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IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

COORDINATED PROCEEDINGS SPECIAL TITLE (RULE 1550(b)),

ESSURE PRODUCTS CASES
______________________________/

JCCP No. 4887
Case No. R-2135744

MEMORANDUM OF POINTS & AUTHORITIES IN SUPPORT OF MOTION FOR LEAVE TO PARTICIPATE AS AMICUS, TO UNSEAL COURT RECORDS, AND TO AMEND THIS COURT'S PROTECTIVE ORDER

Unlimited Civil Case

Date: March 20, 2020
Time: 10:00 a.m.
Dept: 21
Hon. Winifred Y. Smith
Reservation No. R-2162987

Assigned for all purposes to Hon. Winifred Y. Smith – Dept. 21

Filed By Fax

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1
I. INTRODUCTION

2 Proposed Amicus Dr. Joseph Ross seeks to appear in this case to make public important
3 information about Bayer's systematic failure to investigate and disclose the serious dangers of
4 medical device Essure. This information is vital to helping medical professionals effectively treat
5 the hundreds of thousands of people with Essure devices still implanted in their bodies, to
6 understanding the ways the current regulatory structure failed to protect against the risks Essure
7 posed, and to ensuring that similar disasters do not occur if Essure is brought back to market or
8 with other medical devices. As a member of the public, under California law Dr. Ross must be
9 permitted to enter the case for the purpose of seeking to make these litigation documents public.
10 Bayer seeks to keep vital public health and safety information secret by filing or lodging
11 documents with the Court under seal. Bayer filed hundreds of pages of critical documents
12 without any party having moved for sealing and without any court order approving sealing. Both
13 this Court's rules—California Rules of Court 2.550 and 2.551—and the First Amendment
14 require that, where a party puts forth no justification for sealing, the documents *must* be made
15 public. Further, both this Court's rules and the First Amendment require that any effort to seal
16 court records be done in a timely fashion. It is too late for any party to attempt to make such a
17 showing now. Regardless, based on the evidence available to the public, any untimely effort to
18 seal would be futile on the merits. As such, Dr. Ross requests that the Court order any documents
19 for which there is no sealing order be unsealed immediately.
20 Equally critical is information contained in documents produced in discovery that Bayer
21 mass-designated as confidential (as it did to 99% of its production). As more information about
22 what Bayer initially designated as confidential becomes public, it is more and more evident that
23 Bayer abused the process outlined in this Court's protective order and failed to meet the good
24 cause standard for confidentiality laid out by California law. The protective order should be
25 amended to prevent Bayer from continuing to flout it and the law going forward.

26
II. RELEVANT FACTS AND PROCEDURAL HISTORY

27
A. Information about Essure is critical to public health.

28 For more than a decade, the Bayer Defendants and their predecessor Conceptus (together

“Bayer”) marketed Essure as a safe, non-surgical, permanent form of birth control. During this time, Essure was implanted into somewhere between 500,000 and 1,000,000 people. Declaration of Joseph Ross, MD, MHS, dated February 13, 2020 (“Ross Decl.”), filed herewith, ¶ 8. Over time, and as the Plaintiffs here allege, it became clear that Essure—far from being safe—appears to have caused thousands of serious health problems including severe pain, organ perforation, miscarriages, and possibly deaths. Plaintiffs here allege that Bayer failed in its duty to track and investigate adverse events and to notify the Food and Drug Administration (FDA) and the public about the serious risks of Essure. (*E.g.*, Master Compl. ¶¶ 4, 53–87). As a result, Essure stayed on the market for many years without substantial warnings, and was implanted into—and caused injury to—more and more people. Today, Essure is off the market. But Bayer still has not admitted that there are any safety issues with the device. On its website, Bayer claims that it made a “business decision to voluntarily discontinue sales,” saying: “We made this decision based on a decline in Essure sales, and the conclusion that the Essure business is no longer sustainable. There has been no change in the positive safety and efficacy profile of Essure[.]” Declaration of Stephanie K. Glaberson, dated February 13, 2020 (“Glaberson Decl.”), filed herewith, Ex. 1. And the device, intended to be permanent, remains in hundreds of thousands of bodies—bodies of people who may still experience symptoms that they and their medical teams do not immediately connect to Essure. *See* Ross Decl. ¶ 11.

