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Commercial disparagement claim vs. insurer revived

Carrier's policy statement allegedly smeared device maker's product ■ **Eric T. Berkman**

The maker of customized total knee replacements could bring a commercial disparagement claim against a health insurer that amended its policy statement to characterize such products as "experimental and investigational," the 1st U.S. Circuit Court of Appeals has decided.

Defendant insurer Aetna provided coverage for plaintiff Conformis, Inc.'s total knee replacement — or TKR — system for seven years until, in September 2018, it released a revised policy recharacterizing customized TKRs as experimental and because their effectiveness had not been established.

Customized TKRs have been cleared by the federal Food and Drug Administration, covered by Medicare and Medicaid, described in clinical studies as providing favorable outcomes compared to off-the-shelf TKRs, and endorsed by the American Association of Hip and Knee Surgeons. Aetna, meanwhile, apparently offered no explanation for the recharacterization.

But in the wake of the change, orthopedic surgeons allegedly stopped ordering the system for Aetna-covered patients and, in some cases, for other patients as well.

Pisegna

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>
> **—VINCENT J. PISEGNA**

When Conformis sued the insurer for product disparagement and tortious interference, a U.S. District Court judge dismissed the claims, finding that the plaintiff failed to sufficiently allege Aetna entertained serious doubts as to the truth of its publication.

But the 1st Circuit reversed.

"Separating wheat from chaff, we conclude that Conformis plausibly alleges that Aetna ignored credible evidence presented to it that called its statement into serious question," Judge Bruce M. Selya wrote for the panel. "And Aetna's abrupt change in policy, without any explanation at all as to why a previously covered device had suddenly become 'experimental and investigational,' forms the basis for a plausible inference that Aetna must have known that assertion was false."

The panel also found that the District Court judge wrongly dismissed Conformis' claim of tortious interference with advantageous relationships, though it affirmed dismissal of its claim for tortious interference with contractual relation.

The 41-page decision is *Conformis, Inc. v. Aetna, Inc., et al.*, Lawyers Weekly No. 01-014-23.

WITHOUT EXPLANATION

Anthony P. La Rocco of Newark, New Jersey, represented the plaintiff, and Sarah M. Harris of Washington, D.C., was counsel for the defendant. Neither attorney responded to requests for comment.

But William A. Schneider, a Boston attorney who counsels insurance companies, described the decision as a comprehensive review of the elements for product disparagement, which he found useful in the absence of clear Supreme Judicial Court precedent.

Schneider went on to question the lengths the court went to to apply a "common-sense" reading to conclude that the insurer intended its policy statement to refer specifically to Conformis' product, given that Aetna's policy statement did not refer to Conformis by name.

"It seems like a stretch to suggest that the insurer's characterization of treatment it will not cover is a statement of fact 'of and concerning' that treatment" as required to state an actionable claim, he said.

Meanwhile, Schneider predicted that the decision will have broad implications in the area of product disparagement by giving health care providers and medical device manufacturers an avenue to seek damages based solely on how a health insurer internally characterizes certain treatments or products.

"Health insurers may look to insulate themselves through more direct policy statements unaccompanied by internal designations or explanations for decisions not to provide coverage," he said.

Boston business litigator Vincent J. Pisegna said it is not uncommon for insurers to decide they no longer want to cover a product or procedure that is both expensive and gaining traction in the marketplace.

In fact, he said, the case reminded him of one in which he represented a dentist who treated a painful jaw disorder, "TMJ syndrome," with a procedure called "trigger point therapy."

The dentist had performed the procedure a substantial number of times when a major health insurer said it would no longer cover it because it was merely "palliative" and that patients instead would need to go to a surgeon to fix the actual condition.

"My guy rallied the TMJ industry around him and had a number of affidavits from experts, so the insurance company backed down," Pisegna said.

Here, however, Aetna abruptly changed its policy without giving a reason, after covering the procedure for seven years amid a "mountain" of evidence that the product worked, Pisegna said.

"Businesses have to make hard decisions all the time, and many times they choose not to give a reason for the change," Pisegna said. "This case is a good example of what happens when a court is called on to look at the facts and make a judgment as to what the consequences of that change in the policy are."

