IN THE

United States Court of Appeals

FOR THE SEVENTH CIRCUIT

In Re: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION

MEDICAL MUTUAL OF OHIO,

Plaintiff-Appellant,

—v.—

ABBVIE INC., et al.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION
NO. 1:14-CV-08857
HONORABLE MATTHEW F. KENNELLY

JOINT BRIEF FOR DEFENDANTS-APPELLEES

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New York, New York 10019
(212) 836-7740

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SALLY L. PEI
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601 Massachusetts Avenue, NW
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(202) 942-5000

Attorneys for Defendants-Appellees Auxilium Pharmaceuticals, LLC (f/k/a Auxilium Pharmaceuticals, Inc.) and Endo Pharmaceuticals Inc.

WILLIAM F. CAVANAUGH, JR.
JONAH M. KNOBLER
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000

Attorneys for Defendants-Appellees AbbVie Inc., Abbott Laboratories and Abbott Products Inc.

DAVID E. STANLEY
JANET H. KWUON
LISA M. BAIRD
REED SMITH LLP
355 South Grand Avenue, Suite 2900
Los Angeles, California 90071
(213) 457-8036

Attorneys for Defendants-Appellees Eli Lilly and Company, Lilly USA, LLC, Acrux Commercial Party LTD and Acrux DDS Party LTD

(*Counsel continued on inside cover*)

JAMES W. MATTHEWS
KATY E. KOSKI
FOLEY & LARDNER LLP
111 Huntington Avenue
Boston, Massachusetts 02199
(617) 502-3242

DAVID B. GOROFF
FOLEY & LARDNER LLP
321 North Clark Street, Suite 2800
Chicago, Illinois 60654
(312) 832-4500

Attorneys for Defendants-Appellees Actavis PLC, n/k/a Allergan PLC, Actavis, Inc, n/k/a Allergan Finance, LLC, Actavis Pharma, Inc., Watson Laboratories, Inc., n/k/a Actavis Laboratories UT, Inc. and Anda, Inc.

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 19-1500

Short Caption: Medical Mutual of Ohio v. AbbVie Inc.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statement be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

[ ] **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P 26.1 by completing item #3):

AbbVie Inc.

Abbott Laboratories (listed incorrectly on docket as "Abbott Laboratories Inc.")

Abbott Products Inc.

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Patterson Belknap Webb & Tyler LLP

(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

Abbott Laboratories is parent company to Abbott Products Inc.

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

N/A

Attorney's Signature: s/ Jonah M. Knobler Date: April 9, 2019

Attorney's Printed Name: Jonah M. Knobler

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ____ **No** X

Address: 1133 Avenue of the Americas
New York, NY 10036

Phone Number: (212) 336-2000 Fax Number: (212) 336-2222

E-Mail Address: jknobler@pbwt.com

☑

CERTIFICATE OF SERVICE

Certificate of Service When All Case Participants Are CM/ECF Participants

I hereby certify that on April 9, 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ Jonah M. Knobler

☐

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counsel / party:	address:
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

s/_____

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 19-1500

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Patterson Belknap Webb & Tyler LLP

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Abbott Laboratories is parent company to Abbott Products Inc.

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

N/A

Attorney's Signature: s/ William F. Cavanaugh, Jr. Date: April 9, 2019

Attorney's Printed Name: William F. Cavanaugh, Jr.

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** X **No** _____

Address: 1133 Avenue of the Americas
New York, NY 10036

Phone Number: (212) 336-2000 Fax Number: (212) 336-2222

E-Mail Address: wfcavanaugh@pbwt.com

☑

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s/ William F. Cavanaugh, Jr.

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counsel / party:	address:

s/_____

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(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Foley & Lardner LLP, James W. Matthews, David B. Goroff, Jason L. Drori, Jesse Lee Beringer, Katy E. Koski

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i) Identify all its parent corporations, if any; and

Allergan PLC

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

N/A

Attorney's Signature: /s/ David B. Goroff Date: 4/11/2019

Attorney's Printed Name: David B. Goroff

Please indicate if you are Counsel of Record for the above listed parties pursuant to Circuit Rule 3(d). Yes ____ No x

Address: Foley & Lardner LLP, 321 N. Clark St., Suite 2800, Chicago, IL 60654

Phone Number: 312-832-4500 Fax Number: 312-832-4700

E-Mail Address: dgoroff@foley.com

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counsel / party:	address:

s/_____

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Allergan PLC

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N/A

Attorney's Signature: /s/ Katy E. Koski Date: 4/12/2019

Attorney's Printed Name: Katy E. Koski

Please indicate if you are Counsel of Record for the above listed parties pursuant to Circuit Rule 3(d). Yes ____ No X

Address: Foley & Lardner LLP, 111 Huntington Avenue, Suite 2500, Boston, MA 02199-7610

Phone Number: 617-342-4000 Fax Number: 617-342-4001

E-Mail Address: kkoski@foley.com

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s/ Katy E. Koski

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Allergan PLC

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

N/A

Attorney's Signature: /s/ James W. Matthews Date: 4/11/2019

Attorney's Printed Name: James W. Matthews

Please indicate if you are Counsel of Record for the above listed parties pursuant to Circuit Rule 3(d). Yes x No

Address: Foley & Lardner LLP, 111 Huntington Avenue, Suite 2500, Boston, MA 02199-7610

Phone Number: 617-342-4000 Fax Number: 617-342-4001

E-Mail Address: jmatthews@foley.com

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counsel / party:	address:

s/_____

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Appellate Court No: 19-1500

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(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P 26.1 by completing item #3):

Auxilium Pharmaceuticals, LLC

Endo Pharmaceuticals Inc.

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Arnold & Porter Kaye Scholer LLP

(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

Please see attached sheet

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

Please see attached sheet

Attorney's Signature: s/ Robert J. Katerberg Date: April 9, 2019

Attorney's Printed Name: Robert J. Katerberg

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** X **No** _____

Address: 601 Massachusetts Ave., NW
Washington, DC 20001

Phone Number: (202) 942-5000 Fax Number: (202) 942-5999

E-Mail Address: robert.katerberg@arnoldporter.com

(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

Auxilium Pharmaceuticals, LLC is a limited liability company owned by its members Endo Pharmaceuticals Inc. and Generics International (US) 2, Inc.

Endo Pharmaceuticals Inc. and Generics International (US) 2 Inc. are each indirectly owned by their parent public limited company Endo International plc through subsidiaries. None of said subsidiaries is publicly held.

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock.

Endo International plc, a publicly held company, indirectly (through subsidiaries, none of which is publicly held) owns all of the interests in Auxilium Pharmaceuticals, LLC and Endo Pharmaceuticals Inc. No publicly held company owns 10% or more of Endo International plc's stock.

☑

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counsel / party:	address:

s/_____

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 19-1500

Short Caption: In Re: Testosterone Replacement Therapy Products Liability Litigation

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

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(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P 26.1 by completing item #3):

Defendants and Appellees Eli Lilly and Company; Lilly USA, LLC; Acrux Commercial Party LTD.; and Acrux DDS Party LTD.

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Reed Smith LLP - David E. Stanley, Janet H. Kwuon, Lisa M. Baird

(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

Eli Lilly and Company is the publicly-traded ultimate parent of Defendant Lilly USA, LLC.; Acrux LTD. is the ultimate parent of the Acrux defendants-appellees.

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

Eli Lilly and Company and Acrux LTD. state that they have no parent corporation and no publicly held corporation owns 10% or more of their stock.

Attorney's Signature: s/ David E. Stanley Date: 04/30/2019

Attorney's Printed Name: David E. Stanley

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** X **No** ____

Address: Reed Smith LLP, 355 South Grand Avenue, Suite 2900, Los Angeles, CA 90071

Phone Number: 213.457.8085 Fax Number: 213.457.8080

E-Mail Address: DStanley@reedsmith.com

PROOF OF SERVICE

I, Veronica Barreto, declare:

I am employed in the County of Los Angeles, State of California. My business address is Reed Smith LLP, 355 South Grand Avenue, Suite 2900, Los Angeles, California 90071. I am over the age of eighteen years and not a party to the action in which this service is made.

I hereby certify that on April 30, 2019, I electronically filed the foregoing:

APPEARANCE AND CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the appellate CM/ECF system. Participants in the case who are registered appellate CM/ECF users will be served by the appellate CM/ECF system.

I further certify that the below participant(s) in the case is not a registered appellate CM/ECF user(s). Therefore, I served participant(s) via U.S. Postal Mail on this date at the addresses listed below.

Allan Kanner, Esq. (LA Bar No. 20580)
Conlee S. Whiteley, Esq. (LA Bar No. 22678)
Layne C. Hilton, Esq. (LA Bar No. 36990)
KANNER & WHITELEY, L.L.C.
701 Camp Street
New Orleans, Louisiana 70130
Tel: (504) 524-5777
Fax: (504) 524-5763

Ruben Honik (PA Bar No. 33109)
David J. Stanoch (PA Bar No. 91342)
GOLOMB & HONIK P.C.
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Tel: (215) 985-9177

Additional Attorneys for Plaintiff and Appellant Medical Mutual of Ohio

I declare under penalty of perjury under the laws of the United States that the above is true and correct. Executed on April 30, 2019, at Los Angeles, California.

Veronica Barreto

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 19-1500

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Eli Lilly and Company is the publicly-traded ultimate parent of Defendant Lilly USA, LLC.; Acrux LTD. is the ultimate parent of the Acrux defendants-appellees.

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

Eli Lilly and Company and Acrux LTD. state that they have no parent corporation and no publicly held corporation owns 10% or more of their stock.

Attorney's Signature: s/ Janet H. Kwuon Date: 04/30/2019

Attorney's Printed Name: Janet H. Kwuon

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ____ **No** X

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PROOF OF SERVICE

I, Veronica Barreto, declare:

I am employed in the County of Los Angeles, State of California. My business address is Reed Smith LLP, 355 South Grand Avenue, Suite 2900, Los Angeles, California 90071. I am over the age of eighteen years and not a party to the action in which this service is made.

I hereby certify that on April 30, 2019, I electronically filed the foregoing:

APPEARANCE AND CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the appellate CM/ECF system. Participants in the case who are registered appellate CM/ECF users will be served by the appellate CM/ECF system.

I further certify that the below participant(s) in the case is not a registered appellate CM/ECF user(s). Therefore, I served participant(s) via U.S. Postal Mail on this date at the addresses listed below.

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Additional Attorneys for Plaintiff and Appellant Medical Mutual of Ohio

I declare under penalty of perjury under the laws of the United States that the above is true and correct. Executed on April 30, 2019, at Los Angeles, California.

Veronica Barreto

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 19-1500

Short Caption: In Re: Testosterone Replacement Therapy Products Liability Litigation

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statement be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

[ ] **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P 26.1 by completing item #3):

Defendants and Appellees Eli Lilly and Company; Lilly USA, LLC; Acrux Commercial Party LTD.; and Acrux DDS Party LTD.

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Reed Smith LLP - David E. Stanley, Janet H. Kwuon, Lisa M. Baird

(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

Eli Lilly and Company is the publicly-traded ultimate parent of Defendant Lilly USA, LLC.; Acrux LTD. is the ultimate parent of the Acrux defendants-appellees.

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

Eli Lilly and Company and Acrux LTD. state that they have no parent corporation and no publicly held corporation owns 10% or more of their stock.

Attorney's Signature: s/ Lisa M. Baird Date: 04/09/2019

Attorney's Printed Name: Lisa M. Baird

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** X **No** ____

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PROOF OF SERVICE

I, Veronica Barreto, declare:

I am employed in the County of Los Angeles, State of California. My business address is Reed Smith LLP, 355 South Grand Avenue, Suite 2900, Los Angeles, California 90071. I am over the age of eighteen years and not a party to the action in which this service is made.

I hereby certify that on April 9, 2019, I electronically filed the foregoing:

APPEARANCE AND CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the appellate CM/ECF system. Participants in the case who are registered appellate CM/ECF users will be served by the appellate CM/ECF system.