B. Bayer mass-designated 99% of its discovery production as “confidential.”

Bayer designated nearly all the documents it produced in discovery here as confidential, purportedly pursuant to this Court’s protective order (Case Management Order No. 3: Protective Order (“CMO 3”)). That order defines “confidential” information as that which California and federal law consider to be confidential, and provides that any party may designate material, but must exercise “good faith” in doing so. CMO 3 ¶¶ 1(a); 2(a).

And yet, Bayer designated 99% of the pages it produced as “confidential,” regardless of whether they in fact “contain trade secrets or other protectable information.” (Pls’ Mem. In Support of Mot. to Compel Removal of Specific Confidential Designations at 1:3-4).

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C. This Court found that Bayer wrongly designated as "confidential" the vast majority of a small sample of records presented to it for review.

When this Court had the opportunity to examine Bayer's discovery designations, it found them wanting. CMO 3 lays out a procedure for a party to challenge a "confidential" designation, which permits parties to file motions making such challenges under seal if they contain references to confidential information. CMO 3 ¶ 3(b). This procedure applies only to disputes about confidentiality designations and does not apply when parties seek to file documents in support of other motions. For any records submitted "for use at trial or as the basis for adjudication of matters other than discovery motions or proceedings," CMO 3 directs the parties to comply with the procedures laid out in CRC 2.551. *Id.* ¶ 5(b). CMO 3 explicitly warned the parties that "failure to comply with the procedural requirements of CRC 2.551 or failure to present evidence sufficient to support the findings set forth in CRC 2.550(d) may result in the placement of Confidential Materials in the public file." *Id.* ¶ 5(c).

On May 24, 2019, in accordance with the procedures set out in CMO 3 ¶ 3, Plaintiffs moved to compel Bayer to remove confidentiality designations as to specific documents. Plaintiffs identified eighteen documents that they asserted were improperly designated, including certain Establishment Inspection Reports ("EIRs"), Corrective and Protective Action documents ("CAPAs"), FDA Form 483s, FDA Annual Reports, Standards of Operating Procedure ("SOPs"), and the deposition of Michael Reddick. Plaintiffs explained that the documents presented for review represented a "sampling of documents central to the issues at trial," each standing in for a larger category of similar records.

This Court granted Plaintiffs' motion in major part. (11/13/19 Order). Of the eighteen-document sample presented, this Court found that sixteen were improperly designated. Among those, many reveal information important to the public. For instance, one wrongly-designated document shows that, as of September 2008, Conceptus had "approximately 2000 open complaints" that it had not responded to in a timely manner, "due to a lack of resources/personnel." Glaberson Decl. ¶ 2 Ex. 2. Conceptus was given a period of approximately four months to "add additional personnel to address the current backlog issues," and the

document notes that "a consultant ha[d] been hired to assist with these issues." Yet for more than a year following identification of this problem, and with little to no justification, Conceptus's deadline to address this issue was continually extended. *Id*. During that time, the backlog of open, unaddressed complaints about Essure continued to grow. *See id*. [noting backlog of 2500 complaints as of August 2009]. Another—an FDA Form 483 from 2003—shows that Conceptus did not follow its own quality control procedures, failing to document instances in which devices were found to be "nonconforming." Glaberson Decl. Ex. 3. And another reveals information about individuals who were part of early Essure trials and had to have their uterus and fallopian tubes removed following implantation. *Id*. Ex. 4. Yet another, a 2009 amendment to an annual report to the FDA, includes a lengthy list of Essure-related injuries, nearly all of which had not been previously reported as "Medical Device Reports" ("MDRs"). *Id*. Ex. 5.

This Court denied Plaintiffs' request to apply its rulings categorically, leaving Bayer's designations in place as to all but those records specifically challenged. (11/13/19 Order at 5).

D. Bayer has de-designated additional documents in advance of trial that should never have been designated as "confidential" to begin with.

Since this Court's ruling and in advance of trial, at Plaintiffs' urging, Bayer has de-designated dozens of additional documents that previously were unnecessarily shrouded in secrecy. Among these are documents that include no sensitive information, and should never have been designated in the first place, such as: physician training materials, departmental organizational charts, device labelling materials, stale pre-2013 FDA reports, SOPs similar to those this Court de-designated in its November 13, 2019 Order, blank investigation forms, and the FDA's own, publicly-available "Medical Device Safety Action Plan" and "Medical Device Reporting for Manufacturers" guidance document. Glaberson Decl. Exs. 6–27. A number of the documents Bayer has now de-designated shed light on important public health matters. For instance, they show that adverse events were underreported during Essure's "Pivotal Trial" due to a coding and design error in Conceptus' data gathering that failed to capture adverse events that came to light at "unscheduled visits," and that this error was not caught by any internal quality control mechanisms, but instead by vital FDA oversight. *Id*. Exs. 28–29.

