Preventing the Use of Courts to Shield Essential Health Information: Rethinking Confidentiality in Medical Product Litigation

Collaboration for Research Integrity and Transparency
A joint program of Yale Law School, Yale School of Medicine,
& Yale School of Public Health

September 2018

About the CRIT Program

The Collaboration for Research Integrity and Transparency (CRIT) is an inter-disciplinary initiative launched in 2016 at Yale to enhance the quality and transparency of the research base for medical products. Through research, advocacy, and litigation, CRIT is focused on ensuring that the clinical evidence that supports and informs our understanding of the safety and effectiveness of pharmaceuticals, medical devices, and other medical products is accurate, comprehensive, accessible, and reliable.

This meeting report was developed and written by the faculty and staff of the Collaboration for Research Integrity & Transparency (CRIT) at Yale University, with assistance from meeting participants. It was edited by Jeanie Kim (Research Fellow, CRIT), and Margaret E. McCarthy (Executive Director, CRIT). Nothing in this report necessarily reflects the individual opinions of participants or their affiliated institutions.

Funding

CRIT is funded by a three-year grant from the Laura and John Arnold Foundation. CRIT is also supported by a start-up grant from the Oscar M. Ruebhausen Fund at Yale Law School.

Preventing the Use of Courts to Shield Essential Health Information: Rethinking Confidentiality in Medical Product Litigation

Collaboration for Research Integrity and Transparency
A joint program of Yale Law School, Yale School of Medicine,
& Yale School of Public Health

Meeting Report
Yale Law School
September 2018

Table of Contents

Executive Summary

On September 17, 2018, Yale Collaboration for Research Integrity and Transparency (CRIT)—a joint initiative of the law, medical, and public health schools at Yale University—hosted a conference on court secrecy in medical product litigation. We welcomed to New Haven a group of academics and leading litigators, including plaintiffs' attorneys, public interest attorneys, and consumer protection attorneys, to engage in a series of facilitated discussions about the scope and impact of confidentiality in medical product cases. The goals for the meeting were to better understand the problem of court secrecy, to learn from success stories where important information was disseminated, and to identify feasible solutions for promoting greater public access to information.

The day began with a discussion of one of the driving forces of overbroad confidentiality: the practical necessity or convenience of blanket protective orders.

The relevant laws governing unfiled discovery and court records favor openness. Under existing legal standards, courts are prohibited from entering protective orders restricting the disclosure of discovery materials—or sealing orders denying public access to court records—unless the party seeking closure demonstrates a specific need for confidentiality under the applicable legal standards. In practice, because document-by-document assessments can be time-consuming and factually complex, courts and attorneys often bypass the legal requirements, in favor of categorically treating documents as confidential.

Participants identified a range of strategies that together could strengthen the ability to promote public disclosure and access at various stages of medical product litigation. The group proposed a set of **principles** that are compatible with current laws and focus on the public health and safety issues at stake. To implement these principles, participants articulated **best practices** both for directly promoting the public's interest and for supporting potential third-party intervenors that can represent the public's interest. Finally, participants suggested **proposals for judges and legislators** to address unresolved issues and limitations within the existing legal system.

The Report proposes that judges and counsel recognize a set of key principles that should guide confidentiality considerations in medical products litigation and proposes a number of best practices:

PROPOSED PRINCIPLES

Litigation serves a vital public purpose and can unearth critical information about the safety and effectiveness of drugs and devices in three ways: (1) by exposing improper research and marketing practices that compromise scientific evidence and mislead patients, clinicians, and regulators; (2) by making relevant clinical study data available for independent researchers to investigate; and (3) by informing the public of dangerous medical products and bad corporate conduct, so that they can make informed decisions about their health as consumers.

Attorneys have duties to the bar and the public to seek the public disclosure of information that has consequences for public health and safety, whenever possible.

Courts have a distinct obligation to independently assess whether there is a legitimate reason for confidentiality and to apply the correct legal standards before granting protective orders and sealing orders in medical products litigation.

The public's interest in access to critical health and safety information should presumptively outweigh a corporation's private interest in avoiding adverse publicity.

To protect the public interest, efforts to promote public disclosure and public access must begin early and continue through the course of litigation.

Where confidentiality is necessary, it should be limited in scope and not prohibit the dissemination of important public health and safety information.

Experts and third-party intervenors, including researchers, medical journal editors, journalists, patient advocates, and public interest attorneys, can play an important role in presenting a credible and compelling case for the public's interest in disclosure and access.

BEST PRACTICES PROMOTING THE PUBLIC'S INTEREST IN DISCLOSURE AND ACCESS

Committing to Public Disclosure and Access at the Start of Litigation

Attorneys should explain to clients early on their commitment to public disclosure and access.

Attorneys should devote time and resources to challenging secrecy from the beginning of litigation. For multi-district litigations (MDLs), the Plaintiffs' Steering Committee should appoint a Transparency Liaison to lead and coordinate efforts.

Resisting Protective Orders

Attorneys should oppose the entry of any protective order that prevents disclosure of information relevant to public health or safety.

Attorneys should object to specific protective order terms that are contrary to the legal standards for confidentiality, or that create barriers to enforcing the legal standards; and if a protective order is unavoidable, should insist on terms that protect the public's right of access.

Negotiating Blanket Protective Orders

Blanket protective orders should set forth or incorporate the proper legal standards governing confidentiality, and clarify that the blanket protective order is a tool to facilitate discovery. A party's designation of materials as confidential does not substitute for the party's burden of demonstrating the need for confidentiality in order to obtain *court-ordered* protection with respect to specific documents.

Blanket protective orders should establish a de-designation process that allows parties to contest initial confidentiality designations, and requires the party seeking continued confidentiality to affirmatively move for court-ordered protection of specific documents (or portions of documents) within a specified

timeframe. If the party fails to meet its burden with respect to specific discovery materials within that time limit, then the documents should be automatically de-designated.

Blanket protective orders should expressly allow litigants and experts to share health and safety information with relevant government regulators, and to contest confidentiality for the purpose of disclosing public health and safety information to the general public.

Blanket protective orders should ensure that a party's designation of materials as confidential is neither frivolous nor overly broad.

Ensuring the Public's Rights of Access to Court Proceedings and Documents

When discovery documents are relied upon by a party to establish disputed facts on substantive motions, they should be attached to the motion papers for the court's reference, and made part of the presumptively public record of the judicial proceeding.

Attorneys should consistently acknowledge that the public has a right of access to court records, and that a court cannot deny access to court records unless it finds that the proponent of secrecy has met its burdens under the common law and the First Amendment.

MAKING DOCUMENTS AVAILABLE

After discovery materials are de-designated, or court records are filed on the court's public docket, attorneys should deposit them in a centralized repository, such as the Drug Industry Documents Archive (DIDA) hosted by the University of California San Francisco (UCSF) and Center for Knowledge Management. This practice also should apply to discovery materials that were never subject to a protective order.

Best Practices Supporting Potential Third Party Intervenors who Represent the Public's Interest

Attorneys should support experts who wish to de-designate discovery materials or unseal court records to share relevant information on the safety and efficacy of medical products.

Plaintiffs' attorneys should form alliances with public interest attorneys, and regularly discuss issues implicating public health or safety that are likely to arise in future litigation. Where appropriate, and to the extent permitted under any existing protective or sealing orders, attorneys involved in litigation implicating public health or safety should inform third parties who may be interested in intervening or moving to modify a protective or sealing order.

Attorneys should help create repositories of model briefs to support potential third-party intervenors.

Proposals for Judges and Legislators

Standing orders and local rules should expressly set forth the correct legal standards for protective orders and sealing orders, and should incorporate provisions that promote the public's interest in disclosure and access.

Attorneys should educate judges about the applicable legal standards, and the judiciary's independent obligation to apply and enforce those standards when determining whether the entry of a protective order or sealing order is warranted.

Attorneys should support rule changes and legislative changes intended to ensure that important public health and safety information cannot be hidden from the public.

Defining the Problem

> *"Publicity is the very soul of justice"*
>
> Jeremy Bentham, 1793

Courts in the U.S. were built on a foundation of transparency. Public trials have a long history, stretching back to Roman law. Early state constitutions required that courts be open to the public, and the Sixth Amendment to the U.S. Constitution guarantees a right to a public trial in criminal cases.[1] As our justice system has evolved, the courts not only conduct trials, but also maintain official court records.[2] Public access to courts today means not only public trials, but also public access to court records.

This public access is all too often thwarted. In product liability cases, parties typically agree to blanket protective orders to facilitate the exchange of discovery. These allow producing parties to broadly designate discovery materials as confidential without making the requisite showing of a need for confidentiality to the court. Then, as parties file documents with the court, judges, in the absence of an objection, may rely on a party's designation of discovery documents as confidential to justify sealing the documents, failing to conduct the necessary independent assessment of whether there is an interest in confidentiality that overcomes the public's rights of access to court records. Faced with limited capacity and increasing pressure to resolve cases, attorneys understandably fail to prioritize the public's interest in disclosure and access.

A. COURT RULES AND PRACTICES

Both the First Amendment and common law grant a qualified right of access to court records. Despite the courts' key role as an engine of transparency, lack of access to court records and proceedings has been a subject of controversy for decades.[3] The Reporter's Committee for Freedom of the Press, Public Justice, Public Citizen and others regularly litigate cases to obtain access for news media and the public to court documents and proceedings, and to oppose sealing orders and protective orders.

Routine sealing of judicial records and settlements deprives the public of access.[4] In the early 1990's, concerns regarding improper secrecy in the federal courts led the Federal Judicial Center to survey practices in three judicial districts.[5] No changes were recommended as a result of the survey.

A dramatic increase in the amount of information relevant to medical products litigation and sweeping changes to discovery practices have largely removed documents exchanged in discovery from public view. Beginning in 1970, the Federal Rules of Civil Procedure required certain discovery exchanged between parties to be filed with the court clerk.[6] This effectively rendered discovery documents public, absent issuance of a protective order barring public access.[7] Repeated efforts to amend the Federal Rules of Civil Procedure to remove the requirement for court-filed discovery were made, and in 2000 finally succeeded. Eventually, in 2000, with the amendment of the Federal Rules of Civil Procedure, discovery documents were no longer routinely filed with the court clerk, removing them from public inspection.[8]

With the introduction of electronic case filing in the federal courts in the 2000's, additional controversies erupted regarding public access, protective orders, and sealing orders. The Sedona Conference attempted to create consensus guidelines for best practices for protective orders, confidentiality, and public access in civil cases. The Conference published a best practices guideline,[9] but no consensus was reached, and there were opposing views and a rebuttal.[10]

The impact of broad protective and sealing orders continues beyond the life of a lawsuit. Currently, only 1% of civil cases filed in the federal courts are resolved by a trial, and rates for civil trials in most state courts are comparably low.[11] Yet typical civil settlement terms prohibit the parties from discussing the case or disclosing information—even if it implicates public health or safety. Decades of efforts to amend the Federal Rules of Civil Procedure or to pass federal legislation to restrict permissible confidentiality terms so that disclosure of public health or safety information to federal or state agencies is permitted have been unsuccessful.[12]

On the state level, some courts have adopted rules limiting confidentiality for information of public interest. Most notably, Texas (state courts) and South Carolina (state courts and federal district court) have local rules regarding secrecy, sealing, and public health and safety.[13] The Texas rule limiting confidentiality for court records includes unfiled discovery, if the information discovered has a "probable adverse effect upon the general public health or safety."[14] However, in practice, the provision regarding unfiled discovery is readily evaded, and the burden of proving the adverse effects is on the third party seeking disclosure.[15] The South Carolina local federal rule prohibits sealing of a court-ordered settlement agreement, and requires a motion to seal if a party seeks to file documents under seal. The South Carolina state rule requires that the court consider a number of factors when deciding a motion to seal documents or a settlement, including "public health and safety." Yet neither rule pertains to unfiled discovery, and settlement agreements rarely, if ever, contain information implicating public health or safety.[16]

B. IMPACT OF CONFIDENTIALITY IN MEDICAL PRODUCTS LITIGATION

The need for access to court records and information is even more salient in this era of big data. Over the past two decades, high-profile medical product cases have exposed practices that violate scientific standards for clinical research and put the public health at risk. For example, litigation revealed that medical product companies were misrepresenting research findings in scientific publications and regulatory submissions, delayed reporting safety data to the FDA and the public, and promoted misleading or unsubstantiated claims to patients and physicians.[17] The information uncovered in these cases has, in turn, deterred unlawful and dangerous conduct, enhanced regulatory decisions, and improved the clinical evidence base for medical products.

Despite the public health value of disclosure and access, large quantities of information revealed during litigation are kept from the public due to overbroad and unwarranted court secrecy.

> **As a 2011 Senate report on sunshine in litigation stated:**
> *Court secrecy prevents the public from learning about public health and safety dangers. Over the past 20 years, we have learned about numerous cases where court-approved secrecy, in the form of protective orders and sealed settlements, has kept the public in the dark about serious public health and safety dangers.*[18]

Companies seeking FDA approval of drugs, biologics, and the highest-risk medical devices submit study results and summaries to the FDA. FDA scientists then analyze the study information, and decide whether the harms of a treatment are outweighed by the benefits. The FDA's decision-making and analysis is then made public. But once a medical product is approved, the FDA largely relies on passive surveillance, in the form of adverse event reports from companies, clinicians, and the public, to inform the agency of product safety risks.

