NO. 23-_____

In the Supreme Court of the United States

TERRANCE NELSON CATES,

Petitioner,

v.

ZELTIQ AESTHETICS, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Eleventh Circuit affirmed the district court's Order granting summary judgment in favor of Defendant, Zeltiq Aesthetics, Inc., and against Plaintiff, Terrance Nelson Cates.

Three questions are presented:

1. Does a circuit court of appeals' appellate review of the grant of a federal summary judgment under Federal Rule of Civil Procedure 56 require the appellate court to review the evidence considered by the trial judge on a motion for reconsideration?

2. In reviewing the grant of a federal summary judgment under Federal Rule of Civil Procedure 56, does the circuit court of appeals have authority, in applying Rule 56 to a particular case, to go *outside* the record and conduct independent medical research to determine a party's entitlement to judgment as a matter of law?

3. Whether the Eleventh Circuit opinion reflects a clear misapprehension of the federal summary judgment standard in light of prior supreme court precedent, effectively denying a litigant his constitutional right to jury trial?

PARTIES TO THE PROCEEDINGS

Petitioner and Plaintiff-Appellant below

- Terrance Nelson Cates

Respondent and Defendant-Appellee below

- Zeltiq Aesthetics, Inc.

CORPORATE DISCLOSURE STATEMENT

Petitioner Terrance Nelson Cates is an individual person.

To the best of Petitioner's knowledge, Zeltiq Aesthetics, Inc., is owned by a subsidiary of a publicly traded company AbbVie, Inc. (ticker ABBV).

LIST OF PROCEEDINGS

United States Court of Appeals, Eleventh Circuit

No. 21-12085

Terrance Nelson Cates, *Plaintiff-Appellant,* v.
Zeltiq Aesthetics, Inc., *Defendant-Appellee*

Final Opinion: July 21, 2023

United States District Court,
Middle District of Florida Orlando Division

Case No: 6:19-cv-1670-PGB-LRH

Terrance Nelson Cates, *Plaintiff,* v.
Zeltiq Aesthetics, Inc., *Defendant*

Final Order: April 19, 2021

Reconsideration Denial: May 18, 2021

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

PARTIES TO THE PROCEEDINGS ii

CORPORATE DISCLOSURE STATEMENT iii

LIST OF PROCEEDINGS iv

TABLE OF AUTHORITIES viii

OPINIONS BELOW 1

JURISDICTION 1

CONSTITUTIONAL PROVISION, STATUTES AND JUDICIAL RULES INVOLVED 1

STATEMENT OF THE CASE 3

REASONS FOR GRANTING THE PETITION 11

I. Does a Circuit Court of Appeals' Appellate Review of the District Court's Grant of Federal Summary Judgment Under Rule 56 Require the Circuit Court to Review the Evidence Considered by the Trial Judge on a Motion for Reconsideration 14

II. In Reviewing the Grant of Federal Summary Judgment Under Rule 56, Does the Circuit Court of Appeals Have Authority, in Applying Rule 56 to a Particular Case, to Go Outside the Record and Conduct Independent Medical Research to Determine Entitlement to Judgment as a Matter of Law and Whether the Summary Judgment Requirements Have Been Satisfied by the Movant 19

TABLE OF CONTENTS – Continued

Page

III. The Eleventh Circuit Opinion Reflects a Clear Misapprehension of the Federal Summary Judgment Standard in Light of Prior Supreme Court Precedent, and Effectively Denies the Litigant His Constitutional Right to a Jury Trial 22

CONCLUSION..... 39

TABLE OF CONTENTS – Continued

Page

APPENDIX TABLE OF CONTENTS

OPINIONS AND ORDERS

Opinion, United States Court of Appeals for the Eleventh Circuit (July 21, 2023) 1a

Exhibit to Eleventh Circuit Opinion: *Adiposity and Alzheimer's Disease* 22a

Order Granting Motion for Summary Judgment, United States District Court for the Middle District of Florida Orlando Division (April 19, 2021) 40a

RECONSIDERATION ORDERS

Order Denying Motion for Reconsideration, United States District Court for the Middle District of Florida Orlando Division (May 18, 2021) 58a

TABLE OF AUTHORITIES

Page

CASES

Adickes v. S.H. Kress & Co.,
398 U.S. 144, 90 S.Ct. 1598,
26 L.Ed.2d 142 (1970) 22

Anderson v. Liberty Lobby, Inc.,
477 U.S. 242, 106. S.Ct. 2505 (1986) 23, 24

Aubin v. Union Carbide Corp.,
177 So.3d 489 (Fla. 2015)..... 36

Boag v. MacDougall,
454 U.S. 364, 102 S.Ct. 700,
70 L.Ed.2d 551 (1982) 35

Canterbury v. Spence,
464 F.2d 772 (D.C. Cir. 1972) 35

Cates v. Zeltiq Aesthetics, Inc.,
73 F.4th 1342 (11th Cir. 2023)..... 1, 3, 4, 5

Celotex Corp. v. Catrett,
477 U.S. 317, 106 S.Ct. 2548,
91 L.Ed.2d 265 (1986) 23

Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 82 S.Ct. 1404,
8 L.Ed.2d 777 (1962) 23

Dupree v. Younger,
598 U.S. 729 (2023) 12, 13

Eghnayem v. Boston Sci. Corp.,
873 F.3d 1304 (11th Cir. 2017) 10, 36, 38

Felix v. Hoffman-La Roche, Inc.,
540 So. 2d 102 (1989) 10

TABLE OF AUTHORITIES – Continued

Page

Griggs-Ryan v. Smith,
904 F.2d 112 (1st Cir. 1990) 19

Hayes v. Spartan Chemical Co.,
622 So.2d 1352 (Fla. 2d DCA 1993) 36

In Re: Louisiana Crawfish Producers,
852 F.3d 456 (5th Cir. 2017) 18

Lytle v. Household Mfg., Inc.
494 U.S. 545, 110 S.Ct. 1331,
108 L.Ed.2d 504 (1990) 23

Matsushita Elec. Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 106 S.Ct. 1348,
89 L.Ed.2d 538 (1986) 23

McBeth v. Himes,
598 F.3d 708 (10th Cir. 2010) 19

Reeves v. Sanderson Plumbing Products, Inc.,
530 U.S. 133 (2000) 24

State v. Pres. Women's Ctr.,
937 So.2d 114 (Fla. 2006) 35

Templet v. HydroChem Inc.,
367 F.3d 473 (5th Cir. 2004) 18

Tolan v. Cotton,
572 U.S. 650 (2014) 12, 23, 34, 35

Trustees of the Plumbers and Pipefitters Nat. Pension Fund v. Plumbing Services, Inc.,
791 F.3d 436 (4th Cir. 2015) 19, 20