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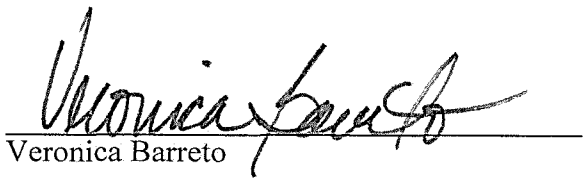
Additional Attorneys for Plaintiff and Appellant Medical Mutual of Ohio

I declare under penalty of perjury under the laws of the United States that the above is true and correct. Executed on April 9, 2019, at Los Angeles, California.



Veronica Barreto

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INTRODUCTION

In this civil RICO case, Plaintiff-Appellant Medical Mutual of Ohio ("MMO"), a health insurer, alleged that Defendants-Appellees misrepresented the safety and efficacy of their FDA-approved testosterone-replacement therapy ("TRT") medications. As a result, MMO alleged, it paid for portions of TRT prescriptions for its insureds when it otherwise would have refused coverage. Characterizing Defendants' promotion as "racketeering," MMO sought those payments back, trebled.

While proceedings were underway, this Court decided *Sidney Hillman Health Center of Rochester v. Abbott Labs.*, 873 F.3d 574 (7th Cir. 2017) ("*Hillman*"), a similar RICO case brought by insurers alleging misrepresentations about drug safety and efficacy. *Hillman* affirmed the dismissal of the insurers' claims on proximate-cause grounds because the alleged misrepresentations were "directed at physicians," not the plaintiffs—and "the causal chain" was thus "too long." *Id.* at 575, 578. If *Hillman* left open any path to RICO recovery in such cases, it is only "when misrepresentations are made *directly* to [insurers], *leading them to add* [the relevant] drugs to their formularies…." *Id.* at 578 (emphases added).

Below, MMO insisted that, unlike the *Hillman* plaintiffs, it relied on direct misrepresentations from Defendants in determining the coverage status of Defendants' TRTs. And it had every opportunity to develop evidence supporting that theory. MMO obtained millions of pages of Defendants' documents; deposed 30 of their employees; and subpoenaed dozens of their vendors and consultants. MMO also

had access to reams of discovery from the related TRT product-liability MDL, overseen by the same District Judge.

But all this discovery failed to uncover a single statement that any Defendant made to MMO about TRT safety or efficacy—false or otherwise. *A fortiori*, there was no evidence that MMO made any coverage-related decision relying on misrepresentations from Defendants. To the contrary, discovery showed that, well after it filed this lawsuit, MMO continued to cover Defendants' TRTs without any restrictions. Only after Defendants moved to dismiss on that basis did MMO consider limiting access—and even then, MMO waited over a year to adopt only token restrictions that would not have prevented payment for the disputed prescriptions.

Defendants therefore moved for summary judgment, arguing (among other things) that MMO could not show proximate cause under *Hillman*. The District Court conducted a painstaking review of the record. It gave MMO the benefit of every reasonable inference, while appropriately declining to "draw[] inferences … supported by only speculation or conjecture." And, applying that standard, it found proximate cause lacking. In particular, MMO conceded during briefing that it had not received direct misrepresentations from Actavis, Auxilium, or Endo. The District Court found no evidence that the remaining Defendants—AbbVie and Lilly—had made direct misrepresentations either. And even assuming, *arguendo*, that Defendants had made such misrepresentations, the District Court found no evidence that they had *any* impact on MMO's coverage-related decisions.

MMO provides no reason to disturb that judgment. It devotes much of its brief to arguing for a "flexible" proximate-cause test that does not require direct misrepresentations or reliance, even though *Hillman*—a recent, published decision of this Court—considered and rejected identical arguments. Remarkably, MMO's brief does not cite *Hillman* even once. To the extent MMO argues that a reasonable jury could "infer" that it received and relied on direct misrepresentations, all it offers are conclusory statements, mischaracterizations of the record, and speculation.

In short, the District Court's summary-judgment order—reached after years of intimate involvement in this case and the related MDL—was well-reasoned, fair, and correct. It should be affirmed. Alternatively, this Court should affirm on one or more of the grounds that the parties briefed but the District Court did not reach: (1) lack of conduct on behalf of a RICO "enterprise"; (2) lack of evidence of damages; (3) statute of limitations; and (4) lack of evidence of a conspiracy.

JURISDICTIONAL STATEMENT

MMO's jurisdictional statement is complete and correct.

COUNTERSTATEMENT OF THE ISSUES

1. Did the District Court correctly grant summary judgment to Defendants for lack of proximate cause, where (a) no Defendant ever made a direct misrepresentation to MMO about the safety or efficacy of its drug; and (b) MMO never made any decision about how to cover any Defendant's drug on the basis of such alleged misrepresentations?

2. Alternatively, was summary judgment for Defendants proper because (a) MMO failed to show that Defendants' alleged conduct was undertaken on behalf

of a RICO "enterprise"; (b) MMO adduced no evidence of damages; (c) MMO's claims were time-barred; and/or (d) as to its conspiracy claim, MMO lacked evidence of a conspiracy among Defendants?

COUNTERSTATEMENT OF THE CASE

A. Medical And Regulatory Background Concerning TRT[1]

1. Hypogonadism

Hypogonadism—sometimes informally called "low testosterone" or "low T"—is a medical condition characterized by abnormally low levels of testosterone. [A-3; D348-1 Ex.23 ¶¶74, 201; D348-1 Ex.25 ¶64; D348-1 Ex.26 ¶18.][2] There are two types of hypogonadism: "primary," in which the testes cannot produce normal amounts of testosterone, and "secondary" (or "hypogonadotropic"), in which the pituitary and/or hypothalamus does not properly signal the testes to produce testosterone. [A-3; D348-1 Ex.23 ¶75; D348-1 Ex.26 ¶¶19-20.] Symptoms of hypogonadism include reduced libido and sexual activity; decreased erections; low bone-mineral density; decreased energy; depressed mood; reduced muscle bulk/strength; and increased body fat. [A-3; D445 Ex.32 at 2537; D348-1 Ex.16 at -5125.]

Both forms of hypogonadism can have many underlying causes, including genetic conditions, physical trauma, exposure to radiation or toxins, and co-

[1] Defendants provide this medical and regulatory background for context only. The District Court made no rulings on these issues, and this Court need not find that these facts have been established beyond genuine dispute to affirm.

[2] Citations beginning with "A" refer to MMO's Appendix. Citations beginning with "D" refer to the corresponding ECF docket number in the District Court for the *MMO* case (No. 1:14-cv-08557). Citations beginning with MDL-D refer to the corresponding ECF docket number in the District Court for the *TRT* MDL as a whole (No. 1:14-cv-01748).

morbidities associated with aging. [D348-1 Ex.23 ¶¶74-75, 111; D348-1 Ex.26 ¶¶19-20, 33-34, 110.] Primary or secondary hypogonadism in aging men is sometimes informally called "age-related" hypogonadism or "andropause." [D348-1 Ex.26 ¶¶33-34.] MMO uses the term "classical" hypogonadism to refer to primary or secondary hypogonadism that is *not* "age-related."

2. Defendants' TRTs

Defendants are manufacturers of five TRTs approved by FDA to treat hypogonadism. Actavis[3] manufactures Androderm (approved 1995); AbbVie[4] manufactures AndroGel (2000); Auxilium manufactures Testim (2002); Lilly[5] manufactured Axiron (2010); and Endo manufactures Fortesta (2010). [D424 Ex.110 at 67-68; D424 Ex.109 at 39-40.] Androderm is an adhesive patch; the others are gels. [*Id.*] Because Defendants' TRTs are applied to the skin, they are called "topical" TRTs, to distinguish them from other forms, such as oral, buccal, and injectable.

The FDA-approved labeling of Defendants' TRTs has always stated their approved indication: "primary" and "hypogonadotropic [*i.e.*, secondary] hypogonadism," either "congenital or acquired." [D348-1 Ex.23 ¶110; D348-1 Ex.16 at -5127.] Often, that labeling also identified hypogonadism's symptoms. For example, for

[3] "Actavis" includes Actavis plc; Actavis, Inc. n/k/a Allergan Finance, LLC; Actavis Pharma, Inc.; Watson Laboratories, Inc. n/k/a Actavis Laboratories UT, Inc.; and Anda, Inc. Anda is a wholesaler that does not manufacture products and had no dealings regarding TRT with MMO or any other insurer. It is no longer owned by Allergan, the successor to Actavis.

[4] "AbbVie" includes AbbVie Inc.; Abbott Laboratories; and Abbott Products Inc. Some AbbVie documents refer to Solvay Pharmaceuticals and Unimed Pharmaceuticals, historical manufacturers of AndroGel that AbbVie acquired in 2010.

[5] "Lilly" includes Eli Lilly and Company; Lilly USA, LLC; Acrux Commercial Party Ltd.; and Acrux DDS Party Ltd.

most of the time period at issue, the AndroGel 1.0% label listed "impotence," "decreased sexual desire," "fatigue," "loss of energy," and "mood depression" as symptoms of hypogonadism and observed that the drug's clinical trial showed, *e.g.*, "significant improvement in libido" and "positive effects on mood and fatigue."[6]

3. FDA's Changing Views On TRT

MMO's allegations about TRT center on (a) its use for "age-related" hypogonadism and (b) its alleged association with cardiovascular events such as heart attacks and strokes. Defendants briefly summarize FDA's treatment of and public statements about these subjects.

a. TRT And "Age-Related" Hypogonadism

For many years, FDA considered TRT safe and effective to treat low testosterone in all adult men, including aging men. In 1970, it confirmed that TRT was "effective" to treat "[m]ale climacteric symptoms … secondary to testosterone deficiency," *Certain Androgen Preparations*, 35 Fed. Reg. 12356, 12357 (Aug. 1, 1970)—referring to a complex of sexual and non-sexual symptoms associated with age-related declines in testosterone, *see* Am. Psychological Ass'n Dictionary of Psychology, *Male Climacteric*, https://dictionary.apa.org/male-climacteric.

Consistent with that view, when FDA approved Defendants' TRTs between 1995 and 2010, it endorsed their use to treat primary or secondary hypogonadism—

[6] MMO incorrectly claims that FDA "refused" to permit language regarding symptom improvement in TRT labeling. [AOB 8.] MMO's cited exhibit reflects FDA's deletion of a proposed sentence from AndroGel's *Patient* Package Insert. [D268 Ex.20 at -028.] That is distinct from the *Physician* Package Insert directed to prescribers, where FDA expressly authorized symptom-improvement language.

"congenital *or acquired*"—without specifying that the origin of the patient's hypogonadism must be unrelated to aging (*i.e.*, what MMO calls "classical"). [D348-1 Ex.23 ¶¶77-83, 108, 110-11; D348-1 Ex.16 at -5125.] Indeed, the population for AndroGel's pivotal clinical trial—whose design FDA reviewed and approved—contained many men whose hypogonadism was expressly labeled "age-related." [D348-1 Ex.23 ¶93; D348-1 Ex.26 ¶¶68-76.]

Subsequently, FDA changed its position. In 2015—after MMO filed this lawsuit—FDA carved primary and secondary hypogonadism associated with aging out from the existing scope of approval and required TRT labels to state that "[s]afety and efficacy … in men with 'age-related hypogonadism' … have not been established." [D445 Ex. 37; D436 Ex.56; D348-1 Ex.23 ¶¶296-97.] Since then, rigorous new studies have found that TRT safely provides symptom relief in men with "age-related" hypogonadism. [D348-1 Ex.23 ¶¶136-38; D348-1 Ex.24 at 6-7; D348-1 Ex.25 ¶¶192-99, 203-05; D348-1 Ex.26 ¶¶157-164, 214-15; D348-1 Ex.27 ¶¶151-61.]

b. TRT And Cardiovascular Safety

When FDA approved Defendants' TRTs, it rigorously reviewed their clinical trial results and found no basis for concern that the medications could increase the risk of cardiovascular events. [D348-1 Ex.23 ¶¶107-09, 183-88, 264-70; MDL-D1745 Ex. 68 at E68-104-14 (FDA Memorandum of Review for AndroGel 1.62% concluding that the evidence "do[es] not support an association between TRT and increased risk of cardiovascular events").]