When information about health and safety risks uncovered in product liability lawsuits is kept secret, the FDA, researchers, clinicians, and the public, are all deprived of needed information. FDA regulators are unable to make fully informed decisions about the risks and benefits of medical products, and may not have the information necessary to decide if actions such as placing a warning label on a product, restricting its use, or removing a product from the market are merited. Researchers conduct medical research, and write publications, without a complete understanding of product risks, resulting in a biased and inaccurate scientific understanding of medical products. Clinicians are unable to make fully informed medical treatment recommendations to patients based, placing their patients at risk. Patients and their families are unable to make fully informed medical decisions, and may face hidden safety risks.

When the FDA attempted to obtain information kept secret by a protective order, it has largely been unsuccessful, and unable to use the information to make it public.

For example, the Bjork-Shiley Convexo Concave prosthetic heart valve was taken off the market in 1986 after hundreds of device failures and deaths.[19] Yet tens of thousands of patients still had devices implanted in their hearts, and patients needed advice about whether to have the heart valves removed and replaced. In product liability litigation, Pfizer had obtained protective orders prohibiting the disclosure of discovery documents, including those regarding the company's knowledge of heart valve failures, the subsequent coverup, and the delay in informing the FDA about heart valve failures. Even after Pfizer agreed to release litigation documents to the FDA, the protective orders barred the FDA from releasing the documents to the public.[20] The New York Times reported that according to an FDA report, court protective orders had "hobbled" the agency's investigation. [21] The FDA indicated to the New York Times that the protective orders prevented the agency from promptly obtaining the facts, and as a result of the delay, patients experienced "physical and emotional harm".[22]

In the early 2000's, use of nutritional supplements containing Ephedra was linked to serious cardiovascular events, including stroke and death.[23] One supplement company, Metabolife International, had falsely claimed to the FDA that it had never received any reports of adverse events from customers for Ephedra-containing products. Product liability litigation against Metabolife International was ongoing. Thousands of adverse event reports made to Metabolife International had been turned over in discovery in a product liability case in California, but never reported to the FDA.[24] In 2000, the FDA and Department

of Justice tried to obtain the adverse event reports, which were subject to a protective order, by intervening in the product liability case. The judge denied the FDA's motion to obtain the documents.[25] Eventually, in 2002, the company turned over more than 14,000 previously hidden adverse event reports to the FDA.[26] Before these hidden risks were revealed, more deaths linked to ephedra use occurred. In 2004, the FDA banned nutritional supplements containing Ephedra.[27] In 2008, Metabolife International and its co-founder were convicted of making false statements to the FDA.[28] Protective orders have kept key health and safety information from FDA advisory committees.

The FDA convenes advisory committees, composed of medical experts and patient representatives, to obtain advice on difficult regulatory decisions, such as whether to approve a medical product, restrict access to an approved product, or remove a product from the market due to risks. Advisory committee members review documents and hear public testimony prior to making a recommendation. Yet protective orders have repeatedly prevented advisory committees from obtaining full information about the risks of medical products.

In 1988, an FDA advisory committee was convened regarding Dow Corning silicone breast implants. An attorney, a chemical engineer, and a medical professor appeared to testify at the hearing. Each witness testified that he had relevant testimony to offer regarding the hazards of the silicone breast implants but was prohibited from testifying due to protective orders. As a result, the committee had inadequate information.[29]

In 2011, the FDA convened an advisory committee meeting regarding the risk of blood clots from hormonal contraceptives, in particular, from drospirenone-containing contraceptives.[30] Kaitlyn Dietrich, the plaintiff in one product liability case against Bayer AG, the manufacturer of Yaz and Yasmin, moved to modify the protective order to permit her to testify at the advisory committee hearing, and present selected documents disclosed in discovery and subject to the protective order to the FDA. The court denied her request, prohibiting the disclosure of documents relating to the increased risk of venous thromboembolism associated with drospirenone-containing contraceptives.[31]

Settlement Terms Prohibit Discussion and Keep Health and Safety Information from the Public.

For decades, Phenylpropanalomine (PPA) was an ingredient in over-the-counter cough medicines and weight loss products. However, PPA was associated with a risk of hemorrhagic stroke, which could be deadly. Many product liability cases were filed against manufacturers, who obtained protective orders keeping discovery information revealing the risks secret. Members of the public were not informed about the risks revealed in litigation due to these protective orders. In one widely reported case, a seven-year old child given a PPA-containing product in 1996 suffered a hemorrhagic stroke and was in a coma for 3 years, eventually dying in 1999. The parents filed suit, alleging that had they known of the risk of stroke, they would never have given their child PPA. Under the terms of a settlement agreement, reached in 2005, the parents were prohibited from disclosing any details of the lawsuit–even though the drug was no longer on the market.[32] In 2000, after a longitudinal study found that PPA use in appetite suppressants significantly increased the risk of hemorrhagic stroke in women, the FDA had issued a public health warning, and requested that manufacturers remove PPA from products.[33] In 2005, the FDA took steps to remove PPA from over-the-counter products.[34]

Protective Orders Result in Information Regarding Public Health and Safety Being Withheld from Congress.

Witnesses at Congressional hearings are similarly prevented from testifying about information kept secret by protective orders. For example, at a 2007 hearing, an attorney testified that he was prevented by protective orders and confidential settlements from testifying regarding public health and safety issues involving Vioxx, Bextra, Ortho Evra, Kugel Mesh, and Avandia.[35]

Revealing Public Health and Safety Information Despite a Protective Order Results in Court-Imposed Sanctions.

Zyprexa, an atypical antipsychotic drug initially approved in 1999 for treatment of psychotic disorders, and later approved for bipolar disorder, carried a risk of obesity and development of diabetes. Thousands of product liability cases were heard before one federal judge handling multi-district litigation beginning in 2004, and a protective order barred disclosure of documents exchanged in discovery.[36] Eli Lilly, the manufacturer, eventually settled claims with more than 28,000 patients. An expert witness arranged the disclosure of records by subpoena to an attorney, who in turn disclosed the records to the New York Times, National Public Radio, and congressional staffers. The court issued an injunction against the expert witness and others, requiring the return of the discovery documents.[37] The expert witness settled the potential civil and criminal liability for violation of the protective order with an agreement to pay $100,000 to Eli Lilley.[38] As a result of the New York Times articles exposing the efforts made by Eli Lilly to minimize the risks of Zyprexa and to market it for unapproved uses, the FDA, as well as members of Congress, demanded that Eli Lilly provide them with the documents made secret by the protective order.[39] Yet despite multiple attempts by the plaintiffs' attorneys to vacate the protective order, the documents produced in discovery remained secret under the protective order until they were unsealed in another Zyprexa lawsuit in 2008.[40] Eli Lilley was criminally convicted of marketing Zyprexa for unapproved uses, and paid the largest criminal fine ever assessed against a corporation.[41]

As is clear from the above examples, litigants, their attorneys, and experts are regularly prohibited from sharing critical and often life-saving information with the public, or even the FDA, as a result of overly broad protective orders, sealing orders, and secret settlements. Improper research and marketing practices can continue unchecked, while documentation of past conduct remains confidential, and such information may take years to come to light otherwise, or may never come to light at all.

Successful Grant of Public Access to Documents Reveals Health and Safety Risks

Examples where attorneys, experts, and third-party intervenors have succeeded in contesting the confidentiality of documents illustrate the potential detriments of overbroad secrecy, if left unchallenged. In 2009, PLOS Medicine[42] and the New York Times, represented by Public Justice, intervened in a multi-district litigation against Wyeth Pharmaceuticals and convinced a federal judge to grant public access to evidence revealing Wyeth's "ghostwriting" practices.[43] Troves of discovery documents—which had previously been treated as confidential—showed how Wyeth had distorted the medical literature on its hormone replacement therapy Prempro by downplaying the increased risk of stroke, heart attack, blood clots, and cancer, and by routinely failing to disclose its role in preparing medical journals articles that promoted Prempro as safe.

More recently, in 2018, plaintiffs' attorneys, with the support of expert witnesses, persuaded a federal court to permit public disclosure of documents that exposed Forest Laboratories' deliberate misrepresentation of clinical trial data in its effort to obtain regulatory approval for its antidepressant Celexa.[44] This permitted the attorneys to inform regulators and government authorities of Forest's scientific misconduct and fraud, and also permitted the expert witnesses to publicly urge a psychiatry journal to retract a 2004 publication where Forest obscured key data to claim positive results for the pediatric use of Celexa. The study was unblinded when some participants received pink Celexa pills instead of white pills that looked identical to the placebo.[45] Forest had been criminally convicted for illegally marketing the drug to children, when it was only approved for adults.[46]

This report describes the best practices in more detail, and provides legal background and references for the use of attorneys committed to promoting public access to information on drugs and devices.

Our aim in producing this report is to highlight key points of agreement and to present practical solutions for promoting disclosure and access where public health and safety are at stake. The report acknowledges that there are contexts where confidentiality is warranted. However, the current trends in complex medical product litigation have allowed confidentiality beyond what is properly permitted by law, and without adequate consideration of the detrimental public health consequences. This report encourages attorneys and courts to recognize ways that confidentiality can be limited so as not to deprive patients, health professionals, researchers, and regulators of information that concerns the safety and efficacy of pharmaceutical drugs and medical devices.

Legal Principles and Practical Considerations

A. KEY PRINCIPLES

The legal standards that govern the confidentiality of discovery materials and court documents presume openness, and set a high bar for parties seeking to restrict disclosure or deny public access to the information that is important to the resolution of litigated disputes.

Under relevant federal law, courts cannot grant protective orders and sealing orders unless the proponent of secrecy meets the burden of demonstrating a specific need for confidentiality. Federal Rule of Civil Procedure 26(c) requires the party seeking to restrict the dissemination of discovery materials to demonstrate "good cause" with respect to each document. Fed. R. Civ. P. 26(c)(1)(A).[47] Once discovery materials are submitted to the court with a substantive motion or entered as trial exhibits, they become judicial records, which are subject to the public's rights of access. The public's qualified common law and First Amendment constitutional rights impose a much higher bar for justifying confidentiality, typically requiring the demonstration of a compelling need for any secrecy.

In practice, however, courts and attorneys often bypass the legal requirements for individual assessments of confidentiality in favor of broad protective orders and sealing orders that improperly treat documents as confidential categorically.

Because document-by-document assessments of confidentiality can be time-consuming and factually complex, courts and attorneys have developed the practice of using overly broad protective orders and sealing orders that categorically treat documents as confidential, in order to facilitate discovery and motion practice. When people who believe they have been injured by medical products seek internal company documents, their attorneys face pressure to agree to "blanket" protective orders in order to obtain documents quickly. Instead of making a document-by-document showing of the need for confidentiality as required by Rule 26(c), blanket protective orders permit the producing party to broadly designate discovery materials as confidential. In theory, during or after discovery, attorneys can alert the court if producing parties over-designate or if documents are sealed without merit pursuant to the blanket protective order, as is often the case.

However, once a blanket protective order is in place, it may structurally shift the burden to the party challenging confidentiality to identify documents to the court and raise arguments opposing confidentiality. This is contrary to the legal standards, which clearly place the burden of proof on the proponent of secrecy at all stages. In addition, disputing the confidentiality of specific documents can take significant time and resources. By the time attorneys have access to discovery, and begin reviewing documents, they are likely preparing for or already engaged in motion practice. As such, attorneys often have limited capacity to prepare de-designation or unsealing papers.

As a result, attorneys and experts are regularly in possession of critical and often life-saving information that they cannot share with patients, clinicians, researchers, and regulators under the terms of a blanket protective order. Even without changes in existing laws, however, changes in practice by courts and attorneys could make it significantly more likely that such information is disseminated to the public. Toward this end, the following principles should guide the conduct of medical products litigation.

A. PROPOSED PRINCIPLES

- Litigation serves a vital public purpose, and can unearth critical information about the safety and effectiveness of drugs and devices in three ways: (1) by exposing improper research and marketing practices that compromise scientific evidence and mislead patients, clinicians, and regulators; (2) by making relevant clinical study data available for independent researchers to investigate; and (3) by informing the public of dangerous medical products and bad corporate conduct, so that they can make informed decisions about their health as consumers.
- Attorneys have duties to the bar and the public to seek the public disclosure of information that has consequences for public health and safety, whenever possible.
- Courts have a distinct obligation to independently assess whether there is a legitimate reason for confidentiality and to apply the correct legal standards before granting protective orders and sealing orders in medical products litigation.
- The public's interest in access to critical health and safety information should presumptively outweigh a corporation's private interest in avoiding adverse publicity.
- To protect the public interest, efforts to ensure public disclosure and protect access should begin early, and continue through the course of litigation.

- Where confidentiality is necessary, it should be limited in scope, and not prohibit the dissemination of important public health and safety information.
- Experts and third-party intervenors, including researchers, medical journal editors, journalists, patient advocates, and public interest attorneys, can play an important role in presenting a credible and compelling case for the public's interest in disclosure and access.

B. BEST PRACTICES PROMOTING THE PUBLIC'S INTEREST IN DISCLOSURE AND ACCESS

The following are best practices that attorneys can adopt to directly promote the public's interest in disclosure and access. While our goal was to identify best practices where there is broad consensus among participants, some proposals may require further discussion and debate to fully implement.

Committing to Public Disclosure and Access at the Start of Litigation

BEST PRACTICE: Attorneys should explain to clients early on their commitment to public disclosure and access.