Upjohn Co. v. MacMurdo,
562 So. 2d 683 (Fla. 1990) 15, 16

TABLE OF AUTHORITIES – Continued

Page

CONSTITUTIONAL PROVISIONS

U.S. Const. amend. VII 1, 2, 12

STATUTES

28 U.S.C. § 1254(1) 1

28 U.S.C. § 2072 ..... 2, 12

JUDICIAL RULES

Fed. R. Civ. P. 38 ..... 2, 12

Fed. R. Civ. P. 56 ..... i, 3, 12-14, 19, 20, 22, 23, 36, 39

Fed. R. Civ. P. 59(e) 19

REGULATIONS

21 C.F.R. § 803 17

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Eleventh Circuit is reported at *Cates v. Zeltiq Aesthetics, Inc.*, 73 F.4th 1342 (11th Cir. 2023) and is included in the Appendix ["App."] at 1a. The Eleventh Circuit affirmed the decision of the United States District Court for the Middle District of Florida on July 21, 2023, reported at 535 F.Supp.3d 1222 and include at App.39a.

JURISDICTION

The Eleventh Circuit opinion was rendered on July 21, 2023. [App.1a]. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISION, STATUTES AND JUDICIAL RULES INVOLVED

U.S. Const. amend. VII

> In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any court of the United States, than according to the rules of the common law.

28 U.S.C. § 2072
Rules of procedure and evidence; power to prescribe

(a) The Supreme Court shall have the power to prescribe general rules of practice and procedure and rules of evidence for cases in the United States district courts (including proceedings before magistrate judges thereof) and courts of appeals.

(b) Such rules shall not abridge, enlarge or modify any substantive right. All laws in conflict with such rules shall be of no further force or effect after such rules have taken effect.

(c) Such rules may define when a ruling of a district court is final for the purposes of appeal under section 1291 of this title.

2023 Federal Rules of Civil Procedure, Foreword

FOREWORD

This document contains the Federal Rules of Civil Procedure together with forms, as amended to December 1, 2022. The rules have been promulgated and amended by the United States Supreme Court pursuant to law, and further amended by Acts of Congress. . . .

Fed. R. Civ. P. 38
Right to a Jury Trial; Demand

(a) RIGHT PRESERVED. The right of trial by jury as declared by the Seventh Amendment to the Constitution—or as provided by a federal statute—is preserved to the parties inviolate.

Rule 56(a)—Summary Judgment

> (a) MOTION FOR SUMMARY JUDGMENT OR PARTIAL SUMMARY JUDGMENT. A party may move for summary judgment, identifying each claim or defense—or the part of each claim or defense—on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. The court should state on the record the reasons for granting or denying the motion.

STATEMENT OF THE CASE

Cates sustained permanent body deformities and other injuries resulting from the administration of the very popular CoolSculpting device and procedure. CoolSculpting a multibillion-dollar business which advertises itself throughout the country as a "nonsurgical" and "non-invasive" procedure to reduce and/or remove stubborn body fat. [Doc. No. 27; 117; 136]

The concept of Cryolipolysis is based on a theory that fat tissue is more vulnerable to cold temperatures than the skin; therefore, if cold is applied to a person's unwanted fat bulge, the cold temperature will kill the fat cells and leave the skin intact. *Id.*

The U.S. Food and Drug Administration ("FDA") cleared Zeltiq's Cryolipolysis CoolSculpting device for the performance of Cryolipolysis services to specific

body areas. The CoolSculpting device is the only medical device in the United States with FDA clearance to offer body contouring services via Cryolipolysis. *Id*.

In order to facilitate Cryolipolysis, the CoolSculpting device's suction applicators are applied to a person's body and cool the treatment area for 30 to 60 minutes. Each application of the applicator is called a "cycle". A person may undergo multiple cycles in one CoolSculpting session, depending on the size of the area they desire to treat with Cryolipolysis. *Id*.

The CoolSculpting System has received substantial press coverage in the national media since its clearance by the FDA for non-invasive, cosmetic, body-contouring, including features on television shows such as The Today Show, Good Morning America, The CBS Early Show, The Rachael Ray Show, The Dr. Oz Show, Extra, Nightline, The Doctors, and E! News, and in magazines such as O, Elle, Marie Claire, Allure, Men's Fitness, Town & Country, Elevate, W, and Vie. *Id*.

The CoolSculpting medical device is specifically programmed to only function with the use of consumable cards, called "cycles", which CoolSculpting providers must buy from Zeltiq to operate the medical device. "A cycle is an authorization to perform one procedure to one specific area on the body; [providers] can only perform a treatment if they have purchased a cycle." *Id*.

Zeltiq actually makes more money on selling the consumable cards to CoolSculpting providers than on selling the CoolSculpting devices. In 2018, it made $235.3 million on selling consumable cards and $126.3 million on selling the CoolSculpting devices and applicators. *Id*.

Cates brought suit in federal court against the manufacturer of the device, claiming that Zeltiq knew that its CoolSculpting device could cause patients to develop a condition called Paradoxical Adipose Hyperplasia (PAH) (also referred to as Paradoxical Hyperplasia or "PH" by Zeltiq), which is a permanent condition. [Doc. No. 27; 117-7; 136-55]

PAH causes *permanent* pathological change to the microstructure of the tissue in the CoolSculpting treatment area, affecting various types of cells, including adipocytes, vascular cells, blood cells, macrophages, endothelial cells, stem cells, and interstitial cells. The tissue affected by PAH becomes fibrous and different from regular, untreated tissue resulting in enlarged and sometimes hardened tissue masses that are disfiguring to the body. [Doc. No. 117; 136]

PAH tissue is consistent with *fibroplasia*, which is fibrosis of the treated tissue. Fibroplasia is scarring (fibrosis) of the affected tissue resulting from the body's wound healing process after an injury. It is an irreversible process. PAH is not simply an enlargement of fat in the treatment area; it is a disease of the tissue that results in a *deformation* of the body. Unlike regular fat tissue, PAH does not resolve on its own. To manage the fibroplasia, the tissue must be surgically excised. And a patient can be subjected to many types of surgeries. *Id*.

PAH tissue and its deforming effect can *recur* after surgery, and in some cases, cannot be fully removed. *Id*.

Cates position was that Zeltiq's warnings were legally insufficient because they did not relay the severity of PAH. [Doc. No. 27; 117; 136]

Cates' position was that despite knowing about the severity and permanency of this condition, Zeltiq manipulated, in its favor, important information regarding PAH to induce prospective patients to undergo, and providers to recommend, the CoolSculpting procedure. It did so by making misrepresentations about PAH to CoolSculpting providers and concealing the number of patients who have developed PAH, causing CoolSculpting providers to believe that the condition was not as serious, permanent, and frequent as Zeltiq knew it to be. [Doc. No. 27; 117-7; 136-55]

Although Zeltiq provided *some* information regarding PAH to CoolSculpting providers, it was misleading and written in such a way as to give the providers the impression that the condition causes a less serious effect and is not likely to occur.