However, between 2010 and 2014, four published studies claimed to have detected an association between TRT and cardiovascular events for the first time. [MDL-D1745 Ex.4 at 7-14; D348-1 Ex.24 at 8, 22-29; D348-1 Ex.25 ¶¶159, 173-90; D348-1 Ex.26 ¶¶224-38.] In January 2014, FDA issued a public Drug Safety Communication stating that, because of these new studies, it would "investigat[e] the risk of stroke, heart attack, and death in men taking [TRT]." [MDL-D1745 Ex.71.] That July, FDA published an analysis of these studies, concluding that they had "significant limitations"; that "other studies … contradict[ed]" them; and that there remained "*insufficient evidence of a causal link* between [TRT] and adverse cardiovascular outcomes." [MDL-D1745 Ex.4 at 5, 15-16.]

Nonetheless, in March 2015—months after this suit was filed—FDA decided, in an excess of caution, to add carefully qualified language to all TRT labels. [D445 Ex.37.] That language stated:

> [E]pidemiologic studies and randomized controlled trials have been *inconclusive* for determining the risk of major adverse cardiovascular events (MACE)…. Some studies, *but not all*, have reported an increased risk of MACE…. Patients should be informed of this *possible* risk when deciding whether to use or continue to use [TRT].

[D436 Ex.56 (emphasis added).] Since that time, several new studies also have found either no increased risk of cardiovascular events, or a *decreased* risk, in TRT users. As of the close of discovery, no new studies had found an increased risk. [D348-1 Ex.23 ¶¶303-04; D348-1 Ex.24 at 29-50; D348-1 Ex.25 ¶¶192-213; D348-1 Ex.26 ¶¶199-215; D348-1 Ex.27 ¶¶142-208; MDL-D2737.]

B. Insurance Coverage Of Prescription Drugs

1. Formularies And Utilization Management

Insurers that offer prescription-drug coverage typically pay or reimburse their insureds for some portion of the cost of eligible prescriptions.[7] [D424 Ex.110 at 62-63.] Insurers have various tools for limiting expenditures on prescription medications. The most basic is the "formulary," a list of medications that the insurer agrees to cover. [*Id.* at 26, 36, 68.] An insurer can generally avoid paying for a drug by refusing to include it on, or removing it from, its formulary. [*Id.* at 38.] Insurers may also employ more fine-grained "utilization restrictions" or "utilization management" tools, including prior authorization and step therapy. Under prior authorization, a drug will be covered only if the patient's doctor first certifies to the insurer that certain criteria are met—*e.g.*, that the patient has a particular diagnosis. Under step therapy, a drug will be covered only if the patient has unsuccessfully tried one or more other (usually cheaper) drugs. [*Id.* at 27, 30, 58-60.]

"Financial considerations" play a major—often decisive—role in determining "whether different drugs will be covered … and whether utilization restrictions will be imposed." [*Id.* at 27-28.] Manufacturers routinely jockey for favorable status by offering "advantageous rebate terms … to encourage [an insurer] to move a competitor drug to a [less favorable] tier or knock it out of the formulary altogether." [*Id.* at 53-54.] MMO's brief recognizes the pivotal role of financial considerations in de-

[7] Insurers generally do not receive product directly from, or pay money directly to, pharmaceutical manufacturers. [D424 Ex.110 at 142-44.] MMO never alleged—let alone presented evidence—that it had any contractual or other buyer-seller relationship with Defendants.

termining status on its formulary. [AOB 5 ("A drug receives preferred [formulary] status either because a favorable price [was] negotiated …, or because favorable rebates would be awarded to [MMO]….").]

2. How Coverage Determinations Are Made

An insurer may manage its formulary internally, or it may outsource that role to a business known as a Pharmacy Benefit Manager or "PBM." The leading PBMs—including MMO's PBM, Express Scripts, Inc. ("ESI")—are enormous businesses, each managing pharmacy benefits for more than 60 million insureds. [D424 Ex.110 at 32.] As some of the most sophisticated entities in the health-care sector, these PBMs have "large clinical staff[s] that can devote time to conducting independent research." [*Id.* at 50.]

Whether at an insurer or a PBM, decisions regarding formulary status and utilization restrictions are ordinarily made by a Pharmacy and Therapeutics ("P&T") Committee. [*Id.* at 41.] P&T Committees are composed of pharmacists and physicians capable of assessing drug safety, efficacy, and cost-effectiveness. [*Id.* at 42-44.] As the District Court found, the process by which P&T Committees select sources to review and come to their conclusions is "complex and individualized." [D406 at 42-44.] They generally evaluate a wide variety of materials, including published research, statements of government bodies and professional societies, experience abroad, first-hand knowledge, and financial data. [D424 Ex.110 at 36-37, 42, 50-51.] They *may or may not* consider literature created by drug manufacturers—but as a general rule, they do not rely "solely or even principally" on such ma-

terials. [*Id.* at 37, 49, 96.] MMO's VP of Pharmacy admitted that this is true of MMO. [*Id.* at 37-38, 96; D416 Ex.4 at 233-34.]

C. MMO

1. MMO's Approach To Pharmaceutical Coverage

MMO is an Ohio-based health insurer. At all relevant times, its pharmacy benefits were managed by an outside PBM. From 2000-2010, that was Medco, "a large, sophisticated, national PBM." [D424 Ex.110 at 44.] In 2012, ESI, "an even larger PBM," acquired Medco and assumed that role. [*Id.*] MMO adopted Medco/ESI's formulary wholesale, so it never reviewed individual drugs for formulary inclusion. [A26; D415 ¶¶13-14.]

However, MMO claimed that its Pharmacy Quality Management ("PQM") Committee—its version of a P&T Committee—made its own decisions (with Medco/ESI's input) on utilization restrictions, such as prior authorization and step therapy. [AOB 5-6; D434 ¶¶13-14.] As the District Court found, MMO's use of these restrictions "did not comport with industry standards." [D406 at 34; D424 Ex.110 at 68.] MMO's VP of Pharmacy conceded that MMO employed them less frequently than "the industry generally." [D424 Ex.110 at 70; D348-1 Ex. 21 at 49.]

2. MMO's Coverage Of TRT

The record showed that, over the relevant time period, MMO considered how to cover TRT on just a handful of occasions. There was no evidence that its decision on any of these occasions was influenced, in whole or in part, by any information provided by Defendants, directly or indirectly.

a. 2004: MMO Disregards Its PBM's Recommendation Regarding "Andropause."

From 2000 to 2004, MMO had no restrictions on its coverage of any TRT. [D424 Ex.109 at 54.] In January 2004, Medco adopted a new policy position on androgens (including TRT), specifying that "coverage [should] not be provided for … andropause." [D424 Ex.110 at 73.] Medco advised MMO of that recommendation, but MMO did not adopt it. [*Id.* at 73-75; A11.] There was no evidence that MMO considered any representations from Defendants in connection with this decision.

b. 2008-2009: MMO Adopts Prior Authorization For TRT, But Specifically Exempts Topical TRTs.

At three meetings in 2008, MMO's PQM Committee discussed adopting a prior-authorization requirement for androgens (including TRT) to limit coverage to "conditions for which they have been shown to be effective." [D424 Ex.110 at 73-75.] Medco representative Dan Resetar presented two choices: one applicable to all androgens, and one that exempted topical forms. [*Id.*] MMO chose the latter, leaving Defendants' TRTs unrestricted. [*Id.*] The meeting minutes list two reasons for this choice. First, Resetar "suggested" that "injectables, tablets and buccals" were "the most abused forms." [D437, Ex. 70.] Second, it was noted that topical TRTs "have rebates." [*Id.*] There was no evidence that Resetar's comments or MMO's decision was influenced by any representations from Defendants.

At the close of 2008, Medco provided MMO with a summary document on "Androgens," which "discussed the alleged increase in the number of prescriptions being written for … 'andropause'" and a study purporting to find "no benefit" from such prescriptions. [*Id.*] MMO made no changes to its prior-authorization policy

upon receiving this document. [*Id.*] There was no evidence that any representations from Defendants played any role in this decision.

In September 2009, MMO's PQM Committee revisited its prior-authorization policy for androgens. It felt that "there [was] enough opportunity for abuse … to justify continuing" that policy and opted to retain it without expansion or modification. [*Id.* at 76.] Again, there was no evidence that any representations from Defendants played any role in this decision.

c. 2012: MMO Disregards ESI's Recommendation To Extend Prior Authorization To Topical TRTs.

In August 2012, shortly after acquiring Medco, ESI sent MMO a memo that "reviewed ESI's prior authorization policy" for TRT and "stated that prior authorization was recommended for topical testosterone products." [D424 Ex.110 at 77.] ESI's memo "highlight[ed] the differences between MMO's prior authorization policy and [its own] policy," noting that MMO's policy omitted topical TRT. [*Id.*] Despite this recommendation, MMO made no changes to its policy. [*Id.*] There was no evidence that any representations from Defendants played any role in this decision.

d. 2014: MMO Adopts ESI's Preferred Drug Step Therapy Program And Ignores FDA's Drug Safety Communication.

Between 2012 and 2014, an AbbVie representative occasionally communicated with MMO about an ESI program called Preferred Drug Step Therapy ("PDST"). [A32-33; D444 ¶28.] PDST was an option ESI offered to its insurer-clients in many drug categories, not just TRT. If an insurer chose to participate, its insureds would need to try one of ESI's "preferred" drugs in a category without therapeutic success before obtaining coverage for a "non-preferred" drug. [D444 ¶28.] In exchange for

imposing this requirement, the insurer would receive "enhanced rebates" from ESI on prescriptions in the category. [*Id.*] In the TRT category, ESI's "preferred" drugs were AndroGel and Axiron, due to their favorable rebate levels. [*Id.*]

In February 2014, MMO agreed to participate in the PDST program for TRT.[8] [A33.] As the District Court found, "no jury could reasonably conclude that MMO made [this] decision … based on safety or efficacy criteria provided by the [D]efendants." [*Id.*] The relevant discussions between AbbVie and MMO referred solely to the extra "rebates" MMO could obtain. [D444 ¶28; *see, e.g.*, D421 Ex.97 (email from AbbVie representative suggesting MMO "take a look" at PDST to "maximiz[e] … rebates available to [it] through ESI").] Internally, MMO called it "the testosterone PDST program *for driving rebates*" and expected to net an "annual savings of $309K" by adopting it. [D444 ¶28.] As the District Court noted, MMO has never argued—and there is no evidence—that "it gave preference to AndroGel and Axiron via the [PDST] policy because it believe[d] those drugs were safer or more effective than the [non-preferred] drugs." [A13.]

Meanwhile, as noted above, FDA announced in January 2014 that it was "investigating" whether TRT might raise cardiovascular risk. *Supra* at 8. In February 2014, MMO received an email advising of FDA's investigation and asserting that TRT had been "linked to serious health risks" such as "[h]eart attack," "[s]troke," and "even death." [D424 Ex.110 at 78; D436 Ex. 46.] MMO pharmacist Shaleen Joshi forwarded the email to VP of Pharmacy Katharine Canaday. Joshi's accom-

[8] At the same time, MMO chose to participate in the PDST program for another drug category: fenofibrates. [A33.]

panying message was: "Oh the irony. We just recommended [AndroGel and Axiron] for the [ESI] step therapy program. I am guessing we still move forward….?" [*Id.*][9] Canaday responded: "Agree to proceed with st [step therapy]. It will most likely come back that the drugs can still be used, so we should have in place." [*Id.*] Thus, as the District Court found, "MMO made a calculated decision to continue" its existing coverage of TRT, "notwithstanding its actual knowledge of" the FDA investigation and the reasons therefor. [D406 at 32; D415 ¶16.]

e. 2016-2017: MMO Finally Extends Prior Authorization To Topical TRT, But In A Limited Fashion.

MMO filed this lawsuit in November 2014, accusing Defendants of promoting their TRTs for unsafe and ineffective uses. Despite that fact, MMO continued to cover Defendants' TRTs without restrictions. And it continued to do so even after FDA added limitations about "age-related" hypogonadism and a warning of possible cardiovascular risk to TRT labels in March 2015. [D415 ¶¶16, 18.]

