UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, et al., Plaintiffs, v. MCKESSON CORPORATION, et al., Defendants.	Case No. 21-mc-80065-JCS **ORDER DENYING MOTION TO COMPEL WITHOUT PREJUDICE** Re: Dkt. No. 1

United States District Court
Northern District of California

I. INTRODUCTION

Plaintiff-Relator Omni Healthcare, Inc. ("Omni") brings a Motion to Compel third party California State Board of Pharmacy ("Board") to comply with the subpoena duces tecum that Omni served on it in connection with a False Claims Act case that is currently pending in the Federal District Court for the Eastern District of New York, *United States of America, et al., ex rel. Omni Healthcare Inc. v. McKesson Corporation, et al*., Case No. 12-cv-06440-NG-ST ("the Underlying Litigation"). The Board objects to the subpoena on the grounds that it is overbroad and unduly burdensome and contends various privileges apply to the discovery Omni seeks. A hearing on the Motion was held on May 21, 2021. For the reasons stated below, the Motion is DENIED without prejudice.

II. BACKGROUND

A. The Underlying Litigation

In the Underlying Litigation, *qui tam* plaintiff Omni asserts claims against McKesson Corporation and various related entities (collectively, "McKesson" or "McKesson entities") under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*., and comparable State laws, including the California False Claims Act ("CFCA"), Cal. Gov't Code § 12651(a)(1), on behalf of

the United States, various States (including the State of California), the District of Columbia, and two cities. Declaration of George F. Carpinello in Support of Motion to Compel California State Board of Pharmacy to Comply with Subpoena Duces Tecum ("Carpinello Decl."), Ex. 7 (Second Amended Complaint in Underlying Litigation ("SAC")). Omni describes the conduct that is the basis for its claims as follows:

> 6. This action arises from Defendants' unlawful conduct in connection with their manufacture, distribution, and sale of various injectable oncology, anemia, and related drugs in pre-filled syringes for administration to cancer patients undergoing chemotherapy treatment as well as other immuno-compromised patients (the "Pre-Filled Syringe Program"). The drugs at issue include Aloxi®, Procrit®, Aranesp®, Neupogen®, Taxotere®, and Kytril® (in both brand and generic forms) (the "Oncology Drugs"), which all contained significant amounts of overfill. Combined, Defendants engaged in their unlawful conduct from 2001 until at least 2010, and engaged in this conduct with respect to [Omni] from 2007 through 2010.
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> 7. Specifically, and as described in greater detail below, Defendants repackaged or compounded the Oncology Drugs in an unlawful manner that was unapproved by the United States Food and Drug Administration ("FDA") and in non-sterile conditions, resulting in false claims being submitted (i) for drugs that were unapproved by the FDA; (ii) for adulterated and misbranded drugs that were repackaged or compounded in a manner in which they could become compromised, lacking purity, and generally below the standards they were represented or expected to possess by the governments; (iii) for improperly harvesting overfill, such that the governments were billed improperly for drug product that was not covered for reimbursement; (iv) for improperly harvesting overfill and charging for that overfill, along with the original drug product, in pre-filled syringes when the overfill in question was not used to calculate the Average Sales Price ("ASP"), causing the governments to pay artificially inflated prices for the drug product; and (v) for Oncology Drugs purchased as a result of Defendants' unlawful kickback to physicians for purchasing pre-filled syringes.
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> 8. To ensure that a doctor is able to withdraw the full amount of a drug sold in an FDA-approved container, typically a glass vial, the containers holding the Oncology Drugs contain more of the product than the amount indicated on the label. This excess amount is called "overfill." Providers are not allowed to bill for any excess drug, such as overfill, for which the drug manufacturer does not charge. Nor are they allowed to bill for unapproved drugs, such as those repackaged in unapproved facilities or otherwise in violation of FDA guidelines.
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> 9. Moreover, most of these vials are expressly marked for "single use," i.e., the contents may be extracted only once because they do not contain preservatives or antiseptic chemicals to prevent bacterial or fungal growth.
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> 10. Nonetheless, Defendants learned that they could maximize profits

> at the governments' expense by harvesting overfill in covered drug products such as the Oncology Drugs, pooling the Oncology Drugs, and then repackaging them in bulk into non-sterile and plastic pre-filled syringes, despite the clear risk to vulnerable cancer patients.
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> 11. Defendants would sell the pre-filled syringes to oncology centers, medical practices, and physicians (collectively, "healthcare providers"), who, in turn, would seek reimbursement for amounts sold in the government-approved vials and quantities. As a result, the governments were billed for an amount of drug product in the pre-filled syringes greater than the amount of vials originally sold by the drug manufacturers, thus allowing Defendants or the healthcare providers to obtain government funds for drugs that were never, in fact, charged for by the drug manufacturers.

Id. ¶¶ 6-11. Omni alleges McKesson knowingly defrauded the federal and State governments on whose behalf it brings the Underlying Litigation and seeks treble damages on its claims. *Id.*, Prayer for Relief.

B. The Board

According to the Board's executive officer, Anne Sodergren, the Board was formed in 1891 and is a state healthcare oversight agency created to protect public health and safety. Declaration of Anne Sodergren in Support of Nonparty California Board of Pharmacy's Opposition to Omni Healthcare, Inc.'s Notice of Motion and Motion to Compel California State Board of Pharmacy to Comply With Subpoena Duces Tecum ("Sodergren Decl.") ¶ 2 (citing Cal. Bus. & Prof. Code, § 4001.1). This goal is accomplished, in part, through the Board's licensing, regulation, and enforcement of the pharmacy practice, including regulating "individuals and businesses that dispense, compound, provide, store and distribute prescription drugs and devices and pharmaceutical services to the public or to other health care practitioners, in compliance with state and federal law." *Id.* The Board also licenses "pharmacists, pharmacist interns, pharmacy technicians, designated representatives, pharmacies, wholesalers, [and] outsourcing facilities, among other facilities." *Id.* ¶ 3. Sodergren states that in the fiscal year 2019-2020, there were 141,741 Board licensees in the State of California. *Id.*

The Board maintains files on licensees that often include personal information, including not only social security numbers and dates of birth but also criminal history, information about mental or physical illness and financial information. *Id.* ¶ 3. These records are organized by licensee name and number; the Board does not maintain records by drug product name or the type

of disease that a drug treats." *Id.* ¶ 13. The Board has a legacy computer system that maintains very basic information, and it does not have a text search function. *Id.* ¶ 19.

The Board employs licensed pharmacist inspectors to conduct pharmacy/wholesaler inspections and investigations. *Id.* ¶ 4. There are currently 57 such inspectors employed by the Board. *Id.* "[I]nspections are triggered for a variety of reasons including: receipt of consumer complaints, required annual inspections for specific license types, mandated inspections as a condition of licensure or renewal, monitoring of probationers, or routine inspections to determine if a pharmacy complies with all state and federal laws and regulations." *Id.* According to Sodergren, in the 2018-2019 fiscal year, the Board conducted approximately 3,462 inspections in California. *Id.* When an inspection is conducted, the Board inspector issues a written inspection report to the licensee. *Id.* Although the Board maintains "a central network file for investigation reports[,]" "investigations are not saved based on the type of investigation that was conducted." *Id.* ¶ 19.

When the Board receives complaints from consumers involving pharmaceutical care, the complaint is first evaluated to determine whether it falls within the Board's jurisdiction, that is, if it involves an individual or entity regulated by the Board and if the complaint violates California Pharmacy law. *Id.* ¶ 5. If it does, the complaint is referred to a Board inspector for investigation. *Id.* According to Sodergren, "[d]uring the last fiscal year, the Board received 2,647 complaints and closed 2,910 investigations." *Id.* She further states that "[f]rom July 1, 2009, to June 30, 2019, the Board closed 35,631 investigations and substantiated violations in 20,376 of those investigations." *Id.* As of June 15, 2020, there were 1,371 Board investigations pending. *Id.* The Board's investigation files range from a few hundred pages to thousands of pages in length and often contain confidential and private information about the licensee, as well as third-party patients, doctors, and consumers. *Id.* ¶ 6. "These files typically include the investigation report prepared by the Board inspector, a copy of the patient/ consumer complaint, and multiple other items received or reviewed in the course of the investigation." *Id.* Many investigation files are stored at the Board's off-site state records facility, which charges for the retrieval and refiling of the records, as well as courier and/or mail delivery services." *Id.* ¶ 19.

