PROTE Solutions FORYOU

Diversity In Clinical Trials

The Need For Diversity To Ensure Safety And Efficacy

Federal Removal Statutes

A Review Of The Federal Courts Jurisdiction And Venue Clarification Act Of 2011

Communication With Your PR Firm

Endangering The Attorney-Client Privilege



We seek to make *Pro Te: Solutio* relevant to concerns pharmaceutical and medical device companies deal with every day, from seemingly simple inter-office communications to the more complicated work of developing clinical trials.

Just typing on an email or memorandum "Attorney-Client Privilege" or "Attorney Work Product" is not what makes a document privileged. *Communication to Your Public Relations Firm: Privileged or Not?* explores the basic tenets of privilege and the law as to what types of communications to your public relations firm may be privileged.

No Missing Pieces: The Importance of Diversity in Clinical Trials is a thoughtful article that explores the importance of making sure your clinical trials are medically, ethically, and legally sound by considering diversity in developing protocols for such trials.

The Federal Courts Jurisdiction and Venue Clarification Act of 2011 went into effect on January 6, 2012. Did it reach its goal of clarity? *Changes to the Federal Removal Statutes: Questions Still Remain* focuses on the issue.

Some states have a statute of repose for bringing an action. We have explained how those statutes might be helpful to you in defending a lawsuit and have compiled them in *Product Liability Statutes of Repose*.

We hope this issue of Pro Te: Solutio will assist you in dealing with the various matters you face every day.



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PROTE: Solutio

SHARING SOLUTIONS

It's human nature to share problems. But how often is someone willing to share solutions? Butler Snow wants to do just that — provide scenarios and the solutions that turned a client's anxiety into relief and even triumph. That's why we created this magazine, *Pro Te: Solutio*, which explores how real-life legal problems have been successfully solved.

That's also why we at Butler Snow redesigned and expanded our unique health-oriented industry group, now comprised of two major sections that handle business and litigation. The Pharmaceutical, Medical Device, and Healthcare Industry Group has more than 50 multi-disciplinary attorneys who provide creative solutions for the complex issues of the healthcare industry. This group includes product liability and commercial litigators; corporate, commercial, and transaction attorneys; labor and employment attorneys; intellectual property attorneys; and those experienced in government investigations.

Pro Te: Solutio is a quarterly magazine available only to the clients of Butler Snow. If you have questions or comments about its articles, you're invited to contact Christy Jones and Charles Johnson, as well as any of the attorneys listed on the last page of this publication.

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THE IMPORTANCE OF DIVERSITY

in **CLINICAL TRIALS**

Checkmate! You've succeeded. After years of laboratory and other pre-clinical work, your company has earned the green light to begin clinical trials to test its groundbreaking new drug. In preparing the protocol and designing each phase of the clinical trial, there are critical questions that every sponsor must answer. One of the most important of these is, "In whom should we study the drug?" Of course, this answer will depend largely upon the population for whom the drug is intended, the sponsor's ability to recruit study participants, and other factors. Nevertheless, it is essential that clinical trials are sufficiently diverse to ensure safety and efficacy and, also, to withstand scrutiny.

The game of chess is a near perfect metaphor for diversity in clinical trials. The "chess protocol" accounts for every contingency, and nothing is left to chance. There are no missing pieces. In case you are not a chess Grandmaster, like Bobby Fischer, here are a few basics. A chessboard is made up of 64 squares evenly divided between 32 light/ white squares and 32 black/dark squares. A proper chessboard is perfectly symmetrical, with eight ranks and eight files. To play the game correctly, the chessboard must be oriented so that a light/white square is in the bottom right corner of the board. Without a properly oriented chessboard to serve as a foundation, the game cannot be played properly. In addition, players must have all the

pieces placed in their designated squares. If even one piece is missing, the game cannot be played as intended. The same is true of clinical trials. There can be no missing pieces.

In this analogy, having clinical trials that are scientifically, ethically, and legally sound is "king." And, even an amateur chess player knows that protecting the king is essential. If the king is in jeopardy, simply put, nothing else matters. The purpose of this article is to provide some basic strategies and reminders to assist you in protecting your king.

WHY IS DIVERSITY IN **CLINICAL TRIALS IMPORTANT?**

Racial and ethnic minorities are the fastest growing segment of the U.S. population.

It is well-known in the medical and scientific community that some medicines have the potential to work differently depending upon a patient's race or ethnicity. In fact, "[e]thnicity is one factor that may account for the observed differences in both pharmacokinetics (PK) and pharmacodynamics (PD) of drugs, resulting in variability in response to drug therapy."1 Further, "[g]iven that the applicability of clinical study results to the treatment of an individual patient is a critical consideration in a physician's choice of drug therapy, drug development should seek to ensure that a clinical pharmacologic evaluation includes a population that is representative of the target therapeutic population."2 In short, because ethnic differences

may be one factor in determining the riskbenefit ratio of a drug therapy in a specific patient, these differences should be considered during drug development.³

In addition to the scientific and medical cases for diversity in clinical trials, in some instances, study funding may be contingent upon a showing of diversity. For example, in 1993, Congress enacted the National Institutes of Health (NIH) Revitalization Act of 1993 (PL 103-43). In studies conducted or supported by NIH, the Revitalization Act requires that the Director of NIH ensure, among other things, that:

• Women and minorities are included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of NIH that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research;

• Phase III clinical trials include women and minorities in numbers adequate to allow for valid analyses of differences in intervention effect;

• Cost is not allowed as an acceptable reason for excluding these groups; and,

• NIH initiates programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as volunteers in clinical studies.

Finally, but not least significantly, in addition to scientific/medical considerations and potential funding requirements, FDA has expressly stated that "if there is an inadequate evaluation for safety and/or effectiveness of the population intended to use the drug, including pertinent subsets, such as gender, age, and racial subsets, the Agency may refuse to file the [NDA]."⁴

Defining, Collecting, and Reporting "Diversity"

The FDA has taken steps to provide standardized methods of defining, collecting, and reporting race and ethnicity information in clinical trials to ensure consistency in demographic subset analyses, to compare results across studies, and to assess potential subgroup differences in safety and effectiveness. In 1998, the FDA published the *Demographic Rule*, which requires IND and NDA⁵ sponsors to present a summary of safety and effectiveness data by demographic subgroups (e.g., age, gender, race).⁶ The 1998 *Demographic Rule* also requires sponsors to provide an analysis of whether

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IN SOME INSTANCES, FUNDING AND EVEN DRUG APPROVAL MAY BE WITHHELD IF CLINICAL TRIALS ARE NOT SUFFICIENTLY DIVERSE OR IF DATA REGARDING DIVERSITY IS NOT PROPERLY COLLECTED AND REPORTED. ENSURING DIVERSITY IN CLINICAL TRIALS CANNOT BE LEFT TO CHANCE. JUST AS CHESS IS A GAME OF STRATEGY, SO ARE DEVELOPING AND CONDUCTING SUFFICIENTLY DIVERSE CLINICAL TRIALS.

modifications of dose or dosage intervals are needed for specific subgroups.⁷

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In September 2005, FDA published its Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials. While the Guidance does not address the level of participation of racial and ethnic groups in clinical trials, it is a useful guide for ensuring demographic information is properly collected and reported. As noted in the Guidance, the United States Department of Health and Human Services (HHS) does not follow anthropologic or scientifically based designations, but instead, has adopted the standardized approach of the Office of Management and Budget (OMB). HHS, like OMB, chose to adopt standardized categories "because the categories are relevant to assessing various health-related data, including public health surveillance and research."8 Accordingly, HHS recommends the following:

• Request race and ethnicity information

in a two-question format, with the question about ethnicity preceding the question about race;

• Provide for self-reporting of race and ethnicity information whenever feasible and allow for the designation of multiracial identity;

• For ethnicity, provide "Hispanic or Latino" and "Not Hispanic or Latino" as minimum choices.