Many of the participants stressed that both they and their clients believe that litigation can and should serve not only the individuals who were already harmed, but also the public. Many people who have suffered injuries from medical products come to court in part to ensure that others do not suffer the same harms, and many plaintiffs' attorneys work in this area because they believe that it can serve the public good. Advocating for disclosure and access, however, takes time and resources, and at times may conflict with a client's interest in short-term relief. For this reason, it is important for attorneys to convey—early on to potential clients—the public value of protecting transparency during litigation. Because the Rules of Professional Conduct[48] require attorneys to defer to their clients' wishes, some attorneys developed the practice of disclosing their commitment to public disclosure and access when agreeing to represent a client, to ensure that the client is supportive of this approach. For example, the attorney may draft a retainer agreement stating that as of the date of the agreement, the client has no intention of agreeing to keep information relevant to public safety or health secret.

BEST PRACTICE: Attorneys should devote time and resources to challenging secrecy from the beginning of litigation. For multi-district litigations (MDLs), the Plaintiffs' Steering Committee should appoint a Transparency Liaison to lead and coordinate efforts.

Participants emphasized the importance of dedicating time and resources to challenging confidentiality—whether objecting to overbroad protective and sealing orders or disputing the confidentiality of specific documents. In MDLs, where there are hundreds or thousands of clients, attorneys have more control in shaping the course of litigation. Plaintiffs' Steering Committees can appoint a Transparency Liaison to coordinate and prioritize public disclosure and access at various stages of litigation, such as requesting the appointment of special masters to adjudicate issues of confidentiality. Some participants suggested that preparing briefs opposing protective and sealing orders could serve as opportunities for more junior attorneys to obtain valuable legal writing experience.

Resisting Protective Orders

BEST PRACTICE: Attorneys should oppose the entry of any protective order that prevents disclosure of information relevant to public health or safety.

Raising appropriate objections to overly-broad protective orders has strategic value, even when the objections are not initially successful. The failure to object early in litigation to excessive confidentiality can lead judges to be skeptical that the party or attorney later challenging confidentiality really cares about public disclosure and access. This can undermine later efforts to de-designate or unseal documents (despite the fact that the burden is properly placed on the party seeking secrecy). By objecting to the entry of a protective order, attorneys can create a record of their consistent opposition to unwarranted secrecy from the beginning.

Similarly, many participants noted that if expert witnesses fail to object to a protective order when they join as an expert and are first bound by the order,[49] that failure or silence may be used to question the legitimacy of their interest in transparency, or the significance of the underlying public health concern. Thus, by objecting to protective orders, attorneys can better preserve the ability of experts to later request permission to use the data to testify at the FDA about safety risks or to publish scientific articles on safety and efficacy of the medical product at issue.

BEST PRACTICE: Attorneys should object to specific protective order terms that are contrary to the legal standards for confidentiality, or that create barriers to enforcing the legal standards; and if a protective order is unavoidable, should insist on terms that protect the public's right of access.

Among the practices that should be avoided:

- Protective orders should not permit the automatic sealing of documents that are filed with the court, without requiring the proponent of secrecy to meet the heightened standard applicable to court records, and requiring prompt judicial review.
- Protective orders should not require parties to explain the evidentiary "relevance" of documents when disputing confidentiality.
- Protective orders should not set a deadline within which documents' confidentiality must be challenged, and after which no confidentiality challenges can be made.
- Protective orders should not require parties challenging confidentiality to specify individual documents rather than permitting challenges to categories of documents, such as FDA correspondence.
- Protective orders should not shift the cost of production to parties seeking disclosure and access.
- Protective orders should not require parties to return or destroy discovery materials at the end of litigation. Attorneys should always have the opportunity to dispute confidentiality after litigation, and post-litigation events may raise questions as to whether continued confidentiality is justified. Return or destroy provisions violate ethical obligations of the attorneys involved, and should not be included in protective orders.[50]

Negotiating Blanket Protective Orders[51]

While it is strategic to raise objections to protective orders from the outset, participants reiterated that it is unlikely that litigation can proceed at a reasonable pace without some kind of protective order in place that prohibits wholesale disclosure of documents exchanged in discovery. When anticipating voluminous discovery, attorneys rely on the producing party to start rolling out documents quickly. Producing parties insist that without a blanket protective order, discovery would take years, as they would need to obtain court-ordered protection for individual documents—i.e., whether there is good cause under Rule 26(c) to restrict the dissemination of specific documents.[52] Thus, as a practical matter, blanket protective orders can facilitate discovery, at least in medical products liability litigation which typically involves substantial exchange of company documents and data.

Where blanket protective orders are necessary to facilitate discovery, they should be limited in scope and purpose. Attorneys should negotiate provisions so that blanket protective orders (1) set forth or incorporate the relevant legal standards for confidentiality and clarify that the order is a tool for facilitating discovery, (2) establish a de-designation process that requires the party seeking continued confidentiality to affirmatively move for court-ordered protection within a specified timeframe, (3) expressly allow litigants and experts to dispute or contest the confidentiality provided by a blanket protective order to disclose information for public health purposes, and (4) ensure that confidentiality designations are not frivolous or overly broad.

BEST PRACTICE: Blanket protective orders should set forth or incorporate the proper legal standards governing confidentiality, and clarify that the blanket protective order is a tool to facilitate discovery. A party's designation of materials as confidential does not substitute for the party's burden of demonstrating the need for confidentiality in order to obtain *court-ordered* protection with respect to specific documents.

Many participants noted that it would be helpful for blanket protective orders to set forth the relevant law governing the confidentiality of discovery materials and court records.

BEST PRACTICE: Blanket protective orders should establish a de-designation process that allows parties to contest initial confidentiality designations, and requires the party seeking continued confidentiality to affirmatively move for court-ordered protection of specific documents (or portions of documents) within a specified timeframe. If the party fails to meet its burden with respect to specific discovery materials within that time limit, then the documents should be automatically de-designated.

Blanket protective orders should provide a process for de-designating documents that requires the party seeking secrecy to move for court-ordered protection within a specified time frame. This framework will ensure that as required by Rule 26(c) and analogous state provisions, the burden for obtaining court-ordered protection for discovery remains on the party seeking confidentiality. Both the Northern District of California's standing protective order and Public Justice's model protective orders contain helpful language and can serve as a model (see Appendix).

- **Meet and Confer.** Parties should first meet and confer to attempt to resolve disputes over confidentiality designations. Participants agreed that there should not be deadlines or limitations for challenging confidentiality.
- **Judicial Intervention.** If parties cannot resolve the dispute on their own, the party seeking secrecy must move for court-ordered protection, and bear the burden of establishing "good cause" under Rule 26(c) with respect to specific document(s). Participants recommended *in camera* review to adjudicate disputes.
- **Sunset provision.** Regardless of whether confidentiality designations are challenged, if the party seeking confidentiality fails to move for court-ordered protection with a specified time frame, the documents at issue should be automatically de-designated.

BEST PRACTICE: Blanket protective orders should expressly allow litigants and experts to share health and safety information with relevant government regulators, and to contest confidentiality for the purpose of disclosing public health and safety information to the general public.

- **De-Designation.** In addition to a general de-designation process, blanket protective orders should create a special de-designation process for discovery documents that actively affect public health and safety, such as evidence of an increased risk of an adverse event, or information that explains a past public health harm. Where discovery documents implicate public health, blanket protective orders should explicitly permit litigants and experts to contest initial confidentiality designations without first meeting and conferring with the opposing party, and to directly alert the court of the pressing need to independently review and de-designate documents accordingly.[53]
- **Modification.** If de-designation, which would allow unrestricted disclosure to the general public, is not appropriate, blanket protective orders should expressly permit litigants and experts to request a modification of the order for the limited purpose of disclosing public health and safety information. To encourage courts to modify protective orders for public health purposes, blanket protective orders should articulate specific circumstances that warrant modification, such as (1) allowing injured parties and expert witnesses to use discovery documents to testify at FDA committee hearings; (2) allowing clinicians and researchers who serve as experts to publish peer-reviewed scientific articles about the safety and efficacy of medical products; and (3) allowing expert witnesses to share conclusions and high-level summaries of documents reviewed to inform the public of any health concerns.

BEST PRACTICE: Blanket protective orders should ensure that a party's designation of materials as confidential is neither frivolous nor overly broad.

While participants agreed that protective orders should deter frivolous or overbroad confidentiality designations, further discussion is necessary to effectuate this best practice. For example, there was a suggestion that protective orders should contain a "self-imploding" provision, so that if a party abuses the protective order or designates documents as confidential in bad faith (e.g., designating published scientific articles or other documents that are already public), there should be a mechanism to request an invalidation of the protective order or other designations.

Another suggestion involved including a provision in blanket protective orders that prohibits designating entire depositions as confidential. The better practice would be that, once a deposition is taken, the attorney representing the deponent can specify particular portions to be preliminarily designated as confidential and then must meet its burden under Rule 26(c) with respect to the specified portions of the transcript within a set period of time, e.g., 30 days.

Ensuring the Public's Rights of Access to Court Proceedings and Documents

BEST PRACTICE: When discovery documents are relied upon by a party to establish disputed facts on substantive motions, they should be attached to the motion papers for the court's reference, and made part of the presumptively public record of the judicial proceeding.

BEST PRACTICE: Attorneys should consistently acknowledge that the public has a right of access to court records, and that a court cannot deny access to court records unless it finds that the proponent of secrecy has met its burdens under the common law and the First Amendment.

Participants reiterated the need to clarify and differentiate the standards for sealing court records from the less stringent good cause standard for protecting discovery materials under Rule 26(c). Once discovery documents are attached to substantive motions for judicial review or entered as trial exhibits, the documents are considered court records, which are subject to the public's right of access under the common law and the First Amendment. If parties provisionally file documents under seal, the documents cannot remain sealed unless the party seeking secrecy meets its burden of overcoming the public's rights of access. Attorneys should remind courts that they have an independent obligation to enforce the correct legal standards under the common law and the First Amendment. Court records cannot be sealed pursuant to a blanket protective order or on the basis of Rule 26(c), which governs unfiled discovery but not filed court records.

Making Documents Available

BEST PRACTICE: After discovery materials are de-designated, or court records are filed on the court's public docket, attorneys should deposit them in a centralized repository, such as the Drug Industry Documents Archive (DIDA) hosted by the University of California San Francisco (UCSF) and Center for Knowledge Management. This practice also should apply to discovery materials that were never subject to a protective order.

Participants expressed that there needs to be a better system for storing, standardizing, and disseminating documents once they are made public. To ensure that documents are easily accessible and usable by researchers and the public, attorneys should deposit documents with centralized databases such as the Drug Industry Documents Archive (DIDA) hosted by the University of California San Francisco Library and Center for Knowledge Management. DIDA is a robust archive of documents related to pharmaceutical companies' advertising, manufacturing, marketing, sales, and scientific research—much of which was made public through litigation. DIDA categorizes documents based on drug product, company, and litigation, so that the documents are searchable and accessible. In addition, participants recommended a press release or other communications strategy to help inform the public when documents are made available.

C. BEST PRACTICES SUPPORTING POTENTIAL THIRD PARTY INTERVENORS WHO REPRESENT THE PUBLIC'S INTEREST

There are many individuals, from researchers, to medical journal editors, to journalists, to patient advocates, who might wish to have access to important health and safety information, and who can also help call attention to the important public interest in concealed documents. Third parties such as these have successfully intervened to access documents exchanged in litigation, both through de-designation motions and unsealing motions. These interventions can be quite valuable, but are impeded because it is hard for interested outsiders: (1) to identify cases where important information could be disclosed; and (2) to mobilize the resources to challenge confidentiality.

The following are best practices that attorneys can adopt to support potential third-party intervenors who can represent the public's interest in disclosure and access.

BEST PRACTICE: Attorneys should support experts who wish to de-designate discovery materials or unseal court records to share relevant information on the safety and efficacy of medical products.

Individual experts who are retained to evaluate evidence can play an important role in defending the public interest in access to information, because they are often the best people to identify secret documents that implicate public health and safety, and can readily demonstrate that they have legitimate reasons to publish about the revealed data. Many of the legal challenges discussed during the day where information was unsealed or released from protection were brought at the behest of expert witnesses, who wished to publish about the data.

Experts can insist in retainers that plaintiffs' attorneys support them if they wish to make data public. If the plaintiffs' attorneys are unwilling to make efforts to have data revealed, experts can also seek outside counsel to bring their own motion to the court. When seeking to make information public, experts have even greater authority if they are joined by interested parties who are not involved in the litigation, such as journalists, medical organizations, academics, or doctors.

BEST PRACTICE: Plaintiffs' attorneys should form alliances with public interest attorneys, and regularly discuss issues implicating public health or safety that are likely to arise in future litigation. Where appropriate, and to the extent permitted under any existing protective or sealing orders, attorneys involved in litigation implicating public health or safety should inform third parties who may be interested in intervening or moving to modify a protective or sealing order.

Third parties can find it difficult and time-consuming to identify appropriate cases in which to intervene since the documents that would be of interest are subject to a protective order and/or sealed. If there were a conduit or a coalition of potential third-party intervenors, attorneys would be able to more easily reach out and notify outsiders of cases involving medical products in which critical info relevant to public safety or health has been uncovered. The coalition could include news organizations, patient groups, researchers, public interest legal organizations, and academics.

Participants discussed strategies for making known cases where a corporation is concealing important public health or safety information, and third-party intervention may therefore be warranted. Plaintiffs' attorneys could negotiate terms in protective orders that permit experts, and even plaintiffs, to go to the press with conclusions or high-level summaries of documents reviewed, or to share their opinions.[54]

Participants also recommended exploring software solutions, such as data mining programs and automated court docket monitoring to identify protective orders and sealing orders. They also suggested that courts could catalogue protective orders and sealing orders on a publicly accessible website, as is done for key orders in multi-district litigation. This would create a repository that third parties could access and identify cases appropriate for intervention.