E. The record is replete with sealed filings that have not been the subject of a motion to seal or sealing order.

Information that should be public is missing from the record because the parties filed or conditionally lodged numerous documents under seal without this Court's approval. These include filings related to Bayer's multiple summary judgment motions, numerous motions in limine, and more. For example: (1) filings related to Defendants' motion for summary judgment or, in the alternative, for summary adjudication (Valerie George), such as the Declaration of Amy Eskin in support of Plaintiff George's Opposition, Plaintiff George's Opposition, and Plaintiff George's Response to Defendants' Statement of Undisputed material facts; (2) filings related to Defendants' motion for summary judgment (statute of limitations), such as exhibits to the Supplemental and Amended Declaration of Elizabeth Graham in support of Plaintiffs' opposition; and (3) filings related to Plaintiffs' motion in limine to exclude evidence and argument that MDRs were not a factor in FDA's 2015 decisions, such as exhibits to the Declaration of Amy Eskin.[1]

This Court has rejected virtually all of the limited sealing requests the parties have made. According to the public record, only three motions to seal have been filed: Bayer's motion to seal the complaint of Katie Elder, Plaintiffs' motion to seal personal information in motions for summary judgment, and Bayer's motion to seal certain documents regarding audits. This Court denied Bayer's motion to seal the Elder complaint and Plaintiffs' motion to seal information in motions for summary judgment, save for certain personally-identifying information. (10/17/2019 Order). On February 5, 2020, this Court rejected Bayer's motion to seal audit records. The Court observed that "[u]nless confidentiality is required by law, court records are presumed to be open." (Order at 2 (citing CRC 2.550(c))). The Court rejected Bayer's argument that FDA regulations mandate secrecy, and found that Bayer had "not demonstrated that the information is confidential business information that has current commercial value." *Id.* at 3–4. The Court found that two of the documents, being from 2008, were "stale," and that Bayer had failed to demonstrate any overriding interest in keeping more recent documents confidential. (*Id.* at 4).

[1] It is not possible for Dr. Ross, as a member of the public and not a party to this case, to determine with certainty each document currently under seal. This list is presented merely as a sample, and is not intended to be exhaustive.

The first bellwether trial in this case is set to begin on March 9, 2020.

III. ARGUMENT

A. THIS COURT SHOULD GRANT DR. ROSS LEAVE TO APPEAR AS AMICUS CURIAE TO SEEK ACCESS TO COURT RECORDS AND TO MODIFY THIS COURT'S PROTECTIVE ORDER.

The Court should permit Dr. Ross to participate in this case under California Rule of Court 2.551. That rule provides that any "member of the public may move, apply, or petition . . . to unseal a record." The proper mechanism by which to bring a Rule 2.551 motion is for a member of the public to appear as amicus curiae, and Dr. Ross does so here. *Overstock.com, Inc. v. Goldman Sachs Grp., Inc.* (2014) 231 Cal. App. 4th 471, 489, 180 Cal. Rptr. 3d 234, 249.Because Dr. Ross "must be given an opportunity to be heard on the question of [his] exclusion" from court records and proceedings, this Court must grant his motion to participate in the case as amicus to seek to unseal court records under Rule 2.551. *NBC Subsidiary (KNBC-TV), Inc. v. Super. Ct.* (1999) 20 Cal. 4th 1178, 1217 n.36, 980 P.2d 337, 365.

Even if this Court had the discretion to deny Dr. Ross' motion, it should not do so here.[2] Although any person can move to unseal court records and no special interest is necessary under Rule 2.551, *In re Marriage of Nicholas* (2010) 186 Cal. App. 4th 1566, 1577, 113 Cal Rptr. 3d 629, 637, Dr. Ross also has a particular interest in the proceedings here. He is a medical doctor, academic, and advocate who has written and advocated about the Essure medical device. *See* Ross Decl. ¶¶ 1, 2, 7, Ex. 1. He has also written about the harmful impact on public health of secrecy in litigation—both in terms of sealing of court records and "overly broad" confidentiality orders. Dr. Ross is a co-founder and co-director of the Collaboration for Research Integrity and Transparency (CRIT) at Yale Law School, an inter-disciplinary initiative that aims to enhance the quality and transparency of the research base for medical products, in part by promoting transparency and access to medically-relevant data. (*Id.* ¶¶ 4–5). In September 2018, CRIT published a conference report titled "Preventing the Use of Courts to Shield Essential Health Information: Rethinking Confidentiality in Medical Product Litigation," which advocated the