CONFORMIS, INC. v. AETNA, INC. ET AL.

THE ISSUE: Could the maker of customized total knee replacements bring a commercial disparagement claim against a health insurer that amended its policy statement to characterize such products as "experimental" and "investigational?"

DECISION: Yes (1st U.S. Circuit Court of Appeals)

LAWYERS: Anthony P. La Rocco of K&L Gates, Newark, New Jersey (plaintiff)
Sarah M. Harris of Williams & Connolly, Washington, D.C. (defense)

Boston attorney Johanna L. Matloff, who represents health insurers, said that while insurance companies have considerable latitude to write policies and define plan terms, the problem Aetna faced was explaining why it would no longer cover the product.

"If you're going to take coverage away, the better practice would have been to be more transparent that this is what you're doing," Matloff said. "It wasn't clear from the decision what the carrier's reasoning was. But if cost was the issue, the carrier might have addressed that more directly by increasing policy premiums."

Tory A. Weigand of Boston noted that most commercial or product disparagement claims are between competitor manufacturers or sellers, while here it was between an insurance provider and a manufacturer.

Weigand said it was particularly interesting that the action initially began as a claim by a patient who had the device implanted and sued Aetna when it denied coverage under the policy, and that the patient and Aetna settled, leaving only the claims by Conformis, which joined the action later.

"Regardless, the result is largely a function of the unique facts and the modest standard as to motions to dismiss," Weigand said. "Disparagement remains a difficult claim … although the allegations put forth by the manufacturer are certainly noteworthy."

POLICY CHANGE

The Conformis iTotal Knee Replacement System is a customized TKR designed to improve on the limitations of uniform, off-the-shelf knee replacements.

The FDA gave clearance to the Conformis system in February 2011. Since then, more than 100,000 patients have received the system and more than 90 percent of commercial payors cover it, as does Medicare and Medicaid.

Additionally, a number of clinical studies have concluded that customized TKRs in general and Conformis in particular showed favorable outcomes compared to off-the-shelf TKRs.

Aetna covered the Conformis system from 2011 until September 2018, when the insurer released a revised policy that found customized TKRs were experimental and investigational because their effectiveness had not been established.

The policy did not explain the reason for the recharacterization. Separately, Aetna's website, in its glossary of terms, defined "experimental services or procedures" and "investigational services" as "newer drugs, treatments or tests [that] are not yet accepted by doctors or by insurance plans as standard treatment [and] may not be proven as effective or safe for most people."

The change had apparently profound financial consequences for Conformis, as orthopedic surgeons stopped ordering the system for patients on Aetna plans.

And, to avoid further uncertainty about reimbursement, some orthopedic surgeons stopped ordering the system for patients covered by other plans.

When Aetna refused Conformis' demands for a policy revision, while also disregarding entreaties from the American Association of Hip and Knee Surgeons, Conformis filed suit in U.S. District Court bringing state common law claims for product disparagement and tortious interference with both contractual and advantageous relations.

Judge Indira Talwani granted Aetna's motion to dismiss for failure to state a claim, and Conformis appealed.

REVERSAL OF JUDGMENT

In reversing dismissal of the product disparagement claim, the 1st Circuit rejected Aetna's argument that Conformis could not show that the policy statement was "of and concerning" its products or services.

"Admittedly, [the] statement does not refer to Conformis by name. Instead, it refers only to 'customized [TKRs],'" Selya wrote. "But a commonsense reading of the Policy is required, and such a reading leaves little doubt that Aetna intended the words to refer to Conformis's product."

Selya pointed out that Conformis has been a leading producer of customized TKRs for years, which Aetna was well aware of, and the background section of the policy had a subsection dedicated to the "ConforMIS Knee Implant," the only customized TKR singled out that way.

The court also found that Conformis had sufficiently alleged that Aetna's statement could reasonably be understood as either fact or opinion as necessary to survive a motion to dismiss.

"A reasonable reader could interpret [the] statement as a statement of fact because such a reader could interpret it as a verifiable assertion that the Conformis system is 'not clinically effective and not accepted by doctors and insurance providers as a standard treatment,'" Selya stated. "No more need be said at this stage."