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Electronic Cigarettes

Where There's Smoke, There's Litigation

By Ronald J. Levine and Gabrielle C. Wilson

Electronic cigarettes, or e-cigarettes, have gained widespread popularity in recent years as an alternative to traditional cigarettes. While the traditional variety use burning tobacco to create smoke that is inhaled, e-cigarettes are battery-powered devices that vaporize a liquid containing nicotine (and may also contain propylene glycol, vegetable glycerin, and flavorants) that the consumer inhales without the combustion involved in traditional cigarettes. While e-cigarette manufacturers and distributors promote the potential advances of this new technology over traditional cigarettes, the degree to which e-cigarettes are safe is the topic of great debate, and the source of litigation.

However, as e-cigarettes are a relatively new development, state and federal regulations and case law are in a state of evolution, as many of the claims made against designers, manufacturers, distributors and sellers of e-cigarettes are in their infancy. Federal regulations governing e-cigarettes have not been finalized. The U.S. Food and Drug Administration (FDA) has promulgated proposed rules that are in the review stage and have yet to be adopted. These proposed

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Maintaining the Attorney-Client Privilege Even with a Third-Party Presence

By Andrew K. Solow, Danelco Moxey and David A. Kerschner

The modern business landscape is replete with examples of privileged legal communications occurring outside traditional corporate silos. For years, it has been appreciated by litigants (and courts) that bankers, experts and consultants could sufficiently implicate legal issues and strategies and, as a result, some communications with them may be protected under the attorney-client privilege. More recently, faced with pressure to increase efficiency, companies have increased their dependence on outside entities to complete tasks that were once reserved for in-house employees.

In a similar vein, companies are turning more and more to joint ventures as they attempt to exploit synergies with other companies — sometimes even competitors — to accomplish tasks that companies traditionally completed on their own. For example, in the pharmaceutical industry, companies that develop a compound routinely enter into co-promotion agreements with other pharmaceutical companies to promote and market the approved product. Typically, the companies in the co-promotion agreement create one or more joint committees consisting of employees from each company to handle tasks ranging from overall strategic oversight to the review and approval of promotional materials. In the highly regulated pharmaceutical industry, these committees are continually seeking and obtaining legal advice, and companies and their counsel should be diligent in considering whether such communications are privileged and, in turn, protected.

When viewed in hindsight (during litigation), these complex corporate relationships necessitate a careful evaluation of potential applicable assertions of privilege. This article looks at two of the more recent trends to assert and maintain a privilege over communications with non-corporate employee: 1) third parties being considered functional equivalents of company personnel or working as agents for company attorneys in order to maintain an attorney-client relationship; and

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2) joint ventures maintaining sufficient common interest with a company to protect communications under a claim of the work-product privilege.

The Use of Third-Party Agents and the Functional Equivalent Doctrine

As with any assertion of privilege, it is important to understand that properly asserting and maintaining the privilege with third parties has two components: 1) ensuring that communications involving third parties and company attorneys (whether company counsel or outside counsel) are covered by the attorney-client and/or work-product privilege; and 2) maintaining that privilege by avoiding any claim of waiver.

Traditional black-letter law teaches that the presence of an outside, or third, party on an otherwise privileged communication will waive privilege. However, courts have found two exceptions to this rule: 1) where the third party is participating to assist an attorney in understanding and interpreting complex principles, and 2) where the third party is so thoroughly integrated into the company that he or she should be treated as functionally equivalent to an employee.

Third Parties Who Assist in Understanding and Interpreting Complex Principles

Courts have long recognized that few lawyers can practice without the assistance of messengers, clerks and secretaries who are not themselves attorneys, and thus these third parties will not break privilege. Use of these quasi-legal third parties does not significantly differ from an attorney's use of a language interpreter to translate documents. Courts have made the jump from the need to interpret foreign languages to the need to interpret concepts that may be just as foreign to many lawyers, such as complex financial terms or accounting concepts. *See United States v. Kovel*, 296 F.2d 918, 922 (2d Cir. 1961). Applying a mix of agency concepts and the interpretive concept, courts have routinely held that third parties who are assisting an attorney in providing adequate legal advice to a client do not break privilege. For example, in *Stafford Trading, Inc. v. Lovely*, No. 05-C-4868, 2007 WL 611252 (N.D. Ill. Feb. 22, 2007), the court recognized that, "in today's market place, attorneys need to be able to have confidential communications with investment bankers to render adequate legal advice."

