United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 11-2082

Paul Schilf; Cynthia Schilf, as Special Administrators for the Estate of Peter Raymond Schilf, Deceased; Paul Schilf; Cynthia Schilf, Individually,	*	
	*	Appeal from the United States
Appellants,	*	District Court for the
	*	District of South Dakota.
v.	*	
	*	
Eli Lilly & Company; Quintiles Transnational Corporation,	*	
	*	
Appellees.	*	

Submitted: February 14, 2012
Filed: August 3, 2012

Before GRUENDER, BENTON, and SHEPHERD, Circuit Judges.

BENTON, Circuit Judge.

Paul R. and Cynthia J. Schilf sued Eli Lilly & Company and Quintiles Transnational Corporation ("Lilly"). They alleged Lilly's failure to warn and deceit caused the death of their son, Peter Raymond Schilf. Lilly moved for summary

judgment, which the district court granted. Jurisdiction being proper under 28 U.S.C. § 1291, this court reverses and remands.

I.

This court states the facts most favorably to the Schilfs.

On November 26, 2004, Cynthia Schilf accompanied her sixteen-year-old son Peter to an appointment to discuss his depression with their family practitioner Dr. Richard G. Briggs. Peter complained of having various symptoms of depression since at least the prior summer. Dr. Briggs diagnosed Peter with depression and gave him samples of the antidepressant medication Cymbalta. These samples had been removed from the packaging and thus had no warning information. Dr. Briggs spoke with Cynthia and Peter Schilf about the risks of antidepressant treatment. Dr. Briggs recalls telling them that while there "may be an increased association with anti-depressants and suicidal ideations and gestures," "[n]o completed suicides occurred during the clinical trials," and "Cymbalta was not specifically studied." Dr. Briggs was referencing an FDA study and chose to prescribe Cymbalta in part because he believed it was less linked to suicide than another antidepressant evaluated in that study, Prozac.

In fact, there were five completed suicides in Lilly-sponsored clinical trials of Cymbalta, which was studied separately from the drugs Dr. Briggs referenced. Just over a month before Peter's appointment, the FDA issued a Public Health Advisory telling the public that it directed manufacturers of antidepressants to include in their packaging a "black box" warning: "Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders." A black box warning describes special problems, particularly those that may lead to death or serious injury, in a prominently-displayed box so that it is readily apparent. On the same day, the FDA

issued a press release entitled, "FDA Launches a Multi-Pronged Strategy to Strengthen Safeguards for Children Treated with Antidepressant Medications." In a separate letter to manufacturers, the FDA said, "A causal role for antidepressants in inducing suicidality has been established in pediatric patients."

Within a day of receiving the medication samples, Peter, with the oversight of his father, searched the internet for Cymbalta and found Lilly's website for it. Peter's father testified that if he had noticed a warning about suicidality, he would not have allowed Peter to take the medication.

On December 24, 2004, Peter committed suicide. One month later, Lilly revised the Cymbalta literature to include the FDA-approved black box warning.

II.

This court reviews de novo a grant of summary judgment. ***Mason v. Corr. Med. Servs., Inc.***, 559 F.3d 880, 884 (8th Cir. 2009). Summary judgment should be granted when—viewing the facts most favorably to the nonmoving party and giving that party the benefit of all reasonable inferences—the record shows that there is no genuine issue of material fact. *See* **Fed. R. Civ. P. 56(c)**; ***Torgerson v. City of Rochester***, 643 F.3d 1031, 1042 (8th Cir. 2011) (en banc). An issue is "genuine" if the evidence is sufficient to persuade a reasonable jury to return a verdict for the nonmoving party. ***Anderson v. Liberty Lobby, Inc.***, 477 U.S. 242, 248 (1986). "As to materiality, the substantive law will identify which facts are material." ***Id.*** At summary judgment, the court's function is not to weigh the evidence and determine the truth of the matter itself, but to determine whether there is a genuine issue for trial. ***Id.*** at 249.