Zeltiq creatively chose words that were ambiguous and did not provide enough specificity on the details that were necessary for a CoolSculpting provider to understand the condition.

As the result of Zeltiq's conduct, Cates was not aware (nor were his providers) of the serious risk of undergoing the CoolSculpting procedure before he elected to do so and consequently developed PAH on his abdomen and flanks. In his sworn declaration, Cates stated had he known of these serious risks, he would not have undergone the CoolSculpting procedure. [Doc. No. 117-7; 136-55]

Zeltiq used the following language to describe the disfiguring condition of PAH in the User Manuals for the CoolSculpting device, dedicating only two lines to inform the provider about the permanent condition, stating:

Rare Side Effects

- Paradoxical hyperplasia: Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical intervention may be required.

[Doc. No. 117-4; 136-37] (e.s.).

Zeltiq used similarly vague language to describe PAH to CoolSculpting providers in its slide-show presentations which it used during its online and live training on how to operate the device. [Doc. No. 136-29]

Cates' position was that Zeltiq's "warnings" about PAH to CoolSculpting providers were *inaccurate* in content and *ambiguous* in the manner of expression. The language used by Zeltiq did not relay the seriousness, permanency, and frequency of the condition.

Zeltiq's inadequate disclosure about PH *failed* to inform the CoolSculpting providers:

a. That PH is a disease of the tissue;

b. That the CoolSculpting device damages the tissue;

c. That PH results in a physical deformity;

d. That a single patient can suffer multiple deformities on the body from PH;

e. That the deformity will never resolve on its own because it is permanent;

f. That PH changes the microstructure of the tissue;

g. That invasive surgeries are required to attempt to remedy the affected tissue;

h. That surgery may not resolve PH affected tissue;

i. That the CoolSculpting device can cause cutaneous tissue laxity requiring surgery to cut, lift, and sew the skin;

j. That PH has a wide range of physical effects on the body;

k. That the frequency of occurrence of PH is not rare and that thousands of people have suffered from the condition after undergoing CoolSculpting.

The district court granted Zeltiq's motion for summary judgment, finding that Zeltiq's warnings about PAH were adequate as a matter of law. [App.39a-56a; Doc. No. 132]

The Eleventh Circuit decided the Zeltiq warnings were "accurate, clear, and unambiguous" as a matter of law. [App.1a-38a][1]

In so holding, the Eleventh Circuit relied on the language in the consent form:

> b) Rare side effects/risks include, but are not limited to:
>
> > a. Paradoxical hyperplasia, or an enlargement of fat in the service area of varying size and shape, may occur in the

---

[1] Based on such ruling, the Eleventh Circuit affirmed the district court's grant of summary judgment on Cates' remaining claims of strict product liability—defective design; strict product liability—failure to warn; negligence; negligent misrepresentation; fraudulent misrepresentation and concealment, on the theory that such claims were tantamount to "failure to warn" claims. [App.6a]

> months to year following the treatment. If paradoxical hyperplasia occurs, it is unlikely that it will resolve on its own. The enlargement can be removed through liposuction or related surgery.

[Doc. No. 112-7]

The Eleventh Circuit also relied upon Zeltiq's CoolSculpting User Manual:

> Zeltiq also warns healthcare providers that administer CoolSculpting cycles about PAH. Under "Rare Adverse Events" in its CoolSculpting manual, Zeltiq includes, "Paradoxical hyperplasia: Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical intervention may be required."

[App.5a]

The panel made references to two plastic surgeons that Cates had visited after his diagnosis of PAH:

> Moreover, after Cates's initial PAH diagnosis, he visited two plastic surgeons who did not diagnose him with fibroplasia, but instead, described Cates's masses as "subcutaneous adiposity" and "hyperplastic fat." And both recommended liposuction to remove the masses. In other words, both doctors concluded that Cates's masses were fat cells [fn3] and recommended liposuction to resolve the problem. Zeltiq's warnings were, thus, legally sufficient as directed to trained medical professionals to warn about the condition Cates experienced. *See Eghnayem*, 873 F.3d

> at 1321-22; *accord Felix*, 540 So. 2d at 105 (determining, "as to physicians, the warnings concerning the dangerous side effects" were "quite clear," even if the average consumer would not fully appreciate them).

[App.11a-12a]

Footnote 3 refers to the Eleventh Circuit's independent research regarding "adiposity". The Eleventh Circuit attached a 12-page medical research article (from 2009) titled "Adiposity and Alzheimer's Disease" to its opinion. [App.1a-38a] This article was not part of the trial court record. The Eleventh Circuit relied on that article and its own "independent medical research" in its analysis as to whether there existed a genuine issue of material fact regarding the adequacy of Zeltiq's warning in this case.

Cates filed a motion for rehearing/reconsideration and submitted additional evidence in response to the motion for summary judgment. [Doc. No. 136] *See* pp.28-34, *infra*.

The district court stated in its order denying the motion for reconsideration that it considered all the evidence submitted. [Doc. No. 138]

Appeal was taken to the Eleventh Circuit. The Eleventh Circuit issued a 22-page Opinion upholding the summary judgment. [App.1a-38a] The Eleventh Circuit made clear in its opinion that it did not consider the evidence Cates had submitted with his motion for reconsideration – even though such evidence was considered by the district court. [App.10a-11a] Nor did the Eleventh Circuit consider the contradictory evidence submitted by the non-movant. *See* pp.19-23, *infra*.

In addition, the Eleventh Circuit misapprehended and misapplied the current federal summary judgment standard, and in effect created a "new" federal summary judgment standard—a standard which effectively violates a litigant's constitutional right to a jury trial.

REASONS FOR GRANTING THE PETITION

CoolSculpting is an extremely popular medical procedure/device which is present in almost every community in the United States. Health is of course of primary importance to most citizens, and CoolSculpting appeals to the individual's desire to be healthy by removing "fat". Every citizen is entitled to be safe from harm from a medical procedure/device, and every citizen is entitled to be warned of the risks and potential dangers associated with such a procedure.

If a patient is harmed by such a popular medical procedure, what is the patient's remedy? While the adequacy of warning is determined by state substantive law, the determination of whether the patient's failure to warn case goes to a jury is determined by the federal summary judgment standard.

The United States Supreme Court determines this standard. This Court's review of a deviation from or misapprehension of the standard created by this Court, or even creation of a new standard by a circuit court of appeal, is critical to maintaining uniformity of the federal summary judgment standard throughout the United States, and of course directly affects an individual's right to a jury trial under Federal Rule of

Civil Procedure 38 and the Seventh Amendment to the United States Constitution. *See* 28 U.S.C. § 2072.