The determination that the third party does not break privilege rests, in part, on whether or not the third party was acting in an interpretive function for the attorney by rendering expert advice to assist the attorney in delivering legal advice to the company. In another example, in *Calvin Klein Trademark Trust v. Wachner*, 124 F. Supp. 2d 207 (S.D.N.Y. 2000), Calvin Klein and its attorneys communicated with bankers from Lazard to assist in drafting documents disclosing material information to a potential purchaser. The court reasoned that because the question of what information is material is a mixed question of fact and law, and a law firm would benefit from an investment banker's business advice, Lazard was serving an interpretive function and did not break privilege. Consistent with this approach, courts have routinely found that, in situations where company lawyers communicate with third-party bankers for the purpose of obtaining or providing legal advice, those communications are privileged.

Similarly, courts have also routinely maintained privilege claims in cases involving consultants, accountants, investigators, public relations firms and non-testifying experts. *See*

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Off-Label Promotion And Product Liability

Are Industry's Recent Court Wins in One Space A Win in the Other?

By Alan G. Minsk

The pharmaceutical industry has recently felt empowered and emboldened by one final court decision and another pending case that would seemingly allow companies to distribute, proactively, information about unapproved uses, *i.e.*, off-label, so long as the information is truthful and not misleading. However, companies must, nevertheless, consider potential product liability ramifications. There is no indication that, because firms may now be allowed certain latitude in one area, they are immune from product liability exposure.

Amarin Pharma v. FDA

With *Amarin Pharma, Inc. v. United States Food and Drug Administration*, No. 15 Civ. 3588 (PAE) (S.D. N.Y. Aug. 5, 2015), the U.S. Food and Drug Administration (FDA) lost yet another court decision challenging its ability to restrict a company's commercial free speech rights. There, the U.S. District Court for the Southern District of New York granted Amarin's preliminary injunction to prohibit the FDA from taking enforcement action against the company's distribution of information about an unapproved use of its FDA-approved fish oil, triglyceride-lowering prescription drug product, Vascepa® (icosapent ethyl).

Vascepa is approved as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. These patients would also be treated with statins. The product is composed of pure eicosapentaenoic acid (EPA), an omega-3 fatty acid. Amarin wanted to promote the product for a wider group of patients than approved, *e.g.*, patients treated with statins with high but not very high triglyceride levels. This is an "off-label" use. The company sought to make health care professionals aware of clinical study results concerning the efficacy of the drug in certain patients, which the FDA had questioned, but with qualified statements, such as: "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease."

Amarin was prepared to provide additional information, such as a selection of peer-reviewed scientific articles on the potential effect of EPA on the reduction of the risk of coronary heart disease. It was also willing to include disclosures and disclaimers to doctors, such as that the drug had not been approved for certain uses, among other qualifiers.

According to Amarin, the FDA intimated that the dissemination of such information would be off-label (because the drug was only approved to treat very high triglyceride levels) and would misbrand the drug product, potentially resulting in enforcement action. The FDA (after convening an advisory panel) did not approve the drug product for the additional indication. Thus, Amarin took the preemptive step of seeking a preliminary injunction.

Amarin claimed that the statements were truthful and non-misleading speech, and thus should be protected by the First Amendment, citing a previous U.S. Court of Appeals for the Second Circuit decision (the 2012 *United States v. Caronia* case). In a June 5 letter, perhaps intended to make the case moot, the FDA noted during the court proceeding that it would not consider the dissemination to be evidence of misbranding if the company met certain conditions. The FDA indicated it did not have concerns with much of the information the company proposed to communicate. Amarin was willing to agree to some, but not all, of the FDA-requested disclosures.

Highlights of the *Amarin* Decision

The district court said that the FDA June 5 letter did not make the case moot, because Amarin had not agreed to all of the conditions and, thus, the letter continued to expose the company to potential FDA enforcement action. The court noted, "Because Amarin faces a non-extinguished threat of a misbranding prosecution for speech it proposes to undertake as to Vascepa, there remains a live case or controversy."

The court, citing *Caronia*, said that the government cannot prosecute companies and their representatives under the Federal Food, Drug, and Cosmetic Act for truthful, non-misleading discussion, even if that discussion is about off-label uses: "The Court's considered and firm view is that, under *Caronia*, the FDA may not bring such an action based on truthful promotional speech alone, consistent with the First Amendment." According to the court, unlike the FDA's contention, the *Caronia* decision was not limited to the facts of that specific case.

