KeyCite Yellow Flag - Negative Treatment

1. Declined to Extend by [Hexum v. Eli Lilly and Company,](https://1.next.westlaw.com/Document/Id6b2019047de11e599358612e0bf9496/View/FullText.html?navigationPath=RelatedInfo%2Fv4%2Fkeycite%2Fnav%2F%3Fguid%3DId6b2019047de11e599358612e0bf9496%26ss%3D2029301530%26ds%3D2036919578&listSource=RelatedInfo&list=NegativeCitingReferences&rank=0&originationContext=docHeader&transitionType=NegativeTreatment&contextData=%28sc.Search%29) C.D.Cal., August 18, 2015

700 F.3d 1161

United States Court of Appeals,

Eighth Circuit.

In re LEVAQUIN PRODUCTS LIABILITY LITIGATION.

John Schedin, Plaintiff–Appellee

v.

[Ortho–McNeil–Janssen Pharmaceuticals, Inc.](http://www.westlaw.com/Search/Results.html?query=advanced%3a+OAID(4296827622)&saveJuris=False&contentType=BUSINESS-INVESTIGATOR&startIndex=1&contextData=(sc.Default)&categoryPageUrl=Home%2fCompanyInvestigator&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem), Defendant–Appellant.

No. 11–3117.

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Submitted: May 17, 2012.

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Decided: Nov. 30, 2012.

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Rehearing and Rehearing En Banc Denied Jan. 23, 2013.[\*](#co_footnote_B0012029301530_1)

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| [\*](#co_footnoteReference_B0012029301530_ID0E) | Judge [Murphy](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0168282001&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)) and Judge [Bye](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0118506901&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)) would grant the petition for rehearing en banc. |

**Synopsis**

**Background:** Patient brought action against drug manufacturer, alleging failure to warn about certain risks associated with its drug. After jury verdict and damages award in patient’s favor, The United States District Court for the District of Minnesota, [John R. Tunheim](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0129294501&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), J., [808 F.Supp.2d 1125,](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2025992546&pubNum=4637&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)) denied manufacturer’s motions for new trial and for judgment as matter of law. Manufacturer appealed.

**Holdings:** The Court of Appeals, [Riley](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0208157001&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), Chief Judge, held that:

[[1]](#co_anchor_F62029301530_1) jury reasonably concluded that manufacturer did not adequately communicate its warning to patient’s doctor;

[[2]](#co_anchor_F112029301530_1) evidence supported causation element of patient’s claim; and

[[3]](#co_anchor_F142029301530_1) punitive damages award was not supported by evidence.

Affirmed in part and reversed in part. [Bye](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0118506901&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), Circuit Judge, concurred in part and dissented in part in separate opinion.

**Attorneys and Law Firms**

**\*1163** [Charles Lifland](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0141098301&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), argued, Los Angeles, CA, [Tracy Joan Van Steenburgh](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0275340901&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), [Dana M. Lenahan](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0330125701&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), Minneapolis, MN, [John Dames](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0204572901&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), Chicago, IL, [Cynthia Ann Merrill](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0395540701&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), Los Angeles, CA, on the brief, for appellant.

[Charles M. Wolfson](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0404007201&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), argued, New York, NY, [Ronald S. Goldser](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0115666601&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), Minneapolis, MN, [Lewis J. Saul](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0276556401&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), New York, NY, on the brief, for appellee.

Before [RILEY](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0208157001&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), Chief Judge, [BYE](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0118506901&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)) and [MELLOY](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0134215401&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), Circuit Judges.

**Opinion**

[RILEY](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0208157001&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), Chief Judge.

In 2005, John Schedin suffered [Achilles tendon ruptures](http://www.westlaw.com/Link/Document/FullText?entityType=injury&entityId=Ib89a8210475411db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) while taking the drug Levaquin, which Ortho–McNeil–Janssen Pharmaceuticals, Inc. (OMJP) markets in the United States. Schedin sued OMJP and others for failing to warn adequately of the risk of tendon rupture in patients who, like Schedin, are elderly and taking concomitant corticosteroids. A jury found OMJP primarily liable, awarding Schedin compensatory and punitive damages. OMJP appeals the district court’s denials of its motions for judgment as a matter of law (JMOL) and a new trial. We affirm in part and reverse in part.

**I. BACKGROUND**

**A. Factual Background**

[Levofloxacin](http://www.westlaw.com/Link/Document/FullText?entityType=gdrug&entityId=I3b6a8033475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) is a fluoroquinolone antibiotic OMJP marketed in the United States under the brand name Levaquin.[1](#co_footnote_B00212029301530_1) In February 2005, Dr. John Beecher prescribed both [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) and a corticosteroid to Schedin, who was then seventy-six years old. Schedin suffered a rupture of his left Achilles tendon and a partial tear of his right Achilles tendon after taking the drug combination.

