TADC PRODUCTS LIABILITY NEWSLETTER

Selected Case Summaries
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Editor:

Joseph S. Pevsner
Thompson & Knight LLP

Contributing Editor:

Alex H. Bailey
Thompson & Knight LLP

I. Summary

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2. Texas' "substantial factor" causation requiring proof of aggregate dose extends beyond asbestosis cases and also applies to mesothelioma cases.

Smith v. Kelly-Moore Paint Co., Inc., No. 2-08-198-CV, 2010 WL 682343 (Tex. App.—Fort Worth Feb. 25, 2010, no pet.).

3. Physician is not a "seller" entitled to indemnity under Chapter 82 from a drug manufacturer.

Hadley v. Wyeth Lab., 287 S.W.3d 847 (Tex.—App. [14th Dist.] 2009, pet. filed).

II. Discussion

1. *Centocor, Inc. v. Hamilton*, No. 13-07-00301-CV, 2010 WL 744212 (Tex. App.—Corpus Christi March 4, 2010, no pet. h.)

In *Centocor*, the court of appeals recognized an exception to the learned intermediary doctrine generally applicable when doctors prescribe medicines, an exception applying when a drug manufacturer directly advertises to consumers in a fraudulent manner.

Patricia Hamilton suffered from Crohn's disease, an autoimmune disease that causes a chronic inflammation of the intestines. Hamilton also had a history of rheumatoid arthritis. To treat Hamilton's Crohn's disease, her doctor—Dr. Hauptman—prescribed a series of doses of Remicade, a drug manufactured by Centocor. Remicade is an immunosuppressant that works by blocking the harmful effects of tumor necrosis factor, a natural bodily substance that causes inflammation. When Centocor first received FDA approval for Remicade, the drug was approved to treat Crohn's disease. Later, it was also approved to treat rheumatoid arthritis.

As required by the FDA, Remicade packages included an insert containing warnings and other information about the drug. Among other things, the Remicade package insert warned that treatment with Remicade could, in rare circumstances, result in the development of a lupus-like syndrome, and that treatment with Remicade should be discontinued should a patient develop symptoms suggestive of a lupus-like syndrome. Among the symptoms of lupus-like syndrome are joint pain and swelling. A patient with Crohn's disease or rheumatoid arthritis could also present with joint pain and swelling.

Hamilton testified that when Dr. Hauptman prescribed Remicade, he did not inform her of the risk of developing a lupus-like syndrome. Based on Dr. Hauptman's recommendation, Hamilton consented to take Remicade, and made appointments to receive a series of doses. A dose of Remicade is administered by intravenous infusion, a process which takes two to three hours.

When Hamilton arrived for her first infusion appointment, the administering doctor—Dr.

Bullen—gave her a Remicade information sheet. The sheet did not contain a warning about lupus-like syndrome, and neither Dr. Bullen nor the attending nurse warned Hamilton about lupus-like syndrome. While Hamilton received her first infusion, Dr. Bullen showed her a video produced by Centocor touting the benefits of Remicade. In the video, Remicade patients are shown walking, running, carrying their children, and exclaiming how great they feel. Also in the video, a doctor explains the benefits of Remicade and repeatedly emphasizes that side effects are minor and extremely rare. The doctor describes the possible side-effects, and at the end of the video, a disclaimer listing the drug's side effects rolls across the screen. No part of the video lists lupus-like syndrome as a possible side effect.

Hamilton stated that after viewing the video, she did not have any concerns about taking additional infusions, and did not believe she needed to do any additional research. After receiving three doses of Remicade over about six weeks, Hamilton's Crohn's disease symptoms improved significantly. She also experienced relief from her joint pain. But about eight weeks after her third dose, Hamilton began to suffer numerous body aches and other symptoms that made it difficult for her to perform normal functions. Because Remicade had improved Hamilton's joint pain before, her doctor prescribed more doses of Remicade.

During the next year and a half, Hamilton received about a dozen more doses of Remicade. After each dose, her joint pain and other symptoms would improve significantly for a period, but finally return worse than before. Over time, the flares of joint pain became more intense, and the duration of the relief periods following treatment became shorter and shorter. Eventually, Hamilton's doctors determined that her recurring severe joint pain was not a symptom of rheumatoid arthritis or Crohn's disease, but of drug-induced lupus, caused by Remicade. Hamilton ceased taking Remicade and her joint pain finally went away.

Hamilton sued Centocor for fraud, claiming that by excluding all mention of lupus-like syndrome from its video, Centocor fraudulently misrepresented the risks of Remicade and failed in its duty to warn Hamilton of the risk of developing lupus-like syndrome by taking Remicade. The jury found for Hamilton and awarded her actual and punitive damages, and the court entered judgment against Centocor.

