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NHTSA Revs Up Campaign Against Distracted Driving

By Daniel Campbell and Ariel Applebaum-Bauch

Concerned that driver distraction plays a role in a high percentage of automobile accidents, the National Highway Traffic Safety Administration (NHTSA) has been waging an ongoing campaign to reduce driver distraction. As part of this campaign, in June 2012, NHTSA released its *Blueprint for Ending Distracted Driving*, describing NHTSA's past and ongoing efforts to curb distracted driving. Among other goals, the blueprint sets forth NHTSA's plans to issue three sets of guidelines aimed at limiting driver distraction from electronic devices.

On April 26, 2013, NHTSA released final guidelines for in-vehicle electronic devices, the first of the three planned sets of guidelines. Visual-Manual NHTSA Driver Distraction Guidelines for In-Vehicle Electronic Devices, 78 Fed. Reg. 24,818 (Apr. 26, 2013). The new guidelines recommend restrictions on drivers' use of built-in electronic devices that require visual-manual operation. "Visual-manual operation" refers to any task that requires a driver to look at the device, operate it by hand, and then wait for a reaction to his or her input.

The guidelines' primary recommendation is that motor vehicle manufacturers "lock out" certain features of built-in electronic devices, preventing a driver from engaging with these features while driving. Built-in electronic devices are devices built into the vehicle at the time of manufacture, including navigation, entertainment, and communications systems.

Electronic Devices Recommended for "Per Se Lockout"

The devices recommended for lockout fall into two categories. First, NHTSA has designated certain device functions for "per se lockout." NHTSA recommends that these functions always be inaccessible to the driver while driving. NHTSA also recommends that most of these activities be inaccessible to a passenger if the electronic device's display is within view of the driver. Tasks designated for per se lockout are

- manual text entry for the purpose of text-based messaging, other communication, or Internet browsing;
- displaying video (with some enumerated exceptions);
- displaying images (also with enumerated exceptions);
- display of scrolling text that moves at a pace not controlled by the driver;
- visual presentation of textual information unrelated to driving, including books, periodicals, webpage content, social media content, text-based advertising and marketing, and text-based messages and correspondence; and
- all other "device functions and tasks not intended to be used by a driver while driving."

Other Functions Recommended for Lockout

Second, in addition to the specific tasks designed for per se lockout, NHTSA recommends that manufacturers evaluate certain other tasks to see if they divert the driver's attention from the road. Tasks that do not meet the guidelines' testing criteria are recommended for lockout. NHTSA designates two different modes of testing, both designed to measure how long the

driver's eyes are engaged by certain tasks. NHTSA prefers that tasks engage the driver's glance for no more than two seconds at a time and for no more than 12 seconds in total.

Tasks slated for manufacturer testing include all "non-driving-related tasks," such as making phone calls. The guidelines do *not* recommend testing of most driving-related tasks, including operating the steering wheel, throttle, brake pedal, and other driving controls; tasks relating to the proper use of a driver safety warning system; or the use of any electronic device that has a function, control, or display governed by the Federal Motor Vehicle Safety Standards (FMVSS). But even some driving-related tasks are subject to the guidelines, including cruise control operation, resetting trip odometers or computers, and observation of emissions controls. The guidelines are applicable not just to relatively new technologies such as GPS navigation systems but also to "conventional" electronic devices, including radios, clocks, and temperature controls. They do not apply to devices that are accessible only to backseat passengers.

Additional Recommendations
In addition to designating activities for lockout and potential lockout, the guidelines also make the following recommendations about built-in electronic device design:

- No part of an electronic device should obstruct the driver's view of the roadway or of any vehicle controls or displays required for driving.
- Electronic devices should be mounted in a location easy to see and reach while driving.
- The electronic device display should be within a certain range of driver's forward line of sight (the driver should not have to look too far down to see display).
- Text displayed on electronic devices should meet minimum size requirements.
- The sound level of electronic devices should be limited so as not to mask any safety warning sounds or cause distraction.
- The sound level of electronic devices should be fully mutable.
- Operation of electronic devices should require no more than one hand, allowing the driver to maintain one hand on the steering wheel at all times.
- The driver should always have the option to pause while inputting information into an electronic device (e.g., the device should not automatically delete input from the driver if the driver stops inputting information).
- The electronic device should respond to driver's input in under 0.25 seconds or, alternatively, should display a clear message that a response is pending.
- All electronic devices should be able to be turned off or disabled.

For the purposes of the guidelines, NHTSA has defined "driving" to include any time the vehicle's engine or motor is running, unless the vehicle is in "park" or, for vehicles without a "park" position, three conditions are met: The parking brake is engaged, the transmission is in neutral position, and the speed is less than five miles per hour. The agency specifically rejected the suggestion from some commenters that "driving" include any motion of the vehicle up to five miles per hour. NHTSA explained that it does not want drivers engaging with electronic devices at traffic lights or stop signs.

Impact on Vehicle Manufacturers and Other Stakeholders
Although extensive, the guidelines are not Federal Motor Vehicle Safety Standards. NHTSA therefore cannot require any company to report failures to comply with the guidelines. It also

cannot require recalls of noncomplying vehicles or equipment. NHTSA has also clarified that failure to adhere to the guidelines would not in itself lead NHTSA to determine the existence of a safety-related defect, but it is possible that, in general, a device subject to the guidelines could malfunction in a way that constitutes a safety-related defect.

Although the guidelines are not binding, they may have a significant impact on vehicle manufacturers. NHTSA has announced that it "intend[s] to monitor manufacturers' voluntary adoption of" the guidelines. 78 Fed. Reg. at 24,821. NHTSA "plan[s] to test actual production vehicles, either internally by NHTSA or through outside contractors. Vehicles will be selected for such monitoring so that they cover a large portion of all makes and models." *Id.* at 24,842. NHTSA will consider making its monitoring results available to the public. NHTSA has stated that it expects compliance with the guidelines to occur within three years for both existing and new vehicle models. The guidelines may also foreshadow future regulations. NHTSA has "emphasize[d] that the issuance of voluntary guidelines at this time does not represent a decision to never issue regulations in this area." *Id.* at 24,830.