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| [1](#co_footnoteReference_B00212029301530_ID0) | Levofloxacin is marketed under other names elsewhere. We refer to levofloxacin as “Levaquin” throughout this opinion for consistency. |

**\*1164** At that time, [Levaquin’s](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) package insert warned, in relevant part:

**Tendon effects:** [Ruptures of the ... Achilles tendon](http://www.westlaw.com/Link/Document/FullText?entityType=injury&entityId=Ib89a8210475411db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) ... that required surgical repair or resulted in prolonged disability have been reported in patients receiving quinolones, including [[Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0)]. Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant corticosteroids, especially in the elderly.

The warning had been largely in this form since 2001, when OMJP voluntarily added the second sentence. In 2004, the United States Food and Drug Administration (FDA) made this language mandatory for all fluoroquinolones.[2](#co_footnote_B00322029301530_1)

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| [2](#co_footnoteReference_B00322029301530_ID0) | We refer to the 2001 and 2004 warning labels collectively as the “2001 warning” because the FDA’s 2004 requirement did not substantially change the 2001 language about corticosteroids and the elderly. |

The [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) package insert consisted of over fifteen pages of small print information about the drug, including its proper use and possible side effects. The tendon warning appears in the last of the ten paragraphs in the “Warnings” section. The package insert also contained sections titled “Contraindications,” “Precautions,” and “Adverse Reactions,” among others. The tendon warning from [Levaquin’s](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) package insert also appeared in the Physicians’ Desk Reference (PDR), a common medical publication that contains label information about numerous drugs.

The tendon warning remained largely unchanged between 2001 and 2008. In 2008, the FDA sent OMJP a letter directing OMJP to set off [Levaquin’s](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) tendon warning in a black box because the 2001 warning was inadequate (2008 letter). In the 2008 letter, the FDA expressed concern about the large number of adverse event reports about [tendon injuries](http://www.westlaw.com/Link/Document/FullText?entityType=injury&entityId=Ib8533f5a475411db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) it continued to receive, despite the tendon warnings required for fluoroquinolones as a class. The FDA concluded, based upon its new analysis of such reports, “the current [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) labeling does not adequately warn healthcare providers and patients.” OMJP had access to all adverse event reports relating to [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0).

In 2002, the United Kingdom Medicines Control Agency (MCA) issued a report linking [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) to a greater incidence of [tendon injuries](http://www.westlaw.com/Link/Document/FullText?entityType=injury&entityId=Ib8533f5a475411db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) than other fluoroquinolones. The MCA recommended reviewing data from the United States to determine whether that data supported this conclusion. An OMJP affiliate sponsored a study (Ingenix study) in 2002 that concluded [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) did not materially increase the risk of tendon rupture more than other fluoroquinolones.

In addition to package inserts, drug companies communicate with physicians about their products using the PDR, in-person visits by sales representatives, “Dear Doctor” letters sent to individual physicians, and other methods. One article suggested properly worded and highly publicized “Dear Doctor” letters may contribute to reducing undesirable prescribing practices.

Dr. Beecher testified he learns about drug side effects from package inserts, a summary of the PDR, medical literature, sales representatives, and his colleagues. Dr. Beecher testified he prescribes 250 to 300 drugs in his practice and does not have enough time to check all package inserts for changes to the warnings. He reported relying on sales representatives “only minimally,” saying he “probably relie[s] on drug reps more than [he] think[s],” but tries “very hard to be objective.” Dr. Beecher noted he would have appreciated having more knowledge about the risk of **\*1165** prescribing [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) and a corticosteroid together.

Though Dr. Beecher knew of the risk of tendon rupture associated with [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0), he did not read and was not aware of the 2001 warning, regarding elderly patients taking corticosteroids, when he prescribed [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) to Schedin. OMJP did not send a “Dear Doctor” letter about the 2001 warning, and there is no evidence OMJP’s sales representatives attempted to communicate that warning personally to Dr. Beecher. Monica Sadar, an OMJP sales representative who visited Dr. Beecher several times per year, testified (1) her practice was “to discuss package insert changes with all practitioners,” but she did not specifically remember discussing the 2001 warning with Dr. Beecher; (2) her notes from meetings with Dr. Beecher do not indicate such a discussion; and (3) the [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) sales aids she used did not mention the risk of tendon rupture.