On appeal, Centocor argued—among other things—that the "learned intermediary" doctrine precluded Hamilton's recovery because, as a matter of law, Centocor's warnings to Hamilton's physicians were adequate, as Centocor had no duty to warn Hamilton directly. The court of appeals disagreed, recognizing an exception to the learned intermediary doctrine when a drug manufacturer engages in direct-to-consumer advertising that fraudulently touts the drug's efficacy while failing to warn of the risks.

In the drug context, the learned intermediary doctrine provides that although drug companies have a duty to warn about dangers and risks associated with their products, that duty can be satisfied by warning physicians, who are "learned intermediaries" between the drug company and the patient. The learned intermediary doctrine does not extinguish drug companies' duty to warn consumers; it merely provides a means for drug companies to show they met that duty.

The court of appeals opened its opinion by commenting on the significant changes to the way drugs are marketed and advertised that have occurred since the learned intermediary doctrine was first established. Back then, pharmaceutical manufacturers never advertised their products to patients, but rather directed all sales efforts at physicians. Now, however, drug manufacturers directly advertise products to consumers on the radio, television, the internet, billboards on public transportation, and in magazines.

To determine whether the learned intermediary doctrine still applies in the changed drug-marketing landscape, the court first enumerated the doctrine's theoretical underpinnings. The court determined that there are five main rationales for applying the learned intermediary doctrine: (1) the choice of which drugs to prescribe properly belongs to the doctor because prescription drugs are manufactured for administration only by a physician or other authorized person; (2) only a physician understands the propensities and dangers involved; (3) direct warnings from drug manufacturer to patient may interfere with the physician-patient relationship; (4) doctors are generally better positioned to warn their patients than are drug manufacturers; and (5) it is

difficult for manufacturers to translate labeling aimed at physicians into language easily understood by lay patients.

Applying those rationales, the court concluded the learned intermediary doctrine does not apply when a drug manufacturer directly markets to its consumers. The court observed the following consequences of directly marketing drugs to consumers: (1) doctors spend less time passing on warnings to patients, (2) patients make ultimate decisions about which drugs to take and often ask for drugs by name; (3) drug manufacturers undermine their own argument that only physicians can understand the propensities and dangers of drugs; and (4) drug manufacturers undermine their own argument that providing direct warnings to patients would interfere with the physician-patient relationship, since drug advertisements, by their very nature, interfere with the physician-patient relationship.

In short, the court concluded that the premises behind the learned intermediary doctrine are unpersuasive in light of the consequences of direct marketing to patients. The court therefore recognized an exception to the learned intermediary doctrine, holding that when a pharmaceutical company directly markets to a patient, it must do so without fraudulently misrepresenting the risks associated with its product. Accordingly, the court affirmed the trial court's judgment against Centocor.

If upheld, the *Centocor* decision may have implications for drug manufacturers that advertise directly to consumers. Manufacturers would be well advised to carefully consider advertising content and to understand that such content may determine their liability.

2. ***Smith v. Kelly-Moore Paint Co., Inc.***, No. 2-08-198-CV, 2010 WL 682343 (Tex. App.—Fort Worth Feb. 25, 2010, no pet.)

In *Smith*, the court of appeals held that the "substantial factor causation" test established by the Texas Supreme Court in *Borg-Warner Corp. v. Flores*, 232 S.W.3d 765 (Tex. 2007), applies not only in asbestos-exposure asbestosis cases, but in asbestos-exposure mesothelioma cases as well.

Dorman Smith began working in the construction business as a self-employed drywall finisher using joint compound in 1955. He continued to perform the same type of work through the mid 1980s. Doctors eventually diagnosed him with mesothelioma in 2005. As a result, he and his family sued several defendants, including Kelly-Moore, claiming that exposure to asbestos in those defendants' joint compound products proximately caused Dorman's mesothelioma. Dorman died soon after filing suit.

Before trial, Kelly-Moore moved for traditional and no-evidence summary judgment, contending that the Smiths had presented no evidence that Dorman's exposure to any of Kelly-Moore's chrysotile asbestos-containing joint compound product caused his mesothelioma, under the test set forth in *Borg-Warner*. The trial court granted Kelly-Moore's no-evidence summary judgment motion. The Smiths appealed.

In reviewing the trial court's summary judgment, the court of appeals began by restating *Borg-Warner's* "substantial factor causation" test. According to *Borg-Warner*, to prove specific causation in an asbestos exposure case, there must be some evidence of an aggregate dose of exposure to the plaintiff that was a substantial factor in causing the asbestos-related disease; in other words, there must be some evidence that that the dose to which the plaintiff was exposed exceeds a minimum dose, or "threshold," at which an increased risk of developing the injury has been shown.