In May 2016, Defendants moved to dismiss based (in part) on the fact that MMO "ha[d] not … changed its TRT prescription coverage upon discovering the purported misrepresentations." [D161 at 1-2.] Less than a month later, MMO suddenly began inquiring about extending its prior-authorization policy to topical TRT. Even then, however, "rebates" remained the deciding criterion. In June 2016, Marko Blagojevich, MMO's Manager of Clinical Pharmacy Programs, asked ESI: "If we added a PA [prior authorization] to check for off label use to the topical testosterone

[9] MMO misrepresents Joshi's email, claiming that she "queried as to what steps [MMO] should take in light of the fact that [D]efendants' representations might not be accurate." [AOB 30-31.] In fact, Joshi said nothing about any "representations" by Defendants.

step [therapy policy], would we still receive rebates?" [D420 Ex.89.] Several days later, MMO pharmacist Brandi Klaich confirmed that, with respect to "topical testosterone …, PA would be determined by rebates most likely." [*Id.*]

In July 2016, MMO's PQM Committee finally voted to include topical TRT in its prior-authorization requirement. [D424 Ex.110 at 80.] MMO has produced no internal documents that indicate a clinical reason for its choice to act at this particular time. Indeed, MMO did not actually *implement* any change to its prior-authorization policy until late 2017—over a year after that vote—when Defendants began asking about its policy in depositions. [*Id.*]

Moreover, the written policy that MMO ultimately implemented did not "restrict[] access to [D]efendants' drugs for Low T," as MMO asserts. [AOB 36.] The minutes of MMO's July 2016 PQM Committee meeting state that the Committee voted to "limit[] coverage … to only those uses that are FDA approved or have sufficient clinical evidence in the literature that is supportive." [A9-10.] But whatever transpired at this meeting, MMO's policy *as actually put into effect* in late 2017 merely requires the doctor to attest that the patient has a low testosterone level and symptoms such as fatigue, low libido, or depressed mood. The policy does *not* require the doctor to specify *why* the patient's testosterone is low. [D415 ¶18; D444 ¶30; D445 Ex.32.] Thus, even now, MMO knowingly reimburses for TRT prescriptions for "age-related" hypogonadism.

D. Procedural History

After FDA's January 2014 Drug Safety Communication, plaintiffs began filing personal-injury lawsuits against TRT manufacturers. These were centralized in the Northern District of Illinois before Judge Kennelly. *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, MDL No. 2545, No. 1:14-cv-01748 (N.D. Ill.).[10]

In November 2014, MMO filed this lawsuit, alleging that Defendants had engaged in "deceptive marketing scheme[s]" to promote their TRTs "for … 'off-label' uses"—*i.e.*, uses not approved by FDA. [D1 ¶2.] These supposedly included "age-related" hypogonadism (or "andropause") and maladies "such as erectile dysfunction, diabetes, AIDS, cancer, depression, and obesity." [A14; D1 ¶¶2, 4.] MMO also alleged that Defendants "concealed" a purported link between TRT and cardiovascular risk. [A14; D1 ¶3.] Based on these allegations, which Defendants deny,[11] MMO asserted RICO (18 U.S.C. § 1962(c)), RICO conspiracy (18 U.S.C. § 1962(d)), and various state-law claims. MMO also initially sought to represent a nationwide class of all health insurers and other third-party payors that paid for Defendants' TRTs. [D1 ¶621.]

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[10] This Court has decided other appeals arising out of this MDL. *See Guilbeau v. Pfizer, Inc.*, 880 F.3d 304 (7th Cir. 2018); *Owens v. Auxilium Pharms., Inc.*, 895 F.3d 971 (7th Cir. 2018). Those decisions are not relevant to this appeal.

[11] To the extent any Defendant promoted TRT for use in men whose hypogonadism was "age-related," until 2015, Defendants' TRTs were approved to treat primary/secondary hypogonadism *regardless* of the underlying cause. *Supra* at 7. To the extent any Defendant mentioned erectile dysfunction, depressed mood, etc., these are FDA-recognized symptoms of hypogonadism and not "off-label." *Supra* at 4-6. As for cardiovascular risk, as FDA recognizes, no such link has been shown. *Supra* at 7-8. In any case, Defendants "concealed" nothing: they disclosed all adverse-event data in their possession to FDA and followed FDA's instructions regarding what warnings they should give. [D348-1 Ex.23 ¶¶218-63.]

Motions to dismiss and amended pleadings narrowed and clarified MMO's claims. At one oral argument, MMO's counsel "emphasized" that MMO's theory was one of first-party reliance: that it received "direct misrepresentations" from Defendants, which induced it to grant "access to [its] formulary" for their TRTs. [D139 at 25; *see also* D1 ¶¶106, 201, 558, 1039 (alleging that Defendants made "false and misleading sales pitches" directly to MMO and other insurers "to encourage favorable formulary placements," which were "relied upon … in deciding whether and how to include [Defendants' TRTs] on their formularies").] Indeed, MMO's counsel "conceded" in open court "that without such allegations," the causal chain would be "too attenuated" to satisfy RICO's proximate-cause requirement. [D139 at 25.]

Accepting this framing of the case, the District Court allowed MMO's RICO, RICO conspiracy, and Ohio negligent-misrepresentation claims to proceed to discovery.[12] That discovery was extensive. MMO deposed 30 of Defendants' employees and obtained millions of pages of their documents. MMO subpoenaed documents from, and took a Rule 30(b)(6) deposition of, Medco/ESI. MMO also subpoenaed documents from dozens of Defendants' outside vendors and consultants. Finally, MMO had access to hundreds of Defendants' custodial files and scores of additional employee depositions from the TRT product-liability MDL.

In July 2018, the District Court denied MMO's motion for class certification. [D406.] First, the District Court found that MMO's unusually lax coverage-

[12] As to Actavis, the District Court found that MMO had failed to plausibly allege any direct misrepresentations to MMO concerning its TRT, Androderm. Actavis remained in the case only because MMO alleged that Actavis had "conspired" with the *other* Defendants. [D170 at 11-12, 15-18.]

management practices, and its "calculated decision to continue covering TRTs notwithstanding its actual knowledge" of its claims, made it an inadequate class representative. [*Id.* at 31-35.] Second, the District Court held that the proximate-cause element of MMO's claims would require individualized inquiries. [*Id.* at 37-45.] In reaching this conclusion, it relied on *Hillman*, which held that misrepresentations "to physicians" at large cannot establish proximate causation. [*Id.* at 20-21, 23, 42.] MMO did not attempt to appeal that decision at the time, *see* Fed. R. Civ. P. 23(f), and it does not appeal that decision now.

After fact discovery closed, and with the Court's approval, the parties agreed to postpone merits-stage expert discovery until after the Court's ruling on Defendants' planned summary-judgment motion. [D411.] Defendants filed that motion in October 2018, raising five arguments: (1) MMO could not show proximate causation; (2) MMO could not show conduct on behalf of a RICO "enterprise"; (3) MMO had no proof of damages; (4) MMO's claims were time-barred; and (5) MMO could not show a "conspiracy" among Defendants or any subset of them. [D427, D428.]

In February 2019, the District Court granted Defendants' motion. In a thorough 44-page opinion, it held that there was "insufficient evidence from which a reasonable jury could find that [D]efendants' alleged misrepresentations … proximately caused MMO's alleged injuries." [A2-3.] Again citing *Hillman*, the District Court observed that "governing principles in [this] Circuit require MMO to show … [that] it (1) received direct misrepresentations from [D]efendants and (2) relied on them to make formulary-related decisions…." [A20.] After reviewing the record,

the District Court found that no rational jury could conclude that MMO (or its PBM, Medco/ESI) "relied on [any] alleged misrepresentations [from any Defendant] to make any formulary or utilization management decision" about TRTs. [A21.] Given that conclusion, the District Court did not reach Defendants' other arguments.

SUMMARY OF ARGUMENT

I. The District Court correctly held that no reasonable jury could have found for MMO on the required element of proximate causation.

A. MMO argues that RICO permits a "flexible" proximate-cause analysis that does not require reliance on direct misrepresentations. This was the exact argument that the insurer-plaintiffs advanced in *Hillman*, and this Court rejected it. At minimum, *Hillman* holds that proximate cause does not exist unless "misrepresentations are made directly to [insurers], leading them to add certain drugs to their formularies." 873 F.3d at 578. Indeed, *Hillman* suggests (if not holds) that proximate cause may *never* exist in this type of case—*even if* the insurer received direct misrepresentations—because the initial injury from any improper promotion of pharmaceuticals would always fall on the patients who consume them, and because an insurer's damages from such a scheme are inherently speculative.

B. MMO argues that the District Court got its reliance story "backwards." Supposedly, the District Court thought MMO was claiming that it relied on misrepresentations in *imposing* restrictions on Defendants' TRTs. In reality, MMO states, its claim was that it relied on misrepresentations in choosing *not to impose* restrictions. But the District Court understood MMO's theory perfectly. It stated on

multiple occasions that MMO could show causation if a Defendant "made misrepresentations to [MMO] that caused it to *refrain from* taking steps to [restrict a TRT's] formulary status." And it granted summary judgment after finding an absence of evidence that MMO relied on misrepresentations from Defendants in making "*any* … decision" with respect to TRT—affirmative or negative.

C. MMO argues that there was sufficient evidence for a jury to "infer" (1) that it received direct safety/efficacy misrepresentations about TRT from Defendants; and (2) that it relied on those misrepresentations in deciding not to place utilization restrictions on Defendants' TRTs. As the District Court correctly concluded, however, the undisputed evidence is to the contrary.

There was no documentary evidence that any Defendant ever conveyed safety or efficacy information about its TRT to MMO—let alone *false* information. And at their depositions, none of MMO's employees recalled receiving such information from Defendants. MMO's brief points to certain documents in the record that purportedly contain misrepresentations—AbbVie's "Pinnacle" materials, for example—but, as the District Court observed, there was no evidence that anyone at MMO ever received or viewed these documents.

The record was also devoid of evidence that MMO *relied on* any misrepresentation from any Defendant. On the handful of occasions when MMO made utilization-restriction decisions as to TRT, there is no evidence—either documentary or testimonial—that MMO's choices were affected by information it might have received from Defendants. To the contrary, as the District Court recognized, the rec-

ord affirmatively shows *non*-reliance: even after MMO learned of the safety and efficacy issues that Defendants allegedly misrepresented, it "made a calculated decision to continue covering" Defendants' TRTs without restrictions, and it covers them for "age-related" hypogonadism even now.

D. MMO advances two alternative causation theories, which the District Court correctly rejected. First, MMO argues that Defendants might have made misrepresentations to its PBM, Medco/ESI, and that its PBM might have relied on those misrepresentations in making faulty recommendations to MMO, which MMO then accepted. As a matter of law, this multi-step causal theory fails *Hillman*'s "directness" test. In any case, as the District Court found, there was no evidence that Medco/ESI considered or relied on misrepresentations from Defendants in making any recommendation to MMO. Indeed, Medco/ESI's corporate representative insisted that the company "would not [have] accept[ed] information from a manufacturer at face value," and Medco/ESI in fact repeatedly advised MMO to *restrict access* to Defendants' TRTs.

MMO also argues that Defendants are liable on a "fraudulent omission" theory because they did not preemptively contact MMO and state that their TRTs were supposedly unsafe or ineffective. This theory fails for multiple reasons. First, RICO does not impose liability for "mere failure to disclose." It requires affirmative misrepresentations or "half-truths" that are misleading by virtue of what is left out. Just as there is no evidence that Defendants made affirmative misrepresentations to MMO, there is no evidence that Defendants communicated any "half-truths" to

MMO. This omissions theory also fails because MMO's behavior upon learning "the truth" shows that any purported omissions were immaterial and/or were not the cause of its utilization-management decisions.

II. In the alternative, the judgment should be affirmed on one or more of the additional grounds briefed below. *First*, there was no evidence that, in making the alleged misrepresentations, Defendants were acting on behalf of any of the purported RICO "enterprises," rather than merely carrying out "their own [allegedly fraudulent] affairs." *Second*, because MMO refused to produce evidence concerning its alleged damages in discovery, the record provided no basis for a jury to make any monetary award. *Third*, MMO's claims against certain Defendants were time-barred because it had notice of the alleged off-label marketing well more than four years before it filed suit. *Finally*, MMO's RICO conspiracy claim (the only remaining claim against Actavis) failed because there was no evidence of any conspiracy.