Next Steps
As part of the blueprint and its continued campaign against distracted driving, NHTSA expects to release two additional sets of guidelines: one governing portable electronic devices not built into the vehicle—including aftermarket GPS navigation systems, smart phones, electronic tablets and pads, and other mobile communications devices (phase two guidelines)—and one covering voice-activated controls in factory-installed aftermarket and portable devices (phase three guidelines).

NHTSA has expressed a desire to maintain open lines of communication with manufacturers and other stakeholders as it moves through the next steps of its driver distraction elimination plan. Specifically, NHTSA "is interested in working with all interested parties to keep the NHTSA Guidelines up-to-date and, to the extent possible, to coordinate future efforts and research." *Id.* at 24,821. NHTSA may hold a workshop for stakeholders interested in the development of the guidelines. NHTSA has also indicated that it welcomes requests for interpretation letters and is open to meeting with interested parties that have concerns about the guidelines.

Keywords: litigation, products liability, NHTSA, guidelines, in-vehicle electronic devices, motor vehicle manufacturers, driver distractions

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Inside the Learned Intermediary Doctrine

By Chris A. Johnson, Alicia J. Donahue, and Paula Sarti

Generally, product manufacturers have a duty to warn consumers directly of all material, foreseeable risks associated with the use of their product. *Restatement (Third) of Torts: Prods. Liab.* § 2(c) (1998). However, many courts have recognized an exception in situations in which the product is recommended or prescribed to the consumer by a learned third party, such as a physician. That exception is called the learned intermediary doctrine. *Restatement (Third) of Torts: Prods. Liab.* § 6 cmt. d (1998).

The doctrine is important to drug manufacturers because it allows them to discharge their duty to warn consumers about their products by informing the learned intermediary, commonly the prescribing physician, of all material risks associated with their use. *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1116 (1996). The prescribing physician is ultimately responsible for directly informing the patient about the potential benefits and risks of using the medication. *Restatement (Third) of Torts: Prods. Liab.* § 6 cmt. b (1998) Thus, prescription drug manufacturers' duty to warn consumers flows through the patients' prescribing physicians, not directly to consumers.

For prescription drug manufacturers, the rationale behind the doctrine is based largely on the fact that prescription drugs' actions are complex and the prescribing physician is the one best able to determine the drug's potential benefits and risks for a particular patient. *Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 191 (Tex. 2004) (stating that the doctrine is based on the idea "that it is better for the patient for the warning to come from his or her physician"); *Restatement (Third) of Torts: Prods. Liab.* § 6(d)(1) cmt. b (1998) ("The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy.").

Because prescription drugs are complex products whose effects can vary from consumer to consumer, patients can obtain them only through a prescribing physician. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 154 (Tex. 2012), *reh'g denied* (Aug. 17, 2012). It is thus "reasonable for the manufacturer" of the prescription drug "to rely on the health-care provider to pass on its warnings" because "the learned intermediary understands the propensities and dangers involved in the use of a given drug, and as the prescriber, he stands between this drug and the ultimate consumer." *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 91 (Tex. App. 2000).

There are many policy reasons for adopting, and firmly applying, the learned intermediary doctrine in the context of prescription drugs, including (1) prescribing physicians are "in a superior position to impart the warning and can provide an independent medical decision as to whether use of the drug is appropriate for treatment of a particular patient"; (2) manufacturers lack the means to provide warnings directly to patients; and (3) direct warnings to patients would interfere with the doctor-patient relationship. *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 763 (Ky. 2004).

Although this doctrine has been officially adopted by the state supreme court or legislature in only 22 states, the doctrine has been applied in 48 states (including federal courts predicting state law), Puerto Rico, and the District of Colombia. *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 903–5 (W. Va. 2007); *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806–9 (E.D. Tex. 2002). Some courts, however, have recognized limited exceptions to the doctrine as applied to certain prescribed products, including mass immunization vaccines, contraceptive drugs and devices, and, more recently, products that have been featured in direct-to-consumer (DTC) advertising. *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968); *MacDonald v. Ortho Pharm. Corp.*, 394 Mass. 131, 138–39 (1985); *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1254–58 (N.J. 1999).

While the exceptions for mass immunization vaccines and contractive drugs and devices are based on the lack of or limited involvement by physicians, the rationale for the DTC advertising exception is that patients' active participation in their own health care negates their reliance on a learned intermediary. *Davis*, 399 F.2d at 131; *MacDonald*, 394 Mass. at 136–38; *Perez*, 734 A.2d at 1256.

The DTC advertising exception was created in 1999 by the New Jersey Supreme Court in *Perez*. Specifically, the court held that prescription drug manufacturers marketing their products directly to consumers could not use the learned intermediary doctrine to shield themselves if their advertising failed to provide adequate warnings and information about the side effects of the product.

The *Perez* court found that DTC advertisements (1) encroach on the doctor-patient relationship because the patient may come into the doctor's office asking about a particular drug and (2) rebut the notion that prescription drugs or devices are too complex to warn the patient adequately about all risks in the abstract. At the same time, the court also held that a manufacturer's adherence to the Food and Drug Administration's (FDA's) approved warning label and packaging requirement created a rebuttable presumption of adequacy.

Given the tremendous increase in DTC advertisements for prescription medications over the past few decades, some initially feared that this exception raised the potential that the learned intermediary doctrine would ultimately be obliterated. *U.S. Ad Spend Falls Nine Percent in 2009*, Nielsen Wire, Feb. 24, 2010 (the amount of money spent on DTC advertising for prescription drugs rose from $1.3 billion in 1998 to $4.5 billion in 2009). As a result, a popular debate continues on whether more DTC advertisements with truthful, non-misleading statements about prescription medications benefit society. At issue in this debate is the conflict between a paternalistic view of consumers and the value placed on access to truthful information.