When a Board investigation results in a referral for disciplinary action, the first step in the formal disciplinary process is typically the filing of an "accusation," which is the initial pleading. *Id.* ¶ 7. The disciplinary process may be resolved through a settlement agreement ("stipulation"); or, if a settlement is not reached, an administrative hearing is conducted and a proposed decision is rendered by an administrative law judge ("ALJ"). *Id.* The Board then makes its final decision and order based on consideration of the stipulation or the ALJ's proposed decision. *Id.* An administrative record typically consists of the pleadings, the stipulation (where one was reached), motions, briefs, the final decision and order, the reporter's transcript if one was ordered, and any exhibits offered at the hearing. *Id.* According to Sodergren, exhibits can be voluminous (sometimes thousands of pages). *Id.* Further, "[a]ny document admitted into evidence under seal (typically those containing a consumer, licensee, or patient's personal identifying information and/or medical, prescription, or employment records) may not be opened except by order of the Board of Pharmacy, Office of Administrative Hearings, or by a reviewing court." *Id.*

In addition to the investigation files and administrative records discussed above, the Board maintains probationary files "for licensees who are participating in the Board's probationary program as a term of their discipline." *Id.* ¶ 10. According to Sodergren, "[a]t of the end of the last fiscal year, the Board had 346 licensees on probation." *Id.* She states that these files, "[l]ike the other types of files, . . . contain significant personal information about licensees, including personal identifying information (date of birth, social security numbers, etc.), employment records, medical and prescription records and information, substance abuse treatment records, and other confidential documents." *Id.*

The Board's website posts information about disciplinary action dating back to January 2005. *Id.* ¶ 9. Sodergren states that the following information is posted on the Board's website: "(A) If a licensee has been disciplined or formally accused of wrongdoing by the Board; (B) If a licensee is currently on suspension and/or probation with the Board; or (C) If a license was revoked, voluntarily surrendered, suspended, or if a cease practice order was issued." *Id.* The Board's website also posts the Board's "publications, reports, newsletters, press releases, Board and committee meeting minutes, any of which may include information about presentations by or

discussion about various topics given by Board staff." *Id.* ¶ 11. Sodergren further states that "[t]he Board's laws and regulations regarding disciplinary matters and renewal requirements are also posted on the website, as well as the formal rulemaking documents for more recent regulations." *Id.*

C. The Subpoena

On October 27, 2020, Omni served on the Board the subpoena that is the subject of the instant motion (the "Subpoena"). Declaration of Eileen Smiley in Support of Non-Party California Board of Pharmacy's Opposition to Omni Healthcare, Inc.'s Notice of Motion and Motion to Compel California State Board of Pharmacy to Comply With Subpoena Duces Tecum ("Smiley Decl.") ¶ 2 & Ex. A (Subpoena). The Subpoena commands production of documents responsive to the following requests ("Requests"):

1. All Documents and Communications concerning Pre-Filled Syringes and/or the use, extraction, or sale of Overfill, including communications between You and/or McKesson relating to Pre-Filled Syringes, Overfill, or Repackaging Activities.

2. All Documents relating to licensing or registration for any facility owned by, operated by, or affiliated with McKesson.

3. All Documents relating to any inspection(s) of any facility owned by, operated by, or affiliated with McKesson.

4. All Documents relating to Your inspection(s) of any entity engaged in creating, distributing or selling Pre-Filled Syringes containing any Oncology Drugs.

5. All Documents reflecting or relating to Communications between You and any entity engaged in creating, distributing or selling Pre-Filled Syringes containing any Oncology Drugs.

6. All Documents relating to any violations, citations, or sanctions pertaining to any entity engaged in creating, distributing or selling Pre-Filled Syringes containing any Oncology Drugs.

7. All Documents relating to the ordering and order forms for Pre-Filled Syringes, including the requirement, if any, to provide patient-specific information and a valid prescription for a specific patient.

8. All Documents relating to Your consideration of and understanding of the Governing Laws, Rules, Regulations and Guidance applicable

to the creation of Pre-Filled Syringes, including all Documents relating to the requirements, regulations, and guidelines for repackaging, compounding, harvesting, manufacturing, re-entering of vials, labeling, storing or distributing of drug product(s) as Pre-Filled Syringes.

9. All Documents relating to Your consideration of and understanding of whether the creation of Pre-Filled Syringes qualifies as compounding by a licensed pharmacist.

10. All Documents relating to the safety and efficacy of Pre-Filled Syringes.

11. All Documents relating to Your consideration of the Governing Laws, Rules, Regulations and Guidance applicable to the extraction or use of Overfill by pharmacies, repackagers, distributors, and Healthcare Providers.

12. All Documents reflecting or relating to Communications with Healthcare Providers concerning the extraction or use of Overfill by pharmacies, repackagers, distributors, and Healthcare Providers.

13. All Documents reflecting or relating to Communications with Healthcare Providers concerning Pre-Filled Syringes for Oncology Drugs.

14. All Documents and/or Communications relating to the package inserts or labeling of Oncology Drugs or Pre-Filled Syringes, including but not limited to the expiration dates of Oncology Drugs.

15. All Documents relating to any complaints from any source whatsoever, including but not limited to Healthcare Providers, patients or drug manufacturers, about the extraction or use of Overfill, or about Pre-Filled Syringes, including but not limited to issues of adulteration; contamination; compliance with applicable statutes, regulations and policies, mislabeling; and improper handling and distribution.

The Subpoena provides that it "applies to all Documents and Communications created or distributed between January 1, 2001 and the present." Smiley Decl., Ex. A (Subpoena, Appendix A).

D. The Board's Response and Meet and Confer Efforts

According to counsel for the Board, the Subpoena that was served on October 27, 2020 "failed to indicate that it was served on all parties to the litigation" and did not include a Notice of

Subpoena. *Id.* In a letter to Omni dated November 24, 2020, the Board objected to the Subpoena on the ground that it was invalid under Rules 45(a)(4) and 30(b) of the Federal Rules of Civil Procedure because it did not provide proof of service of the required notice to the other parties to this lawsuit. *Id.*, Ex. B ("November 24, 2020 Objections") at 1. The Board also objected that the requests in the Subpoena were vague, overbroad and unduly burdensome and on the grounds that the Subpoena requested documents likely covered by various privileges. *Id.* at 2. It stated, however, that the scope of the requests "ma[de] it near impossible to determine whether any of the documents requested are covered by privilege." *Id.*

The Board also provided individual responses to each of the Requests in its November 24, 2020 Objections. In those responses, it explained that "it maintains a website https://www.pharmacy.ca.gov/ and its publicly available enforcement actions are searchable by licensee." *Id.* at 8. It also provided a list of the active and cancelled licensing files relating to the McKesson entities, including the name, license number, location of the entity, and information about disciplinary actions (including a link to the publicly filed Accusation and Decisions). Smiley Decl. ¶ 3 & Ex. B (November 24, 2020 Objections), Exhibit A attached thereto.

On December 16, 2020, counsel for the Board and Omni met and conferred by telephone. Smiley Decl. ¶ 4; Carpinello Decl. ¶ 4. It appears that Omni agreed to re-serve the Subpoena to cure the defect with respect to notice of service discussed above and that counsel discussed the Board's production obligations once a valid Subpoena was served on it. *Id.* According to Omni's counsel, "as a preliminary compromise, [the Board] agreed to produce relevant inspection reports and records of citations and fines." Carpinello Decl. ¶ 4.

On December 22, 2020, the Board sent a substantive follow-up letter in which it addressed questions that had been raised by Omni's counsel in the December 16, 2020 telephone call. Smiley Decl. ¶ 5 & Ex. C (December 22, 2020 Letter). The Board treated the Subpoena as a public records requests because of the defect discussed above, stating that "complaints and investigations are exempt from public disclosure pursuant to [California] Government Code section 6254, subdivision (f)" and that "[i]nvestigative records do not lose their exempt status due to the passage of time, a failure to prosecute, or the close of an investigation." Smiley Decl., Ex.

C (December 22, 2020 Letter) at 2. The Board explained that its "investigations and complaint process are formal and confidential in nature" and that "[t]he necessity for preserving the confidentiality of the information outweighs the necessity for disclosure." *Id.* In support of this position, the Board stated as follows:

> Release of the files pertaining to investigations would unnecessarily impede the ability of the Board in carrying out its statutorily mandated oversight and regulation of Board licensees. Beyond privacy concerns, the Board has a legitimate interest in the "chilling effect" that disclosure of its complaint and investigative files would have both on its complaint handling process and the effective enforcement of the laws under its jurisdiction. . . .[I]nspection reports that are tied to complaints and/or investigations are not produced as they are part of the complaint and/or investigation matter. For these reasons, the Board never produces in response to a subpoena in a private litigation its investigation or complaint files, including inspection reports that are part of or related to those matters.

Id.