Does this Court's federal summary judgment standard, and Rule 56, authorize a circuit court of appeals to conduct its own "independent" medical research which relates to key factual disputes in a case when deciding the propriety of summary judgment?

Does this Court's federal summary judgment standard, and Rule 56, authorize a circuit court of appeals to *in effect* act as a seventh juror and "weigh the evidence"; not credit contradictory evidence; and not view the record evidence in the light most favorable to the non-movant with respect to the central facts of the case. *See Tolan v. Cotton*, 572 U.S. 650, 657-59 (2014).

Does this Court's federal summary judgment standard, and Rule 56, give the circuit court of appeals the option to not review the entire record, including the record evidence provided on a motion for reconsideration—where that motion for reconsideration evidence was considered by the district court?

The Supreme Court has accepted certiorari in recent years in cases that involve interpretation and application of the rules of civil procedure, including Federal Rule of Civil Procedure 56 ("Rule 56") regarding summary judgment. *See Tolan v. Cotton*, 572 U.S. 650 (2014) ("[W]e intervene here because the opinion below reflects a clear misapprehension of summary judgment standards in light of our precedents.").

Most recently, Rule 56 interpretation took place in *Dupree v. Younger*, 598 U.S. 729 (2023). That case involved the question of whether the preservation requirement extends to a purely legal issue resolved

at summary judgment. The Court answered this question in the negative. *Id.* at 1387.

> Next, Younger complains that Dupree's rule creates a two-track system of summary judgment, in which factual and legal claims follow different routes. Summary judgment is summary judgment, Younger insists, so the claims should all travel the same line. But nothing in Rule 56 demands such uniformity. On the contrary, the Rule provides that summary judgment is appropriate when "the movant shows that there is no genuine dispute as to any material fact *and* the movant is entitled to judgment as a matter of law." Fed. Rule Civ. Proc. 56(a) (emphasis added). Rule 56 thus contemplates that the court will sometimes deny the motion because the facts are genuinely in dispute and other times because the law does not support the movant's position. Fitting the preservation rule to the court's rationale (factual or legal) is therefore consistent with the text.

Id. at 1390.

Further, the procedural issue of whether a circuit court of appeals is required to consider additional evidence submitted at the motion for reconsideration stage following a summary judgment order, especially where such evidence was considered by the district court judge, has not yet been addressed by this Court.

I. Does a Circuit Court of Appeals' Appellate Review of the District Court's Grant of Federal Summary Judgment Under Rule 56 Require the Circuit Court to Review the Evidence Considered by the Trial Judge on a Motion for Reconsideration.

In this case, Cates submitted additional evidence in support of his motion for rehearing/reconsideration.

In this case, the district judge did consider this evidence. The district judge stated in his order on Cates' motion for rehearing/reconsideration:

> Plaintiff also purports to cite evidence "overlooked" by the Court. To be sure, the Court did not discuss each and every piece of evidence cited by the parties. However, none of the evidence emphasized by Plaintiff in the instant Motion change the Court's ultimate conclusion: "[T]here was nothing inaccurate or misleading about Defendant's warning that PH was a rare side effect causing visibly enlarged tissue volume that does not go away on its own and may require surgical intervention." (Doc. 132, p. 11-12).

[App.59a]

But in its opinion, the Eleventh Circuit did not consider that additional evidence considered by the district court. As stated by the Eleventh Circuit in its opinion:

> First, Cates asserts that Zeltiq's warnings failed to alert medical providers about the severity of PAH because PAH is not "a mere increase in fat cells." Cates posits that PAH

> "is fibroplasia" or firm, scar-like tissue. But here, as in *Upjohn*, there is hardly any support in the record that PAH "is fibroplasia." *See Upjohn Co.*, 562 So. 2d at 683 n.4. In fact, none of the five medical articles Cates proffered to oppose summary judgment link CoolSculpting to fibroplasia or suggest that fibroplasia causes PAH. [fn2] On this record, we see no legally significant distinction between a warning about PAH, which Zeltiq provided, and a warning about fibroplasia, which Zeltiq did not provide.

[App.10a-11a (e.s.)]

In Footnote 2 of the opinion, the Eleventh Circuit cites to the five medical articles provided by Cates in response to Zeltiq's motion for summary judgment. The Eleventh Circuit cites to these medical articles for the proposition that these articles do not "link CoolSculpting to fibroplasia or suggest that fibroplasia causes PAH." [App.10a-11a] But the Eleventh Circuit ignored the numerous medical articles submitted by Cates on his motion for reconsideration – which do provide such a link and demonstrates the relationship between CoolSculpting, PAH, and fibroplasia. *See* pp.28-34, *infra*. Other evidence submitted and considered by the district judge on Cates' motion for reconsideration include specific patient case reports showing a relationship between CoolSculpting, PAH, and fibroplasia [Doc. No. 136-1; 136-2; 136-3; 136-5; 117-17; 117-19; 117-22]; expert testimony showing the relationship (*see* pp.24-28, *infra*); and other evidence, including correspondence from the FDA itself, questioning Zeltiq's representation that PAH is "rare". [Doc. No. 136-51] *See* pp.28-34, *infra*.

"Rarity" was a big issue to the Eleventh Circuit, but Cates had submitted medical literature stating that PAH should be reclassified as "common"—not "rare":

> As we are now seeing that PAH occurrence rates reported from clinical settings are trending upwards and have reached a rate of 1.0%, we recommend that PAH should be reclassified as "common" or "frequent" instead of as a "rare" adverse event.

[Doc. No. 136-18] [*See also* Doc. No. 136-23.]

The evidence submitted established that a side effect is "common" if the frequency is equal to or greater than 1% and less than 10%. Rare is less than 0.1%. *Id*.

Cates submitted evidence from which a jury could conclude that Zeltiq manipulated its wording, which affected the accuracy of its warnings, in order to promote successful marketing of its product. In an email from Zeltiq to the FDA on September 11, 2015, Zeltiq told the FDA that it did not want to classify PAH as an "adverse event":

> We retained the original wording of "side effects" rather than using the term "adverse events." These effects are typically expected, minor, and resolve quickly without intervention. These are not considered serious and could potentially cause confusion if the term was changed due to the fact that "adverse event" implies more serious events.

[Doc. No. 117-5]

Note that Zeltiq's User Manual does not reference PAH as an "adverse event". [Doc. No. 117-4, pp.5, 8]

Yet this is contrary to other statements Zeltiq made regarding PAH – that it "may" require surgical intervention. Even Zeltiq's corporate representative recognized that in 2014 PAH was recognized as the "newfound adverse effect of CoolSculpting." [Doc. No. 136-56, p.4][2]

These are inferences and ambiguities to be resolved by a jury—not by way of summary judgment. The federal summary judgment standard does not authorize the court to draw these types of inferences and resolve conflicts in the evidence submitted.