However, although such advertisements can be seen routinely on television and other media, the learned intermediary doctrine is still alive and well. William A. Dreier, *Liability for Drug Advertising, Warnings, and Frauds*, 58 Rutgers L. Rev. 615, 646 (2006) (since *Perez*, there has

been no New Jersey court decision applying the DTC exception to hold a drug manufacturer liable). Other jurisdictions have overwhelmingly rejected application of the exception. At least six jurisdictions addressing the issue have rejected the *Perez* rationale and refused to adopt a DTC advertising exception.

For example, after carefully considering the reasoning underlying the *Perez* ruling, the Texas Supreme Court in *Centocor* overturned its lower court adoption of a DTC exception, succinctly stating:

> Although pharmaceutical companies have increased DTC advertising since courts first adopted the learned intermediary doctrine, the fundamental rationale for the doctrine remains the same: prescription drugs require a doctor's prescription and, therefore, doctors are best suited to communicate the risks and benefits of prescription medications for particular patients through their face-to-face interactions with those patients.

Centocor, Inc., 372 S.W.3d 140, 162 & n.21.

In fact, in the 14 years since *Perez*, only one state's highest court has been persuaded by its rationale. *State ex rel. Johnson & Johnson Corp.*, 647 S.E.2d at 913–14 (rejecting application of the learned intermediary doctrine altogether based in part on the reasoning of *Perez*). Thus, even with the DTC exception and the increase in DTC advertising of prescription drugs, the learned intermediary doctrine remains a strong and important defense for drug manufacturers in failure-to-warn cases. The exception that could have potentially swallowed the rule is severely limited by the presumption of adequacy for following FDA-mandated label and packaging requirements and has not gained much traction.

Keywords: litigation, products liability, learned intermediary doctrine; direct-to-consumer advertising, prescription drug manufacturer

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Workers' Compensation Immunity for Companies with Separate Corporate Entities

By Michelle Molinaro Burke and Roy Alan Cohen

Corporate and tax attorneys often advise their clients to create separate business entities for manufacturing, distribution, property ownership, and leasing purposes. This advice often is given as a strategy for insulating certain entities from liability to those injured on premises or in the course of their employment. What works for tax or other purposes may not protect separate corporate entities that are not intertwined with the employer-employee relationship, which through their state's workers' compensation statute would protect against all civil tort liabilities arising from workplace injuries except those involving an "intentional wrong." *See, e.g.*, N.J. Stat. Ann. § 34:15-8; *see also Tomeo v. Thomas Whitesell Constr. Co., Inc.*, 176 N.J. 366, 377–78 (2003); *Millison v. E.I. du Pont de Nemours & Co.*, 101 N.J. 161, 177 (1985); *Kaczorowska v. Nat'l Envelope Corp.*, 342 N.J. Super. 580, 587 (App. Div. 2001). However, clients should be aware that their corporate organizational structure may put them at risk of civil liability for tort or occupational exposure-based injuries, even without proof of conduct that rises to an "intentional wrong."

Risk of Civil Tort Liability for Corporate Affiliates

In New Jersey and other jurisdictions, the law is clear that corporate affiliates of an employer are not entitled to workers' compensation immunity. *See, e.g.*, *Volb v. G.E. Capital Corp.*, 139 N.J. 110 (1995), *Roy v. Bachmann*, 994 A.2d. 676 (Conn. App. Ct. 2010). In *Volb v. G.E. Capital Corp.*, the injured worker's widow obtained workers' compensation benefits through her husband's employer but also brought common-law tort claims against two subsidiaries that were wholly owned by the employer. 139 N.J. 110. The New Jersey Supreme Court agreed with the view adopted by the majority of jurisdictions and held that the workers' compensation immunity provided to employers does not extend to affiliated entities, parents, or subsidiaries. *Id.* at 122. The court reasoned as follows:

> [W]e have no doubt that companies that elect for sound business considerations to operate their enterprise by using multiple affiliated companies anticipate the risk of intra-corporate tort liability and therefore purchase liability insurance to offset that risk. Presumably, the decision to operate through interlocking corporations reflects the pragmatic determination that the specific advantages derived from the multi-corporate enterprise outweigh the risk of tort liability that the form of enterprise entails. Neither legislative history, precedent, nor public policy suggests that this Court should second-guess the reasonableness of such a business decision.

Id. at 126.

As a result, "'[t]hose incorporators or their successors, while entitled to the benefits that flow from incorporation, must also accept the burdens that flow from the use of the corporate structure. One of the burdens to be accepted is that a corporation may not share the immunity

N.J.S.A. 34:15-8 provides to a sister subsidiary corporation.'" *Id.* at 125 (quoting *Vernon v. Supermarket Servs. Corp.*, 250 N.J. Super. 8, 10 (App. Div. 1991)).

Along these same lines, workers' compensation immunity does not extend to corporate principals as courts are reluctant to pierce the corporate veil to protect them. *See, e.g.*, *Croxton v. Crowley Mar. Corp.*, 817 P.2d 460 (Alaska 1991); *Lyon v. Barrett*, 89 N.J. 294 (1982). For example, in *Lyon v. Barrett*, the plaintiff sustained injuries while working at a dental office organized as a professional corporation on property owned individually by the defendant, who was the sole principal of the corporation. 89 N.J. at 298; *see also Radar v. Omni Fin. Servs., Inc.*, 2009 N.J. Super. Unpub. LEXIS 2723 at *16 (App. Div. Oct. 29, 2009). The plaintiff sought to hold the defendant landowner liable on a premises liability claim. The defendant landowner argued that the claims against him were barred by workers' compensation immunity because he and the corporation were a "unitary employer-entity." *Id.* In this scenario, the court refused to pierce the corporate veil to extend immunity to the landowner and found that the landowner could not escape tort liability.