BEST PRACTICE: Attorneys should help create repositories of model briefs to support potential third-party intervenors.

Since potential third-party intervenors may lack the legal support or funds to oppose protective and sealing orders, participants discussed the importance of developing shared resources, including a clearinghouse of sample briefs. Public Citizen and Public Justice have started such repositories, and the Attorneys' Information Exchange Group has a members-only web repository of documents related to product defect cases.[55]

Some participants proposed creating a listserv to connect potential third-party intervenors with attorneys or firms who are willing to draft briefs. Law school clinics that work on issues related to court secrecy, such as the Knight First Amendment Institute at Columbia University, the Civil Liberties and Transparency Clinic at University of Buffalo School of Law, and the First Amendment Clinic at the University of Virginia Law School, may also be able to assist with creating model briefs and memoranda of law.

D. PROPOSALS FOR JUDGES AND LEGISLATORS

While earlier discussions focused on how attorneys can work to achieve more transparency within the current framework, participants later discussed structural changes that would educate or further empower judges to protect the public's interest in disclosure and right of access.

BEST PRACTICE: Standing orders and local rules should expressly set forth the correct legal standards for protective orders and sealing orders, and should incorporate provisions that promote the public's interest in disclosure and access.

Individual judges have standing orders, and individual courts have local rules. One important avenue for action would be to ensure that these enforce the correct legal standards, and in particular, distinguish between blanket protective orders issued to facilitate discovery and Rule 26(c) protective orders issued after a particularized showing of good cause. Standing orders should also differentiate between the standard required for protective orders, and the heightened standard required to seal court records. In addition, judges might include in their standing order model provisions that incorporate the most important elements described above. Judges might, for example, adopt standing orders that contain a clear de-designation process that ensures that the party seeking to maintain confidentiality after discovery affirmatively moves for court-order protection with respect to specific documents.

BEST PRACTICE: Attorneys should educate judges about the applicable legal standards, and the judiciary's independent obligation to apply and enforce those standards when determining whether the entry of a protective order or sealing order is warranted.

Participants who have succeeded in getting documents to the public emphasized that judges' familiarity with the legal standards, and their obligation to apply those standards, makes a significant difference. In addition to reaching out to individual judges with standing orders and model briefs, another approach to educating the judiciary is through the Federal Judicial Center. Some participants also noted that the Code of Judicial Conduct could be changed so that judges have an affirmative obligation to inform the public if a health risk is disclosed in an ongoing suit, making it an ethical violation to permit that information to remain secret.

BEST PRACTICE: Attorneys should support rule changes and legislative changes intended to ensure that important public health and safety information cannot be hidden from the public.

Several states have access-friendly state rules and local rules; examples include Texas Rule of Civil Procedure 76a. Texas Rule 76a provides that *unfiled* discovery materials are "court records," and presumed to be open to the general public, if they concern matters that have a probable adverse effect on public health or operations of government. It is not clear whether Texas Rule 76a has been very effective in practice. One of the primary obstacles is that under Texas Rule 76a, the party seeking openness has the initial burden of demonstrating that documents fall under the definition of "court records"—i.e., that documents have a probable adverse effect on the public health. Despite this threshold barrier, most agreed that Texas Rule 76a is a potential model for changing the rules around discovery to promote the disclosure of important public health and safety information, both in other states and at the federal level.

Courts and legislatures could also implement sunshine laws with respect to settlement agreements, building on rules like South Carolina State Rule 41.1 that requires the court to consider a number of factors, including public health and safety when deciding a motion to seal documents or a settlement, and the federal District of South Carolina's Local Rule 5.03, which forbids the sealing of all settlements.[56] However, because many federal court settlements involve a voluntary dismissal of the case, with settlements not submitted to courts for approval, such rules would have limited impact.

Judges do have authority to impact even "out-of-court" settlement agreements in certain contexts, because they can refuse to order dismissal of a case unless they are satisfied that the settlement does not harm the public interest. If sufficiently aware of the issues that impact public health and safety, judges in certain limited circumstances might refuse dismissal until all parties have certified that there is no health and safety information relevant to the public that should be disclosed before permitting dismissal. In federal court, this is only possible, however, where a plaintiff is a minor, or where the case is a class action, and court approval is required for settlement, voluntary dismissal or compromise pursuant to Rule 23(e).

Endnotes

1 Judith Resnik, *Bring Back Bentham: "Open Courts," "Terror Trials," and Public Sphere(s), 5 Law & Ethics of Human Rights 226 (2011), Faculty Scholarship Series. Paper 3856. http://digitalcommons.law.yale.edu/fss_papers/3856*

2 Id.

3 Seymour Moskowitz, *Discovering Discovery: Non-Party Access to Pretrial Information in the Federal Courts 1938-2006, 78 U. Colo. L. Rev. 817 (2007); David S. Ardia, Court Transparency and the First Amendment, 38 Cardozo L. Rev. 835 (2017); Judith Resnik, Uncovering, Disclosing and Discovering How the Public Dimensions of Court-Based Processes Are at Risk, 81 Chicago Kent L. Rev. 521 (2006),* http://digitalcommons.law.yale.edu/fss_papers/696.

4 David S. Sanson, *The Pervasive Problem of Court-Sanctioned Secrecy and the Exigency of National Reform, 53 Duke L.J. 807 (2003).*

5 Elizabeth C. Wiggins, Melissa J. Pecherski, and George Cort, *Protective Order Activity in Three Federal Judicial Districts, Report to the Advisory Committee on Civil Rules, Federal Judicial Center, April 1996 (1996). https://www.fjc.gov/sites/default/files/2015/0029_0.pdf*

6 Although many product liability cases are litigated in state courts, under state procedural rules, for the purpose of simplicity, we refer to the Federal Rules of Civil Procedure throughout.

7 Moskowitz, *supra note 3.*

8 Id.

9 The Sedona Conference Working Group on Protective Orders, Confidentiality & Public Access (WG2). *The Sedona Guidelines: Best Practices Addressing Protective Orders, Confidentiality & Public Access in Civil Cases. (2007).* https://thesedonaconference.org/publication/Working_Group_2_Guidelines

10 *Opposing Views of the Undersigned Members of the Sedona Conference Working Group on Protective Orders, Confidentiality & Public Access (WG2) to the Sedona Guidelines on Protective Orders, Confidentiality & Public Access in Civil Cases, April 6, 2007 (2007).* https://thesedonaconference.org/publication/Working_Group_2_Guidelines; David A. Schulz, *A Personal Response to the Opposing Views (2007).* https://thesedonaconference.org/publication/Working_Group_2_Guidelines

11 Jeffrey Q. Smith & Grant R. MacQueen, *Going, Going, But Not Quite Gone. Trials Continue to Decline in Federal Courts. Does It Matter? Judicature, Winter 2017, Volume 101 Number 4 (2017)* https://judicialstudies.duke.edu/wp-content/uploads/2018/01/JUDICATURE101.4-vanishing.pdf, with appendices at https://judicialstudies.duke.edu/wp-content/uploads/2018/01/JUDICATURE101-4_VANISHING-TRAIL-APPENDICES.pdf

12 *See, for example, Sunshine in Litigation Act of 1995, S. 374, 104th Cong. §1 (1995); Safety Over Secrecy Act of 2016, S. 3370, 114th Cong. §2 (2016); Sunshine in Litigation Act of 2017, H.R. 1053, 115th Cong. §1 (2017).*

13 South Carolina Judicial Department, South Carolina Rules of Civil Procedure, Rule 41.1, Sealing Documents and Settlement Agreements (May 7, 2003); Local Civil Rules for the U.S. District Court, District of South Carolina, Rule 5.03: Filing Documents Under Seal (August 20, 2014); Texas Rules of Civil Procedure, Rule 76a. Sealing Records (1990).

14 Texas Rules of Civil Procedure, Rule 76a(1)(a)(2).

15 The Honorable Craig Smith, Grant Schmidt, & Austin Smith, *Finding a Balance Between Securing Confidentiality and Preserving Court Transparency: A Re-Visit of Rule 76A and Its Application to Unfiled Discovery, 69 SMU L. Rev. 309 (2016)* https://scholar.smu.edu/smulr/vol69/iss2/2

16 Sanson, *supra note 4.*

17 Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks, 297 J. Am. Med. Ass'n 308 (2007).*

18 U.S. Senate, Committee on the Judiciary, *Sunshine in Litigation Act of 2011,* S. Rpt. 112-45, (August 2, 2011), at 2, https://www.congress.gov/congressional-report/112th-congress/senate-report/45/1

19 *The Bjork-Shiley Heart Valve: "Earn as You Learn" Shiley Inc.'s Breach of The Honor System and FDA's Failure in Medical Device Regulation*. Staff Report prepared for the use of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, (February 1990), https://babel.hathitrust.org/cgi/pt?id=pst.000016115477; U.S. Senate, Committee on the Judiciary, *Sunshine in Litigation Act of 2011,* S. Rpt. 112-45, (August 2, 2011) https://www.congress.gov/congressional-report/112th-congress/senate-report/45/1

20 Sonni Efron, *Report States Shiley Misled FDA on Heart Valve Defects*, Los Angeles Times (September 14, 1991), http://articles.latimes.com/1991-09-14/business/fi-2111_1_shiley-heart-valve; Gina Kolata, *Manufacturer of Faulty Heart Valve Barred Data on Dangers, F.D.A. Says*, New York Times, (March 21, 1992), https://www.nytimes.com/1992/03/21/us/manufacturer-of-faulty-heart-valve-barred-data-on-dangers-fda-says.html

21 Id.

22 Kolata, *supra* note 20.

23 Snigdha Prakash, *The Secret of Ephedra's Questionable Success–Diet Aid Makes Billions Despite Claims of Health Risks, National Public Radio,* National Public Radio, All Things Considered (November 22, 2002), https://www.npr.org/templates/story/story.php?storyId=850679

24 Penni Crabtree, *Court Orders Often Keep Companies' Darkest Secrets Hidden,* Copley News Service (September 7, 2002 Saturday), *https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:46PG-3980-000H-031N-00000-00&context=1516831.*

25 Crabtree, *supra* note 24*;* Public Citizen Health Research Group, *Letter to HHS Secretary Tommy Thompson Urging Him to Direct the FDA to Open a Criminal Investigation of Metabolife (HRG Publication #1635)* (August 15, 2002), https://www.citizen.org/our-work/health-and-safety/letter-urging-criminal-investigation-metabolife-issuing-false; U.S. Senate, Committee on the Judiciary, *Sunshine in Litigation Act of 2011,* S. Rpt. 112-45, (August 2, 2011), at 5, https://www.congress.gov/congressional-report/112th-congress/senate-report/45/1

26 U.S. House of Representatives, Minority Staff Report, Special Investigations Division, Committee on Government Reform, *Adverse Event Reports from Metabolife* (October 2002),https://web.archive.org/web/20070106151745/http://oversight.house.gov/documents/20040827102309-56026.pdf

27 21 C.F.R.119.1; 69 FR 6853 (Feb. 11, 2004)

28 Amanda Ernst , *Metabolife CEO Gets 6 Months For Misleading FDA,* Law 360 (June 10, 2008) https://www.law360.com/articles/58799/metabolife-ceo-gets-6-months-for-misleading-fda

29 Norman Anderson, *The Impact of Court Imposed Secrecy Orders on Regulatory Control of Silicone Gel-Filled Breast Implants*, in U.S. Senate, *The Sunshine in Litigation Act, Hearing before the* Subcommittee on Courts and Administrative Practice of the Committee on the Judiciary, S. Rpt. 112-45, (August 2, 2011), at 17-21, https://www.congress.gov/congressional-report/112th-congress/senate-report/45/1

30 U.S. Food and Drug Administration, *FDA Drug Safety Communication: Safety review update on the possible increased risk of blood clots with birth control pills containing drospirenone (September 26, 2011),* https://wayback.archive-it.org/7993/20170406044047/ https://www.fda.gov/Drugs/DrugSafety/ ucm273021.htm

31 *In Re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Product Liability Litigation*, Case 3:09-md-02100-DRH-PMF, Document 2081, Case Management Order No. 45 (Denying Motion to Petition the FDA) (S.D. Ill., 2011) https://www.ilsd.uscourts.gov/Documents/mdl2100/Order45.pdf

32 William McCall, *Parents Sue Dimetapp Maker*, Deseret News, (May 22, 2001) https://www.deseretnews.com/article/844089/Parents-sue-Dimetapp-maker.html; Kathleen Flynn Peterson, President, American Association for Justice, Washington D.C., Additional Submission for the Record, in *[Errata] The Sunshine in Litigation Act: Does Court Secrecy Undermine Public Health and Safety?* S. Hrg. 110-263, Hearing before the Subcommittee on Antitrust, Competition Policy and Consumer Rights of the Committee on the Judiciary, United States Senate, at 250 (December 11, 2007), https://fas.org/sgp/congress/2007/litigation-errata.pdf

33 U.S. Food and Drug Administration, *FDA Issues Public Health Warning on Phenylpropanolamine* (November 6, 2000). https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm150763.htm

34 U.S. Food and Drug Administration, *Phenylpropanolamine (PPA) Information Page* (October 14, 2016), https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm150738.htm