The court also held that Amarin may engage in truthful and non-misleading speech promoting off-label use of Vascepa, and that such speech may not form the basis of a prosecution for misbranding.

Further:

- The FDA failed to persuade the court that its regulation of off-label promotion should be exempt from First Amendment scrutiny.
- The court recognized that the FDA has a substantial interest in protecting consumers from potentially ineffective drugs, and encouraging companies to utilize the drug approval process to include new uses in the product label. However,

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the court said that the FDA could have used less restrictive approaches to accomplish its goals. In this case, Amarin's proposed statements and disclaimers, with possible tweaks to explain the status and limitations of the research, might have made the statement not misleading. As a result, the court enjoined the FDA from considering the off-label communications to be evidence of misbranding.

- The district court rejected the FDA's position that, for prescription drugs, any such communications should be supported by "significant scientific agreement."
- The decision made clear that false or misleading statements are not protected speech. In addition, the government could prosecute non-communicative, unlawful promotional activities (*e.g.*, rewarding doctors for prescribing a product for off-label uses). The court said that *Caronia* protects off-label promotion "where it wholly consists of truthful and non-misleading speech."
- Because the agency can take enforcement action against misleading statements (*e.g.*, one-sided or incomplete), companies should consider voluntary restrictions or appropriate qualifiers.

The court offered a "final observation":

> Although the FDA cannot require a manufacturer to choreograph its truthful promotional speech to conform to the agency's specifications, there is practical wisdom to much of the FDA's guidance, including that a manufacturer vet and script in advance its statements about a drug's off-label use. A manufacturer that leaves its sales force at liberty to converse unscripted with doctors and off-label use of an approved drug invites a misbranding action if false or misleading (*e.g.*, one-sided or incomplete) representations result. *Caronia* leaves the FDA free to act against such lapses. A manufacturer may also conclude that it is prudent to consult with the FDA before promoting off-label use. Reasonable minds may differ over whether a given statement is misleading in context; and developments in science or medicine may make a once-benign statement misleading. Prior consultation with the FDA may prove a helpful prophylactic, and may avert misbranding charges where the FDA and the manufacturer would take different views of a statement.

Another Potential Loss?

Fresh off its loss in the *Amarin* court decision concerning off-label promotion, the agency again finds itself the defendant in a similar lawsuit concerning whether it can silence a company's truthful and non-misleading communications about off-label uses. This time, it is Pacira Pharmaceuticals, Inc. challenging the FDA's authority. Perhaps not surprisingly, Pacira brought its challenge in the U.S. District Court for the Southern District of New York, the same forum where the FDA lost the *Amarin* case, hoping for a similar result.

Here are some background facts:

- Pacira has approval to market its prescription drug, Exparel® (bupivacaine liposome injectable suspension), for single-dose administration into a surgical site to produce post-surgical analgesia.
- In September 2014, the FDA issued a Warning Letter to Pacira, contending that the company promoted its product for pain relief in surgeries not listed on the label — *i.e.*, unapproved and off-label uses — and, thus, misbranded the product. The FDA has since removed the Warning Letter from its website.
- Pacira cites its First Amendment free speech rights to promote its product in a truthful and non-misleading manner (Amarin made similar arguments). The company maintains that the information presented is, indeed, consistent with the approved, on-label indication.
- The company also claims that, under the Due Process Clause of the Fifth Amendment, the FDA must establish rules that expressly notify it of the prohibitions for a particular drug. Pacira asserts that it has a broad, approved indication and, after three years post-approval, the FDA attempted to limit promotion of the product beyond two specific indications — surgeries for bunions and hemorrhoids. Pacira contends that the agency's regulations as applied to the company are vague. In addition, it alleges that the FDA failed to provide fair notice about what Pacira could lawfully promote and what it considered to be prohibited, thus representing a retroactive, *ex-post-facto* penalty.
- Pacira alleges that the FDA violated the Administrative Procedure Act when it attempted to narrow what the company believes was a broad indication, and where it had supporting clinical data for the claims promoted, without following regulatory rules to modify the drug's label.
- In the Complaint, Pacira claims it sought to meet with the FDA to better understand the agency's interpretation, but to no avail. The FDA ultimately issued a close-out letter to Pacira, indicating that it considered the Warning Letter issue to be resolved.
- Pacira's Complaint seeks declaratory relief and a preliminary and/or permanent injunction to prevent the FDA

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from taking enforcement action that could violate the company's legal rights.

