**F I L E D**
**United States Court of Appeals**
**Tenth Circuit**

**August 21, 2007**

**Elisabeth A. Shumaker**
**Clerk of Court**

PUBLISH

**UNITED STATES COURT OF APPEALS**

**TENTH CIRCUIT**

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TMJ IMPLANTS, INC., a Colorado corporation,

Plaintiff - Appellant,

v.

AETNA, INC., a Pennsylvania corporation; CIGNA; CONNECTICUT GENERAL CORPORATION, a Florida corporation; CONNECTICUT GENERAL LIFE INSURANCE COMPANY, a Connecticut corporation; CIGNA DENTAL HEALTH, INC., a Florida corporation; CIGNA HEALTH CORPORATION, a Delaware corporation; HEALTHSOURCE, INC., a New Hampshire corporation; CIGNA DENTAL HEALTH OF COLORADO, INC., a Colorado corporation; CIGNA HEALTHCARE OF COLORADO, INC., a Colorado corporation,

Defendants - Appellees.

No. 06-1020
No. 06-1146

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**APPEAL FROM THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLORADO**
**(D.C. NO. 05-cv-783 LTB-CBS)**

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Reid, Gerash Law Firm, Denver, Colorado, with him on the brief), for Plaintiff - Appellant

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Before **HARTZ**, **SEYMOUR**, and **O'BRIEN**, Circuit Judges.

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**HARTZ**, Circuit Judge.

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This appeal concerns a suit by plaintiff TMJ Implants, Inc. (TMJI) against defendants Aetna, Inc. and CIGNA[1] for defamation and related torts. TMJI is a Colorado corporation that manufactures prosthetic total- and partial-temporomandibular-joint (TMJ) implants for use in patients suffering from TMJ disorders. Aetna and CIGNA provide health and dental insurance under various benefit plans. Both companies produce bulletins explaining what treatments and procedures they cover. In its bulletin describing coverage for treatment of TMJ

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[1]The amended complaint filed in the district court named eight CIGNA defendants: CIGNA Corporation; Connecticut General Corporation; CIGNA Dental Health, Inc.; CIGNA Dental Health of Colorado, Inc.; CIGNA Health Corporation; Healthsource, Inc.; CIGNA Healthcare of Colorado, Inc.; and Connecticut General Life Insurance Company. The amended complaint refers to these defendants collectively as CIGNA, and they have filed one brief as the CIGNA appellees. We also refer to them collectively as CIGNA.

disorders, Aetna states that it will not cover either the total or partial TMJ implants manufactured by TMJI. In a similar bulletin CIGNA states that it will not cover TMJI's partial-joint device. TMJI contends that the coverage bulletins defamed and disparaged its products, tortiously interfered with prospective business advantage, and tortiously interfered with existing and prospective contracts.

TMJI filed suit in Denver County District Court, but Aetna and CIGNA removed the case to the United States District Court for the District of Colorado, *see* 28 U.S.C. § 1441(a) (removal statute); *id*. § 1332 (diversity jurisdiction). Aetna and CIGNA then moved under Fed. R. Civ. P. 12(b)(6) to dismiss the complaint for failure to state a claim. The district court granted the motions on the ground that the bulletins were protected statements of opinion. TMJI appeals. We have jurisdiction under 28 U.S.C. § 1291 and affirm.

## I. BACKGROUND

We summarize the allegations of the amended complaint: Approximately 30 million Americans suffer from TMJ disorders, which can cause jaw pain and inhibit normal jaw function. Dr. Robert Christensen developed prosthetic TMJ implants to replace parts of the mandible that had been surgically removed. After refining and obtaining patents on his devices, he established TMJI to manufacture and market them. The total-joint prosthesis is available in three sizes (for both the right and left sides of the jaw) and can also be custom made; the partial-joint

prosthesis is available in 44 premade sizes (for both sides of the jaw). TMJI is the only manufacturer of a partial-joint prosthesis. Approximately 25,000 of TMJI's devices have been implanted in patients, 40% of which have been partial-joint prostheses. Clinical studies have shown that the partial-joint implants "reduce the need for further significant surgical intervention of a total joint replacement in over 95% of the cases." Aplt. App. at 6 (Amended Complaint). Fewer than 10% of the partial-joint devices implanted in patients have later been removed.

The total and partial prostheses have "been the subject of various peer reviews in peer-reviewed journals." *Id*. at 7. There have also been "two clinical studies conducted by [TMJI] that support the safety and effectiveness of the implants." *Id*. The Food and Drug Administration (FDA) approved both the total and partial implants in 2001. The FDA has approved one other manufacturer, TMJ Concepts, to make custom total-joint prostheses.

Aetna has published, in several editions, Clinical Policy Bulletin (CPB) 28, which describes the limitations on what it will cover for treatment of TMJ disorders. CIGNA also publishes a bulletin, Coverage Position Number (CPN) 156, regarding the limitations on what it will cover for TMJ disorders. Both CPB 28 and CPN 156 are available to the public over the internet. TMJI challenges several statements in Aetna's CPB 28 regarding TMJI's total-joint and partial-joint prostheses. Some statements refer to the prostheses as "experimental" and

"investigational." Others question the adequacy of research supporting their use. TMJI also challenges similar statements in CIGNA's CPN 156 regarding TMJI's partial-joint prosthesis. The amended complaint alleges that these statements about TMJI's products were false and defamatory, disparaged its products by publication of injurious falsehoods, and tortiously interfered with its business advantage and existing and prospective contracts.

Aetna and CIGNA moved to dismiss the amended complaint for failure to state a claim on several grounds, including that the allegedly defamatory statements were not defamatory as a matter of law and were protected statements of opinion. Aetna and CIGNA attached copies of their bulletins to their motions to dismiss, contending that because the bulletins were central to TMJI's amended complaint, the district court should consider them in deciding the motions. TMJI's response asserted the sufficiency of its claims and argued that the court should not consider the version of the bulletin proffered by Aetna because it was an amended version. Three versions of CPB 28 and one version of CPN 156 were attached to the response.

The district court considered the bulletins and granted the motions to dismiss. It held that although it could not say as a matter of law that the bulletins were incapable of defamatory meaning, the statements were not actionable. Following Colorado Supreme Court opinions, it reasoned that Aetna's and CIGNA's statements that TMJI's devices were experimental and investigational

were protected statements of opinion because they were incapable of being proved false and a reasonable person reading the bulletins would conclude that the statements were ones of opinion rather than fact. It further held that the statements were protected under the First Amendment because they were on a matter of public concern and did not imply the allegation of undisclosed defamatory facts. As for the remaining tort claims, the court held that Aetna's and CIGNA's protected statements of opinion were not improper; so neither defendant could be liable for disparagement, tortious interference with business advantage, or tortious interference with contract, each of which requires the commission of an improper act.

TMJI appeals, contending (1) that the district court resolved several factual issues against it despite its duty to view the facts in the light most favorable to the nonmoving party; (2) that CPB 28 and CPN 156 are not protected statements of opinion because the terms *experimental* and *investigational* have sufficiently definite meanings in the medical community to be proved true or false and an average reader would understand the bulletins to be asserting fact; and (3) that Aetna and CIGNA forfeited any privilege accorded their statements of opinion because they were based on an incomplete and inaccurate evaluation of outdated facts, were published to avoid payment of claims rather than to convey a coverage determination, and were published with malice. We reject these arguments, substantially agreeing with the district court's analysis.

## II. DISCUSSION

We review de novo a dismissal of a complaint under Rule 12(b)(6) for failure to state a claim, applying the same standard that the district court should have applied. *See County of Santa Fe, N.M. v. Pub. Serv. Co. of N.M.*, 311 F.3d 1031, 1034 (10th Cir. 2002). We accept as true "all well-pleaded factual allegations in the amended complaint," and view those allegations "in the light most favorable to the nonmoving party." *Id.* (internal quotation marks omitted). Although we ordinarily limit our review to the allegations in the complaint, we consider documents "incorporated into the complaint by reference." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509 (2007). Our review of the bulletins shows that the differences between various editions are immaterial to the following analysis. To give TMJI the benefit of the doubt, however, we have relied on the editions of CPB 28 and CPN 156 that TMJI references in its opening brief on appeal.

Because this case arises under the federal court's diversity jurisdiction, the law governing TMJI's causes of action is the law that would be applied if the case had been brought in Colorado state court. *See Butt v. Bank of Am., N.A.*, 477 F.3d 1171, 1179 (10th Cir. 2007) ("When exercising diversity jurisdiction, we apply state law with the objective of obtaining the result that would be reached in state court."). "Where no controlling state decision exists, the federal court must attempt to predict what the state's highest court would do." *Wade v. Emcasco*

*Ins. Co.,* 483 F.3d 657, 666 (10th Cir. 2007) (internal quotation marks omitted). The parties agree that the applicable substantive law is that of Colorado, although subject to any restrictions on the alleged torts that may be imposed by the United States Constitution. We therefore assume that this case is governed by Colorado substantive law (and, of course, the federal constitution). *See Clark v. State Farm Mut. Auto. Ins. Co.*, 319 F.3d 1234, 1240 (10th Cir. 2003) (applying substantive law of state that parties agree controls).