To survive summary judgment, the Schilfs must establish a genuine issue of material fact whether an adequate warning would have altered Dr. Briggs' decision

to prescribe Cymbalta. *See* ***In re Prempro Prods. Liab. Litig.***, 586 F.3d 547, 569 (8th Cir. 2009); *see also* ***Ehlis v. Shire Richwood, Inc.***, 367 F.3d 1013, 1016 (8th Cir. 2004) ("The learned intermediary doctrine states that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly."). The Schilfs rely on the heeding presumption—the presumption that a reasonable person (here, Dr. Briggs) would act according to an adequate warning. *See* **Restatement (Second) of Torts § 402a cmt. j.** It is likely that South Dakota would adopt this presumption. *See* ***McElhaney v. Eli Lilly***, 739 F.2d 340, 340 (8th Cir. 1984). The district court, relying on *Thom v. Bristol-Myers Squib Co.*, 353 F.3d 848, 856 (10th Cir. 2003), ruled that Dr. Briggs' behavior rebutted the presumption because he prescribed Cymbalta with knowledge of its risks.

A.

The district court first found that "a warning from [Lilly] would not have informed Dr. Briggs of anything he did not already know" about the risks of Cymbalta. The court wrote: "Dr. Briggs was aware of the same warnings that [the Schilfs] now say [Lilly] should have given to prescribing physicians such as Dr. Briggs." *See* ***Ehlis***, 367 F.3d at 1016 (8th Cir. 2004) (noting that a plaintiff cannot prevail on a failure-to-warn claim if the prescribing physician knew the information that would have been in an adequate warning).

The Schilfs' desired warnings were that (1) five suicides occurred during Cymbalta clinical trials (including one during a trial for a condition other than depression), (2) there is a causal role for Cymbalta in suicidality, and (3) the suicide risk in taking antidepressants is increased in children and adolescents.[1] Dr. Briggs

[1]The dissent states that the Schilfs did not state a desire for a causal role warning "[u]ntil this appeal." This is incomplete. In addition to twice referencing

did not recall any suicides occurring in the clinical trials of Cymbalta, and he believed that no causal connection had been established between Cymbalta and suicidality.

Dr. Briggs was not aware of the five suicides that occurred during clinical trials of Cymbalta. He testified he reviewed the Cymbalta package insert, which cautions that "completed suicide" and "suicide attempt" were "infrequent adverse events." At his deposition, he did not recall this warning and was interested in "see[ing] the information." The insert did not state the number of suicides that occurred during the clinical trials. It also did not indicate in any way that the "completed suicide" and "suicide attempt" adverse events were more significant than the other events detailed in fine-print surrounding them. Dr. Briggs testified that before prescribing Cymbalta, he would have wanted to know the details about any suicide that occurred during its clinical trials.

Dr. Briggs testified that while he was not aware of a causal link between Cymbalta and suicide, he was aware of an association. The package insert clearly

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causality in the amended complaint, the Schilfs presented the argument several other times. In their opposition to Lilly's motion for summary judgment, the Schilfs stated that summary judgment was inappropriate because "Dr. Briggs had no idea that causality had been established for antidepressant induced pediatric suicidality." In the district court's hearing on the matter, counsel for the Schilfs stated no less than three times that "causality has been established." The Schilfs' counsel stated once even more plainly: "This pill can cause you to take your own life." The Schilfs' expert on this point was also the subject of several motions by Lilly. In the opinion on general causation, the expert wrote that Cymbalta "can cause younger patients to become suicidal." The district court also understood causality to be one thrust of the Schilfs' arguments. In its order granting summary judgment, the district court wrote that it would presume the warnings inadequate for the purposes of the summary judgment determination because "[a]lthough suicidality is mentioned, the warnings provided by Lilly prior to the black box warnings do not convey a causal connection between taking Cymbalta and suicidality."

said that "a causal role for antidepressants in inducing suicidality has not been established," but did caution that patients should "[n]evertheless" be observed for suicidality. Dr. Briggs' understanding of the FDA's determination was that there was an association between antidepressants and suicide but that "[t]hey weren't saying the risk was there."[2] Asked what he understood in 2004 about the increased risk in taking antidepressants and suicide, he answered: "I think it was unknown at that time based on the information available." Asked whether "there's an increase in suicide risk when taking antidepressants," Dr. Briggs answered, "I think it remains to be seen, yeah." A warning that an adverse effect is "associated" with a medication—like the one Dr. Briggs gave—is not a warning that a causal connection exists. *See* ***Thom***, 353 F.3d at 853-54 (collecting cases to that effect).

