

FOR PUBLICATION
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CAROL ADAMS, <i>Plaintiff-Appellant,</i> v. SYNTHES SPINE COMPANY, LP, <i>Defendant-Appellee.</i>

No. 00-35094
D.C. No.
CV-98-03083-EFS
OPINION

Appeal from the United States District Court
for the District of Eastern Washington
Edward F. Shea, District Judge, Presiding

Submitted October 16, 2001¹
Seattle, Washington

Filed August 8, 2002

Before: Warren J. Ferguson, Andrew J. Kleinfeld, and
Ronald M. Gould, Circuit Judges.

Opinion by Judge Kleinfeld;
Dissent by Judge Ferguson

¹The panel unanimously finds this case suitable for decision without oral argument. See Fed. R. App. P. 34(a)(2).

COUNSEL

David A. Williams (briefed), Bellevue, Washington, for the appellant.

Christopher W. Tompkins (briefed), Betts, Patterson & Mines, P.S., Seattle, Washington, for the appellee.

OPINION

KLEINFELD, Circuit Judge:

This is a products liability case involving no questions of federal law, just a question of state law.²

Facts

Carol Adams had persistent severe back and neck pain,

²This opinion is published pursuant to Ninth Circuit Rule 36-2(g).

radiating down into her fingers. The pain was caused by spurting on her vertebrae and deterioration of the disks in her neck. It did not respond to steroids, traction, or other conservative treatment, so she elected to have surgery to remove the spurs and the bad disks. Her neurosurgeon removed three disks and parts of three vertebrae. To maintain the stability of the spine, he removed a piece of bone from her hip and inserted it in the gap in her neck vertebrae. This is a standard way to do the cervical fusion operation he was performing.

The neck has to be held still during the three months or so until the piece of hip bone fuses with the neck bones to form a solid and stable substitute for the removed pieces of vertebrae. This used to be done, in an operation of this magnitude, by requiring the patient to wear a halo for four months. Holes would be drilled into the skull of the patient in order to screw the halo to the skull, and the halo would be held in place by a kind of vest. Obviously, this was hard for the patient to bear.

In 1991, Synthes Spine came out with a device to avoid the halo. Instead of drilling holes in the patient's head and requiring the patient to wear the affixed halo, the surgeon would screw a metal plate to the bones of the spine during the surgery. This would hold the bones in place while they fused. Ms. Adams' doctor, Leslie Bornfleth, M.D., testified that while patients were routinely advised that they could have the halo instead, none wanted it once they could opt for the Synthes Spine plate. Ms. Adams made that election.

The operation went fine. The bones in Ms. Adams' neck properly fused. But three years later, in 1998, Ms. Adams had neck pain and difficulty swallowing, and consulted Allan J. Drapkin, M.D. (Dr. Bornfleth had by then retired from practice). Dr. Drapkin's x-rays showed that the plate had broken and one of the screws had come partly out. The fusion was solid, and the plate was no longer necessary to hold her spine together, so Dr. Drapkin recommended surgery to "remove the plate, and particularly remove that screw" in order to

relieve “mechanical compression on the esophagus.” He performed the removal surgery, and it succeeded without complication.

A person can’t buy one of these Synthes Spine plates at the drugstore. They are sold only to physicians. Dr. Bornfleth, a neurosurgeon who installed quite a few, did not even have them in his office. They were kept at the hospital. This was a medical device, fairly new when Dr. Bornfleth installed it in 1995 (four years after its introduction), and was sold to and used by physicians such as Dr. Bornfleth.

The directions that come with the device say to remove it once the bones have fused. In the “*Precautions*” section of the “SUGGESTIONS CONCERNING ORTHOPAEDIC METALLIC INTERNAL FIXATION DEVICES,” the instructions say that these implants can break. So “[w]hile the surgeon must make the final decision,” the instructions recommend that the implants be removed once the bones have fused:

Removal after fracture healing. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management to avoid refracture.

Despite this manufacturer’s recommendation, a lot of surgeons don’t remove the implants. Dr. Bornfleth went to meetings where surgeons discussed how to use the implants, and the consensus was “there is no reason to take the plates out because if the fusion is solid and the plate is there, it’s going

to cause no problem.” As Dr. Drapkin, who removed the broken plate, testified, the risk of a plate breaking is “very small,” so ordinarily “there is no reason to expose the patient to a risk of a second surgery on a routine basis” to remove it. Dr. Drapkin said he would still use a Synthes Spine plate if he were performing this sort of surgery, even after Ms. Adams’ plate broke. She was the unfortunate person for whom the “very small” risk materialized, necessitating removal.