**A. Issues Disposed of Summarily**

We can briefly dispose of two issues raised by the parties on appeal. TMJI contends that the district court resolved several issues of fact against it and ignored issues of disputed material fact. But because our review is de novo, we need not concern ourselves with any such alleged misstatements or errors by the district court. Second, Aetna appears to contend that TMJI has presented no evidence to support some allegations in its complaint and is not entitled to discovery to elicit such evidence. It points out that TMJI did not ask the district court to convert the motions for dismissal into ones for summary judgment and to delay its decision pending the results of discovery. We reject Aetna's apparent contention because TMJI had no obligation to provide evidentiary support for its allegations, nor did it have an obligation to request that the court convert the motions into ones for summary judgment. When Aetna moved to dismiss the complaint under Rule 12(b)(6), it could not contest the truth of the complaint's

factual allegations. *See County of Santa Fe, N.M.*, 311 F.3d at 1034. Of course, if the allegations are sufficient, so that dismissal is improper, TMJI would then need to prove those allegations. At that stage of the proceeding, discovery would be proper. TMJI's opposition to the Rule 12(b)(6) motion hardly waived or forfeited its right to conduct discovery at a later stage of the litigation.

### B. Defamation Claims

#### 1. Applicable Law

##### a. Sources of Law

Claims for defamation are deeply rooted in the common law. Since *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964), however, courts have had to supplement their common-law analysis with a federal constitutional inquiry to determine whether a claim can survive. Moreover, a number of states, including Colorado, have invoked state constitutions to restrict defamation claims. *See, e.g.*, *NBC Subsidiary (KCNC-TV), Inc. v. Living Will Ctr.*, 879 P.2d 6, 9 (Colo. 1994) ("[t]o decide the issues . . . we must first identify the appropriate standard for evaluating when defamatory statements are constitutionally protected under the First Amendment to the United States Constitution and article II, section 10 of the Colorado Constitution."). When there are multiple sources of applicable law, we must be careful in determining what deference is due to state-court decisions. A federal court must follow the state's highest court in pronouncing or construing the state's common law, statutory law, or constitutional law. But it owes no

deference to state-court interpretation of the United States Constitution. *See Ace Cycle World, Inc. v. Am. Honda Motor Co.*, 788 F.2d 1225, 1228 (7th Cir. 1986). Thus, if we disagree with the state court's view that the federal constitution imposes a particular limitation on defamation claims, we will not impose that limitation. On the other hand, if state law imposes that limitation, we must recognize that limitation even if the federal constitution is not so restrictive. Accordingly, when a state-court decision imposes a limitation on defamation claims, particularly when we doubt whether that limitation is required by the federal constitution, it is important that we determine whether the state court imposed that limitation as a matter of state law or federal constitutional law.

Unfortunately, the task of determining the source of a limitation in a state-court decision can be rather difficult. Because the common law of defamation, federal constitutional law, and the constitutional law of the various states reflect many of the same underlying principles and adopt similar propositions, it is often unclear to what extent a court decision relies on each. We have found this to be true in some of the leading Colorado opinions on defamation. To assist us in determining the source of Colorado court pronouncements, we rely on two observations. First, the Colorado Supreme Court has been willing to recognize limitations on the defamation cause of action that are not required by the federal constitution. In *Walker v. Colorado Springs Sun, Inc.*, 538 P.2d 450, 457 (Colo. 1975), *overruled on other grounds by Diversified Management, Inc. v. Denver*

*Post, Inc.*, 653 P.2d 1103 (Colo. 1982), the court imposed a malice requirement when the allegedly defamatory statement related to a matter of public concern, even though the United States Supreme Court requires malice only when the alleged victim is a public official or public figure. *See Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 342–43 (1974).

Second, the Colorado Supreme Court, both in its opinions[2] and in the

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[2]*See Denver Pub. Co. v. Bueno*, 54 P.3d 893, 899 n.9, 900–01 (Colo. 2002) (citing Restatement (Second) of Torts (1977) (Restatement) § 570 for categories of statements recognized as defamatory as a matter of law and §§ 564 and 652E cmt. b to compare elements of defamation to elements of false light); *In re Green*, 11 P.3d 1078, 1084 (2000) (stating that opinions that imply undisclosed false statements of fact are not protected under the First Amendment and citing Restatement § 566 for support); *Robert C. Ozer, P.C. v. Borquez*, 940 P.2d 371, 379 (Colo. 1997) (referring to Restatement § 652D cmt. a to distinguish the term "publication" used in tort of defamation from the term "publicity" used in tort of invasion of privacy); *Living Will Ctr.*, 879 P.2d at 15 (citing Restatement § 564 for proposition that "allegedly defamatory remark is not actionable if it cannot reasonably be understood as an assertion of actual fact pertaining to the plaintiff" (emphasis omitted)); *Keohane v. Stewart*, 882 P.2d 1293, 1300 n.10 (Colo. 1994) (quoting Restatement § 564 for support of proposition that defamatory statement not referring to plaintiff by name is actionable if listeners reasonably understood statement to be about plaintiff); *Churchey v. Adolph Coors Co.*, 759 P.2d 1336, 1343–45 (Colo. 1988) (construing Restatement § 577 cmt. k regarding self-publication); *Dominguez v. Babcock*, 727 P.2d 362, 364, 365–66 (Colo. 1986) (discussing qualified privilege in Restatement § 596, and loss of privilege under § 600); *Burns v. McGraw-Hill Broad. Co.*, 659 P.2d 1351, 1357–59 (Colo. 1983) (adopting Restatement § 559 and its cmt. e regarding when statement may be defamatory, citing Restatement § 563 regarding determination of defamatory meaning, and relying on Restatement § 566 and its cmt. b regarding protected opinions); *Bucher v. Roberts*, 595 P.2d 239, 241–42 (Colo. 1979) (relying on Restatement § 566 and its cmts. c and e regarding protected opinion).

Uniform Jury Instructions it promulgates, *see* Colorado Jury Instructions, Civil (4th ed. 2007) (copyrighted by Supreme Court of Colorado)[3], has displayed great respect for the formulations of the tort of defamation in the Restatement (Second) of Torts (1977) (Restatement).[4] We therefore think it a safe presumption (though

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[3]*See* Colorado Jury Instructions, Civil, ch. 22.1 (4th ed. 2007) (citing Restatement §§ 558–581 as source and authority for instruction on defamation per se), *id*. Ch. 22.2 (citing Restatement §§ 566 cmt. c and 614 in discussion of libel-per-quod instruction); *id*. Ch. 22.6 (citing Restatement §§ 577 and 578 in discussion of instruction defining *published*); *id.* Ch. 22.7 (basing definition of *defamatory* on Restatement § 559); *id*. Ch. 22.8 (citing Restatement § 564 as source and authority for instruction on about-the-plaintiff element); *id.* Ch 22.9 (citing Restatement § 563 for discussion of instruction on meaning of a statement); *id*. Ch. 22.10A (citing Restatement § 563 cmt. b in support of instruction that statement be considered in context); *id*. Ch. 22.12 (citing Restatement § 575 as source and authority for special-damages instruction); *id*. Ch. 22.13 (citing Restatement §§ 621–623 as source and authority for definition of actual damages); *id*. Ch. 22.14 (citing Restatement § 581A in support of instruction on substantial-truth defense); *id*. Ch. 22.15 (citing Restatement §§ 585–592A in discussion of absolute-privilege defenses); *id*. Ch. 22.16 (citing Restatement §§ 599–605A for instruction on when qualified privilege may be lost); *id*. Ch. 22.17 (citing Restatement § 611 for instruction on privilege for reports of official proceedings); *id*. Ch. 22.18 (citing Restatement § 612 for discussion of privilege for provider of means of publication); *id*. Ch. 22.20 (citing Restatement § 583 for instruction on affirmative defense of consent).

[4]*See also Wilson v. Meyer*, 126 P.3d 276, 279 (Colo. Ct. App. 2005) (citing Restatement § 611 regarding privilege for report of official proceeding); *Gordon v. Boyles*, 99 P.3d 75, 78 (Colo. Ct. App. 2004) (citing Restatement § 568A for statement that "radio broadcast of defamatory matter is defamation by libel"); *Hayes v. Smith*, 832 P.2d 1022, 1024 (Colo. Ct. App. 1991) (discussing slander per se with reference to Restatement §§ 571–574); *Brooks v. Jackson*, 813 P.2d 847, 848 (Colo. Ct. App. 1991) (quoting Restatement § 559's definition of when a communication is defamatory); *Teilhaber Mfg. Co. v. Unarco Materials Storage, a Div. of Unarco Indus., Inc.*, 791 P.2d 1164, 1167 (Colo. Ct. App. 1989) (citing Restatement § 566 regarding when statements of opinion are unprotected in defamation and product-disparagement actions); *Lind v. O'Reilly*, 636 P.2d 1319, (continued...)

not an irrebuttable one) that the Colorado Supreme Court will adopt as part of its common law of defamation the various provisions of the Restatement, even if those provisions may impose restrictions not required by controlling authority from the United States Supreme Court.

