cal. App. 3d 711 (1985) and *Mt. Diablo Hospital v. Superior Court,* 183 Cal.App.3d 30 (1986) is misguided. *Santa Rosa* held that Section 1157 extends to hospital committees that include "hospital personnel." In this case, however, the federally mandated IRB includes *non-hospital personnel.* Moreover, under federal law, the hospital administration must have an IRB to review research, and *Santa Rosa* confirmed that a hospital administration cannot render

such administration files immune from discovery by simply designating them a medical staff committee. Finally, *Mt. Diablo* is distinguishable because that case involved a true "peer review" committee tasked with determining which physicians should have staff privileges to use a new drug. In this case, Pomona Hospital has conceded that IRBs do not engage in peer review and, thus, *Mt. Diablo* is inapplicable. As such, Pomona Hospital's petition should be denied.

RETURN BY ANSWER TO PETITION FOR WRIT OF MANDATE OR OTHER APPROPRIATE RELIEF

Real party in interest April C. Cabana, in answer to petitioner Pomona Hospital's Petition for Writ of Mandate, admits, denies and alleges as follows:

1. Admits the allegations in paragraph 1 of the Petition.

2. Admits the allegations in paragraph 2 of the Petition.

3. Admits that OP-1 Putty was approved by the FDA under the Humanitarian Device Exemption, admits that Calstrux (a bone void filler) received 510(k) approval, and admits that the FDA has never approved the mixed use of OP-1 Putty and Calstrux.

Except as so admitted and stated, Cabana denies the remaining allegations of Paragraph 3 of the Petition.

4. Because Cabana's Complaint speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's incomplete characterization of her allegations.

5. Admits OP-1 Putty received FDA approval in 2004 as a Humanitarian Use Device (meaning that its efficacy has not been established). Admits that, due to the experimental nature of Humanitarian Use Devices, under federal law, Pomona Hospital's IRB was required to approve the use of OP-1 Putty before it could be implanted in subjects/patients. Except as so admitted and stated, Cabana denies the remaining allegations of Paragraph 5 of the Petition.

6. Because Cabana's Complaint speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's incomplete characterization of her allegations.

7. Because Cabana's Complaint speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's incomplete characterization of her allegations.

8. Because Cabana's interrogatories and requests for production of documents speak for themselves, Cabana neither admits nor denies the accuracy of Pomona Hospital's incomplete characterization of her discovery requests.

9. Admits that Pomona Hospital produced its Medical Staff Bylaws, but denies that the bylaws were produced in response to discovery. Denies that Pomona Hospital "produced all documents and provided all [requested] information" that was not part of the IRB files or proceedings. Except as so admitted and stated, Cabana denies the remaining allegations of Paragraph 9 of the Petition.

10. Because Pomona Hospital's discovery responses speak for themselves, Cabana neither admits nor denies the accuracy of Pomona Hospital's characterization of its responses.

11. Because Pomona Hospital's discovery responses speak for themselves, Cabana neither admits nor denies the accuracy of Pomona Hospital's characterization of its responses.

12. Admits that she filed a motion to compel further responses. Because her motion speaks for itself, Cabana neither

admits nor denies the accuracy of Pomona Hospital's incomplete characterization of her arguments.

13. Admits that she filed a separate statement of items in dispute as required by California Rules of Court. Because her separate statement speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's incomplete characterization of her arguments in the separate statement.

14. Admits that her attorney, Bijan Esfandiari, submitted a declaration and attached documents in support of her motion to compel. Because Esfandiari's declaration and the attached exhibits speak for themselves, Cabana neither admits nor denies the accuracy of Pomona Hospital's characterization of these documents.

15. Admits the allegations in paragraph 15 of the Petition.

16. Admits that Pomona Hospital filed an opposition to the motion to compel. Because Pomona Hospital's opposition speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's characterization of its arguments. Cabana denies that the proceedings and records of the IRB are protected by Section 1157. Cabana admits that Linda Kane submitted a declaration in support of Pomona Hospital's opposition brief. Because Kane's declaration

speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's characterization of Kane's attestation. Cabana specifically denies that the IRB is a legitimate committee of the Medical Staff, denies that "all information pertaining to the investigation performed by the IRB is reflected solely in the records and proceedings of the Medical Staff at the hospital," denies that the only way to provide this information is to review the records and proceedings of the Medical Staff and denies that such disclosure is held to be confidential. Except as so admitted and stated, Cabana denies the remaining allegations of Paragraph 16 of the Petition.

17. Because Pomona Hospital's opposition speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's characterization of its arguments. Cabana denies that Section 1157 extends to federally mandated IRBs or that the information requested by plaintiff falls within the protection of Section 1157.

18. Cabana lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations set forth in paragraph 18, and therefore denies the allegations set forth in paragraph 18 of the Petition.

19. Admits that Pomona Hospital filed its own separate statement in support of its opposition. Because Pomona Hospital's separate statement speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's characterization of its arguments. Cabana denies that the disputed document requests and interrogatories are protected by Section 1157. Except as so admitted and stated, Cabana denies the remaining allegations of Paragraph 19 of the Petition.

20. Admits that she filed a reply brief in support of her motion to compel. Because her reply brief speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's incomplete characterization of her arguments.

21. Admits the allegations in paragraph 21 of the Petition.

22. Admits that the trial court issued a tentative ruling and heard oral argument on plaintiff's motion to compel. Because the trial court's detailed ruling speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's characterization of the trial court's ruling and reasoning. Except as so admitted and stated, Cabana denies the remaining allegations of Paragraph 22 of the Petition.

23. Admits that Pomona Hospital's counsel made arguments during the May 15, 2012 hearing on the motion to compel. Because the oral argument transcript speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's characterization of its arguments. Cabana denies that an IRB is a legitimate committee of the Medical Staff, denies that Section 1157 applies to IRBs, denies that the fact that IRBs are federally mandated and regulated entities "is of no import," and denies that the IRB records and proceedings are immune from review and disclosure. Except as so admitted and stated, Cabana denies the remaining allegations of Paragraph 23 of the Petition.

24. Admits that her counsel made arguments during the May 15, 2012 hearing on the motion to compel. Because the oral argument transcript speaks for itself, Cabana neither admits nor denies the accuracy of Pomona Hospital's incomplete characterization of her counsel's arguments. Except as so admitted and stated, Cabana denies the remaining allegations of Paragraph 24 of the Petition.

25. Admits the allegations in paragraph 25 of the Petition.

26. Admits that Pomona Hospital filed a writ and sought an immediate stay, but denies that the IRB documents are protected by Section 1157 and denies that the trial court's order was in contravention to the purpose and effect of Section 1157. Except as so admitted and stated, Cabana denies the remaining allegations of Paragraph 26 of the Petition.

Real party in interest, April Cabana, alleges the following additional facts:

27. IRBs are federally mandated committees that approve, oversee and monitor human research and experimentation. *See* 21 C.F.R. § 56.109. Federal laws mandate that IRBs must consist of at least five members of varying backgrounds, including at least one member who is not affiliated with the hospital and one who is not a scientist. 21 C.F.R. § 56.107; *see also* 45 C.F.R. § 46.107.

28. Pomona Hospital's IRB consists of at least two lay members of the public who are *not* affiliated with Pomona Hospital. *See* 3 App., Exh. 11 at 672.

29. Pomona Hospital concedes that IRBs do not engage in peer review. *See* 3 App., Exh. 12 at 689-690

30. To ensure transparency, hospitals must, *inter alia*, disclose the names, capacities and affiliations of their IRB members and must disclose the written procedures that the IRB will follow. *See* 45 C.F.R.§46.103(b)(1)-(4).

31. Many California hospitals, including but not limited to, UCLA, USC, Charles R. Drew University, U.C. Irvine, U.C. Riverside and Cal Poly Pomona appreciate that IRBs are not a protected medical staff committee and publicly provide information regarding their respective IRBs, including the names and affiliations of their IRB members and/or the procedures of their IRBs. *See* 1 App., Exh. 4 at 234-237; *see also* 3 App., Exh. 9 at 653.

32. The trial court granted plaintiff's request for judicial notice and took judicial notice of the fact that UCLA and USC list their IRB members on their respective publicly accessible websites. *See* 3 App., Exh. 11 at 669; *see also* 1 App., Exh. 4 at 234-237.

33. The IRB records and proceedings are not confidential but rather, under federal law, FDA and other federal regulators are allowed to examine, review and copy all of the hospital's IRB records, including research proposals, minutes of IRB meetings, IRB correspondence and written procedures. *See* 21 C.F.R. §56.115(b).

34. Pomona Hospital has shared some of its purported privileged internal IRB records with co-defendant Stryker and Stryker recently produced these records to plaintiff in this case. *See* Declaration of Bijan Esfandiari and Attachments 1 - 3 (attached to this brief).

35. In response to discovery, Pomona Hospital *falsely* stated that its IRB had not approved the use of OP-1 Putty. *See* 1 App., Exh. 4 at 149-150. Evidence subsequently produced by co-defendant Stryker confirmed that Pomona Hospital's IRB had indeed approved the use of OP-1 Putty. *See* Attachments 1-3 (attached hereto).

36. Pomona Hospital appears to have been conducting an undisclosed "research project" wherein some patients were being randomized to OP-1 Putty and others placed on other treatment options. See Attachment 1 ("If efficacy is obvious, should ***the research project*** and ***randomization*** be continued?")