When race and ethnicity information are collected separately, provide the following minimum choices: "American Indian or Alaska Native," "Asian," "Black or African," "Native Hawaiian or Other Pacific Islander," and "White."⁹ More detailed information may also be gathered and reported, but these designations are acceptable.

BARRIERS TO ACHIEVING DIVERSITY

Despite a near consensus that diversity in clinical trials is important, it has been noted that barriers to achieving adequate representation persist, despite the best efforts of sponsors.¹⁰ Some examples of these barriers include:

• Economic factors, such as transportation or child care costs;

• Language factors, especially illiteracy and lack of English proficiency;

• Negative cultural attitudes about clinical studies;

• Distrust and fear of being test subjects for new treatments; and

• Limited access to routine and preventative healthcare.

Opportunities to Improve Representation¹¹

Although barriers persist, there are opportunities to improve, including:

• Design clinical trials that include healthcare needs specific to ethnically diverse populations;

• Work with ethnically diverse physicians to recruit patients;

• Ensure clinical trials involve ethnically diverse investigators;



• Develop and support community outreach programs;

- Utilize community-based focus groups
- Utilize appropriate educational information translated into native language(s)
- Distribute materials about the prevalence of certain diseases, available prevention programs, and access to clinical trials

• Work with existing programs, such as the National Medical Association's Project I.M.P.A.C.T., the W. Montague Cobb/NMA Health Institute, and the National Hispanic Medical Association.

Conclusion

Lack of diversity in a clinical trial may negatively impact a healthcare professional's ability to ensure the applicability of certain reported outcomes to an individual patient, especially with respect to the risk-benefit calculus. Additionally, in some instances, funding and even drug approval may be withheld if clinical trials are not sufficiently diverse or if data regarding diversity is not properly collected and reported. Ensuring diversity in clinical trials cannot be left to chance. Just as chess is a game of strategy, so are developing and conducting sufficiently diverse clinical trials. To avoid the pitfalls, you must employ long-range planning to place trials at a tactical advantage when it comes to ensuring diversity. In sum, you must ensure there are no missing pieces.

¹ Su Yasuda, L. Zhang, and S-M Huang, "The Role of Ethnicity in Variability in Response to Drugs: Focus on Clinical Pharmacology Studies," *Clinical Pharmacology & Therapeutics*, Vol: 84, Number: 3 (September 2008) at 417.

² Id.

³ *Id.* at 422.

⁴ Guidance for Industry: Collection of Race and Ethnicity

Data in Clinical Trials, Food and Drug Administration, September 2005, 2 n.6. (Referenced in subsequent notes herein as "Guidance.")

⁵ With respect to medical devices, as opposed to drugs, the 2005 Guidance notes that "[a]lthough the regulations governing medical devices do not include requirements for the collection of demographic data comparable to those for INDs and NDAs, for those cases in which race and ethnicity data are relevant to determining the safety and effectiveness of a device, FDA encourages sponsors to collect the data [...]." Guidance at 2.

⁶21 CFR 314.50 (d)(5)(v) and (vi)(a).

⁷ Id.

⁸ Guidance at 3.

⁹Guidance at 5.

¹⁰ See, e.g., Virk, Karen P., "The Missing Minorities," Good Clinical Practice Journal at 16 (November 2008).

¹¹ See, e.g., id.; see also, www.impact.nmanet.org.



Written by Adam Spicer

Pre-service removal of a state court lawsuit has been a valuable tool in the arsenal of defendants across the country. Virtually every pharmaceutical and medical device manufacturer would rather be in federal court versus state court, the belief being that federal courts offer defendants a more fair forum.

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CHANGES TO THE FEDERAL REMOVAL STATUTES OUESTIONS STILL REMAIN

THE FEDERAL COURTS JURISDICTION AND VENUE CLARIFICATION ACT OF 2011 ("Act") went into effect on January 6, 2012. The stated purpose of the Act was to "bring [...] more clarity to the operation of the Federal jurisdictional statutes and facilitate [...] the identification of the appropriate State or Federal court where actions should be brought."¹ In fact, Title I of the Act is called "Jurisdictional Improvements." For the most part, this is an accurate description, but litigants, and some courts, do not necessarily agree. Despite the changes and Congress' attempt to make "jurisdictional improvements," certain legal theories continue to be hotly contested, particularly pre-service removal and the forum defendant rule. This article is a brief review of how the courts have addressed these issues pre-Act, the implementation of the Act, and a report of two cases that have addressed the issues since implementation of the Act.

Why Remove the Case?

Pre-service removal of a state court lawsuit has been a valuable tool in the arsenal of defendants across the country. Virtually every pharmaceutical and medical device manufacturer would rather be in federal court versus state court, the belief being that federal courts offer defendants a more fair forum. In the pharmaceutical and medical device world, the typical scenario involves a state court action against a manufacturer who is not deemed a citizen of the forum state for diversity jurisdiction purposes, and a local defendant, the plaintiff's prescribing physician, for example, so that diversity of citizenship is destroyed, preventing removal to federal court. In most cases, the plaintiff has no real intention of pursuing a claim against the physician. The goal of naming a local defendant is to prevent the "real" defendant (the manufacturer) from removing the case to federal court, thus keeping the case in the plaintiff attorney's

own backyard. By naming a local defendant, the plaintiffs are attempting to invoke the "forum defendant" rule: "[R]emoval is improper if the defendant is a citizen of the state in which the suit is originally filed."²

Over the years, defendant manufacturers have successfully defeated this tactic by removing such cases to federal court by filing a notice of removal prior to service of the local defendant, relying on the "properly joined and served as defendants" language of 28 U.S.C. § 1441(b).3 "The purpose of the 'joined and served' requirement is to prevent a plaintiff from blocking removal by joining as a defendant a resident party against whom it does not intend to proceed, and whom it does not even serve."4 Plaintiffs have vigorously opposed these removals, claiming that defendants have engaged in gamesmanship and attempted to circumvent the true intent of Congress when it comes to the removal statutes, specifically the forum defendant rule.