In the December 22, 2020 Letter, the Board also updated the list it had previously provided to include administrative (non-disciplinary) actions and provided copies of the citations and letters of admonishment issued by the Board against the McKesson entities as well as inspection reports that were not initiated by a complaint or part of an investigation, amounting to approximately thirty pages of documents. *Id.*; *see also* Carpinello Decl. ¶ 5. The inspection reports were partially redacted. Smiley Decl., Ex. C.

On January 11, 2021, Omni responded to the Board's December 22, 2020 letter. Smiley Decl., Ex. D. Omni objected to the Board's withholding of complaints and some investigative reports and its redaction of the investigative reports it did produce, arguing that the Board's reliance on California Government Code section 6254(f) was misplaced because that section applies to public records requests and not to subpoenas. *Id.* at 1. It also challenged the Board's "suggest[ion] that the Board possesses a freestanding, nonstatutory privilege with respect to complaints and investigative files because, in general, disclosure of such material might have a 'chilling effect' on the Board's work." *Id.* at 2. According to Omni, the Board offered no authority to support the existence of such a privilege, and federal common law – which applies to the enforcement of Omni's Subpoena – does not provide for such a privilege. *Id.*

Omni proposed in its January 11, 2021 Letter that the Board produce, without redactions, "inspection reports for inspections of McKesson-related entities initiated in response to a complaint or as part of an investigation during the relevant period;" and "the underlying complaints or investigative referral documents that initiated such inspections." *Id.* Omni also provided a copy of the protective order in the Underlying Litigation, pointing to provisions in it that authorize a nonparty to designate its productions "confidential," and placing limits on the disclosure of confidential materials produced in discovery. *Id.* at 2-3 & Ex. A to January 11, 2021 Letter (stipulated protective order in Underlying Litigation).

On January 18, 2021, Omni provided the Board with a Subpoena reflecting that it had been served on McKesson and the United States Attorneys' Office. Smiley Decl., Ex. D, F. Counsel for Omni and the Board met and conferred by telephone on January 19, 2021. Smiley Decl. ¶ 7; Carpinello Decl. ¶ 7. According to Omni, the Board's counsel "agreed to categorize the types of documents they had searched and collected and to log, by category, the particular reasons for the Board's refusal to produce those documents" but did not do so. Carpinello Decl. ¶¶ 7-8. Omni's counsel also states that the Board's attorney told him in this meet and confer that "it 'generally' asserts the official information privilege and the deliberative process privilege" in response to subpoenas. Carpinello Decl., ¶ 7.

In a January 29, 2021 letter, the Board acknowledged that the defect with respect to proof of service had been cured but continued to object to the Subpoena on the grounds that it was overbroad, burdensome, and sought privileged documents and communications. Smiley Decl., Ex. F ("January 29, 2021 Objections").

Omni's counsel met and conferred with two Board attorneys on February 22, 2021. Carpinello Decl. ¶ 9; Declaration of Molly Selway in Support of Non-Party California Board of Pharmacy's Opposition to Omni Healthcare, Inc.'s Notice of Motion and Motion to Compel California State Board of Pharmacy to Comply With Subpoena Duces Tecum ("Selway Decl.") ¶ 3. There appears to have been some misunderstanding between counsel, with each believing the other would be following up. *See* Carpinello Decl. ¶ 9 (Omni's counsel understood that the Board's attorneys "would follow up and confirm whether the Board had produced all that it would

produce"); Selway Decl. ¶ 3 (the Board's attorney understood that Omni's counsel "intended on reviewing the documents already provided to them by the Board, as well as the information available on the Board's website, and then would determine whether additional information was necessary").

On March 12, 2021, Omni's attorney emailed the Board's counsel demanding that the Board inform Omni of whether it would comply with the Subpoena. Carpinello Decl., Ex. 6. The Board's attorney responded a week later, stating that she had understood Omni's counsel was going to confer with co-counsel to determine what documents Omni was interested in. *Id.* She further stated that while the Board would consider de-redacting portions of some inspection reports, it "maintain[ed] the previous objections and [would] not be producing investigations and complaints." *Id.* Although she also stated that "[a]n additional meet and confer call may be useful to discuss the requested documents[,]" Omni rejected that suggestion and filed the instant motion instead. *Id.;* Selway Decl. ¶ 4.

E. Contentions of the Parties

1. The Motion

In the Motion, Omni seeks to compel compliance with all of the Requests in the Subpoena.[1] With respect to Requests 1, 3, 4, 5 and 15, seeking "complaints, investigation files, inspection reports, and related communications pertaining to McKesson and similarly-situated drug distributors[,]"[2] Omni contends these requests "are plainly relevant to Omni's claims of fraud, targeted, precise, and easy for the Board to search and produce." Motion at 3. To the extent the Board objects to these requests based on the official information privilege, the deliberative process privilege and the work product doctrine, Omni contends, these arguments have no merit. *Id.* at 4-8. It further rejects the Board's assertion that these requests are overbroad and unduly burdensome. *Id.* at 4, 8-11.

[1]At the motion hearing, Omni's counsel stipulated that although the Motion did not reference Requests 2 and 6, this was an oversight.

[2] At the motion hearing, Omni's counsel clarified that in the motion, it uses the term "similarly situated drug distributors" to refer to drug distributors engaged in the harvesting of overfill using prepackaged vials, regardless of the drug contained in the vials.

Omni further asserts that the Board should be compelled to respond to Requests 12 and 13, which seek "documents 'reflecting or relating to Communications with Healthcare Providers' regarding harvesting of overfill and prefilled syringes." *Id.* at 11. According to Omni, as to these Requests the Board has made "rote assertions of official information privilege, deliberative process privilege, work product doctrine, overbreadth, and privacy—all of which should be rejected for the reasons discussed above." *Id.* In addition, Omni rejects the Board's objection on the grounds of attorney-client privilege as well as its response "that it 'does not oversee healthcare providers, except pharmacies.' " *Id.* Omni argues that "neither position requires an objection" because responsive material is shielded by attorney-client privilege so long as the Board produces a privilege log and as to the latter response, the Board can satisfy its obligations by affirming that it has no responsive documents. *Id.* at 11-12. Omni, however, notes that "the Board has not represented that it does not *communicate* with healthcare providers but rather that it does not *oversee* those entities." *Id.* at 12 (emphasis in original). Omni argues that "[i]f the Board *has communicated* with healthcare providers regarding harvesting overfill or prefilled syringes—for example, to warn them about the serious risk to patient safety incurred by using prefilled syringes prepared from vial overfill—then it is not credible that the Board has no way to recollect or identify records of those communications, regardless of how their files are organized." *Id.* (emphasis in original).

Omni also contends the Board should be compelled to respond to Request Nos. 7, 8, 9, 10. 11 and 14, which "command documents about Board policies, requirements, and knowledge regarding medication order forms; repackaging, compounding, and manufacturing; harvesting of overfill; and the safety and efficacy of prefilled syringes" *Id.* According to Omni, the "Board's knowledge about (and positions on) these issues is directly relevant to proving illegality, materiality of fraud, and scienter." *Id.* Omni offers two examples to illustrate this point. First, it argues that "if the Board understands governing law to require that drug order forms be accompanied by particular patient names, that will tend to show that McKesson's order forms (which did not require patient names) were illegal, and consequently, that claims to Medicare and California government payors for prefilled syringes should not have been paid." *Id.* As another

example, it asserts that "if the Board understands the term 'compounding' to refer narrowly to the practice of custom-mixing drugs pursuant to a particular prescription for an individual patient (as it is typically understood), that may tend to show that McKesson deliberately misled regulators about its practice, in which it harvested overfill from vials to make prefilled syringes in the absence of a prescription or even a patient name." *Id.*

Omni argues that the Board's objections to these requests based on privilege and overbreadth lack merit for the reasons discussed above and that its assertion of the deliberative process privilege is "particularly incongruous . . . because the 'working law exception' to the deliberative process privilege 'requir[es] disclosure of "opinions and interpretations which embody the agency's effective law and policy" and "have the force and effect of law." ' " *Id.* at 13 (quoting *Am. C.L. Union of N. California v. United States Dep't of Just*., 880 F.3d 473, 490 (9th Cir. 2018) (quoting *N. L. R. B. v. Sears, Roebuck & Co*., 421 U.S. 132, 153 (1975))." According to Omni, rather than seeking to use the Board as an unpaid legal expert, as the Board contends in its objections, Omni seeks "documents that provide a written explanation of how relevant laws are interpreted and enforced by the agency in California that is responsible for interpreting and enforcing them." *Id.* In light of its mission as a policy-making body, Omni asserts, the Board "of course possesses documents stating and explaining its 'understanding of the Governing Laws' . . . , likely including policy memoranda, guidance documents, circulars, newsletters, and direct communications among staff and with regulated entities regarding regulatory positions, enforcement priorities, and the like." *Id.* Moreover, Omni argues, "the Board surely possesses institutional factual knowledge regarding safety and efficacy of pharmacy practices" as the Board "routinely issues publications and reports in keeping with its mission to 'educat[e]' and 'communicat[e]' with the public." *Id.* at 14.