37. April Cabana was one of the unwitting subjects in Pomona Hospital's OP-1 Putty "research project." See Attachment 1; *see also* 1 App., Exh. 1 at ¶¶ 90, 193-196.

38. By February 2010, at least 17 test subjects had, like Cabana, been participants in the OP-1 Putty research project. *See*

Attachment 2. In January 2012, Pomona Hospital's OP-1 Putty study was closed to further patient accrual and designated for permanent closure. *See* Attachment 3.

DEFENSES

Real party in interest, April Cabana, alleges the following defenses:

39. The Petition does not state a basis upon which a writ of mandate may be granted.

40. By providing *false* substantive responses to some of the discovery requests at issue, Petitioner has waived its claims of privilege.

41. Petitioner is not entitled to any relief because the Superior Court did not abuse its discretion in holding that Evidence Code Section 1157 does not apply to IRBs and granting Cabana's motion to compel further responses.

PRAYER FOR RELIEF

WHEREFORE Real Party in interest, April Cabana prays for relief as follows:

1. The petition for writ of mandate or other appropriate relief be denied;

2. The Respondent's May 15, 2012 ruling granting plaintiff's motion to compel further responses be affirmed;

3. The immediate stay this Court issued on June 6, 2012 be lifted;

4. The petitioner takes nothing by these writ proceedings;

5. Real party in interest, April Cabana, recovers her costs in this writ proceeding; and

6. This Court grant any other relief it deems just and proper.

DATED: June 29, 2012

Respectfully submitted,

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

By: _____

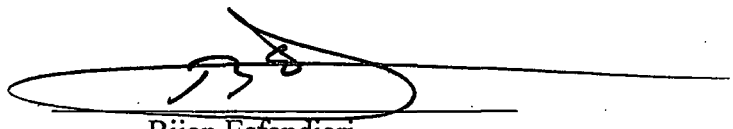
Bijan Esfandiari
Attorneys for Real Party in Interest
APRIL CHRISTINE CABANA

VERIFICATION

I Bijan Esfandiari, declare as follows:

I am one of the attorneys for real party in interest, April C. Cabana. I have read the foregoing Return to Petition for Writ of Mandate and know its contents. The facts alleged in this return are within my own knowledge and I know them to be true. Because of my familiarity with the ruling and facts pertaining to the trial court's proceedings, I, rather than my client verify this return.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this verification was executed on June 29, 2012, at Los Angeles, California.



Bijan Esfandiari

MEMORANDUM OF POINTS AND AUTHORITIES

STATEMENT OF THE CASE

To be legally sold in the United States, medical devices must receive the approval of the Food and Drug Administration ("FDA"). *See* 21 U.S.C. §301 *et seq.* OP-1 Putty is manufactured by Stryker Biotech, LLC ("Stryker") and is part of a family of devices known as Bone Morphogenic Proteins ("BMP") which have the ability to stimulate and regenerate bone growth.[2] 1 App., Exh. 1 at ¶22.[3]

Unlike most devices that receive full pre-market approval after establishing efficacy and safety, OP-1 Putty has only received approval as a Humanitarian Use Device, meaning that it has *not* been shown to be effective and can only be used to treat rare conditions, i.e., conditions afflicting less than 4,000 people annually. *Id.* at ¶19D; 1 App., Exh. 4 at 245; *see also* 21 C.F.R. §814.3(n).

In light of the experimental nature of humanitarian use devices, FDA Regulations mandate that, prior to using a humanitarian use device on patients, the hospital's IRB must review and

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[2] The other BMP that was available on the market during this time is Infuse which is manufactured by co-defendant Medtronic, Inc. Unlike OP-1 Putty, Infuse has received full pre-market FDA approval. 1 App., Exh. 1 at ¶¶64-65.

[3] All citations to the Appendix refer to Pomona Hospital's Appendix submitted with its Petition for Writ.

approve the use of the device, and FDA further recommends that the IRB should ensure that appropriate consent forms regarding the device are provided to patients. 21 C.F.R. §814.124(a); *see also* 1 App., Exh. 4 at 258-259, 262.

Under the applicable FDA rules and regulations, including 21 C.F.R. Sections 814.124, Pomona Hospital's IRB was required to approve the use of OP-1 Putty prior to it being implanted into April Cabana and, as outlined in the applicable FDA Guidance Documents (e.g. 1 App., Exh. 4 at 261-62, 264), the Hospital's IRB should have ensured that adequate consent forms were provided to subjects regarding the use and risks associated with the off-label use of OP-1 Putty.

Pomona Hospital should have informed Cabana that the efficacy of OP-1 Putty had not been approved by the FDA and at the very least, provided her with the OP-1 Putty patient information packet. 1 App., Exh. 4 at 261-62 ("the patient *should always* receive the [humanitarian device] holder's patient information packet.") (emphasis added).

I. Without Informed Consent, Cabana Was Implanted With a Humanitarian Use Device (OP-1 Putty) That Required Advanced IRB Approval

On September 26, 2008, Cabana was admitted to Pomona Hospital to receive surgery on her lower back. 1 App., Exh. 1 at ¶87. Without her consent or knowledge, the primary medical device used during her surgery was the humanitarian use device OP-1 Putty. *Id.* at ¶¶ 87-93. Notwithstanding the fact that, under applicable federal rules and FDA guidance documents, Pomona Hospital was obligated to inform Cabana regarding the experimental nature of her surgery and inform her that the efficacy of OP-1 Putty had never been established (see e.g., 1 App., Exh. 4 at 261-62), Pomona Hospital never undertook any effort to ensure appropriate consent was obtained from Cabana and, indeed, she was never given *any* consent forms or information regarding OP-1 Putty nor the experimental nature of her surgery. 1 App., Exh. 1 at ¶¶ 90, 193-196.

Adding insult to injury, at the recommendation of the Stryker sales representative, Cabana's surgeon, Ali Mesiwala, M.D., proceeded to use OP-1 Putty in an off-label manner (i.e., in a non-FDA approved manner where *safety* had not been established). *See* 1 App., Exh. 1 at ¶¶87-93. Specifically, in performing the surgery, at

the direction of Stryker, Dr. Mesiwala mixed OP-1 Putty with another Stryker product called Calstrux – the safety of the mixed use of Calstrux and OP-1 Putty had never been established.

Stryker knew the mixed use of Calstrux and OP-1 Putty can lead to the migration and development of unwanted bone growth. *Id.* The mixed use of OP-1 Putty and Calstrux eventually resulted in the formation and migration of excess bone growth in Cabana's lower back which compressed her nerves and required a second remedial surgery that was again performed at Pomona Hospital. *Id.*[4]

II. Recently Produced Discovery Reveals that Cabana (Along with Other Human Subjects) Was an Unwitting Guinea Pig in Pomona Hospital's "Research Project"

When Cabana initially filed her lawsuit, she believed her case was an isolated incident at Pomona Hospital. However, IRB documents recently produced by co-defendant Stryker appear to reveal that Pomona Hospital was conducting a non-consensual and uncontrolled clinical trial at the hospital wherein some patients/ subjects were randomly placed on OP-1 Putty and others randomly placed on other products so that Pomona Hospital and its

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[4] April Cabana has never recovered from her surgeries and, despite being only 34-years-old, she is currently on permanent disability and still requires additional curative surgeries. 1 App., Exh. 1 at ¶98.

researchers could analyze the results. In January 2009 (prior to the revelation of Cabana's injuries) the researchers apparently informed Pomona Hospital's IRB that the research looked promising and OP-1 Putty appeared to be effective on the test subjects. In response, the Pomona Hospital IRB asked "If efficacy is obvious, should ***the research project*** and ***randomization*** be continued?" See Attachment 1 (emphasis supplied).[5] By February 2010, a total of 17 patients had been enrolled in the OP-1 Putty research study (see Attachment 2) and, in January 2012, the research study officially terminated.[6] See Attachment 3.

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[5] Pursuant to Rule of Court 8.204(d), copies of these recently produced Pomona Hospital IRB records are attached to this brief as Attachments 1 through 3. These IRB records were produced to Plaintiff by co-defendant Stryker on or about May 30, 2012 (two-weeks *after* the trial court had ruled on Plaintiff's motion to compel). Given that writs, unlike appeals, are an original proceeding, the Court of Appeal may properly consider new information that was not presented to the trial court. *See McCarthy v. Superior Court*, 191 Cal. App. 3d 1023, 1031, n.3 (1987) ("Although the Veit declaration was not before respondent, on an original petition for mandamus relief, the reviewing court in its discretion may consider it together with all other relevant evidence."); *Bruce v. Gregory*, 65 Cal. 2d 666, 670-71 (1967) ("It has been held that a judge hearing a mandamus proceeding may properly consider, in deciding whether to issue a peremptory writ, all relevant evidence, including facts not existing until after the petition for writ of mandate was filed.") Given that these IRB records were not produced to plaintiff until *after* the trial court had ruled upon plaintiff's motion to compel, this Court may in its discretion rely upon these newly produced IRB records.

[6] Curiously, Pomona Hospital's IRB must have been aware that some test subjects/patients must have suffered injuries from the use of the

Contrary to being an isolated patient, Cabana was apparently one of at least 17 unwitting guinea pigs who had been participants in Pomona Hospital's "research project." See Attachments 1 & 2.