A frequent factual setting in toxic tort cases involves a chemical manufacturer that operates its manufacturing facility on real property owned by a separate corporate entity. The manufacturer, or even a third entity, may employ the worker who has been injured through occupational exposure. In this scenario, the landowner entity must be aware that when a direct employee claims that he or she is injured as a result of occupational exposure or other dangerous condition on the property, the landowner likely cannot avail itself of the same immunity that its employer affiliate enjoys.

Moreover, the landowner entity must also be aware that its direct involvement in the business operation or safety program of the employer entity may subject it to potential independent or joint civil liability. To avoid this risk, there are a few steps that the affiliated entity should consider to enhance the argument that it is shielded from civil tort liability based on the affiliated entity's direct involvement.

Minimizing Risk under Direct Involvement Theories

First, the affiliate landowner entity can minimize the risk of "direct participant" liability for directing the subsidiary-employer in activities that could result in foreseeable harm. In some jurisdictions,

> [w]here there is evidence sufficient to prove that a parent company mandated an overall business and budgetary strategy *and* carried that strategy out by its own specific direction or authorization, surpassing the control exercised as a normal incident of ownership in disregard for the interests of the subsidiary, that parent company could face liability.

Forsythe v. Clark USA, Inc., 224 Ill. 2d 274, 290 (2007) (emphasis in original).

As a result, an entity could be found liable for foreseeable injuries if it authorizes or directs a specific activity or when it "mandates an overall course of action and then authorizes the manner in which specific activities are undertaken." *Id.* Thus, "if parent companies do interfere directly in the manner their subsidiaries undertake certain activities, they must do so with reasonable care." *Id.* at 291.

Second, the affiliate landowner should consider the extent to which it voluntarily undertakes the obligation to provide a safe workplace to the operating entity's employees. In some jurisdictions, courts have taken the unusual step of imposing liability on the parent-landowner "for unsafe conditions at a subsidiary only if it assumes a duty to act by affirmatively undertaking to provide a safe work environment." *Muniz v. Nat'l Can Corp.*, 737 F.2d 145, 148 (1st Cir. 1984). To determine whether such a duty exists, courts look "to the scope of the parent's involvement, the extent of the parent's authority, and the underlying intent of the parent to determine whether the parent corporation affirmatively undertook the duty [ordinarily] owed by the subsidiary." *Bujol v. Entergy Servs., Inc.*, 922 So. 2d 1113, 1131 (La. 2004).

Liability in these circumstances is typically reserved for the rare case where the parent-landowner undertakes a safety obligation on behalf of or in place of the affiliated employer. *Id.* (internal citations omitted). For instance, this standard was met when the parent-landowner was found to have negligently designed and installed a ventilation system that caused the death of 15 miners at a subsidiary's mine. *Id.* at 1133 (internal citation omitted). By contrast, "neither a parent's concern with safety conditions and its general communications with the subsidiary regarding safety matters, nor its superior knowledge and expertise regarding safety issues, will create in the parent corporation a duty to guarantee a safe working environment for its subsidiary's employees." *Id.* at 1133. In addition, courts have declined to find that the parent-landowner made an "affirmative undertaking" when it hired the safety director who worked for the subsidiary, assisted the subsidiary in evaluating and inspecting the safety conditions at the subsidiary's plant, or conducted a negligent inspection. *Id.* at 1132 (internal citations omitted).

Third, the landowner entity should consider formally conveying the real property to the employer through a lease agreement. This lease could unequivocally delegate responsibility for maintenance and repair to the employer-tenant. In *McBride v. Port Authority of New York and New Jersey*, 295 N.J. Super. 521 (App. Div. 1996), the court examined the precise issue of whether an employee of a commercial tenant in exclusive possession of premises may hold the tenant's landlord liable for personal injuries suffered as a result of improper maintenance or repair where the lease delegated maintenance responsibilities to the employer. The court observed that "'historically, a lease was viewed as a sale of land and that as a result, the landlord was not responsible to maintain the leased premises.'" *Id.* at 525 (citing *Michaels v. Brookchester*, 26 N.J. 379, 382 (1958)). However, two exceptions to this rule were considered. These exceptions include the situation in which the landlord entity remains responsible to use reasonable care with regard to portions of the leased premises that remain in the landlord entity's control. In addition, the entity serving as landlord, although it has shifted its maintenance responsibilities, may still be subject to a covenant to repair that still obligates it to use reasonable

care in performing any repairs or improvements. *Id.* at 525 (citing *Michaels*, 26 N.J. at 383–85). Keeping these obligations in mind, the court held that because the lease unambiguously placed responsibility for maintenance and repairs on the employer-tenant, the landlord could not be held liable for injuries to the tenant's employee that arose as a result of a defective condition on the premises. *Id.* at 526–27.

Fourth, the landowner entity could unequivocally relinquish any rights to and delegate responsibility for the design and construction of future improvements on the property to the employer-tenant. As noted, where preexisting improvements or repairs performed by the landowner are defective, the landowner entity may be subject to liability if a worker is injured as a result of a defective repair or construction. For instance, in *Geringer v. Hartz Mountain Development Corp.*, 388 N.J. Super. 392, 402 (2006), *cert. denied*, 190 N.J. 254 (2007), the court found that the lease carefully defined the tenant-employer's role with respect to repairs and maintenance, and the landowner could not be subject to liability for injuries stemming from these obligations. However, because the employee claimed that he was injured in a stairway that was defectively designed and built by the landowner, not the employer, the court held that the employee plaintiff could maintain a negligence action against the landowner, given that the landowner in this instance was in the best position to exercise reasonable care.