Pre-Act Law

Before implementation of the Act, a clear majority of courts interpreting 28 U.S.C. § 1441(b) held that the "properly joined and served as defendants" language of the statute permitted removal where a forum defendant had been named but was not served at the time of removal.⁵

Plaintiffs often countered with "[r]emoval is strongly disfavored by Congress and thus the removal statutes are to be narrowly construed to limit federal court jurisdiction."⁶ The minority view is that allowing a defendant to remove an action before the forum defendant has been served could not be what Congress intended.⁷

Arguments against pre-service removal hinge on whether a plaintiff can successfully convince the court that some exception exists to the plain meaning of the "properly joined and served as defendants" language of § 1441(b) — "Judge, that is not what Congress intended."⁸ Interestingly, even minority courts concurring with *Ethington*'s conclusion concede that an exhaustive review of the legislative history concerning § 1441(b) fails to reveal any specific statement from "Congress [or] the advisory Committee on Revision of the Judicial Code [...] regarding the addition of the 'properly joined and served' language."⁹

Prior to becoming law, the original bill was vetted via a clearinghouse process with prominent legal scholars and stakeholder groups, such as the American Bar Association, Lawyers for Legal Justice, the Federal Bar Association, the American Association for Justice, and the U.S. Chamber of Commerce.¹⁰ The impetus for the Act was judicial concern that the then current rules forced courts "to waste time determining jurisdictional issues at the expense of adjudicating underlying litigation."11 Legal scholars developed and endorsed the rule changes "to identify and delete those provisions that were considered controversial by prominent legal experts and advocacy groups."12 As the Senate committee report noted, "[t]wo of these scholars are the authors of removal chapters in, respectively, Moore's Federal Practice and Wright and Miller's Federal Practice and Procedure [...]."13

Both of those treatises promote a literal reading of Section 1441(b) to allow removal where the forum defendant has not yet been served. Wright and Miller states: "[T]he language in Section 1441(b) [...] implies that a diverse but resident defendant who has not been served may be ignored in determining removability" and that "if the diverse resident defendant is served with process after the case has been removed, neither he nor any other party would have a valid objection to the removal based on his residence [...]."¹⁴ Moore's treatise states:

Removal is permissible only if none of the parties in interest properly joined and served as defendants is a citizen of the state in which the action is filed. [Footnote omitted.] Thus, even if complete diversity exists, removal is precluded if a local defendant is served; after service, even nonresident defendants may not seek removal.¹⁵

The Act

The recent enactment of the Federal Courts Jurisdiction and Venue Clarification Act of 2011, H.R. 394, P.L. 112-6316 has rejuvenated the forum defendant rule and pre-service removal debate. The Act made several changes to the removal statutes, some substantive and some not, and also left in place certain language important to the pre-service removal procedure. Despite the conflicting jurisprudence surrounding pre-service removal and the forum defendant rule, and the substantive amendments to other aspects of the removal statute, Congress left the "properly joined and served as defendants" language of 28 U.S.C. § 1441(b) unchanged when it amended the Act. By leaving the controversial language unchanged, particularly in the context of an overhaul of the code sections relating to removal, Congress made a clear statement that it meant what it said (and continues to say) in the plain language of 1441(b).

So, how have courts reacted since the Act went into effect? Has the Act accomplished its stated purpose of providing more "clarity" to the operation of federal jurisdictional statutes? Here is a look at some recent opinions that have addressed these issues.

CASES DECIDED POST-ACT Regal Stone Ltd. v. Long's Drug Stores Cal. L.L.C.

*Regal Stone*¹⁷ is a curious case and not one that will likely be seen often, but does provide an interesting twist to the "properly joined and served" language of § 1441(b). The case arises from a well-publicized incident in which a 900-foot-long container ship struck the San Francisco-Oakland Bay Bridge while under the command of a registered bay pilot. Plaintiffs' theory of recovery is that the defendants negligently provided prescription medications to the bay pilot, thus causing the bridge collision.

Plaintiffs' original suit was filed in California state court on January 31, 2011, and an amended complaint was filed on March 9, 2011. Both the original complaint and the first amended complaint were filed under a motion to seal because the bay pilot operating the vessel at the time of the collision claimed a protected privacy interest in medical information. The publicly available version of the complaint was heavily redacted due to the protected privacy interest so there was very little information available to the defendants. On September 7, 2011, the plaintiffs filed another amended complaint, also under seal.

From the filing of the original complaint to the filing of the second amended complaint, hearings on the motion to seal were set by the state court, but never occurred due to continuances by the court sua sponte or at the request of plaintiffs. Important to the court's analysis is that the plaintiffs never attempted to serve any of the defendants because they were waiting for the court to rule on the motion to seal and issue guidelines on how to treat the bay pilot's medical information. On September 13, more than seven months after the case began, one of the defendants removed the case to federal court. Plaintiffs quickly thereafter moved for remand.

The court first provided a basic tutorial in removal practice, analyzed the "pro-removal" decisions and the "pro-remand" decisions across the circuits and discussed at length the "properly joined and served as defendants" language of the Act. The court ultimately identified the issue as: *May a defendant remove to federal court when a forum defendant has been properly joined but not served?*

One of the named defendants was a citizen of California (i.e., a forum defendant), but as of the date of removal, no defendant had been served. Plaintiffs argued that 28 U.S.C. § 1446 made removal improper, because it required that the notice of removal had to be filed within thirty days of receipt by the defendants through service or otherwise.¹⁸

It is undisputed that all defendants had received a copy of the initial pleading and that removal did not occur within thirty days of receipt. Thus, the plaintiffs argued, this language created: 1) a thirty-day window within which removal would have been proper; 2) the removal window opened before service; and 3) removal before service Before implementation of the Act, a clear majority of courts interpreting 28 U.S.C. § 1441(b) held that the "properly joined and served as defendants" language of the statute permitted removal where a forum defendant had been named but was not served at the time of removal.





was premature. The defendants countered with § 1441(b) and the "properly joined and served as defendants" language.