III. Stryker Biotech Sales Representatives Have Pled Guilty to Falsifying IRB Records and Promoting OP-1 Putty for Illegal Off-Label Uses

The manufacturer of OP-1 Putty, co-defendant Stryker, employed a team of approximately 30 sales representatives and, to date, some of its sales representatives, including a Southern California sales representative, have pled guilty to various *felonies* arising out of their illegal off-label promotion of OP-1 Putty (i.e., promoting OP-1 Putty to be mixed with Calstrux). 1 App., Exh. 1 at ¶¶57-58. One of these representatives pled guilty to falsifying the IRB records from a Wisconsin hospital in order to make it appear that the hospital's IRB had approved the use of OP-1 Putty. 1 App., Exh. 4 at 269-273.[7]

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experimental OP-1 Putty devices since the IRB asks the researcher: "How are *the other* patients doing generally?" See Attachment 3 (emphasis added).

[7] This "Agreed Statement of Facts" was executed at a time in which the U.S. government was still investigating the manufacturer Stryker and, thus, to preserve the integrity and secrecy of the investigation, the document does not name Stryker or OP-1 Putty but rather refers to them by code. Stryker has since confirmed in discovery responses that Darnell Martin was one of its employees who pled guilty to a felony.

PROCEDURAL HISTORY

In light of the fact that OP-1 Putty is a humanitarian device requiring IRB approval, the fact that Pomona Hospital's IRB failed to provide her with any consent forms or information regarding OP-1 Putty and the fact that Stryker sales representatives had *pled guilty* to falsifying IRB records and engaging in illegal off-label promotion of OP-1 Putty, Cabana naturally sought from Pomona Hospital various information, including the hospital's communications with Stryker as well as information regarding its approval of OP-1 Putty. Specifically, Cabana questioned Pomona Hospital on the following topics:[8] (a) whether the hospital informed the FDA or Stryker Biotech regarding the device-related adverse events plaintiff suffered (Interrogatory Nos. 35-40); (b) communications between the hospital and Stryker regarding Stryker's OP-1 Putty device (Interrogatory Nos. 63-66; and RFP Nos. 1, 4, 5, 6, 7, 9); (c) communications between the hospital and co-defendant Ali

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[8] All of plaintiffs' discovery requests (and Pomona's Responses) are reproduced in the Petitioner's Appendix. 1 App., Exh. 4 at 128-174 (Interrogatories) and 1 App. Exh. 4 at 178-213 (Request for Documents). The specific discovery requests that were the subject of the motion to compel are delineated (and grouped into appropriate categories) in Plaintiff's Separate Statement filed with the trial Court. *See* 1 App. Exh. 3 at 74-123.

Mesiwala, M.D. regarding the use of OP-1 Putty (Interrogatory No. 79-84; and RFP Nos. 20, 23-29, 38); (d) the hospital's Institutional Review Board ("IRB") approval of OP-1 Putty (Interrogatory Nos. 85-98, 102-104; and RFP Nos. 58-61); (e) the prior use of OP-1 Putty at the hospital (Interrogatory Nos. 110-118); (f) the policies and procedure in effect at the hospital regarding use of devices and obtaining patient consents (Interrogatory Nos. 121-122; RFP Nos. 62-76); and (g) documents in the hospital's possession regarding April Cabana and the devices used on her (RFP No. 51, 53, 55, 81, 84-86, 90, 102-104). In response to all of these requests, Pomona Hospital lodged objections claiming the responsive documents were privileged from discovery pursuant to *Evidence Code* Section 1157. *See* 1 App., Exh. 4 at 128-174 (Interrogatories); and 1 App. Exh. 4 at 178-213 (Request for Documents).

While Pomona Hospital asserted its Section 1157 objections, it did provide substantive responses to some of these requests. Most notably, in response to the question of whether its IRB had ever approved OP-1 Putty, Pomona Hospital responded "No":

> **Special Interrogatory No. 85 to Pomona Hospital:** Has YOUR IRB approved the use of OP-1 Putty?

> **Pomona Hospital's Response to Special Interrogatory No. 85:** Defendant objects to this interrogatory as being vague, ambiguous and unintelligible given the definition of YOU making any meaningful response thereto impossible. Defendant objects to this interrogatory as calling for information maintained exclusively by the Institutional Review Board, an organized committee of the medical staff of Pomona Valley Hospital Medical Center. Such information is immune from discovery pursuant to California Evidence Code §1157. Without waving the forgoing objections and subject thereto, **no.**

See 1 App., Exh. 4 at 149-150. Pomona Hospital's response that it had not approved the use of OP-1 Putty was significant given that, as previously mentioned, Stryker's sales representative had pled guilty to falsifying various hospitals' IRB approval records and Pomona Hospital's Interrogatory response made it appear as if it was possibly another victim of Stryker's IRB fraud. This response has since proven to be false.[9] As to many of the remaining requests

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[9] In response to a similar Interrogatory, Stryker stated that Pomona Hospital had approved the use of OP-1 Putty. During oral argument, even the trial Court was perplexed at the conflicting responses given to this interrogatory. 3 App. Exh. 12 at 685-686. Documents produced by Stryker following oral argument have confirmed that Pomona Hospital's IRB had indeed approved and on multiple occasions renewed the approval of the use of OP-1 Putty for a "research project" involving the use of OP-1 Putty on human patients/test subjects. *See* Attachments 1 through 3 (attached to this brief). Thus, it appears that Pomona Hospital provided a false verified response to Plaintiff's Interrogatory No. 85. The fact that Pomona Hospital provided a *false* substantive response to this (and other similar interrogatories) constitutes a potential waiver of Pomona Hospital's Section 1157 objections.

at issue, Pomona Hospital failed to provide any substantive responses or responsive documents and claimed that all of the requested information was protected by Section 1157.

Cabana, thereafter, moved to compel Pomona Hospital to provide responses and produce the responsive documents. In her papers, Cabana argued that Pomona Hospital's Section 1157 objections were not well taken given (a) an IRB is not among the list of committees and medical organizations delineated in Section 1157; (b) that, despite multiple amendments (including amendments in 1975, 1978, 1982, 1983, 1985, 1990, 1994, 2000 and 2011), the California legislature never once added IRBs to the list of entities governed by Section 1157; (c) that no California Court has ever extended Section 1157 to cover IRBs; (d) an IRB is not a "peer review" committee because it does not engage in the review of peers; (e) an IRB is not a "medical staff" because it is a federally mandated committee and, under federal regulations, at least one of the IRB members must be a non-scientist and one member must be *unaffiliated* with the hospital; (f) Pomona Hospital's IRB cannot have any expectation of confidentiality as to the documents sought by plaintiff because, under law and by practice, many of the requested

documents have already been disclosed to unaffiliated third parties or are accessible to third parties;[10] (h) Section 1157 applies to medical staff committees that are organized to *evaluate and improve the quality of medical care rendered* at the hospital and the federally mandated IRB (which as outlined *supra* is not a medical staff committee), is not tasked with improving the quality of medical care, rather, the federal government mandated IRBs to protect subjects of human experimentation; (i) that other California hospitals, including UCLA, USC, Charles R. Drew University in Los Angeles, U.C. Irvine, U.C. Riverside and Cal Poly Pomona do not consider IRBs to be a protected medical staff committee and publicly provide information regarding their respective IRBs, including the names of IRB members and/or the procedures of their IRBs; and (j) Pomona Hospital's claims of privilege conflict with applicable California and federal laws which have been enacted to protect patients' rights by mandating greater transparency and disclosure between researchers

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[10] By way of example, Stryker was in possession of some of Pomona Hospital's internal IRB records and, following the trial court's ruling, Stryker produced the IRB documents in its possession custody and control. *See* Attachments 1 through 3 (attached to this opposition brief). Moreover, under federal law, the FDA is permitted unfettered access to hospital IRB records. See 21 CFR §56.115(b).

and patients. *See* 1 App., Exh. 2 at 55-73; and 3 App., Exh. 9 at 647-658.

Pomona Hospital did not dispute most of Cabana's arguments. Indeed, Pomona Hospital *conceded* that: IRBs are not delineated in Section 1157; no court has extended Section 1157 to IRBs; IRBs do not engage in peer-review; IRBs are federally mandated committees; its IRB contains two *unaffiliated* non-scientist members; and other California hospitals publicly provide the IRB information which Pomona Hospital claims is protected. Rather, Pomona's only argument appeared to be that, because it listed its federally mandated IRB as part of its medical staff committee, its IRB records should be immunized from discovery, and this has allowed Pomona to make patently false statements in response to Interrogatories.

Following a detailed review and analysis of the party's arguments, the trial court noted that this is an issue of first impression under California law. The court held that the cases on which Pomona Hospital relied did not support its arguments. 3 App., Exh. 11 at 671. The court further held that Pomona Hospital's factual statements (including statements regarding the makeup of its IRB) were not fully accurate and "designed to mislead the Court."

Id. at 672. This being an issue of first impression under California law, the court found persuasive the cases from other jurisdictions which had addressed similar privilege issues dealing with IRBs (see *Id.* at 669-671), and in a detailed and cogent opinion, the court held that "Evidence Code §1157 does not apply to IRBs and accordingly, the plaintiff's motion to compel further responses is GRANTED." *Id.* at 672.

Pomona Hospital filed the instant petition for writ claiming that the trial court abused its discretion in refusing to extend the privilege afforded by Section 1157 to federally mandated IRB records. For the reasons outlined herein, Pomona Hospital's writ should be denied and this Court should affirm the trial court's ruling.