STANDARD OF REVIEW

This Court "review[s] a district court's grant of summary judgment de novo." *Skiba v. Ill. Cent. R.R. Co.*, 884 F.3d 708, 717 (7th Cir. 2018). "Summary judgment is appropriate if … there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Id.* (cleaned up). Although the Court must "draw all *reasonable* inferences" in favor of the nonmoving party, it need not draw "every conceivable" inference. *Id.* at 717, 721 (emphasis added). In particular, "[its] favor toward the nonmoving party does not extend to drawing inferences … supported by only speculation or conjecture." *Id.* at 721 (cleaned up).

ARGUMENT

I. THE DISTRICT COURT CORRECTLY HELD THAT NO REASONABLE JURY COULD HAVE FOUND FOR MMO ON THE ELEMENT OF PROXIMATE CAUSATION.

A. MMO Intentionally Ignores *Hillman*, Which Forecloses Its Arguments Regarding RICO's Proximate-Cause Standard.

To prevail on a civil RICO claim, a plaintiff must show that the defendant's violation "not only was a 'but for' cause of his injury, but was the proximate cause as well." *Holmes v. SIPC*, 503 U.S. 258, 268 (2010).[13] "[I]n the RICO context, the focus" of proximate cause "is on the directness of the relationship between the conduct and the harm." *Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 12 (2010). This requirement "is meant to prevent … intricate, uncertain inquiries from overrunning RICO litigation." *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 460 (2006).

MMO argues that RICO's proximate-cause standard is "flexible" and does not require first-hand "reliance on … misrepresentations." [AOB 20-22.] It is enough, MMO insists, that increased costs to insurers are "a foreseeable and natural consequence" of off-label pharmaceutical promotion. [AOB 20-22.] For these propositions, MMO cites two cases: *Bridge/BCS* and *Neurontin*. *See Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008), *on remand sub nom. BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750 (7th Cir. 2011); *In re Neurontin Mktg. & Sales Practices Litig. (Kaiser)*, 712 F.3d 21 (1st Cir. 2013).

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[13] MMO conceded below that the same proximate-cause standards that govern its RICO claims also govern its Ohio negligent-misrepresentation claim [D406 at 22; A43-44], and it does not argue otherwise on appeal.

MMO ignores that, in *Hillman*, this Court rejected these precise arguments, after analyzing these same authorities. MMO's failure to address—or even cite—*Hillman* cannot be mere oversight, as that decision was the linchpin of the District Court's class-certification and summary-judgment orders. [D406 at 20-21; D465 at 19-20.] This Court has often criticized such tactics. *See Gonzalez-Servin v. Ford Motor Co.*, 662 F.3d 931, 934 (7th Cir. 2011) ("The ostrich-like tactic of pretending that potentially dispositive authority against a litigant's contention does not exist is as unprofessional as it is pointless.").

Like this case, *Hillman* was a RICO action brought by insurers alleging that "off-label" promotion had caused them to pay for unsafe and ineffective prescriptions. On appeal, the insurers argued that the district court had "erred" by requiring them to allege that they had received and relied on "direct[] … misrepresentations" from the manufacturer. No. 17-1483, Doc. 9 at 8-9. RICO has no "first-party reliance requirement," they maintained; it was enough that their injuries were "a foreseeable and natural consequence of [the alleged] scheme." *Id.* at 12. Like MMO, the insurers cited *Bridge/BCS* and *Neurontin* in support. *Id.* at 9-16.

This Court rejected the insurers' arguments. While it agreed that first-party reliance is not a formal *element* of a RICO claim, it held that in the particular context of the health-insurance business, there were "[too] many layers, and [too] many independent decisions, between promotion and payment" to satisfy proximate cause. 873 F.3d at 578. It distinguished *Bridge/BCS*, observing that "[d]isentangling the effects of improper promotions from the many other influences on physicians' pre-

scribing practices would be … much more difficult than following the one-step causal link in *Bridge*." *Id.* at 577. And it expressly disapproved the First Circuit's reasoning in *Neurontin*. *See id.* at 578 ("[T]o the extent there is a conflict the Second Circuit [and not the First] has this right.").

MMO's arguments for a flexible "foreseeability" test are thus foreclosed. *See also Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296, 1306 (2017) (citing RICO precedents in holding that "foreseeability alone does not ensure the close connection that proximate cause requires"). At minimum, insurers bringing RICO claims must point to direct misrepresentations and resulting reliance of the sort missing in *Hillman*. Indeed, MMO's counsel "conceded" below "that without … direct misrepresentations" resulting in formulary decisions, MMO's claims would be "too attenuated." *Supra* at 18. Having urged the District Court to adopt this theory, MMO cannot fault it for having done so. *See Int'l Travelers Cheque Co. v. BankAmerica Corp.*, 660 F.2d 215, 224 (7th Cir. 1981).

Indeed, *Hillman* actually suggests (if not holds) that proximate cause may *never* exist in insurers' RICO actions based on pharmaceutical promotion. *Hillman*'s concluding paragraph noted the Third Circuit's position that "recovery under RICO is possible when misrepresentations are made directly to [insurers], leading them to add certain drugs to their formularies." 873 F.3d at 578 (discussing *In re Avandia Mktg.*, 804 F.3d 633 (3d Cir. 2015)). But this Court merely *acknowledged* the Third Circuit's rule; it did not endorse it. That rule, moreover, is difficult to reconcile with *Hillman*'s actual proximate-cause analysis.

Proximate cause, *Hillman* explained, generally does not "go beyond the first step" in the causal chain. *Id.* at 576. When a manufacturer promotes a drug improperly, insurers "are not … the most directly[] injured parties." *Id.* Rather, it is "[p]atients" whose "health and financial costs come first in line." *Id.* Nor is it apparent that insurers "bear the *principal* costs of off-label promotions," because it is "difficult" to compare their financial losses with "patients' health [and insurance] costs." *Id.* These things are true *whether or not* an insurer receives direct misrepresentations from the manufacturer that lead it to add a drug to its formulary.

Other "difficulties," too, confirmed the absence of proximate cause in *Hillman*. *Id.* at 577. "[S]ome off-label uses … may be beneficial to patients." "Disentangling the effects of the improper promotions from the many other influences on physicians' prescribing practices" is prohibitively "difficult." And the challenged promotion may even leave insurers "better off" if the promoted drug "is cheaper than" the drug that otherwise would have been prescribed. *Id.* at 577-78. These "difficulties," too, are present *whether or not* an insurer receives direct misrepresentations from the manufacturer.

Thus, under *Hillman*'s reasoning, proximate cause is absent in cases like this one, *even assuming* the insurer relied on direct misrepresentations. If this Court agrees, it may affirm irrespective of the record evidence that the District Court carefully and correctly analyzed. Regardless, *Hillman* at a minimum forecloses MMO's argument that, in this context, "foreseeability" suffices and reliance on direct misrepresentations is not required.

B. The District Court Did Not Get MMO's Reliance Story "Backwards."

MMO accuses the District Court of misunderstanding MMO's theory of reliance. According to MMO, the District Court "required [it] to prove that it *adopted* a utilization management limitation" relying on misrepresentations from Defendants. [AOB 2, 16-17 (emphasis added).] This, MMO insists, got its story "backwards": its actual claim was that, because of Defendants' alleged misrepresentations, it "*did not* [adopt] … restrict[ions] … that it otherwise would have." [AOB 1, 17, 24-25 (emphasis added).]

There was no such misunderstanding. As the District Court described MMO's theory at the motion-to-dismiss stage: MMO "could have taken steps to limit payments for off-label uses of TRT," and "any misrepresentations *preventing it from doing so* … cause[d] … its injury." [D139 at 29 (emphasis added).] Subsequently, the District Court opined that MMO could show causation if a Defendant "made misrepresentations to [MMO] that caused it to *refrain from* taking steps to [restrict a] drug's formulary status." [D170 at 8 (emphasis added).]

At summary judgment, the District Court analyzed *all* of MMO's decisions with regard to TRT: both the occasions when it chose to impose restrictions, and those when it chose not to. It concluded that "no reasonable jury could find that MMO … ma[de] *any* formulary or utilization management decision"—affirmative or negative—on the basis of any alleged misrepresentation by a Defendant. [A21 (emphasis added).] The District Court, in other words, understood MMO's causal theory perfectly; it just found a lack of any supporting evidence.

C. The District Court Correctly Concluded That No Reasonable Jury Could Have Found That MMO Received And Relied On Misrepresentations From Defendants.

"[A] jury's determination of proximate cause must be based upon provable facts and cannot be based on mere guess, conjecture, surmise, possibility, or speculation." *Trask-Morton v. Motel 6 Operating L.P.*, 534 F.3d 672, 678 (7th Cir. 2008). As the District Court properly found, there was no evidence that MMO received a single misrepresentation from any Defendant about TRT safety or efficacy. *A fortiori*, there was no evidence that any such misrepresentation affected MMO's coverage decisions for any TRT. All that MMO offers on either score is mischaracterizations of the record and impermissible "conjecture" and "speculation."

1. No Reasonable Jury Could Have Found That Defendants Made Direct Safety/Efficacy Misrepresentations To MMO.

Four years of litigation produced no evidence that MMO received a single statement from any Defendant about the safety or efficacy of TRT—let alone a *false* one. Among the millions of pages exchanged, none showed such a statement made to MMO. [D415 ¶4.] Defendants also deposed every MMO employee with even tangential responsibility for formulary oversight and utilization-management decisions from 2000-2014, and not one claimed to have received such representations from Defendants, orally or in writing. [D415 ¶¶5-9.] Indeed, in its opposition to summary judgment, MMO *conceded* that it had no evidence of direct misrepresentations from Actavis, Auxilium, or Endo [A4], and it does not argue otherwise here.

On appeal, MMO *claims* that it received misrepresentations from AbbVie and Lilly. But as the District Court found after "carefully review[ing]" the record, "[n]o

reasonable jury could conclude from [MMO's cited] documents … that AbbVie and Lilly misrepresented the safety or efficacy of their TRT drugs to MMO." [A22-23.] MMO's argument on appeal about Lilly [AOB 10] is conclusory and contrary to the record. [*See, e.g.,* D348-1 Ex.3 at 180:4-7 (MMO's Manager of Clinical Pharmacy testifying that he had no recollection of discussing TRT safety or efficacy with any Lilly representative).] As to AbbVie, MMO picks out a few innocuous snippets from the record; mischaracterizes them; and tries to divine from them that AbbVie employees *might* have made unspecified misrepresentations to MMO at some unspecified time. Such "speculation that [a defendant] made misleading misrepresentations is insufficient to survive summary judgment." *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016).

a. That Some Defendants Communicated With MMO Does Not Permit The Inference That They Made Safety/Efficacy Misrepresentations.

A few MMO employees met or exchanged emails with AbbVie and Lilly representatives over the years. [AOB 11.] But none of the cited emails contains any safety or efficacy information. And as for the meetings, none of the participants on either side recalled any discussion of TRT safety or efficacy. [D415 ¶¶5, 12; D444 ¶¶2, 3, 9; D449 Ex.13 at 206:6-208:21.]

Nor can it be *assumed*, absent evidence, that such discussions occurred at these meetings.[14] Defendants' representatives were tasked with promoting dozens

[14] In denying class certification, the District Court rejected MMO's assertion that Defendants' promotional efforts were "standardized," such that exposure to misrepresentations could be "inferred." [D406 at 39-40.]

of products; they could not possibly discuss all of them in a given encounter; and TRT was far from their top priority (or the top priority of insurers). [D444 ¶14; *see also* D158 ¶256 ("[R]elative to the thousands of other drugs on [insurers'] formularies, TRT drugs … remain[ed] 'under the radar'").] And it was undisputed that, when TRT did come up, insurers were usually interested in contract terms and rebates, not clinical information. [*Id.*] Indeed, it would have been futile for those Defendants that met with MMO to spend their limited face-time discussing TRT safety or efficacy, because Defendants knew MMO outsourced safety/efficacy evaluation to its PBM. [D158 ¶¶369, 550.]

b. MMO Did Not Receive TRT Dossiers.

MMO notes that some Defendants prepared documents, called "dossiers," that contained clinical information about their TRTs. [AOB 9.] Citing its own briefing below, MMO claims these dossiers "suggested that [D]efendants' TRT drugs were clinically proven to be safe and effective for … various off-label uses …, and carried no potential increased risk of cardiovascular or thromboembolic events." [*Id.*] This characterization is unsupported and untrue.