On March 14, 2016, Zeltiq submitted a 10(k) Report to the FDA, citing to literature review for evidence of adverse events caused by CoolSculpting and reporting that there have been only six cases of serious adverse events which include Paradoxical Hyperplasia. By 2016, Zeltiq was aware of thousands of PH reports. [Doc. No. 27-1]

Additional evidence submitted by Cates in his motion for reconsideration included the following:

1. Zeltiq's response to interrogatories in another case whereby it admitted that the incidence of PAH was much higher than it represented in the Cates case. This evidence did not become available to Cates until May 5, 2021—after the summary judgment order. [Doc. No. 136-45]

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[2] Note that PAH is a reportable adverse event under 21 C.F.R. § 803 due to the permanency and severity of the condition, and because surgical intervention is the only means of resolving, or attempting to resolve, the permanent disfiguring condition.

2. A Florida trial court issued an order denying Zeltiq's motion for summary judgment in another case [*Ricky Patel v. Miami Skin and Vein, LLC et al*; Eleventh Judicial Circuit Court in and for Miami-Dade County, Florida, Case No. 2017-006416-CA-01] on the grounds that it found Zeltiq's warning to be inadequate. [Doc. No. 136-12] This was the same warning that Zeltiq relied upon in the present case. Again, this evidence did not become available to Cates until May 4, 2021 – after the summary judgment order.

In this case, the additional evidence which Cates submitted with his motion for reconsideration is part of the summary judgment record on review. *In Re: Louisiana Crawfish Producers*, 852 F.3d 456, 463 (5th Cir. 2017).

The Eleventh Circuit was required to consider this evidence. But it did not.

Further, because the trial court did consider this additional evidence, the appellate court was required to review the denial of the motion for reconsideration *de novo*. *In Re: Louisiana Crawfish Producers*, 852 F.3d 456 (5th Cir. 2017); *Templet v. HydroChem Inc.*, 367 F.3d 473 (5th Cir. 2004) (If materials attached to plaintiffs' motion to alter, amend, and reconsider ruling granting summary judgment to defendants were considered by district court, appropriate appellate standard of review of the denial of motion was *de novo*; however, if district court refused to consider the materials, reviewing court applies the abuse of discretion standard. Fed. R. Civ. P. 59(e), 28 U.S.C.A.).

The *de novo* standard of review applies to a federal appellate court's review of a district court's grant of summary judgment. Therefore, the appellate court reviews the entire record to determine whether a genuine issue of material fact exists and, if not, whether the substantive law was correctly applied, construing the facts in the light most favorable to the nonmoving party. *McBeth v. Himes*, 598 F.3d 708, 722–23 (10th Cir. 2010).

The appellate court must view the entire record in the light most hospitable to the party opposing summary judgment, with all reasonable inferences in that party's favor. *Griggs-Ryan v. Smith*, 904 F.2d 112, 115 (1st Cir. 1990) (citations omitted). Federal appellate courts review summary judgment orders *de novo*, based on their independent review of the entire record. *Trustees of the Plumbers and Pipefitters Nat. Pension Fund v. Plumbing Services, Inc.,* 791 F.3d 436, 446 (4th Cir. 2015).

II. In Reviewing the Grant of Federal Summary Judgment Under Rule 56, Does the Circuit Court of Appeals Have Authority, in Applying Rule 56 to a Particular Case, to Go Outside the Record and Conduct Independent Medical Research to Determine Entitlement to Judgment as a Matter of Law and Whether the Summary Judgment Requirements Have Been Satisfied by the Movant.

Federal Rule of Civil Procedure 56 provides:

> (a) Motion for Summary Judgment or Partial Summary Judgment. A party may move for summary judgment, identifying each claim or defense—or the part of each claim or defense

> —on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. The court should state on the record the reasons for granting or denying the motion.

There is no authority in Rule 56 for a reviewing court to go outside the record and conduct and rely upon its own medical research in resolving a key medical issue which is a key component of a litigant's claim/cause of action.

The reviewing court is bound by the record which the parties have made before it. *See Trustees of the Plumbers & Pipefitters Nat. Pension Fund v. Plumbing Servs., Inc.*, 791 F.3d 436 (4th Cir. 2015) (circuit court of appeals reviews summary judgment orders *de novo*, "based on our independent review of the entire record.")

What the Eleventh Circuit has effectively demonstrated in its opinion [App.1a-38a] is the creation of a new standard and/or modification to the current federal summary judgment standard—whereby the determination of whether summary judgment is appropriate can be based, in whole or in part, on independent medical (non-legal) research related to a key medical fact at issue in the case.

In the present case, a critical issue as to the adequacy of Zeltiq's warning regarding the CoolSculpting procedure was whether Paradoxical Adipose Hyperplasia ("PAH") is fibroplasia. Cates' position was that PAH was not just a "mere increase in fat cells" – but that PAH causes a permanent pathological change to

the tissue; the tissue affected by PAH becomes fibrous and different from regular, untreated tissue resulting in enlarged and sometimes hardened masses that result in disfigurement to the body. Surgeries are required, but not always successful, in removing this scar tissue.

Yet the Eleventh Circuit took it upon itself to conduct its own medical research on this issue. Attached to the opinion is a 2009 medical research article that is not from the record in this case. And in its opinion, the Eleventh Circuit purports to rely on that article for a definition of "adiposity"—that "[a]diposity refers to the amount of adipose (fat) tissue in the body."

The Eleventh Circuit cites to this article and definition as a footnote to its inference/conclusion that "both doctors concluded that Cates's masses were fat cells [fn3]". [App.11a] And *see* p.35-36, *infra*. The Eleventh Circuit also referenced two plastic surgeons Cates had visited after his PAH diagnosis. *See* p.9-10, *supra*. But those doctors specifically stated that liposuction is not expected to fully resolve the physical deformities, and that more surgery may be needed in Cates' case. [Doc. No. 117-2; 117-3; *see also* 117-7] The doctors also stated there was risk for "additional scarring." [Doc. No. 117-3; *see also* 117-7]

The question of adiposity and its relevance to the medical issues in this case—and to the issue of the *seriousness* of the adverse effects of the CoolSculpting procedure—was a big issue in this case.

On the record that was before the district court, there was evidence that Paradoxical Adipose Hyperplasia ("PAH") is fibroplasia—*i.e.*, fibrosis of the affected tissue—which requires multiple types of surgeries to

correct; and in some cases, cannot be corrected by surgery. *See* pp.24-34, *infra*.