35 Testimony of Richard D. Meadow, The Lanier Law Firm, PLLC, in *The Sunshine in Litigation Act: Does Court Secrecy Undermine Public Health and Safety?,* S. Hrg.110-263, Hearing before the Subcommittee on Antitrust, Competition Policy and Consumer Rights of the Committee on the Judiciary, United States Senate, at 54-64 (December 11, 2007), https://fas.org/sgp/congress/2007/sunshine.pdf

36 Case Management Order No. 3 (Protective Order), *In Re Zyprexa Prod. Liab. Litig., Case 1:04-md-01596-JBW-RLM (E.D.N.Y., August 9, 2004) (Docket No. 61).*

37 *In Re Zyprexa Injunction, 474 F. Supp. 2d 385 (E.D.N.Y 2007)*

38 *Doctor Who Leaked Documents Will Pay $100,000 to Lilly, New York Times (September 8, 2007), https://www.nytimes.com/2007/09/08/business/08lilly.html*

39 Berenson, A. *Eli Lilly Said to Play Down Risk of Top Pill, New York Times (December 17, 2006),* https://www.nytimes.com/2006/12/17/business/17drug.html;

40 Leslie A Bailey, Public Justice, Questions for the Record, Subcommittee on Commercial and Administrative Law, Hearing on H.R. 1508, the "Sunshine in Litigation Act of 2009", June 4, 2009, in *Sunshine in Litigation Act of 2009, Hearing, Subcommittee on Commercial and Administrative Law of the Committee on the Judiciary, on H.R. 1508, Serial No. 111-40, (June 4, 2009) at 128-136,* https://web.archive.org/web/20160911182555/https://judiciary.house.gov/_files/hearings/printers/111th/111-40_50069.PDF

41 U.S. Department of Justice, *Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa, $515 Million Criminal Fine Is Largest Individual Corporate Criminal Fine in History; Civil Settlement up to $800 Million [press release],(January 15, 2009),* https://www.justice.gov/archive/opa/pr/2009/January/09-civ-038.html

42 PLOS Medicine is a peer-reviewed, open-access medical journal published by the Public Library of Science (PLOS, formerly styled as PLoS).

43 *See In Re Prempro Products Liability Litigation (MDL DOCKET NO. 4:03-CV-1507-WRW)* Order (Document 2120) (E.D. Arkansas, Wilson, J., July 24, 2009) https://docs.justia.com/cases/federal/district-courts/arkansas/aredce/4:2003cv01507/20369/2120

44 Dr. Jay Amsterdam, et al., Letter to Dr. Robert Freedman, Editor, American Journal of Psychiatry (February 20, 2018), http://freepdfhosting.com/00225391b9.pdf; *see also Ed Silverman, Psychiatry journal is urged to retract controversial Celexa study over newly disclosed details, STAT News (February 21, 2018)* https://www.statnews.com/pharmalot/2018/02/21/psychiatry-journal-retract-celexa/

45 Jon N. Jureidinia, Jay D. Amsterdam, & Leemon B. McHenry, The citalopram CIT-MD-18 pediatric depression trial: Deconstruction of medical ghostwriting, data mischaracterisation and academic malfeasance, *International Journal of Risk & Safety in Medicine, 28*, 33–43 (2016), http://freepdfhosting.com/4608bf86ca.pdf

46 U.S. Department of Justice, *Drug Maker Forest Pleads Guilty; To Pay More Than $313 Million to Resolve Criminal Charges and False Claims Act Allegations* [press release] (September 15, 2010), https://www.justice.gov/opa/pr/drug-maker-forest-pleads-guilty-pay-more-313-million-resolve-criminal-charges-and-false

47 *See, e.g., Foltz v. State Farm Mut. Auto Ins. Co., 331 F.3d 1122, 1130 (9th Cir. 2003) ("A party asserting good cause bears the burden, for each particular document it seeks to protect, of showing that specific prejudice or harm will result if no protective order is granted."); Pansy v. Borough of Stroudsburg, 23 F.3d 772, 786-87 (3d Cir. 1994) ("The burden of justifying the confidentiality of each and every document sought to be covered by a protective order remains on the party seeking the orders.").*

48 RPC 1.8

49 Expert witnesses are typically required to sign a document agreeing to comply with any protective order(s) in place before they are permitted to review documents provided to the attorneys in discovery. These blanket protective orders are usually entered long before the expert is involved in the case, and do not typically contain provisions allowing experts to disclose information crucial to health or safety.

50 The American Bar Association has passed a resolution barring orders that require attorneys to return or destroy documents exchanged in discovery. American Bar Association, *Resolution Approved, American Bar Association House of Delegates (Report No. 123), (February 16-17, 1987), see also Leslie A. Bailey, Fighting Protective and Secrecy Orders, in American Association of Justice Convention, Advocacy Track: Anatomy of a Personal Injury Lawsuit (July 22, 2013, San Francisco, CA), at 5-6,* https://www.americanbar.org/content/dam/aba/events/professional_responsibility/2015/May/Conference/Materials/bailey_2013_07_22_aaj_fighting_protective_and_secrecy_orders.pdf

51 The strategies here can be accomplished via negotiation of the protective order before it is submitted to the court or through clarification or modification of an already-existing protective order.

52 Many participants noted that even where there is voluminous discovery, producing parties generally review individual documents before turning them over. Thus, some participants were skeptical that assessing for confidentiality on a document-by-document basis would significantly delay discovery production.

53 There were suggestions that blanket protective orders should contain a carve-out or exception for evidence of safety risk or other public health hazards and expressly allow parties and experts to share such information. However, it is unlikely that courts will allow parties and experts to decide for themselves what information implicates public health and safety.

54 *See Dustin B. Benham, Dirty Secrets: The First Amendment in Protective-Order Litigation 35 Cardozo Law Review 1781 (2014),* https://ssrn.com/abstract=2348168, for a discussion of whether the First Amendment restricts a judge's power to issue a protective order.

55 CRIT has also submitted an amicus brief at the U.S. Court of Appeals of the Third Circuit in support of unsealing summary judgment records in a case involving Avandia, a diabetes medication, and plans to host sample briefs and resources on its website.

56 South Carolina Judicial Department, South Carolina Rules of Civil Procedure, Rule 41.1, Sealing Documents and Settlement Agreements (May 7, 2003); Local Civil Rules for the U.S. District Court, District of South Carolina, Rule 5.03: Filing Documents Under Seal (August 20, 2014); Texas Rules of Civil Procedure, Rule 76a. Sealing Records (1990).

Table of Contents to Appendix

CHALLENGING COURT SECRECY IN MEDICAL PRODUCT LITIGATION

Yale Collaboration for Research Integrity and Transparency (CRIT)

September 16–17, 2018

The Collaboration for Research Integrity and Transparency (CRIT)—a joint initiative of the law, medical, and public health schools at Yale University—works to ensure that the public has meaningful access to information about drugs and medical devices. Because pharmaceutical companies sponsor most of the safety and efficacy studies for medical products, there is a critical need to independently scrutinize the underlying research that companies use to obtain regulatory approval and to market products to physicians and patients. Since its launch in 2016, CRIT has secured important legal victories for data transparency, including a Freedom of Information Act case involving Gilead Sciences' blockbuster hepatitis C drugs Sovaldi and Harvoni, and has collaborated with researchers, clinicians, and journalists to put pressure on drug makers and regulators to systematically release more data.

On September 17, 2018, CRIT will host a small, closed-door conference with the country's leading plaintiff-side complex tort litigators to address court secrecy in medical product litigation. Tort litigation can expose previously unknown drug risks, corporate malfeasance, and fraudulent marketing practices. However, a significant portion of the information on drugs and devices that is revealed through litigation is kept from the public because of overly broad protective orders, sealing orders, and confidential settlements. This court-sanctioned secrecy has exposed patients to dangerous and ineffective medical products and has compromised public health and safety.

The goals for this meeting are to build consensus among the plaintiffs' attorneys on how to best challenge court secrecy in cases involving medical products and to propose recommendations for judges, policymakers, and regulators. Following the conference, CRIT will release two work products to reflect these goals:

1. Best Practices & Commitments for Plaintiff-Side Attorneys
2. Meeting Report: Conclusions and Recommendations for Judges, Policymakers, & Regulators

We hope that this conference will be the start of long-term collaborative efforts, that reach beyond this group to other stakeholders. We look forward to our discussions, and to learning more about the shape that such collaborations might take.

AGENDA OVERVIEW

Sunday, September 16

3:00 – 6:00 PM	Hotel Check-in, Omni New Haven
6:00 – 8:00 PM	Dinner at Barcelona Restaurant & Wine Bar

Monday, September 17

(Greenberg Conference Center, Yale University)

8:30 – 9:00 AM	Breakfast & Coffee
9:00 – 9:30 AM	Welcome and Overview of Conference Goals
9:30 – 10:30 AM	**Session 1:** *Mapping Key Legal & Practical Barriers* (1 hour)
10:30 – 10:45 AM	Break
10:45 – 12:15 PM	**Session 2**: *Resolving Tensions Between Law and Practice* (1.5 hours)
12:15 – 1:15 PM	Lunch
1:15 – 2:15 PM	**Session 3:** *Collaborating with Third Parties* (1 hour)
2:15 – 2:30 PM	Break
2:30 – 4:00 PM	**Session 4:** *The Role of Judges, Policymakers, & Regulators* (1.5 hours)
4:00 – 5:00 PM	Commitments, Next Steps, & Closing Remarks (1 hour)
6:00 – 7:30 PM	Dinner at Heirloom Restaurant

Greenberg Conference Center, Yale University
391 Prospect Street
New Haven, CT 06511

Contacts
Katherine Lawton
Jeanie Kim

SUNDAY, SEPTEMBER 16

3:00 - 6:00 PM – Hotel Check-In
Omni New Haven Hotel at Yale
155 Temple St.
New Haven, CT 06510

6:00 - 8:00 PM – Dinner at Barcelona Restaurant & Wine Bar
CRIT faculty directors will provide welcome remarks.

Amy Kapczynski, Yale Law School
Harlan Krumholz, Yale School of Medicine

Barcelona Restaurant & Wine Bar
155 Temple St. (corner of Temple St. and Crown St.)
New Haven, CT 06510

MONDAY, SEPTEMBER 17

Maurice R. Greenberg Conference Center, Yale University
391 Prospect Street
New Haven, CT 06511

8:30 - 9:00 AM – Breakfast & Coffee

9:00 - 9:30 AM – Welcome and Overview of Conference Goals
Joseph Ross, Yale School of Medicine
Amy Kapczynski, Yale Law School

9:30 -10:30 AM – Session 1: Mapping Key Legal and Practical Barriers

The goal of this session is to map the key legal and practical barriers to challenging court secrecy. The moderator will facilitate an open conversation among all attendees, discussing obstacles such as: (1) case management and pressure to resolve cases; (2) misinterpretation or misapplication of legal standards for confidentiality; (3) lack of resources and time to challenge confidentiality; (4) tension between the public's interest in disclosure and clients' interests.

Moderator: **Amy Kapczynski**, Professor of Law, Yale Law School
Reporter: **Chris Morten**, Clinical Lecturer in Law and Staff Attorney, Collaboration for Research Integrity and Transparency, Yale Law School

10:30 -10:45 AM – Break

10:45 AM - 12:15 PM – Session 2: Resolving Tensions Between Law and Practice

There are well-established legal standards that place the burden on the party seeking confidentiality and require courts to make specific findings on the need for closure. However, judges and attorneys have ignored or misinterpreted the legal standards, often in favor of practical considerations.

The goals of this session are to discuss how to resolve the tensions between the legal standards and practical realities and to propose solutions that are compatible with the current law. The moderator will facilitate an open conversation among all attendees and structure the conversation around the various stages of litigation—(1) protective orders before the discovery phase, (2) sealing orders during substantive motions practice and trial, and (3) non-disclosure terms in settlement negotiations.

Suggested Readings (available in the shared drive under "Session Materials"):

- Dustin Benham, *Dirty Secrets: The First Amendment in Protective-Order Litigation* (2014)
- Patrick Malone and Jon Bauer, *When Secret Settlements Are Unethical* (2010, updated 2015)
- Judith Resnik, *Uncovering, Disclosing, and Discovering How The Public Dimensions of Court-Based Processes Are at Risk* (2006)

Discussion Questions:

- **Negotiating protective orders:** What provisions can be negotiated in protective orders to narrow the scope of the order and to ensure that the burden remains with the producing party at later stages of litigation?
- **De-designating discovery vs. unsealing court records:** At what stage of litigation is it most strategic to challenge confidentiality?
- **Resisting secret settlements:** What leverage do plaintiffs have to refuse secret settlements and non-disclosure terms?

Moderator: **David Schulz**, Floyd Abrams Clinical Lecturer in Law, Media Freedom and Information Access Clinic, Yale Law School
Reporter: **Jeanie Kim,** Fellow and Research Scholar, Collaboration for Research Integrity and Transparency, Yale Law School

12:15 - 1:15 PM – Lunch
Lunch will be catered at the Greenberg Conference Center.

1:15 - 2:15 PM – Session 3: Collaborating with Third Parties

Third parties have an interest in the data exchanged in litigation, and have at times successfully intervened to unseal such data. But there are obvious challenges for interveners who do not have access to the documents at issue. This session will focus on whether and how medical experts and third-party interveners can more readily identify opportunities to intervene, and/or assist plaintiffs' attorneys with supportive testimony and briefing.