Dr. Beecher testified he would not have prescribed [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) to Schedin if he had known about the 2001 warning or what he knows now. Dr. Beecher also stated he no longer prescribes [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) unless a patient specifically requests it.

**B. Procedural History**

Schedin sued OMJP in federal district court, properly invoking the court’s diversity jurisdiction. *See* [28 U.S.C. § 1332](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000546&cite=28USCAS1332&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=LQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)). Schedin alleged he was injured by OMJP’s failure to warn Schedin and Dr. Beecher sufficiently about the risk of tendon rupture in elderly patients taking [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) and concomitant corticosteroids.[3](#co_footnote_B00432029301530_1) Schedin claimed OMJP negligently failed to (1) take adequate steps to alert doctors to the information in the 2001 warning, and (2) warn of [Levaquin’s](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) tendon toxicity relative to other fluoroquinolones.

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| [3](#co_footnoteReference_B00432029301530_ID0) | Schedin asserted other claims against OMJP, OMJP’s parent company, Johnson & Johnson, and another affiliate that are not at issue in this appeal. |

After a jury found OMJP primarily liable, awarding Schedin compensatory damages of $630,000 (after reducing the overall assessment of damages by 15% due to Dr. Beecher’s contributing fault) and punitive damages of $1,115,000, OMJP moved for JMOL and a new trial. OMJP appeals from the district court’s denial of OMJP’s motions. We have jurisdiction under [28 U.S.C. § 1291](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000546&cite=28USCAS1291&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=LQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)).

**II. DISCUSSION**

**A. Applicable Law and Standard of Review**

[**[1]**](#co_anchor_F12029301530_1) We apply Minnesota law to Schedin’s failure-to-warn claim.[4](#co_footnote_B00542029301530_1) *See* [*Winthrop Res. Corp. v. Stanley Works,* 259 F.3d 901, 904 (8th Cir.2001)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2001665651&pubNum=506&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_506_904&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_506_904) (“As a federal court sitting in diversity jurisdiction, we apply the law that the forum state would apply.”). In addition, “[w]hen federal jurisdiction is premised on diversity of citizenship, a federal district court applies the sufficiency standards of the state in which it sits,” in this case Minnesota. [*Carpenter v. Auto. Club Interinsurance Exch.,* 58 F.3d 1296, 1301 (8th Cir.1995)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1995143017&pubNum=506&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_506_1301&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_506_1301).

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| [4](#co_footnoteReference_B00542029301530_ID0) | Neither party disputes the district court’s application of Minnesota law. |

A district court must grant JMOL if “there is no legally sufficient evidentiary basis for a reasonable jury to find for [the non-moving] party.” [Minn. R. Civ. P. 50.01(a)](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000044&cite=MNSTRCPR50.01&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=LQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)); *see* [Minn. R. Civ. P. 50.02](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000044&cite=MNSTRCPR50.02&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=LQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)) (concerning renewed motions for judgment as a matter of law). We review de novo the district court’s denial of JMOL. *See* [*Weber v. Strippit, Inc.,* 186 F.3d 907, 912 (8th Cir.1999)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1999177536&pubNum=506&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_506_912&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_506_912).

**\*1166** [**[2]**](#co_anchor_F22029301530_1) The standard for granting a new trial is “less rigorous than the standard for granting” JMOL. [*Clifford v. Geritom Med, Inc.,* 681 N.W.2d 680, 687 (Minn.2004)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2004623363&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_687&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_687). A new trial is merited when “the verdict is so contrary to the preponderance of the evidence as to imply that the jury failed to consider all the evidence, or acted under some mistake.” [*Id.*](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2004623363&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)) (quoting [*LaValle v. Aqualand Pool Co.,* 257 N.W.2d 324, 328 (Minn.1977)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1977131093&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_328&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_328)) (internal marks omitted); see also [Minn. R. Civ. P. 59.01(g)](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000044&cite=MNSTRCPR59.01&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=LQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)). We review the district court’s denial of “a new trial for a clear abuse of discretion.” [*Harrison v. Purdy Bros. Trucking Co.,* 312 F.3d 346, 351 (8th Cir.2002)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2002754909&pubNum=506&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_506_351&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_506_351) (quoting [*Duty v. Norton–Alcoa Proppants,* 293 F.3d 481, 495 (8th Cir.2002)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2002375235&pubNum=506&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_506_495&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_506_495)) (internal quotation marks omitted).