The FDA has not said much, if anything, post-*Amarin*, except it is public knowledge that Amarin and the FDA are discussing settlement options. We believe the agency is struggling to find a balance whereby it can maintain its jurisdictional authority to take enforcement action against what it perceives to be unlawful promotion, while possibly conceding some authority when the off-label information is truthful and not misleading.

Conclusion

In light of recent developments, many companies are re-evaluating potential off-label promotional dissemination approaches. The courts have not given carte-blanche power to manufacturers to promote off-label. The information must still be truthful and not misleading, which might require prominent disclosures, disqualifiers, or limitations in promotional pieces, among other things. It bears repeating that the Federal Food, Drug, and Cosmetic Act provides that, in determining whether a promotion is misleading, it must be taken into account (among other things) not only representations made or suggested, but also "the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling, or advertising thereof or under such conditions of use as are customary or usual."

A company's Promotional Review Committee must remain the gatekeeper. Furthermore, non-FDA-related issues, such as product liability exposure, must be considered and not discounted or dismissed. A jury might not be as forgiving if little Johnny or Grandma is injured as a result of a product's off-label use, which could be traced back to a manufacturer's promotional efforts.

It is important that the cases settled and pending are fact-specific, and that each is focused in one jurisdiction (Connecticut, New York or Vermont). While it might be possible to create product information, even if off-label, that will pass legal scrutiny, it is important to remember that the "truthful and not misleading" standard seems to be the norm, however that might be interpreted. So, a company should recognize that this broad standard might be beneficial in an FDA sense (allowing more freedom to distribute) but, potentially, problematic to a company named as a defendant in a product liability lawsuit (where a judge and jury might impose a strict and narrow interpretation favoring an injured party).

In sum, distribution of an off-label piece, without internal review, is not advisable, notwithstanding the potential FDA opportunities, when one factors in possible product liability exposure.

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CASE NOTES

'Similar Incident' Evidence Permitted at GM Trial

Evidence of similar incidents involving ignition defects and air bag deployment failures in General Motors vehicles may be introduced at the company's trial that began in January, a federal judge has ruled. Southern District Judge Jesse Furman said the plaintiff, in the first bellwether product liability trial on alleged ignition defects that cause vehicles to lose power, "established a *prima face* case for admission of at least some OSI" or "other similar incident" evidence. However, Furman cautioned that, during pre-trial, he would seriously vet evidence of 15 OSIs being offered by lawyers for plaintiff Robert Scheuer.

Furman's ruling came the last week of December in *In re General Motors LLC Ignition Switch Litigation*, 14-MD-2543, a multi-district litigation being pursued by hundreds of plaintiffs against General Motors.

Seeking more details from the plaintiff, the judge deferred ruling on specific evidence of 15 other similar incidents that Scheuer, who was injured when his 2003 Saturn Ion crashed in Oklahoma in 2014, wants to introduce at the trial. But Furman held that, "as a general matter" the "15 other incidents at issue are 'substantially similar' to be admitted, certainly to prove notice, but also to prove causation."

The judge said a significant factor on admissibility in the product liability context is whether the OSIs being offered, the earliest of which go back to 2003, involve the same defect. "The 15 incidents identified by plaintiff all involved the same allegedly defective ignition switch as the one at issue here; all involved airbag non-deployment despite substantial frontal-impact collisions, as here; and nearly all involved off-road conditions, as here," he said.

Furman said the company, now calling itself New GM after bankruptcy, "itself effectively treated the incidents as substantially similar" until it was faced with having them admitted at trial. "Nearly all of the 15 other incidents were included in New GM's various admissions to crashes caused by the ignitions switch defect-including submissions made to the National Highway Traffic Safety Administration, the statement of facts to which New GM agreed as part of the deferred prosecution agreement with the Department of Justice, and the Valukas Report," he said, referring to the report prepared on the ignition scandal by Jenner & Block chairman Anton Valukas. **— Mark Hamblett**, *New York Law Journal*

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NXIVM Corp. v. O'Hara, 241 F.R.D. 109, 138 (N.D.N.Y. 2007) (investigators and accountants); *H.W. Carter & Sons, Inc. v. William Carter Co.*, No. 95 CIV. 1274, 1995 WL 301351, at *3 (S.D.N.Y. May 16, 1995) (public relations consultants); *U.S. Postal Serv. v. Phelps Dodge Ref. Corp.*, 852 F. Supp. 156, 161 (E.D.N.Y. 1994) (accountants, and non-testifying experts); *see also In re Copper Mkt. Antitrust Litig.*, 200 F.R.D. 213, 217 (S.D.N.Y. 2001).