Cates had submitted to the district court a declaration from his clinical expert witness [Doc. No. 117-9; 136-1] who explained that based on the medical literature discussing the nature of PH tissue, the condition is consistent with fibrosis. [Docket 117-9; Paragraph 39] *See* pp.24-28, *infra*.

The Eleventh Circuit acknowledged in its opinion that Zeltiq gave no warning for fibroplasia. [App.11a]

III. The Eleventh Circuit Opinion Reflects a Clear Misapprehension of the Federal Summary Judgment Standard in Light of Prior Supreme Court Precedent, and Effectively Denies the Litigant His Constitutional Right to a Jury Trial.

This Court has articulated the federal summary judgment standard as follows:

> [A] "judge's function" at summary judgment is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson,* 477 U.S., at 249, 106 S.Ct. 2505. Summary judgment is appropriate only if "the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. Rule Civ. Proc. 56(a). In making that determination, a court must view the evidence "in the light most favorable to the opposing party." *Adickes v. S.H. Kress & Co.,* 398 U.S. 144, 157, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970);

see also Anderson, supra, at 255, 106 S.Ct. 2505.

Tolan v. Cotton, 572 U.S. 650, 656-57 (2014).[3]

> In the analogous context of summary judgment under Rule 56, we have stated that the court must review the record "taken as a whole." *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). And the standard for granting summary judgment "mirrors" the standard for judgment as a matter of law, such that "the inquiry under each is the same." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 250-251, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); *see also Celotex Corp. v. Catrett,* 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). It therefore follows that, in entertaining a motion for judgment as a matter of law, the court should review all of the evidence in the record.
>
> In doing so, however, the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence. *Lytle v. Household Mfg., Inc.,* 494 U.S. 545, 554-555, 110 S.Ct. 1331, 108 L.Ed.2d 504 (1990); *Liberty Lobby, Inc., supra,* at 254, 106 S.Ct. 2505; *Continental Ore Co. v. Union Carbide & Carbon Corp.,* 370 U.S. 690, 696, n. 6, 82 S.Ct. 1404, 8 L.Ed.2d 777 (1962). "Credibility

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[3] *See also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) (court views the evidence and makes reasonable inferences in the non-movant's favor).

> determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Liberty Lobby, supra,* at 255, 106 S.Ct. 2505. Thus, although the court should review the record as a whole, it must disregard all evidence favorable to the moving party that the jury is not required to believe. *See* Wright & Miller 299.

Reeves v. Sanderson Plumbing Products, Inc., 530 U.S. 133, 150-51 (2000) (e.s.).

The Eleventh Circuit opinion demonstrates an evisceration of this standard—toward what is tantamount to an application of a "seventh juror" standard.

Not only did the Eleventh Circuit not consider the evidence submitted on reconsideration – which became part of the summary judgment record, *In Re: Louisiana Crawfish Producers*, 852 F.3d 456 (5th. Cir. 2017); it ignored clear conflicting evidence on the central issues in this case.

For example, Cates presented the expert declaration of Dr. Kathryn H. Dalton,[4] wherein Dr. Dalton declared:

> 30. Based on Zeltiq Aesthetics Inc.'s internal investigation and based on reports published in medical literature by plastic surgeons that have operated on the PH tissue, PH is not an increase in fat, it is fibrosis of the subcutaneous tissue.

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4 [Doc. No. 117-9, ¶¶ 4-5; 136-1, ¶¶ 4-5]

31. Based on Zeltiq Aesthetics Inc.'s internal investigation, in 2012, it found that although PH masses appear to look like "fat bulges" the condition is actually *fibroplasia*. Fibroplasia is the process of forming fibrous tissue as a wound healing response of the body.

32. Fibroplasia or fibrosis is not an increase of regular healthy fat tissue. Fibrous masses will never resolve on their own and will not react to diet and exercise like regular fat tissue would. The tissue is scar-like in nature and must be physically removed through surgery.

33. The condition caused by the CoolSculpting device, which Zeltiq named Paradoxical Hyperplasia, is *irreversible tissue damage*.

34. PH can only be corrected with various types of surgeries including liposuction, abdominoplasty, excision, and panniculectomy, which Zeltiq knew by 2013.

35. Tissue affected by PH is unpredictable and appears differently depending on the area of the body in which it is developed and on each patient's individual bodily constitution. Skin laxity or looseness of the skin may also occur in the affected area, requiring skin tightening surgery such as abdominoplasty or excision. A person that develops PH masses may need multiple types of surgeries to reconstruct the body. A full reconstruction of the body may not be possible due to contour irregularity and fibrosity of the affected tissue. A patient may develop the PH masses in all areas of the body treated by the

CoolSculpting device, like Plaintiff did in this case.

36. Fibrous tissue is difficult to remove through liposuction. This is why there have been reports in the medical literature of the need for secondary surgery. The fibrous tissue can also grow back after surgery, therefore recurrence of PH after surgery is possible.

37. The 2014 JAMA article written by Zeltiq's consultants (and Dr. Anderson the inventor of Cryolipolysis) is misleading. It not only erroneously names the condition "Paradoxical Adipose Hyperplasia" which suggests that the condition caused by the CoolSculpting device is an increase in fat. It also states that the condition is "a delayed increase in adipose tissue at the treatment site."

38. Zeltiq does not use the word "adipose" in its internal naming of the condition. It consistently uses the term "Paradoxical Hyperplasia." It has also called the condition "hyperplasia of connective tissues."

39. By November 2015, an independent study was published finding "contrary" results to those reported by inventors of the Cryolipolysis process. The study revealed that when comparing PH affected tissue to untreated adipose tissue, the affected tissue was both hypovascular and hypocellular, evidencing damage to blood vessels from Cryolipolysis. The independent authors of the study suggested that based on the microscopic evidence, the masses do not appear to be an

increase of regular adipose tissue but rather a fibrous, less vascularized, more hypoxic effected adipose tissue, wherein in response to the hypoxia/ischemia, resident fibroblasts rearrange the extracellular matrix and produce collagen. The study suggests that there may be other cells (such as macrophages, tissue-resident stem cells, and fibroblasts) that are affected by the CoolSculpting device.

40. Zeltiq Aesthetics Inc. knew that PH is a permanent injury that required multiple surgeries to remedy.

41. By 2017, Zeltiq Aesthetics Inc. knew that PH was the most frequently reported adverse event of CoolSculpting.

* * *

43. The information that Zeltiq Aesthetics Inc. provided to Isis Bucci and other CoolSculpting providers like myself misrepresented the condition caused by the CoolSculpting device.

44. Zeltiq never warned that PH is fibrosis of the treated tissue. This is a fundamental misrepresentation of the condition. An increase in regular fat tissue is different from fibrosis. Fat tissue can be reduced through diet and exercises or could be successfully removed through a single liposuction. To the contrary, fibrous and scar-like tissue is hard to remove and requires multiples surgeries.