Moderator: **John Langford**, Clinical Lecturer in Law and Staff Attorney, Media Freedom and Information Access Clinic, Yale Law School
Reporter: **Chris Morten**, Clinical Lecturer in Law and Staff Attorney, Collaboration for Research Integrity and Transparency, Yale Law School

2:15 - 2:30 PM – Break

2:30 - 4:00 PM – Session 4: The Role of Judges, Policymakers, & Regulators

While earlier discussions focus on how plaintiff attorneys can work to achieve more transparency, here we will shift to what other actors can and should do. Are there structural ways that judges, policymakers, and regulators can promote public access to data disclosed in pharmaceutical and medical device litigation? The moderator will facilitate a discussion, and conclusions from the discussion will be included in the post-conference meeting report.

Suggested Readings (available in the shared drive under "Session Materials"):

- David Sanson, *The Pervasive Problem of Court-Sanctioned Secrecy and the Exigency of National Reform* (2003)

Discussion Questions:

- How might judges act to influence local rules, standing orders, or more actively engage the parties during litigation to promote the public's interest in access?
- What has the experience been with access-friendly State Rules and Local Federal Rules: Texas Rule 76a, South Carolina Local Rule 5.03? Could/should similar rules be passed elsewhere?
- Could proposed legislation make a significant difference (e.g. Senator Whitehouse's bill, past Sunshine in Litigation bills), and is there potential for this avenue?
- Could the FDA or DOJ play a more proactive role in learning from tort litigation?

Moderator: **Judith Resnik,** Arthur Liman Professor of Law, Yale Law School
Reporter: **Jeanie Kim,** Fellow, CRIT, Yale Law School

4:00 - 5:00 PM – Commitments, Next Steps, & Closing Remarks

This session will review points of consensus regarding best practices, and identify steps that participants can take, for example to address resource concerns, or provide better access to documents that are successfully unsealed. We hope to cover:

Best Practices & Commitments:

- Protective Orders
- Sealing Orders
- Settlements

Report Summary and Recommendations:

- Attorneys (drawn from above)
- Judges, Policymakers, Regulators

Next steps:

- Process for review of the two post-conference work products: (1) Best Practices & Commitments; and (2) Meeting Report
- Future gatherings and work

Moderators: **Amy Kapczynski, Jeanie Kim**

6:00 - 7:30 PM – Dinner at Heirloom Restaurant
1157 Chapel St., New Haven, CT 06511

PARTICIPANTS

Leslie Bailey
Public Justice
lbailey@publicjustice.net

Lauren Barnes
Hagens Berman Sobol Shapiro LLP
Lauren@hbsslaw.com

Laura Baughman
Baron Budd
lbaughman@baronbudd.com

Michael Baum
Baum Hedlund Aristei Goldman
MBaum@BaumHedlundLaw.com

Rachel Bloomekatz
Gupta Wessler
rachel@guptawessler.com

Jayne Conroy
Simmons Hanly Conroy
jconroy@simmonsfirm.com

Alex Egilman
CRIT/Yale School of Medicine
alexander.egilman@yale.edu

Yvonne Flaherty
Lockridge Grindal Nauen
ymflaherty@locklaw.com

Matthew Herder
CRIT/Dalhousie University
matthew.herder@yale.edu

Amy Kapczynski
CRIT/Yale Law School
amy.kapczynski@yale.edu

Aaron Kesselheim
Yale Law School/Harvard Medical School
akesselheim@bwh.harvard.edu

Jeanie Kim
CRIT/Yale Law School
jeanie.kim@yale.edu

Harlan Krumholz
CRIT/Yale School of Medicine
harlan.krumholz@yale.edu

John Langford
CRIT/Yale Law School
john.langford@yale.edu

Mark Lanier
Lanier Law Firm
wml@lanierlawfirm.com

Fred Longer
Levin Sedran Berman
flonger@lfsblaw.com

Ben Martin
The Law Offices of Ben C Martin
bmartin@bencmartin.com

Margaret McCarthy
CRIT/Yale Law School
margaret.e.mccarthy@yale.edu

Paul Miller
Howie Sacks Henry
pmiller@hshlawyers.com

Chris Morten
CRIT/Yale Law School
christopher.morten@yale.edu

Chris Placitella
Cohen, Placitella, and Roth
cplacitella@cprlaw.com

Ellen Relkin
Weitz & Luxenberg
erelkin@weitzlux.com

Judith Resnik
Yale Law School
judith.resnik@yale.edu

Conor Reynolds
Yale Law School
conor.d.reynolds@gmail.com

Joe Ross
CRIT/Yale School of Medicine
joseph.ross@yale.edu

Anisa Rowhani-Farid
CRIT/Yale School of Medicine
anisa.rowhani-farid@yale.edu

David Schulz
CRIT/Yale Law School
david.schulz@yale.edu

Fred Thompson
Motley Rice
fthompson@motleyrice.com

Aimee Wagstaff
Andrus Wagstaff
aimee.wagstaff@andruswagstaff.com

Joshua Wallach
CRIT/Yale School of Public Health
joshua.wallach@yale.edu

R. Brent Wisner
Baum Hedlund Aristei Goldman
RBWisner@BaumHedlundLaw.com

Audrey Zhang
Yale School of Medicine
audrey.zhang@yale.edu

Allison Zieve
Public Citizen
azieve@citizen.org

Genevieve Zimmerman
Meshbesher and Spence
gzimmerman@meshbesher.com

MODEL PROTECTIVE ORDERS

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Plaintiff,v. Defendant.
Case No.

STIPULATED PROTECTIVE ORDER FOR STANDARD LITIGATION

1. PURPOSES AND LIMITATIONS
Disclosure and discovery activity in this action are likely to involve production of confidential, proprietary, or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation may be warranted. Accordingly, the parties hereby stipulate to and petition the court to enter the following Stipulated Protective Order. The parties acknowledge that this Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords from public disclosure and use extends only to the limited information or items that are entitled to confidential treatment under the applicable legal principles. The parties further acknowledge, as set forth in Section 12.3, below, that this Stipulated Protective Order does not entitle them to file confidential information under seal; Civil Local Rule 79-5 sets forth the procedures that must be followed and the standards that will be applied when a party seeks permission from the court to file material under seal.

2. DEFINITIONS
2.1 Challenging Party: a Party or Non-Party that challenges the designation of information or items under this Order.

2.2 "CONFIDENTIAL" Information or Items: information (regardless of how it is generated, stored or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26(c).

2.3 Counsel (without qualifier): Outside Counsel of Record and House Counsel (as well as their support staff).

2.4 Designating Party: a Party or Non-Party that designates information or items that it produces in disclosures or in responses to discovery as "CONFIDENTIAL."

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

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

2.7 House Counsel: attorneys who are employees of a party to this action. House Counsel does not include Outside Counsel of Record or any other outside counsel.

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

2.9 Outside Counsel of Record: attorneys who are not employees of a party to this action but are retained to represent or advise a party to this action and have appeared in this action on behalf of that party or are affiliated with a law firm which has appeared on behalf of that party.

2.10 Party: any party to this action, including all of its officers, directors, employees, consultants, retained experts, and Outside Counsel of Record (and their support staffs).

2.11 Producing Party: a Party or Non-Party that produces Disclosure or Discovery Material in this action.

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

2.13 Protected Material: any Disclosure or Discovery Material that is designated as "CONFIDENTIAL."

2.14 Receiving Party: a Party that receives Disclosure or Discovery Material from a Producing Party.

3. SCOPE

The protections conferred by this Stipulation and Order cover not only Protected Material (as defined above), but also (1) any information copied or extracted from Protected Material; (2) all copies, excerpts, summaries, or compilations of Protected Material; and (3) any testimony, conversations, or presentations by Parties or their Counsel that might reveal Protected Material. However, the protections conferred by this Stipulation and Order do not cover the following information: (a) any information that is in the public domain at the time of disclosure to a Receiving Party or becomes part of the public domain after its disclosure to a Receiving Party as a result of publication not involving a violation of this Order, including becoming part of the public record through trial or otherwise; and (b) any information known to the Receiving Party prior to the disclosure or obtained by the Receiving Party after the disclosure from a source who obtained the information lawfully and under no obligation of confidentiality to the Designating Party. Any use of Protected Material at trial shall be governed by a separate agreement or order.

4. DURATION

Even after final disposition of this litigation, the confidentiality obligations imposed by this Order shall remain in effect until a Designating Party agrees otherwise in writing or a court order otherwise directs. Final disposition shall be deemed to be the later of (1) dismissal of all claims and defenses in this action, with or without prejudice; and (2) final judgment herein after the completion and exhaustion of all appeals, rehearings, remands, trials, or reviews of this action, including the time limits for filing any motions or applications for extension of time pursuant to applicable law.

5. DESIGNATING PROTECTED MATERIAL

5.1 Exercise of Restraint and Care in Designating Material for Protection. Each Party or Non-Party that designates information or items for protection under this Order must take care to limit any such designation to specific material that qualifies under the appropriate standards. The Designating Party must designate for protection only those parts of material, documents, items, or oral or written communications that qualify—so that other portions of the material, documents, items, or communications for which protection is not warranted are not swept unjustifiably within the ambit of this Order.

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

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

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

Designation in conformity with this Order requires:

(a) for information in documentary form (e.g., paper or electronic documents, but excluding transcripts of depositions or other pretrial or trial proceedings), that the Producing Party affix the legend "CONFIDENTIAL" to each page that contains protected material. If only a portion or portions of the material on a page qualifies for protection, the Producing Party also must clearly identify the protected portion(s) (e.g., by making appropriate markings in the margins).

A Party or Non-Party that makes original documents or materials available for inspection need not designate them for protection until after the inspecting Party has indicated which material it would like copied and produced. During the inspection and before the designation, all of the material made available for inspection shall be deemed "CONFIDENTIAL." After the inspecting Party has identified the documents it wants copied and produced, the Producing Party must determine which documents, or portions thereof, qualify for protection under this Order. Then, before producing the specified documents, the Producing Party must affix the "CONFIDENTIAL" legend to each page that contains Protected Material. If only a portion or portions of the material on a page qualifies for protection, the Producing Party also must clearly identify the protected portion(s) (e.g., by making appropriate markings in the margins).

(b) for testimony given in deposition or in other pretrial or trial proceedings, that the Designating Party identify on the record, before the close of the deposition, hearing, or other proceeding, all protected testimony.

(c) for information produced in some form other than documentary and for any other tangible items, that the Producing Party affix in a prominent place on the exterior of the container or containers in which the information or item is stored the legend "CONFIDENTIAL." If only a portion or portions of the information or item warrant protection, the Producing Party, to the extent practicable, shall identify the protected portion(s).

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

6. CHALLENGING CONFIDENTIALITY DESIGNATIONS

6.1 Timing of Challenges. Any Party or Non-Party may challenge a designation of confidentiality at any time. Unless a prompt challenge to a Designating Party's confidentiality designation is necessary to avoid foreseeable, substantial unfairness, unnecessary economic burdens, or a significant disruption or delay of the litigation, a Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed.

6.2 Meet and Confer. The Challenging Party shall initiate the dispute resolution process by providing written notice of each designation it is challenging and describing the basis for each challenge. To avoid ambiguity as to whether a challenge has been made, the written notice must recite that the challenge to confidentiality is being made in accordance with this specific paragraph of the Protective Order. The

parties shall attempt to resolve each challenge in good faith and must begin the process by conferring directly (in voice to voice dialogue; other forms of communication are not sufficient) within 14 days of the date of service of notice. In conferring, the Challenging Party must explain the basis for its belief that the confidentiality designation was not proper and must give the Designating Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain the basis for the chosen designation. A Challenging Party may proceed to the next stage of the challenge process only if it has engaged in this meet and confer process first or establishes that the Designating Party is unwilling to participate in the meet and confer process in a timely manner.

6.3 Judicial Intervention. If the Parties cannot resolve a challenge without court intervention, the Designating Party shall file and serve a motion to retain confidentiality under Civil Local Rule 7 (and in compliance with Civil Local Rule 79-5, if applicable) within 21 days of the initial notice of challenge or within 14 days of the parties agreeing that the meet and confer process will not resolve their dispute, whichever is earlier. Each such motion must be accompanied by a competent declaration affirming that the movant has complied with the meet and confer requirements imposed in the preceding paragraph. Failure by the Designating Party to make such a motion including the required declaration within 21 days (or 14 days, if applicable) shall automatically waive the confidentiality designation for each challenged designation. In addition, the Challenging Party may file a motion challenging a confidentiality designation at any time if there is good cause for doing so, including a challenge to the designation of a deposition transcript or any portions thereof. Any motion brought pursuant to this provision must be accompanied by a competent declaration affirming that the movant has complied with the meet and confer requirements imposed by the preceding paragraph.

The burden of persuasion in any such challenge proceeding shall be on the Designating Party. Frivolous challenges, and those made for an improper purpose (e.g., to harass or impose unnecessary expenses and burdens on other parties) may expose the Challenging Party to sanctions. Unless the Designating Party has waived the confidentiality designation by failing to file a motion to retain confidentiality as described above, all parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation until the court rules on the challenge.

7. ACCESS TO AND USE OF PROTECTED MATERIAL

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

Protected Material must be stored and maintained by a Receiving Party at a location and in a secure manner that ensures that access is limited to the persons authorized under this Order.