**b. Expressions of Opinion**

To state a cause of action for defamation under Colorado law, the plaintiff must allege "(1) a defamatory statement concerning another; (2) published to a third party; (3) with fault amounting to at least negligence on the part of the publisher; and (4) either actionability of the statement irrespective of special damages or the existence of special damages to the plaintiff caused by the publication." *Williams v. Dist. Ct., Second Judicial Dist.*, 866 P.2d 908, 911 n.4 (Colo. 1993). This case turns on the first element.

The specific issue before us is how to distinguish a defamatory statement from a protected expression of opinion. We must consider two sources of law to resolve the issue. One is the Restatement. The Restatement recognizes two types of defamatory communication: (1) statements of fact, *see* Restatement § 565, and (2) expressions of opinion, *see id.* § 566. Of the latter, the Restatement states: "A defamatory communication may consist of a statement in the form of an

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[4](...continued)
1321 (Colo. Ct. App. 1981) (quoting Restatement § 575 cmt. b regarding special damages); *Costa v. Smith*, 601 P.2d 661 (Colo. Ct. App. 1979) (citing Restatement § 583 cmt. d illus. 2 regarding consent as a defense).

opinion, but a statement of this nature is actionable only if it implies the allegation of undisclosed defamatory facts as the basis for the opinion." *Id*. § 566. The other source is the United States Supreme Court's discussion in *Milkovich v. Lorain Journal Co.*, 497 U.S. 1 (1990), of the constitutional protection for expressions of opinion.

In resolving contentions that a statement is a protected expression of opinion, the Colorado Supreme Court has referred to both the Restatement and *Milkovich*. To the extent that it adopts the Restatement as a matter of state common law, we are bound. To the extent that it relies on *Milkovich*, however, we follow the Colorado court's interpretation of the United States Supreme Court's First Amendment jurisprudence only insofar as we agree with that interpretation. Accordingly, it is important that we compare *Milkovich*'s holding to the Restatement's provisions to determine whether the latter provides greater protection than *Milkovich* in the circumstances of this case. If it does, we must predict whether the Colorado Supreme Court would recognize that additional restriction on defamation claims. We begin with an analysis of *Milkovich*.

The *Milkovich* Court rejected the suggestion that it add to previous doctrine "a wholesale defamation exemption for anything that might be labeled 'opinion.'" 497 U.S. at 18. In its view, use of the term *opinion* obscures analysis, and the purposes to be served by such an exemption were already well served by existing

doctrine. Concerning the first point the Court observed that "expressions of 'opinion' may often imply an assertion of objective fact." *Id*. It explained:

> If a speaker says, "In my opinion John Jones is a liar," he implies a knowledge of facts which lead to the conclusion that Jones told an untruth. Even if the speaker states the facts upon which he bases his opinion, if those facts are either incorrect or incomplete, or if his assessment of them is erroneous, the statement may still imply a false assertion of fact. Simply couching such statements in terms of opinion does not dispel these implications; and the statement, "In my opinion Jones is a liar," can cause as much damage to reputation as the statement, "Jones is a liar." As Judge Friendly aptly stated: "[It] would be destructive of the law of libel if a writer could escape liability for accusations of [defamatory conduct] simply by using, explicitly or implicitly, the words 'I think.'" *See Cianci* [*v. New Times Pub. Co.*, 639 F.2d 54, 64 (2d Cir. 1980)]. It is worthy of note that at common law, even the privilege of fair comment did not extend to "a false statement of fact, whether it was expressly stated or implied from an expression of opinion." Restatement (Second) of Torts, § 566, Comment *a* (1977).

*Milkovich* at 18–19. The Court then stated that existing doctrine adequately protected freedom of expression "without the creation of an artificial dichotomy between 'opinion' and fact." *Id*. at 19. In particular, it pointed to precedent providing "that a statement on matters of public concern must be provable as false before there can be liability under state defamation law, at least in situations . . . where a media defendant is involved." *Id*. at 19–20. Accordingly, it continued, "a statement of opinion relating to matters of public concern which does not contain a provably false factual connotation will receive full constitutional protection." *Id*. at 20. The Court further observed that "'rhetorical hyperbole'" is protected by doctrine requiring that allegedly defamatory statements (such as the

characterization of a union dissident as a "traitor") "reasonably be interpreted as stating actual facts." *Id*. (brackets omitted).

We note four differences between § 566 and the Supreme Court's formulation of the constitutional standard in *Milkovich*. First, § 566 requires that the statement (in the form of an opinion) "impl[y] the allegation of undisclosed defamatory facts." In other words, an opinion is not actionable if it is based on defamatory facts that are disclosed. *Milkovich*, in contrast, observes that "[e]ven if the speaker states the facts upon which he bases his opinion, if those facts are either incorrect or incomplete, or if his assessment of them is erroneous, the statement may still imply a false assertion of fact," *id*. at 18–19, thereby suggesting that the opinion is not constitutionally protected. The difference between the two formulations, however, is more apparent than real. As noted in the comments to § 566, although an *opinion* based on disclosed defamatory facts is not itself subject to liability, the disclosure of the defamatory facts on which the opinion rests may still create liability if the facts themselves are false; it is the publication of the defamatory facts, however, rather than the expression of opinion, that is actionable. *See* § 566 cmt. b (when speaker states facts on which opinion is based, "[t]he statement of facts and the expression of opinion . . . are separate matters . . . , and at common law either or both could be defamatory"); *id*. cmt. c illus. 5 ("If the defendant bases his expression of a derogatory opinion . . . on his own statement of false and defamatory facts, he is subject to liability for

the factual statement but not for the expression of opinion."); § 578 (liability of republisher). Thus, Restatement § 566 is no more protective than *Milkovich*, and we need not decide whether the Colorado Supreme Court would impose a limitation on the defamation tort beyond what *Milkovich* requires in this regard.

A second difference between *Milkovich* and § 566 is that *Milkovich* protects statements that are not provably false only if they are "on matters of public concern." 497 U.S. at 19. Section 566 has no such restriction, *see* § 566 cmt. c at 173 ("Although it is . . . possible that [the Supreme Court will treat] private communications on private matters . . . differently, the logic of the constitutional principle would appear to apply to all expressions of opinion of the first, or pure, type."). That difference is not material in this case, however, because the statements by Aetna and CIGNA are undoubtedly on matters of public concern.

In the context of the First Amendment, a matter is of public concern when it is "a subject of legitimate news interest; that is, a subject of general interest and of value and concern to the public at the time of publication." *City of San Diego, Cal. v. Roe*, 543 U.S. 77, 83–84 (2004). "Whether . . . speech addresses a matter of public concern must be determined by [the expression's] content, form, and context . . . as revealed by the whole record." *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 761 (1985) (brackets and ellipses in original, internal quotation marks omitted). Although TMJI contends that the Aetna and CIGNA bulletins were not on matters of public concern, we think this

contention untenable. Indeed, its pleadings below are inconsistent with its present position. The amended complaint states that "The acts of Aetna and/or CIGNA [in publishing the bulletins] . . . denied suffering and injured persons the availability and use of the Christensen partial prosthetic implants and denied the public a necessary medical device . . . and . . . have, therefore, caused and continue[d] to cause great distress, pain, and suffering to the many persons who could benefit from the Christensen partial prosthetic implant." Aplt. App. at 13 (Amended Complaint). It added that "dentists, oral surgeons, dental and medical clinics, and hospitals, and their patients, have relied and continue to rely upon the factual truthfulness and accuracy of the . . . statements made and disseminated by Aetna and/or CIGNA . . . regarding [TMJI]." *Id*. at 12. Even on appeal, TMJI's opening brief recites that approximately 30 million Americans suffer from TMJ disorders and that at least 100,000 patients had received TMJ implants between 1988 and 1998. Twenty-five thousand of its devices have been used by at least 800 hospitals and clinics. Because thousands of people, including those with TMJ disorders, those who have received or are seeking implants, and physicians and dentists treating TMJ-disorder patients, have a legitimate interest in the utility of TMJI's devices, the matter is undoubtedly of public concern. Any distinction between the Restatement and *Milkovich* on this issue is therefore inconsequential here.

The third difference between § 566 and the *Milkovich* formulation is that *Milkovich* states that the not-provably-false test *may* apply only "where a media defendant is involved," 497 U.S. at 19–20, whereas § 566 contains no such requirement. We doubt that Aetna and CIGNA could properly be described as media defendants. In this respect, then, § 566 may well impose a restriction on TMJI's claim not imposed by the federal constitution. Accordingly, we must decide whether the Colorado Supreme Court would extend this protection even if not required to do so by federal constitutional law. We are confident that it would—that is, that it would not confine the reach of the protection of not-provably-false statements to those made by media defendants. Indeed, in a pre-*Milkovich* opinion the Colorado Supreme Court applied § 566 to a private defendant (the plaintiff's supervisor). *See Bucher*, 595 P.2d at 241. And more recently the Colorado Supreme Court discussed *Milkovich's* not-provably-false standard without a mention of the United States Supreme Court's possible media-defendant restriction and affirmed the dismissal of a claim against a defendant who had written letters to the editor without any discussion of whether the author of such letters is a media defendant. *See Keohane*, 882 P.2d 1293.