Dr. Briggs' testimony is unclear about what he knew about the increased risk of suicide among children and adolescents who take Cymbalta. He testified that he had not seen any reports on the effects of Cymbalta on people under the age of 18 but could "remember seeing Cymbalta mentioned with pediatrics use." No one asked Dr. Briggs the source or the contents of the "mention."

The district court incorrectly stated that Dr. Briggs testified that he "read" the 2004 FDA press release and that the Schilfs admit he did so. To the contrary, Dr. Briggs testified that he was "aware" of the press release because it was "in the media"—"on the news, radio, televisions, all those." He also did not answer a question whether he had read the FDA study that was the basis of the press release. He answered yes to a question whether he had "seen and become aware of" the press

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[2]The dissent's argument that Dr. Briggs understood the contents of the FDA study misses the mark. Even if Dr. Briggs was familiar with this information, he did not understand that the study also represented the risks of taking antidepressants other than those specifically studied, including Cymbalta, and based his prescription decision on that belief. There is a genuine issue of material fact whether he knew the suicide-related risks of *Cymbalta*.

release. No one elicited testimony about what Dr. Briggs thought the press release said.

There are genuine issues of material fact whether Dr. Briggs knew the suicide-related information that an adequate warning would have contained.[3] *See* ***Ehlis***, 367 F.3d at 1016 (8th Cir. 2004).

B.

The district court found that Dr. Briggs would have prescribed Cymbalta to Peter even if he knew of its actual risks. *See* ***In re Prempro Prods. Liab. Litig.***, 586 F.3d at 569 (noting that a plaintiff cannot prevail on a failure-to-warn claim if an adequate warning would not have changed the prescribing physician's decision).

Dr. Briggs' deposition is unclear whether he would have still prescribed Cymbalta if given information about the clinical trial suicides or any causal role for Cymbalta in inducing suicidality. No one asked Dr. Briggs whether he would have prescribed Cymbalta to Peter if Lilly—through a black box warning, a letter, or its sales representatives—had informed him of the suicide-related information. Dr. Briggs stated that he has not made a decision not to prescribe Cymbalta given the information about suicides, but he could not remember whether he had prescribed it

[3]Lilly asserts that federal pre-emption justifies summary judgment. Lilly argues that because the FDA did not approve its language asserting a causal role for Cymbalta in suicidality, the Schilfs' failure-to-warn claim on that basis is pre-empted. (Without mentioning pre-emption, the dissent also intimates that the FDA's determination not to allow the "causal role" language in antidepressant labeling resolves the warning issue.) Lilly's argument—restricted to the one sentence the FDA rejected—would not resolve this case. Additionally, Lilly does not argue it was barred from disseminating information through its sales representatives. Last, the Schilfs' claim is not limited to the time after the FDA issued its Public Health Advisory, press release, and new warnings; they point to those events as evidence of Cymbalta's alleged misbranding.

to an adolescent since Peter's suicide. The district court relied heavily on Dr. Briggs' statement that he still believed his prescription decision was appropriate, finding that he testified that "he would prescribe Cymbalta for Peter Schilf given adequate warnings." The question Dr. Briggs was asked could be asking if Dr. Briggs' decision was appropriate at the time it was made, given the information he had then. Read this way, the question would be consistent with those asked earlier in the deposition. When asked if there were anything he would have done differently, Dr. Briggs answered: "*Not at the time*. I did – I did exactly what I *would have* done." The district court's conclusion that Dr. Briggs would prescribe Cymbalta to Peter again with an adequate warning also fails because, even at the time of his deposition, Dr. Briggs was not aware of the suicide-related information.

