The Mounting Attacks on Company-Sponsored Science, Speech, and Experts

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Exercise of First Amendment Rights of Free Speech, Association, and Petitioning the Government Should Not Be a Basis of Civil Liability in a Products Liability Case

I. Introduction

Plaintiffs frequently sue corporate product liability defendants alleging causes of action for strict liability, negligence, negligent misrepresentation, fraud, and breach of warranties. In addition, plaintiffs often plead conspiracy claims, alleging that defendants either in concert with one another or with other third-parties committed an unlawful act or used unlawful means to commit a lawful act. One type of evidence plaintiffs use to support such allegations are defendants' lawful attempts to present, directly or through an industry trade association, their views of the scientific and medical evidence to various governmental agencies or regulatory/advisory bodies. Plaintiffs are often critical of any industry's involvement in scientific studies, insinuating and even stating overtly (without any proof) that industry "buys" scientists to say what they want.[1] In such instances, plaintiffs use their *litigation* disagreement with defendants' interpretation of the science to claim defendants were attempting to "improperly influence" such entities before litigation was instituted. Recent illustrations include allegations made by plaintiffs in the talc-based body powder ovarian cancer litigation and in the lawsuits alleging Roundup (glyphosate) caused or contributed to Non-Hodgkins lymphoma.

In the talc cases, for example, plaintiffs' counsel argued to one jury:

> Remember talking about the NTP [the federal government's National Toxicology Program]? There are only two groups that can make [defendants] do anything, it's the NTP and the FDA. Rigged them both. They want -- they rig them both and they come in here and say they did nothing. That must be a nice, it must be nice to say that. Unbelievable.
> . . . .
> I want to go to the jury verdict form. Because like I told you, only you 12 people, my good jurors, can do this. Nobody else can. They rigged the NTP, they rigged the FDA. I don't know what they're going to do next unless y'all do something about it.

[1] This phenomenon is also not limited to litigation. There is a general "distrust" of industry involvement in science that is only highlighted and amplified by the current trend of litigation. It is unfortunate that industry may develop the perception that it cannot feasibly be involved in scientific research, due to criticism, especially considering reports indicate that industry provides nearly 2/3 of all research funding in the United States. *Academic Bias Against Industry is Toxic Hypocrisy*, American Counsel of Science and Health, 11/5/2019 ("According to *R&D Magazine*, in 2019, industry paid for $375.8 billion of the $581 billion spent on research and development in the United States. If industry research were to disappear, America's dominance in science and technology would evaporate along with it.")

Similarly, in glyphosate litigation, plaintiffs claimed in the closing arguments of the *Pilliod* trial that the EPA is "not working for the public; this is an agency that's working for Monsanto." In the *Johnson* trial, plaintiffs' counsel argued that "EPA "ha[s] a dog in the fight," and asked "Why does Monsanto get special treatment from the EPA? I don't know. ..Maybe there's something more sinister. I don't know. But what I do know is they got it wrong." These arguments were combined with arguments that Monsanto employees participated in "ghostwriting" of scientific studies, despite clear acknowledgements of Monsanto's involvement in them, and that it participated in defense of its product in ways that were portrayed as improper.

This is not a new tactic, but it has been taken to new levels. In the 2015 *Walker* trial against Monsanto in the city of St. Louis, plaintiffs continually insinuated that Monsanto had influenced scientific literature on the health impacts of PCBs, suggesting something akin to fraud:

> The Treon document, [Monsanto] wants you to believe that when Treon tells Monsanto privately in 1955 that seven animals who have been exposed to Aroclor 1242 die and only three of them can he attribute to pneumonia and one of them he can attribute to cancer and the other two, one -- the other one is uncertain and other two are so severely screwed up when they open them up, they can't even do a postmortem autopsy, he wants to tell you that all that information made its way into that public report that said seven of these, they died from pneumonia, because that's what it says.
>
> Now, can I prove to you that Monsanto made him say that? No. Can I prove to you Monsanto knew that wasn't true? Yes. Because they had a private report that said it wasn't true.