The Functional Equivalent Doctrine

Another factual predicate supporting claims of privilege is when a third party is so integrated in the company that he or she becomes a functional equivalent of an employee. Under the functional equivalent doctrine, communications between a company's lawyers and its independent contractor merit protection if, "by virtue of assuming the functions and duties of [a] full-time employee, the contractor is a de facto employee of the company." *Exp.-Imp. Bank of the U.S. v. Asia Pulp & Paper Co.*, 232 F.R.D. 103, 113 (S.D.N.Y. 2005). Thus where a consultant has a close working relationship with a company and performs a similar role to that of an employee, confidential communications that are made for the purpose of obtaining or providing legal advice should be subject to the attorney-client privilege.

In a recent case out of the Eastern District of Pennsylvania, the plaintiffs sought to compel the production of privileged communications between a company and a consulting firm that was hired to assist in a marketing campaign. The court determined that the consulting firm was a functional equivalent of an employee because: 1) it was an integrated member of the company's marketing team; 2) it played a significant role on that team; 3) the consulting firm's employees were intimately involved in the creation, development and implementation of the project; and 4) the documents and communications exchanged between the consulting firm and the company remained confidential throughout their collaborative process. *In re Flonase Antitrust Litig.*, 879 F. Supp. 2d 454, 454 (E.D. Pa. 2012).

The functional equivalent doctrine is different from privilege based on the interpreter concept, as discussed above. The Southern District of New York has explained that the functional equivalent doctrine will apply where the third party was retained by a company and functions like an employee; whereas in the situation where a third party is hired to assist an attorney to represent a company and there is no suggestion that the third party performed any business functions for the client or entered into communications with counsel for that purpose, the analysis will focus on the third party acting as an interpreter for the attorney. *In re Copper Mkt. Antitrust Litig.*, 200 F.R.D. 213, 220 n4 (S.D.N.Y. 2001).

Joint Venture and Co-Promotion Agreements

The common-interest privilege doctrine is another exception to the black-letter rule that the presence of a third party waives the attorney-client or work-product privilege. The common-interest privilege is typically invoked when privileged communications are exchanged among parties involved in such joint ventures. It is important to understand the basic elements of the common-interest privilege so that counsel can appropriately structure communication channels to protect the privilege.

As a preliminary matter, the common-interest privilege is not an independent basis for protection, and therefore, all communications must meet the basic requirements of the attorney-client and/or work-product privilege in order to qualify for protection. Although the law varies by jurisdiction, courts typically require — in addition to the basic attorney-client or work-product privilege requirements — that a party establish that the parties shared a common legal interest for the privilege to attach.

Traditionally, courts only recognized a common legal interest for parties involved in an ongoing litigation. This is, in part, because the common-interest privilege originated from the joint-defense privilege, which protects communications among co-defendants involved in a criminal case. The majority of jurisdictions have since expanded the scope of the doctrine to include communications among co-parties involved in civil litigations, and between parties with a common interest related to pending or anticipated litigation. For example, in *Johnson Elec. N. Am., Inc. v. Mabuchi N. Am. Corp.*, No. 88 CIV. 7377 (JES), 1996 WL 191590, at *3 (S.D.N.Y. Apr. 19, 1996), the court found that privileged communications between a vendor that was involved in a patent infringement litigation and its customer concerning the customer's potential liability for the patent infringement claims were protected communications under the common-interest privilege.

A recent shift in the law has begun to expand the common-interest work-product privilege beyond the artificial restraints of the "ongoing litigation" requirement. In *In re Teleglobe Commc'ns Corp.*, 493 F.3d 345, 364 (3d Cir. 2007), the U.S. Court of Appeals for the Third Circuit found that the common interest "applies in civil and criminal litigation and even in purely transactional contexts." While the Third Circuit was clear to point out that simply working together to achieve a commercial goal cannot, by itself, result in a common interest between the parties, there was a recognition that legal advice, and resulting work-product, is not limited to pending or anticipated litigation.