The court briefly reviewed the split among the courts on this issue — pro-removal and pro-remand — and noted that the courts have assumed that the removal statutes are *clear and unambiguous*.¹⁹ The court then addressed the Act and how both sides pointed out that the Act did not change the language of § 1441(b) or § 1446.²⁰ In urging the court to remand the case, the plaintiffs emphasized the use of the mandatory "shall" in combination with the prepositions "within" and "after," thus triggering a 30-day removal period. The plaintiffs argued that this language confirms Congress' intent for service to trigger a thirty-day removal period within which removal may be proper.²¹ The court rejected the plaintiff's argument, holding that the plaintiff's proposed reading would "improperly discard pivotal parts of the statute as mere surplusage" and denied plaintiff's motion to remand, holding that the "properly joined and served" language of § 1441(b) trumped § 1446.²²

Judge Conti also took the opportunity to provide commentary on the legislative history of the Act. In explaining his ruling, he notes that when Congress amended the removal statutes, "it simply did not have the issue of premature removal in mind."²³ The Judge went on to say:

As much as the Court may wish that Congress had taken the [Act] as an opportunity to speak clearly and affirmatively on this point, Congress did not do so, and it is well-settled that where Congress amends part of a statute and leaves another part unchanged, a court must interpret Congress' inaction as satisfaction with the unamended portion, *or at least tolerance of its inadequacies*. (Emphasis added.)²⁴

Boyer v. Wyeth Pharm., Inc.²⁵

In this products liability case, the plaintiffs filed their complaint on February 9, 2012, in the Court of Common Pleas of Philadelphia County against Wyeth Pharmaceuticals, Inc. ("Wyeth"), and Pfizer, Inc. ("Pfizer"). On February 13, 2012, and prior to service of any defendant, Pfizer removed the case to federal court, citing diversity jurisdiction. Plaintiffs moved for remand on the grounds that the forum defendant rule precludes removal based on diversity jurisdiction where a defendant, here, Wyeth, is a citizen of the state in which the action was filed.

The plaintiffs are citizens of Ohio; Pfizer is organized under the laws of Delaware with a principal place of business in New York. Wyeth is organized under the laws of Delaware with a principal place of business in Pennsylvania. The plaintiffs complained in their remand papers that the forum defendant rule precluded removal because Wyeth was a citizen of Pennsylvania. They also argued that the removal statutes are to be strictly construed against removal and "all doubts should be resolved in favor of remand."26 The defendants countered that the language of the forum defendant rule, read in conjunction with § 1441(b), is plain and unambiguous — the forum defendant rule applies only where a forum defendant has already been "properly joined and served."27

So here we have removal by a non-forum defendant where a forum defendant has not yet been served and both parties arguing that strict construction of the removal statutes favors their respective positions. What did the court decide?

The court analyzed a series of opinions within its district recognizing the propriety of removal by a non-forum defendant where a forum defendant has not yet been served and that pre-service of removal has been recognized. Ultimately, in a brief analysis, the court adopted the defendants' interpretation of the removal statutes and held that the preservice removal by a non-forum defendant where the forum defendant had not been served "[...]was proper under the unambiguous language of § 1441(b)." Interestingly, however, the court never mentioned the Act and relied solely on cases interpreting the removal statutes prior to the amendments.

Conclusion

The stated purpose of the Act was to "bring [...] more *clarity* to the operation of the Federal jurisdictional statutes and *facilitate* [...] the identification of the appropriate State or Federal court where actions should be brought." Has the stated purpose been fulfilled?

As the United States Supreme Court has "repeatedly held, the authoritative statement is the statutory text, not the legislative history or any other extrinsic material."²⁸ If Congress intends a different result than that required by the plain language, "it is up to Congress rather than the courts to fix it."²⁹ Congress had full opportunity to amend the statute to change its plain language, but declined to do so.

² Allen v. GlaxoSmithKline PLC, 2008 WL 2247067, at *2 (citations omitted).

³ For pre-service removal by defendants, the operative language is found at 28 U.S.C. § 1441(b), which states: "Any civil action of which the district courts have original jurisdiction founded on a claim or right arising under the Constitution, treaties, or laws of the United States shall be removable without regard to the citizenship or residence of the parties. Any other such action shall be removable only if none of the parties in interest *properly joined and served* as defendants is a citizen of the State in which such action is brought." (Emphasis added.)

⁴ Stan Winston Creatures, Inc. v. Toys "R" Us, Inc., 314 F.Supp.2d 177, 181 (S.D.N.Y. 2003).

⁵ See, e.g., North v. Precision Airmotive Corp., 600 F.Supp. 2d 1263 (M.D. Fla. 2009)(stating that the "majority of courts" have concluded that a non-forum defendant may remove despite the fact that plaintiff has joined, but not yet served, a forum defendant.); Taylor v. Cottrell, Inc., No. 4:09CV536, 2009 WL 1657427 (E.D. Mo. June 10, 2009); Ott v. Consol. Freightways Corp. of Del., 213 F.Supp.2d 662, 665 (S.D. Miss. 2002) (observing that despite some disagreement, "courts have held, virtually uniformly, that where, as here, diversity does exist between the parties, an unserved resident defendant may be ignored in determining removability under 28 U.S.C. § 1441(b)"); Vitatoe v. Mylan Pharms., Inc., 2008 WL 3540462, (N.D.W.Va. Aug.13, 2008) (denying the motion to remand because plaintiff's "construction of § 1441(b) would require this Court to ignore the 'and served' language of the statute"); Stan Winston Creatures, Inc. v. Toys "R" Us, Inc., 314 F.Supp.2d 177, 181 (S.D.N.Y. 2003); Maple Leaf Bakery v. Raychem Corp., 1999 WL 1101326, *1 (N.D.Ill. 1999) ("The plain language of Section 1441(b) indicates that an action may be removed unless a properly joined and served defendant is a resident of State in which the action was initiated"); Wensil v. E.I. Dupont De Nemour & Co., 792 F.Supp. 447, 449 (D. S.C. 1992) ("The statute is clear. The presence of unserved resident defendants does not defeat removal where complete diversity exists"); Republic Western Ins. Co. v. Intern'l Ins. Co., 765 F.Supp. 628, 629 (N.D. Cal. 1991) (holding in a case where complete diversity of citizenship existed that "a resident defendant who has not been served may be ignored in determining removability"). McCall v. Scott, 239 F.3d 808, 813 n.2 (6th Cir. 2001).

⁶ Ethington v. General Elec. Co., 575 F.Supp.2d 855, 860 (N.D. Ohio 2008) (citations omitted).

⁷ DeAngelo-Shuayto v. Organon USA, Inc., 2007 WL 436531 (holding that the plain language interpretation of § 1441(b) leads to the untenable result that forum defendants can remove actions from state court as long as they do so before they are served); *Ethington*, 575 E.Supp.2d at 861, citing *DeAngelo-Shuayto*, *supra*; *Brown v. Organon Int'l*, *Inc.* 2008 WL 2833294 at *4 (D.N.J. 2008) (explaining that "[r]eading the statute literally would give rise to the absurd 'untenable'" results as articulated in *DeAngelo-Shuayto*.")

⁸ Ethington v. Gen. Elec. Co., 575 F.Supp.2d 855, 861 (N.D. Ohio 2008) (rejecting the plain language of the statute, surmising that Congress could not have intended the result dictated by the actual words in the statute). See also, NFC Acquisition, LLC v. Comerica Bank, 640 F.Supp. 2d 964 (N.D. Ohio 2009).

⁹ Sullivan v. Novartis Pharm. Corp. 575 F.Supp.2d 640 (D. N.J. 2008).

¹⁰ H.R. 112-10, at 2-3.

¹¹ Id. at 1-2.