The district court's conclusion is also inconsistent with Dr. Briggs' behavior. Dr. Briggs testified that he does not tell a patient every warning and precaution for a drug he prescribes, but he does discuss the ones that are "most likely to apply." He discussed suicide with the Schilfs before prescribing Cymbalta—noting his belief that no completed suicides occurred in the trial. He also specifically chose Cymbalta because it was not included in the pooled study on which the FDA based its suicide warning.

Alternatively, Lilly argues that the 2004 Cymbalta warnings were adequate because Peter's father would not have allowed him to take the medication if he had read the suicide-related statements in the warnings. There is no testimony, however, about how Peter's father would have evaluated those statements in the original context. Considering the suicide-related statements contextually is critical because the 2004 Cymbalta warning also stated that "a causal role for antidepressants in inducing suicidality has not been established."

Dr. Briggs' testimony and behavior indicate that knowledge of the five suicides during the Cymbalta trials or of any causal role for Cymbalta in inducing suicidality

may have changed his prescribing behavior. There are genuine issues of material fact whether an adequate warning would have changed Dr. Briggs' decision to prescribe Cymbalta to Peter. *See* ***In re Prempro Prods. Liab. Litig.***, 586 F.3d at 569.

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The judgment of the district court is reversed, and the case remanded for further proceedings consistent with this opinion.

GRUENDER, Circuit Judge, concurring in part and dissenting in part.

I agree with the Court that the grant of summary judgment with respect to the Schilfs' desired warning that five suicides occurred during the Cymbalta clinical trials must be reversed because South Dakota likely would adopt the learned intermediary doctrine and the heeding presumption, *see ante* at 4, and because Lilly failed to rebut the heeding presumption. Although Dr. Briggs testified that he had reviewed the Cymbalta package insert, he did not recall that the insert cautioned that "completed suicide" was an observed adverse reaction to Cymbalta use. In fact, the Cymbalta package insert in use at the time Dr. Briggs prescribed Cymbalta for Peter disclosed a rate of completed suicide of between one-in-one-hundred and one-in-one-thousand trial participants. Because Dr. Briggs was unaware of this suicide rate and conceded that he would want to know about incidents of completed suicide when deciding whether to prescribe Cymbalta, I agree that the Schilfs raised a jury question as to whether the size, font, and location of the suicide rate disclosures in the package insert were adequate to warn Dr. Briggs of those risks.

I respectfully dissent, however, from the Court's holding that the Schilfs' "desired warnings" included a warning of "a causal role for Cymbalta in suicidality" separate from the actual warnings contained in the FDA's October 2004 Public Health Advisory ("PHA"), *see id.*, and that there are genuine issues of material fact

as to whether Dr. Briggs knew about the risks disclosed in the PHA. Until this appeal, the Schilfs' "desired warnings" were limited to (1) a disclosure of the five suicides that occurred during the Cymbalta clinical trials, and (2) the FDA's recommended class-wide "black box" warning regarding the increased risk of pediatric suicide from all antidepressants, including Cymbalta, as detailed in the PHA. With regard to the second desired warning, the Schilfs relied on the PHA to establish that Lilly was aware of the increased risk of suicidality among pediatric antidepressant users, so the scope of their desired warning is limited to the warning conveyed by the PHA. *See Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 854 (10th Cir. 2003) ("In determining the adequacy of a warning, a court must also look to evidence concerning the manufacturer's knowledge of the danger of the product."). The Court correctly points out that "causality" was mentioned in the complaint and before the district court.[4] *Ante* at 4 n.1. However, on the few occasions where the Schilfs addressed causation in relation to the FDA studies, it was not to argue that Lilly should have given a separate warning that causality has been established, but rather to argue that the PHA and the studies underlying it would have conveyed such a warning specifically to Dr. Briggs. Establishing that the content of the PHA included a disclosure of a causal link was relevant because it allowed the Schilfs to argue that Dr. Briggs was not familiar with the "full import" of the warning contained in the PHA, contradicting his claim that he had "seen and become aware" of the PHA.[5]

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[4]In collecting examples of how "causality" was at issue before the district court, the Court confuses the "causation" element of the Schilfs' tort claims (*i.e.*, whether the alleged failure to warn proximately caused the harm to Peter Schilf) with the completely separate issue of whether Lilly should have known that a causation warning was necessary based on the FDA studies underlying the PHA. Contrary to the Court's conflation of these issues, only the latter type of "causality" is at issue in this appeal.