Conclusion

The organization of corporate affiliates requires particular attention to detail and an understanding of how courts view corporate separateness and veil piercing to take full advantage of workers' compensation immunity. Creating separate corporate entities may not effectively protect clients from civil tort liability if they are not protected by workers' compensation immunity. A careful analysis of the range of potential risks of liability that a corporation faces will be critical in determining the appropriate corporate structure. Although the strategies outlined here are no guarantee, a more proactive and informed approach will help to minimize the potential liability risk.

Keywords: litigation, products liability, workers' compensation immunity, corporate affiliates, premises liability

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The FDA's 510(k) Approval Process in Medical-Device Litigation

By Troy Roberts

Any litigator knows evidence makes or breaks a case. One piece of admissible evidence may not determine a matter outright, but it may be that crucial nudge for a jury to tip the scales of justice for one side or the other. In medical-device trials, Food and Drug Administration (FDA) 510(k) regulatory approval may be that evidence. This dynamic was never more evident when two separate juries, one in March and one in April, determined whether or not DePuy's ASR XL metal hip implants caused injuries to the plaintiffs. At the conclusion of the March trial, the first in the ongoing ASR XL metal-hip litigation, a Los Angeles jury awarded the plaintiff an $8.3 million verdict because the hip was defective and negligently manufactured. The next month, in Chicago, DePuy's second ASR XL hip trial resulted in a full defense verdict.

What made the difference? In Chicago, where the jurors found for the defense, the judge allowed evidence and testimony that DePuy fully complied with the FDA's 510(k) regulatory approval process. In Los Angeles, where the jurors found for the plaintiff, the judge did not. However, surely the respective cases did not hinge solely on the 510(k) evidence. Opposing sides presented weeks of evidence on many evidentiary issues, such as the plaintiffs' past medical history. But equally as sure, the 510(k) evidence (or lack thereof) played a role in determining the divergent outcomes. This article's purpose is to revisit the status of the FDA's 510(k) medical device approval process and to address related legal considerations.

The 510(k) Process

As early as 1906, Congress regulated medical devices. Initial regulations were not nearly as rigorous as we see today because medical devices in that era were relatively basic and safety was not a significant concern. Fast-forward to 1976. Medical devices had markedly evolved in their complexity and use. So had their potential harm to consumers. Applying consumer-protection policy at the time to medical devices, Congress passed into law more device-centric requirements. Created was our current three-tiered medical-device class system and the stringent premarket approval process (PMA). Based on market and social interests at the time, Congress also determined that certain medical devices could be eligible for "fast track" FDA approval, i.e., the 510(k) process.

The 510(k) process has developed significantly since 1976 due to similar transformative policy principles. Currently, according to the FDA's website, "a 510(k) is a premarketing submission made to the FDA to demonstrate that the [medical] device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval (PMA)." Under 510(k), a manufacturer's submission to the FDA may vary in scope and complexity, depending on the current status of the device, FDA consensus standards, and other varying factors. Basically, a manufacturer designs and creates a medical device with the same intended use as a product already legally approved, and it then petitions the FDA for approval so that the manufacturer may introduce the new product to the general consumer. The manufacturer has to show that the product has the same technological aspects of the predicate device or that any new technological characteristics do not raise safety and effectiveness concerns.

The FDA generally has 90 days to review a manufacturer's 510(k) submission. However, the review process may exceed the 90-day time frame for varying reasons. Once the FDA approves a device, the manufacturer receives a decision letter, or order, approving the device for marketing in the United States. After approval, the FDA requires manufacturers to track certain medical devices once they enter the marketplace. Changes or modifications to an existing device require new FDA approval, usually through the 510(k) process.

Despite these proactive steps addressing consumer safety, the 510(k) process has been and continues to be a controversial consumer-safety policy. The battle lines in this respect have been clearly drawn.

Differing Opinions on the 510(k) Process and Their Effect

In 1996, the U.S. Supreme Court, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), weighed in on the FDA's PMA and 510(k) approval processes, albeit for preemption purposes. Pertinent here, the Court observed that the FDA spent on average about 20 hours evaluating each 510(k) submission, while for each PMA submission, which is generally required for the more potentially dangerous Class III medical devices, the FDA spent an average of 1,200 hours per PMA submission. The Court came to the obvious conclusion that PMA process was a much more rigorous safety test than 510(k) process. This conclusion forms part of the foundation on which the current 510(k) policy battle rages.

Opponents of 510(k) roundly criticize the 510(k) process's relative lack of FDA scrutiny compared with PMA or other potential approval processes. They argue that the 510(k) "substantially equivalent" test simply does not go far enough and, therefore, the 510(k) does not effectively safeguard consumers. For example, critics point to past instances where the FDA did not require distinct clinical trials or human testing for new 510(k) devices. To drive home their message, 510(k) opponents cite helpful statistical studies that address 510(k) Class I recall rates (recall classification for dangerous or defective products, a separate classification determination than that for types of devices). One exemplar study found that 71 percent of Class I recalls between 2005 and 2009 involved devices that had been approved through the 510(k) process. Other arguments are that the FDA does not have access to full information that the manufacturers possess and that that the FDA is too understaffed to perform its mandate properly. And, of course, 510(k) opponents cite past blockbuster lawsuits relating to defective devices.

Meanwhile, 510(k) proponents maintain that the 510(k) process offers the proper balance between patient safety and consumer access. The medical devices eligible for 510(k) approval receive a proportional amount of scrutiny in relation to the dangers they pose. To support their position, 510(k) proponents also cite statistical studies. One study revealed that the 510(k) process has a 99.8 percent safety rate over a period of time similar to the one in the opponents' studies—meaning that only 0.2 percent of 510(k) approved devices faced Class I recalls. They argue that this number and similar statistics depict the program's success in weeding out unsafe devices while timely introducing in the market new and improved medical devices that save lives and improve consumer quality of life. In addition, the substantially equivalent standard is a logical demonstration of safety and effectiveness because the FDA has already vouched for the safety of the predicate devices. And, as noted above, the FDA *expressly* states the substantially equivalent standard addresses the issue of safety.