¹⁴ 14B Charles Alan Wright & Marthur R. Miller, Federal Practice & Procedure § 3723 (4th ed. 2011).

¹⁵ 16 Moore's Federal Practice § 107.14[2][e] (3d ed. 2011) (emphasis added).

¹⁶ The Act went into effect on January 6, 2012, and applies to cases commenced in federal court on or after January 6, 2012, and cases removed from state court that had been commenced on or after January 6, 2012.

¹⁷ Regal Stone Ltd. v. Long's Drug Stores Cal. L.L.C., 2012
 WL 685756 (N.D. CA. 2012).

¹⁸ Id. at *4.

¹⁹ Id.

²⁰ The court noted that the Act did not apply because the case was filed prior to enactment, but that it was still relevant as it purports to clarify the removal statutes and provides evidence of prior Congressional intent.

²³ Id. at *4, citing H.R. Rep. No. 112-10, at 11-16 (omitting mention of district court split).

²⁵ Boyer v. Wyeth Pharm., Inc., 2012 WL1449246 (E.D.Pa, 2012).

²⁶ Id. at *1, citing Boyer v. Snap-On Tool Corp., 913
F.Supp.2d 108, 111 (3d Cir. 1990).

²⁷ *Id.* at *2.

²⁸ Exxon Mobil Corp. v. Allapattah Servs., Inc., 545 U.S. 546, 568 (2005).

²⁹ *Id.* at 565.



WRITTEN by CHIP MORROW

¹ H.R. 112-10, at 1.

¹² Id. at 2.

¹³ Id.

²¹ Id.

²² Id.

²⁴ Id.

PRODUCT LIABILITY STATUTES OF REPOSE

LAW

WHETHER FOCUSING ON BILLABLE HOURS, calculating pleading deadlines, or complying with a court's scheduling order, every lawyer understands the importance of time (or the lack thereof) in the practice of law. Litigators especially appreciate the frustrations and importance of time running out, i.e., the expiration of time in which to designate an expert or to file a complaint. A statute of repose is yet another timekeeper, and depending on the applicable state, it may save a product liability defendant (and defense lawyer) some time and litigation expense.

WHAT IS A STATUTE OF REPOSE?

A statute of limitations is based on a period of time between the date of a plaintiff's injury and the date upon which the plaintiff can assert a cause of action. Similar to a statute of limitations but distinctive from it, a statute of repose is defined as a statute that bars any suit brought later than a specified time after the defendant acted (i.e., by designing or manufacturing a product).¹ In the context of products liability cases, a statute of repose extinguishes the right to sue not based on the date of injury, but on the date of sale of the product at issue. The purpose of a statute of repose is to limit a manufacturer's liability at some definite point in time so much so that a plaintiff literally may not have any cause of action.² A claim may be barred even before the product at issue allegedly causes any harm or injury.

The Statute of Repose at Work

In *Lackey v. DePuy Orthopaedics, Inc.*, plaintiff had a prosthetic hip implanted on January 19, 1998.³ The plaintiff eventually experienced complications and had a total hip revision in June 2009 to address the defective hip prosthetic.⁴ Thereafter, the plaintiff filed a lawsuit against the manufacturer of the prosthetic hip.⁵ Although the plaintiff asserted causes of action for breach of implied warranty, breach of express warranty, and negligent infliction of injury, the defendant manufacturer argued that plaintiff's claims were tantamount to products liability claims.⁶ The defendant also argued that the then-enacted six-year statute of repose barred plaintiff's claims against it.⁷ The plaintiff argued that North Carolina's modified twelve-year statute of repose applied.⁸ The court, however, found that the six-year statute of repose applied to plaintiff's claims based on plaintiff's January 1998 purchase and the enactment and effective dates of the six-year statute of repose.⁹ As such, the plaintiff's right to sue the defendant manufacturer expired in January 2004.¹⁰ Finding the statute of repose an "insurmountable bar to any recovery," the court dismissed plaintiff's claims.¹¹

In *Campbell v. Coca-Cola Enterprises, Inc.*, a man was electrocuted while servicing a vending machine on August 26, 2009.¹² The man died, and his widow sued the vending machine manufacturer for multiple causes of action to include negligence and strict products liability.¹³ The manufacturer moved for summary judgment on the grounds that it shipped the vending machine at issue on March 30, 1998, to the initial user or consumer, and the ten-year statute of repose in Illinois barred the plaintiff's product liability causes of action against it.¹⁴ Finding that the statute of repose expired on March 30, 2008, which was over a year before the incident at issue, the court granted summary judgment and dismissed the plaintiff's product liability claims with prejudice.¹⁵

In *Salgado v. Great Dane Trailers*, plaintiffs filed suit against the manufacturer of a trailer in which plaintiffs' decedents became trapped and died.¹⁶ Plaintiffs'

2010 complaint asserted several causes of action against the trailer manufacturer to include strict liability, negligence, and breach of express and implied warranties.¹⁷ The defendant manufacturer, however, moved for summary judgment on the grounds that the Texas product liability statute of repose barred plaintiffs' claims as the defendant had manufactured and sold the trailer at issue over fifteen years prior to plaintiffs' complaint.¹⁸ As the defendant manufacturer had sold the trailer at issue on July 15, 1997, plaintiffs were required to bring any claims against it by July 15, 2007.¹⁹ The court granted summary judgment and found that the statute of repose barred plaintiffs' product liability claims because plaintiffs filed their action eighteen years after the trailer was first sold.²⁰

STATES WITH PRODUCT LIABILITY STATUTES OF REPOSE

The following states have a statute of repose applicable to product liability claims:

Colorado: Colo. Rev. Stat. § 13-80-107

- Applies to actions against manufacturers, sellers, or lessors of new manufacturing equipment.
- While there are exceptions, the statute of repose bars actions arising more than seven (7) years after the manufacturing equipment is first used for its intended purpose.

CONNECTICUT: Conn. Gen. Stat. § 52-577a

- Applies to actions based on product liability claims brought after October 1, 1979.
- While there are exceptions, the statute of repose bars any action later than ten (10) years from the date when a party last parted with possession or control of the product at issue.

FLORIDA: Fla. Stat. § 95.031(2)(b)

- Applies to actions for products liability.
- While there are exceptions, the statute of repose bars actions for harm caused by any product with an expected useful life of ten (10) years or less if the harm was caused by use of the product more than twelve (12) years after delivery of the product to its first purchaser.
- For aircraft, vessels, railroad equipment, elevators, and escalators, the statute of repose bars product liability actions more than twenty (20) years after delivery of the product to its first purchaser.

GEORGIA: Ga. Code § 51-1-11(b)(2)

- Applies to actions against manufacturers for negligence.
- While there are exceptions, the statute of repose bars actions after ten (10) years from the date of the first sale for use or consumption of the product at issue.