[5]The Schilfs also argued before the district court that Dr. Briggs's testimony was not credible because he provided no contemporaneous proof of his familiarity

Even if there is a genuine controversy as to whether the FDA studies concluded that a causal connection exists between suicidality and pediatric antidepressant use, this issue is not *material* to this case, *see* Fed. R. Civ. P. 56(c), because the Schilfs' desired warning from Lilly was not a causal warning in the abstract, but rather a replication of the specific warning contained in the PHA.[6] Thus, Lilly was entitled to summary judgment if Dr. Briggs already had "seen and become aware" of the "black box" warning in the PHA when he prescribed Cymbalta for Peter.

I agree with the district court that there is no genuine issue of fact as to whether Dr. Briggs was aware of the PHA and familiar with the warning disclosed therein. As a threshold matter, the Schilfs concede that Dr. Briggs was "aware of the recent FDA recommendation for a class wide suicide warning." Dr. Briggs testified in his deposition that he became aware of that recommendation shortly after the FDA issued the PHA on October 15, 2004. Furthermore, he testified that, before he prescribed Cymbalta for Peter, he had "seen and become aware of the [PHA] regarding antidepressants in pediatric populations and the issue of suicidality." When asked whether he told Cynthia Schilf that the FDA had recommended a "black box" warning for antidepressants, including Cymbalta, Dr. Briggs answered, "I can't recall

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with the PHA at the time he prescribed Cymbalta to Peter and because his description of the warnings he gave to the Schilfs differed from how Cynthia Schilf described the warnings related to them by Dr. Briggs. These arguments before the district court confirm that the Schilfs were contending not that Lilly should have given a warning of a causal link, but rather that Lilly should have given the specific warning contained in the PHA.

[6]The district court's assumption, for purposes of its decision, that Lilly's package insert was inadequate because it did not "convey a causal connection between taking Cymbalta and suicidality" merely reflects its understanding that the Schilfs interpreted the PHA, the warning they desired, as conveying such a causal connection. This interpretation is evidenced by the district court's conclusion that "Dr. Briggs was aware of the same warnings that [the Schilfs] now say [Lilly] should have given to prescribing physicians such as Dr. Briggs." *Ante* at 4.

using those terms . . . [b]ut I know we breached that subject specifically." Dr. Briggs explained, "I told her about the FDA studies that were done . . . . I told her exactly what those studies were indicating." When asked whether he told Peter and Cynthia "how much the increased risk was [in the PHA] with respect to antidepressants and suicide," Dr. Briggs responded that the PHA relied on several studies but that the "average is 2 percent to 4 percent." When asked whether he had understood "what the FDA had indicated, that [the risk] had gone from 2 percent to 4 percent, back in October 2004," Dr. Briggs confirmed that he had, "[i]n the context of how the studies were interpreted." Furthermore, Dr. Briggs testified that he warned Peter and Cynthia about the risk of pediatric suicide, repeatedly asked Peter whether he was having suicidal thoughts, and asked Cynthia to watch for suicidal tendencies. He testified, "We specifically discussed that issue, though, the FDA and their recommendations or warnings." Dr. Briggs's undisputed testimony establishes that he was familiar with the PHA warning of an increased risk of suicidality in pediatric users of antidepressants and the need to warn pediatric Cymbalta users and their families to watch for signs of suicidal tendencies. Thus, there is no genuine issue of material fact as to whether Dr. Briggs was familiar with the PHA and the risks disclosed therein, including its recommended "black box" warning of the increased risk of suicidality, regardless of Lilly's failure to include it in the packaging for Cymbalta.