It is essential for practitioners to stay apprised of these policy arguments and the evolving nature of the policy itself to better prepare for the prosecution or defense of lawsuits. Furthermore, the differing points of view help set the stage for 510(k) evidentiary battles during medical device litigation. Whether it is a defendant presenting evidence to a jury that the FDA approved its product or a plaintiff presenting evidence of a particular device's flawed 510(k) approval process, advantageous 510(k) evidence can be quite valuable.

510(k) Approval Process Considerations

Plaintiffs' and defense attorneys must continually assess case-specific 510(k) evidence to determine its effectiveness for, or against, their client's case. Whether the assessment is conducted prior to filing a complaint, during discovery, or prior to trial, practitioners must address 510(k) evidence and adapt their litigation strategy accordingly.

Medical-device defense attorneys by and large wish to present 510(k) compliance evidence before a jury. Such evidence shows that their clients played by the rules and worked hand in hand with a safety regulatory agency before selling their product on the open market. Ideally, defense counsel want a jury to equate the FDA's 510(k) approval to society's safety stamp of approval and find that the device manufacturer was a responsible member of society. Predictably, plaintiffs generally do not want 510(k) evidence presented to the jury. Like opponents of the process, plaintiffs' attorneys argue the 510(k) substantially equivalent standard does not truly represent a viable safety standard, which, perhaps, the PMA standard does. They worry the jury may place considerable weight on the fact that the medical device passed "FDA safety standards," albeit a less stringent standard.

To some degree, this dynamic played a role in DePuy's trial victory in Chicago, where DePuy was permitted to present evidence that it complied with the 510(k) process. DePuy introduced testimony from a former FDA device compliance chief that DePuy thoroughly complied with the 510(k) process and that DePuy adhered to post-approval tracking requirements. It is not far-fetched to say that the lack of such evidence in Los Angeles made it much easier for the plaintiff's counsel to depict DePuy as a corporation motivated more by profit than concern for consumer safety.

The two DePuy cases demonstrate that judicial 510(k) evidentiary determinations will vary. Practitioners must be cognizant of this and should closely evaluate each jurisdiction's rules of evidence and case law to best structure their arguments for or against the admission of 510(k) approval. For example, a plaintiff should identify jurisdictional conditions and defendants in multiparty cases that would allow them to bring, or maintain, their case in a "friendly" evidentiary venue, keeping in mind various removal techniques employed by defendants. Or a defendant may structure deposition examinations and discovery to better support their pretrial argument that 510(k) evidence should be allowed.

Practitioners must also evaluate 510(k) evidence specific to their case, such as the behavior or actions taken by a manufacturer during the 510(k) process. Evidence regarding the tone of a defendant's communications with the FDA, documents made available, willingness to comply, and other specifics during the submission review can have significant effects on a jury. For example, in April, a New York district court judge ruled the FDA could revoke the FDA 510(k) marketing clearance for ReGen's Menaflex knee implant despite having approved the device nearly two years earlier. The judge determined this particular manufacturer's 510(k) submission

and approval had been so tainted by irregularities and political pressure that the FDA could legally rescind its approval. Imagine what would have happened if DePuy's ASR XL hip implant had gone through a similar approval process prior to its recall and subsequent litigation. Compensatory damages at the Los Angeles trial would have been the least of DePuy's worries. Instead, DePuy's cooperation with the FDA during the hip implant's approval process may have been the evidence that saved the day in Chicago.

If 510(k) evidence is allowed, there are tactical considerations. Take the voir dire process as an example. Parties might inquire into a potential juror's trust in the government to keep him or her safe or whether he or she could trust a manufacturer to present supporting documents regarding safety, design, or clinical trials to the FDA. The list of tactical considerations for practitioners goes on and on. The important point is that each practitioner must develop his or her own strategy tailored to a specific case and then tactically address 510(k) evidence.

Last, manufacturers can assist in their defense long before an alleged injury to a consumer. For instance, to make a 510(k) approval "safety" or "responsible" argument more powerful, device manufacturers could hire a neutral third party to steer their medical device through the 510(k) process. This approach could remove potentially damaging approval issues that a jury may attribute directly to the manufacturer. A jury may also consider the neutral party an additional layer of safety.

Conclusion

Manufacturers should consult with legal counsel to determine the most effective way to implement approval strategies for their devices, keeping in mind the risk of future lawsuits and the societal perceptions reflected in juries. Legal practitioners on both sides must keep a close eye on 510(k) legal matters because of the evolving consumer safety policy environment. Also, as shown in the ReGen Menaflex case, the legal landscape can radically shift in a single day. Preparation and knowledge are key; otherwise, a client may be on the wrong end of a jury decision.

Keywords: litigation, products liability, DePuy, medical devices, 510(k)

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The Case for Leaving the 510(k) Argument Out of a Pleading

By Prof. Jim O'Reilly

A well-written article in this issue brings a younger, fresher perspective to the defense of medical-device makers, and I encourage you to carefully consider those viewpoints. With due respect, I represent a very vanishing breed, the creators of the 1976 Medical Device Amendments, so it may be useful to have some history of the 510(k) "on the record" before this dinosaur fades from the scene.

"Medical devices" as a regulatory category had been ignored, sitting quietly in the corner of a very active regulatory field as bad drugs and foods were challenged from 1906 into the 1970s, and remained in obscurity as the Supreme Court struggled with diagnostic products in *United States v. Bacto-Unidisk*, 394 U.S. 784 (1969), a decision that had to stretch far to call diagnostics "drugs" for lack of any other vehicle for their regulation. By the mid-1970s, General Electric's painful experiences with bad electrical lead wires for heart pumps drew public attention to physical and mechanical objects that would not fit the "drug" world. Who would step in? The then-new (1972) consumer product safety legislation had excluded these human-use medical items, and there was reluctance in the post-Nixon era to create another federal agency. The Centers for Disease Control and Prevention, the National Institutes of Health, and the states all had some roles in the process, on issues as small as Massachusetts hearing aid rules, which gave impetus to the preemption provision of the 1976 law.