After reviewing the evidence, the court determined that the Smiths had raised a genuine issue of material fact as to the aggregate dose of Kelly-Moore asbestos-containing joint compound to which Dorman was exposed. But the court also determined that the Smiths had not presented any evidence establishing a minimum threshold level of chrysotile asbestos exposure from which to measure whether Dorman had an elevated risk of mesothelioma. The Smiths therefore failed the *Borg-Warner* test for showing specific causation in asbestos injury suits.

The Smiths had claimed *Borg-Warner* did not apply because the *Borg-Warner* plaintiff suffered from asbestosis, not mesothelioma. The Smiths offered evidence that asbestosis is a dose-related disease: the more one is exposed to asbestos, the more likely one will suffer

asbestos-related disease. Moreover, there are over 100 causes of asbestosis. Mesothelioma, on the other hand, is a signature disease, meaning that it does not typically occur in the absence of asbestos exposure. Moreover, it is generally accepted that a person can develop mesothelioma from only low levels of amphibole asbestos exposure. The Smiths claimed that the differences between asbestosis and mesothelioma distinguished their case from *Borg-Warner*, and made the *Borg-Warner* requirements of showing a total and threshold dose unnecessary.

The court disagreed. It explained that although there is a more evident causative link between asbestos exposure and mesothelioma than between asbestos exposure and asbestosis, such that asbestos exposure in any amount other than general background levels may cause mesothelioma, *Borg-Warner* still applies in mesothelioma cases. The court therefore held that a plaintiff who claims to have acquired mesothelioma from asbestos exposure must prove both an aggregate does of exposure from the defendant's product, and a minimum threshold dose above which an increased risk of developing mesothelioma occurs. Since the Smiths did not show the latter, the court affirmed the trial court's judgment.

Defense practitioners may consider arguing that the *Smith* case's extension of the *Borg-Warner* standard may suggest that the standard should be applied to other toxic tort cases, especially since the *Borg-Warner* court held the new standard was an application of existing Texas causation law.

3. ***Hadley v. Wyeth Lab.***, 287 S.W.3d 847 (Tex.—App. [14th Dist.] 2009, pet. filed).

In *Hadley*, the court of appeals held that a doctor who prescribes drugs during the provision of medical services to patients is not a seller and therefore is not entitled to indemnity from a drug manufacturer under section 82.002(a) of the Civil Practice and Remedies Code.

Dr. Arthur Hadley and Wyeth Laboratories, Inc. were sued by a woman who suffered personal injuries after taking diet drugs prescribed by Dr. Hadley and manufactured by Wyeth Laboratories. Dr. Hadley filed a cross-claim against Wyeth claiming he was an innocent seller and entitled to indemnity from Wyeth under chapter 82. Wyeth filed a summary judgment motion asserting there was no evidence that Dr. Hadley was a "seller" entitled to indemnity. The trial court granted summary judgment and Dr. Hadley appealed.

Section 82.002(a) grants a "seller" indemnity rights against a manufacturer for losses arising out of certain products liability actions. A seller is defined as "a person who is engaged in the business of distributing or otherwise placing, for any commercial purpose, in the stream of commerce for use or consumption a product or any component part thereof."

On appeal, Dr. Hadley argued that the trial court erred because he was a seller under chapter 82 as a matter of law. The court of appeals disagreed. The court first observed that under the common law, doctors are not considered sellers for product liability purposes. Under the common law, a seller is a person "engaged in the business of selling" products. Doctors do not fall within that definition because they are engaged in the business of medical services, and even if they use products or prescribe drugs as part of that process, the essential nature of their relationship with patients is still a professional, medical one.

Dr. Hadley argued that the statutory definition of seller is much broader than the common law and therefore the common law cases holding that doctors are not sellers do not apply under chapter 82. But the court held that it had to presume the legislature was aware of the common law when it passed chapter 82, and if the legislature had intended to change the common law standard, it could easily have done so. The court found no legislative intent to broaden the definition of sellers beyond the common law in the context of doctors prescribing drugs as part of their provision of medical services.

Dr. Hadley argued that excluding doctors excluding doctors from the definition of seller ignores the reality that doctors are essential to the chain of pharmaceutical commerce—that without a doctor's prescription, drugs would never get to patients. But the court of appeals observed that doctors are more than merely cogs in the machinery of distributing pharmaceuticals. Rather they must use their judgment to

determine whether prescribing medicine is appropriate in each case. And it is that unique role that removes doctors prescribing medicine from the definition of seller under chapter 82.

Accordingly, the court affirmed the trial court's judgment, holding that a doctor who prescribes drugs during the provision of medical services to patients is not a seller and therefore is not entitled to indemnity under section 82.003(a).

Hadley may represent one of the first retreats from indemnity to sellers under Chapter 82 and its application under *Meritor*. Under *Hadley*, a seller must actually be in the business of selling, and the court must examine the essential nature of the providers' business under common law, which *Hadley* holds is still applicable in interpreting Chapter 82.