The Court's finding of some ambiguity as to whether Dr. Briggs understood the warning in the PHA is based on a misinterpretation of Dr. Briggs's testimony. While the Schilfs seek to interpret the studies underlying the PHA as sufficient to establish a causal role for antidepressant use in suicidality, Dr. Briggs testified that, at the time he prescribed Cymbalta to Peter Schilf, he interpreted the studies as merely supporting the existence of a correlation between the two. Thus, Dr. Briggs's assertion during his deposition that neither the FDA studies underlying the PHA nor subsequent studies established that antidepressant use causes pediatric suicidality evidences a nuanced understanding of the FDA studies, not a lack of familiarity. Most importantly, there is no evidence that Dr. Briggs's interpretation of the studies

would have been different if Lilly had directly provided the "black box" warning to him.[7] Dr. Briggs's interpretation of the PHA is supported by the fact that, although the FDA initially sent Lilly and other antidepressant manufacturers a letter suggesting that they amend their package inserts to state that "[a] causal role for antidepressants in inducing suicidality has been established in pediatric patients," the FDA subsequently required Lilly to "excise" the causation language and replace it with an "increased risk" warning to better reflect the information contained in the "black box" warning originally published in the PHA. The revised FDA-approved Cymbalta package insert states that "[p]atients with major depressive disorder . . . may experience worsening of their depression and/or emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, *whether or not they are taking antidepressant medications*" (emphasis added). This statement is consistent with the current FDA-approved "black box" warning for Cymbalta, which discloses that antidepressants "increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children," but also notes that "depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide."[8]

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[7]Contrary to the Court's statement, *ante* at 6 n.2, Dr. Briggs's familiarity with the PHA is the dispositive issue, not whether he believed the information it contained or interpreted it in the same way the Schilfs currently do. Dr. Briggs offered uncontradicted testimony that he understood in 2004 that the FDA had determined "that there was an association between antidepressants and suicide." *Id.* at 6. Even if the Court is correct that Dr. Briggs did not believe that the FDA study "represented the risks of . . . Cymbalta," *id.* at 6 n.2, this merely demonstrates that Lilly has rebutted the heeding presumption in this case because Dr. Briggs was familiar with the warning in the PHA, exactly what the Schilfs desired that Lilly should have provided to him, and chose to disregard it. *See In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 569 (8th Cir. 2009).

[8]Contrary to the Court's suggestion, *ante* at 7 n.3, I do not rely on the FDA's clarification that the PHA warning is one of association and not one of causation to show that the Schilfs' state-law claims are preempted by the FDA's decision. Rather, I rely on this information merely to show that Dr. Briggs's interpretation of the PHA

In summary, Dr. Briggs's denial that a causal role for pediatric antidepressant use in suicidality had been established in 2004 does not create a genuine issue of fact as to whether he was familiar with the PHA and the suicidality warning it contained.

Because the Schilfs relied on the PHA to establish what information regarding suicidality Lilly should have provided to Dr. Briggs, *see Thom*, 353 F.3d at 854, Dr. Briggs's familiarity with the relevant information in the PHA at the time he prescribed Cymbalta to Peter rebuts the heeding presumption and breaks the chain of causation between Lilly's failure to warn the Schilfs about the suicide risk disclosed in the PHA and Peter's tragic death. *See Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004) ("[T]he causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." (quoting *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995))).

For the foregoing reasons, the grant of summary judgment should be affirmed as to the Schilfs' failure-to-warn claim based on Lilly's failure to inform Dr. Briggs of the FDA's proposed "black box" warning as detailed in the PHA.

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and the underlying FDA studies is not unreasonable. Having established that Dr. Briggs's interpretive disagreement with the Schilfs does not contradict his testimony that he was familiar with the risks disclosed in the PHA, this disagreement becomes *immaterial* to the resolution of this appeal because Dr. Briggs was familiar with the Schilfs' desired warning, as set forth in the PHA, and disagreed with the Schilfs' interpretation of it.