[2] This Court generally has the "inherent power" to exercise "reasonable control over all proceedings connected with the litigation before it, including by authorizing the participation of amici curiae. *Cooper v. Super. Ct. In & For Los Angeles Cty.* (1961) 55 Cal. 2d 291, 301; *In re Marriage Cases* (2008) 43 Cal. 4th 757, 791, 183 P.3d 384, 407.

adoption of a set of best practices to improve public access to "critical information about the safety and effectiveness of drugs and [medical] devices" often unearthed through litigation. (*Id.* ¶ 6). Accordingly, Dr. Ross not only has a strong interest in accessing the judicial records and documents at issue here, but can also provide this Court with an important and well-founded perspective on the effects of its sealing and confidentiality orders.

For these reasons, this Court should grant Dr. Ross's application to appear as amicus curiae here to pursue his and the public's right of access to this Court's records. Under *NBC Subsidiary*, however, if the court denies Dr. Ross's application, it must provide him another avenue by which to pursue access to the records. *NBC Subsidiary,* 20 Cal. 4th at 1217, n.36.

B. THIS COURT SHOULD UNSEAL ITS RECORDS.

1. The records should be made public because no party has asserted any basis for sealing them.

This Court should immediately make public any records currently under seal for which it has not issued a sealing order because no party has moved to seal those records as this Court's procedures require. Moreover, because no party has even attempted to show that the high bar imposed by the First Amendment (and this Court's rules) for sealing has been met, the records should be unsealed.

California Rules of Court 2.550 and 2.551, which implement First Amendment principles and which were not followed here, require a specific procedure before a court may order a record sealed. Under Rule 2.551, the "party requesting that a record be filed under seal must file a motion or an application for an order sealing the record," and must support its motion with "facts sufficient to justify the sealing." Rule 2.551(b)(1). The court may grant a properly-filed motion to seal "only if it expressly finds facts that establish: (1) There exists an overriding interest that overcomes the right of public access to the record; (2) The overriding interest supports sealing the record; (3) A substantial probability exists that the overriding interest will be prejudiced if the record is not sealed; (4) The proposed sealing is narrowly tailored; and (5) No less restrictive means exist to achieve the overriding interest." *Id.* 2.550(d). The court's sealing order must "[s]pecifically state the facts that support the findings" and direct the sealing of only those

"portions" of the documents and pages "needs to be placed under seal." *Id.* Here, the failure of the parties to file motions to seal in accordance with Rules 2.550 and 2.551 should be the end of the inquiry. The records should be made public.

Unsealing is likewise warranted under the First Amendment because the parties fail even to attempt to show the records should be sealed. Indeed, the First Amendment requires that a high bar be met to overcome the public's First Amendment right of access to court records. *See Nixon v. Warner Commc'ns, Inc.* (1978) 435 U.S. 589, 597; *Overstock.com, Inc. v. Goldman Sachs Grp., Inc.* (2014) 231 Cal. App. 4th 471, 483–86. This First Amendment "right of access 'serves the important functions of ensuring the integrity of judicial proceedings.'" *KNSD Channels 7/39 v. Super. Ct.* (1998) 63 Cal. App. 4th 1200, 1203, 74 Cal. Rptr. 2d 595 [quoting *United States v. Hubbard* (D.C. Cir. 1980) 650 F.2d 293, 315].[3] It "plays an important and specific structural role" in judicial proceedings, promoting public confidence by demonstrating "that justice is meted out fairly," providing "a means by which citizens scrutinize and change the use and possible abuse of judicial power," and "enhance[ing] the truthfinding function of the proceeding." *Mercury Interactive Corp. v. Klein* (2007) 158 Cal. App. 4th 60, 96.

The First Amendment therefore requires that any document used at trial or "filed in court as a basis for adjudication," be presumed public. *NBC Subsidiary,* 20 Cal. 4th at 1208 n.25. Likewise, Rules 2.550 and 2.551 apply to "discovery materials that are used at trial or submitted as a basis for adjudication of matters other than discovery motions or proceedings." C.R.C. 2.550(a)(3). This includes "all discovery materials submitted to a court in support of and in opposition to a pending motion," regardless of whether the court actually relies on the particular material. *Overstock.com, supra*, 231 Cal. App. 4th at 492.