2. Opposition

In its Opposition, the Board argues that the factors courts considering in determining whether to enforce a Rule 45 subpoena – "relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed" – support its position that Omni's Subpoena

imposes an undue burden upon it and therefore should not be enforced. *Id*. at 7 (quoting *Moon v. SCP Pool Corp*., 232 F.R.D. 633, 637 (C.D. Cal. 2005)). It also contends its status as a non-party and confidentiality concerns weigh in its favor. *Id.* (citing *Cascade Yarns, Inc. v. Knitting Fever, Inc*., 755 F.3d 55, 58-59 (1st Cir. 2014); *Slate v. ABC*, 802 F. Supp. 2d 22, 26-27 (D.D.C. 2011)).

With respect to relevance, the Board rejects Omni's assertion that the information it seeks is relevant to its claims of fraud and will prove or disprove how McKesson "presented false claims for payments or approval under Medicaid and other California State-funded programs." *Id.* at 7 (citing Motion at 3, 9). According to the Board, as a regulatory agency, it is not a recipient of any "false claim" payments and it does not have control over Medicaid programs. *Id.* Moreover, it asserts, cases cited by Omni, in which the subpoenas sought information that was directly related to the underlying lawsuits, are distinguishable because the information Omni requests from the Board is only tangentially related to the Underlying Litigation, seeking information about licensees who are not named as parties in the Underlying Litigation and about drugs other than the oncological drugs that are the subject of Omni's claims. *Id.* (citing *U.S. ex rel. Ortiz v. Mount Sinai Hosp*., 169 F. Supp. 3d 538 (S.D.N.Y. 2016); *Williams v. C. Martin Co. Inc*., Civil Action No. 07-6592, 2014 WL 3095161, at *4-5 (E.D. La. July 7, 2014)). The Board also rejects Omni's arguments that the information it seeks will show what behavior the Board "condoned or condemned," arguing that as a non-party to the Underlying Litigation its actions in this respect are not relevant. *Id.* at 8. In any event, it asserts, the behavior it has condemned can be found on the Board's website, where the Board's official actions are available as public records. *Id.*

Similarly, the Board contends the information sought in Request Nos. 7, 8, 9, 10, and 11, which seek material relevant to the Board's understanding of the law, is also irrelevant to the Underlying Litigation as it is not a trier of fact or a party. *Id.* at 8. Nonetheless, it asserts, its understanding of the law can be found in its publications, which also are posted on its website. *Id.*

The Board also argues that the time period encompassed by the Requests, which is another *Moon* factor, supports the conclusion that the Subpoena is overbroad. *Id.* at 9. It points out that while the complaint in the Underlying Litigation alleges that McKesson "engaged in a massive campaign of pharmaceutical fraud over the course of at least eight years (from 2005 to 2013)[,]"

the Subpoena demands that the Board produce documents for a twenty-year period, from 2001 to the present. *Id.*

Next, the Board argues that the Requests in the Subpoena do not describe what Omni seeks "with any particularity," thus also supporting the Board's position under *Moon*. *Id.* It offers as an example Omni's requests for documents involving "similarly-situated distributors," which do not identify specific distributors and broadly seek "all documents" and/or "all communications," relating to those "similarly-situation distributors." *Id.* at 9-10. It also points to Requests 14 and 15, which it contends "are so expansive that they encompass documents not remotely related to the litigation." *Id.* at 10. According to the Board, "these requests would require Board staff to review each communication or document received over the course of twenty years to ascertain whether specific documents are responsive to the subpoena and determine if any privilege is applicable." *Id.* Nor is it reasonable for Omni to assert that the Board can "recollect" communications over a twenty-year period regardless of how its records are store, the Board contends. *Id.* (citing Motion at 12).

The Board further contends that compliance with the Subpoena would be a "severe burden" that "cannot be squared with *Moon*." *Id.* at 10. The Board points to the fact its records are organized by licensee name and number and cannot be searched by subject matter, meaning its staff would have to manually review the files of more than 141,000 licensees. *Id.* at 11. According to the Board, the scope of the Requests makes it nearly impossible to determine whether any of the documents are covered by privilege. *Id.; see also* Sodergren Decl. ¶ 20 (estimating that it would take a staff member approximately one hour to review each investigation file and therefore that reviewing the closed investigation records for the period July 1, 2009, to June 30, 2019, would take a minimum of approximately 35,631 hours; and stating that it would take "hundreds of thousands of hours" more to manually redact responsive documents). The Board also contends some of the information Omni seeks is available on the Board's website and that Omni should be able to obtain other information from McKesson. *Id.* While the Board acknowledges that Omni has told it that McKesson's production has not been adequate, it points out that Omni has not "state[d] what efforts it made to obtain responsive documents from

McKesson, including whether it filed a motion to compel against McKesson before seeking the same documents from non-party Board." *Id.* Under Rule 26, the Board contends, the discovery Omni seeks from the Board should be limited because it could be obtained from McKesson. *Id.*

Finally, the Board represents that the severe burden compliance with the Subpoena will place on its staff will be exacerbated by the COVID-19 pandemic, "when substantial resources are being utilized, in addition to its normal licensing, inspection and enforcement-related actions, on necessary actions to waive provisions of rule[s] to permit licensees to operate and respond to a global pandemic." *Id.* at 12 (citing Sodergren Decl. ¶¶ 29, 31). The Board is also "involved in facilitating through its actions the distribution of COVID vaccines, including approvals of temporary licenses and facilitating the administration of vaccines by personnel under its jurisdiction." *Id.* Further, even as its resources are stretched by the pandemic, the Board represents that it has a number of vacant positions and its ability to hire is constrained by the state budget process. Sodergren Decl. ¶ 30. Moreover, many of its staff are working remotely and cannot access physical documents to conduct document review. *Id.* In sum, Sodergren states, complying with Omni's demands "would result in the severe disruption of the Board's day-to-day operations and functions, with consequent delays in performing all of its statutorily mandated tasks." *Id.*

In addition to the challenges to the Subpoena based on the *Moon* factors, discussed above, the Board argues that Omni's motion should be denied on the additional grounds that the Subpoena requests documents that are protected from discovery under the official information privilege, the deliberative process privilege, attorney-client privilege and work product. Opposition at 12-17. With respect to the official information privilege, the Board asserts that federal common law provides for a qualified privilege where the potential benefits of disclosure are outweighed by its disadvantages and that this privilege has been found to apply to "a wide array of confidential data, communications, and information collected and compiled by government agencies." *Id.* at 12-13 (citing *Sanchez v. City of Santa Ana*, 936 F.2d 1027, 1033-34 (9th Cir. 1990); *Kelly v. City of San Jose*, 114 F.R.D. 653, 655 (N.D. Cal. 1987)). According to the Board, while federal common law is controlling, "state law is nevertheless instructive" when

determining when this privilege applies. *Id.* at 13 (citing *Kelly*, 114 F.R.D. at 655, 656).

Here, the Board contends, in determining whether the official information privilege applies the Court should consider California Evidence Code section 1040, "which provides a privilege to a public entity to refuse to disclose information acquired in confidence if' 'there is a necessity for preserving the confidentiality of the information that outweighs the necessity for disclosure.' " *Id.* (quoting *Sander v. State Bar of Cal*., 58 Cal.4th 300, 325 (2013)). According to the Board, the California Court of Appeal has expressly held "that the Board's investigations (and the complaints contained therein) are subject to the official information privileged[,]" observing that the Board "rel[ies] on the confidentiality of complaints, witnesses, deliberations, and the proceedings in general to protect vulnerable patients and witnesses . . . and maximize the truth-seeking function of their efforts." *Id.* at 14 (quoting *Cal. State Bd of Registered Nursing v. Super. Ct. of Orange County*, 59 Cal. App.5th 1011, 1041-1042 (2021)). The Board contends that in this case, the benefits of disclosure are far outweighed by its disadvantages because Omni has not demonstrated that the information it seeks is relevant to the Underlying Litigation whereas its disclosure is likely to impede the Board's ability to conduct its oversight obligations, have a chilling effect on its efforts and also implicate privacy concerns. *Id.*