STANDARD OF REVIEW

As Pomona Hospital concedes, discovery orders are reviewed for an abuse of discretion. *See* Writ at 21; *see also Crab Addison, Inc. v. Superior Court*, 169 Cal. App. 4th 958, 965 (2008). The Supreme Court defines abuse of discretion as follows:

> Discretion is abused whenever, in its exercise, the court exceeds the bounds of reason, all of the circumstances before it being considered. The burden is on the party complaining to establish an abuse of discretion, and

> unless a clear case of abuse is shown and unless there has been a miscarriage of justice a reviewing court will not substitute its opinion and thereby divest the trial court of its discretionary power.

Denham v. Superior Court, 2 Cal. 3d 557, 566 (1970). With respect to claims of privilege, the Supreme Court has held: "When the facts, or reasonable inference from the facts, shown in support of or in opposition to the claim of privilege are in conflict, the determination of whether the evidence supports one conclusion or the other *is for the trial court*, and a reviewing court may not disturb such finding if there is any substantial evidence to support it." *D. I. Chadbourne, Inc. v. Superior Court*, 60 Cal. 2d 723, 729 (1964) (emphasis added). The party resisting discovery carries the burden of showing that the evidence it seeks to suppress is within the terms of the statute. *Id.*; *see also Brown v. Superior Court*, 168 Cal. App. 3d 489, 500-01 (1985). Pomona Hospital has failed to meet its demanding burden of demonstrating that the trial court abused its discretion in holding that the records of the hospital's IRB are not governed by Evidence Code Section 1157.

ARGUMENT

I. The History and Formation of IRBs

A. IRBs Were Initially Mandated in 1974 by the National Research Act to, Among Other Things, Ensure That Appropriate Consent Forms Were Obtained From Human Subjects

It has been said that "it is the pursuit of right that lures men wrong"[11] and a cursory review of the history of science reveals that a minority of physicians have engaged in great atrocities in the name of science and "the greater good." From the early contributors of science, such as the First Century Roman physician, Aulus Cornelius Celsus, who thought it appropriate to conduct life threatening scientific experiments on criminals,[12] to the Twentieth Century Nazi physicians, who performed criminal and inhumane experimentation on Jewish inmates, both well-intentioned and evil-minded physicians have engaged in non-consensual experimentations on human subjects. Unfortunately, such atrocities are not limited to antiquity and war criminals, but also involve American physicians and institutions, including for example Roberts Bartholow a physician at

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[11] Jalal al-Din Rumi, *The Soul of Goodness in Things Evil* (circa 1264).

[12] CELSUS, DE MEDICINA (B.C. 47) ("It is not cruel to inflict on a few criminals sufferings which may benefit multitudes of innocent people through all centuries.")

Good Samaritan Hospital in Cincinnati who in 1874 utilized deadly, untested and unconventional procedures to treat patients with cancer; the 1941 University of Michigan study wherein patients without consent were administered influenza to study its effects; the 1962 Jewish Chronic Disease Hospital study in Brooklyn, New York wherein unknowing patients were administered cancer cells to study its results; and the well-documented 1932-1972 Tuskegee Syphilis Study performed by the U.S. Public Health Service, wherein African-American patients infected with syphilis were not informed of the availability of penicillin for treatment of the illness (so the doctors could continue research on the effects of the illness).[13] *See Grimes v. Kennedy Krieger Institute, Inc.*, 366 Md. 29, 43-45 (2001) (discussing history of non-consensual medical research).

These and other similar non-consensual experimentations caused Congress to introduce legislation to protect patients and research subjects. In that regard, in 1974 Congress passed the National Research Act[14] which, among other things, required that all

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[13] Curan W.J., *The Tuskegee Syphilis Study*, 289 NEW ENGLAND JOURNAL OF MEDICINE 730 (1973).

[14] Pub. L. No. 93-348, 88 Stat. 342 (1974) (codified as amended at 42 U.S.C. § 289).

hospitals, universities and institutions engaged in research establish an Institutional Review Board ("IRB") to serve as an oversight entity to ensure that patients/subjects were not subjected to non-consensual procedures. The main function of the IRB is to assess the protocols of the project, determine whether the consent procedures are adequate, and review the potential safety and health hazard impact of the project on patients. *Grimes*, 366 Md. at 39-40 ("An IRB's primary role is to assure the safety of the human research subjects"); *see also Konrady v. Oesterling*, 149 F.R.D. 592, 594 (D.Minn. 1993) (same).

B. Federal Regulations Govern the Composition and Duties of IRBs Which Include Regulations Mandating that IRBs Be Staffed With Non-Scientists and Non-Hospital Affiliated Members

To ensure the goals of the National Research Act are met, the FDA and the Department of Health and Human Services set detailed rules regarding the implementation and expectations of IRBs. Specifically, to truly ensure the safety of patients, the IRB is required to include at least five members of varying backgrounds *including one member who is **not affiliated** with the hospital* and one whose primary concern is ***non-scientific***. 21 C.F.R. §56.107(a)-(c); *see also* 45 C.F.R. §46.107.

C. To Ensure Transparency, Federal Rules Mandate That Hospital's Publicly Disclose the Names and Affiliations of Their IRB Members

To ensure transparency, the hospital/university must publicly disclose the names, capacities and affiliations of its IRB members and must disclose the written procedures the IRB will follow. *See* 45 C.F.R.§46.103(b)(1)-(4) (mandating that hospital IRBs provide to the federal government the names of their IRB members, the written procedures the IRB will follow and other relevant information); *see also* 21 C.F.R. §56.115(a)(5). In that regard, many California hospitals including UCLA and USC publicly disclose on their respective websites the names of their IRB members and further identify which members are non-scientists and non-affiliated members. 1 App., Exh. 4 at 234-237.[15] For example, the USC IRB includes as its non-scientist and non-affiliated member, a prisoner-advocate attorney.

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[15] At Plaintiff's request, the Court took judicial notice of the fact UCLA and USC publicly list the names of their IRB members. *See* 3 App., Exh. 11 at 669 ("Plaintiff's request for judicial notice is GRANTED.") Moreover, as outlined in Cabana's reply brief to the trial court, in addition to UCLA and USC, other Southern California hospitals, including but not limited to, Charles R. Drew University in Los Angeles, U.C. Irvine, U.C. Riverside and Cal Poly Pomona also publicly disclose information (including membership information and standard operating procedures) regarding their respective IRBs. *See* 3 App., Exh. 9 at 653.

Id. at 237.[16] These IRB regulations as proven by the conduct of UCLA, USC and other California hospitals demonstrate that the IRB is not intended to be a cloister or a secret society but is a transparent entity that is subject to scrutiny and federal oversight. *See* 21 C.F.R. §56.115(b) (mandating that hospital IRB records, including minutes, be subject to inspection and copying by FDA and federal regulators); *see also Esdale v. Am. Cmty. Mut. Ins. Co.*, 1995 WL 263479, *4 (N.D. Ill. May 3, 1995) (IRB records are subject to public and federal scrutiny) (available in the Appendix at 2 App., Exh. 5 at 280).[17]

II. Evidence Code Section 1157 Does Not Apply to Federally Mandated IRB Records

Pomona Hospital's reliance upon Evidence Code Section 1157 to shield the IRB records and other requested documents is misplaced. Section 1157 provides in relevant part:

> Neither the proceedings nor the records of organized committees of *medical...staffs* in hospitals, or of a *peer review* body, as defined in Section 805 of the Business

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[16] Pomona Hospital has taken the extreme position that, even the names of its IRB members as well as the operating procedures for its IRB are privileged from discovery.

[17] It is worth emphasizing that under federal law, the FDA has every right to investigate, review and copy Pomona Hospital's internal IRB records, including minutes, procedures and study protocols. *See* 21 C.F.R. §56.115(b). Pomona Hospital certainly cannot assert Section 1157 privilege against the FDA investigators and thus it makes no sense why it should be allowed to assert it against plaintiff.

> and Professions Code having the responsibility of evaluation and improvement of the quality of care rendered in the hospital, or for that peer review body, or medical or dental review... *having the responsibility of evaluation and improvement of the quality of care,* shall be subject to discovery.

Evid. Code § 1157 (emphasis added). As the Hospital concedes, the statute does not make any reference to IRBs, yet the hospital wants to expand the statute to include IRBs. This is an impermissible expansion of the statute and conflicts with California's statutory interpretation protocols. Second, the statute provides that only "peer review bodies" or "medical staff committees" that have *"the responsibility of evaluation and improvement of the quality of care"* are protected by the privilege. Pomona Hospital concedes that the IRB does not perform peer review and solely relies upon the "medical staff committee" prong. However, as outlined herein, because the IRB is a federally mandated committee that *must* include *unaffiliated* non-scientists, it does not qualify as a "medical staff committee." Finally, as Pomona Hospital concedes, the purpose of the IRB is to evaluate "research" (see Petition for Writ at 2) and, thus, the IRB is not really concerned with the evaluation and improvement of the quality of care but rather is purely concerned with protecting

research subjects and ensuring that researchers comply with federal guidelines regarding human experimentation and informed consent.