Iдано: Idaho Code § 6-1403

- Applies to actions for product liability.
- While there are exceptions, the statute of repose raises a presumption in cases where the harm was caused more than ten (10) years after delivery of the product at issue. The presumption may be rebutted only by clear and convincing evidence.

ILLINOIS: 735 Ill. Comp. Stat. 5/13-213.

- Applies to product liability actions after January 1, 1979.
- While there are exceptions, the statute of repose bars strict liability actions twelve (12) years from the date of first sale or delivery by a seller or ten (10) years from the date of sale or delivery to its initial user or consumer, whichever period expires earlier.

INDIANA: Ind. Code § 34-20-3-1

- Applies to negligence and strict liability in tort actions.
- While there are exceptions, the statute of repose bars actions ten (10) years after delivery of the product at issue to the initial user or consumer.

Iowa: Iowa Code § 614.1(2)(A)(a)

- Applies to products liability actions.
- While there are exceptions, the statute of repose bars actions fifteen (15) years after a product was first purchased or installed for use or consumption.

Kansas: Kan. Stat. § 60-3303

- Applies to actions for products liability.
- While there are exceptions, the statute of repose raises a presumption in cases where the harm was caused more than ten (10) years after delivery. The presumption can be rebutted by clear and convincing evidence only.

Кентиску: Ку. Rev. Stat. § 411.310

- Applies to actions for product liability.
- While there are exceptions, the statute of repose raises a presumption in cases where the harm occurred more than five (5) years after the sale to the first consumer or more than eight (8) years after the date of manufacture. The presumption can be rebutted by a preponderance of the evidence.

NEBRASKA: Neb. Rev. Stat. § 25-224

- Applies to actions for product liability.
- While there are exceptions, the statute of repose bars actions ten (10) years after the product was first sold for use or consumption if manufactured in Nebraska.
- For products manufactured outside of Nebraska, the statute of repose bars actions based on the applicable statute of repose of the state where the product was manufactured but in no event less than ten (10) years.

North Carolina: N.C. Gen. Stat. § 1-46.1

- Applies to actions for product liability.
- Applies to actions that occur on or after October 1, 2009.
- While there are exceptions, the statute of repose bars actions twelve (12) years after the date of initial purchase.

North Dakota: N.D. Cent. Code § 28-01.4-04

- Applies to aviation product liability actions.
- While there are exceptions, the statute of repose raises a presumption in cases where the harm occurred ten (10) years after the date of delivery to the first user. The presumption may be rebutted by clear and convincing evidence.

Оню: Ohio Rev. Code § 2125.02(D)(2)(a)

· Applies to wrongful death actions for product liability.

• While there are exceptions, the statute of repose bars wrongful death causes of actions related to a product liability claim later than ten (10) years from the date the product was delivered to its first purchaser.

OREGON: Or. Rev. Stat. § 30.905

- Applies to actions for product liability.
- While there are exceptions, the statute of repose bars actions ten (10) years after the date the product was first purchased.
- Where the product was manufactured in a state with a statute of repose, the applicable state's statute of repose applies.

TENNESSEE: Tenn. Code § 29-28-103

- Applies to actions for product liability.
- While there are exceptions, the statute of repose bars actions ten (10) years from the date the product was first purchased or within one (1) year after the expiration of the expected life of the product, whichever is shorter.

TEXAS: Tex. Civ. Prac. & Rem. Code § 16.012

- Applies to actions for product liability.
- While there are exceptions, the statute of repose bars actions fifteen (15) years from the date of sale of the product.

WASHINGTON: Wash. Rev. Code § 7.72.060

- Applies to actions for product liability.
- While there are exceptions, the statute of repose raises a presumption in cases where the harm occurred more than twelve (12) years after the time of delivery. The presumption may be rebutted by a preponderance of the evidence.

¹ Bl	lack's I	Law	Dictionary.	1451	(8th	Ed.	2004)	
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² Lackey v. DePuy Orthopaedics, Inc., No. 5:10-cv-00030-RLV-DSC, 2011 WL 2791264, at *2 (W.D.N.C. July 14, 2011)(original citations omitted).

³ No. 5:10-cv-00030-RLV-DSC, 2011 WL 2791264, at *1 (W.D.N.C. July 14, 2011).
 ⁴ Id.

- ⁵ Id.
- ⁶ *Id.* at *2.
- ⁷ Id.
- ⁸ Id.

⁹ *Id.* at *3.

¹⁰ Id. ¹¹ Id.

¹² No. 11 C 1674, 2012 WL 1158746, at *1 (N.D.Ill. April 4, 2012).

¹³ *Id.* at *2.

- ¹⁴ *Id.* at *3. ¹⁵ *Id.*
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¹⁶ No. V-10-82, 2012 WL 401484, at *1 (S.D.Tex. Feb. 6, 2012).

¹⁷ Id. ¹⁸ Id.

¹⁹ Id. at *3.

²⁰ Id.



WRITTEN by META M. COOPER



ONNUMERION ONNUMERION SPUBLIC RELATIONS FIRM: PRIVILEGED ON NOT?

A COMPANY EXECUTIVE wakes up one morning and routinely checks his email on his smartphone. Fresh in the inbox is a news report containing complaints about his company's products. Almost out of habit, the executive clicks "forward," sending the negative news story to his lawyer and his public relations (PR) firm with the note "This looks bad, let's get going on damage control." Before he's even had time to finish his morning coffee, this executive may have just created Exhibit A in future litigation.

When a legal crisis hits, a corporate executive's first call should be exclusively to his company lawyer. In the era of the 24-hour news cycle and instant communication, though, the first call is often to a PR consultant. Where attorneys and PR firms merely work for the same client, however, communications between the PR firm and attorneys may not be protected by the attorney-client privilege. The privilege may be available if either: 1) the PR firm is an independent contractor hired by the law firm to assist it in the provision of legal services; or 2) the PR firm is the functional equivalent of an employee of the client. Additionally, the usual elements of the privilege must all be met. In the alternative, even where the attorney-client privilege does not apply, work product immunity may shield documents prepared in anticipation of litigation.

Courts have been cautious about an unwarranted blurring of the lines between legal and PR consultation in extending the attorney-client privilege. As one court succinctly put it, "[a] media campaign is not a litigation strategy."¹ Accordingly, companies and their legal representatives should be careful in their communications with attorneys and PR firms where confidentiality is of the essence.

The Oldest Privilege in Our Law

The attorney-client privilege is the oldest privilege in American common law jurisprudence.² As recognized by the United States Supreme Court, the purpose of the privilege Even if a document is not subject to attorney-client privilege, it still may be shielded from discovery if it qualifies for work-product immunity. The attorney-client privilege and work-product immunity are often confused. The two are distinct bars to discovery, with different tests for the application of each. Even if not found protected by attorney-client privilege, documents concerning communications between an attorney and a PR firm may be found protected by the work-product doctrine.