Such assertions are not based on defendants' or the third-party trade associations' presentation of *false or inaccurate* data to governmental agencies, but simply their assertion of viewpoints or summaries of the scientific evidence with which plaintiffs in the particular litigation at issue disagree.[2]

II. The Talc Example

In the first case alleging that a woman's use of talc-based body powder in the genital area after bathing caused her ovarian cancer, the federal court granted summary judgment for a defendant. In doing so, the court found that plaintiff produced no evidence that the defendant disseminated false information about talc or otherwise conspired in any way to hide information about talc. *See* July 22, 2013 Order in *Berg v. Johnson & Johnson, et al.*, No. 4:09-cv-04179-KES, at 8-9.[3] The court concluded that plaintiff had offered no support whatsoever for the

[2] For a thorough survey of the issue, see James M. Sabovich, *Petition Without Prejudice: Against the Fraud Exception to Noerr-Pennington Immunity from the Toxic Tort Perspective*, 17 Penn State Environ. L. Rev. 101 (2008)

[3] *Berg v. Johnson & Johnson*, No. 09-4179-KES, 2013 U.S. Dist. LEXIS 41029 (D. S.D. Mar. 25, 2013).

allegation that defendant offered "fraudulent medical and scientific data, literature, or test reports that distorted the dangers of talc. . . . . Because Berg failed to produce any facts in support of her civil conspiracy claim, the court finds that Berg failed to show that a genuine issue for trial exists on that claim."

The allegedly wrongful activities that formed the basis of plaintiffs' civil conspiracy allegation were defendant's membership in the industry trade association and that association's participation in the federal regulatory process, which plaintiffs characterized as defendants' use of "influence over governmental and regulatory bodies regarding talc." In particular, the NTP prepares and periodically updates a congressionally-mandated *Report on Carcinogens* ("the Report") that lists substances "which either are known to be human carcinogens or may reasonably be anticipated to be human carcinogens." NTP Call for Public Comments, 65 Fed. Reg. 17,889 (Apr. 5, 2000). "Throughout the review process," the NTP provides "multiple opportunities for public input," including during an open public meeting. *Id.* The NTP also provides notice of proposed additions to the Report in the Federal Register, including an opportunity for the public to submit comments. *Id.* at 17,890. In reviewing nominations of substances for potential inclusion in the Report, the NTP evaluates "all available data and public comments." *Id.* at 17,889.

In the early 2000s, talc defendants' trade association communicated with the NTP regarding the inclusion of talc in the NTP's Report by submitting detailed and documented opinions of a number of retained scientists on the issue of talc and cancer. This was done in response to the NTP's specific request for public input and discussion. In the talc lawsuits, plaintiffs' pleadings set forth no wrongful agreement, unlawful action, or tortious activity on the part of defendants; no submission of false or fraudulent data; or any other specific evidence the defendants conspired to distort the science or prevent warnings on body powders. As a result, plaintiffs had no proof that the defendants in that litigation engaged in any illegal activity of any kind that would support a civil conspiracy claim. Plaintiffs simply implied that the information the trade association submitted to the NTP was false. Yet they failed to explain how this was so, other than making the conclusory allegation that the trade association (on behalf of defendants) somehow lied when it argued that there was no valid medical or scientific link between the perineal use of talc and ovarian cancer. In fact, *substantial scientific evidence* supported the trade association's and its experts' representation of the state of the science on talc and ovarian cancer.