45. Zeltiq never warned that PH affected tissue may need to be excised with multiple

> surgeries, including abdominoplasty which is a major abdominal surgery.
>
> 46. Zeltiq's vague language in the User Manual about the nature of the "enlargement of tissue volume" in the treatment area is insufficient to put the users on notice about the nature and gravity of this adverse effect. It also misleadingly states that "surgery may be required" even though it knew that surgery is required to remove PH masses.
>
> 47. Likewise, Zeltiq's slide presentation presents PH as an increase in fat. It also erroneously states that "surgical intervention may be required."

[Doc. No. 117-9; 136-1] (e.s.).

This evidence was never addressed in the Eleventh Circuit opinion.

Other contrary evidence submitted by Cates, which was ignored by the Eleventh Circuit, included the following:

1. Zeltiq was aware PH tissue was consistent with fibroplasia since 2012.
    a. Manufacturer's investigation into PH revealed fibroplasia.
    b. Zeltiq's consultant, Dr. Barbara Egbert, Stanford pathologist, confirmed fibroplasia in PH case. [Doc. No. 117-9, ¶¶ 30-32; 117-17; 136-1; 136-2; 136-3]
2. Declaration of Cates' clinical expert witness that PH tissue is consistent with fibrosis of

the affected tissue. [Doc. No. 117-9, ¶ 39; 136-1, ¶ 39]

3. In 2016 a group of unbiased authors[5] wrote a scholarly article describing their observations of PH affected tissue which were "contrary to prior reports from the inventors". [Doc. No. 136-7] They found evidence of fibrosis of the tissue. [Doc. No. 136-7] Others have noted the presence of fibrosis in PH tissue. [Doc. No. 136-6; 136-7; 136-8; 136-9]

4. Plastic surgeons with personal experience in operating on PH tissue described the difficulty in removing the fibrous and scar-like tissue, noting that multiple surgeries may be required. [Doc. No. 136-8]

5. Moreover, the recurrence of PH after liposuction was reported in a publication in August 2017 by Friedmann et al [Doc. No. 136-17] and discussed again by Wang et al stating: "A case of PAH recurring after liposuction has been described, highlighting that PAH may represent an ongoing concern for some patients." [Doc. No. 136-18]

6. Cates provided numerous medical articles stating that PH tissue is fibrous and scar-like; that the "increased mass of PAH may be due to the fibrosis of the adipose tissue"; "histopathology of PAH demonstrates septal thickening, which may be a result of fibrosis

[5] Not paid by CoolSculpting manufacturers.

stemming from hypoxic injury in adipocytes." [Doc. No. 96-13; 117-26; 136-9][6]

7. In its warnings to providers, Zeltiq stated that PH "will probably not resolve on its own" and that it "can be removed by means of a surgical procedure such as liposuction" and that "surgical intervention may be required." [Doc. No. 132, p.9; 112-10, p.2 of 4 (PDF p.3 of 5)]

8. Cates also submitted FDA findings regarding the purported "rarity" of PH. In July 2015 correspondence by FDA to Zeltiq, FDA informed Zeltiq of its findings:

> "You have defined paradoxical hyperplasia (PH) to be a visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment, and state that PH is permanent, does not self-resolve, and that the correction of PH requires surgical intervention such as liposuction. You state that "PH is a rare side effect with an incidence rate of 0.022%," that it is listed in the warnings section in the user manual and that a root cause analysis of PH has not shown any root cause related to treatment site. You report that since April 2013, PH cases are no longer

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[6] Eleventh Circuit made a statement in its opinion that based on this article, "that fibrosis is the cause of observed PAH is speculative at this point." But this is different from the conclusions of the medical literature, and Cates' position that fibrosis is present in PH tissue and may result from tissue injury.

> reported to the FDA as it was deemed not to meet the reporting criteria (life threatening or serious injury) by the FDA auditor during a routine inspection.

[Doc. No. 136-51]

> "However, you also report that PH has constituted 13% of post-market complaints. During our MDR review, we found 52 reports of PH or treatment site enlargement. In addition, we note that your G140083 Final Report Appendix D (Ultrasound measurement of fat reduction (ZA14-002)) lists treatment site enlargement in 6 of 60 (10%) subjects treated under the conditions of this study. Since the typical timeframe for PH observation is at 3-5 months post-treatment, the shorter 12-week follow-up in this study may not have been sufficient to capture the incidence and severity of treatment site enlargement (paradoxical hyperplasia) that occurred in G140083 subjects. Longer follow-up may be warranted to allow assessment of the incidence and severity of PH in CoolSculpting treated subjects. We also note that your ZA13-005 NSR study report (p24 of 31) lists 2 of 35 (5.7%) per protocol subjects with an approximately 0.6 and 1.4 mm increase in fat layer thickness at 16 week follow-up, suggesting potential PH in 5.7% of subjects who were treated under the conditions of this study.

[Doc. No. 136-51]

9. Cates presented considerable evidence that the rarity of PH and incidence rate of PH is highly questionable.

10. Cates submitted medical articles that reveal that PH is not rare, and there is considerable underreporting. For example, Kelly et al wrote, "Recently, we reported a much higher incidence of [PAH] than the manufacturer's data . . . [PAH] is an underreported clinical entity of significant burden to patients." [Doc. No. 136-38, p.21e.] Similarly, Singh et al states: "In our practice, the incidence of PAH is 0.47% or 2 in 422 cryolipolysis treatments. This is 100 times greater than the reported incidence. The number of confirmed cases in the literature may be an inaccurate representation of the true incidence of [PAH]. . . . " [Doc. No. 136-6, p.478]

11. Zeltiq's statistics regarding number of incidents were skewed/diluted by inclusion of the number of cycles that were "shipped" to a provider, as opposed to actual procedures on patients performed. [Doc. No. 136-2] Even in its response to FDA concerns, Zeltiq confirmed that the PAH rates it provided were based on "confirmed cases and cycles shipped" (and not on patient use). [Doc. No. 136-51] (e.s.)

12. In one of the articles submitted by Cates, November 14, 2017, the authors found that:

> The occurrence rate of PAH has been a subject of discussion amongst physicians and patients, as the manufacturer's

> reported rate seems to be incongruent with clinical experience . . . Overall, this case series adds to and supports the growing body of literature which suggest that the incidence rate of PAH is under-reported . . . we recommend that PAH should be reclassified as 'common' or 'frequent' instead of as a 'rare' adverse event."