The rules—and the constitutionally-grounded presumption of openness they embody—therefore apply here to any exhibits that will be used at the upcoming trial, and filings submitted by either party in support of or opposition to motions for summary judgment, motions in limine, or other matters for this Court's adjudication (except for discovery motions). As this Court has

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[3] Throughout the California Supreme Court's right of access jurisprudence, it has relied on United States Supreme Court and federal case law as a guide. *See, e.g.*, *NBC Subsidiary*, 20 Cal. 4th at 1197–1209 (reviewing U.S. high court cases); *Overstock.com*, 231 Cal. App. 4th at 484–85 (relying on federal appellate decisions).

already recognized, the public's right of access is at its zenith with regard to exhibits introduced at trial and papers submitted "for purposes of adjudication on the merits." *E.g.* 2/5/20 Order at 2 ["the public interest in the transparent adjudication of claims by the judicial system increases as a case moves closer to adjudication on the merits"]. Likewise, the Court's adjudication of what evidence will be admitted at trial, and whether applicable rules of evidence are followed as the Court makes its evidentiary rulings, are among those matters which this Court should be "very reluctant" to seal. *See id*. Indeed, as the U.S. Supreme Court said in *Waller v. Georgia*, evidentiary hearings "often are as important as the trial itself." (1984) 467 U.S. 39, 46. The structural purpose that openness serves—ensuring that the Court and litigants before it "carry out their duties responsibly"—is "no less pressing" when the court is dealing with evidentiary matters than it is at the substantive moments of trial. *Id.*

That a party might someday file a motion to seal is not good enough to permit prolonged conditional secrecy. Having failed to comply with the sealing rules through the course of litigation, the parties cannot now move to seal this Court's records. California courts have expressed particular "concern about delayed rulings on sealing issues." *Overstock.com*, 231 Cal. App. 4th at 496. The public's right of access "should be immediate and contemporaneous,"—unnecessary delay would "defeat the purpose of the rules." *Id.* (quoting *Mercury*, 158 Cal. App. 4th at 92; *Savaglio v. Wal-Mart Stores* (2007) 149 Cal. App. 4th 588, 601). The rules' timelines for compliance, therefore, are short: A party seeking to seal papers it produced that are filed by another party must file its motion within ten days of receiving notice of the intended filing. CRC 2.551(b)(3); *Savaglio*, 149 Cal. App. 4th 588, 601. Although the rules do not specifically lay out a time limit for motions to seal a party's own filings, "any reading of rules 2.550 and 2.551 that encourages an open-ended time frame for filing a motion to seal records . . . would defeat the purpose of the rules" and be contrary to this Court's constitutional duty to construe the rules broadly in favor of access. *Savaglio*, 149 Cal. App. 4th at 601; *see also* Cal. Const. art. I, § 3 ["A statute, court rule, or other authority . . . shall be broadly construed if it furthers the people's right of access, and narrowly construed if it limits the right of access."]. The Court is without discretion to "entertain a belated motion to seal." *Savaglio*, 149 Cal. App. 4th at 601.

This Court's own protective order warned the parties that failure to follow the necessary sealing procedures could "result in the placement of Confidential Material in the public file." CMO 3 ¶ 5(c). And the parties have shown themselves capable of filing sealing motions, albeit unsuccessfully and belatedly, as to certain records. Yet even as they did so, they neglected the numerous other records currently shielded from public view. This neglect should result in the documents being unsealed. *Id.*; CRC 2.551(b)(3)(B) [where party fails to file motion to seal, "clerk must promptly transfer all the documents" to the public file].

Because no party has even attempted to meet the burdens imposed by this Court's rules and the First Amendment, the records—including, but not limited to filings supporting summary judgment and motion in limine briefing—must be immediately unsealed.

2. No sealing order is warranted.

The party bringing a motion to seal must prove that the prejudicial effect of unsealing the material outweighs the public's strong right of access. CRC 2.550(d). Not only has no party attempted to meet the burden to seal, but there is no indication that the parties could meet the stringent standard for sealing. That standard requires the Court to find that (1) There exists an overriding interest that overcomes the right of public access to the record; (2) The overriding interest supports sealing the record; (3) A substantial probability exists that the overriding interest will be prejudiced if the record is not sealed; (4) The proposed sealing is narrowly tailored; and (5) No less restrictive means exist to achieve the overriding interest." CRC 2.550(d). The greater the public interest, the greater the competing interest must be to overcome it. *Shane Grp., Inc. v. Blue Cross Blue Shield of Mich.* (6th Cir. 2016) 825 F.3d 299, 305. No party can make such a showing here.