More importantly, however, a disagreement as to the validity of scientific studies cannot be an "unlawful act" upon which a conspiracy claim may be based.[4] Allowing such a claim would halt free speech in its tracks, stifle industrial investment in science and innovation, and penalize those who seek input and express a view about scientific and health issues under consideration by governmental bodies *if there is any disagreement on the subject*. Such result would run directly counter to the express public policy objective of the NTP and other federal agencies to promote and encourage transparency and as full public comment and participation as possible on governmental regulatory activities. Such scientific discussion and exchange of ideas

[4] In *Berg*, the plaintiff conceded that defendants' opposition to talc being listed as a carcinogen "was because they felt that labeling talc as a carcinogen was incorrect based on the sound science." *Berg*, 2013 U.S. Dist. LEXIS 41029, at *19. This concession, of course, was grounded on the same evidence plaintiff sought to present to the jury in support of her theory of the case.

plainly is protected under the First Amendment's guarantees of freedom of speech, freedom of association, and freedom to petition the government. As such, these activities cannot be unlawful and cannot form the basis for liability.

III. Constitutional Freedoms Implicated in Products Liability Litigation

A. Freedom of Speech

As a fundamental matter, a defendant's participation in the scientific discussion and debate over the safety of a product is constitutionally-protected. *See C.B.C. Distrib. & Mktg. v. Major League Baseball Advanced Media, L.P.*, 443 F. Supp. 2d 1077, 1092-93 (E.D. Mo. 2006) (holding dissemination of factual information and historical data protected by the First Amendment), *aff'd* 505 F.3d 818 (8th Cir. 2007); *Senart v. Mobay Chem. Corp.*, 597 F. Supp. 502, 505-06 (D. Minn. 1984) ("*[P]laintiffs assail defendants for taking a particular view in a scientific debate and for trying to retain a regulatory standard which defendants preferred.* Not only do these actions not constitute torts, they are protected by the first amendment") (italics supplied). "[T]he creation and dissemination of information are speech within the meaning of the First Amendment." *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2667 (2011) ("Facts, after all, are the beginning point for much of the speech that is most essential to advance human knowledge and to conduct human affairs").

Given such constitutional protection, a defendant cannot be subject to liability for its role in the dissemination of scientific information to the federal government (especially in response to a governmental agency's specific request for information), the press, or the public. *See id.* at 2665-66 ("an individual's right to speak is implicated when information he or she possesses is subjected to restraints on the way in which the information might be 'used' or disseminated") (quoting *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 32 (1984); *Zink v. Lombardi*, No. 12-04209-CV-C-BP, 2014 U.S. Dist. LEXIS 182689, at *41 (W.D. Mo. May 2, 2014) (noting that "an individual's right to speak is implicated when information he or she possesses is subjected to restraints on the way in which the information might be used or disseminated") (quoting *Sorrell*, 131 S. Ct. at 2665-66).

B. Freedom of Association

Further, participation in a trade association that petitions the government is protected by the First Amendment's right to freedom of association, which "restricts the ability of the State to impose liability on an individual solely because of his association with another." *N.A.A.C.P. v. Claiborne Hardware Co.*, 458 U.S. 886, 918-19 (1982); *Anderson v. Waddle*, No. 4:06CV919 HEA, 2008 U.S. Dist. LEXIS 80763, at *25 (E.D. Mo. Oct. 10, 2008) ("we have long understood as implicit in the right to engage in activities protected by the First Amendment a corresponding right to association with others in pursuit of a wide variety of political, social, economic, educational, religious, and cultural ends.") (citations omitted), *aff'd in part and appeal dismissed in part, Heartland Acad. Cmty. Church v. Waddle*, 595 F.3d 798 (8th Cir. 2010). "Joining organizations that participate in public debate, making contributions to them, and attending their meetings are activities that enjoy substantial First Amendment protection." *In re Asbestos Sch. Litig.*, 46 F.3d 1284, 1294 (3d Cir.1994) (citing *Citizens Against Rent Control/Coal. for Fair Hous. v. City of Berkeley*, 454 U.S. 290,294-96 (1981)); *Buckley v. Valeo*, 424 U.S. 1, 14-25 (1976); *N.A.A.C.P. v. Alabama*, 357 U.S. 449, 466 (1958)).