**B. Failure to Warn**

Schedin presents two theories of failure-to-warn liability, alleging OMJP negligently failed to (1) use adequate means to inform Dr. Beecher of the 2001 warning against use of [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) with elderly patients on corticosteroids, and (2) include comparative tendon toxicity information in the package insert. Because OMJP was not entitled to JMOL or a new trial in light of Schedin’s first theory, we need not address whether the district court erred in denying OMJP’s motions based upon Schedin’s comparative toxicity theory because any such error was harmless—Schedin was entitled to compensatory damages based on the first theory, even if the district court erred as to the comparative toxicity theory. *Cf.* [*Thomlison v. City of Omaha,* 63 F.3d 786, 791 (8th Cir.1995)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1995175135&pubNum=506&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_506_791&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_506_791) (determining any error in granting JMOL on certain claims was harmless where the “the district court’s judgment [on plaintiff-appellant’s other claim] preserved her full monetary and other relief”).

[**[3]**](#co_anchor_F32029301530_1) [**[4]**](#co_anchor_F42029301530_1) [**[5]**](#co_anchor_F52029301530_1) A plaintiff asserting a negligent failure-to-warn claim under Minnesota law “must show: (1) the defendant[ ] had reason to know of the dangers of using the product; (2) ‘the warnings fell short of those reasonably required,’ breaching the duty of care; and (3) the lack of an adequate warning caused the plaintiff’s injuries.” [*Tuttle v. Lorillard Tobacco Co.,* 377 F.3d 917, 924 (8th Cir.2004)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2004789912&pubNum=506&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_506_924&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_506_924) (quoting [*Erickson ex rel. Bunker v. Am. Honda Motor Co.,* 455 N.W.2d 74, 77 (Minn.Ct.App.1990)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1990074530&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_77&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_77)). “[T]he existence of a duty to warn is a” question of law. [*Balder v. Haley,* 399 N.W.2d 77, 81 (Minn.1987)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1987002954&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_81&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_81). Under the learned intermediary doctrine,[5](#co_footnote_B00652029301530_1) as adopted in Minnesota, prescription drug manufacturers can satisfy their duty to warn by warning prescribing physicians of the risks associated with a drug, rather than warning patients directly. *See* [*Mulder,* 181 N.W.2d at 885 & n. 1](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1970126326&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_885&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_885).

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| [5](#co_footnoteReference_B00652029301530_ID0) | The learned intermediary doctrine provides that a drug “manufacturer has no duty to warn the lay public regarding prescription drugs,” but rather must warn the prescribing physician. [*Mulder v. Parke Davis & Co.,* 288 Minn. 332, 181 N.W.2d 882, 885 & n. 1 (1970)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1970126326&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_885&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_885). The reason for this rule is that the physician “is in the best position to give a highly individualized warning to a patient based on the physician’s knowledge of the patient and the inherent risks of the drug.” [*Kociemba v. G.D. Searle & Co.,* 680 F.Supp. 1293, 1305 (D.Minn.1988)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1988030654&pubNum=345&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_345_1305&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_345_1305). |

OMJP does not dispute it had notice of the risk of tendon rupture in elderly patients taking concomitant corticosteroids. The parties debate whether OMJP’s warning and the means of communicating that warning were adequate, and, if not, whether any inadequacy caused Schedin’s injury. Because OMJP’s arguments for JMOL and a new trial on Schedin’s failure to warn claim are substantially similar, we address the district court’s rulings on OMJP’s motions together.

**\*1167** **1. Inadequate Communication of 2001 Warning**

[**[6]**](#co_anchor_F62029301530_1) The district court denied OMJP’s motion for a new trial, finding the jury’s verdict that OMJP did not adequately communicate the 2001 warning to Dr. Beecher was not against the great weight of the evidence and thus was not a miscarriage of justice under Minnesota law.[6](#co_footnote_B00762029301530_1) Though OMJP changed the tendon warning in the package insert, there is just enough evidence to support a reasonable jury finding OMJP did not use sufficient means, under the circumstances of this case, to advise Dr. Beecher of the 2001 warning once OMJP learned the package insert was ineffective.