The public interest in these records is particularly strong. The sealed records promise to reveal information that is vital to public health and safety. *Kondash v. Kia Motors Am., Inc.*, (6th Cir. 2019) 767 F. App'x 635, 637 ["The presumption in favor of public access is strong when public safety is implicated."]. They promise to reveal information that is necessary to ensure that similar problems do not recur with Essure if it is brought back to market. Additionally, the information they contain is needed to improve medical care for those currently implanted with

Essure. And the records also are likely to improve public understanding of the evaluation and regulatory requirements that should be imposed on other medical devices currently in development, under FDA review, or currently marketed and being used in clinical practice. Ross Decl. ¶¶ 10–12. Where such information is at stake, "the interests of public health and safety will often outweigh any confidentiality interests that might be implicated." *Id.* [quotation omitted].

No party can show a countervailing interest in confidentiality sufficient to override the public's strong interest. First, to the extent Bayer may argue that there is commercially sensitive information in the records, such an argument is meritless—and has already been rejected by this Court as to numerous records in this case. Trade secrets and other commercially sensitive information lose their commercial value—and protection—over time. *See, e.g.*, *Whyte v. Schlage Lock Co.* (2002) 101 Cal. App. 4th 1443, 1452; *Biles v. Dep't of Health & Human Servs.* (D.D.C. 2013) 931 F. Supp. 2d 211, 225, n.17 [collecting cases]. Although still vital to the public in understanding the Essure story and the failings that led to it, the information at issue in this case is stale from a business standpoint. The important events in this case occurred from approximately 2002, when Essure entered the market, to 2015, when public pressure resulted in more robust FDA regulatory action. *See* Master Compl. ¶¶ 29–88. As this Court has previously explained, documents from the vast majority of this period will not qualify for protection from disclosure. *See, e.g.*, 2/5/20 Order at 4 [finding documents from 2008 to be "stale"]; 11/13/19 Order at 7–9 [finding documents from 2001–2009 to have lost any protections they might once have had]. Where documents do not warrant a confidentiality designation—a lower bar—they certainly do not warrant sealing.

What's more, Essure is now off the market, and Conceptus no longer exists. [Master Compl. ¶¶ 12, 98–99]. Even when Essure was on the market, it was a unique product, with no competition. Despite having no competition, Bayer claims that it decided to pull the product from the market because "the Essure business is no longer sustainable." Glaberson Decl. Ex. 1. In this context, it would be difficult, if not impossible, for Bayer to show how old information, much of which relates to a defunct company, about a discontinued product that was discontinued because (they claim) it was not profitable, could be used to cause it competitive harm. *See Cole's*

Wexford Hotel, Inc. v. Highmark, Inc. (W.D. Pa. May 31, 2019) No. 2:10-CV-01609-JFC, 2019 WL 3778090, at *24 [old information about discontinued product "stale"].

This Court has also already confronted—and rejected—Plaintiffs' only sealing request in this case, to keep certain personal information private. This Court found that Plaintiffs had placed that information "at issue when they filed their complaints alleging that they had Essure procedures and Essure has caused them to suffer personal injuries." (10.17.2019 Order at 4). Thus to the extent any party claims that documents should be sealed because of personal information, that argument, too, would be rejected.[4]

C. THIS COURT SHOULD AMEND ITS PROTECTIVE ORDER.

This Court should amend its protective order to ensure that Bayer does not continue using that order as a shield to unnecessarily keep important public health information secret. Bayer has a track record in this case of abusing this Court's protective order by mass designating 99% of its disclosures as confidential, when all evidence suggests there is no reason to shield the vast majority of those records. This Court should prevent Bayer from doing so going forward.