7.2 Disclosure of "CONFIDENTIAL" Information or Items. Unless otherwise ordered by the court or permitted in writing by the Designating Party, a Receiving Party may disclose any information or item designated "CONFIDENTIAL" only to:

(a) the Receiving Party's Outside Counsel of Record in this action, as well as employees of said Outside Counsel of Record to whom it is reasonably necessary to disclose the information for this litigation and who have signed the "Acknowledgment and Agreement to Be Bound" that is attached hereto as Exhibit A;

(b) the officers, directors, and employees (including House Counsel) of the Receiving Party to whom disclosure is reasonably necessary for this litigation and who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);

(c) Experts (as defined in this Order) of the Receiving Party to whom disclosure is reasonably necessary for this litigation and who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);

(d) the court and its personnel;

(e) court reporters and their staff, professional jury or trial consultants, mock jurors, and Professional Vendors to whom disclosure is reasonably necessary for this litigation and who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);

(f) during their depositions, witnesses in the action to whom disclosure is reasonably necessary and who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A), unless otherwise agreed by the Designating Party or ordered by the court. Pages of transcribed deposition testimony or exhibits to depositions that reveal Protected Material must be separately bound by the court reporter and may not be disclosed to anyone except as permitted under this Stipulated Protective Order.

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

8. PROTECTED MATERIAL SUBPOENAED OR ORDERED PRODUCED IN OTHER LITIGATION

If a Party is served with a subpoena or a court order issued in other litigation that compels disclosure of any information or items designated in this action as "CONFIDENTIAL," that Party must:

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

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

(c) cooperate with respect to all reasonable procedures sought to be pursued by the Designating Party whose Protected Material may be affected.

If the Designating Party timely seeks a protective order, the Party served with the subpoena or court order shall not produce any information designated in this action as "CONFIDENTIAL" before a determination by the court from which the subpoena or order issued, unless the Party has obtained the Designating Party's permission. The Designating Party shall bear the burden and expense of seeking protection in that court of its confidential material – and nothing in these provisions should be construed as authorizing or encouraging a Receiving Party in this action to disobey a lawful directive from another court.

9. A NON-PARTY'S PROTECTED MATERIAL SOUGHT TO BE PRODUCED IN THIS LITIGATION

(a) The terms of this Order are applicable to information produced by a Non-Party in this action and designated as "CONFIDENTIAL." Such information produced by Non-Parties in connection with this litigation is protected by the remedies and relief provided by this Order. Nothing in these provisions should be construed as prohibiting a Non-Party from seeking additional protections.

(b) In the event that a Party is required, by a valid discovery request, to produce a Non-Party's confidential information in its possession, and the Party is subject to an agreement with the Non-Party not to produce the Non-Party's confidential information, then the Party shall:

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

(2) promptly provide the Non-Party with a copy of the Stipulated Protective Order in this litigation, the relevant discovery request(s), and a reasonably specific description of the information requested; and (3) make the information requested available for inspection by the Non-Party.

(c) If the Non-Party fails to object or seek a protective order from this court within 14 days of receiving the notice and accompanying information, the Receiving Party may produce the Non-Party's confidential information responsive to the discovery request. If the Non-Party timely seeks a protective order, the Receiving Party shall not produce any information in its possession or control that is subject to the confidentiality agreement with the Non-Party before a determination by the court. Absent a court order to the contrary, the Non-Party shall bear the burden and expense of seeking protection in this court of its Protected Material.

10. UNAUTHORIZED DISCLOSURE OF PROTECTED MATERIAL

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

11. INADVERTENT PRODUCTION OF PRIVILEGED OR OTHERWISE PROTECTED MATERIAL

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

12. MISCELLANEOUS

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

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

12.3 Filing Protected Material. Without written permission from the Designating Party or a court order secured after appropriate notice to all interested persons, a Party may not file in the public record in this action any Protected Material. A Party that seeks to file under seal any Protected Material must comply with Civil Local Rule 79-5. Protected Material may only be filed under seal pursuant to a court order authorizing the sealing of the specific Protected Material at issue. Pursuant to Civil Local Rule 79-5, a sealing order will issue only upon a request establishing that the Protected Material at issue is privileged, protectable as a trade secret, or otherwise entitled to protection under the law. If a Receiving Party's

request to file Protected Material under seal pursuant to Civil Local Rule 79-5(d) is denied by the court, then the Receiving Party may file the information in the public record pursuant to Civil Local Rule 79-5(e) unless otherwise instructed by the court.

13. FINAL DISPOSITION

Within 60 days after the final disposition of this action, as defined in paragraph 4, each Receiving Party must return all Protected Material to the Producing Party or destroy such material. As used in this subdivision, "all Protected Material" includes all copies, abstracts, compilations, summaries, and any other format reproducing or capturing any of the Protected Material. Whether the Protected Material is returned or destroyed, the Receiving Party must submit a written certification to the Producing Party (and, if not the same person or entity, to the Designating Party) by the 60 day deadline that (1) identifies (by category, where appropriate) all the Protected Material that was returned or destroyed and (2) affirms that the Receiving Party has not retained any copies, abstracts, compilations, summaries or any other format reproducing or capturing any of the Protected Material. Notwithstanding this provision, Counsel are entitled to retain an archival copy of all pleadings, motion papers, trial, deposition, and hearing transcripts, legal memoranda, correspondence, deposition and trial exhibits, expert reports, attorney work product, and consultant and expert work product, even if such materials contain Protected Material. Any such archival copies that contain or constitute Protected Material remain subject to this Protective Order as set forth in Section 4 (DURATION).

IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.

DATED: _____ _____

Attorneys for Plaintiff

DATED: _____ _____

Attorneys for Defendant

PURSUANT TO STIPULATION, IT IS SO ORDERED.

DATED: _____ _____

United States District/Magistrate Judge

EXHIBIT A

ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND

I, _____ [print or type full name], of _____ [print or type full address], declare under penalty of perjury that I have read in its entirety and understand the Stipulated Protective Order that was issued by the United States District Court for the Northern District of California on [date] in the case of _____
[**insert formal name of the case and the number and initials assigned to it by the court**]. I agree to comply with and to be bound by all the terms of this Stipulated Protective Order and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Stipulated Protective Order to any person or entity except in strict compliance with the provisions of this Order.

I further agree to submit to the jurisdiction of the United States District Court for the Northern District of California for the purpose of enforcing the terms of this Stipulated Protective Order, even if such enforcement proceedings occur after termination of this action.

I hereby appoint _____ [print or type full name] of _____ _____ [print or type full address and telephone number] as my California agent for service of process in connection with this action or any proceedings related to enforcement of this Stipulated Protective Order.

Date: _____

City and State where sworn and signed: _____

Printed name: _____

Signature: _____

SAMPLE PROTECTIVE ORDER
PUBLIC JUSTICE (www.publicjustice.net)
As of May 9, 2018

ABC, Plaintiff(s), vs. XYZ, Defendant(S).

[PROPOSED] STIPULATED PROTECTIVE ORDER

Plaintiff ABC ("Plaintiff") and Defendant XYZ ("Defendant") having agreed to the following, and IT IS HEREBY ORDERED as follows:

PURPOSES AND LIMITATIONS

Disclosure and discovery activity in this action may involve production of confidential, proprietary, or private information for which special protection from public disclosure may be warranted. The parties acknowledge that this Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords extends only to the limited information or items that are entitled to be treated as confidential under the terms of this Order and applicable legal principles. Furthermore, the parties acknowledge that neither this Order—nor the confidentiality designations thereunder—constitutes a ruling by this Court that any specific information is, in fact, confidential. Nor does it entitle parties to file any information under seal.

CONFIDENTIAL INFORMATION

"Confidential Information" shall mean information or tangible things for which there is good cause for secrecy under Federal Rule of Civil Procedure 26(c)[1]—that is, information that will cause a clearly defined and serious injury to the Designating Party (defined below) if disclosed. Examples of such information include social security or taxpayer-identification numbers; dates of birth; names of minor children; financial account numbers; home addresses; and trade secrets or other similar confidential research, development, or commercial information that would cause severe competitive harm to the Designating Party if disclosed. "Confidential Information" does not include any information that:

a. is in the public domain at the time of disclosure;
b. becomes part of the public domain through no fault of the Receiving Party (defined below);
c. the Receiving Party can show was in its rightful and lawful possession at the time of disclosure; or
d. the Receiving Party lawfully receives at a later date from a third party without restriction as to disclosure.

Parties and non-parties may designate any Confidential Information supplied in any form, or any portion thereof, as Protected Material (defined below) for purposes of these proceedings. Such designations shall constitute a representation to the Court that counsel believes in good faith that the information (1) constitutes Confidential Information and (2) that there is good cause for the Confidential Information to be protected from public disclosure. The parties and non-parties shall make a good faith effort to designate information so as to provide the greatest level of disclosure possible, but still preserve confidentiality as appropriate. If only part of a document contains confidential information, the whole document shall not be designated confidential. Instead, solely the specific information that is confidential shall be so designated.

1 Or, if in state court, insert relevant state law analogue.

ADDITIONAL DEFINITIONS

3.1 Party: any party to this action, including all of its officers, directors, consultants, retained experts, and outside counsel (and their support staff).

3.2 Non-party: any individual, corporation, association, or other natural person or entity other than a party.

3.3 Disclosure or Discovery Material: all items or information, regardless of the medium or manner generated, stored, or maintained (including, among other things, testimony, transcripts, or tangible things) that are produced or generated in disclosures or responses to discovery in this matter.

3.4 Protected Material: any Disclosure or Discovery Material that is designated by a Party or Non-party as "confidential" according to paragraphs 2 and 5, unless the Receiving Party challenges the confidentiality designation and (a) the Court decides such material is not entitled to protection as confidential; (b) the Designating Party fails to apply to the Court for an order designating the material confidential within the time period specified below; or (c) the Designating Party withdraws its confidentiality designation in writing.

3.5 Receiving Party: a Party that receives Disclosure or Discovery Material from a Producing Party.

3.6 Producing Party: a Party or Non-party that produces Disclosure or Discovery Material in this action.

3.7 Designating Party: a Party or Non-party that designates information or items that it produces in disclosures or in responses to discovery as Protected Material. The Party or Non-party designating information or items as Protected Material bears the burden of establishing good cause for the confidentiality of all such information or items.

3.8 Challenging Party: a Party that elects to initiate a challenge to a Designating Party's confidentiality designation.

3.9 Outside Counsel: attorneys who are not employees of a Party but who are retained to represent or advise a Party in this action.

3.10 House Counsel: attorneys who are employees of a Party.

3.11 Counsel (without qualifier): Outside Counsel and House Counsel (as well as their support staffs).

3.12 Expert: a person who has been retained by a Party or its/her/his Counsel to serve as a testifying or non-testifying expert witness or as a consultant in this action, including any person specially retained to provide expert opinions in a hybrid capacity. This definition includes a professional jury or trial consultant retained in connection with this litigation. Nothing about this definition or this Order is meant to preclude exchange of information under this Order or otherwise with any consultant or testifying expert, regardless of whether they are specially retained for the purposes of this litigation.

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

DURATION

This Order is intended to facilitate discovery. It therefore expires twenty-one (21) days after the termination of litigation, at which time any and all protections afforded by the Order will cease, unless the parties agree otherwise, in writing, or there is a subsequent court order.[2]

---

2 If the other side will not agree to a protective order that expires at the end of the litigation absent further stipulation or court order, and insists on a perpetual order, here's sample language for an alternative duration provision that extends the order indefinitely:

Even after the termination of this litigation, the confidentiality obligations imposed by this Order shall remain in effect until a Designating Party agrees otherwise in writing or a court order otherwise directs.

DESIGNATING PROTECTED MATERIAL

5.1 Exercise of Restraint and Care in Designating Material for Protection. Each Party or Non-party that designates information or items for protection under this Order must use good faith efforts to limit any such designation to specific material that qualifies under the appropriate standards. A Designating Party must use good faith efforts to designate for protection only those parts of material, documents, items, or oral or written communications that qualify—so that other portions of the material, documents, items, or communications for which protection is not warranted are not unjustifiably designated confidential.

Mass, indiscriminate, or routine designations are strictly prohibited. Designations that are shown to be clearly unjustified, or that have been made for an improper purpose (e.g., to unnecessarily encumber or retard the case development process, or to impose unnecessary expenses and burdens on other parties), may subject the Designating Party to sanctions upon appropriate motion to the Court.

If it comes to a Designating Party's attention that information that it designated confidential does not qualify for protection, that Designating Party must promptly notify all other parties that it is withdrawing the mistaken designation.

5.2 Manner and Timing of Designations. Except as otherwise provided in this Order, or as otherwise stipulated or ordered, material that qualifies for protection under this Order must be clearly so designated before the material is disclosed or produced.

Designation in conformity with this Order requires:

a. *For information in documentary form* (apart from transcripts of depositions or other pretrial or trial proceedings), the Producing Party must affix the legend "CONFIDENTIAL" at the bottom of each page that contains protected material. If only a portion or portions of the material on a page qualifies for protection, the Producing Party also must clearly identify the protected portion(s) (e.g., by making appropriate markings in the margins, but not over text).