Reaching consensus on the Medical Device Amendments of 1976 was not too difficult by today's standards. General Electric, Abbott, Medtronic, and other big players were assured that the Food and Drug Administration's (FDA's) new drug approval delays would not be imposed. Hundreds of smaller medical products makers were assured that Congress would allow friendly industry-FDA committees to write Class II standards for most medical devices. As the youngest in-house lawyer at a large manufacturer that was starting a hospital-supplies sideline, I had the junior seat at the table, ready to absorb knowledge, just as my client's disposable paper drapes would be absorbing the cuttings of the surgeons—a role not dissimilar from the role of lobbying veterans who were crafting the new law in numerous rounds of drafts with FDA and House staffers.

We drafters faced a bridging problem. There was certainly going to be enough money for writing and adopting classification standards, defining what each existing set of devices would do and what their labels would say. But the FDA would not have enough engineers and scientists with time to vet all of the "me-too" competing look-alike products that would flow through its portals under section 510's registration powers. Once the classification rule had defined a device group, each new version would match up to that standard or would have to go through specific detailed approval; our benchmark was the success (as of that time) of FDA Chief Counsel Peter Hutt's 1972 genius in designing the over-the-counter (OTC) drug review. Under that system, me-too versions of aspirin or cold remedies would match the OTC standard and simply notify the FDA of their marketing and their compliant comparison with the standard.

The bridge of registration by adding (k) to section 510 was to be temporary while the classification standard was written. With all the brilliant self-promotion a young attorney can muster, I assured my client that we had arranged under new section 510(k) that our me-too versions of devices would rapidly zip through the FDA screening, with a, literally, one-page checklist comparing each newly registered item to an existing product that had been on the market as of May 28, 1976, the effective date of the bill that President Ford signed. And zip they did—few medical device firms opted for Class III premarket approval, FDA panels and scientists focused on the complex new surgical and life-sustaining items, and the 510(k) stimulated a great deal of attention. A tiny percentage were rejected, but the one-page reviews zoomed through the FDA mill.

This novel bridge was a pure "negative option"; sponsors said the device was "substantially equivalent" for safety and for effectiveness compared with older device X or Class II device Y. If the FDA said nothing in 90 days, the newly registered device was deemed cleared for market, because its predicate earlier device had been on sale before the new law was enacted. In early May 1976, a few weeks before the grandfathering date of "enactment," a truckload of my client's newest devices were shipped from Tennessee to Mississippi, making them "predicates" for future 510(k) me-too expansions. I treasured the invoice proving their actual interstate movement and became device "official correspondent" for our 510(k)s.

So the 510(k) me-too one-page checklist was launched, but the shock of domestic discretionary budget cuts on the Department of Health, Education, and Welfare aborted its plans for Class II standards writing. The OTC drug review has continued to this day, but there are not specific performance-focused standards for hundreds of medical devices in the FDA's regulations. Our 510(k), without the funds for FDA standards writing, became a bridge to nowhere. Bureaucracies faced with shortfalls make do as best they can, so the FDA slowly tightened the one-page review into some more detail. At a meeting with chief executive officers of device manufacturers and their lawyers and new management of the FDA's device center, which I watched as a junior observer, FDA leaders began talks that showed a nascent desire for clinical trials to be done, even on me-too 510(k) products. The industry pushed back that the FDA did not have physicians to review the clinical data and that its budget would not allow for cautious doctors from the drug center to be imported as gatekeepers for device clearances. The rate of 510(k) questions slowly increased, and the Congress eventually signed off on the 1990 compromise that changed the "negative option" and required the FDA to say within 90 days whether the product was acceptable.

I was surprised when the Supreme Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), asserted that our drafting of the 1976 preemption provision meant to cover jury verdicts. No, it didn't at all; it was aimed at a Massachusetts hearing aid rule that the national lobby for hearing aid firms disliked. State "requirements" could be preempted, but the drafters did not debate jury verdicts at all.

Today, defense litigants are tempted to say to juries that a 510(k) is an FDA approval, so tort plaintiffs should lose. Creative advocacy? Yes. Accurate? No. The one-page checklists had cleared thousands of devices with silence and sometimes with "no objections," determined by one or two staffers in a matter of hours. Just as registration is easy under 510, so the claim of me-too status under 510(k) was meant to be easy, and for decades it was. I cannot reconstruct the budgeted hours assigned to this function inside the center responsible for this role, but the FDA did not spend dedicated detailed efforts on the fire-hose-like volume of registrations whose paperwork had few constraints after 1976.

Take it from one who was present at the creation: The concept offered to juries today, that the 510(k) has equaled regulatory approval, is an entertaining fantasy. After 1990, when there needed to be a formalized acceptance, the FDA did more clearance internally, but nothing like the premarket approval steps that the Supreme Court's decisions in *Lohr* and in *Medtronic, Inc. v. Riegel*, 552 U.S. 312 (2008), addressed. Be a good defense advocate with other claims, but leave the 510(k) argument out of a pleading, if you wish to be historically accurate and wish to pass the Rule 11 laugh test of creative motions.