Most recently, in *Ambac Assurance Corp., v. Countrywide Home Loans, Inc.*, 2014 WL 6803006, No. 651612/10 (1st Dep't 2014), a New York appellate court, guided by recent Federal decisions and Delaware law, abandoned the litigation requirement altogether. Specifically, the court noted that "[t]he 'attorney

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client privilege is not tied to the contemplation of litigation,' because 'advice is often sought, and rendered, precisely to avoid litigation, or facilitate compliance with the law, or simply to guide a client's course of conduct.'" Further, the court held that encouraging parties with common legal interests to seek legal advice "'to meet legal requirements and to plan their conduct accordingly' … 'serves the public interest by advancing compliance with the law, facilitating the administration of justice and averting litigation.'"

Conclusion

The *Ambac* decision and the recent functional equivalent cases are the tip of the spear in the effort to assert and protect your company or client's privileged communications. As market pressures continue to force companies to find efficiencies through outsourcing typical in-house functions or engaging in joint ventures to promote or develop a product, counsel should be careful to properly structure the communication channels among vendors, third parties and joint venture partners so as not to waive any privilege. Taking a proactive approach to understanding the privilege rules of the relevant jurisdiction — which will most likely be the rules of the state in which the communications were made — before sharing privileged communications with a vendor or joint venture partner will save a great deal of stress in the future. Likewise, litigation counsel must be diligent in asserting these privileges during discovery, in order to educate opposing counsel and the courts on the recent shifts in the law.

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e-Cigarettes

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regulations could become a barrier to entry into the business, and will set new requirements for those companies currently in the business. But because federal regulations have yet to be finalized, companies in the e-cigarette business cannot point to final regulations to bar state claims, and must be ready to defend individual suits or class actions.

Thus, with the changing legal landscape, product liability lawyers who represent any entity in the e-cigarette business, or any company that is contemplating entering the business, must stay up to date on potential claims that may be brought against any such company. Litigation concerning e-cigarettes has generated a wide variety of potential claims. This article briefly outlines some of those claims and specifically provides examples of the types of product liability claims a company in the e-cigarette business should be prepared to defend. Such claims include: state consumer fraud lawsuits raising claims that e-cigarettes are misleading in their marketing as safer alternatives to traditional cigarettes; personal injury claims arising from fires and other harm caused by product malfunction; and claims based on failure to warn about potentially harmful chemicals in the product.

Consumer Fraud, Unfair Competition and False Advertising

E-cigarettes, in many cases, have been marketed as a safer alternative to other traditional tobacco cigarettes. However, those challenging the products have asserted that, due to the nascent use of these products, the health effects of e-cigarettes are largely unknown. Thus, consumers have brought suit alleging that companies have made false marketing claims by purporting that their products have health benefits, when there may be a lack of evidence that they do. For example, in September 2014, a consumer brought a class action in California against an e-cigarette manufacturer alleging that the company made false claims that its devices could help consumers cease smoking, or would lead to "healthy smoking." The complaint sought damages for deceptive advertising, breach of express warranty, unfair competition and violations of California's Consumer Legal Remedies Act.

A more recent class action suit was filed against an e-cigarette manufacturer for allegedly promoting its products as a safe alternative to smoking, notwithstanding a government report showing that e-cigarettes contain carcinogens and other chemicals. The action also alleged that the manufacturer made contradictory claims when it stated that the product was not designed to help people to stop smoking (in order to avoid federal regulation), while making contrary statements on its website. The plaintiffs claimed violations of California Consumers Legal Remedies Act, California's Unfair Competition Law, and Florida's Deceptive and Unfair Trade Practices Act. Recently, however, the court refused to certify the class, holding that the plaintiffs' damages methodology was deficient under Supreme Court precedent because it did not permit the court to calculate the product price absent the alleged misrepresentations.

In other recent federal actions, plaintiffs have brought claims alleging that marketing statements such as "only vapor" were misleading where the product allegedly contained carcinogenic chemicals, like formaldehyde, but omitted any mention of carcinogens in the advertising and labeling of the product. Plaintiffs with these type of claims have alleged that consumers incorrectly believed that they were only inhaling a safe water vapor, and have sought money damages, including restitution and punitive damages, and injunctive relief

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requiring proper warnings about harmful chemicals on e-cigarette packaging.