The Board rejects Omni's argument that the "privilege only applies in federal cases involving the disclosure of law enforcement personnel files or in civil rights cases against the government or officers, and not to complaints and investigations of regulatory agencies." *Id.* (citing Motion at 4). According to the Board, there is no authority that supports this proposition, *Id.* at 15. The Board also points out that there is a "separate and distinct 'Law Enforcement Privilege.' " *Id.* at 15 (citing *Hemstreet v. Duncan*, CV-07-732-ST, 2007 WL 4287602, at *2 (D. Or. Dec. 4, 2007)). It also rejects Omni's assertion that the Board believes it is "categorically immune from all subpoenas in all circumstances[,]" pointing out that it has already produced some documents in response to the Subpoena. *Id.* (citing Motion at 5). As to Omni's argument that the Board has provided insufficient information to demonstrate that the privilege is applicable, it contends the broad scope of the Subpoena has made it impossible to provide such specific facts but that the case law and declarations it has supplied are sufficient to demonstrate that the

privilege applies to documents requested in the Subpoena. *Id.* According to the Board, "If Plaintiff's subpoena was reasonably particularized, clear, and specific, the Board could search for and produce for this Court's *in-camera review* all of the responsive documents so that this Court could apply the proper balancing test." *Id.* Finally, the Board argues that the existing protective order, which Omni contends addresses the Board's concerns, is insufficient, especially as to disclosure of on-going investigations and complaints. *Id.* at 15-16 (citing Sodergren Decl. ¶ 17). Moreover, it asserts, "disclosure of unsubstantiated complaints and investigations, or dismissed actions could be detrimental, disparaging, or threatening to a licensee's reputation, rights, benefits, privileges, or qualifications." *Id.* at 16.

The Board further asserts that the Requests seek documents that are protected by the deliberative process privilege, which affords "senior officials of all three branches of government . . . a qualified, limited privilege not to disclose or to be examined concerning not only the mental processes by which a given decision was reached, but the substance of conversations, discussions, debates, deliberations and like materials reflecting advice, opinions, and recommendations by which government policy is processed and formulated." *Id.* at 16 (citing 5 U.S.C. § 552(b)(5) and quoting *San Joaquin County Local Agency Formation Commission v. Superior Court*, 162 Cal.App.4th 159, 170-171 (2008)). According to the Board, the test for this privilege is the same balancing test that applies to the official information privilege. *Id.* (citing *Shepherd v. Sup. Ct.*, 17 Cal.3d 107, 125 (1976)). The Board rejects Omni's argument that this privilege does not apply to complaints, investigative files, inspection reports and related communication, asserting that because Omni is "requesting complaints and investigative files that are either open or did not lead to formal discipline by Board[,]" "[w]hether or not the Board decides to move forward with discipline, or how it conducts its investigation is exactly what is protected under the deliberative process privilege." *Id.* at 16-17. To the extent Omni asserts that the Board has not provided sufficient factual support to establish that this privilege applies, the Board contends it is because of the overbreadth of the Requests, which it make it impossible to provide a log of responsive documents to which this privilege applies. *Id.* at 17. It again contends that if Omni's subpoena "was reasonably particularized, clear, and specific, the Board could

search for and produce for this Court's *in-camera* review all of the responsive documents subject to the Deliberative Process Privilege." *Id.*

The Board asserts that Omni's Requests "are so overly broad and vague, [they] encompasses documents and communications that are protected by the attorney-client privilege and work-product privilege." *Id.* One example of such communications, they contend, are communications between Board staff and the Office of Attorney General, which represents the Board in litigation and "regularly communicates with Board staff about disciplinary actions and investigations against entities, including providing legal strategy and opinions." *Id.* The Board contends such communications fall under Omni's Requests for communications relating to McKesson, "similarly-situated distributors," and other "Healthcare Providers." *Id.* It further asserts that some of the requests encompass even documents prepared in anticipation of litigation that fall under the work product doctrine. *Id.* at 16-17. According to the Board, to require it to provide a privilege log describing each of these documents is onerous. *Id.* at 17.

In addition to the privileges described above, the Board contends federal law allows it to invoke the right to privacy in opposition to the Subpoena. *Id.* at 18 (citing *Johnson by Johnson v. Thompson*, 971 F.2d 1487, 1497 (10th Cir. 1992); *DeMasi v. Weiss*, 669 F.2d 114, 119-120 (3rd Cir. 1982)). The Board points to the California Constitution as the primary source of privacy rights in California. *Id.* (citing *Davis v. Leal*, 43 F. Supp. 2d 1102, 1110–11 (E.D. Cal. 1999) (citing California Const. Art. I § 1)). Under federal law, the Board argues, "[w]hen the constitutional right of privacy is involved, 'the party seeking discovery must demonstrate a compelling need for discovery, and that compelling need must be so strong as to outweigh the privacy right when these two competing interests are carefully balanced.' " *Id.* (quoting *Artis v. Deere & Co.*, 276 F.R.D. 348, 352 (N.D. Cal. 2011) (internal quotations and citations omitted)). According to the Board, the Subpoena "seeks the production of private information, including the medical/prescription documents relating to patients, consumers, and licensees which are part of the Board's investigation files[,]" without demonstrating a compelling need for that information. *Id.* In addition, it contends, the investigation files requested may include licensees', consumers', and patients' personal, medical, prescription, and employment information, the production of which

would be "a substantial unwarranted invasion of the right of privacy guaranteed by the California Constitution and federal law." *Id.*

The Board asks that the Court issue a protective order or modify or quash the Subpoena for the reasons stated above. *Id.* at 19. It further asserts that if it is ordered to produce any documents in response to the Subpoena, the Court should shift to Omni the costs of compliance. *Id.* (citing *Legal Voice v. Stormans Inc*., 738 F.3d 1178, 1184-85 (9th Cir. 2013)). In particular, the Board contends Omni should bear the costs of reproduction, retrieval of the documents from from offsite storage, travel, postage costs and reasonable clerical costs for locating, compiling and redacting the records. *Id.*

3. Reply

In its Reply brief, Omni reiterates its arguments that the documents it seeks are relevant and that its Requests are not overbroad. Reply at 3-5. It contends it "can show that the claims submitted as a result of McKesson's prefilled syringe program were false by showing that the prefilled syringes were created without a prescription, or that they were created, warehoused, or distributed in unsanitary conditions." *Id.* It further asserts that it "knows, through documents obtained from McKesson and other third parties, that McKesson had facilities operating in California, and that it sold and warehoused prefilled syringes there." *Id.* (citing Declaration of George F. Carpinello in Support of Reply Memorandum of Law on Motion to Compel California State Board of Pharmacy to Comply With Third-Party Subpoena ("Carpinello Reply Decl."), Ex. 1). In particular, it represents that "[i]n addition to the McKesson facilities that the Board has already identified, Omni has obtained a document showing that Ivpcare/OTN had a facility located at 373 Van Ness Avenue, Torrance, California, which was inspected by the Board on several occasions." Carpinello Reply Decl. ¶ 4. The document – described as "an index for 'Project Steelers,' which was McKesson's name for the operation overseeing the RTI program" – lists inspection reports for "ivpcare inc." dated September 12, 2005, August 17, 2006, September 13, 2007 and September 25, 2007. Carpinello Reply Decl., Ex. 1 at pp. 27, 29.

Omni further contends the Board "could comply with the majority of the requests with little-to-no difficulty." *Id.* at 4. With respect to Requests 1, 2, and 3, which "deal only with

McKesson and its related entities and any communications between the Board and McKesson[,]" Omni contends these documents are "readily available" as "the Board has stated that it can pull documents by licensee." *Id.* As to Requests 8, 9, 10, 11, and 12, Omni says that it is "simply asking for information reflecting the Board's understanding of the legality of the use of overfill in creating prefilled syringes." *Id.* Omni acknowledges that "[t]he remaining requests, which primarily ask for documents related to certain delineated categories, are wider ranging" but asserts that they are "not unusually so." *Id.* Moreover, Omni contends, "it strains credulity" that the Board cannot search by topic because files are stored by licensee. *Id.* In fact, it asserts, "[t]he Board's employees have extensive institutional knowledge" and "[i]f the Board cannot locate files on prefilled syringes and overfill by searching its files, it can make reasonable inquiry of its employees and their institutional knowledge of the topics." *Id.* at 4-5.