A. Evidence Code Section 1157 Does Not Make Any Reference to IRB Records and, Under Established California Law, "Courts May Not Add to the Statutory Privileges"

Under California's liberal discovery statute, "information is discoverable if it is unprivileged and is either relevant to the subject matter of the action or reasonably calculated to reveal admissible evidence." *Valley Bank of Nevada v.* Superior *Court,* 15 Cal. 3d 652, 655–656 (1975); *see also* Code Civ. Proc., § 2017.010. Rules creating discovery privileges "are strictly statutory" and cannot be judicially espoused and "[c]ourts may not add to the statutory privileges." *Am. Airlines, Inc. v. Superior Court,* 114 Cal. App. 4th 881, 887 (2003). Importantly, "[t]he party claiming a privilege shoulders the burden of showing that the evidence it seeks to suppress falls within the terms of an applicable privilege statute." *L.A. Unified Sch. Dist. v. Trustees of the S. California IBEW-NECA Pension Plan,* 187 Cal. App. 4th 621, 628 (2010); *see also Brown,* 168 Cal. App. 3d at 500-501. Finally, under California law, the general rule is that "privileges are to *be narrowly construed* ... because they operate to prevent the admission of relevant evidence and impede the correct determination of

issues." *L.A. Unified Sch. Dist.*, 187 Cal. App. 4th at 630-31 (emphasis added); *Greyhound Corp. v. Superior Court*, 56 Cal. 2d 355, 377, 396 (1961) (same).

B. Neither the California Legislature Nor California Courts Have Ever Applied Nor Intended to Apply Section 1157 to IRB Records

Applying the foregoing statutory construction to Evidence Code Section 1157 reveals that the California legislature never intended to apply Section 1157 to IRBs. *First*, while Evidence Code Section 1157 has been amended multiple times, including in 1975, 1978, 1982, 1983, 1985, 1990, 1994, 2000, and 2011, through all of these revisions (which added various medical review bodies to the scope of the privilege), never once did the California legislature include IRBs as part of the board/bodies governed by the statute.[18] As previously mentioned, Congress mandated the formation of IRBs in 1974. Certainly, if the California legislature intended to include IRBs amongst the entities covered by Section 1157, the legislature had multiple opportunities to do so, but never did. *Second*, no California court has ever extended Section 1157 to IRBs. *Finally*, the application of the principle of statutory construction, *expressio unius*

[18] *See* 1 App., Exh. 4 at 276 (summarizing each of the amendments to Section 1157).

est exclusio alterius, precludes the expansion of the limited privilege afforded by Section 1157. Under that canon of statutory construction, "where exceptions to a general rule are specified by statute, other exceptions are not to be implied or presumed..." *People v. Galambos,* 104 Cal. App. 4th 1147, 1161 (2002). Here, Section 1157 creates an exception to the general rule permitting discovery and delineates *specific* medical bodies which are privileged from discovery and, each time the legislature has sought to add a new medical body to the statute, it has amended the statute to name the new medical body. The fact that IRBs are not part of the list of medical bodies identified in the statute (and never included amongst the multiple amendments) confirms that it was not meant to be covered by the statute. *See e.g. Esdale,* 1995 WL 263479 at * 4 ("If the Texas legislature had intended to include institutional review boards within the scope of the confidentiality statutes, the legislature would have expressly so provided").

C. IRBs Are Not "Medical Staff" or "Peer Review" Committees

The hospital insists that, while Section 1157 does not specifically identify IRBs and, while no court has extended Section 1157 to include IRBs, they are covered by the statute's reference to

hospital "*medical...staffs.*" EVID. CODE § 1157. Pomona Hospital's arguments are factually and legally flawed. First, the IRB is not a "medical staff" because, as mandated by the applicable federal rules and regulations, the IRB must include at least one "non-scientist" and at least one person who is "not-affiliated" with the hospital. The inclusion of a "non-affiliated" person takes the IRB outside of the "medical staff" category because its members by law are not all "medical staff" and are not all affiliated with the hospital. 21 C.F.R. §56.107(a)-(c).[19]

Thus, from a purely textual perspective, the federally mandated inclusion of non-scientists and unaffiliated members removes an IRB from the "medical staff" umbrella given that an IRB's membership is *not* entirely composed of *medical* professionals or *staff* members. Pomona Hospital seeks to sidestep this factual and textual hurdle by marshalling in the self-serving declaration of its Medical Staff Coordinator, Linda Kane, and its 2007 Medical Staff Bylaws. 3 App., Exh. 8 at 460-464. Rather than support its position,

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[19] Section 1157 also protects peer review bodies. However, Pomona Hospital has since conceded that the IRB is not a peer review body (see 3 App., Exh. 12 at 689-690) and case law from other jurisdictions has confirmed that an IRB does not engage in "peer review." *Konrady*, 149 F.R.D. at 598 ("An IRB, on the other hand, does not have *peer* review as its purpose").

the Kane declaration simply demonstrates Pomona Hospital's lack of candor with the court and that the Bylaws actually lend further support to Plaintiff's arguments.

In her declaration, Kane cited the Bylaws and sought to convince the Court that the Pomona Hospital IRB consists of a purely medical staff committee by stating that the IRB members consist of "physicians, representatives of the Board of Directors, Hospital Administration, Nursing Administration and the Director of Pharmacy." *See* 3 App., Exh. 8 at 463 (¶4(b)). Reading Kane's declaration, one gets the impression that the IRB is composed of nothing but medical staff members who are all affiliated with the hospital. However, a closer examination of the Bylaws confirms that Kane's declaration is a half-told tale. Rather, the Bylaws confirm (what plaintiff argued all along) that the Pomona Hospital IRB includes "at least two (2) lay persons from the community." See 3 App., Exh. 8 at 612-613. The membership of the two lay community members is completely absent from Kane's declaration and was a not-so-subtle attempt by Pomona Hospital to mislead the trial court into thinking the IRB is completely composed of medical staff. Notably, in its ruling, the trial court noted that Pomona Hospital's

arguments in this regard were "designed to mislead the Court." See 3 App., Exh. 11 at 672.

Second, the Hospital's Bylaws define the term "Medical Staff" as follows: "MEDICAL STAFF or STAFF means the formal organization of *all licensed physicians, dentists, and podiatrists who are privileged to attend patients* in the Hospital." See 3 App., Exh. 8 at 474 (emphasis added).[20] Again, even Pomona Hospital appreciates that the term "medical staff" means affiliated medical professionals and thus participation of *unaffiliated* lay persons in the IRB removes it from the "medical staff" umbrella. Tellingly, to date, Pomona Hospital has failed to cite a single case in which a court extended Section 1157 to a federally mandated medical staff committee that included *unaffiliated* lay community members as part of its roster.

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[20] In that regard, the California legislature has also defined the term "Medical Staff" as consisting of medical professionals. *See* CAL. CODE REGS. TIT. 22, § 70703 ("the medical staff shall be composed of physicians...") and, while California case law has extended this term to include other *medical professional employees* of the hospital (e.g. nurses), *see Santa Rosa Memorial Hosp. v. Superior Court,* 174 Cal. App. 3d 711 (1985), no California case or statute has ever defined the term to include unaffiliated non-medical lay persons.

D. IRBs Are Charged With Protecting the Rights of *Human Subjects* and Thus Are Not Organized to Evaluate and Improve the Quality of Medical Care

Finally, Section 1157 only applies to medical staff committees that are organized to *evaluate and improve the quality of medical care rendered* at the hospital. *See* Evid. Code §1157. The IRB (which as outlined *supra* is not a medical staff committee), is not tasked with improving the quality of medical care, rather, the role of the federally mandated IRB is to protect subjects of human experimentation (which are not limited to hospital patients, but include, *inter alia,* prisoners, institutional inmates and volunteer subjects). *Konrady,* 149 F.R.D. at 596 (IRBs are concerned with human research and not evaluating patient care, and thus holding IRB records are not privileged by Minnesota's medical organization privilege); *Grimes,* 366 Md. at 39; *see also* 1 App., Exh. 4 at 224.

Konrady is instructive. There, the *district* court was tasked to determine whether IRB records were privileged by a Minnesota privilege statute which, like California's Section 1157, protected the records of a medical committee whose purpose is "evaluating and improving the quality of health care." *Konrady,* 149 F.R.D. at 594

(quoting MINN. STAT, §145.61).[21] The district court held that the IRB had a "differing purpose" than the committees protected by the Minnesota statue because the IRB was not concerned about "the improvement of patient care" but rather was focused on the "protection of human subjects." Thus, the district court held that the IRB records were not protected by the privilege statute. *Konrady*, 149 F.R.D. at 595-97.

III. Pomona Hospital's Authorities Are Irrelevant and Its Lead Case Supports Cabana's Position

The case law Pomona Hospital relies upon is inapposite and irrelevant. First, none of the cases concern the issue of IRBs. Second, none hold that Section 1157 applies to IRBs. Third, none of the cases ever applied Section 1157 to a committee or entity that includes lay members of the public. Finally, the primary cases on which Pomona Hospital relies, *Santa Rosa Mem'l Hosp. v. Superior Court*, 174 Cal. App. 3d 711 (1985), actually support Cabana's arguments.

Santa Rosa concerned the deposition of a hospital nurse who also served on the hospital's infection control committee. The Court

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[21] The Minnesota privilege statute in this regard is nearly identical to California's Section 1157. *Compare* Minn. Stat, §145.61 (protecting a committee that is charged with "evaluating and improving the quality of health care.") *with* Evid. Code §1157 (protecting committee charged with "evaluation and improvement of the quality of care").

of Appeal held that Section 1157 extends to hospital "nurses" who serve on a proper medical staff committee. Notably, the Court emphasized that Section 1157 extends to committees that include "*hospital personnel.*" *Santa Rosa,* 174 Cal. App. 3d at 718. In our situation, however, the IRB consists of *non-hospital affiliated* lay members and, thus, even under *Santa Rosa,* Section 1157 is inapplicable.