Ms. Adams sued Synthes Spine for selling a defective product. Her damages were for the pain in her throat after the plate broke, the anxiety of the several days between Dr. Drapkin’s telling her it was broken and performing the surgery to remove it, and associated pain and suffering and medical expenses. The district court granted summary judgment against Ms. Adams, and she appeals on the theory that the product was defectively designed because it could break.

Analysis

We review summary judgment de novo, to determine whether, viewing the evidence in the light most favorable to the nonmoving party, there are any genuine issues of material fact.³ Having so reviewed the case, we have concluded that the district judge’s carefully analyzed decision was correct, and we affirm.

The theory of the plaintiff’s case, as briefed on appeal, is that the plate didn’t conform to the reasonable expectations of the consumer, Dr. Bornfleth, because it broke, and he wasn’t adequately warned that it could break.

[1] The applicable Washington statute on products liability says that in determining whether a product is “reasonably

³See *United States v. Shumway*, 199 F.3d 1093, 1102-03 (9th Cir. 1999); Fed. R. Civ. P. 56(c).

safe,” the trier of fact “shall consider whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer.”⁴ Under Washington law, the “consumer” of a prescription-only medical device such as this is the physician, not the patient in whom it is installed,⁵ a critical point which plaintiff concedes.

[2] The Washington Supreme Court held in *Terhune v. A.H. Robins Co.*⁶ that the manufacturer of the Dalkon Shield was not strictly liable to a woman whose uterus was perforated by one, because medical products “available only on prescription or through the services of a physician”⁷ are, in Washington, treated as falling under comment k of the Restatement (Second) of Torts § 402A.⁸ As the Restatement puts it, some products are “incapable of being made safe” but, because of their benefit, are not “*unreasonably* dangerous,” such as “many . . . drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.”⁹ Where “proper warning is given,” the seller “is not to be held to strict liability for unfortunate consequences attending their use.”¹⁰

[3] Washington applies this rule not only to such medical products as vaccines for deadly diseases, but, as the Dalkon Shield case illustrates, much more broadly, to medical products where the physician acts as a “learned intermediary between the manufacturer or seller and the patient.”¹¹ In *Ter-*

⁴Wash. Rev. Code § 7.72.030(3).

⁵See *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978).

⁶*Id.*

⁷*Id.* at 978.

⁸*Id.* at 977.

⁹Restatement (Second) of Torts § 402A cmt. k (1965) (emphasis in original).

¹⁰*Id.*

¹¹*Terhune*, 577 P.2d at 978.

hune, the issue was whether to apply the rule to a product, the Dalkon Shield, that was not essential to “cure a malady” but merely “require[d] a physician’s services, his knowledge and his skill.”¹² The court held that the manufacturer’s duty to warn ran only to the physician, not to the patient, and “the manufacturer should not be held to account if it has done its duty in this regard” and provided appropriate information to the physician, “even though the physician decides, in the exercise of his own judgment, to withhold the information from his patient.”¹³

Had there been any doubt about the vigor and breadth of *Terhune*, it would have been eliminated by the more recent case of *Young v. Key Pharmaceuticals, Inc.*¹⁴ In *Young*, an asthma treatment caused severe, permanent brain damage in a small child, a known risk that occasionally materialized.¹⁵ The Washington Supreme Court held that comment k applied (which is to say that strict liability did not apply) to “prescription medical products” without any separate determination on a case-by-case basis “because of the character of the medical profession and the active, intermediate involvement of a physician.”¹⁶

[4] This is a strict liability case. The plaintiff offered no evidence in district court and no argument here for a negligence theory. And Washington law rules out strict liability for prescription medical products such as the Synthes Spine plate, provided that proper warning is given to the physician.

[5] As for whether the given warning was adequate, appellant’s argument is basically that the warning wasn’t clear

¹²*Id.*

¹³*Id.* at 979.

¹⁴922 P.2d 59 (Wash. 1996) (en banc).

¹⁵*Id.* at 61.