The fourth and final difference we note between the § 566 and *Milkovich* formulations is in the expression of the ultimate test for whether a statement is actionable. The Restatement asks whether a statement "implies the allegation of [an] undisclosed defamatory fact[]." Restatement § 566. *Milkovich* asks whether

a statement is "provable as false" and is not "rhetorical hyperbole," *Milkovich*, 497 U.S. at 19–20. Again, however, we believe that the tests are essentially identical in application. If no fact is implied by a statement, then there is no way to prove it false. And *Milkovich*'s rhetorical-hyperbole standard is simply a recognition that an expression of opinion that appears to imply an allegation of fact (such as, "X is a traitor") may, in context, be mere hyperbole that a reasonable person would not view as a factual assertion. Apparently the Colorado Supreme Court also views the two formulations as congruent. In two pre-*Milkovich* opinions the court followed § 566 and determined whether an allegedly defamatory statement implied undisclosed defamatory facts. *See Bucher*, 595 P.2d at 241; *Burns*, 659 P.2d at 1358–60. Then in *Keohane*, 882 P.2d 1293, the Colorado Supreme Court stated that the standard in its precedents "was subsequently fortified by *Milkovich*," *id*. at 1297. As it explained:

> *Milkovich* and *Burns* . . . provide the necessary framework to determine if a statement is protected. This framework involves two inquiries. The first inquiry is whether the statement is "sufficiently factual to be susceptible of being proved true or false." *Milkovich*, 497 U.S. at 21. The second inquiry is whether reasonable people would conclude that the assertion is one of fact. *Id*. The factors relevant to the second inquiry are: (1) how the assertion is phrased; (2) the context of the entire statement; and (3) the circumstances surrounding the assertion, including the medium through which the information is disseminated and the audience to whom the statement is directed. *Burns*, 659 P.2d at 1360.

*Keohane*, 882 P.2d at 1299 (footnotes omitted). The second inquiry is necessary only if the first inquiry is answered in the affirmative. *See also id*. at 1300–03;

*Wilson,* 126 P.3d at 280 (citing *Keohane* for proposition that "[c]ourts determine whether a statement is protected as opinion by inquiring first whether the statement is susceptible of being proved true or false. If the answer is yes, courts then inquire whether reasonable persons would conclude that the assertion is one of fact").

In sum, we find little difference between § 566 and the *Milkovich* standard; and to the extent that the differences are relevant in this case, we are confident that Colorado would apply the more restrictive § 566 formulation. We now apply the above analysis to the parties' arguments on appeal.

**2. TMJI's Allegations**

**a. The Terms *Experimental* and *Investigational***

The heart of TMJI's complaint is that Aetna and CIGNA defamed it by calling its products *experimental* and *investigational.* In response to Aetna's and CIGNA's defense that they were only expressing opinions, TMJI argues that within the medical community the terms *experimental* and *investigational* have definite meanings based on "objective criteria," and that statements labeling its devices as experimental and investigational are therefore not mere matters of opinion but are assertions of fact. Aplt. Br. at 13–14. In support of this contention TMJI's appellate briefs discuss three cases and cite several more in a footnote. They also point to some FDA definitions and a definition retrieved through an Aetna website. We are not persuaded.

The first case discussed by TMJI is *Leonhardt v. Holden Business Forms Co.*, 828 F. Supp. 657 (D. Minn. 1993). Plaintiff Penelope Leonhardt had sought coverage for an autologous bone marrow transplant (ABMT) to treat her cancer. The administrator of her group health plan denied the treatment on the grounds that ABMT was "experimental" and "investigational." *Id*. at 662. Ms. Leonhardt sought a preliminary injunction enjoining the administrator from denying coverage because the procedure had to be performed promptly if she was to benefit fully. *See id*.

First, the district court found that the administrator's actions in denying coverage had violated the terms of the plan. Not only did the plan not include an exclusion for investigational procedures, but the administrator had failed to advise Ms. Leonhardt of "what deficiencies her application had to overcome to be successful on appeal," *id*. at 668 (brackets and internal quotation marks omitted), and had improperly denied her (1) the right to submit evidence supporting her position that the treatment was not experimental and (2) the right to challenge the evidence on which the administrator had relied, *see id*. at 669.

The district court then considered what the appropriate remedy should be. Although it acknowledged that it would ordinarily remand to the administrator for reconsideration, it said that to do so in this case "would be inappropriate" because time was of the essence and the administrator's conduct "call[ed] into question its ability to process [Ms.] Leonhardt's claim impartially," *id*. at 670. Therefore, it

analyzed whether Ms. Leonhardt had satisfied the standards for granting a preliminary injunction. In addressing whether she was likely to succeed on the merits of her claim, the court "step[ped] into the shoes of the Plan administrator [and made] a *de novo* determination of whether [Ms.] Leonhardt's proposed ABMT treatment [was] experimental under the Plan definition." *Id*. The court did not, as TMJI's argument would suggest, simply apply the definition of *experimental* purportedly recognized throughout the medical community. Rather, it applied the Plan's definition of *experimental medical procedure* as a procedure that "'is (a) not proven in an objective manner to have therapeutic value or benefit, (b) restricted to use at medical facilities capable of carrying out scientific studies; or (c) of questionable medical effectiveness.'" *Id*. at 670–71 (quoting the Plan). The court found that the definition had not been satisfied because the treatment had achieved partial or complete remission in 80% of patients treated, the treatment was not restricted to medical facilities capable of carrying out scientific studies, and the plaintiff was a good candidate for the treatment.

The court rejected the administrator's proffers intended to show that the treatment was experimental. An affidavit from a Dr. Altman stated that ABMT would be considered experimental "until the medical community is presented with at least two randomized, controlled studies indicating a significant statistical and practical increase in the disease-free survival and overall survival rate for patients undergoing [ABMT] as opposed to patients undergoing standard therapy." *Id*.

(internal quotation marks omitted). The other support for the administrator's position was a report from a medical research information clearinghouse concluding that ABMT treatment for Ms. Leonhardt's type of cancer was experimental. The court did not reject this evidence on the ground that the expert and the report used a definition of *experimental* contrary to accepted usage. Its reason for rejecting the evidence was simply that the *Plan* used a different definition. *See id*. at 671 ("Although this may be Dr. Altman's understanding of the term 'experimental,' it is not the definition articulated in the Plan."). *Leonhardt* thus does not support TMJI's contention that the term *experimental* has a single, universal definition.

The other opinion discussed in TMJI's opening brief is *Bucci v. Blue Cross-Blue Shield of Connecticut, Inc.*, 764 F. Supp. 728 (D. Conn. 1991). The defendant insurer had denied plaintiff's request for coverage of a combination of high-dose chemotherapy (HDCT) and ABMT treatment for her breast cancer. The basis for the insurer's denial was that plaintiff's policy excluded coverage for services "'which are experimental or investigational in nature; meaning any treatment, procedure . . . drugs, drug usage . . . not recognized as accepted medical practice,'" *id*. at 729 (quoting policy, ellipses in original), and that HDCT/ABMT for breast cancer fell into this category. Although the court noted the substantial risks of the treatment and the limited data on its effectiveness, *see id*. at 730–31, it ordered the insurer to cover the treatment. For our purposes, two

components of the court's analysis are salient. First, the court did not define *experimental* or *investigational*, but merely applied the policy's definition of these terms. *See id*. at 729. Second, in construing the term *accepted medical practice* in the policy definition, it apparently felt compelled to minimize the plan administrator's discretion in determining coverage by selecting an objective meaning. *See id*. at 732–33. It appeared to believe that the only possible definition of *accepted medical practice* meeting that standard was that

> a procedure may be found not to constitute accepted medical practice only where there is no reasonably substantial, qualified, responsible, relevant segment of the medical community which accepts the procedure as properly within the range of appropriate medical treatment, under the circumstances of the case, as judged by the standards of the medical community.

*Id*. at 732. Thus, the court was hardly providing what it thought to be a definition of *experimental* or *investigational* generally accepted in the medical community.

The third case discussed by TMJI, *White v. Caterpillar, Inc.*, 765 F. Supp. 1418 (W.D. Mo. 1991), is mentioned only in the reply brief. It, too, provides TMJI no support. In that case the plaintiff sought a preliminary injunction after her insurer denied her request for coverage of HDCT/ABMT treatment. The opinion provides no definition of the term *investigational*, nor does it quote any plan provision using the term. Rather, the plan's standard for coverage appears to have been whether the procedure was a "generally accepted surgical operation," *id*. at 1420 (internal quotation marks omitted), although the administrator had

denied coverage on the ground that the procedure did not meet that standard because the procedure was "investigational," *id*. (internal quotation marks omitted). This case hardly suggests that the term *investigational* has a universally understood definition. Likewise, the cases TMJI cites in a footnote in its opening brief do not support the contention that the terms *experimental* and *investigational* have definite meanings in the medical community.