Failure to Warn

E-cigarette companies may also be exposed to claims of failure to warn consumers of things in their products that could potentially cause illness. Notably, in California, the state health department in January 2015 reportedly characterized e-cigarettes as a "community health threat" and cautioned that the nicotine in e-cigarettes is just as addictive as in traditional cigarettes. Additionally, second-hand exposure would include at least 10 chemicals on the state's list of substances known to cause physical harm. A public interest group subsequently sued 19 companies that sell the products and their liquids for failing to provide consumer warnings under the California state regulation. The group brought claims based on the defendants' failure to warn consumers about exposure to the carcinogens formaldehyde and acetaldehyde.

Similarly, in another putative federal class action in California, plaintiffs alleged violation of state consumer protection laws when a company advertised and sold e-liquid flavors that allegedly included diacetyl and acetyl propionyl — chemicals that have reportedly been shown to cause scarring in lungs, emphysema and other respiratory issues — but failed to warn of the dangers of these chemicals on its website.

Product Malfunction, Design Defect and Fires

E-cigarettes may rely on lithium-ion batteries and chargers to heat up the nicotine liquid in the device and create the vapor. The lithium-ion batteries and chargers are used in a variety of products, but allegedly have a potential to fail and cause fires in e-cigarettes because they may not have the built-in safety features other devices contain. Thus, the products may be subject to a manufacturing defect, and design defect claims arising from the possibility of fires or other similar problems. Accordingly, plaintiffs in some cases allege that e-cigarettes, including lithium-ion batteries and chargers, are unsafe and that the suppliers of these products fail to warn of harmful defects. Notably, in an October 2014 report, the United States Fire Administration (USFA) identified 25 e-cigarette fire incidents reported in the news media between 2009 and August 2014.

The report found that most of the incidents occurred while the battery was charging, and that a majority were caused by e-cigarettes being connected to a charger which was not sold with the device. The external charger can provide a current that may be too high, allegedly resulting in a fire. However, the report also indicated that fires caused by e-cigarettes are rare. Yet, these concerns regarding battery fires also led the Federal Aviation Administration (FAA) to warn airlines that they should require passengers to pack e-cigarettes in carry-on bags rather than in checked luggage. One such case of an e-cigarette malfunctioning and causing a fire resulted in a $2 million verdict. The plaintiff alleged that the e-cigarette battery exploded while she was charging it in her car, sending metal shrapnel throughout the car and setting fire to her seat and dress. The plaintiff allegedly suffered second-degree burns on her legs, buttocks and hands, and sued the distributor, wholesaler and retailer. The distributor claimed that the charger must have provided 5 volts or more to the device while charging, and the company warned users not to charge the devices with more than 4.2 volts. The plaintiff alleged that there was no warning until after the injury. The jury's award included payment for future medical costs, past physical pain, mental suffering, loss of enjoyment of life and other noneconomic losses.

In another similar case, an e-cigarette allegedly exploded near the plaintiff's face, burning his mouth and dominant hand, which was holding the device. The doctors amputated his finger and he had to undergo surgery on his tongue, which has allegedly impeded his ability to eat. The plaintiff filed suit against the e-cigarette's manufacturer and designer and the stores where he purchased the devices.

A consumer has also filed suit against an e-cigarette distributor in cases where an e-cigarette exploded in his pocket and burned his leg, requiring him to need skin grafts; and against an e-cigarette distributor and seller of the device claiming that an e-cigarette exploded near his face, blasting a large hole in his cheek and giving him a concussion.

Conclusion

As e-cigarettes gather popularity, there will be a greater number of cases filed, accompanied by new theories of liability. Strict manufacturing controls and clear and accurate labeling will go a long way to reduce the exposure to suits arising from the use of these products. Manufacturers and other companies that are part of the chain of distribution for e-cigarettes should keep in mind that the scrutiny will come not only from plaintiffs' lawyers, but also from federal and state agencies that have only begun to scrutinize the use and sale of these new devices. Moreover, because consumers may base their claims on a host of theories, law practitioners should advise companies to obtain sufficient equity and/or insurance to withstand the cost of defending those claims, which could come in the form of individual lawsuits or even private class actions.

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