Omni rejects the Board's reliance on *Moon*, which Omni contends is distinguishable because it involved a subpoena that requested documents with no temporal limitation where the documents could more easily be obtained from another source. *Id.* at 5. In contrast, Omni asserts, the Subpoena at issue here is temporally limited and "crucially, Omni has painstakingly attempted to obtain the requested documents from McKesson, but has been unable to do so, because the requested documents evidently have been destroyed." *Id.* In support of the latter point, Omni supplies a reply declaration from its counsel describing its efforts to obtain documents from McKesson. According to Mr. Carpinello, "Omni has exhaustively tried to obtain additional discovery about this case from McKesson, but McKesson appears to have destroyed a substantial amount of relevant material." Carpinello Reply Decl. ¶ 5. In particular, in response to Omni's request for documents related to a McKesson program to repackage single-use vials of oncology drugs Aloxi and Procrit into prefilled syringes called the Ready-to-Inject ("RTI") program, McKesson informed Omni's counsel that in mid-2015 McKesson lifted a document hold it had put in place in response to a 2013 subpoena from the United States Attorney for the Eastern District of New York ("EDNY Subpoena") relating to the program. Carpinello Reply Decl. ¶ 5 & Ex. 3. McKesson's counsel explained that the RTI program ended in March 2010 and McKesson had already produced documents in response to the EDNY Subpoena and had had no communications

with the United States Attorney about that subpoena for over a year. *Id.*

Omni rejects the Board's assertion of the official information and deliberative process privileges, arguing that the Board may only look to State law to fill in gaps in the federal common law whereas the Board has relied on California law to supply rules of decision where there are no such gaps. *Id.* at 5-6. Instead, it asserts, California law governing executive privileges is in conflict with federal common law because "[u]nder federal common law, the assertion of either [the official information or deliberative process privilege] requires a specific factual showing, including why the documents requested could not be produced under a protective order, or with certain portions redacted. By contrast, California courts apply the executive privileges according to the standard of Cal. Evid. Code § 1040(b)(2), which requires only a showing that disclosure would be 'against the public interest.' " *Id.* at 6.

Under federal common law, Omni contends, the Board has not made a sufficient showing that either privilege applies. *Id.* at 6-9. As to the official information privilege, Omni argues that this privilege is narrow and that "the Board has the burden, through the declaration of its executive, to show 'how disclosure, under a carefully crafted protective order, would create a substantial risk of harm to significant government interests,' given the fact that '[t]he use of a carefully drafted protective order. . . substantially reduces the confidentiality interests' that the Board asserts." *Id.* at 6-7 (quoting *Soto v. City of Concord*, 162 F.R.D. 603, 614 (N.D. Cal. 1995)). The Board's burden cannot be met with general assertions that disclosure might result in harm to the investigatory process or have a chilling effect, Omni asserts. *Id.* at 7 (citing *Chism v. Cty. of San Bernardino*, 159 F.R.D. 531, 534–35 (C.D. Cal. 1994); *Kelly v. City of San Jose*, 114 F.R.D. 653, 672 (N.D. Cal. 1987)). As the Board has not yet collected the documents that are responsive to Omni's Requests, it has failed to supply the specific facts required to support this privilege, according to Omni. *Id.* Moreover, it contends, because Omni is bringing this action on behalf of the State of California its interests are aligned with the Board's interests and therefore, "there is little basis for finding that disclosure would be contrary to the government interest." *Id.* (citing *Denison v. Oregon*, 211 F.R.D. 408, 410–11 (D. Or. 2002)). Nor has the Board explained why its concerns cannot be addressed by use of a carefully drafted protective order, Omni

contends. *Id.* Omni notes that in the Opposition the Board expressed particular concern about the disclosure of information about ongoing investigations but did not state that there are any such investigations that relate to the topics addressed by the Subpoena. *Id.* at 8.

The deliberative process privilege available under federal common law is also narrow, Omni asserts. *Id.* "While the privilege can protect 'communications designed to directly contribute to the formulation of important public policy,' *Soto*, 162 F.R.D. at 612, it does not apply to 'purely factual, investigative matters.' " *Id.* (quoting *Ctr. for Biological Diversity v. U.S. Army Corps of Engineers*, No. CV 14-1667 PSG CWX, 2015 WL 3606419, at *5 (C.D. Cal. Feb. 4, 2015); and citing *Scott Paper Co. v. U.S.*, 943 F. Supp. 489, 465 (E.D. Pa. 1996); *Reino De Espana v. Am. Bureau of Shipping*, No. 03CIV3573LTSRLE, 2005 WL 1813017, at *11 (S.D.N.Y. Aug. 1, 2005)). Omni contends the investigative files it seeks are not protected by the deliberative process privilege because they "contain purely investigative and factual information related to the conditions within the facilities in which McKesson and other companies illicitly transferred, under non-sterile conditions, medications from single-use vials into single-use syringes, and/or warehoused or sold those products." *Id.* at 8.

Omni also rejects the Board's assertion that the same balancing test that applies to the deliberative process privilege under California law also applies under federal common law. *Id.* at 9. According to Omni, under federal common law, the standards are "quite different[,]" requiring the party asserting the privilege to show: "

> 1) specific facts demonstrating why each document is "deliberative" and "predecisional"; 2) specific facts concerning: a) the degree and type of harm that would result from requiring production of each document; and b) what type of protective order would be necessary to reduce that harm or, alternatively, why a protective order would not reduce this harm; and 3) what portions of each document are deliberative and, if specific sections are purely factual, why those sections cannot be produced.

Id. (quoting *In re McKesson Governmental Entities Average Wholesale Price Litig.*, 264 F.R.D. 595, 602 (N.D. Cal. 2009)). The Board has not satisfied these requirements, Omni contends, because "it has failed to show that any document relates to the formation of important public policy[,]" and "discovery in the underlying case is already subject to a protective order." *Id.*

Omni further contends the "deliberative process privilege does not permit the blanket withholding of entire categories of documents, but rather requires targeted redaction of deliberative material" and the Board "has made no attempt to show why complaints or investigative files could not be redacted." *Id.*

Similarly, Omni rejects the Board's argument that attorney-client privilege and the work product doctrine apply, arguing that these cannot be invoked before the documents have been collected and without a providing a privilege log. *Id.*

Finally, Omni argues that "the Board's argument that the right to privacy militates against enforcement of the Subpoena is based on the Board's repeated, false assertion that Omni is seeking the production of the private information." *Id.* at 10. In fact, Omni contends, it is "not seeking the private information of any individual."

III. ANALYSIS

A. Legal Standards

1. Rule 45

Rule 45(d)(2)(B)(i) of the Federal Rules of Civil Procedure allows a party seeking enforcement of a subpoena to bring a motion in "the court for the district where compliance is required for an order compelling production or inspection." Fed. R. Civ. P. 45(d)(2)(B)(i). Under Rule 45(d)(3), "the court for the district where compliance is required must quash or modify a subpoena that . . . (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or (iv) subjects a person to undue burden." "[T]he party who moves to quash a subpoena has the 'burden of persuasion' under Rule 45(c)(3)." *Moon v. SCP Pool Corp*., 232 F.R.D. 633, 637 (C.D. Cal. 2005) (citing *Travelers Indem. Co. v. Metropolitan Life Insur. Co*., 228 F.R.D. 111, 113 (D.Conn. 2005); *Concord Boat Corp. v. Brunswick Corp*., 169 F.R.D. 44, 48 (S.D.N.Y. 1996); *United States v. IBM*, 83 F.R.D. 97, 104 (S.D.N.Y. 1979)).

"In federal question cases, federal privilege law applies." *N.L.R.B. v. N. Bay Plumbing, Inc*., 102 F.3d 1005, 1009 (9th Cir. 1996) (citing Fed. R. Evid. 501; *Kerr v. United States District Court*, 511 F.2d 192, 197 (9th Cir.1975), aff'd, 426 U.S. 394 (1976)). As explained in the Advisory Committee notes to Rule 501, however, state law is not necessarily irrelevant to the

existence of a privilege under federal common law:

> In those situations where a federal court adopts or incorporates state law to fill interstices or gaps in federal statutory phrases, the court generally will apply federal privilege law. As Justice Jackson has said:
>
> > A federal court sitting in a non-diversity case such as this does not sit as a local tribunal. In some cases it may see fit for special reasons to give the law of a particular state highly persuasive or even controlling effect, but in the last analysis its decision turns upon the law of the United States, not that of any state.
>
> *D'Oench, Duhme & Co. v. Federal Deposit Insurance Corp*., 315 U.S. 447, 471, 62 S.Ct. 676, 86 L.Ed. 956 (1942) (Jackson, J., concurring). When a federal court chooses to absorb state law, it is applying the state law as a matter of federal common law. Thus, state law does not supply the rule of decision (even though the federal court may apply a rule derived from state decisions), and state privilege law would not apply. See Charles A. Wright, Federal Courts 251–252 (2d ed.1970); *Holmberg v. Armbrecht*, 327 U.S. 392, 66 S.Ct. 582, 90 L.Ed. 743 (1946); *De Sylva v. Ballentine*, 351 U.S. 570, 581, 76 S.Ct. 974, 100 L.Ed. 1415 (1956); 9 Charles A. Wright & Arthur R. Miller, Federal Rules and Procedure § 2408.