TMJI also relies on definitions of *investigational device* and *investigation* in the FDA regulations governing "Investigational Device Exemptions." 21 C.F.R. pt. 812. Under the regulations the maker of medical devices may obtain approval to conduct "clinical investigations of devices to determine [their] safety and effectiveness." *Id*. § 812.2(a). An approved device may be shipped for the purpose of conducting investigations without complying with the usual performance and marketing standards. *Id*. Section 812.3 defines *investigational device* as "a device . . . that is the object of an investigation." *Id*. § 812.3(g). *Investigation* is defined as "a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device." *Id*. § 812.3(h). These definitions may be suggestive of general usage, but they do not purport to be universally applicable. For regulations to provide adequate guidance they must use terms with precision. Often, however, no common word has such a precise meaning, so the regulation must use an imprecise word and give it a precise definition. This process is a common one. For example, this

circuit uses the adjective *unpublished* to refer to opinions with no precedential force even though such opinions are widely "published" in the usual meaning of the term. Accordingly, we view the FDA definitions as authoritative only in the special context of the regulations in which they are used.

Finally, TMJI relies on a definition that it obtained through Aetna's website for health-care information, http://www.intelihealth.com. To the extent that TMJI is suggesting that Aetna has adopted that definition for its coverage policy bulletins, we are not persuaded. First, all the website does is provide a link to the Merriam Webster Medical Dictionary; the definitions are not ones provided by Aetna itself. Second, the definition referenced is not a definition of *experimental* or *investigational*. Rather, it is the following definition of *investigational new drug*: "a drug that has not been approved for general use by the Food and Drug Administration but is under investigation in clinical trials regarding its safety and efficacy first by clinical investigators and then by practicing physicians using subjects who have given informed consent to participate—abbreviation *IND*; also called *investigational drug*." Aplt. App. at 322. Again, the definition is an effort to explain the meaning of a technical term used by the FDA for regulatory purposes. *See* 21 C.F.R. § 312.3 (defining *IND* and *investigational new drug*). It does not purport to be, and should not be read as, a universal definition of the term *investigational*, or even as providing the sole meaning in a medical context.

Contrary to TMJI's assertion, several courts have expressly stated the view that the terms *experimental* and *investigational* do not have a settled meaning in the insurance-coverage context. *See Heasley v. Belden & Blake Corp.*, 2 F.3d 1249, 1260 (3d Cir. 1993) (in insurance context, term *experimental* is "resistant to precise definition"); *Dahl-Eimers v. Mut. of Omaha Life Ins. Co.*, 986 F.2d 1379, 1383 (11th Cir. 1993) ("[i]n the context of a major medical insurance policy, the term 'experimental,' . . . is ambiguous when it is undefined."); *Johnson v. Dist. 2 Marine Eng'rs Beneficial Ass'n*, 857 F.2d 514, 516 (9th Cir. 1988) ("In the context of modern medicine, the term 'experimental' seems clearly ambiguous on its face."); *Reed v. Wal-Mart Stores, Inc.*, 197 F.Supp.2d 883, 888–89 (E.D. Mich. 2002) (terms *experimental* and *investigational* used in insurance plan are ambiguous); *Steil v. Humana Kansas City, Inc.*, 124 F. Supp. 2d 660, 665 (D. Kan. 2000) (*experimental* is ambiguous in medical context); *Nichols v. Trustmark Ins. Co.*, 1 F. Supp. 2d 689, 699 (N.D. Ohio 1997) (terms *investigational* and *experimental* used in insurance plan were ambiguous).

More importantly, it is apparent from the cases that the terms are not applied, as TMJI would have us believe, only to medical procedures and devices that are undergoing research. In particular, perhaps as the result of growing concern that new, expensive treatments are no better than old standbys, it is apparently unremarkable for plan definitions and independent experts to consider a treatment to be experimental or investigational until it has established its

*superiority* to current treatment. *See Martin v. Blue Cross & Blue Shield of Va., Inc.*, 115 F.3d 1201, 1208 (4th Cir. 1997) (plaintiff's expert agreed with administrator that whether treatment was experimental or investigative depended on whether it produced better outcomes than standard alternatives); *Hendricks v. Cent. Reserve Life Ins. Co.*, 39 F.3d 507, 513 (4th Cir. 1994) (professor of medicine testified that because cancer treatment had no demonstrated "survival advantage" over conventional therapy, it was investigational); *Pinckney v. Blue Cross Blue Shield of Tenn., Inc.*, No. 3:05-00962, 2007 WL 108886, at *3 (M.D. Tenn. Jan. 9, 2007) (plan defines services as experimental or investigational if "further research is necessary in order to define safety, toxicity, efficacy, or effectiveness of that Service compared with conventional alternatives"); *Reed*, 197 F. Supp. 2d at 889 (one of defendant's experts defined terms *investigational* and *experimental* as "whether a sufficient number of clinical trials had been performed to demonstrate that the therapy is either inferior, equivalent, or superior to standard treatment"); *Nichols*, 1 F. Supp. 2d at 698 (plaintiff's expert stated that treatment was not experimental or investigational because its "effectiveness had previously been established to be superior to any other known therapy") (internal quotation marks omitted); *Leonhardt*, 828 F. Supp. at 671 (defendant's expert stated that "procedure will be considered experimental until the medical community is presented with at least two randomized, controlled studies indicating a significant statistical and practical increase in the disease-free

survival and overall survival rate for patients undergoing this therapy as opposed to patients undergoing standard therapy") (internal quotation marks omitted).

In short, neither the authority cited by TMJI, nor any we have found, supports its contention that *experimental* and *investigational* have definite meanings in the medical community. Because there is no universally accepted definition for these terms, we must discern their meanings from the context in which the defendants use them. We begin with the Aetna bulletin.

**b. Aetna CPB 28**

**i. Description of the Bulletin**

CPB 28 addresses Aetna's coverage determinations for treatment of TMJ syndrome and TMJ disorders. It contains several statements about TMJI's products that TMJI alleges are defamatory. We proceed to put these statements in context to determine whether they are actionable. In our quotations from CPB 28, we have italicized the allegedly defamatory statements.

The bulletin begins with an "Important Note" stating the sources on which Aetna has relied in reaching the conclusions the bulletin sets forth. The note reads, in part:

> This Clinical Policy Bulletin expresses Aetna's determination of whether certain services or supplies are medically necessary. Aetna has reached these conclusions based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading

> national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors).

Aplt. App. at 177. The bulletin then cautions readers that a conclusion in CPB 28 that Aetna considers a procedure to be medically necessary does not mean that the procedure is covered for a specific policy holder—rather, individual coverage determinations can be made only with reference to the individual's benefit plan, as the individual benefit plan controls over any determination made in the bulletin. Although not stated expressly, the implication of this statement is that a treatment determined in the bulletin not to be medically necessary will never be covered, but the specific circumstances determine whether there is coverage for a treatment that can be medically necessary.

The next section, entitled "Policy," sets forth Aetna's medical-necessity determinations. Following that section is the "Background" section, which explains the bases for those determinations. We now explore these sections in some detail.

The Policy section lists several nonsurgical treatments that Aetna considers medically necessary. For example, the use of intra-oral devices such as bite guards is considered medically necessary when the patient has documented evidence of difficulty chewing because of TMJ pain or limited joint functionality. Physical therapy is considered medically necessary without the need to demonstrate pain or lack of functionality, but documentation of need is required

before coverage will be provided for more than a six-week course of 14 sessions. Various categories of drugs are also considered medically necessary to treat different types of TMJ-related pain, as are relaxation and behavior-modification therapies. Treatment in specialized pain centers, however, is considered medically necessary only for "those few individuals who have been unresponsive to less comprehensive interventions." *Id.* at 179. Other medically necessary pain-management techniques include acupuncture, injecting pain medication into the joint, and dry needling (sticking a needle into TMJ-related muscles without injecting any substance).

Surgical management options are much more restricted. The bulletin reminds readers that any request for surgical intervention must be reviewed by the Oral and Maxillofacial Unit and will be granted only when the patient has been unresponsive to nonsurgical treatments and surgery is the only remaining option. Acceptable surgical interventions include arthrocentesis (surgically flushing fluid from the TMJ joint and stretching it), arthroscopy (using an instrument to diagnose and repair the joint), and joint-reconstruction surgery.

The bulletin describes TMJ implants as the most invasive surgical option. Regarding such surgery, CPB 28 states:

> Aetna considers the TMJ Concepts prosthesis medically necessary when used as a salvage device for treatment of end-stage TMJ disease, when no other viable therapeutic alternatives are available. *The use of the Christensen TMJ Fossa-Eminence Prosthesis System (partial TMJ prosthesis) and the Christensen TMJ Fossa-*

> *Eminence/Condylar Prosthesis System (Christensen total joint prosthesis) are considered experimental and investigational.*

*Id*. (emphasis added and internal quotation marks omitted). In other words, use of the TMJ Concepts device is strictly circumscribed, whereas TMJI's devices are not considered medically necessary under any circumstances because Aetna has determined that they are experimental and investigational.