C. Freedom to Petition the Government

Finally, participation in the regulatory process is protected by the First Amendment's freedom to petition the government. As the Supreme Court has made clear, "the First Amendment protects the right of corporations to petition legislative and administrative bodies." *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 355 (2010) (quoting *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 778 n. 31 (1978)); *see also In re IBP Confidential Bus. Documents Litig.*, 797 F.2d 632, 640 (8th Cir. 1986) (recognizing that "petitioning, 'like other guarantees of first amendment . . . is an assurance of a particular freedom of expression'") (quoting *McDonald v. Smith*, 105 S. Ct. 2787, 2789 (1985)).

The fundamental right to petition the government also protects the right of corporations to advocate points of view that promote their economic interests in combination with other corporations who have similar interests. *See Cal. Motor Transp. Co. v. Trucking Unlimited.*, 404 U.S. 508, 510-11 (1972) ("We conclude that it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests vis-à-vis their competitors.") (applying *E. R.R. Presidents Conference v. Noerr Motor Freight Inc.*, 365 U.S. 127 (1961) and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965), collectively known as the "Noerr-Pennington" doctrine). In *Noerr*, an antitrust case, the plaintiff truckers alleged that defendant railroad companies, their trade association, and their public relations firm had conspired by jointly conducting a publicity campaign to influence the Pennsylvania legislature and governor. Plaintiffs alleged the railroad defendants' campaign was "designed to foster the adoption and retention of laws and law enforcement practices destructive of the trucking business, to create an atmosphere of distaste for the truckers among the general public, and to impair the relationships existing between the truckers and their customers." The Supreme Court held such constitutional "lobbying" activities could not be a basis for liability under the Sherman Act. *See also Tuosto v. Philip Morris USA, Inc., No. 05 Civ. 9384 (PKL), 2007 U.S. Dist. LEXIS 61669, at *[13-16] (S.D.N.Y. Aug. 21, 2007)* (applying *Noerr-Pennington* to plaintiff's fraud claim in a product liability case); *Gorman Towers, Inc. v. Bogoslavsky*, 626 F.2d 607, 615 (8th Cir. 1980) (noting the *Noerr-Pennington* doctrine's application beyond the antitrust context).

Hamilton v. Accu-Tek, 935 F. Supp. 1307 (E.D.N.Y. 1996) is instructive. Plaintiffs sued firearms manufacturers for personal injuries and cited lobbying activities by their trade associations as grounds for liability. The court found such conduct was protected by the First Amendment and could not be a basis for tort liability:

> The First Amendment guarantees "the right of the people . . . to petition the Government for a redress of grievances." *U.S. Const. Amend. I.* Under what is known as the *Noerr-Pennington* doctrine, many actions under various antitrust or tort theories against businesses or individuals are prohibited where the challenged activity involves lobbying, despite the defendant's anticompetitive or otherwise injurious purpose or effect [citing *Noerr* and *Pennington*]. The doctrine developed in large part to protect the First Amendment right to petition government. See *Noerr*. 365 U.S. at 132-33. 81 S. Ct. at 530. see also Daniel R. Fischel, *Antitrust Liability for Attempts to Influence*

> *Government Action: The Basis and Limits of the Noerr-Pennington Doctrine*, 45 U. Chi. L. Rev. 80, 94-104 (1977) (noting that the First Amendment, not construction of the antitrust statute, is the real basis of the doctrine). Shielded activity includes petitioning legislatures, administrative bodies, and the courts. See *California Motor Transport v. Trucking Unlimited*, 404 U.S. 508. 92 S. Ct. 609, 30 L. Ed. 2d 642 (1972).
> . . . .
>
> A core principle of the *Noerr-Pennington* doctrine is that lobbying alone cannot form the basis of liability, although such activity may have some evidentiary value. It is not enough to show that the defendants act in some coordinated fashion as an industry. *See, e.g. Centrone v. Schmidt*, 114 Misc. 2d 840, 452 N.Y.S.2d 299, 302 (Sup. CL Nassau Co. 1982) (concert of action theory not applicable where concerted action not tortious or inherently dangerous). Lobbying before either federal or state authorities was not tortious.