Moreover, MMO does not even claim to have *received* such "dossiers"—merely that they "were commonly provided to … health plans." [*Id.*] And there was no evidence that anyone at MMO ever saw a TRT dossier. The former chair of MMO's PQM Committee testified that "[n]obody [at MMO] reviewed dossiers." [D415 ¶7.] Defendants' employees gave unrebutted testimony that dossiers were provided only in response to an insurer's unsolicited request, and "[n]ot every account wanted …

them." [D415 ¶19.] And AbbVie's records, which go back to 2010, showed that only *six* managed-care entities received an AndroGel dossier—and neither MMO nor its PBM was among them. [D415 ¶20.]

c. MMO Did Not View AbbVie's "Pinnacle" Materials.

MMO claims that it was exposed to AbbVie's "Pinnacle" materials. [AOB 28, 34.] MMO describes Pinnacle as a "program to improve access of AndroGel onto health plan formularies." [*Id.* 28.] But the evidence was undisputed that Pinnacle was intended to educate *patients* about *diseases* (not products) relevant to men (*e.g.*, hypogonadism, heart disease, prostate cancer). There was no evidence Pinnacle was intended to influence insurers' coverage decisions. [D444 ¶9.] MMO also claims that the Pinnacle materials "promoted the use of AndroGel for various off-label uses." [AOB 28.] That is untrue: the materials did not even *mention* AndroGel, let alone "promote[]" it (for "off-label uses" or otherwise). [D444 ¶10.]

Regardless, as the District Court found, there is no evidence that anyone at MMO ever viewed the Pinnacle materials. MMO points to a 2005 email in which AbbVie's Lisa Cooper *offered* to present them to MMO. [AOB 28 (citing D434 Ex.5).] But Cooper did not attach any materials to her email, and no evidence "show[ed] that any meeting [about Pinnacle] ever actually occurred." [A23; D444 ¶9-10.] MMO's Chad Hendricks—the recipient of that email—testified that he did not recall any meeting resulting from the exchange. [*Id.*][15]

[15] MMO claims Hendricks "testified that there were times that pharmaceutical sales representatives came to talk about" a program resembling Pinnacle. [AOB 35.] He actually said that "[t]here *might* have been a time where *somebody* came in and told us … about a program *like* something to assist with diabetes or … hypertension overall or depression, men's

MMO argues that a jury could *infer* that "AbbVie presented [the] Pinnacle Program to [MMO] during 2005" because *three years later* in 2008, MMO sent a mailing to unspecified recipients about men's-health topics. [AOB 28, 35-36.] Given this three-year gap, such an inference defies credulity. *Cf. Mintz v. Caterpillar Inc.*, 788 F.3d 673, 681 (7th Cir. 2015) (nine-month gap between complaint and allegedly retaliatory act too long "to support an inference of causation"). Moreover, MMO's description of its 2008 mailer—that it "promoted Defendants' products for treating many of the same health issues that the Pinnacle Program discussed"—is wildly inaccurate. [AOB 28.] The unauthenticated hodgepodge of materials that supposedly constitute MMO's 2008 mailer say *nothing* about TRT, hypogonadism ("age-related" or otherwise), or any issue in this case. [D434 Exs. 7 & 8.]

d. MMO Did Not View The AndroGel "Value Proposition" Deck.

MMO points to a slideshow called the AndroGel "Value Proposition" deck, which it claims contained misleading safety and efficacy claims. [AOB 9.] That is inaccurate. But, regardless, there was no evidence that anyone at MMO ever viewed the AndroGel "Value Proposition" deck—let alone the specific portions of that lengthy presentation with which MMO takes issue. [D415 ¶¶5, 9; D444 ¶14.]

The undisputed evidence was that AbbVie only used this deck during *some* AndroGel-related discussions with insurers; that, when it was used, only *some* of its slides were shown, depending on the insurer's interests (*e.g.*, clinical vs. financial);

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health, MS." [D434 Ex.6 at 96:19-24.] Not only was this phrased as a sheer possibility; Hendricks did not even identify hypogonadism as a potential topic.

and that its content evolved over the years. [D415 ¶¶21-23; D406 at 40 ("[B]ecause '[e]very payer is different,' [AbbVie] does not always present the slide decks, or presents only portions of them….").] Thus, it would be sheer speculation to "infer" that anyone at MMO saw any challenged statement in this deck.

MMO points to a 2011 email in which AbbVie's Mark Hollinden *sought* a meeting with MMO's Sonny Borja to "present our value proposition deck." [D435 Ex.22.] But MMO misleadingly filed a *redacted* version of the email in the District Court. The unredacted version (also produced to MMO) makes clear that the "value proposition deck" Hollinden wanted to show Borja was "for *Humira*," a different AbbVie product. [D444 ¶14 n.1; D445 Ex.33.] In any case, neither Hollinden nor Borja recalled the meeting occurring [D444 ¶14], and Borja did not recall having seen safety or efficacy information from a TRT manufacturer *at any time* [D416 Ex.1 at 24:6-11, 29:3-9].

Finally, MMO cites an email from AbbVie employee Craig Geikie to his colleague Michael Broadhead, "advis[ing]" Broadhead to "tak[e] them through the Androgel value prop slide deck." [D437 Ex.62.] That email contains no indication of who was meant by "them"—let alone that "them" referred to MMO as opposed to the thousands of other managed-care entities in the United States. And there has never been any allegation or evidence that Broadhead (an AbbVie representative for the *Mountain West* region) interacted with MMO, an Ohio insurer, at any point.

2. No Reasonable Jury Could Have Found That MMO Made Any Coverage-Related Decision In Reliance On Direct Misrepresentations From Defendants.

As the District Court correctly held, "[e]ven if a reasonable jury could find that [D]efendants made false or misleading statements to MMO about the safety or efficacy of their TRT drugs, it could not find that MMO relied on them to make any formulary or utilization management decision regarding the drugs." [A26.] Here, as below, all that MMO offers on this point is conjecture. But summary judgment may not be avoided by "speculat[ion] … as to the possible factual connection between an alleged [misrepresentation] and the transaction said to have been induced by it." *FDIC v. Lauterbach*, 626 F.2d 1327, 1337 (7th Cir. 1980). Indeed, the undisputed evidence affirmatively *forecloses* any inference of reliance.

a. Reliance May Not Be "Inferred" Absent Evidence.

MMO argues that reliance may be "inferred" in RICO cases. [AOB 21-22.] However, as the District Court understood, this case is very different from the cases that MMO cites. [A44-45.] For example, *Torres v. S.G.E. Management, L.L.C.*, 838 F.3d 629 (5th Cir. 2016), held that reliance can be inferred when a plaintiff joins an illegal pyramid scheme that is "bound to lose money," because no reasonable person would do so unless she had been deceived. *Id.* at 641, 643. Similarly, *In re U.S. Foodservice Inc. Pricing Litig.*, 729 F.3d 108 (2d Cir. 2013), held that reliance on an inflated invoice can be inferred from the fact of payment, because no reasonable businessperson would pay an invoice they knew was fraudulent. *Id.* at 120.

As the District Court noted, there are "plausible explanations" *other than* reliance on direct misrepresentations for why an insurer would place or keep TRT on

its formulary without restrictions. [D406 at 44-45.] Perhaps it reviewed the science and independently concluded that TRT was safe and effective—as many experts have done. *Supra* at 6-8. Perhaps the insurer wanted to keep TRT freely available to "maximize rebates." *Supra* at 9-10. [*See also* D406 at 43 (noting that MMO's "#1 objective for 2013 [was] rebate aggregation").] Perhaps the insurer "voluntarily assumed the risk of paying for … prescriptions for off-label uses" and "adjusted [its] premiums upward" to compensate. *Ironworkers Local Union 68 v. AstraZeneca Pharms., LP*, 634 F.3d 1352, 1366-69 (11th Cir. 2011). Or perhaps the insurer was focusing its attention on other, more costly drug categories. [D158 ¶256.]

In short, an insurer's decision to cover TRT, with or without particular restrictions, "is not the 'same more-or-less one-dimensional decisionmaking process' as the financial transactions" in MMO's cited cases. *Tropical Sails Corp. v. Yext, Inc.*, 2017 U.S. Dist. LEXIS 38913, at *40 (S.D.N.Y. Mar. 17, 2017) (quoting *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 88 (2d Cir. 2015)); *see Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1087 (N.J. 2007) (noting that insurers do not "react[] in a uniform or even similar manner" to information from drug manufacturers).

The record bears this out. It was undisputed that some insurers placed restrictions on Defendants' TRTs from the outset, while others chose not to restrict them (or *removed* restrictions) even after FDA's 2014 Drug Safety Communication. [D424 Ex.109 at 17, 21-24, 72-74, 80-98; D406 at 33.] This variation is inconsistent with the one-dimensional decisionmaking that MMO's requested inference presup-

poses. *See Sergeants Benevolent*, 806 F.3d at 93 ("[H]ad doctors' prescribing decisions truly been one-dimensional, one would expect sales of Ketek to cease entirely after the new safety information was made available. But [they did not].").

b. The Record Contained No Evidence Of Reliance.

None of MMO's employees with coverage-related responsibilities dating back to 2000 could identify a single decision that MMO made with respect to any TRT on the basis of information from Defendants—false or otherwise. [D415 ¶¶11-12.] This included MMO's hand-picked Rule 30(b)(6) witness on the topic of its alleged reliance on misrepresentations. [*See* D416 Ex.6 at 296:24-97:20 ("Q…[D]id [MMO] ever make a decision not to impose prior authorization in reliance on … conversations [with Defendants]? … A. *I do not know*.").] The documentary record is equally barren: as the District Court noted, MMO's PQM Committee made decisions about TRT on just handful of occasions, and the relevant meeting minutes say nothing about any information provided by Defendants. [D415 ¶15.]

MMO argues that a jury could "infer" that it relied on unspecified direct misrepresentations in 2008, when it "declin[ed] to implement a prior authorization on topical testosterone products," and/or in 2014, when it chose to participate in ESI's Preferred Drug Step Therapy (PDST) program for TRT. [AOB 10-11, 29-30.] But that would not be "inference"—it would be speculation. As noted, there was no evidence that these choices were driven by safety or efficacy claims from any Defendant. To the contrary, all available evidence showed that they were driven by "re-

bates"—and, in the former case, Medco's view that non-topical forms of TRT were more widely "abused." *Supra* at 12-15.

MMO points to generic testimony from its employees to the effect that "[MMO's] primary consideration in deciding whether to adopt a utilization management tool was clinical evidence; including evidence provided by the drug manufacturers." [AOB 30, 32-33, 37.] However, as the District Court correctly found, vague statements about MMO's "general practice[s]" [*id.* 33] would not permit a reasonable jury to conclude that the *specific decisions at issue* were caused by direct misrepresentations from Defendants. [A28-29.] *See King v. Ford Motor Co.*, 872 F.3d 833, 841 (7th Cir. 2017) ("Assertions at such a high level of generality do not suffice at [the summary-judgment] stage…."). That is especially true here, given that there is direct evidence that something *other than* safety/efficacy misrepresentations *did* motivate those specific decisions.

With respect to MMO's adoption of the Preferred Drug Step Therapy (PDST) program, there is an additional consideration that precludes any inference of reliance on purported safety/efficacy misrepresentations from Defendants. That decision resulted in the *unequal* treatment of Defendants' TRTs on MMO's formulary: AbbVie's AndroGel and Lilly's Axiron remained available without restrictions (as before), but other topical TRTs were available only if the patient had tried AndroGel and Axiron without success. *Supra* at 13-14.

As to Auxilium, Endo, and Actavis, MMO's theory defies plausibility: MMO does not, and cannot, explain how it might have relied on representations by those

Defendants in adopting a program that placed their products *at a disadvantage*. Moreover, as the District Court noted, MMO has never argued—and it does not argue here—that "it believed [AndroGel and Axiron] were *safer* or *more* effective than [other TRT] drugs." [A13, 33 (emphasis added).] Thus, MMO's decision to prefer those two topical TRTs over the others cannot rationally be explained by its putative beliefs about TRT safety or efficacy, whether those beliefs resulted from Defendants' statements or otherwise. [*Id.* 33.]