TMJI's devices are not unique in this regard. The list of treatments that Aetna will not cover because it has determined them to be experimental and investigational includes 10 diagnostic procedures and 16 nonsurgical management treatments. Four surgical treatments are considered "*experimental and investigational for diagnosis and treatment of TMJ disorders*":

> . . .
> - *Christensen total TMJ prosthesis*
> - Modified condylotomy [(surgical division of the condyle)] or intraoral vertical ramus osteotomy [(cutting of the ramus)]. . . when submitted with a diagnosis of internal derangement of the temporomandibular joint
> - Treatment of alveolar cavitational osteopathosis . . .
> - *Partial temporomandibular joint prostheses.*

*Id*. at 179–180 (emphasis added).

The "Background" section contains a comprehensive explanation of Aetna's Policy decisions. The thrust of the discussion is that caution should be used in treating TMJ dysfunction, and surgery of any kind is an option of last resort. The bulletin explains that the causes of TMJ dysfunction are generally unknown, but that it is thought to be the result of trauma to the joint. The cause

of some TMJ trauma is obvious, such as extreme force applied to the joint (as may occur in an accident), whereas other causes, such as stress, anxiety, and sleep disorders, create the damage over time. According to the bulletin, because of "a paucity of evidence-based outcome research and lack of consensus on the appropriate management of [TMJ dysfunction]," *id*. at 180–81, there is wide variation in how clinicians treat TMJ dysfunction. It states that there is a lack of "[s]cientifically valid clinical trials" for most TMJ therapies and there is no "objective, generally accepted" diagnostic approach for identifying TMJ dysfunction. *Id*. at 181. As general support for its limitations on coverage, the bulletin quotes the National Institutes of Health's (NIH) recommendation that TMJ therapies be "CONSERVATIVE & REVERSIBLE." *Id*.

The Background section then proceeds to discuss specific surgical treatments. A number of surgical techniques are considered experimental and investigational because of a lack of evidence supporting their efficacy. For example, it states:

> Aetna considers modified condylotomy to be experimental and investigational. There are no controlled studies of modified condylotomy. Controlled studies are important because, according to an NIH Consensus Conference, up to 90 percent of TMJ patients[']symptoms resolve spontaneously. In addition, the literature on modified condylotomy comes almost exclusively from a single group, raising questions about the generalizability of findings. Furthermore, disc displacement is extremely common, and there is no direct evidence that disc displacement is a cause of TMJ symptoms.

*Id*.

The discussion of the partial- and total-joint devices is lengthy:

A partial TMJ prosthesis consists of a meniscectomy and placement of a metallic glenoid fossa metal prosthesis (Christensen fossa-eminence prosthesis, TMJ, [sic] Inc., Golden, CO) in place of the meniscus, such that a natural condyle articulates with a metal fossa prosthesis. *There is inadequate evidence from published clinical outcome studies of the safety and effectiveness of partial joint prostheses in the treatment of [temporomandibular disorders].* The U.S. Food and Drug Administration Dental Products Advisory Panel reviewed clinical studies of the Christensen fossa prosthesis, and advised the FDA to approve the total prosthesis, but to not approve the partial joint prosthesis because of *a lack of clinical data on its safety and effectiveness. The information submitted to the FDA on the safety and effectiveness of the partial TMJ prosthesis is limited and has not been published in a peer-reviewed journal.* In an editorial, Laskin (2001), former editor-in-chief of the Journal of Oral and Maxillofacial Surgery, the official journal of the American Association of Oral and Maxillofacial Surgeons, commented on the data on the partial TMJ prosthesis presented to the FDA Dental Products Advisory Panel:

> At that meeting [of the FDA Dental Products Advisory Panel where the partial TMJ prosthesis was considered] the FDA staff presentation expressed concern regarding the lack of data on the effect of the natural condyle articulating against a metal fossa, the limited number of patients with long term follow-up, and the broad diagnosis of internal derangement as an indication for its use. The panel expressed similar concerns about these issues, as well as the fact that the registry data provided in support of the product did not include all the patients treated and the sample size was insufficient for each of the individual indications. They recommended clarification of the patient inclusion criteria in the clinical study, evaluation of failures and additional patient follow-up, more clearly defined indications for use of the device, and that a power analysis of the clinical data be done to place the PMA in an approvable form. However, despite these criticisms, and the panel's opinion that adequate safety and effectiveness data for the given surgical indications were lacking, the device was approved by the FDA for distribution in February 2001.

> Laskin (2001) concluded that "there are insufficient data" to answer questions about the safety and effectiveness of the partial TMJ prosthesis. "For example, how reliable are clinical data based on a registry that did not include all patients treated with the device, in which there was a very small number of total patients with serial data and even smaller numbers in each diagnostic subcategory, and where in 1 group of 97 patients with a diagnosis of internal derangement and/or inflammatory arthritis, only 30% (12 subjects) had a follow-up of 3 or more years and 70% were either lost to follow-up, withdrawn, or potentially lost to follow-up. How can one make an informed decision with such information?"
>
> *Aetna considers the Christensen total joint prosthesis experimental and investigational because it has not been shown to be as effective as the TMJ Concepts total joint prosthesis.* An evaluation study has reported significantly better post-surgical outcomes with the TMJ Concepts total joint prosthesis than the Christensen total joint prosthesis. Wolford, et al. (2003) reported the results of a study comparing the Christensen total joint prosthesis (TMJ, Inc., Golden, CO) with the TMJ Concepts total joint prosthesis (TMJ Concepts Inc., Camarillo, CA) in 45 patients, 23 of whom were treated with the Christensen prosthesis, and 22 of whom were treated with the TMJ Concepts Prosthesis. The investigators reported that, although subjects treated with either total joint prosthesis showed good skeletal and occlusal stability, the subjects treated with the TMJ Concepts Prosthesis had statistically significant improved outcomes compared to subjects treated with the Christensen prosthesis with respect to [various indicators]. The investigators concluded "[a]s a result of our study, it appears that [TMJ Concepts Prosthesis] provides a more biologically accepted and functional prosthesis than the [Christensen prosthesis] for the complex TMJ patient."

*Id*. at 181–82 (emphasis added). Finally, the bulletin concludes with a list of 57 references on which Aetna based its TMJ treatment-coverage determinations.

**ii. Liability**

Aetna is subject to liability only for those statements in CPB 28 that are false statements of fact or expressions of opinion that imply the existence of

undisclosed defamatory facts. *See* Restatement §§ 565, 566. TMJI challenges as defamatory three statements in CPB 28 regarding TMJI's total-joint prosthesis and five regarding its partial-joint prosthesis: (1) "[t]he use of the . . . Christensen TMJ Fossa-Eminence/Condylar Prosthesis System (Christensen total joint prosthesis) [is] considered experimental and investigational," Aplt. App. at 179; (2) "Aetna considers the [Christensen total TMJ prosthesis] experimental and investigational for diagnosis and treatment of TMJ disorders," *id*.; (3) "Aetna considers the Christensen total joint prosthesis experimental and investigational because it has not been shown to be as effective as the TMJ Concepts total joint prosthesis," *id.* at 182; (4) "[t]he use of the Christensen TMJ Fossa-Eminence Prosthesis System (partial TMJ Prosthesis) . . . [is] considered experimental and investigational," *id*. at 179; (5) "Aetna considers [partial TMJ prostheses] experimental and investigational for diagnosis and treatment of TMJ disorders," *id*.; (6) "[t]here is inadequate evidence from published clinical outcome studies of the safety and effectiveness of partial joint prostheses in the treatment of [temporomandibular disorders]," *id.* at 181; (7) there is "a lack of clinical data on [the partial-joint prosthesis's] safety and effectiveness," *id*.; and (8) "[t]he information submitted to the FDA on the safety and effectiveness of the partial TMJ prosthesis is limited and has not been published in a peer-reviewed journal," *id*. Statements 1, 2, and 3 are formulations of Aetna's determination that TMJI's total-joint device is experimental and investigational, while statements 4 and 5

express its determination that the partial-joint device is also experimental and investigational. Statements 6, 7, and 8 provide support for its determination regarding the partial-joint device.

CPB 28 nowhere provides an explicit definition of the terms *experimental* and *investigational*. Thus, its explanation in the Background section of why it has determined that certain treatments are *experimental* and *investigational* amounts to its definition of those terms as they are used in the bulletin. For example, the bulletin states that "Aetna considers the Christensen total joint prosthesis experimental and investigational because it has not been shown to be as effective as the TMJ Concepts total joint prosthesis." *Id*. at 182. In other words, when Aetna says that the total joint prosthesis is *experimental* and *investigational*, it is saying that the total-joint prosthesis "has not been shown to be as effective as" the TMJ Concepts prosthesis. The statement that the prosthesis is "experimental and investigational" therefore is defamatory only if it is defamatory to say that the prosthesis "has not been shown to be as effective as" the TMJ Concepts prosthesis. In our view, this latter statement is not defamatory because it is not provably false. Different people will make different judgments on whether a product "has been shown to be as effective as" another. Some may require only one study; others may require the gold standard of a double-blind study, or even multiple such studies.