¹⁶*Id.* at 64 (internal citations and quotation marks omitted).

enough for a doctor to notice or understand, and “most convincingly, it was obvious that the ‘warning’ was inadequate because NO ONE FOLLOWS IT.”¹⁷ As for whether it was clear enough for a physician to read and understand it, there was no evidence that it wasn’t. Dr. Bornfleth testified that he probably read it. The words in the warning are perfectly clear. What’s more, this isn’t something where physicians just mail away for it, read the directions, and start screwing these things onto patients’ spines. Dr. Bornfleth testified that he went to professional meetings where use of these devices was discussed by professionals in the field, and his understanding was that the device shouldn’t be removed, even though the manufacturer said it should be.

That the surgeons usually did not remove the device does not show that they didn’t understand the warning, just that they generally didn’t agree with the recommendation. Dr. Drapkin explained why — the risk of the surgery to remove the plate exceeded the risk of leaving it in, because in most cases it wouldn’t break. A second surgery could safely be left for the rare cases when it broke. Even the rarest events happen sometimes, to someone. It is extremely unfortunate that Ms. Adams was that someone, that she suffered pain and anxiety from a broken Synthes Spine plate. (Because her argument implies that, had Synthes Spine given an adequate warning, Dr. Bornfleth would have opened up her neck and performed a second surgery to remove the device after her bones fused, she can’t really be complaining about *getting* a second surgery, just that the breaking of the plate caused a great deal of mental distress and pain *leading up to* the second surgery.)

There isn’t any evidence in the record from which reasonable jurors could conclude that the warning was inadequate. It plainly said that the plate could break and that the manufacturer recommended removal. That physicians didn’t follow

¹⁷Brief for Appellant at 9, *Adams v. Synthes Spine Co.*, No. 00-35094 (emphasis in original).

the recommendation doesn't show that they couldn't or didn't read it and understand it, just that in their medical judgment, it wasn't wise to follow it. Dr. Bornfleth testified that he was "surprised" that the plate broke in Ms. Adams' case. That doesn't show anything inadequate about the warning, just that breakage was rare. Whenever a rare event occurs, the occurrence is surprising. People often choose to bear the risk of a rare event in order to avoid a certain and unattractive alternative, which in this case would be a second surgery, unnecessary in most cases.

The dissent seems to be based on the notion that, had the warning been adequate, all physicians would know that they ought to remove the Synthes Spine plate after the bones have fused. That is simply a substitution of our dissenting colleague's medical judgment for the medical judgment of the neurosurgeons and orthopaedic surgeons who actually have the experience and knowledge needed to make competent medical judgments about whether and when such a device ought to be removed. Their judgment differs from his. It is not reasonable to suppose that that is because the words "precaution," "the plate may fracture," and "the plate should be removed" are too difficult and obscure for neurosurgeons and orthopaedic surgeons to read and understand. They've just decided that one surgery is better than two, except in the occasional instances where the device breaks. As Dr. Bornfleth testified, the surgery to remove the device entails the usual surgical risks of anaesthesia, infection, etc., and in his judgment, that risk wasn't worth running.

AFFIRMED.

FERGUSON, Circuit Judge, dissenting:

This case should go to a jury and, thus, I respectfully dissent. In this case, the District Court granted summary judg-

ment for Synthes Spine. A grant of summary judgment is reviewed de novo. *Delta Sav. Bank v. United States*, 265 F.3d 1017, 1021 (9th Cir. 2001) (citations omitted). Our review is governed by the same standard used by the trial court under Rule 56(c) of the Federal Rule of Civil Procedure. *Id.* (citation omitted). Thus, we must determine, viewing the evidence in the light most favorable to Ms. Adams, whether the District Court correctly applied the relevant substantive law and whether there are any genuine issues of material fact. *Id.* (citation omitted). We must not weight the evidence or determine the truth of the matter, but only determine whether there is a genuine issue of material fact for trial. *Meade v. Cedarapids, Inc.*, 164 F.3d 1218, 1221 (9th Cir. 1999) (citation omitted).

The record in this case gives rise to two genuine issues of material fact, which preclude the granting of summary judgment in favor of Synthes Spine: (1) whether the plate manufactured by Synthes Spine was defective under the “reasonable expectation of the consumer” test,¹ and (2) whether Synthes Spine was sheltered by the affirmative defense of comment k of the Restatement (Second) of Torts.