Speaker ex rel. Speaker v. Cty. of San Bernardino, 82 F. Supp. 2d 1105, 1109 (C.D. Cal. 2000) (quoting Fed.R.Evid. 501 advisory committee's note). Thus, the court in *Speaker* concluded, "the Court may look to state law to fill in gaps in federal common law, but state law cannot supply the rule of decision." *Id.* "Further, if the Court were to adopt a state's law of privilege, it becomes a matter of federal common law." *Id.*; *see also Kelly v. City of San Jose*, 114 F.R.D. 653, 656 (N.D. Cal. 1987) (observing that even though federal common law governs privilege issues in federal question cases, "[a]s a matter of comity, federal courts should attempt to ascertain what interests inspire relevant state doctrine and should take into account the views of state authorities about the importance of those interests.").

An evaluation of undue burden under Rule 45 requires courts to "weigh the burden to the subpoenaed party against the value of the information to the serving party" by considering " 'such factors as relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed.' " *Moon*, 232 F.R.D. at 637 (quoting *Travelers Indem. Co. v. Metropolitan Life Insur. Co.*, 228 F.R.D. at 113 (internal quotations and citation omitted)).

2. The Official Information Privilege

"Federal common law recognizes a qualified privilege for official information." *Soto v. City of Concord*, 162 F.R.D. 603, 613 (N.D. Cal. 1995) (citing *Kerr v. U.S. Dist. Ct. for the Northern Dist*., 511 F.2d 192, 198 (9th Cir. 1975)). Courts conduct a case by case balancing analysis to determine the level of protection that should be afforded by this privilege, weighing the interests of the party seeking discovery against the interests of the governmental entity asserting the privilege. *Id.* (citing *Kelly v. City of San Jose*, 114 F.R.D. at 660; *Miller v. Pancucci*, 141 F.R.D. at 300; *Hampton v. City of San Diego*, 147 F.R.D. at 230–31; Sanchez v. City of Santa Ana, 936 F.2d 1027, 1033–34 (9th Cir.1990), cert den., 502 U.S. 957, 112 S.Ct. 417, 116 L.Ed.2d 437 (1991)).

Before courts will engage in this balancing test, a party must properly invoke the privilege by making a "substantial threshold showing." *Soto*, 162 F.R.D. at 613. To meet this requirement, the party asserting the privilege must "submit a declaration or affidavit from a responsible official with personal knowledge of the matters to be attested to in the affidavit." *Id.* "The affidavit must include: '(1) an affirmation that the agency generated or collected the material in issue and has maintained its confidentiality; (2) a statement that the official has personally reviewed the material in question; (3) a specific identification of the governmental or privacy interests that would be threatened by disclosure of the material to plaintiff and/or his lawyer; (4) a description of how disclosure subject to a carefully crafted protective order would create a substantial risk of harm to significant governmental or privacy interests, and (5) a projection of how much harm would be done to the threatened interests if disclosure were made.'" *Id.* (citation omitted).

3. Deliberative Process Privilege

The purpose of the deliberative process privilege is "to allow agencies freely to explore possibilities, engage in internal debates, or play devil's advocate without fear of public scrutiny." *Assembly of State of Cal. v. U.S. Dep't of Com.*, 968 F.2d 916, 920 (9th Cir. 1992), as amended on denial of reh'g (Sept. 17, 1992). A document must be "both 'predecisional' and 'deliberative[ ]' " to be shielded from disclosure under this privilege. *Id.* (citing *Nat'l Wildlife Fed'n v. U.S. Forest Serv*., 861 F.2d 1114, 1117 (9th Cir. 1988)). "A 'predecisional' document is one prepared in order

to assist an agency decisionmaker in arriving at his decision, . . . , and may include recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency . . . ." *Id.* (citing *Formaldehyde Inst. v. Department of Health and Human Services*, 889 F.2d 1118, 1122 (D.C.Cir.1989)) (internal quotations and citations omitted). "A predecisional document is a part of the 'deliberative process,' if the disclosure of [the] materials would expose an agency's decision making process in such a way as to discourage candid discussion within the agency and thereby undermine the agency's ability to perform its functions." *Id.* (internal quotations and citations omitted).

While the "earliest cases to examine the deliberative process privilege contrasted 'factual' and 'deliberative' materials[,]" the Supreme Court has warned against the "wooden" application of this distinction. *Id.* at 921 (quoting *Env't Prot. Agency v. Mink*, 410 U.S. 73, 91 (1973)). "The key to the inquiry is whether revealing the information exposes the deliberative process." *Id.* (citing *National Wildlife Fed'n*, 861 F.2d at 1119). "The factual/deliberative distinction survives, but simply as a useful rule-of-thumb favoring disclosure of factual documents, or the factual portions of deliberative documents where such a separation is feasible." *Id.* (citing *Julian v. Department of Justice*, 806 F.2d 1411 (9th Cir.1986)). Even where material in a document is purely factual, it may be protected under the deliberative process privilege if it "is so interwoven with the deliberative material that it is not severable." *FTC v. Warner Communications, Inc.*, 742 F.2d 1156, 1161 (9th Cir.1984).

As a general rule, the deliberative process privilege may be invoked only by the agency head after personally reviewing the documents for which the privilege is asserted. *See United States v. Rozet*, 183 F.R.D. 662, 665 (N.D.Cal.1998) (citing *Coastal Corp. v. Duncan*, 86 F.R.D. 514, 516–517 (D.Del.1980)). This requirement is intended to "deter governmental units from too freely claiming a privilege that is not to be lightly invoked[.]" *Coastal Corp.*, 86 F.R.D. at 517.

B. Whether the Subpoena is Unduly Burdensome

To determine whether the Subpoena imposes an undue burden on the Board, the Court weighs the burden the Requests impose on the Board against the value to Omni of the requested

material, considering the factors set forth in *Moon*, namely, relevance, Omni's need for the documents, the breadth of the Requests, the time period covered by them, and the particularity with which the documents are described. For the reasons set forth below, the Court concludes that the Subpoena imposes an undue burden on the Board.

1. Relevance and Omni's Need for Requested Documents

Under the FCA, any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable for a civil penalty "plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1)(A)-(B). The elements of an FCA claim are: "'(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due.'" *United States Ex Rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1017 (9th Cir. 2018), cert. denied sub nom. *Stephens Inst. v. U.S. ex rel. Rose*, 139 S. Ct. 1464 (2019) (quoting *United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166 (9th Cir. 2006)). "The FCA allows private individuals, referred to as 'relators,' to bring suit on the Government's behalf against entities that have violated the Act's prohibitions." *U.S. ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 569 (9th Cir. 2016) (citing 31 U.S.C. § 3730(b)(1)).

Like the federal FCA, the California False Claims Act ("CFCA") imposes liability on any person who "[k]nowingly presents or causes to be presented to an officer or employee of the state . . . a false claim for payment or approval." Cal. Gov.Code, § 12651(a)(1). The CFCA "is patterned on similar federal legislation" and therefore courts look to precedent construing the equivalent federal act when applying the CFCA. *State of California v. Altus Fin.*, 36 Cal. 4th 1284, 1299 (2005) (internal quotations and citation omitted).

Omni contends the documents it requests are likely to show falsity, scienter and materiality because they could show that "the prefilled syringes were created without a prescription, or that they were created, warehoused, or distributed in unsanitary conditions." Reply at 3. It also contends "complaints and inspection reports of McKesson or McKesson-related entities could

either establish or lead to other evidence that the claims were false[,]" that "inspection reports or complaints against McKesson would tend to prove that McKesson knew that its RTI program was illegal, and thus that the claims were false" and that "the requests about other entities and the Board's understanding of the legality of harvesting overfill would tend to show that the State of California believed McKesson's RTI program was illegal [and] [h]ence, Medi-Cali would not have paid the claims had it known about McKesson's activities." *Id.*

There is little doubt that some of the documents Omni requests may be relevant to its claims in the Underlying Litigation. Certainly, complaints, investigation reports and inspection reports about McKesson entities alleged to have engaged in misconduct relating to harvesting of overfill for the time period that is at issue in the Underlying Litigation are likely to be directly relevant, especially to the extent they involved the oncology drugs that are the subject of Omni's FCA claims. Further, to the extent that this conduct may not have resulted in disciplinary action, which would be reflected in a formal "accusation" that can be found on the Board's website, Omni has demonstrated the relevance of such material. Moreover, it appears to be undisputed that such documents cannot be obtained from McKesson.