[Doc. No. 136-18]

13. The incidence of PAH is estimated to be between 0.021% according to the manufacturer and 0.78% according to the most recent publications, but it is probably underestimated. In our series, we found an incidence rate of 1%. A recent publication has found 16 cases published in the literature. Today, many of the more than 2 million patients treated with cryolipolysis worldwide are affected by PAH. [Doc. No. 136-23 – "*Paradoxical Adipose Hypertrophy (PAH) After Cyrolipolysis*"]

14. The incidence of PAH is 0.47% or 2 in 422 cryolipolysis treatments. This is 100 times greater than the reported incidence. The number of confirmed cases in the literature may be an inaccurate representation of the true incidence of paradoxical adipose hyperplasia due to patient underreporting and delay in development of this side effect. [Doc. No. 136-6]

15. The most recent study, published by Singh et al, showed the incidence of PAH is as high as 2%, almost 100 times higher than that

> reported by the manufacturers. [Doc. No. 136-8]
>
> 16. Little emphasis was given to the most challenging and limiting factor we have encountered: paradoxical adipose hyperplasia. Our reported incidence is 0.78 percent, more than 100 times higher than the device manufacturer – reported incidence of 0.0051 percent. Ours is not a unique experience, as a dermatology practice in Houston, Texas, recently reported a paradoxical adipose hyperplasia incidence of 0.47 percent. Although our treatment numbers are low when considering the popularity of the procedure, we believe that paradoxical adipose hyperplasia is underreported. [Doc. No. 136-11]

None of this evidence was credited to the nonmovant in this case.

In *Tolan v. Cotton*, 572 U.S. 650 (2014), this Court held that the court of appeals interpreted and applied the federal summary judgment standard as a seventh juror. Just as the Eleventh Circuit had done in this case, "the Fifth Circuit failed to view the evidence at summary judgment in the light most favorable to Tolan with respect to the central facts of this case." *Id.* at 657. As stated by this Court in *Tolan*:

> By failing to credit evidence that contradicted some of its key factual conclusions, the court improperly "weigh[ed] the evidence" and resolved disputed issues in favor of the moving party, *Anderson,* 477 U.S., at 249, 106 S.Ct. 2505.

572 U.S. at 657.

As this Court stated in *Tolan v. Cotton*, 572 U.S. 650 (2014):

> Considered together, these facts lead to the inescapable conclusion that the court below credited the evidence of the party seeking summary judgment and failed properly to acknowledge key evidence offered by the party opposing that motion. And while "this Court is not equipped to correct every perceived error coming from the lower federal courts," *Boag v. MacDougall* 454 U.S. 364, 366, 102 S.Ct. 700, 70 L.Ed.2d 551 (1982) (O'Connor, J., concurring), we intervene here because the opinion below reflects a clear misapprehension of summary judgment standards in light of our precedents.

572 U.S. at 659.

The Eleventh Circuit performed its own "medical" research to assist it in speculating on the issue of a causal relationship between PAH and Cates's condition. Causation is a jury question.

The Eleventh Circuit also decided the Informed Consent form signed by Cates was significant. But the effect of that Informed Consent form on the circumstances of this case was a question of fact within the province of the jury. An Informed Consent form given to a patient in the middle of a medical procedure is invalid. Significantly, the question of whether the language in the form itself was sufficient to warn Cates of the risk/dangers of CoolSculpting was a question of fact for the jury. *See State v. Pres. Women's Ctr.*, 937 So.2d 114, 116 (Fla. 2006); *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

With respect to the issue of whether the warnings were adequate to inform the medical provider, the panel states:

> Whether the warning is legally adequate is based on the "reasonable person" or, here, the reasonable medical provider.

[App.12a]

But again, this is a jury function. Whether a warning was adequate is a question of fact for the jury. *See Hayes v. Spartan Chemical Co.*, 622 So.2d 1352, 1354 (Fla. 2d DCA 1993). The inferences the Eleventh Circuit made in its opinion are not the type of inferences to be made by a reviewing court under this Court's summary judgment standard and Rule 56.

Cates submitted evidence from which a jury could conclude that the CoolSculpting warnings did not "accurately, clearly, and unambiguously describe PAH and its consequences." *See* pp.24-34, *supra.*

The issue of whether PAH is fibroplasia, and whether the warnings Zeltiq gave were adequate, are questions of fact for a jury.[7]

The Eleventh Circuit's new standard even conflicts with its prior opinion in *Eghnayem v. Boston Scientific Corporation*, 873 F.3d 1304, 1322 (11th Cir. 2017). In that case, the Eleventh Circuit rejected the manufacturer's argument that its warnings were sufficiently clear that they merited judgment as a matter of law:

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[7] Note further that a party is entitled to have the jury instructed on its theory of its case when the evidence supports that theory. *Aubin v. Union Carbide Corp.*, 177 So.3d 489, 516 (Fla. 2015).

At trial Eghnayem argued that BSC failed to warn doctors that, in the event of a problem with the Pinnacle, it could be difficult or even impossible to remove. The Pinnacle's directions for use contained the following warnings:

> Hysterectomy may be needed in the future; Use of mesh may make future hysterectomies more difficult due to tissue in-growth and scarring.
>
> In the event that infection presents post procedure, the entire mesh many have to be removed or revised.
>
> Tissue responses to the implant could include local irritation at the wound site, vaginal erosion or exposure through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation, foreign body reaction, and inflammation. The occurrence of these responses may require removal or revision of the mesh.

Eghnayem offered expert testimony from Dr. Margolis that these warnings failed to inform doctors that "a patient may need multiple operative procedures to remove the mesh"; that "when you remove portions of the mesh, part of the normal tissue has to come out with it," so that "you can[not] just take the mesh out and everything is fine"; and that mesh implantation ultimately may be "irreversible."

Eghnayem carried her burden here. While the Pinnacle's warnings may have been

> sufficient to notify doctors that multiple procedures might be needed to remove the mesh, the warnings do not even remotely suggest that removal might be impossible. Indeed, the repeated warnings that removal might be necessary suggest just the opposite. And the warnings also failed to notify doctors that removal of the mesh might require removal of healthy tissue as well. The closest they come is by warning that "future hysterectomies [may be] more difficult due to tissue in-growth and scarring," but that warning is not so unambiguous that it would be unreasonable for a jury to hold BSC liable for failure to warn.

Eghnayem, 873 F.3d at 1322.

CONCLUSION

The Eleventh Circuit created a summary judgment standard that essentially usurped the jury function. The Eleventh Circuit ignored a significant part of the record submitted with the motion for reconsideration; evidence submitted in response to the motion for summary judgment; and it conducted its own medical research. The Eleventh Circuit did not credit conflicting evidence to the non-movant, and drew inferences that are to be drawn by a jury and not by a reviewing court under this Court's summary judgment standard and Rule 56.

For the foregoing reasons, Petitioner respectfully requests that the Supreme Court grant review of this matter.

Respectfully submitted,

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