A. Reasonable Expectation of the Consumer Test

Under the reasonable expectation of the consumer test, the issue is whether the reasonable expectations of Dr. Leslie Bornfleth, the prescribing physician, were met.² The District Court held that Dr. Bornfleth’s expectations of the product were met as a matter of law because Dr. Bornfleth knew that screws could break, fracture, and migrate.

¹Although not specifically described as the “reasonable expectation of the consumer” test, this is the same test that the majority discusses as arising under the Washington Products Liability Act. Maj. Op. at 11533-34.

²As stated by the majority, the relevant “ordinary consumer” under the consumer expectation test is the prescribing physician in this case. *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978).

However, the District Court incorrectly overlooked other parts of the record that raised a genuine issue as to whether Dr. Bornfleth expected that the plate itself could fracture, thus requiring removal. In his deposition, Dr. Bornfleth stated:

I don't know the circumstances of the breakage. I mean, if she had a solid fusion and for some reason the plate broke, I would be kind of surprised, number one, but unless she were, say, in some kind of accident or something bad happened. But I am kind of at a loss to explain why the plate would fracture, and if I were faced with that, I don't know whether I would take the plate out or what I would do.³

Dr. Bornfleth also testified that he remembered hearing of cases in which the screws had backed out or sheered off, but he did not remember hearing of any cases in which the cervical plate itself broke. In fact, during his consultation with Ms. Adams, he did not mention that the plate could break if subjected to stresses. At the time, he did not know why a cervical plate might fracture. Moreover, Dr. Bornfleth testified that, at the time of the implant, he did not understand either that the implant should be removed or that Synthes Spine recommended that it be removed.

In addition, while participating in meetings of the American Associations of Neurological Surgeons and the Congress of Neurological Surgeons, Dr. Bornfleth attended courses and presentations given by representatives of Synthes Spine and other doctors regarding the product. From these courses and presentations, Dr. Bornfleth concluded that there was "no reason to take the plates out because if the fusion is solid and the plate is there, it's going to cause no problem." Both Dr. Bornfleth and Dr. Allan Drapkin, Ms. Adams' subsequent physi-

³Nothing in the record indicates that Ms. Adams was in an accident or had undergone any type of physical trauma.

cian, testified that they did not think that other doctors were removing the plates routinely.

Dr. Bornfleth testified that he did not recall seeing or remember reading the package insert that came with Synthes Spine's plate products. Even after reading it during the deposition, he concluded that the warnings in the package insert might not apply to cervical plates because of the minimal weight of the head compared to other parts of the body. His conclusion indicates a lack of clarity in the warnings' language.⁴

Thus, the record presents a genuine issue of material fact regarding whether Dr. Bornfleth's reasonable expectations in the use of the plate were met. He did not expect that the plate could break or that the screws would extrude, as indicated by his statement that he was "surprised" that such would occur. Although Dr. Bornfleth recognized that occasional breakage of plates was theoretically possible, he had not heard of and would not have expected the cervical plate to break in the manner and under the circumstances that occurred here. In addition, his testimony indicates that he did not think removal of Ms. Adams' plate was necessary because: (1) the presentations of other doctors and Synthes Spine, (2) the practices within the medical profession in using the product, and (3) a lack of clarity in the warning. Thus, there are genuine issues of material fact for a jury to resolve regarding the reasonable expectations of Dr. Bornfleth and whether those expectations were met.

B. Adequacy of Warning

The District Court also erred in determining that the warning provided by Synthes Spine adequately warned of the possibility of breakage. As discussed by the majority, it appears that the reasonable expectation of the consumer test cannot be

⁴The adequacy of the warning and Dr. Bornfleth's testimony regarding the warning is further discussed in the Section B, *infra*.

met if there is no genuine issue of material fact regarding whether the warning was adequate. *See Reece v. Good Samaritan Hosp.*, 953 P.2d 117, 123 (Wash. Ct. App. 1998) (finding that the consumer expectation test could not be met where the manufacturer had “adequately warned consumers of the risks associated with using a product”). However, if there is a factual dispute regarding the warning’s adequacy, Synthes Spine cannot be sheltered by this affirmative defense.