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| [6](#co_footnoteReference_B00762029301530_ID0) | The district court did not address these arguments under the standard for JMOL because the district court “determined those arguments fail under the less stringent standard of that for a new trial.” We agree. *See* [*Clifford,* 681 N.W.2d at 687](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2004623363&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_687&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_687). |

Courts disagree about whether simply changing the package insert warnings insulates a drug manufacturer from failure-to-warn liability, and Minnesota courts have not decided this issue. Many courts considering the question have held a properly worded package insert is a sufficient warning as a matter of law, at least when it is combined with an entry in the PDR. *See*, *e.g.,* [*Foister v. Purdue Pharma., L.P.,* 295 F.Supp.2d 693, 705–08 (E.D.Ky.2003)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2004077407&pubNum=4637&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_4637_705&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_4637_705); [*MacPherson v. Searle & Co.,* 775 F.Supp. 417, 425 (D.D.C.1991)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1991173193&pubNum=345&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_345_425&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_345_425); [*Weinberger v. Bristol–Myers Co.,* 652 F.Supp. 187, 190 (D.Md.1986)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1987007294&pubNum=345&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_345_190&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_345_190); [*Dunkin v. Syntex Labs., Inc.,* 443 F.Supp. 121, 124 (W.D.Tenn.1977)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1978197337&pubNum=345&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_345_124&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_345_124). On the other hand, applying South Dakota law, our court concluded, “when the dangers of the prolonged use of [a] drug ... became reasonably apparent, it was not unreasonable to find that the [manufacturer] should have employed all its usual means of communication, including [sales representatives], to warn the prescribing physicians of these dangers.” [*Sterling Drug, Inc. v. Yarrow,* 408 F.2d 978, 992 (8th Cir.1969)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1969117795&pubNum=350&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_350_992&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_350_992). We do not address this split by deciding the issue as a matter of law because, on the narrow facts of this case, there was sufficient evidence for a reasonable jury to find OMJP should have known that the package insert and PDR warnings were not adequately communicating the 2001 warning to physicians.

The 2001 warning added a sentence to the last paragraph of the ten paragraph “Warnings” section of the package insert. It was surrounded by more than fifteen pages of other small print. More importantly, the FDA’s 2008 letter indicates the FDA received a large number of reports about [tendon injuries](http://www.westlaw.com/Link/Document/FullText?entityType=injury&entityId=Ib8533f5a475411db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) related to [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) use. The jury could infer at least some of the reports were made between 2001 and Schedin’s 2005 prescription and injury. OMJP had access to these adverse event reports. From this evidence, a reasonable jury could find OMJP should have realized the adverse event reports indicated physicians were unaware of the 2001 warning. The district court did not abuse its discretion in deciding it was not against the preponderance of the evidence or a miscarriage of justice under Minnesota law for the jury to find OMJP had reason to know it needed to do more to inform physicians of the 2001 warning, such as sending “Dear Doctor” letters or directing sales representatives to warn physicians directly. The district court properly denied JMOL for the same reasons.

[**[7]**](#co_anchor_F72029301530_1) OMJP maintains the district court erred in admitting the 2008 FDA letter into evidence because OMJP “cannot be liable for knowledge [OMJP] could not have possessed until later.” OMJP argues the letter contains such later-acquired information because (1) the FDA can require **\*1168** label changes based only on new information; and (2) most of the events to which the letter refers must have occurred after Schedin’s February 2005 injury because the 2008 letter “emphasized reliance on adverse event reports received after the” FDA approved the revised tendon warning for all fluoroquinolones in 2004.

[**[8]**](#co_anchor_F82029301530_1) As discussed above, the 2008 letter provides some corroboration of the probability OMJP had some knowledge of the adverse event reports before Schedin’s injury in February 2005. Although the FDA must notify drug manufacturers of “new safety information that the Secretary believes should be included in” a drug label, [21 U.S.C. § 355(*o* )(4)](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000546&cite=21USCAS355&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=LQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), nothing in the definition of “new safety information” excludes information that was known or knowable before a label change, *see* [21 U.S.C. § 355–1(b)(3)](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000546&cite=21USCAS355-1&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RB&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_d801000002763). In fact, such information “may be based on a new analysis of” information that existed when the FDA initially approved a drug. [21 U.S.C. § 355–1(b)(3)(A)](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000546&cite=21USCAS355-1&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RB&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_609d000059b95). The jury reasonably could have found some reports were made before Schedin’s 2005 injury. The district court could have found the letter inadmissible, but did not abuse its considerable discretion in admitting the FDA’s 2008 letter. *See* [*Der v. Connolly,* 666 F.3d 1120, 1130–31 (8th Cir.2012)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2026920752&pubNum=506&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_506_1130&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_506_1130) (standard of review).