More importantly, the *Santa* Rosa Court took care to hold that a hospital may not avoid discovery by simply transferring ordinary hospital administration functions to a medical staff committee:

> [A] hospital cannot render its files immune from discovery simply by disclosing them to a medical staff committee. Hospital administrators cannot, in other words, evade their concurrent duty to insure the adequacy of medical care provided patients at their facility-the duty articulated in *Elam*-simply by purporting to have delegated that entire responsibility to medical staff committees.

Santa Rosa Mem'l Hosp., 174 Cal. App. 3d at 724. The Court went on to note that the "the responsibilities of hospital administrators are independent of those resting with medical staff committees" *see id.,* and held that because, under law, "the hospital *as a corporate entity* must establish and implement an adequate infection control program," it cannot immunize such records from discovery, *see Id.* at 725, and that only the records of a legitimate hospital medical staff

committee that is set up to "monitor the effectiveness" of the infection control program are immune under Section 1157. *Id.* Applying the foregoing to this case, federal law mandates that hospitals as corporate entities must establish IRBs to oversee human research and, thus, under *Santa Rosa*, the files and records of the IRB are not governed by Section 1157 and are not immune from discovery.[22] Moreover, many of the documents Pomona refuses to produce pertain to basic hospital administration. By way of example, Pomona refuses to produce the policies and procedures in effect at the hospital regarding obtaining IRB approval. See 1 App., Exh. 4 at 196-201 (Request for Document Nos. 62-76). Federal regulations mandate that hospitals must publicly disclose and provide written assurances regarding their IRB policies, procedures and codes of conduct and disclose the names of their IRB members to the U.S. Department of Health and Human Service. *See* 45 C.F.R.

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[22] This point is further bolstered by the fact that, under federal regulations, hospitals may choose to hire *an outside* entity to perform their IRB functions. See 1 App., Exh. 4 at 224 (¶6). The fact that an independent outside entity can perform a hospital's IRB function further confirms that the IRB is not truly a committee of the "medical staff." Thus, for example, if Pomona Hospital had exercised its option to utilize an outside entity to perform its IRB duties, that independent outside entity could not assert the Section 1157 privilege - and neither should Pomona Hospital be able to assert it in this case.

46.103(b)(1)-(5). These are the federally mandated responsibilities of the hospital's administration. Under the reasoning of *Santa Rosa,* the fact that Pomona Hospital has chosen to delegate this task to a purported "medical committee" does not immunize such documents from discovery.[23] *Santa Rosa Mem'l Hosp.*, 174 Cal. App. 3d at 724.

Pomona Hospital also relies extensively upon *Mt. Diablo Hospital v. Superior Court,* 183 Cal. App. 3d 30 (1986) to support its contention that IRB records are protected by Section 1157. *Mt. Diablo* is inapposite. In *Mt. Diablo,* the hospital created an ad hoc committee to determine which physicians should receive privileges to use a new drug called Chymopapain to treat patients. *Mt. Diablo,* 183 Cal. App. 3d at 33. The hospital (unlike Pomona Hospital) produced its standard operating procedures for this ad hoc committee but refused to produce the committee's minutes. *Id.* The Court of Appeal held that the minutes of the committee were protected by Section 1157. *Mt. Diablo,* 183 Cal. App. 3d at 35. *Mt. Diablo* is

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[23] Federal law also mandates that hospitals submit device adverse event reports for serious injuries to device manufacturers or the FDA. *See* 21 C.F.R. 803.30(a)(2). Cabana's requests asked whether Pomona submitted any adverse event reports regarding Cabana's serious injuries to either Stryker or the FDA as it was obligated to do under federal law. Pomona Hospital asserted that any information regarding such mandatory hospital administrative tasks are immune from discovery. See 1 App., Exh. 3 at 76-80.

distinguishable. First, the committee at issue in *Mt. Diablo* was akin to a traditional peer review committee in that the committee was not determining whether the drug should be used, but rather was determining *which physicians* should be permitted to use the drug. *Mt. Diablo,* 183 Cal. App. 3d at 33. Thus, the committee's focus in *Mt. Diablo* was on physician privileges and not product approval. Second, *Mt. Diablo* did not involve an investigation or humanitarian use device and thus did not involve the IRB. Rather, the ad hoc committee in *Mt. Diablo* was a committee that was *voluntarily* organized to assess physician privileges for the use of a specific drug. The case was not concerned with human research, experimentation or the conduct of a federally *mandated* IRB. Third, it appears the committee at issue in *Mt. Diablo* was composed solely of hospital staff and medical professionals and there is no indication that any non-affiliated lay members of the community were involved in determining which physicians should receive hospital *privileges* to use Chymopapain. Thus, the lack of involvement of non-affiliated lay members of the community distinguishes the ad

hoc Chymopapain committee from a federally mandated IRB which, by law, must include unaffiliated non-scientists.[24]

A. Courts From Other Jurisdictions Have Held that IRB Records Are Discoverable and Not Protected By Medical Committee and Peer Review Privilege Statutes

Given the lack of California case law on this issue, plaintiff reviewed the case law from other jurisdictions. California is not alone in having a statute that protects hospital review organization and peer review records from discovery. Even though virtually every state has a peer review privilege law, plaintiff's research has revealed only four extra-jurisdictional cases wherein the issue of the discoverability of IRB records was specifically addressed by a court. Three of these cases held that IRB records are discoverable. *See Konrady*, 149 F.R.D. at 598 (IRB records are discoverable and are not protected from discovery by the Minnesota medical "review organization" privilege); *Esdale*, 1995 WL 263476 at *3 (IRB records are

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[24] The *Mt. Diablo* court also observed that the involvement of certain hospital "departments" may take them outside the scope of the medical staff "committee" given they do not have the name "committee" in their title. *See Mt. Diablo*, 183 Cal.App.3d at 33,n.2 ("Upon remand, however, the trial court may, in its discretion, afford real parties an opportunity to attempt to refute the Hospital's assertion that the Orthopedics 'Department' and the Surgery 'Department' are medical staff committees.") Whatever merit this reasoning has, it is worth noting that the Institutional Review *Board* does not have the name "committee" in its title.

discoverable and not protected by Texas's broad "medical committee" privilege); *P.J. ex rel. Jensen v. Utah*, 247 F.R.D. 664, 671 (D. Utah 2007) (IRB records are not protected by the Utah peer/care review privilege and ordering "the University to produce the IRB file to Plaintiffs in its entirety").[25]

The district court's ruling in *Konrady* is instructive. *Konrady*, like this case, involved a medical malpractice and products liability action where the plaintiff sought discovery from the hospital's IRB regarding the medical device that was the subject of his litigation. In rejecting the hospital's medical "review organization" statutory privilege objections, the court held the statutory privilege did not apply to IRBs because:

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[25] The *sole* case Plaintiff has located wherein the court refused to allow the release of IRB records is *Doe v. Illinois Masonic Med. Ctr.*, 297 Ill. App. 3d 240, 245 (1998). *Doe* is distinguishable, however, because the court was analyzing the Illinois Medical Studies Act privilege statute which is far broader than California's Section 1157. Specifically, the Illinois statute specifically protected discovery of "medical studies" records and the plaintiff's child in *Doe* had participated in the hospital's *medical study* on cystic fibrosis. The Court held that, because the Illinois statute specifically protected "medical study" records, it concluded that the "medical study" records incorporated the IRB records. Without addressing the merits of the *Doe* decision, the case is clearly distinguishable, since California's more narrow Section 1157 statute does not include "medical studies" records within its protection/language. Thus, *Doe* is factually and legally distinguishable.

> The goal of an IRB is the protection of human subjects "rights and welfare" with respect to a specific investigational device. One of the ways that protection is achieved is by the collection and dissemination of information about the human subjects to the FDA, to the manufacturer, and even to the public. Record-keeping and the inspection of those records by the FDA is thus critical to the operation of the IRB. An IRB does not exist to formulate or generally review hospital policies and personnel; rather, it exists to carry out certain functions prescribed by the federal government to further the advancement of medical science. The specificity of this function, and its lack of impact on the overall control of patient care, distinguish the Institutional Review Board from the types of functions described in the Minnesota statute.

Konrady, 149 F.R.D. at 596. The district court thus held that the plaintiff was entitled to obtain the IRB's records regarding a device used during his surgery. *Id.* at 598.

In granting Cabana's motion to compel, the trial Court relied upon the reasoning and policy considerations outlined in *Konrady*. In its writ petition, Pomona Hospital argues that the Minnesota statute at issue in *Konrady* is different than Section 1157. A close review of *Konrady* and the applicable Minnesota statutes (MINN. STAT §§145.61 and 145.64) reveal that the Minnesota privilege statues, like Section 1157, concerned hospital professional staff committees whose purpose is evaluating and improving the quality of patient health care. Thus, while the *Konrady* decision is certainly

not binding on this honorable Court, its analysis of a very similar privilege statute is certainly persuasive.