Ordinarily, parties are free to share documents they receive in discovery with the public. *See San Jose Mercury News, Inc. v U.S. Dist. Ct.-N. Dist.t (San Jose)* (9th Cir. 1999) 187 F.3d 1096, 1103. Indeed, California courts have recognized that the public has an interest in accessing discovery records. *See Westinghouse Elec. Corp. v. Newman & Holtzinger* (1995) 39 Cal. App. 4th 1194, 1208 [secrecy agreements and protective orders impair the public's access to discovery records]. While courts may enter protective orders limiting the parties' ability to further disseminate discovery to facilitate discovery, they should only do so on showing of "good cause." Cal. Civ. Proc. Code § 2031.060. "Because the judicial process is frequently the avenue by which the public and regulatory agencies learn of significant health and safety hazards, blocking this avenue may prove detrimental to the public well-being." *Westinghouse*, 39 Cal. App. 4th at 1208. For this reason, and as this Court has noted, "[w]here the subject matter of a protective order concerns health and safety matters," the Court must consider the public interest

[4] This Court permitted Plaintiffs to seal certain identifying information such as social security numbers and dates of birth. Obviously, that information could be easily redacted and does not warrant sealing documents—or pages of documents—in full.

in access to the information. Order at 4 [citing *Westinghouse*, 39 Cal. App. 4th at 1208].

In an attempt to facilitate the discovery process, this Court issued its preliminary, blanket protective order allowing the parties to designate their own materials as confidential in the first instance. CMO 3. But a party's own confidentiality designations do not substitute for a judicial finding of good cause. *See Cipollone v. Liggett Group* (3rd Cir. 1986) 785 F.2d 1108, 1122. A blanket protective order can only protect documents "initially." *Id.* The burden of establishing the need for confidentiality is at all times on the party asserting it. *Bridgestone/Firestone, Inc. v. Super. Ct.* (1992) 7 Cal. App. 4th 1384, 1393, reh'g denied and opinion modified (July 23, 1992).[5] Blanket protective orders like that issued here "are by nature overinclusive and are, therefore, peculiarly subject to later modification." *Pansy v. Borough of Stroudsburg* (3rd Cir. 1994) 23 F.3d 772, 790 n. 26. Where, as here, there is evidence that the court's protective order is being abused, the Court can and should modify that order. *Cf.* Cal. Civ. Code, § 3424, § 533 [court may modify or dissolve injunction upon material change in facts or law, or where "ends of justice would be served"].

Here, Bayer has abused this Court's protective order by mass-designating 99% of its production confidential, when there is evidence that much, if not most, of its production does not answer to that description. First, Bayer's designation of 99% of its disclosures in and of itself make those designations suspect. *See, e.g.*, *Procaps S.A. v. Patheon Inc.* (S.D. Fla. July 20, 2015) No. 12-24356-CIV, 2015 WL 4430955, at *7 [collecting cases finding 95% (and lower) designation rates "absurd"]; *In re ULLICO Inc. Litig.* (D.D.C. 2006) 237 F.R.D. 314, 317 [99% designation rate "gross[] abuse[]" and in bad faith]; *Minter v. Wells Fargo Bank, N.A.* (D. Md. Dec. 23, 2010) No. CIV WMN-07-3442, 2010 WL 5418910, at *2 [finding that "defendants violated the Confidentiality Order in failing to exercise good faith in the designation of vast

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[5] Nationwide, courts agree that the burden remains at all times with the proponent of confidentiality. *See, e.g.*, *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.* (3d Cir. 2019) 924 F.3d 662, 671 [proponent of protective order bears burden as to "each and every document"]; *In re Roman Catholic Archbishop of Portland in Or.* (9th Cir. 2011) 661 F.3d 417, 424; *Foltz v. State Farm Mut. Auto. Ins. Co.* (9th Cir. 2003) 331 F.3d 1122, 1130 [same]; *Midwest Athletics & Sports All. LLC v. Ricoh USA, Inc.* (E.D. Pa. 2019) 332 F.R.D. 159, 160 [same]; *Mampe v. Ayerst Labs.* (D.C. 1988) 548 A.2d 798, 804 n.11 [in cases involving "umbrella" protective orders, burden remains "at all times" with proponent]. Some write this requirement explicitly into their model protective orders. *See, e.g.*, N. Dist. of California Model Protective Order at ¶ 6.3, available at https://www.cand.uscourts.gov/wp-content/uploads/forms/model-protective-orders/CAND_StandardProtOrd.pdf.

amounts of the produced documents as 'confidential'"]. This Court has already found, upon review of a small subset of designated records, that the majority of Bayer's designations are improper. (11/13/19 Order). In deciding Plaintiffs' motion to compel Bayer to lift certain designations, this Court reviewed a sample of eighteen documents, finding that all but two should not remain confidential. There is no reason to believe these documents are unique among Bayer's production—in fact, Plaintiffs specifically argued that they stand in for and are similar to larger categories of records Bayer produced and designated. And Bayer itself has now de-designated a series of documents that confirm that its initial designations fell far short of the good faith standard. *See supra* at 4 [describing Bayer's de-designation of blank documents, organizational charts, and other non-confidential information]. All evidence indicates that Bayer has consistently misused the confidentiality designation. *See THK Am., Inc. v. NSK Co.* (N.D. Ill. 1993) 157 F.R.D. 637, 646 [designation of public material "suggests misuse of the designation"].