Id. at 1316, 1321. *See also, Lynn v. Amoco Oil Co.*, 459 F. Supp.2d 1175 (D.Al. 2006)

First Amendment protection extends not only to direct communications with the government, but also to "those activities reasonable and normally attendant to effective petitioning." *In re IBP Confidential Bus. Documents Litig.*, 755 F.2d 1300, 1310 (8th Cir. 1985); *see also id*. at 1313 ("courts may not award compensation for the consequences of protected activity" of petitioning one's government). In the talc litigation discussed above, defendants' expression of these rights through their direct activities and those of their trade association should not have been admitted into evidence and they could not support plaintiffs' claims as a matter of law.

In *Senart v. Mobay Chemical Corporation*, 597 F. Supp. 502 (D. Minn. 1984) the court rejected a claim that defendants had engaged in a civil conspiracy because they were members of a trade organization that opposed a safety proposal by the National Institute for Occupational Safety and Health ("NIOSH") that would have imposed stricter safety standards on their industry. 597 F. Supp. at 505. The court found that defendant's actions in opposing the NIOSH proposal, while admittedly undertaken for economic reasons, were "clearly permissible as first amendment rights to petition the government" and did not support a claim for civil conspiracy. *Id.* at 505-06 ("selfish motivations do not lessen one's right to present views to the government"); *see also Radigan v. Bristol Labs., a Div. of Bristol Myers Co.*, No. E87-0034(L), 1989 U.S. Dist. LEXIS 17767, at *2 (S.D. Miss. Feb. 13, 1989) (holding that a drug manufacturer's "lobbying activities do not constitute actionable torts and, in fact, are protected by the first amendment").[5]

D. Plaintiffs Typically Cannot Establish a Causal Link Between Defendants' Exercise of Speech, Association, and Petitioning Rights and Any Harm Allegedly Suffered

To maintain a claim for civil conspiracy, a plaintiff also must establish by clear and convincing evidence that his damages were proximately caused by the conspiracy. *Koehler v.*

[5] State Anti-SLAPP statutes may also provide protection for lobbying and other statements by products liability defendants. *See, e.g., DuPont Merck Pharm. Co. v. Superior Court*, 78 Cal. App. 4th 562, 92 Cal. Rptr. 2d 755 (2000).

Warren Skinner, Inc., 804 S.W.2d 780, 782 (Mo. App. 1990). Plaintiffs often do not allege, and the evidence rarely shows, that a defendant's exercise of its speech, associational, and petitioning rights had any causal effect that resulted in harm to them. For example, in the talc litigation, there was no evidence that defendants' speech to and petitioning of the NTP, which was only a fraction of the public input the NTP received, were the impetus for the agency's decision to decline the listing of talc in its *Report on Carcinogens*. In fact, the record there reflected that *more than twenty different organizations and individuals* submitted comments to the NTP whether talc should be included in the Report. One such organization was the U.S. Department of the Interior, which questioned whether the NTP had an adequate scientific basis to list talc as carcinogenic.[6] In fact, under plaintiffs' expansive view, each of the commenters who petitioned the NTP not to include talc in its *Report on Carcinogens* would be subject to liability for conspiracy because they agreed with the defendants' and their trade association's perspective that talc is not carcinogenic and shared their views with the NTP.

Moreover, plaintiffs' claims on this basis were suspect because there was no evidence that any actions on the part of defendants with regard to the NTP's review of talc were the proximate cause *of the underlying tort they alleged* – the sale of talc-based body powders to consumers without a warning. While plaintiffs argued that defendants conspired to submit false information to the NTP, they did not demonstrate that any of the information submitted was false or inaccurate or that the products would have contained a warning even if NTP had decided to list talc in the *Report on Carcinogens*.