"is to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice."³ On the other hand, courts recognize the tension between the goals served by the privilege and the truth-seeking function of the judicial system.⁴

Though there are minor variations according to each state's laws, the privilege generally requires that the communications be: 1) between a client or potential client and attorney or their representatives; 2) made confidentially; and 3) for the purpose of facilitating the rendition of professional legal services.⁵ Substance trumps labels: Simply copying an attorney on a communication or marking it "attorney-client privileged" will not be sufficient to make the communication privileged, but rather the elements must be met. Likewise, a party cannot conceal facts otherwise subject to discovery merely by revealing them to its lawyer.⁶

How to Classify the PR Firm

In many cases, the first step for deciding whether communication with a PR firm can be privileged is to classify the role of the PR firm. There are generally two categories of PR entities for which the courts have said the attorney-client privilege might apply: 1) If the PR firm is acting as a contractor assisting the attorney; or 2) If the PR consultant is the functional equivalent of an employee of the company hiring the attorney. Once it is determined that attorney-client privilege is *possible* because of the role of the PR consultant or firm, the general test for attorney-client privilege articulated above must be met.

The PR Firm as a Contractor to the Attorney

As a general matter, attorney-client privilege extends not just to communication with the attorney but to representatives employed to assist the attorney in the provision of legal services such as paralegals, law clerks, or legal secretaries.⁷

Merely because an outside contractor assists an attorney, however, does not necessarily mean such communications will be privileged. The Second Circuit Court of Appeals, for instance, has refused to extend privilege to communications between corporate in-house counsel and an outside tax advisor, which is analogous to a PR firm.8 The court found the purposes of the privilege were not served in that instance, noting that "the privilege protects communications between a client and an attorney, not communications that prove important to an attorney's legal advice to a client."9 Thus, it is not enough that the assistance of another party is merely helpful to the attorney; that party must be necessary to the provision of legal assistance.

How can a PR firm ever be necessary to the provision of legal assistance? In this regard, the PR firm as a contractor to the attorney may have only extremely limited applicability. One case where this approach was successfully applied was *In re Grand Jury Subpoenas*.¹⁰ There, the Southern District of New York applied the attorney-client privilege to communications with a PR firm hired by a law firm to consult regarding the

case of "Target." The court never revealed the Target's name in the opinion, but later rulings showed her to be Martha Stewart. The case is unique because the attorneys made the legal decision that the unbalanced press coverage was detrimental to their client's legal position because of a "clear risk that the prosecutors and regulators conducting the various investigations would feel public pressure to bring some kind of charge."11 The court concluded that the attorney-client privilege would apply, although observing that "Target would not have enjoyed any privilege for her own communications with [the PR firm] if she had hired Firm directly, even if her object in doing so had been purely to affect her legal affectation."12 In the context of the firm's use of the PR firm, though, the court concluded the attorneys were assisting in performing "some of their most fundamental client functions."13 Thus, the court found the PR firm to be assisting in the provision of legal services.

The PR Firm as an Employee of the Company

More often, courts focus more on the role of the PR firm in relation to the client. The Eighth Circuit Court of Appeals has held that attorney-client privilege can be extended to third parties where the third parties are the "functional equivalent" of employees.¹⁴

In its *Bieter* decision, the Eighth Circuit considered an independent contractor who had a long-time relationship with a partnership, worked in the partnership's office, consulted for a monthly fee, and acted as the partnership's representative in various

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 When a legal crisis hits, a corporate executive's first call should be exclusively to his company lawyer. In the era of the 24-hour news cycle and instant communication, though, the first call is often to a PR consultant. Where attorneys and PR firms merely work for the same client, however, communications between the PR firm and attorneys may not be protected by the attorney-client privilege.

contexts. The court held there was "no principled basis to distinguish [the contractor's] role from that of an employee, and his involvement in the subject of the litigation makes him precisely the sort of person with whom a lawyer would wish to confer confidentially in order to understand [the partnership's] reasons for seeking representation [...]. As we understand the record, he was in all relevant respects the functional equivalent of an employee."¹⁵

Numerous courts have followed this "functional equivalent" approach.¹⁶ A recent decision on the subject, A.H. v. Evenflo Co., applied the functional equivalent test and found communications between an attorney and a PR firm protected by the attorneyclient privilege.¹⁷ There, the company had retained a public relations firm to provide public relations consultation relating to a product recall. The PR firm collaborated with the company's counsel to prepare a communications plan regarding the recall, including drafting correspondence to the National Highway Traffic Safety Administration, a press release, and other communications to the general public. The PR firm received input from the company's employees and counsel regarding the drafting of the communications.

Relying on a decision from the Southern District of New York, the court identified three factors that would tend to show that the consultant is the functional equivalent of an employee:

1) whether the consultant had primary responsibility for a key corporate job;

2) whether there was a continuous and

close working relationship between the consultant and the company's principals on matters critical to the company's position in litigation; and

3) whether the consultant is likely to possess information possessed by no one else at the company.¹⁸

The court held that "confidential communications between a party's counsel and a non-testifying expert or consultant, hired in anticipation of litigation, are protected by the attorney-client privilege."19 The court further noted that the company in question did not have an internal public relations department and that the Colorado Supreme Court had cited with approval a New York case where an outside PR firm was found to be the "functional equivalent" of an inhouse public relations department.²⁰ The court reviewed the documents in question and concluded they were "predominantly legal" in nature and that the PR firm consultants were essentially acting as company employees.21

The Role of Work Product Immunity

Even if a document is not subject to attorney-client privilege, it still may be shielded from discovery if it qualifies for work-product immunity. The attorney-client privilege and work-product immunity are often confused. The two are distinct bars to discovery, with different tests for the application of each. Even if not found protected by attorney-client privilege, documents concerning communications between an attorney and a PR firm may be found protected by the work-product doctrine. Work-product immunity provides protection for "documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative."²² The work-product doctrine is "distinct from and broader than the attorney-client privilege."²³ "While the attorney-client privilege protects only confidential communications, the work product doctrine generally protects from disclosure documents prepared by or for an attorney in anticipation of litigation."²⁴ The anticipation of litigation must be a reasonable one and generally requires a specific, identifiable claim or threat of litigation.²⁵

This doctrine, however, does not provide the same level of protection as the attorneyclient privilege. Work product evidence is discoverable "upon a showing that the party seeking discovery has substantial need of the materials [....] and that the party is unable without undue hardship to obtain the substantial equivalent of the materials by other means."²⁶

Several courts have found work-product immunity to apply to PR communications not protected by the attorney-client privilege. In *Calvin Klein Trademark*, the court declined to apply attorney-client privilege but nevertheless found some of the publicist-draft documents qualified as work product.²⁷ The court cautioned, however, that the scope of the immunity would not extend outside the conduct of the litigation "because the purpose of the rule is to provide a zone of privacy for strategizing about the conduct of litigation itself, not for strategizing about the effects of the litigation on the client's customers, the media, In many cases, the first step for deciding whether communication with a PR firm can be privileged is to classify the role of the PR firm. There are generally two categories of PR entities for which the courts have said the attorney-client privilege might apply: 1) If the PR firm is acting as a contractor assisting the attorney; or 2) If the PR consultant is the functional equivalent of an employee of the company hiring the attorney.