**2. Causation**

[**[9]**](#co_anchor_F92029301530_1) [**[10]**](#co_anchor_F102029301530_1) Although, generally, “[w]here warning is given, *the seller may reasonably assume that it will be read and heeded*,” [*J & W Enters., Inc. v. Economy Sales, Inc.,* 486 N.W.2d 179, 181 (Minn.Ct.App.1992)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1992113343&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_181&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_181) (emphasis in [*J & W Enters., Inc.*)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1992113343&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)) (quoting [*Restatement (Second) of Torts* § 402A](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=0290694188&pubNum=0101577&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=TS&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), cmt. j (1965)) (internal quotation marks omitted), failure to read a warning does not necessarily bar recovery where, as here, the plaintiff claims inadequate communication of the warning caused the failure to read it. *Cf.* [*Johnson v. Niagara Mach. & Tool Works,* 666 F.2d 1223, 1225–26 & n. 3 (8th Cir.1981)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1981152808&pubNum=350&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_350_1225&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_350_1225) (applying Minnesota law on a failure to warn claim, affirming the district court’s grant of a directed verdict for the defendant because the plaintiff had not read the warning, and leaving open the possibility of a different result if the plaintiff had claimed the warning’s form was inadequate). To prove causation in a Minnesota failure to warn case, it is sufficient to present testimony that purchasers would have avoided the risk of harm had they been told of the relevant danger. *See* [*Erickson,* 455 N.W.2d at 78.](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1990074530&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_78&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_78) Because the learned intermediary doctrine applies, OMJP had a duty to warn Dr. Beecher, rather than warning Schedin directly, *see* [*Mulder,* 181 N.W.2d at 885 & n. 1,](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1970126326&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_885&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_885) and the principle of [*Erickson*](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1990074530&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)) should apply with equal force in the learned intermediary doctrine context.

[**[11]**](#co_anchor_F112029301530_1) The district court found sufficient evidence of causation, reasoning “the jury could infer from the fact that [Dr.] Beecher no longer prescribes [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) that **some** piece of information would have altered his prescribing decision since, in fact, he has changed his prescribing patterns as a result of his increased awareness of the risks of the drug.” Dr. Beecher testified he no longer prescribes [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) unless a patient requests it. Even more to the point, Dr. Beecher declared he would not have prescribed [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) for Schedin had Dr. Beecher been aware of the 2001 warning and known what he knows now. *See* [*Erickson,* 455 N.W.2d at 78](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1990074530&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_78&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_78).

OMJP argues Schedin did not prove causation because Dr. Beecher spends little time with sales representatives and did not testify he read or relied on “Dear Doctor” letters. We disagree. Dr. Beecher stated he relies on sales representatives “only minimally” and tries “very hard to **\*1169** be objective.” This reasonably can be interpreted as meaning Dr. Beecher did not rely heavily on sales representatives’ promotional efforts—not that he would have ignored a warning—especially because Dr. Beecher said he would have appreciated having more knowledge about this particular side effect. Also, there is general study evidence indicating properly worded and highly publicized “Dear Doctor” letters may reduce risky prescribing practices. Although Dr. Beecher did not specifically testify he relies on “Dear Doctor” letters, physicians reportedly receive and rely on information about drug warnings from such letters. Dr. Beecher did testify he relies on his colleagues’ comments about particular drugs. Although a stretch, the jury reasonably could infer Dr. Beecher would have learned about the changed warning if OMJP warned Dr. Beecher or his colleagues using sales representatives or publicized “Dear Doctor” letters. The district court did not abuse its discretion in holding such a jury finding was not against the preponderance of the evidence.

The district court did not err in denying OMJP’s motions for JMOL or a new trial based on the jury’s award of compensatory damages.

**C. Punitive Damages**

[**[12]**](#co_anchor_F122029301530_1) [**[13]**](#co_anchor_F132029301530_1) Under Minnesota law, punitive damages are “allowed in civil actions only upon clear and convincing evidence” the defendant “deliberate[ly] disregard[ed] ... the rights or safety of others.” [Minn.Stat. § 549.20 subd. 1(a)](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000044&cite=MNSTS549.20&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=SP&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_2add000034c06). This means the defendant knew of “or intentionally disregard[ed] facts that create a high probability of injury to the rights or safety of others and ... deliberately proceed[ed] to act in conscious or intentional disregard ... or ... with indifference to” that probability. [Minn.Stat. § 549.20 subd. 1(b)](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000044&cite=MNSTS549.20&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=SP&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_2add000034c06). Punitive damages are appropriate where the defendant “did not merely fail to act, but ... continued to market a product which was so mislabeled so as to mislead the public into believing that” the hazard did not exist. [*Olson v. Snap Prods., Inc.,* 29 F.Supp.2d 1027, 1039 (D.Minn.1998)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1998251851&pubNum=4637&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_4637_1039&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_4637_1039). Punitive damages require “a maliciousness, an intentional or willful failure to inform or act,” and are not proper where the defendant “actively sought ways to prevent the dangers associated with its product.” [*Beniek v. Textron, Inc.,* 479 N.W.2d 719, 723 (Minn.Ct.App.1992)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1992018532&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_723&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_723).