[6] These comments were formerly available on the NTP's website. Public Comments re: Talc in 10th Report on Carcinogens, *available at* http://ntp.niehs.nih.gov/pubhealth/roc/publiccomms/allcomments/index-1999.html#talc (last accessed August 4, 2016); Public Comments re: Talc in 12th Report on Carcinogens, *available at* http://ntp.niehs.nih.gov/?objectid=20A477F2-F1F6-975E-7472FC6B0DA56D9C#talc (last accessed August 24, 2016). The NTP now states that "Supplemental materials for events, meetings, and workshops prior to 2016 have been archived. These archived materials frequently include presentations, background materials, and public comments. Email us or use our contact form to request a list or copy of archived materials for the following meeting." All Past Events, *available at* *https://ntp.niehs.nih.gov/events/past/index.html* (last accessed November 27, 2019).

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Tips for Evaluating "Ghostwriting" Allegations

Webster defines the term ghostwriting as writing "(a speech, a book, etc.) for another who is the presumed or credited author." To no one's surprise, lawyers are consummate ghostwriters when they draft testimony in the form of affidavits for lay and expert witnesses to sign and adopt under oath. No one thinks twice about that (1) because non-lawyers typically have no idea of the proper form in which their testimony should appear in an affidavit, and (2) the key concept is that the accuracy and truth of the testimony is vouched for in full by the person signing the affidavit – not by the person drafting it.

Plaintiffs typically avoid the questions of whether the information in an allegedly ghostwritten article is accurate and represents the viewpoints of the author or authors. Instead, they attempt to introduce such evidence as further indication that companies were acting covertly and from bad motive in some nebulous effort "to influence the medical literature." Courts have varied in their views of the admissibility of such ghostwriting evidence, but some have recognized it for the red herring it typically is. For example, the federal judge presiding over the estrogen-progestin hormone replacement therapy (HRT) multi-district breast cancer litigation discussed a typical ghostwriting allegation and noted that:

> In closing argument, Plaintiff asserted that ghostwriting is "exactly the type of conduct that necessitates punitive damages." However, there is no evidence that this practice is inappropriate or that [defendant] supported articles that it knew were false or misrepresented the science. Rather, the articles supported [defendant's] position on the state of the science. Additionally, there was evidence that ghostwriting was a common practice in the industry. In fact, Dr. Parisian conceded that she had done ghostwriting on behalf of Johnson & Johnson.
>
> Regardless of the bad inference Plaintiff placed on ghostwriting, it is apparently the norm in the industry, and without evidence that [defendant] lied or misrepresented the science it chose to support, this evidence does not establish malicious behavior that would permit punitive damages. Additionally, this testimony was introduced through Dr. Parisian, but has no link to FDA regulations -- Dr. Parisian's area of expertise. And, if the inference of reckless disregard is raised, *it is very weak*. There is not enough to support submission to the jury taken alone or considered with all the other admissible evidence.

In re Prempro Products Liability Litigation, 554 F. Supp.2d 871 at 897 (E.D. Ark. 2008) (footnotes omitted) (italics added).[7]

Such evidence has formed the basis of the pending appeal of the *Johnson* glyphosate

[7] An excellent round up of cases in which courts downplayed the significance of ghostwriting is James M. Beck, "Ghostwriters in Disguise, Drug & Device Law (March 18, 2019), available at https://www.druganddevicelawblog.com/2019/03/ghostwriters-in-disguise.html (last accessed on December 1, 2019).

punitive damages award, from the brief of Monsanto (citations removed for ease of reading):