The records already identified as improperly designated reveal information that is important for public health and safety, weighing against continued secrecy. *Pansy*, 23 F.3d at 787 ["[c]ircumstances weighing against confidentiality exist when confidentiality is being sought over information important to public health and safety"]. For example, as discussed above, they show that the issue of Conceptus's backlog in reviewing reports of problems with Essure was recognized but not addressed for more than a year; reveal information about the many people who experienced serious problems as a result of Essure implantation; and provide evidence that Conceptus failed to conduct adequate quality assurance even in Essure's early days. *See supra* at 4. This is information not only tells the important story of the failures with regard to Essure, but could help prevent similar tragedies from occurring in the future.

The public record in this case establishes that Bayer's overbroad designations currently, and unnecessarily, shroud in secrecy information important to public health and safety. To avoid compounding this problem, and to ensure it is not replicated as these cases continue, Dr. Ross therefore asks this Court to amend its protective order to provide more robust protections against

Bayer's continued abuse. Among the amendments Dr. Ross seeks are the following:[6]

(1) require Bayer to provide to Plaintiffs justifications for any confidentiality designations at the time of production as to any materials produced in the future;

(2) upon any party's request, require Bayer to submit its disclosures and justifications to a Special Master for review; and

(3) provide for sanctions for future violations of the duty to act in good faith in designating discovery material "confidential."

IV. CONCLUSION

For all the foregoing reasons, Dr. Ross respectfully requests that this Court (1) grant him leave to appear as amicus in this matter for the purpose of seeking to unseal court records and challenge this Court's protective order; (2) immediately unseal records currently filed or conditionally lodged under seal and (3) amend its protective order to institute more robust protections to prevent Bayer's over-designation of confidential material.

Dated: February 20, 2020

KEMNITZER, BARRON & KRIEG, LLP

By: ______________________________
KRISTIN KEMNITZER
Attorneys for Proposed Amicus Dr. Joseph Ross

[6] Paragraph 2(b) of this Court's order provides that "The Parties agree that they are under no continuing duty to review documents previously produced as "CONFIDENTIAL" to re-determine whether that designation should be withdrawn." Due to Bayer's clear and repeated violation of that same order's requirement of good faith, justice would be served by amending the order to remove this phrase and requiring Bayer to revisit its productions in this case. However, given the impracticability of such an exercise at this time, Dr. Ross limits his requests to forward-looking modifications.

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PROOF OF SERVICE

Re: ***Essure Products Cases***
Alameda County Superior Court JCCP No. 4887

I, Sean R. Barry, certify that I am not a party to the proceeding herein, that I am and was at the time of service over the age of 18 years old, and a resident of the State of California. My business address is 580 California St., Ste. 1211, San Francisco, CA 94104.

On February 20, 2020, I served the following:

NOTICE OF MOTION AND MOTION FOR LEAVE TO PARTICIPATE AS AMICUS, TO UNSEAL COURT RECORDS, AND TO AMEND THIS COURT'S PROTECTIVE ORDER

MEMORANDUM OF POINTS & AUTHORITIES IN SUPPORT OF MOTION FOR LEAVE TO PARTICIPATE AS AMICUS, TO UNSEAL COURT RECORDS, AND TO AMEND THIS COURT'S PROTECTIVE ORDER

DECLARATION OF STEPHANIE K. GLABERSON IN SUPPORT OF MOTION FOR LEAVE TO PARTICIPATE AS AMICUS, TO UNSEAL COURT RECORDS, AND TO AMEND THIS COURT'S PROTECTIVE ORDER

DECLARATION OF DR. JOSEPH S. ROSS IN SUPPORT OF MOTION FOR LEAVE TO PARTICIPATE AS AMICUS, TO UNSEAL COURT RECORDS, AND TO AMEND THIS COURT'S PROTECTIVE ORDER

by submitting an electronic version of the document(s) via file transfer protocol to Case Anywhere through the upload feature at www.caseanywhere.com.

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

Dated: February 20, 2020

Sean R. Barry