[**[14]**](#co_anchor_F142029301530_1) The district court upheld the jury’s award of punitive damages because of evidence OMJP “knew of the potential for the higher tendon toxicity of [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0), assisted in the design of [the Ingenix study,] allegedly to hide that potential and cloud the field of academic literature on the topic, and then failed to adequately warn prescribers.” (internal citations omitted). On this record, this motive allegation is mere speculation.

As a matter of law, the record evidence failed to establish OMJP deliberately disregarded the risk of [tendon injuries](http://www.westlaw.com/Link/Document/FullText?entityType=injury&entityId=Ib8533f5a475411db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) in elderly patients taking corticosteroids, as required for punitive damages under Minnesota law. By warning of that risk in its package insert, OMJP “actively sought ways to prevent the dangers associated with its product.” [*Beniek,* 479 N.W.2d at 723.](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1992018532&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_723&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_723) The 2001 warning also was published in the PDR, a reference widely used by physicians. Regardless of OMJP’s alleged actions relating to the Ingenix study, we cannot characterize OMJP as hiding information it openly published. The 2001 warning was in Dr. Beecher’s physical possession and was specific and clear if read. For drug warnings to succeed in protecting patients, doctors must order their practice and their continuing medical education so as to find time to learn about new **\*1170** and updated warnings for the drugs the doctor is prescribing.[7](#co_footnote_B00872029301530_1)

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| [7](#co_footnoteReference_B00872029301530_ID0) | Schedin was in Dr. Beecher’s care, according to Dr. Beecher, for “15 minutes tops.” |

The evidence is neither clear nor convincing, as a matter of law, that OMJP deliberately disregarded the safety of the users of [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0). The district court erred in denying JMOL for OMJP on punitive damages.[8](#co_footnote_B00982029301530_1)

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| [8](#co_footnoteReference_B00982029301530_ID0) | We therefore do not reach OMJP’s arguments for a new trial based on errors relating to Schedin’s punitive damages claim. |

**III. CONCLUSION**

We affirm in part and reverse in part. We affirm the district court’s denial of OMJP’s motions for JMOL or a new trial on Schedin’s claim for compensatory damages, and reverse the denial of OMJP’s motion for JMOL on punitive damages.

[BYE](http://www.westlaw.com/Link/Document/FullText?findType=h&pubNum=176284&cite=0118506901&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), Circuit Judge, concurring in part and dissenting in part.

I concur in affirming the district court’s decision to deny OMJP’s motions for judgment as a matter of law and for a new trial with respect to the jury’s award of compensatory damages. I believe, however, there was sufficient evidence from which a reasonable jury could conclude OMJP deliberately disregarded the risk of [tendon injuries](http://www.westlaw.com/Link/Document/FullText?entityType=injury&entityId=Ib8533f5a475411db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) in elderly patients who were prescribed [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) in association with corticosteroids. I therefore respectfully dissent from the decision to reverse the denial of OMJP’s motion for judgment as a matter of law on punitive damages.

When reviewing the district court’s denial of the motion for judgment as a matter of law on punitive damages, we “must draw all reasonable inferences in favor of the nonmoving party, and ... may not make credibility determinations or weigh the evidence.” [*Reeves v. Sanderson Plumbing Prods., Inc.,* 530 U.S. 133, 150, 120 S.Ct. 2097, 147 L.Ed.2d 105 (2000)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2000377873&pubNum=708&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)). “Judgment as a matter of law is appropriate only when all of the evidence points one way and is susceptible of no reasonable inference sustaining the position of the nonmoving party.” [*Howard v. Mo. Bone & Joint Ctr., Inc.,* 615 F.3d 991, 995 (8th Cir.2010)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2022750090&pubNum=506&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_506_995&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_506_995) (internal quotation marks and citation omitted).

In denying OMJP’s motion for judgment as a matter of law, the district court emphasized three points: (1) OMJP’s knowledge of [Levaquin’s](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) potential for higher tendon toxicity; (2) OMJP’s assistance in the design of the Ingenix study with the motive to cloud the field of academic literature on the topic of [Levaquin’s](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) potential for higher tendon toxicity; and (3) OMJP’s failure to adequately warn prescribers of [Levaquin’s](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) potential for higher tendon toxicity. *See* [*Schedin v. Ortho–McNeil–Janssen Pharm., Inc.,* 808 F.Supp.2d 1125, 1137 (D.Minn.2011)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=2025992546&pubNum=4637&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_4637_1137&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_4637_1137). In reversing the district court, the majority cryptically states “this motive allegation is mere speculation,” *ante* at 1169, presumably disagreeing with the district court’s second point.