> More fundamentally, and once again, all of these purportedly despicable actions could give rise to a finding of malice only if Monsanto had *actual knowledge* that its herbicides caused cancer, and ignored that knowledge. Plaintiff cannot establish that Monsanto acted despicably simply because it advocated its firmly-held and well-supported belief that its products were safe—a view confirmed by the overwhelming consensus of worldwide international agencies at the time plaintiff was exposed to Monsanto's products, and reaffirmed by numerous scientific and regulatory bodies even after the IARC Monograph was published. Indeed, Monsanto had a constitutional right to advocate its position to regulatory bodies. Under the *Noerr-Pennington* doctrine, which is derived from the First Amendment, civil liability may not rest on advocacy or lobbying efforts conducted before governmental bodies. The punitive damages award cannot rest on Monsanto's lawful and legitimate interactions with the EPA.
>
> Even taking the individual allegations of purported despicable conduct at face value, they do not establish a basis for a finding of malice. As the trial court noted in its tentative ruling, the allegation that "Monsanto tried to 'pollute' the scientific literature by 'ghostwriting' articles" is belied by the fact that in both the Williams (2000) and Kier & Kirkland (2013) articles cited by Plaintiff, *"Monsanto's employees are listed as contributors to those articles and there is no evidence those articles contain material scientific misstatements*."

` Twelve questions defense practitioners should ask when evaluating a claim of "ghostwriting" are set forth below. (In this context, "writer" means alleged "ghostwriter"; "sponsor" means entity for whom the article was written; "named author(s)" means those individuals whose name appears on the byline on of the article):

1. Is there any evidence that statements in the article in question *are untruthful or inaccurate*?

2. Does the article *accurately represent the views* of the named author(s)?

3. What were the disclosure guidelines of the particular journal *at the time the article was published?* (Note that many journals have guidelines that have been implemented or evolved over time.)

4. Was the *specific article at issue* even contracted for by the defendant?

5. Was the article *only one of a number of articles* written by the author(s) on the subject, thus indicating they have expertise in the field beyond to article(s) at issue?

6. Did the alleged writer *discuss the content of the article with the authors before or while* "putting pen to paper"?

7. Did the defendant company's employees *merely review the article for its technical and scientific accuracy* (e.g., appropriate description of the chemical formula of defendant's

product or proper description of defendant's company-sponsored clinical studies)?

8. Did the alleged writer have *significant intellectual input into the content of the article*, or merely provide organizational, grammatical, or reference citation assistance?

9. Did those at the defendant company who retained any right of review of the article *make or require any substantive changes*?

10. Did the named author(s) of the article *review and adopt the final version* of the article?

11. Did the article *have any effect or cause any demonstrable behavior* on the part of the reader (such as a prescribing physician)?

12. Has the named author *been transparent regarding funding for the studies, funding for the article, and input from others* (including any industry parties)?

Interestingly, a blog poster editorializing on the *Scientific American* website has noted a problem in medical writing that is diametrically opposed to the ghostwriting issue – the issue of "guest authorship." The editorial defines "guest author" as "someone whose name appears in a scientific paper's author line *even though she has not made a contribution* that is enough (under whatever set of standards one recognizes for proper authorship) to qualify her as an author of the paper" (italics added). In this situation, the blog poster (and others she cites) note that senior scientists whose role in a published research article is only that they headed the laboratories where the research was performed often will be listed as named authors. The proliferation of such named authors on papers serves to obscure those who made real intellectual contributions to the reported research.[8]

Spurious "ghostwriting" claims are often made by plaintiffs' counsel because the claim sounds superficially bad – a company had some level of involvement, no matter how minimal, in a published article – but was not acknowledged at a level deemed appropriate by that plaintiffs' counsel. Defense counsel must confront such allegations head on and based on the particular circumstances be prepared to show that, in the Immortal Bard's words, those claims are "much ado about . . . nothing."

[8] See Janet Stemwedel, "Scientific authorship: guests, courtesy, contributions, and harms," Scientific American (Nov. 11, 2011) available at https://blogs.scientificamerican.com/doing-good-science/scientific-authorship-guests-courtesy-contributions-and-harms/ (last accessed December 1, 2019).