A product is adequately labeled if it “carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved.” *Tehurne v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978). In determining that Synthes Spine’s warning was adequate as a matter of law, the District Court relied on both the package insert that accompanied the plate and the testimony by Drs. Bornfleth and Drapkin that they would still use the plate on future patients despite the breakage in this case. In finding that the warning was adequate, the District Court erred because it ignored the ambiguous language of the warning and the confusion that arose from the warning.

The only warnings regarding the necessity for removal was included in a package insert entitled “FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON” and “SUGGESTIONS CONCERNING ORTHOPAEDIC METALLIC INTERNAL FIXATION DEVICES.”⁵ Under “*Precautions*,” the following text appears:

3. ***Removal after fracture healing.*** Metallic Implants can loosen, fracture, corrode mitigate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must make the final decision on Implant removal, we recommend

⁵All capitalization and font styles are shown as they were in the warning.

that whenever possible and practical for the individual patient, fixation devices should be removed by adequate postoperative management to avoid refracture.

This paragraph regarding removal is not included in the subsection of the insert entitled “**Warnings**,” rather it is in the subsection entitled “**Precautions**.” This paragraph also uses language, such as “we recommend” and “devices should be removed,” rather than “must,” which is used in other paragraphs in this section. For example, the first paragraph in the “**Precautions**” subsection states, “***Surgical Implants must never be reused.***”

In addition to its discretionary nature, the ambiguity in the insert’s meaning raises a triable issue as to whether the Synthes Spine’s warnings were adequate. Upon reading the package insert during his deposition, Dr. Bornfleth stated:

They imply here that once the need for the fixation device is over, that the implant should be removed. And I don’t think — I don’t think I understood that. In fact I never did take them out except that one case.

* * *

I think the other points are pertinent, but as I read this, I get the sense this is more for a lumbar or extremity type thing because there is not much weight that the neck has to bear, so there is really — applies mostly to weight bearing. Although the head weighs 16 pounds, it’s not a tremendous weight-bearing surface, so a lot of the precautions are I think perhaps not applicable to the cervical plates.

Even after a close read of the warning during his deposition, Dr. Bornfleth was unsure whether the removal recommenda-

tion even applied to cervical plates, such as the one at issue in this case.⁶

Finally, both Dr. Bornfleth and Dr. Drapkin testified that no doctors appeared to know that removal should occur, and no doctors followed such procedures. Thus, the product did not carry “the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved.” *Tehurne*, 577 P.2d at 978. Because the warning was ambiguous in nature and failed to fully apprise doctors that removal was necessary, Synthes Spine’s package insert for its cervical plate does not constitute an adequate warning as a matter of law.

The majority accuses me of wrongdoing, asserting that I am substituting my medical judgment for the medical judgment of a physician.⁷ This charge demonstrates a myopic view of our legal system and what this lawsuit is all about.⁸ Every day in courts throughout the nation, judges and layperson juries as finders of fact substitute their judgments for the judgments of physicians in medical malpractice litigation. That’s our legal system. However, this is not a medical malpractice case against a physician. We are not required to determine whether a physician was right or wrong. Rather, this is a products lia-

⁶In addition to the possibly inadequate written warning, it appears that Synthes Spine failed to give any oral warnings during their presentations at various meetings. As discussed above, Dr. Bornfleth was given the impression that there would be no complications from leaving the plates in if the fusion was solid.

⁷Underlying this statement is the majority’s assertion that physicians chose not to remove the plates based on their medical judgment. However, nothing in the record establishes this fact.

⁸Moreover, the majority ignores the fact that, in this case, the prescribing physician did not testify that he was using his independent judgment when he chose not to remove Ms. Adams’ plate. Rather, he relied on what he had heard from Synthes Spine and his colleagues, not on what he learned from any of his own research or doctor-patient consultations regarding Ms. Adams’ medical needs and requirements.

bility case, which is at the summary judgment stage. The questions before the court are whether the product manufactured by Synthes Spine was defective and whether the warnings regarding the dangers of the product were adequate. As shown above, there are disputed issues of fact regarding these questions, which should be determined by a jury, not by a panel of appellate judges. By failing to recognize these genuine issues, the majority usurps the fact-finding role of the jury and substitutes its judgment for that of the jury.

In sum, because the record sets forth specific facts showing that there are genuine issues for trial regarding (1) whether the physician's reasonable expectations were met, and (2) whether Synthes Spine's warnings were adequate, I would reverse and remand this case.