Moreover, TMJI does not even contend that it was false to say that its product has not been shown to be as effective as the TMJ Concepts product. Instead, TMJI complains that comparing its prosthesis to TMJ Concepts' custom prosthesis is "like saying a Mercedes-Benz is not as good as a Rolls Royce; one is assembly-line produced and the other custom built but both are superior machines." Aplt. Br. at 29. But whether the comparison is an appropriate one is beside the point. It is not defamatory to say that a Mercedes rides less smoothly than a Rolls Royce just because a better comparison would be between a Mercedes and a Jaguar. Thus, statements 1, 2, and 3, expressing Aetna's determination that TMJI's total-joint device is experimental and investigational because it has not been shown to be as effective as the TMJ Concepts product, are not actionable because they are not provably false.

Similarly, neither statements 4 and 5, that Aetna considers TMJI's partial-joint prosthesis *experimental* and *investigational*, nor statement 6, that there is inadequate evidence of the device's safety and effectiveness, are actionable. Statement 6 amounts to Aetna's explanation of why it has reached the determination it makes in statements 4 and 5: "There is inadequate evidence from published clinical outcome studies of the safety and effectiveness of partial joint prostheses in the treatment of [TMJ disorders]." Aplt. App. at 181. To say that the partial-joint prosthesis is *experimental* and *investigational* is thus to say that there is "inadequate evidence" supporting the device's safety and effectiveness.

Again, such a statement is not defamatory because it is not provably false. As noted above, whether one considers evidence to be adequate is a matter of individual taste. *See Info. Sys. & Networks Corp. v. City of Atlanta*, 281 F.3d 1220, 1228 (11th Cir. 2002) (statement that company was fired because its performance was inadequate was one of opinion not capable of being proved false).

Statement 7, that there is "a lack of clinical data on [the partial-joint device's] safety and effectiveness," Aplt. App. at 181, is a paraphrase of the FDA Dental Products Advisory Panel's recommendation that the FDA not approve the partial-joint prosthesis. To the extent that Aetna may be arguing on appeal that it cannot be liable for this statement because it was merely repeating a determination made by others, it is incorrect. Comment b to Restatement § 578 makes clear that one who republishes a defamatory statement may be liable to the same extent as the original speaker because each publication causes a new harm to the plaintiff's reputation. But a republisher is liable only if the original statement is defamatory, and in this instance the statement is not. To say that there is a "lack of clinical data" in this context is not provably false. Like the statement that there is inadequate evidence supporting the device's safety and effectiveness, whether there is a "lack of clinical data" is a statement of opinion. Reasonable people may differ on how much data from clinical studies they require before they are satisfied that such data are no longer wanting or deficient.

We recognize that in some circumstances to say that there is a lack of data is to imply that any such data are absent, and that whether such data were in fact absent could then be proved true or false. But that implication could not follow from the context in which Aetna's statement appears. The sentence containing the allegedly defamatory statement also states that the FDA panel "reviewed clinical studies" of the prosthesis. *Id*. A few lines after the sentence are (1) a quotation from Laskin explaining the panel's recommendation "that a power analysis *of the clinical data* be done," *id*. (emphasis added), and then (2) Laskin's conclusion that the data on the partial prosthesis were insufficient because "how reliable are clinical data based on a registry that did not include all patients . . . ?" *Id*. at 182 (internal quotation marks omitted). In this context no reasonable reader could infer that "lack of clinical data" means *absence* as opposed to *insufficiency*. Because Aetna's statement that there is a lack of clinical data cannot be proved false, it is not actionable.

The last statement in CPB 28 of which TMJI complains is Aetna's statement that "[t]he information submitted to the FDA on the safety and effectiveness of the partial TMJ prosthesis is limited and has not been published in a peer-reviewed journal." *Id*. at 181. The first part of this sentence, that the "information submitted to the FDA on the safety and effectiveness of the partial TMJ prosthesis is limited," is not defamatory because it is not capable of being proved false. To say that information is limited is simply another way of saying

that information is "inadequate" or "lack[ing]." But the statement that the "information submitted to the FDA on the safety and effectiveness of the partial TMJ prosthesis . . . has not been published in a peer-reviewed journal" *is* susceptible of being proved false. To make that determination, one would need only to look at the information submitted to the FDA and investigate whether that same information had been published in a peer-reviewed journal. Nevertheless, TMJI has no claim based on this statement because it does not allege that this statement is false. What it does allege is that "[t]he bulletins state that there are *no* published peer-reviewed studies" of its prostheses, Aplt. Br. at 28 (emphasis added), and that this statement is inaccurate because such studies do exist. But this allegation distorts the record. CPB 28 does not state that there are *no* peer-reviewed studies of the prostheses; it states only that "*[t]he information submitted to the FDA* on . . . safety and effectiveness," *id*. (emphasis added), was not published in a peer-reviewed journal. TMJI has not challenged the accuracy of that statement.

TMJI may be arguing that Aetna's statement, even if literally true, is nonetheless defamatory because it omits a relevant material fact (namely, that peer reviews of its devices exist), and therefore carries a defamatory implication. The Restatement does not address this situation, but a leading treatise notes that liability can be found if the publication gets the facts right but the "gist" wrong:

> [I]f the defendant juxtaposes a series of facts so as to imply a defamatory connection between them, or creates a defamatory implication by omitting facts, he may be held responsible for the defamatory implication, unless it qualifies as an opinion, even though the particular facts are correct. On the other hand, the defendant who states all the particular facts correctly, does not omit facts necessary to put them in context, and does not juxtapose the facts in a far-fetched way to create libelous implications, is not liable.

W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 116A, Supp. at 117 (W. Page Keeton ed., 5th ed. 1984, Supp. 1988) (footnotes omitted); *see Memphis Publ'g Co. v. Nichols*, 569 S.W.2d 412 (Tenn. 1978) (news article that plaintiff was shot when assailant found her husband with plaintiff at plaintiff's house improperly implied adulterous relationship because plaintiff's husband and other guests were also present).

We believe that Colorado would tightly cabin liability in this context. In *Living Will Center,* 879 P.2d 6, the Colorado Supreme Court stated that the omission of what the plaintiff considered to be relevant information would not convert an otherwise nonactionable statement into a defamatory one. The defendant had broadcast a report stating that the plaintiff's product was not worth its purchase price. The plaintiff argued, among other things, that because the broadcast in which the statement appeared had failed to describe its product *fully*, the statement was defamatory. The court disagreed, stating, "[W]e . . . fail to see how providing limited, though accurate, information about the [product] can be regarded as a defamation of [plaintiff] under the facts of this case." *Id*. at 15.

In this case the context of the allegedly libelous statement was a discussion explaining why the FDA advisory committee recommended against approval of the TMJI partial-joint prosthesis. The omitted facts would not affect the gist of this discussion. The bulletin hardly "juxtapose[d] the facts in a far-fetched way to create libelous implications." Keeton et al., *supra*, Supp. at 117. As the court said in *Living Will Center*, "we fail to see how [the omission] can be regarded as a defamation of [TMJI]." *Living Will Ctr.*, 879 P.2d at 15.

**c. CIGNA CPN 156**

Having disposed of the statements in CPB 28, we turn to TMJI's allegations that CIGNA published defamatory statements about TMJI products in its TMJ-surgery bulletin, CPN 156. That bulletin states that "CIGNA HealthCare does not cover partial joint replacement with the Christensen Fossa Eminence Prosthesis™ (TMJ Implants, Inc.) Partial TMJ Replacement System because it is considered experimental, investigational, or unproven," Aplt. App. at 194, and that "[t]here is insufficient evidence in the published medical literature to establish the clinical efficacy or long-term outcome of implantation of partial TMJ prostheses," *id*. at 197. TMJI complains that saying that its partial-joint devices are "considered experimental, investigational, or unproven," *id*. at 194, is defamatory. The bulletin does not otherwise define the terms *experimental, investigational*, or *unproven*; we must therefore discern their meanings from the context in which

they are used. Once again we italicize the allegedly defamatory statements in our quotations from the bulletin.

The bulletin begins with a paragraph instructing the reader on how to use the bulletin. Like Aetna's bulletin, it tells readers that their individual benefit plans always control in the event of a conflict between a statement of coverage in CPN 156 and one in the individual plan. It informs readers that some benefit plans exclude TMJ treatment altogether. It then states that CIGNA covers arthrocentesis, arthroscopy, and arthrotomy (open-joint surgery) when certain listed medical-necessity criteria are met. For such a procedure to be covered, pain must have persisted despite at least six months of "scientifically recognized non-invasive therapies," including pain medication, intra-oral devices, and physical therapy. *Id*. at 193. In addition, clinical examinations must document specific joint conditions for each treatment. The bulletin then states:

> CIGNA . . . covers arthrotomy with total prosthetic joint replacement using The TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis for temporomandibular disorder when ALL the following medical necessity criteria are met and indication for surgery is confirmed by MRI, CT or corrected tomogram:
>
> - inflammatory arthritis involving the TMJ not responsive to other modalities of treatment
> - recurrent fibrosis and/or bony ankylosis not responsive to other modalities of treatment
> - failed tissue graft
> - failed alloplastic joint reconstruction
> - loss of vertical mandibular condylar height due to bone resorption, trauma, developmental abnormality or pathologic lesion

> *CIGNA . . . does not cover partial joint replacement with the Christensen Fossa Eminence Prosthesis™ (TMJ Implants, Inc.) Partial TMJ Replacement System because it is considered experimental, investigational, or unproven.*

*Id*. at 194 (emphasis added). The bulletin does not discuss TMJI's total-joint prosthesis.