The punitive damage award should not, however, rise or fall on whether the jury reasonably found OMJP manipulated the Ingenix study. Even assuming the jury rejected Schedin’s allegations regarding the Ingenix study, the evidence was more than sufficient to allow a reasonable jury to infer that OMJP deliberately acted with indifference to a high degree of probability of injury, *see* [Minn.Stat. § 549.20(1)](http://www.westlaw.com/Link/Document/FullText?findType=L&pubNum=1000044&cite=MNSTS549.20&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=LQ&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)), based on (1) OMJP’s knowledge of the serious risks associated with [Levaquin’s](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) potential for higher tendon toxicity when prescribed to elderly patients in conjunction with corticosteroids, and (2) OMJP deliberately choosing a course of action whereby physicians **\*1171** would not be adequately apprised of the increased risk.

Schedin presented evidence from which a jury could reasonably infer OMJP was more concerned about its profits, and how those profits would be affected by effective warnings, than it was about the possibility [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) could injure elderly patients who were prescribed the drug in association with corticosteroids. As early as 1999, OMJP was aware of an increased risk of [tendon disorders](http://www.westlaw.com/Link/Document/FullText?entityType=disease&entityId=Iae3d4eda475411db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) associated with the use of [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) in patients who had been prescribed a steroid. Schedin presented evidence of OMJP’s perception of the regulatory action taken in Europe in response to numerous adverse event reports associating [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) with [tendon injuries](http://www.westlaw.com/Link/Document/FullText?entityType=injury&entityId=Ib8533f5a475411db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0), evidence which showed OMJP connected an increase in regulation with a decrease in profits. Included in this evidence was a memo in which OMJP linked the sending of a Dear Doctor letter—something the jury’s verdict on compensatory damages clearly infers OMJP should have undertaken in order to satisfy its legal duty to provide an adequate warning—directly to the company’s profits *vis a vis* its marketing of [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0). “[I]f a Dear Dr letter has to go out and consequently reporting goes up—as it will do, leading to an aggravation of the situation and ultimate product withdrawal.” Appellee’s App. at 473.

The original label OMJP issued when it first began marketing Levaquin in the United States contained no mention about the increased risks associated with prescribing [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) to elderly patients. The evidence showed that it is customary for physicians to rely upon Dear Doctor letters, and updates from pharmaceutical representatives, whenever there is a significant change in a product’s labeling after its initial release into the marketplace. But when OMJP revised [Levaquin’s](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) labeling in 2002, it deliberately chose not to issue Dear Doctor letters or even to instruct its pharmaceutical representatives to advise physicians of the label change. Instead, OMJP deliberately chose to bury the updated warning—a single twenty-word sentence—inside thirty pages of fine print in the revised package insert, and then took no further action to ensure physicians would be aware of the label’s revised warnings. The jury could reasonably infer OMJP chose this course of action because issuing Dear Doctor letters, or instructing pharmaceutical representatives to spread the word about the increased risk, would have a direct and adverse affect on OMJP’s profits.

Thus, contrary to the majority’s conclusion that OMJP’s conduct showed the company “actively sought ways to prevent the dangers associated with its product[,]” *ante* at 1169 (quoting [*Beniek v. Textron, Inc.,* 479 N.W.2d 719 723 (Minn.Ct.App.1992)](http://www.westlaw.com/Link/Document/FullText?findType=Y&serNum=1992018532&pubNum=595&originatingDoc=I777da39f3af411e28a21ccb9036b2470&refType=RP&fi=co_pp_sp_595_723&originationContext=document&vr=3.0&rs=cblt1.0&transitionType=DocumentItem&contextData=(sc.Search)#co_pp_sp_595_723)), OMJP’s deliberate choices virtually guaranteed that physicians would remain unaware of the increased risk of prescribing [Levaquin](http://www.westlaw.com/Link/Document/FullText?entityType=bdrug&entityId=I37b91139475111db9765f9243f53508a&originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&vr=3.0&rs=cblt1.0) to elderly patients in conjunction with corticosteroids. By reversing the punitive damage award we encourage other pharmaceutical companies to make the same devious choices OMJP made, instead of affirming the jury’s decision to deter such conduct.

I concur in part, and respectfully dissent in part.

**All Citations**

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