or on the public generally."28 In the Vioxx multidistrict litigation, the court did not address attorney-client privilege because it found an investigative report made by a PR consultant to be protected work product.29 The court noted that "[w]hile the Martin Report may also have been motivated by business purposes such as creating positive media coverage, any potentially alternative motivation cannot be considered primary in light of the prospective Vioxx litigation."30 Rather, the "primary motivating purpose" of Martin's investigation was to "aid in possible future litigation."31 Yet, in Amway Corp v. The Procter & Gamble Co., the court sustained privilege claims for only a handful of public relations-related documents.32 It concluded the remainder were not protected because "on their face [the rejected documents] reflect intense public relations activity," and though they sometimes discussed pending or anticipated litigation, "the context of the comments is related to public relations, not legal matters."33

Conclusion

The attorney-client privilege is endangered when the lines are blurred between PR work and legal work. Accordingly, clients should carefully delineate the scope of communications between the attorneys they hire and the PR firms they hire. Attorneys must recognize that just because they are attorneys does not mean that their advice is always protected: If attorneys appear to be providing non-legal advice on PR strategy, the attorney-client privilege protection may not apply.

So before clicking forward to the PR firm,

that company executive should slow down, finish that cup of coffee, and think about the unintended potential consequences of careless communication. The attorney, PR consultant, and executive may all be on the same team, but communications between each member may not always be privileged.

¹ *Haugh v. Schroder Inv. Mgmt. N. Am., Inc.*, No. 02-civ-7955 2003 U.S. Dist. LEXIS 14586, 9-10 (S.D.N.Y. Aug. 25, 2003) (holding documents protected by work product privilege but not attorney-client privilege and observing that "[s]ome attorneys may feel it is desirable at times to conduct a media campaign, but that decision does not transform their coordination of a campaign into legal advice."

² Upjohn Co. v. United States, 449 U.S. 383, 389 (1981).
 ³ Id.

⁴ United States v. BDO Seidman, LLP, 492 F.3d 806, 815 (7th Cir. 2007) (citing United States v. Frederick, 182 F.3d 496, 500 (7th Cir. 1999)). Because "[t]he cost of these benefits is the withholding of relevant information from the courts," BDO Seidman, 492 F.3d at 815, the Seventh Circuit has stressed that "the privilege is in derogation of the search for the truth and, therefore, must be strictly confined." In re Grand Jury Proceedings, 220 F.3d 568, 571 (7th Cir. 2000); see also Univ. of Pa. v. EEOC, 493 U.S. 182, 189 (1990) (expressing reluctance, because testimonial and evidentiary privileges impede the search for truth, to recognize a testimonial or evidentiary privilege "unless it 'promotes sufficiently important interests to outweigh the need for probative evidence...") (quoting Trammel v. United States, 445 U.S. 40, 51 (1980)).

⁵ 3-503 Weinstein's Federal Evidence § 503.10. In a federal court civil case based on diversity of jurisdiction, state law will govern the applicability of the privilege. Fed. R. Evid. 501.

⁶ See Upjohn Co., 449 U.S. at 395-396.

⁷ 3-503 Weinstein's Federal Evidence § 503.12.

⁸ United States v. Ackert, 169 F.3d 136, 139 (2d Cir, 1999).

⁹ Id. (citing Fisher v. United States, 425 U.S. 391, 403 (1976)).

¹⁰ 265 F. Supp. 2d 321 (S.D.N.Y. 2003).

¹⁵ *Id.* at 938.

¹⁶ *In re Copper Market Antitrust Litig*, 200 F.R.D. 213, 218-19 (S.D.N.Y. 2001) (public relations consultant who consulted with the company's counsel regarding a pending investigation was the functional equivalent of an employee pursuant to federal common law).

¹⁷ *A.H. v. Evenflo Co.*, No. 10-cv-02435, 2012 U.S. Dist. LEXIS 76100 (D. Colo. May 31, 2012) (citing *Horton v. United States*, 204 F.R.D. 670, 672 (D. Colo. 2002), which required a "detailed factual showing" that the third party is the "functional equivalent" of an employee).

¹⁸ Id. (quoting Export-Import Bank v. Asia Pulp & Paper Co., Ltd., 232 F.R.D. 103, 113 (S.D.N.Y. 2005)) (citing LG Electronics U.S.A., Inc. v. Whirlpool Corp., 661 F. Supp. 2d 958, 962 (N.D. Ill. 2009) (adopting the functional equivalent test).

¹⁹ Evenflo, (citing W. Res. v. Union Pac. R.R. Co., 00-20430CM, 2002 U.S. Dist. LEXIS 1911, 2002 WL 181494, at *7 (D. Kan. Jan. 31, 2002); Fru-Con Constr. Corp. v. Sacramento Mun. Utility Dist., S-05-0583 LKK GGH, 2006 U.S. Dist. LEXIS 59066, 2006 WL 2255538 (E.D. Cal. Aug. 7, 2006); In re Grand Jury Subpoenas, 179 ESupp.2d 270, 283 (S.D.N.Y. 2001)).

²⁰ Id. (citing Alliance Constr. Solutions, Inc., 54 P.3d at 868-869).

²¹ Id.

²² Fed. R. Civ. P. 26(b)(3).

²³ United States v. Nobles, 422 U.S. 225, 238, 95 S. Ct. 2160, 45 L. Ed. 2d 141 (1975).

²⁴ Reg'l Airport Auth. of Louisville v. LFG, LLC, 460 F.3d 697, 713 (6th Cir. 2006).

²⁵ Schmidt, Long & Assocs. v. Aetna U.S. Healthcare, Inc., Civ. A. No. 00-CV-3683, 2001 U.S. Dist. LEXIS 7145, at *13 (E.D. Pa. May 31, 2001).

²⁶ Fed R. Civ. P. 26(b)(3).

²⁷ Calvin Klein Trademark Trust v. Wachner et al., 198
 F.R.D. 53, 55 (S.D.N.Y. 2000).

²⁸ Id.

²⁹ In re Viox Prods. Liab. Litig., MDL No. 1657, 2007
 U.S. Dist. LEXIS 23164, *11 n.3 (E.D. La. Mar. 5, 2007).
 ³⁰ Id.

³² 2001 U.S. Dist. LEXIS 4561 at *21 (W.D. Mich. Apr. 3, 2001).

³³ Id.



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¹¹ *Id.* at 323 (quoting witness affidavit).

¹² Id. at 331.

¹³ Id. at 330.

¹⁴ In re Bieter Co., 16 F.3d 929, 930 (8th Cir. 1994).

³¹ Id.

PHARMACEUTICAL, MEDICAL DEVICE & HEALTHCARE GROUP



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