In addition to *Konrady, Esdale* and *P.J. ex rel. Jensen* which specifically held that IRB records are not immune from discovery, other hospital malpractice decisions from around the country reveal that IRB documents are routinely produced in discovery and relied upon in litigation. As way of example, in *Kus v. Sherman Hosp.*, 268 Ill. App. 3d 771, 775 (1995), the issue was whether the hospital's IRB should have taken greater steps to ensure that the patient was provided with informed consent regarding an experimental eye procedure. In reversing the trial court's directed verdict, the Court of Appeal relied upon the internal records, bylaws and actions of the IRB and concluded that the hospital's IRB owed a duty of care to the patient to ensure that the patient was provided with appropriate consent forms and apprised of the experimental nature of the surgery. *Kus,* 268 Ill. App. 3d at 781. Likewise, in *Grimes,* the Maryland Court addressed whether researchers owed a special duty to apartment residents they recruited in a lead paint poison study. *Grimes,* 366 Md. at 37. In holding that a duty exists, the Maryland

Court relied extensively on the University's internal IRB records. *Grimes*, 366 Md. at 39-50.

Cases such as *Konrady* reveal that IRBs are not protected by medical privilege statutes and cases such as *Kus* and *Grimes* further reveal that IRB records are a crucial component of a plaintiff's ability to ferret out the truth.

IV. Pomona Hospital's Claims of Privilege Conflict With California and Federal Laws Which Have Been Enacted to Promote Transparency and Protect Patients

Finally, Pomona Hospital's assertion of Section 1157 privilege to IRB records must be put into perspective. As demonstrated *supra*, IRBs were mandated by Congress following a history of gross violations of personal freedoms by institutions and physicians. In passing the National Research Act, Congress mandated IRBs to ensure that the welfare of subjects/patients is protected and that they are provided with proper informed consent. The California legislature has also been at the forefront of protecting the interests of research subjects. Indeed, California became one of the first states in the Union to codify the spirit of the Nuremberg Code (an advisory code that arose out of the post-World War II trials of Nazi physicians). In passing the Protection of Human Subjects in Medical

Experimentation Act, *see* CAL. HEALTH & SAFETY CODE Section 24170 *et seq.*, the California Legislature observed:

> The Legislature hereby finds and declares that medical experimentation on human subjects is vital for the benefit of mankind, however, such experimentation shall be undertaken with due respect to the preciousness of human life and the right of individuals to determine what is done to their own bodies.
>
> The Legislature further finds and declares that:
>
> (a) The Nuremberg Code of Ethics in Medical Research was developed after the trial of Nazi war criminals for unethical use of persons in medical experiments; subsequently, the Declaration of Helsinki additionally established recommendations guiding doctors in experimentation involving human subjects.
>
> (b) Neither the Nuremberg Code nor the Declaration of Helsinki are codified under law and are, therefore, unenforceable.
>
> (c) It is necessary that medical experimentation be done in such a way as to protect the rights of the human subjects involved.
>
> (d) There is, and will continue to be, a growing need for protection for citizens of the state from unauthorized, needless, hazardous, or negligently performed medical experiments on human beings.
>
> It is, therefore, the intent of the Legislature, in the enacting of this chapter, to provide minimum statutory protection for the citizens of this state with regard to human experimentation and to provide penalties for those who violate such provisions.

CAL. HEALTH & SAFETY CODE § 24171. The California legislature also passed the "experimental subject's bill of rights" mandating informed consent to patients/subjects. *See* CAL. HEALTH & SAFETY CODE § 24172. The legislature further provided for statutory and common law damages against any institution or researcher that is in breach of these laws. *See* CAL. HEALTH & SAFETY CODE § 24176. It is thus evident that both the United States and the State of California have taken specific measures to protect the welfare of patients/ subjects by, among other things, ensuring that such individuals are given informed consent regarding their experimental procedures. The federal government has further mandated that all research institutions establish IRBs to protect the interests of human subjects and further mandates the transparency of IRB rosters, records and policies. *See* 21 C.F.R. §56.115(b) (mandating that hospital IRB records, including minutes, be subject to inspection and copying by FDA and federal regulators); 45 C.F.R.§46.103(b); *see also Konrady,* 149 F.R.D. at 597.

Pomona Hospital has failed to explain why the state and federal legislature would go through the trouble of enacting all of these protections for patients (and requirements of transparency

between patients and researchers) and provide for civil remedies to affected patients, only to have the drafters of the evidence code, without any expressed intent and *sub silentio*, deem all of the patient's IRB records immune from discovery. Surely, if the California legislature intended such an absurd result, it would have expressed its wishes in Section 1157 (which it has never done despite multiple amendments).

CONCLUSION

At the dawn of the Twentieth Century, Germany became the first nation to issue specific legislation protecting the rights of human research subjects with its passage of the *Berlin Code of Ethics* in December 1900. In commenting on the importance of the new law, Ludwig von Bar, a well-regarded German/Prussian lawyer stated: "Respect for rights and morality has the same importance for the good of mankind as medical and scientific progress."[26] Echoes of von Bar's statements can still be heard in the text of the National Research Act (which mandated IRBs) and California's Protection of Human Subjects in Medical Experimentation Act.

---

[26] Jay Katz, *Human Sacrifice and Human Experimentation: Reflections at Nuremberg*, 22 Yale J. Int'l L. 401, 410 (1997).

The goals of transparency and the importance of free-will appear to be lost on Pomona Hospital. A general theme running through Pomona Hospital's brief is that, allowing April Cabana to gain access to the IRB files and records that pertain to her and her experimental device would somehow chill future scientific progress (see e.g., Writ at 33). These fears are unfounded. There is no reason why the preservation of human dignity and transparency cannot live compatibly with scientific innovation.

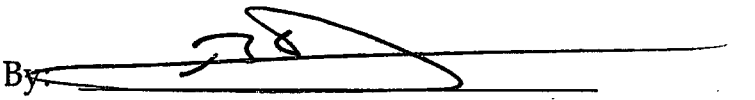
From Pomona Hospital's perspective, every other stakeholder (i.e. the drug company, the researcher, the FDA and the hospital) is entitled to have access to IRB records, yet the very person the IRB is intended to protect, the patient, is expected to remain in the dark. Legislation such as the National Research Act and California's Protection of Human Subjects in Medical Experimentation Act were designed to shed light and transparency on research previously performed in the shadows of secrecy. Through its arguments and invocation of an inapplicable state evidentiary statute, Pomona Hospital seeks to reintroduce the darkness and secrecy state and federal legislation sought to eliminate.

For all of the foregoing reasons, April Cabana respectfully requests that the Court deny Pomona Hospital's petition and hold that the trial court did not abuse its discretion in compelling the production of the requested discovery.

DATED: June 29, 2012

Respectfully submitted,

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.



By: _____

Bijan Esfandiari
Attorneys for Real Party in Interest
APRIL CHRISTINE CABANA

CERTIFICATE OF COMPLIANCE WITH RULE 8.204

I, the undersigned, Bijan Esfandiari, declare that:

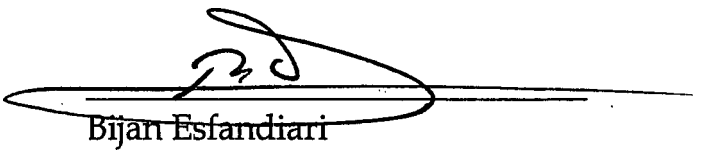
1. I am an associate with the firm of Baum Hedlund Aristei & Goldman, P.C., counsel of record for real party in interest, APRIL CHRISTINE CABANA.

2. This certificate of compliance is submitted in accordance with rule 8.204 of the California Rules of Court.

3. This Opposition to Petition for Writ of Mandate was produced with a computer using Word 2007 word processing software. It is proportionately spaced in 13 point Book Antiqua typeface. The brief contains 11,779 words, including footnotes.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed at Los Angeles, California on June 29, 2012.



Bijan Esfandiari

DECLARATION OF BIJAN ESFANDIARI

I, the undersigned, Bijan Esfandiari, do declare that:

1. I am an attorney at law duly licensed to practice in all of the courts of the State of California. I am an associate with the law firm of Baum Hedlund Aristei & Goldman, P.C., attorneys of record for Real Party in Interest April Cabana ("Cabana" or "plaintiff") in this action. I am the attorney primarily responsible for litigating this case and preparing Cabana's Opposition to Pomona Valley Hospital Medical Center's ("Pomona Hospital") Petition for Writ of Mandate. As a result of said representation, I am thoroughly familiar with the Superior Court file in this matter, as well as the discovery and proceedings in this litigation. I have personal knowledge of the following facts, and if called upon as a witness, I could and would competently testify thereto, under oath.

2. On April 18, 2012, plaintiff April Cabana, filed her motion to compel (and supporting papers) against Pomona Hospital. On May 2, 2012 Pomona Hospital filed its opposition brief and on May 8, 2012 plaintiff filed her reply brief. The trial court held oral argument on May 16, 2012 and granted plaintiff's motion to compel. In its ruling, the court held that "The court finds that Evidence Code §1157 does not apply to IRBs and, accordingly, plaintiff's motion to compel further responses is GRANTED." See 3 App., Exh. 11 at 672.

3. On or about May 30, 2012 (approximately two-weeks after the court issued its aforementioned ruling), co-defendant Stryker Biotech, LLC ("Stryker"), produced approximately 85,000 pages of documents to plaintiff. Amongst these documents were some of Pomona Hospital's Institutional Review Board ("IRB") records that Stryker had in its possession custody and control.

4. Attached to this Opposition Brief as **Attachment 1** is a true and correct copy of a February 4, 2009 letter from Pomona Hospital's IRB which Stryker produced to plaintiff on May 30, 2012.

5. Attached to this Opposition Brief as **Attachment 2** is a true and correct copy of a February 4, 2010 letter from Pomona Hospital's IRB which Stryker produced to plaintiff on May 30, 2012.