Nonetheless, Omni's Requests also encompass several categories of documents and communications that appear to have limited or no relevance to its claims. First, even as to the McKesson entities, it is not apparent that the *entire* investigative file for every complaint lodged against a licensee will be relevant; indeed, to the extent that it is likely that many complaints will have nothing to do with pre-filled syringes, it is likely that requests that require the Board to produce the entire file will result in the production of thousands of irrelevant documents, all of which will likely require redaction. While the investigative files relating to complaints that directly relate to the alleged misconduct by McKesson entities during the relevant period (discussed below) may be have significant relevance, the relevance of many investigative files is likely to be low.

Second, to the extent that Omni seeks documents and communications that relate to the activities of non-McKesson entities who may have engaged in conduct similar to that which is alleged as to McKesson, it has not made a strong showing as to the relevance of such documents

and communications or its need for them. Omni takes the position that documents and communications relating to prefilled syringe activities by non-McKesson entities could demonstrate materiality by showing that the Board believed such activities to be unlawful and therefore, that Medi-Cal would not have paid McKesson's claims. Yet Omni does not dispute that the Board has no involvement in Medi-Cal payments, and it has pointed to no evidence demonstrating the connection between the Board's activities and Medi-Cal payment decisions. The Court further notes that the Board's website already makes available at least some information about complaints that give rise to disciplinary action, including the accusation and, where applicable, the administrative decision. The suggestion that complaints and investigations involving non-McKesson entities will somehow demonstrate materiality as to McKesson's claims seems far-fetched.

Omni also has not demonstrated that the information sought in Request Nos. 7, 8, 9, 10, and 11, relating the Board's understanding of the law, is relevant to the Underlying Litigation. As discussed above, the Board does not make Medi-Cal payments; nor is there any evidence that it is involved in the decision-making related to reimbursement policies. To the extent the Board's positions as to what is wrongful with respect to prefilled syringes might show that McKesson knew its conduct was wrongful, thus demonstrating scienter, it is hard to understand how information that was not public and would not have been known to McKesson could support any such inference. To the extent the Board may have taken any positions on the legal requirements governing prefilled syringes, they are only likely to be relevant if they were made public – for example, in the educational materials that are available on its website or in the published disciplinary decisions that are also available on its website. Therefore, Omni has not demonstrated that it needs the documents and information that are sought in these Requests.

This factor points to the conclusion that the Subpoena imposes an undue burden on the Board.

2. Breadth of Requests

Omni's Requests are extremely broad. The Board has presented evidence that in order to comply, it would have to manually review the files of over 141,000 licensees, and that searching

and redacting the documents Omni requests would consume tens of thousands of hours. This factor also supports the conclusion that the Subpoena imposes an undue burden.

3. Time Period Covered by Requests

Although the Board pointed out that the Requests cover a period of approximately twenty years, Omni offers little justification for refusing to limit the time period covered by its Subpoena. Omni asserts in the Motion that the Underlying Action alleges that McKesson "engaged in a massive campaign of pharmaceutical fraud over the course of at least eight years (from 2005 to 2013)." Motion at 1. Likewise, at the motion hearing, Omni represented that the claims in the Underlying Litigation are based on McKesson's RTI Program, which ran from 2005 into 2010, and the MedPrep program, which ran from 2010 into 2013. Based on that representation, the Court concludes that the time period for which the Requests are likely to produce relevant documents is approximately 2005-2014, which allows for the possibility that in the year after these programs ended documents related to the programs continued to be generated. To the extent that Omni seeks documents and communications for many years after the relevant conduct ended, the time period covered by the Requests supports the conclusion that they pose an undue burden on the Board.

4. Particularity

As discussed above, the Requests as currently framed are very broad. Conversely, the Requests contain virtually no specifics targeting the documents and information that is most likely to be relevant and necessary to Omni. This factor also supports the conclusion that the Requests impose an undue burden on the Board.

5. Conclusion

Weighing the considerations discussed above against the significant burden imposed on the Board, the Court finds that the Subpoena is overbroad and imposes an undue burden. As stated at the motion hearing, the parties shall meet and confer as to Requests 1-6 and 15 to negotiate requests consistent with the discussion above that are narrower and reduce the burden of compliance on the Board by 1) limiting the Requests to the McKesson entities; 2) limiting the time period covered to no more than 2005 through 2014; and 3) limiting requests for complaints,

inspection reports, investigation reports (and potentially a narrow scope of underlying documentation), and documents showing any remedy imposed by the board, relating to the McKesson entities concerning the subject of the harvesting of overfill. The Court will not allow the discovery requested in the remaining Requests.

C. Whether The Subpoena Should be Modified or Quashed Because it Requests Privileged Documents

Because of the overbreadth of the Subpoena, and the massive number of documents that would have had to be reviewed to create privilege logs, the Board was unable to supply detailed information in support of its claims of privilege. Therefore, it is premature for the Court to rule on those objections. Rather, the Court will address this issue, if necessary, when the Board has had an opportunity to respond to the Subpoena as modified herein and provide detailed privilege logs to Omni and the parties have conducted meaningful meet-and-confer discussions to resolve their differences. The Court cautions the parties that it expects issues of privilege to be resolved by the parties whenever possible. The Court generally does not resolve disputes relating to privilege by conducting its own *in camera* review of the documents. To assist the parties, the Court addresses certain issues raised by the parties in connection the privileges asserted by the Board.

1. Official Information Privilege

As discussed above, federal common law affords a qualified privilege to official government information. Information that is collected by the Board in the course of investigating complaints or conducting inspections and that is not made public likely constitutes official information that is eligible for protection under the official information privilege. Moreover, disclosure of this information implicates serious concerns related to the Board's ability to effectively conduct its oversight functions. These concerns were recently recognized by the California Court of Appeal in a case addressing a subpoena that sought, *inter alia*, investigative records from the California State Board of Registered Nursing), the California State Board of Pharmacy (the Board), and the Medical Board of California. *Bd. of Registered Nursing v. Superior Ct. of Orange Cty*., 59 Cal. App. 5th 1011, 1021 (2021), reh'g denied (Feb. 3, 2021), review denied (Apr. 21, 2021). In that case, the court described these concerns as follows:

> [T]he agencies themselves have an interest in protecting the integrity of their investigations and disciplinary proceedings. This interest is reflected in both the official information privilege and the related deliberative process privilege. The agencies rely on the confidentiality of complaints, witnesses, deliberations, and the proceedings in general to protect vulnerable patients and witnesses—including the colleagues of the investigated or disciplined health care professionals—and maximize the truth-seeking function of their efforts. Indiscriminate production of investigatory files and administrative records would discourage cooperation by persons outside the agencies and candid discussion by persons inside the agencies. . . . The interest in confidentiality clearly outweighs defendants' interest in obtaining these broad categories of documents, many of which have little or no relevance to the claims and defenses at issue in this proceeding. . . . This conclusion is especially sound where the agency has ended an investigation without seeking discipline or other legal sanction.

Id. at 1041-1042. While the court in this case was applying California's official information privilege, the concerns it expressed are also applicable under federal common law. Moreover, as discussed above, even when courts apply federal common law, they may look to state law for guidance. Omni's vehement arguments that the Court should ignore California privilege law altogether is unavailing.

Nonetheless, this privilege may not be invoked lightly. In order to find that this privilege applies, the Court will require a detailed explanation addressing not only the potential harm that could result from disclosure of the particular document but also an explanation of why this harm cannot be avoided through redactions and/or a strict protective order.

2. Deliberative Process Privilege

The Board contends the deliberative process privilege may be implicated as to investigations that remain open and as to investigations that the Board chose to close without bringing disciplinary action. As to the former scenario, because the Court has narrowed the Subpoena to cover the time period at issue in the Underlying Litigation, the likelihood that the Subpoena will require production of any documents that relate to ongoing investigations is diminished. The Court reserves judgment on the question of whether the privilege is likely to apply to documents related to investigations that did not result in action by the Board.

IV. CONCLUSION

For the reasons stated above, the Motion is DENIED. Within one week of today, the

parties shall meet and confer via Zoom regarding the scope of the Subpoena to negotiate a compromise consistent with this opinion. While the Court expects that the parties will be able to resolve their disputes based on the guidance provided above, if they are unable to resolve any dispute relating to the scope of the Subpoena and require the Court's intervention, they should file a joint letter, not to exceed five pages, single-spaced, setting forth each side's position and their final proposed compromise positions. If the dispute relates to the Board's assertion of privilege, the parties should bring a formal motion consistent with the Civil Local Rules of this Court governing motion practice.

IT IS SO ORDERED.

Dated: May 21, 2021

JOSEPH C. SPERO
Chief Magistrate Judge

United States District Court
Northern District of California