By contrast, MMO's decision to distinguish among topical TRTs *can* be explained by the increased rebates that MMO could collect from doing so. Not coincidentally, that is the only rationale for MMO's decision that appears in the record. *Supra* at 13-14. [*See also* D444 ¶28 (MMO PQM Committee member was unaware of "any clinical basis to distinguish between AndroGel, Axiron, and the 'non-preferred [TRTs],'" but *was* aware of distinctions in "rebates").] Even MMO's brief concedes that its decision to grant one drug "preferred status" *vis-à-vis* other "brand-name drugs [that] treat the same condition" comes down to "favorable rebates." [AOB 5.]

c. The Record Affirmatively Shows *Non*-Reliance.

Not only is the record devoid of evidence of MMO's claimed reliance on misrepresentations by Defendants in deciding how to cover their TRTs; it is *affirmatively inconsistent* with such reliance.

As discussed above—and as the District Court found based on the undisputed record—MMO imposed no clinical restrictions on Defendants' TRTs "until nearly

four years after it alleges it first received notice of [D]efendants' alleged fraud"; three years after "filing this lawsuit"; and more than two years after FDA revised TRT labels to carve out "age-related" hypogonadism from the approved indication and add language concerning possible cardiovascular risk. [D406 at 32.] Instead, "MMO made a calculated decision to continue covering" Defendants' TRTs without restrictions, "notwithstanding its actual knowledge" of all of the above. [*Id.*]

This "calculated" inaction bars any inference of reliance. *See, e.g.*, *Teamsters Local 237 Welfare Fund v. Astrazeneca Pharms. LP*, 136 A.3d 688, 696 (Del. 2016) ("[Insurers] who continue to pay or reimburse for [defendant's drug after learning the truth] … are neither 'victims' of the allegedly false advertising nor were they injured by reason of or as a result of it."); *Sandoz, Inc. v. State*, 100 So. 3d 514, 533 (Ala. 2012) (where plaintiff "had not adjusted its reimbursement [practices] after discovering the alleged fraudulent [conduct]" by defendant manufacturer, it could not "show that [the alleged] misrepresentation induced [it] to act in a way that he would not otherwise have acted" (cleaned up)); *cf. Reynolds v. E. Dyer Dev. Co.*, 882 F.2d 1249, 1254 (7th Cir. 1989) (dismissing RICO claim where plaintiffs purchased relevant property "even after finding out about the [undisclosed] soil problem").[16]

[16] Additionally, MMO's continued "pay[ment]" for TRT "despite its actual knowledge" of its claims is "very strong evidence" that the alleged misrepresentations were "not material." *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016); *see also United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 831 (7th Cir. 2011) (where plaintiff "failed to take action when it actually learned of the supposed misrepresentation[,] … speculative testimony about how [it] might have acted if it had discovered that misrepresentation earlier cannot raise a genuine issue of fact as to materiality").

MMO points out that it did ultimately decide to place Defendants' TRTs under a prior-authorization requirement. [AOB 31.] But it did so years after it learned of its claims, and only after Defendants moved to dismiss on the ground that such restrictions were lacking. *Supra* at 15-16. Even once MMO voted to take this step, MMO delayed over a year before implementing it. *Supra* at 16. And the criteria that MMO ultimately imposed—a low testosterone level and symptoms such as low libido or fatigue—do not attempt to prevent use for "age-related" hypogonadism, so they would not have prevented MMO's alleged injuries. *Supra* at 16. MMO's belated decision to impose nominal restrictions is not evidence of reliance on misrepresentations, let alone sufficient evidence to create a jury-triable issue.

D. The District Court Correctly Rejected MMO's Alternative Theories Of Causation.

Lacking any evidence that it received or relied on direct misrepresentations, MMO advances two alternative causal theories: "misrepresentations to Medco/ESI" and "fraudulent omissions." As the District Court concluded, these theories fail.

1. "Misrepresentations To Medco/ESI" Theory

MMO argues that, even if *it* never relied on direct misrepresentations, *Medco/ESI* might have done so in making a faulty recommendation to MMO, which MMO then accepted. [AOB 26-27, 29-30.] For example, MMO speculates that Medco's Dan Resetar was acting on unspecified misrepresentations from Defendants when he advised MMO that injectable, oral, and buccal TRTs were more "abused" than topicals—a statement that MMO cited in choosing to exempt topical TRTs from its 2008 prior-authorization policy. [*Id.* 10, 29.]

As a matter of law, this multi-step causal chain could not satisfy RICO's proximate-cause requirement. By its own admission, MMO "d[id] not always follow [its PBM]'s recommendations." [D158 ¶203; A8.] Indeed, for over a decade, MMO *repeatedly disregarded* its PBM's advice to require prior authorization for Defendants' TRTs. This causation theory would thus require disaggregating the purported influence of Defendants from the other influences on Medco/ESI's recommendations to MMO, *and then* disaggregating the various influences on MMO's decisions regarding those recommendations. It is therefore just as "indirect [and] contingent" as the physician-mediated theory rejected in *Hillman*. 873 F.3d at 578.

Regardless, as the District Court correctly found, there was no evidence that any recommendation Medco/ESI made to MMO was affected by a misrepresentation from any Defendant. MMO took no discovery from Dan Resetar or any member of Medco/ESI's P&T Committee, so one could only speculate why Medco/ESI acted as it did. The only Medco/ESI witness who testified was its Rule 30(b)(6) designee, who stated that the company was aware of no "substantive information about the risks, safety, or efficacy of TRT medications that was communicated [to it] by any TRT manufacturer" and that the company "d[id] not know" whether "any information a [D]efendant provided to [it] about their TRT was … considered … in making formulary placement or inclusion decisions." [D415 ¶¶34-36.]

But Medco/ESI's corporate representative was confident about one thing: the company "would not [have] accept[ed] information from a manufacturer at face value without doing [its] own due diligence." [*Id.*] Indeed, he testified that Med-

co/ESI's accomplished clinical staff conducted its own "independent inquiry" for each drug, considering "the full range" of available information and assessing "the purity … of [the] science" underlying each source. [*Id.* ¶31.] The record bears this out: again, by 2004, despite the alleged campaign of misinformation, Medco independently concluded that TRT should not be covered for "andropause." *Supra* at 12. On this record, no reasonable jury could conclude that any Defendant directly deceived Medco/ESI into making faulty recommendations that MMO accepted.

The scattered emails between Medco/ESI and some Defendants do not change this. For example, MMO cites a 2007 email from AbbVie's Jed Cicak to Patrick Moran, who was apparently a Medco employee. [AOB 9 (citing D437-61).] Cicak wrote that he hoped to "partner with" Moran on an educational initiative "at a specific employer" and attached a presentation on hypogonadism. But there was no evidence that Moran ever viewed the attached presentation; that he was in a position to influence Medco's recommendations to MMO concerning TRT; or, *a fortiori*, that those recommendations were affected in any way by Cicak's email.

MMO has argued that Medco/ESI may have relied on unspecified safety and efficacy misrepresentations by AbbVie and Lilly in choosing to make AndroGel and Axiron its "preferred" TRTs under the PDST program. There is no evidence of this. Indeed, as the District Court noted, there has never been any allegation that Defendants claimed their TRTs *differed* as to safety or efficacy, or that Medco/ESI held such a belief. Thus, no jury could rationally attribute Medco/ESI's decision to "prefer" AndroGel and Axiron to safety or efficacy misrepresentations. [*See* A40 ("MMO

does not even argue that ESI developed the [PDST] policy because [it thought] the preferred drugs were superior from a safety or efficacy standpoint….").] Instead, the evidence shows that ESI's decision to "prefer" AndroGel and Axiron was based on those TRTs' superior rebate levels. [D444 ¶28; *see, e.g.*, D421 Ex.97.]

Finally, MMO argues that a jury could infer that Medco/ESI received misrepresentations from Defendants because, in 2015, it "changed its prior authorization limitation for topical [TRTs]" "to include a full section on cardiovascular risk." [AOB 31.] The cited document shows that, in May 2015, ESI issued a revised "Clinical Summary" on "Testosterone" that included a section discussing the same studies that FDA had reviewed and agreeing with FDA that the evidence was ambiguous. [D435-55 at -600-02.] The cited document is not a "prior authorization" policy, as MMO suggests. In any event, Medco's discussion of these studies in a 2015 document raises no inference that Defendants made misrepresentations to Medco/ESI at any earlier time—let alone that Medco/ESI's recommendations to MMO were affected as a result. Indeed, these studies were published in prominent journals that Medco/ESI independently monitors [D415 ¶31; MDL-D1745 Ex.4 at 5 nn. 14-17], so Medco/ESI had access to them as soon as they were published.

2. "Fraudulent Omissions" Theory

MMO's last resort is its "fraudulent omissions" theory: even if Defendants never made any misrepresentations to MMO, it is enough that they did not *affirmatively tell* MMO about the purported safety and efficacy concerns regarding TRT. But accepting this theory would eviscerate *Hillman*. A claim based on misrepresen-

tations to doctors, like the one in *Hillman*, could always be recast as a failure to affirmatively tell insurers about a doctor-directed disinformation campaign.

There is another problem: MMO's RICO claims are premised on alleged mail and wire fraud [A15, AOB 3], and those statutes do not impose liability for "mere failure to disclose." *Reynolds*, 882 F.2d at 1252. As this Court has noted:

> Under the mail and wire fraud statutes … [i]t is unlawful to speak half truths or to omit to state facts necessary to make the statements made in light of the circumstances under which they were made not misleading. *Absent such circumstances, mere omissions do not constitute fraud* under the mail and wire fraud statutes.

United States v. Biesiadecki, 933 F.2d 539, 543 (7th Cir. 1991) (emphasis added).

As discussed above, there is no evidence that Defendants ever made *any* direct statements to MMO about TRT safety or efficacy—let alone statements constituting misleading "half-truths." AbbVie may have spoken to MMO about rebate opportunities available through ESI's PDST program, *supra* at 13, but that does not create a duty to speak on the unrelated topics of cardiovascular safety studies or efficacy for off-label uses. *Cf. Reynolds*, 882 F.2d at 1251-52 (where seller made "general statements" to buyers about a tract of land, but never made any statements that "relate[d] to soil conditions," seller could not be held liable under RICO for "failure … to disclose the [unfavorable] results of … soil boring reports").

Below, MMO argued that Defendants "communicated with MMO … via [their drugs'] labels," and that those labels "omitted" information about cardiovascular risk. MMO does not press this theory on appeal, thus waiving it. In any event, it fails for multiple reasons. *First*, there was no evidence that anyone at MMO ever

read a TRT drug label or made any decision on that basis. [D415 ¶6.] Indeed, the chair of MMO's PQM Committee from 2003-2011 testified that he had "[n]ever reviewed the labels" of Defendants' TRTs "[b]efore being contacted about this lawsuit." [D416 Ex.10 at 24:7-10, 129:11-14.] *Second*, a drug's label is primarily intended for *prescribing physicians*—not insurers.[17] MMO, therefore, could not be "the most directly[] injured part[y]" in connection with any alleged label omissions. *Hillman*, 873 F.3d at 576. And *third*, federal law barred Defendants from warning about potential cardiovascular risk before FDA told them to do so in 2015.[18]

Finally, MMO's omissions theory fails because its own behavior shows that any purported omissions were immaterial and/or not the cause of its coverage decisions. Again, once MMO learned of FDA's 2014 investigation and 2015 label changes, it chose to do nothing—and it kept doing nothing until it seemed that its inaction might scuttle this lawsuit. Even then, MMO waited over a year before implementing a token change that does not prevent coverage for "age-related" hypogonadism. *Supra* at 15-16. Given those facts, MMO's "speculative testimony about how

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[17] *See Proposed Rule: Labeling for Prescription Drugs Used in Man*, 40 Fed. Reg. 15392, 15392 (Apr. 7, 1975) ("The primary objective of prescription drug labeling is to provide the essential information *the practitioner* needs to use the drug safely and effectively in the care of patients." (emphasis added)).

[18] Manufacturers may "unilaterally change [their] label[s]" only "in narrow circumstances." Among other things, they must possess "newly acquired information" of which "*FDA [is not] aware*." *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 806-07, 812, 815 (7th Cir. 2018) (emphasis added), *cert. denied* (May 28, 2019). MMO neither alleged nor proved that, at any relevant time, Defendants possessed new information about TRT and cardiovascular risk not already known to FDA. [D444 ¶37.] In fact, FDA was actively monitoring the literature on this topic at all relevant times, and it knew everything Defendants knew. [*Id.*]

[it] might have acted if it had discovered [the truth] earlier cannot raise a genuine issue of fact." *Yannacopoulos*, 652 F.3d at 831.