6. Attached to this Opposition Brief as **Attachment 3** is a true and correct copy of a January 25, 2009 letter from Pomona Hospital's IRB which Stryker produced to plaintiff on May 30, 2012.

7. As these three documents had not yet been produced to plaintiff at the time plaintiff submitted her briefing to the trial court, they were not presented to and not considered by the trial court.

8. California Rule of Court 8.204(d) permits a party to attach certain material to her briefs. Moreover, given that this is a writ (as opposed to an appeal), the Court of Appeal may properly consider new information that was not presented to the trial court. *See McCarthy v.*

Superior Court, 191 Cal. App. 3d 1023, 1031, n.3 (1987) ("Although the Veit declaration was not before respondent, on an original petition for mandamus relief, the reviewing court in its discretion may consider it together with all other relevant evidence."); *Bruce v. Gregory*, 65 Cal. 2d 666, 670-71 (1967) ("It has been held that a judge hearing a mandamus proceeding may properly consider, in deciding whether to issue a peremptory writ, all relevant evidence, including facts not existing until after the petition for writ of mandate was filed.").

9. These newly produced IRB documents are relevant as they establish that Pomona Hospital provided false responses to discovery. Specifically, in response to Special Interrogatory No. 85, Pomona Hospital stated that its IRB had *not* approved the use of OP-1 Putty (see 1 App., Exh. 4 at 149-150) yet these recently produced documents reveal that its IRB had indeed approved the use of OP-1 Putty and further reveal that Pomona Hospital was conducting an undisclosed "research project" and clinical study on OP-1 Putty. See Attachment 1 ("You mention that the material and procedure under study are very effective. If efficacy is obvious, should the research project and randomization be continued?")

10. While the IRB documents were initially designated as "highly confidential" by Stryker, on June 12, 2012, Stryker's counsel informed me that the documents had been erroneously marked confidential and confirmed that the documents are not confidential.

I declare under penalty of perjury pursuant to the laws of the State of California that the foregoing is true and correct. Executed on June 28, 2012, at Los Angeles, California.

Bijan Esfandiari

INDEX TO ATTACHMENTS

1. Letter from Johnson Lightfoote, M.D., Vice-Chairperson, Pomona Valley Hospital Medical Center IRB, to Ali H. Mesiwala, M.D., dated February 4, 2009, re: Protocol Study: OP-1 Putty: An FDA approved device under the Humanitarian Use Device (HUD) regulations

2. Letter from Sri Gorty, M.D., Chairperson, Pomona Valley Hospital Medical Center IRB, to Ali H. Mesiwala, dated February 4, 2010, re: Protocol Study: OP-1 Putty: An FDA approved device under the Humanitarian Use Device (HUD) regulations

3. Letter from Johnson Lightfoote, M.D., Vice-Chairperson, Pomona Valley Hospital Medical Center IRB, to Ali H. Mesiwala, M.D., dated January 25, 2012, re: Our Study # 2006-008

POMONA VALLEY HOSPITAL
MEDICAL CENTER

2/4/2009

Ali H. Mesiwala, M.D.
Chaparral Medical Group, Inc.
160 E. Artesia Street Ste 360
Pomona, CA 91767

Protocol Study: OP-1 Putty: An FDA approved device under the Humanitarian Use Device (HUD) regulations.

Approval Type: Annual Renewal - Open

Expiration Date: 1/27/2010

Next Report Due: In 10 months

Dear Dr. Mesiwala:

This is to advise you that your request for annual renewal of the above noted protocol was given at the Institutional Review Board meeting held on January 28, 2009. The information submitted is listed:

Annual Renewal:
4 total number accrued
4 Number of subjects still alive
0 Number of subjects expired
4 Number of patients in follow-up

While the PVHMC Board has approved the study, we are requesting the following information to be submitted as soon as possible in order to better understand your study:

1. How many patients are enrolled nationally?
2. You mentioned that the material and procedure under study are very effective. If efficacy is obvious, should the research project and randomization be continued? Is there an ongoing statistical review process to make sure that the incoming study data do not indicate that the study should be terminated?

If there are any unexpected ill effects on the patient(s) as a result of this study, you will need to immediately communicate them to the IRB Office. Approval of this protocol expires on January 27, 2010, however, **Your next annual renewal report is due 10 months from the approval** and the Principal Investigator, Co-Investigator, or Clinical Trials Coordinator must present the annual report to the committee in person. Please submit reports on the number of patients participating in the study, results of the study, and the annual report.

Any information regarding this study can be submitted to IRB Office, at the Cancer Care Center at Pomona Valley Hospital Medical Center, 1910 Royalty Drive, Pomona, CA 91767-9927. Annual reports are due four (4) weeks prior to the meeting and any submissions that are presented after the deadline will be held until the next meeting. If you have any questions, please feel free to contact me at (909) 865-9692.

Sincerely,

Johnson Lightfoote M.D.
Vice-Chairperson
PVHMC Institutional Review Board

POMONA VALLEY HOSPITAL MEDICAL CENTER

Thursday, February 04, 2010

Ali H. Mesiwala
Chaparral Medical Group, Inc.
160 E. Artesia Street Ste 360
Pomona, CA 91767

Protocol Study: OP-1 Putty: An FDA approved device under the Humanitarian Use Device (HUD) regulations.

Approval Type: Annual Renewal - Open

Expiration Date: 1/25/2011

Next Report Due: In 10 months

Dear Dr. Mesiwala:

This is to advise you that your request for annual renewal of the above noted protocol and the Informed Consent form was given at the Institutional Review Board meeting held on January 26, 2010. The information submitted is listed:

17 Total number accrued
17 Number of subjects still alive
0 Number of subjects expired
17 Number of patients in follow-up

You will need to immediately communicate to the IRB Office if there are any unexpected ill effects on the patient(s) as a result of this study. Approval of this protocol expires on January 25, 2011, however, **Your next annual renewal report is due 10 months from the approval** and the Principal Investigator, Co-Investigator, or Clinical Trials Coordinator must present the annual report to the committee in person. Please submit reports on the number of patients participating in the study, results of the study, and the annual report.

Any information regarding this study can be submitted to IRB Office, at the Cancer Care Center at Pomona Valley Hospital Medical Center, 1910 Royalty Drive, Pomona, CA 91767-9927. Annual reports are due four (4) weeks prior to the meeting and any submissions that are presented after the deadline will be held until the next meeting. If you have any questions, please feel free to contact me at (909) 865-9692.

Sincerely,

Sri Gorty M.D.
Chairperson
PVHMC Institutional Review Board

POMONA VALLEY HOSPITAL
MEDICAL CENTER

THE ROBERT AND BEVERLY LEWIS FAMILY CANCER CARE CENTER

January 25, 2012

Ali H. Mesiwala, MD
Chaparral Medical Group, Inc.
160 E. Artesia Street Ste 360
Pomona, CA 91767

RE: Our Study # 2006-008 At: Pomona Valley Hospital

Dear Dr. Mesiwala:

Meeting Date: 1/24/2012

Approved Date: 1/24/2012
Protocol Title:
OP-1 Putty: An FDA approved device under the Humanitarian Use Device (HUD) regulations.

Agenda Category: Annual Renewal

This is to advise you that the above referenced Study 2006-008 has been presented to the Institutional Review Board, and the following action taken subject to the conditions and explanation provided below.

Internal #: 550
Expiration Date: 1/23/2013
On Agenda For: Annual Renewal

Description: Annual Renewal/Closed to Patient Accrual, but open to follow-up. Principal Investigator is also requesting permanent closure of study since patients are beyond normal follow-up care.

IRB ACTION: IRB has approved closing the study to patient accrual. However, before we decide to permanently close the study, we need more information. Please answer the following questions:

1. You stated that the patients are beyond normal follow-up care. What do you consider to be normal follow-up?
2. When was the last follow-up done?
3. How are the other patients doing generally?

Please submit this paperwork to the IRB Coordinator at the PVHMC IRB Office, 1910 Royalty Drive, Pomona, CA 91767 or fax to: 909-865-9658 as soon as possible.

Sincerely yours,

Johnson Lightfoote, M.D.
Vice-Chairperson
PVHMC Institutional Review Board

1910 Royalty Drive • Pomona • California 91767
(909) 865-9555 • FAX (909) 865-9697

*Note: Received by Sales Support on 09 Apr 12 JP 10Apr12

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES.

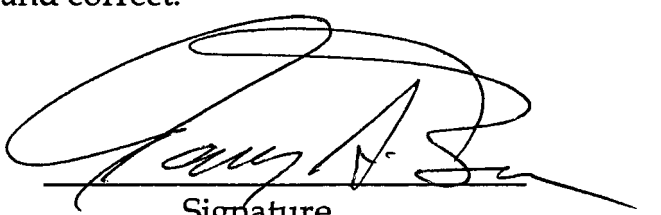
I am employed in the county of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is: 12100 Wilshire Blvd., Suite 950, Los Angeles, CA 90025.

On June 29, 2012, I served the following document(s): **Real Party In Interest's Return to Petition for Writ of Mandate** on the interested parties in this action by placing a true copy thereof enclosed in sealed envelopes addressed as on the attached service list:

[X] BY FEDERAL EXPRESS: I caused such envelopes to be deposited in the Federal Express Depository at Los Angeles, California.

Executed on June 29, 2012, at Los Angeles, California.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.



Gary A. Brown
Typed/Printed Name

Signature

SERVICE LIST

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