A Party or Non-party that makes original documents or materials available for inspection need not designate them for protection until after the inspecting Party has indicated which material it would like copied and produced. During the inspection and before the designation, all of the material made available for inspection shall be treated as confidential. After the inspecting Party has identified the documents it wants copied and produced, the Producing Party must determine which documents, or portions thereof, qualify for protection under this Order, then, before producing the specified documents, the Producing Party must affix the legend "CONFIDENTIAL" at the bottom of each page that contains Protected Material. If only a portion of the material on a page qualifies for protection, the Producing Party also must clearly identify the protected portion(s) (e.g., by making appropriate markings in the margins, but not over text).

b. *For testimony given in deposition or in other pretrial or trial proceedings*, the Party or Non-party offering or sponsoring the testimony must identify on the record, before the close of the deposition, hearing, or other proceeding, all protected testimony. When it is impractical to identify separately each portion of testimony that is entitled to protection, and when it appears that substantial portions of the testimony may qualify for protection, the Party or Non-party that sponsors, offers, or gives the testimony may invoke on the record (before the deposition or proceeding is concluded) a right to have up to fourteen (14) days to identify the specific portions of the testimony as to which protection is sought. Only those portions of the testimony that are appropriately designated for protection within the 14 days shall be covered by the provisions of this Stipulated Protective Order.

The court reporter must affix the legend "CONFIDENTIAL" at the bottom of transcript pages containing Protected Material, as instructed by the Party or nonparty offering or sponsoring the witness or presenting the testimony. If only a portion of the material on a page qualifies for protection, the Producing Party also

must clearly identify the protected portion(s) (e.g., by making appropriate markings in the margins, but not over text).

c. *For information produced in some form other than documentary, and for any other tangible items*, the Producing Party must affix in a prominent place on the exterior of the container or containers in which the information or item is stored the legend "CONFIDENTIAL." If only portions of the information or item warrant protection, the Producing Party, to the extent practicable, shall also identify the protected portions in such a way that does not interfere with the viewing of the evidence.

5.3 Inadvertent Failures to Designate. If timely corrected, an inadvertent failure to designate qualified information or items as "confidential" does not, standing alone, waive the Designating Party's right to secure protection under this Order for such material. If material is appropriately designated as "confidential" after the material was initially produced, the Receiving Party, on timely notification of the designation, must make reasonable efforts to assure that the material is treated in accordance with the provisions of this Order.

5.4 Inadvertent Production of Privileged Information. If a Producing Party inadvertently produces a document or other information that it believes to be subject to a claim of privilege or attorney work product, it will promptly notify the Receiving Party and provide the Receiving Party the legal grounds for its claim of privilege or attorney work product. If the Receiving Party agrees with the claim of privilege or attorney work product, it will promptly return the document or other information and all copies thereof. If the Receiving Party objects to the claim of privilege or attorney work product, it shall promptly state its objection. The Producing Party may then bring the issue to the Court for resolution and will have the burden of establishing before the Court any claim of privilege or attorney work product.

CHALLENGING CONFIDENTIALITY DESIGNATIONS

6.1 Timing of Challenges. Any Party or Non-Party may challenge a designation of confidentiality at any time, including after the litigation has ended. A Party or Non-Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed.

6.2 Procedure for Challenging Confidentiality Designations. A party may challenge the designation of a document or other material as Confidential as follows:

a. If a Party believes that material designated by another as Confidential has not been properly so designated or should be reclassified or revealed to an individual not otherwise authorized to have access to that material under this Order, that party shall provide to the Designating Party written notice of that disagreement, stating the reason(s) for the challenge. During the 10-day period following service of the written challenge on the designating party (the "Meet and Confer Period"), the Challenging and Designating Parties shall try to dispose of such challenge in good faith on an informal basis.

b. If neither the designation nor the objection is withdrawn during the Meet and Confer Period, the Designating Party shall have 20 days from the receipt of the written challenge notice to apply to the Court for an order designating the challenged material as Confidential. Each such motion must be accompanied by a declaration affirming that the movant has complied with the meet and confer requirements imposed in the preceding paragraph. The Designating Party bears the burden of establishing that the material is entitled to protection as Confidential Information. Any material that is designated as Confidential Information that is the subject of a challenge shall remain subject to this Protective Order until the Court rules on the Designating Party's motion or, if no motion is made, until the time for the designating party to bring a motion has expired. Failure by the Designating Party to make such a motion, including the required declaration, within the applicable time period for doing so shall automatically waive the confidentiality designation for each challenged designation.

ACCESS TO AND USE OF PROTECTED MATERIAL

7.1 Basic Principles. A Receiving Party may use Protected Material that is disclosed or produced by another Party or by a Non-party in connection with this case only for prosecuting, defending, or attempting to settle this litigation. Such Protected Material may be disclosed only to the categories of persons and under the conditions as are described herein.

Protected Material must be stored and maintained by a Receiving Party at a location and in a secure manner that ensures that access is limited to the persons authorized under this Order.

7.2 Disclosure of Protected Material. With the exception of material disclosed under Section 7.3 below, unless otherwise ordered by the Court or permitted in writing by the Designating Party, a Receiving Party may disclose any information or item designated CONFIDENTIAL only to:

a. Outside Counsel of record of any Party in this action, including associated personnel necessary to assist Outside Counsel in these proceedings, such as litigation assistants, paralegals, and secretarial and other clerical personnel;

b. Parties to this litigation and their officers, directors, and employees (including House Counsel) to whom disclosure is reasonably necessary for this litigation;

c. Experts (as defined in this Order) of the Receiving Party, including associated personnel necessary to assist Experts in these proceedings, such as litigation assistants, paralegals, and secretarial and other clerical personnel, so long as such Expert has signed the "Acknowledgment and Agreement to Be Bound by Stipulated Protective Order" (Exhibit A);

d. the Court, including associated personnel necessary to assist the Court in its functions, and the jury;

e. litigation support services, including outside copying services, court reporters, stenographers, videographers, or companies engaged in the business of supporting computerized or electronic litigation discovery or trial preparation, retained by a Party or its counsel for the purpose of assisting that Party in these proceedings, for whom a company representative has signed the "Acknowledgment and Agreement to Be Bound by Protective Order" (Exhibit A);

f. other professional vendors to whom disclosure is reasonably necessary for this litigation and for whom a company representative has signed the "Acknowledgment and Agreement to Be Bound by Stipulated Protective Order" (Exhibit A);

g. any actual or potential witness in the action who has signed the "Acknowledgment and Agreement to Be Bound by Stipulated Protective Order" (Exhibit A), provided that counsel believes, in good faith, that such disclosure is reasonably necessary for the prosecution or defense of these proceedings;

h. the author of the document or the original source of the information;

i. Counsel for issuers of insurance policies under which any issuer may be liable to satisfy part or all of a judgment that may be entered in these proceedings or to indemnify or reimburse payments or costs associated with these proceedings and who has signed the "Acknowledgment and Agreement to Be Bound by Stipulated Protective Order" (Exhibit A);

j. any mediator or arbitrator appointed by the Court or selected by mutual agreement of the parties and the mediator or arbitrator's secretarial and clerical personnel, provided that a company representative for the mediator or arbitrator has signed the "Acknowledgment and Agreement to Be Bound by Stipulated Protective Order" (Exhibit A);

k. Counsel representing clients with present or future cases against the same defendant that arise out of the same or similar set of facts, transactions, or occurrences, provided that before disclosing any Protected Material to any such counsel, the Receiving Party must notify the Designating Party ten (10) days before disclosing such material in order to give the Designating Party an opportunity to move for a protective order preventing or limiting such disclosure; and

l. any other person as to whom the Producing Party has consented to disclosure in advance and in writing, on notice to each Party hereto.

7.3 Disclosure to the Government. Notwithstanding this Order or any confidentiality designations thereunder, any party may disclose relevant information to any regulatory or law enforcement agency or government entity that has an interest in the subject matter of the underlying suit.

PROTECTED MATERIAL SUBPOENAED OR ORDERED PRODUCED IN OTHER LITIGATION

If a Receiving Party is served with a subpoena or an order issued in other litigation that would compel disclosure of any information or items designated in this action as "confidential," the Receiving Party must so notify the Designating Party in writing (by e-mail, if possible) within five (5) business days after receiving the subpoena or order. Such notification must include a copy of the subpoena or court order.

The Receiving Party also must promptly notify in writing the party that caused the subpoena or order to issue that some or all the material covered by the subpoena or order is the subject of this Protective Order. In addition, the Receiving Party must deliver a copy of this Stipulated Protective Order promptly to the Party in the other action that caused the subpoena or order to issue.

If the Designating Party timely seeks a protective order from the court where the subpoena or order issued, the Party served with the subpoena or court order shall not produce any information designated in this action as "CONFIDENTIAL" before a determination by that court, unless the Party has obtained the Designating Party's permission. The Designating Party shall bear the burden and expense of seeking protection in that court of its confidential material—and nothing in these provisions should be construed as authorizing or encouraging a Receiving Party in this action to disobey a lawful directive from another court.

UNAUTHORIZED DISCLOSURE OF PROTECTED MATERIAL

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

USE OF PROTECTED MATERIAL IN COURT

Neither this Order, nor any confidentiality designations thereunder, is a sufficient basis for demonstrating that court records may be sealed. The procedure for filing Protected Material with the Court shall be as follows:[3]

a. If the filing party is the Designating Party, it shall not move to seal any material that it does not, in good faith, believe meets the legal standard for sealing—even if it has previously marked such material confidential under this Order. If, after evaluating in good faith whether the information meets the

3 This procedure is loosely based on the local rules governing sealing in the Northern District of California. If you're litigating in that district (or a jurisdiction with similar rules that ensure that court records cannot be sealed simply because they are subject to a blanket protective order and that the burden of demonstrating that records are sealable is on the party seeking sealing), this section can just state: "Neither this Order, nor any confidentiality designations thereunder, is a sufficient basis for demonstrating that court records may be sealed. The procedure for filing Protected Material with the Court shall be that provided in [Rule]."

We also recommend checking to be sure that this procedure does not conflict with the local rules of whatever jurisdiction you are in. In some cases, the procedure may have to be adjusted to accommodate the requirements of those rules.

legal standard for sealing, the Designating Party still seeks to file information under seal, it must file a motion to seal demonstrating with particularity that each document or portion thereof that the party seeks to seal meets the legal standard for sealing. This motion must be accompanied by a declaration that specifically identifies each document or portion thereof the party seeks to seal and provides a factual basis for the party's claim that sealing is warranted. Unless the party believes in good faith that an entire document is sealable, it shall also file a redacted version of the document on the public docket.

b. If the filing party is not the Designating Party, it must file a motion to provisionally seal the Protected Material, accompanied by a declaration identifying the specific documents or portions thereof that have been designated confidential and identifying the Designating Party. Unless an entire document is marked confidential, the filing party shall also file a public version of the document, with the Protected Material redacted, on the public docket.

Within four (4) days of the filing of a provisional motion to seal, the Designating Party must file a further motion to seal, if it believes in good faith that the material should continue to be sealed. This motion must be accompanied by a declaration that specifically identifies each document or portion thereof the Designating Party seeks to seal and provides a factual basis for the Designating Party's claim that sealing is warranted. Absent an order granting an extension, if the Designating Party does not file a motion to seal within this deadline, it waives the right to have the material sealed, and the filing party shall file it on the public docket within seven (7) days. If the Designating Party does file such a motion, the material will remain under seal provisionally unless and until the Court rules otherwise.

MISCELLANEOUS[4]

12.1 Public Health and Safety. Nothing in this Order is intended to prevent any party from raising with the Court any concern that the non-disclosure of certain Protected Material may have a possible adverse effect upon the general public health or safety, or the administration or operation of government or public office, and therefore the public interest in disclosure outweighs any interest in secrecy.

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

12.3 Non-Parties. Nothing in this Order affects the right of non-parties to this action to challenge this Order, any confidentiality designations made pursuant to the Order, or the sealing of any court records in this case.

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

So Ordered, this the _____ day of _____, 20_____.

_____

The Honorable

CONSENTED TO:

Counsel for the Plaintiff:

_____

Counsel for the Defendant:

_____

4. We suggest that parties do not include a provision requiring the return or destruction of material after the case has ended. If, however, the other side insists on such a provision, here's a sample provision that limits its reach that we recommend inserting before the Miscellaneous section:

   FINAL DISPOSITION
   After the final termination of this action, if requested by the Producing Party, each Receiving Party must return all Protected Material to the Producing Party. Notwithstanding this provision, Counsel are entitled to retain an archival copy of all pleadings, motion papers, transcripts, legal memoranda, correspondence and attorney work product, even if such materials contain Protected Material.

EXHIBIT A

ABC, Plaintiff, -v- XYZ, Defendant.	ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND BY STIPULATED PROTECTIVE ORDER

I acknowledge that I have read and understand the Stipulated Protective Order entered in this action on __ _____, 20_____, and agree to abide by its terms and conditions. Because it is necessary for me in the performance of my duties to have access to Confidential Matter and information contained therein that are the subject of said Stipulated Protective Order, I understand and agree that I am personally bound by and subject to all of the terms and provisions of said Order.

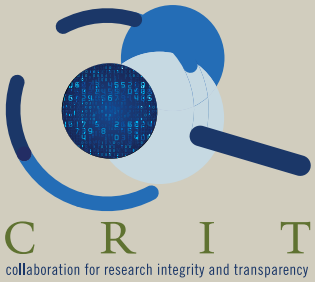
Witness my signature this _____ day of _____, 20_____.

_____

Signature

Address:_____

Telephone:_____



Collaboration for Research Integrity & Transparency
Yale Law School
P.O. Box 208215
New Haven, Connecticut 06520
https://law.yale.edu/crit
crit.admin@yale.edu
@Yale_CRIT
203.436.8420

© 2019 by the Collaboration for Research Integrity & Transparency. *Preventing the Use of Courts to Shield Essential Health Data: Reconfiguring Medical Product Litigation*, is made available under a Creative Commons Attribution-Non-Commercial 4.0 International License.