II. SUMMARY JUDGMENT FOR DEFENDANTS WAS PROPER ON SEVERAL ALTERNATIVE GROUNDS.

This Court "may affirm on any basis fairly presented in the record," whether the District Court "consider[ed]" it or not. *Delatorre v. United States*, 847 F.3d 837, 843 n.2 (7th Cir. 2017). The parties briefed four arguments for summary judgment that the District Court "[did] not reach." [A44 n.14.] If this Court disagrees with the District Court's proximate-cause holding, it should affirm on any or all of those alternative grounds.

A. MMO Failed To Adduce Evidence That Defendants Acted "On Behalf Of" The Alleged RICO "Enterprises."

RICO "makes it unlawful for any person … to conduct … [an] enterprise's affairs through a pattern of racketeering activity." *UFCW Unions & Emp'rs Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 853-54 (7th Cir. 2013). Thus, the RICO "person" (*i.e.*, the defendant) and the RICO "enterprise" must be "distinct entities." *Id.* And, crucially, "[the] 'person' must have 'conducted … the *enterprise's* affairs'" through the complained-of racketeering activity—"not just [its] own affairs." *Id.* (emphasis in original).

Here, MMO initially alleged that each Defendant participated in four "enterprises" (20 "enterprises" in total):[19]

[19] As noted above, the District Court dismissed the substantive RICO claims against Actavis at the 12(b)(6) stage. Thus, by the summary-judgment stage, the case no longer involved allegations that Actavis had formed any "enterprises."

- A "Formulary Access Enterprise," consisting of that Defendant and its outside managed-care-marketing firm(s), which made misrepresentations to insurers to secure formulary access. [D158 ¶¶226, 233-34.]

- A "Publication Enterprise," consisting of that Defendant and its external authors, which solicited, produced, and secured publication of favorable scientific literature. [D158 ¶¶ 228, 311, 315, 322.]

- A "Peer Selling Enterprise," consisting of that Defendant, its conference-organizer vendors, and physician speakers, which developed educational events for physicians. [D158 ¶¶ 227, 268-70.]

- A "Direct-To-Consumer Enterprise," consisting of that Defendant and its consumer advertising agency, which produced ads encouraging patients to seek TRT prescriptions. [D158 ¶¶229, 330.]

At summary judgment, Defendants argued that MMO's RICO claims failed because "'the affairs' that [each Defendant] allegedly 'conducted' through racketeering activity … were [that Defendant's] '*own* affairs'—not the separate affairs of the various purported 'enterprises.'" [D414 at 15 (quoting *Walgreen*, 719 F.3d at 854-55).] "At most," Defendants noted, "a jury could conclude that Defendants retained the services of various vendors, consultants, and speakers to help carry out various strategies intended to boost their own respective bottom lines by increasing the sales of their respective TRT drugs." [*Id.* 16.] As *Walgreen* holds, that is not enough to prove a RICO claim. *See also Richmond v. Nationwide Cassel L.P.*, 52 F.3d 640, 647 (7th Cir. 1995) (no RICO claim where "[t]he RICO person" was a corporation "and the enterprise was the [combination] … of [the corporation] … and [the] advertising and marketing agencies" that assisted it in fraudulently promoting its own products (citing *Brittingham v. Mobil Corp.*, 943 F.2d 297 (3d Cir. 1991)).

In particular, Defendants noted, there was "no evidence … that Defendants 'siphoned off' profits from the sales of their TRT drugs and shared them with the

alleged 'enterprises'; that Defendants and their various vendors and consultants 'involved themselves in [one another's] affairs' to a degree atypical of a pharmaceutical manufacturer and its marketers; or that any Defendant did anything that would have been against its own self-interest unless it and its vendors 'were acting in concert on behalf of a shadow enterprise.'" [D414 at 16-17 (quoting *Walgreen*, 719 F.3d at 854-55).] The mere fact that Defendants' acts were allegedly "fraudulent or illegal" was insufficient. [*Id.* 17 (citing *Walgreen*, 719 F.3d at 855).]

MMO responded—contrary to basic principles of summary judgment—that it had *no obligation* to come forward with evidence on the required element of "enterprise" conduct. [D433 at 41-43.] When it finally laid its cards on the table, MMO merely pointed to the purported "false and misleading statements" that Defendants supposedly made to MMO and consumers. [*Id.* 43-44.] MMO's brief did not even *mention* the other members of the alleged "enterprises" (*e.g.*, Defendants' ad agencies and vendors). In short, MMO did not even meaningfully argue that it could satisfy the enterprise-conduct element of its claims.

B. MMO Failed To Adduce Evidence Of Any Damages.

Summary judgment also was proper because MMO failed to adduce evidence that it suffered damages—let alone evidence from which the amount of its damages could be determined. [D414 at 28-31; D443 at 17-18.]

In discovery, Defendants demanded a variety of documents concerning MMO's alleged damages—but MMO refused to produce them. [D415 ¶56.] Defendants also asked MMO to "[i]dentify each [TRT] prescription … which [it] contend[ed]

[it] would not have paid or reimbursed for" absent the alleged wrongdoing, including "the costs … incurred in connection with [each such] prescription." MMO refused to respond. [D415 ¶¶57-58.]

The summary-judgment record thus contained no information from which a jury (or a potential merits-stage expert witness) could assess MMO's damages—*e.g.*, how many prescriptions of each TRT MMO paid for; how much each prescription cost; how many were for "age-related" hypogonadism or other challenged uses; how many failed to benefit the recipient; how much of these amounts MMO has already recouped (*e.g.*, through rebates or co-pays); or how much MMO would have paid for alternative therapies for the recipients (*e.g.*, erectile-dysfunction drugs or antidepressants) if it had not paid for the challenged TRT prescriptions.[20]

C. MMO's Claims Against AbbVie, Auxilium, and Actavis Are Time-Barred.

Summary judgment was also proper with respect to AbbVie, Auxilium, and Actavis because MMO's claims against them were time-barred under RICO's four-year statute of limitations.[21] [D414 at 31-44; D443 at 18-20.]

That statute of limitations "beg[ins] to run once … the plaintiff[] knew or should have known that [it was] injured." *McCool v. Strata Oil Co.*, 972 F.2d 1452,

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[20] Below, MMO insisted that it had "produced data regarding the total number of TRT drug prescriptions it covered and how much MMO paid for [them]." [D433 at 44 (citing D434 ¶56).] That would not be sufficient. In any event, the cited paragraph of MMO's Rule 56.1 response contained only a naked assertion that MMO had "produce[d] documents responsive to [Defendants'] request[s]" and the Bates numbers of two documents never submitted to the Court. Such "statements of counsel are not summary judgment evidence." *Thomas v. Wichita Coca-Cola Bottling Co.*, 968 F.2d 1022, 1025 (10th Cir. 1992).

[21] Lilly and Endo entered the TRT market less than four years before MMO filed suit.

1464-65 (7th Cir. 1992).[22] The plaintiff need not know that the injury is the result of a "pattern of racketeering," let alone the full extent of that pattern. *Rotella v. Wood*, 528 U.S. 549, 555 (2000). MMO's claims were thus time-barred if, by November 5, 2010—four years before it sued—it "[knew or] should have known" that it had paid for prescriptions resulting "from off-label marketing." *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 782 F.3d 922, 926-29 (7th Cir. 2015).

As Defendants showed below, MMO had constructive notice, at minimum, long before November 2010. Starting by 2000, a string of high-profile articles and broadcasts asserted that TRT was being prescribed for off-label uses, including "andropause"; that such uses were unsafe and/or ineffective; and—crucially—that this was due to allegedly improper promotion by Defendants. [D415 ¶¶59-71.] *See Whirlpool Fin. Corp. v. GN Holdings*, 67 F.3d 605, 610 (7th Cir. 1995) (sophisticated plaintiffs are "presumed to have information available in the public domain"). To give just three examples from the many adduced below:

- A July 2002 *New Yorker* article ("Hormones for Men: Is Male Menopause a Question of Medicine or Marketing?") alleged that AndroGel was being promoted "off label" for "andropause." It discussed ads allegedly promoting AndroGel for "[f]atigue[]," "[d]epressed mood," and "[l]ow sex drive." And it criticized specific practices—*e.g.*, payment of "research grants" and "speaking fees" to physicians—which MMO's complaint identifies as "racketeering conduct." [D415 ¶63.]

- An August 2002 front-page article in the *New York Times* ("Male Hormone Therapy Popular But Untested") asserted that TRT use was "soaring" and critiqued "the industry" for "trumpet[ing]" it as an "antidote for aging." It alleged that men taking the drug for this purpose were "participating in a

[22] The statute of limitations for MMO's Ohio negligent-misrepresentation claim is also four years, but no discovery rule applies. *MISC Berhad v. Advanced Polymer Coatings, Inc.*, 652 F. App'x 316, 329 (6th Cir. 2016).

vast, uncontrolled medical experiment" and asserted a possible increased risk of "heart attacks and strokes." [D415 ¶64.]

- A November 2003 front-page article in the *Washington Post* ("Testosterone Derided As a Health Supplement") claimed that there was "no evidence that the testosterone being used by a growing number of American men to boost their strength, mood or virility is doing them any good." It blamed "aggressive advertising" for these purportedly "off-label" prescriptions and cited an AndroGel ad that mentioned "[f]atigue[,]" "[d]epressed mood[,]" and "[l]ow sex drive[.]" [D415 ¶66.]

These public sources dovetail with similar documents in MMO's contemporaneous possession about the "andropause" controversy. [D415 ¶¶72-76.] Moreover, many leading insurers and PBMs—including MMO's PBM—decided long before 2010 that TRT should not be covered for "andropause." [D424 Ex.110 81-85.] Together, these facts leave no doubt that, before November 2010, a diligent insurer in MMO's position would have had reason to investigate whether it had paid for TRT prescriptions resulting from improper marketing by Defendants.

MMO argued below that "equitable tolling or equitable estoppel" saved its claims from untimeliness. But those doctrines presuppose that the plaintiff "exercis[ed] due diligence" in pursuing its potential claims and are "granted sparingly only when extraordinary circumstances far beyond the litigant's control prevented timely filing." *Hillman*, 782 F.3d at 930-31. Here, MMO was the *opposite* of "diligent"—*e.g.*, repeatedly disregarding recommendations from Medco/ESI to restrict topical TRTs and failing to "comport with industry standards" in its "formulary and utilization management practices." [D406 at 34; D415 ¶78.] Even after MMO learned of the FDA's Drug Safety Communication in February 2014, it "made a calculated decision to continue" with business as usual, rather than to investigate its

potential claims. *Supra* at 14-15. No reasonable jury, therefore, could find that these tolling doctrines apply. *Cf. Hillman*, 782 F.3d at 931 (rejecting tolling as a matter of law where plaintiff insurers "did not … act[] diligently in seeking information about their claims" once news of their potential injuries became public).

D. MMO Failed To Adduce Evidence Of Any "Conspiracy."

The District Court correctly concluded that the lack of proximate cause doomed both MMO's substantive RICO claims and its RICO conspiracy claims. [A44.] Separately, Defendants also showed below that the record lacked evidence from which a reasonable jury could have found a "conspiracy" among all the Defendants, or any subset of them. [D414 at 18-28; D443 at 14-17.] This, too, required summary judgment for Defendants on MMO's conspiracy claims (which were the only claims that remained against Actavis).

CONCLUSION

For the reasons above, the judgment should be affirmed.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify, pursuant to Fed. R. App. P. 32(a)(7) and Circuit Rule 32(b), that the attached brief is proportionally spaced; uses a typeface (Century Schoolbook) of 12 points for the text and 11 points for the footnotes; and contains 13,890 words (excluding portions exempted by Fed. R. App. P. 32(a)(7)(B)), as counted by Microsoft Office Word 2010, which was used to produce this brief.

Dated: New York, New York
July 17, 2019

/s/ William F. Cavanaugh, Jr.

CERTIFICATE OF SERVICE

I hereby certify, on July 17, 2019, I electronically filed the foregoing Joint Brief for Defendants-Appellees with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: New York, New York
July 17, 2019

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