Keywords: litigation, products liability, medical device, 510(k)

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NEWS & DEVELOPMENTS

Don't Blame the Employee

Last month, the Fifth Circuit Court of Appeals handed defendants a victory in the latest skirmish in the broader decades-old battle between plaintiffs and defendants over whether to proceed in a federal or state forum. *Mumfrey v. CVS Pharmacy, Inc*., 2013 WL 2476402 (5th Cir. June 10, 2013). Although *Mumfrey* was a wrongful termination action, the naming of local employees of a corporate defendant is a common tactic used in pharmaceutical and other product liability actions. In most instances, there is no reason to proceed against employees (whether sales representatives, individual pharmacists, or store clerks) when the real claim is against their employer. Naming a local defendant often serves one of two purposes, namely, to defeat an out-of-state corporate defendant's ability to remove the case by defeating complete diversity among the parties or otherwise preclude removal by naming an in-forum defendant. A federal district court has aptly observed that "given the relative financial positions of most companies versus their employees, the only time an employee is going to be sued is when it serves a tactical legal purpose, like defeating diversity." *Ayoub v. Baggett*, 820 F. Supp. 298, 300 (S.D. Tex. 1993).

Under the doctrine of fraudulent (or improper) joinder, an out-of-state defendant can still remove such cases when there is "no reasonable possibility for recovery" against the local employee defendant. Or, put another way, the standard is "whether there is a reasonable basis for the district court to predict that the plaintiff might be able to recover against an in-state defendant." *Mumfrey*, 2013 WL 2476402 at *7. If there is no such basis, a court will disregard the presence of that defendant for purposes of removal.

In *Mumfrey*, the Texas plaintiff had originally sued in Texas state court. He named his former employer, a pharmacy that was not a citizen of Texas, as well as his local supervisors and a store manager. Although there was a lack of complete diversity, the pharmacy removed the action to federal court, asserting that the Texas individual defendants were improperly joined to the lawsuit. The plaintiff moved to remand to state court and the district court denied the motion.

On appeal after a bench trial in favor of the pharmacy, the Fifth Circuit affirmed both the denial of remand and the judgment. Applying Texas law, the Fifth Circuit concluded that there was no basis for a claim against the local individual defendants because the complaint did "not allege that the individual defendants were acting to serve their own personal interest." Indeed, the plaintiff conceded that those defendants "were acting in the scope of their employment at the time of the retaliatory acts." Moreover, the pharmacy "never complained or disciplined the individual defendants for their behaviors" which indicated that that they had not acted contrary to the interests of their pharmacy employer. Accordingly, the Fifth Circuit concluded that there "was no reasonable possibility for recovery against the individual defendants under Texas law" and the individual defendants were improperly joined.

The takeaway from this decision is that (at least under Texas law) employees cannot be held responsible for what in essence are the torts of their employer. As another federal court explained: "While the doctrine of respondeat superior may make a master liable for the torts of its employee merely because of their relationship, the converse does not hold true—a servant is not liable for the torts of his master unless he committed the tort personally." *James v. Parke-Davis*, Case No. 1:00-CV-1203-JEC, at 19 (N.D. Ga. Nov. 30, 2000), reconsideration denied (N.D. Ga. Jan. 16, 2001).

What *Mumfrey* makes clear is that corporate defendants are not powerless in removing cases from state court where plaintiffs also name those defendants' local employees. Where the only allegedly tortious conduct by the employee is serving the interests of the employer, that may well (at least in Texas) shield local employees from personal liability and permit the real target of plaintiff's claims, the out-of-state corporate defendant, to proceed in federal court. *Mumfrey* also addressed a timeliness of removal issue, holding that it was an amended complaint expressly seeking more than $75,000 in damages, and not plaintiff's original complaint that triggered defendant's 30-day clock for removal. The original complaint did not "affirmatively reveal[] on its face" that the plaintiff sought more than the minimum jurisdictional amount.

Keywords: litigation, products liability, *Mumfrey*, corporate defendants, fraudulent joinder, Texas

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Federal Court Orders FDA to Issue New Food Safety Rules

Each year about 48 million people (1 in 6 Americans) report foodborne illnesses. On January 4, 2011, the Food Safety Modernization Act (FSMA) was signed into law. The purpose of the act was to shift the focus toward preventing foodborne diseases, rather than simply responding to outbreaks. To accomplish this goal, Congress provided the U.S. Food and Drug Administration (FDA) with new powers and directed it to enact new regulations covering several specific food safety areas: preventive controls, inspection and compliance, imported food safety, response, and enhanced partnerships between various federal and state food safety officials.

The FDA was expected to accomplish a relatively swift implementation of the FSMA; however, funding and resource limitations as well as the extensive nature of proposed changes have resulted in significant delays. As of June 2013, only a few provisions of the act are currently effective. Other regulations such as those pertaining to hazard analysis and prevention plans and procedures for tracking and tracing food products are in the study or comment phase. Regulations dealing with a foreign supplier verification program and the accreditation of third-party auditors are yet to be addressed.

On June 26, 2013, a federal judge in California ordered the FDA to finalize and publish food safety regulations mandated by the FSMA by June 30, 2015. The ruling resulted from a suit brought by the Center for Food Safety and the Center for Environmental Health challenging the FDA's failure to implement a regulatory scheme for the FSMA in accordance with certain timelines included in the act. The parties' proposed implementation schedules were vastly different. The consumer groups sought a relatively rapid implementation with finalization of regulations by May 1, 2014. The FDA's proposal included a longer timeline and only committed the agency to work toward meeting its targets, citing potential unforeseen circumstances. The court recognized the complexity of the new legislation and the need for comment periods and review by other federal agencies such as the Office of Management and Budget, but the judge wanted a definitive schedule that could result in an injunction if deadlines were not met.

Ultimately, the court ordered the FDA to propose various regulations by November 30, 2013. The agency can then accept comments until March 31, 2014, and has until June 30, 2015, to finalize the rules. Given the limited progress the FDA has made in the 30 months since the FSMA was signed into law, its ability to comply with the court's timetable will be a daunting task. The FDA has not yet indicated whether it intends to appeal the order.

Keywords: litigation, products liability, Food Safety Act, FDA

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