CPN 156 then provides a "General Background" that describes the anatomy of the TMJ and sets forth several symptoms that may indicate the presence of TMJ disorders, including pain in the face or jaw, headaches, dizziness, limited mouth opening, and clicking or popping sounds. It discusses the prevalence of TMJ disorders, noting that "[a] majority of the general population have at least one sign of TM[J disorders]." *Id*. The bulletin states that "[t]here is no widely accepted standard test to diagnose TM[J disorder]," *id*. at 195, but that physical examination combined with reported symptoms generally provides sufficient information for a diagnosis. Regarding treatment options the bulletin states that "[n]on-invasive, reversible therapies are used in the initial treatment of [TMJ disorders]." *Id*. These include pain-control drug therapies, physical therapy, and intra-oral appliances. When these conservative therapies are unsuccessful, surgical options may be considered.

In discussing surgical treatment, the bulletin states that "the most invasive surgical technique to treat" TMJ disorders is arthrotomy, *id*. at 196, which can involve total- or partial-joint reconstruction with prosthetic implants. Because

"[t]here is inadequate guidance in the published medical literature regarding patient-selection criteria for these procedures," this surgical option should be considered only when "all appropriate conservative treatment has failed and minimally invasive surgery . . . is not indicated." *Id*. CPN 156 explains that there are two FDA-approved prosthetic systems, the TMJ Concepts system and TMJI's devices. The TMJ Concepts device is approved for total-joint reconstruction in certain patients but "should only be considered for end-stage [TMJ disorders] when no other medical or surgical options are available." *Id*. As to TMJI's partial-joint prosthesis, the bulletin acknowledges that the FDA approved it in 2001 for use in patients with any of five indications and that a retrospective study reported that patients who had received the implant experienced significant pain relief. But it notes that the study also advised that "rigorously controlled prospective studies" were needed to investigate the procedure. *Id*. at 197. CIGNA thus concludes that "*[t]here is insufficient evidence in the published medical literature to establish the clinical efficacy or long-term outcome of implantation of partial TMJ prostheses*." *Id*. (emphasis added). The bulletin ends with a list of 20 references relied on for the information and determinations in the bulletin.

As with the Aetna bulletin, the terms *experimental, investigational, or unproven* take on meaning only as the CIGNA bulletin explains why a procedure or device merits those adjectives. The bulletin's statement that there is

"insufficient evidence in the published medical literature to establish the clinical efficacy or long-term outcome of implantation of partial TMJ prosthesis" amounts to its definition of those terms as they are used in CPN 156. In other words, in the context of the bulletin, to say that the partial-joint prosthesis is experimental, investigational, or unproven is to say that there is insufficient evidence supporting its efficacy. The statement that evidence is "insufficient," however, is not defamatory because it is not provably false. As we said in the discussion of the Aetna bulletin, people may differ on the quantity or quality of information that they require before they deem it sufficient. The challenged statements in CPN 156 are therefore not defamatory.

**3. Qualified or Conditional Privilege**

TMJI argues that even if the statements in the bulletins are not provably false, they are afforded only a qualified privilege. It contends that Aetna and CIGNA lost the privilege because their opinions were based on an incomplete and inaccurate evaluation of outdated facts, were published to avoid payment of claims rather than to convey a coverage determination, and were published with malice. But TMJI offers no support for its assertion that under Colorado law not-provably-false statements (opinions) are entitled to only a qualified privilege; and we have found none.

TMJI has confused the concepts of (1) nondefamatory statements and (2) defamatory statements that are privileged. We have already concluded that the

statements by Aetna and CIGNA were not defamatory. Accordingly, neither defendant needed a privilege to escape liability. A brief discussion of qualified (or conditional) privilege in the defamation context may help clarify the matter.

Restatement § 593 states: "One who publishes a defamatory matter concerning another is not liable for the publication if (a) the matter is published upon an occasion that makes it conditionally privileged and (b) the privilege is not abused." Conditional privileges protect, for example, information that "affects a sufficiently important interest of the publisher, [if] . . . the recipient's knowledge of the defamatory matter will be of service in the lawful protection of the interest," *id.* § 594, and similar information that affects the interests of third persons, *see id.* § 595, or family members, *see id.* § 597. The Restatement sets forth several circumstances in which these conditional privileges are lost because of abuse. For example, if the speaker makes the statement with knowledge of or reckless disregard for its truth or falsity, *see id.* § 600, or for a purpose other than that for which the privilege was extended, *see id.* § 603, there is no longer a privilege. When there has been no defamatory statement, however, the publisher does not need the protection of a privilege and therefore abuse of the privilege is irrelevant. If the publisher levels a charge for the most evil of motives and without any interest in the charge's truth, the publisher is not liable if the charge turns out to be true. The publisher's motive may have precluded a claim of conditional privilege, but the publisher can prevail without invoking a privilege.

What we decided above is that the challenged statements by Aetna and CIGNA are simply not defamatory statements. A statement in the form of an opinion that does not imply the existence of undisclosed defamatory facts is not actionable and a publisher of such a statement has no need for a privilege. Accordingly, we reject TMJI's contention that Aetna and CIGNA are liable for abuse of a privilege.

### C. Product Disparagement

TMJI claims that the same statements by Aetna and CIGNA that are alleged to be defamatory also constitute product disparagement. The Colorado Court of Appeals has adopted the elements of a product-disparagement claim set forth in Restatement § 623A, stating that a plaintiff making such a claim must show "(1) a false statement; (2) published to a third party; (3) derogatory to the plaintiff's business in general, to the title to his property, or its quality; (4) through which the defendant intended to cause harm to the plaintiff's pecuniary interest, or either recognized or should have recognized that it was likely to do so; (5) with malice; (6) thus, causing special damages." *Teilhaber*, 791 P.2d at 1166. Citing *Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485 (1984), the court in *Teilhaber* added that "[t]he constitutional protections afforded a defendant in a defamation action are applicable to a defendant in a product disparagement action." 791 P.2d at 1167. Accordingly, "a statement of opinion [about a product] will be protected expression" unless "the language is

defamatory and the underlying defamatory facts which provide a basis for the opinion are false and are not disclosed in context." *Id*. We believe that the Colorado Supreme Court would not recognize a product-disparagement claim relying entirely on expressions that could not support a defamation claim. *See also Unelko Corp. v. Rooney*, 912 F.2d 1049, 1057–58 (9th Cir. 1990) (subjecting product-disparagement claim to same First Amendment requirements as defamation claims); *Dairy Stores, Inc. v. Sentinel Publ'g Co., Inc.*, 516 A.2d 220, 226 (N.J. 1986) (extending common-law privileges available in defamation claims to product-disparagement claims); Restatement § 646A (same). Therefore, TMJI's product-disparagement claim fails.

**D. Interference Torts**

Finally, TMJI claims that the statements in the bulletins constituted intentional interference with prospective business relations and contracts. Colorado follows the Restatement with respect to the elements of both intentional interference with prospective business relations and intentional interference with contract:

> "One who intentionally and *improperly* interferes with another's prospective contractual relation (except a contract to marry) is subject to liability to the other for the pecuniary harm resulting from loss of the benefits of the relation, whether the interference consists of
>
> (a) inducing or otherwise causing a third person not to enter into or continue the prospective relation or
> (b) preventing the other from acquiring or continuing the prospective relation."

*Amoco Oil Co. v. Ervin*, 908 P.2d 493, 500–01 (Colo. 1995) (quoting Restatement § 766B) (emphasis added). And

> "[o]ne who intentionally and *improperly* interferes with the performance of a contract (except a contract to marry) between another and a third person by inducing or otherwise causing the third person not to perform the contract, is subject to liability to the other for the pecuniary loss resulting to the other from the failure of the third person to perform the contract."

*Mem'l Gardens, Inc. v. Olympian Sales & Mgmt. Consultants, Inc.*, 690 P.2d 207, 210 (Colo. 1984) (quoting Restatement § 766) (emphasis added). Thus, for either claim to proceed, the interference must have been improper.

If the alleged impropriety, however, is an allegedly defamatory statement, then the interference claim must fail if the statement is not an actionable defamation. We have addressed this issue in a diversity case governed by Colorado law. In *Jefferson County School District No. R-1 v. Moody's Investor's Services*, 175 F.3d 848, 856–58 (10th Cir. 1999), the plaintiff based its claims for intentional interference with contractual and business relations on allegedly defamatory statements made by the defendant. We held that lawful speech could not form the basis of the interference claims because such activity was not improper. *See id*. at 858. Although the speech in that case was *constitutionally* protected, we see no reason to distinguish speech protected from a defamation claim under the common law. The interests served by that protection would be

undermined if the common law recognized a different tort based on the same speech. We are aware of no authority to the contrary.

Accordingly, we affirm the district court's dismissal of TMJI's tortious-interference claims.

## III. CONCLUSION

We AFFIRM the judgment of the district court.