By Judi Abbott Curry

2022 Year in Review

From pharmaceuticals to toothpaste, preemption to public health, New York state and federal courts issued decisions in 2022 that further shaped the landscape in the medical and life sciences legal world. To prepare the best product liability and class action defense strategies for pharmaceuticals, medical devices, personal care, and other FDA regulated products, it is often helpful to step back and review holdings that affected the industry and may shape the years ahead.

In this article, senior partner Judi Abbott Curry reviews, analyzes and shares potential implications for future life science cases based on several key judicial holdings in New York in 2022 pertaining to class actions, pharmaceuticals, and medical devices.

Class Actions

Housey v. Procter & Gamble Company, No. 21cv2286, 2022 U.S. Dist. LEXIS 53603, 2022 WL

874731 (S.D.N.Y. Mar. 24, 2022) affirmed, No. 22cv888, 2002 U.S. App. LEXIS 35392, 2022 WL 17844403 (2d Cir. Dec. 22, 2022)

In a putative class action, plaintiff claimed Crest toothpaste with charcoal was deceptive in its packaging, promising safe whitening, gentle cleaning, and healthier gums. Plaintiff alleged violation of consumer protection statutes and state laws and that there is insufficient scientific evidence to substantiate charcoal toothpaste's safety, cosmetic and health benefits.

The Court found plaintiff's overbroad claims were not plausibly pled to demonstrate that charcoal in the product makes the toothpaste unable to provide the advertised benefits. In defendant's motion to dismiss under FRCP 12(b)(6), P&G correctly pointed out the three published articles principally relied upon by plaintiff did not support her claims. The federal district court found it was proper to consider the articles plaintiff cited in adjudicating a motion to dismiss. Plaintiff was preempted from claiming the toothpaste was ineffective, in light of FDA's monograph on fluoride toothpastes. Finally, in the absence of an alleged personal injury or a true price premium claim, plaintiff did not properly plead an injury. The Second Circuit upheld the New York federal court's decision dismissing the proposed class action, finding the customer failed to show the enamel-safe representations were deceptive and likely to mislead a reasonable consumer, and that she was injured from using the toothpaste.

Goe v. Zucker, 43 F.4th 19 (2d Cir. 2022)

Second Circuit affirmed dismissal of a proposed class action challenging the scope of medical exemptions to New York's mandatory immunization requirements for school-age children. Plaintiffs, parents of medically fragile or immune-compromised children, whose requests for medical exemptions were largely denied, claimed New York's recently revised immunization requirements and their enforcement violated their Due Process 14th Amendment rights. Plaintiffs claimed that when their physicians certify a need for a vaccine exemption, school officials cannot deny a request for an exemption and deprive the children of fundamental rights to life and liberty, and to an education.

The Second Circuit disagreed, holding the regulations in question do not force a child to be vaccinated, but permit a medical exemption where appropriate. Further, there is no *fundamental* right to a medical exemption simply on the say-so of a treating physician. While the right to an education is important, there is no fundamental right to an education. Inasmuch as the new regulations were reasonably related to a legitimate state objective– protecting communities from serious, vaccine- preventable diseases through immunization - the Court affirmed dismissal of the purported class action complaint.

Harris v. Pfizer Inc., 586 F. Supp. 3d 231 (S.D.NY. 2022)

In a proposed class action over a recall of Pfizer's stop-smoking drug Chantix due to contamination with excess levels of nitrosamine (a possible carcinogen), plaintiffs claimed they did not know Chantix contained the chemical and it was not listed as an ingredient. Nitrosamines are common in water and foods, including cured and grilled meats, dairy products, and vegetables, and so everyone is exposed to some level of nitrosamines. The U.S. Food and Drug Administration, in collaboration with regulatory counterparts around the world, has set internationally-recognized acceptable daily intake limits for nitrosamines. If drugs contain levels of nitrosamines above the acceptable daily intake limits, FDA recommends these drugs be recalled by the manufacturer as appropriate.

Pfizer moved to dismiss the case for lack of standing pursuant to FRCP 12(b)(1) and for failure to state a claim pursuant to FRCP 12(b)(6). Plaintiffs were required to plausibly allege Pfizer represented Chantix was free of nitrosamines contamination, which they could not do. Plaintiffs' complaint did not contain any fraudulent misrepresenta-

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tions or misleading statements of Pfizer. Plaintiffs' claim that they did not receive the drug "Chantix" because it was contaminated was insufficient to show fraud.

Because the plaintiffs claimed only economic harm, rather than personal injury, the economic loss doctrine barred their negligent misrepresentation claim. The Southern District of New York, Judge Denise Cote, dismissed the Amended Complaint and entered judgment for Pfizer.

Class Actions | Potential Implications for Future Cases

New York federal courts scrutinize purported class actions involving FDA-regulated products to ensure the claims are plausibly pled and do not hesitate to dismiss complaints at the outset where the complaint lacks plausibility on its face. Although courts typically adjudicate these motions on the four corners of the pleading, it is permissible for courts to go behind the complaint and review the documents they cite, such as publicly available scientific studies, in order to ascertain plausibility of the allegations. An FDA monograph can be a source of preemption where the product is not a drug or a device.

Pharmaceuticals

Vardouniotis v. Pfizer, 2022 N.Y. Misc. LEXIS 75*; 2022 N.Y. Slip Op. 30040(U) (N.Y. Cnty. Jan. 10, 2022)

Plaintiff alleged her use of Chantix to quit smoking caused various injuries, including chronic pain, muscle spasm, arthritic changes in the neck, cervical injuries, exhaustion, depression, and anxiety, among others. Plaintiff alleged Pfizer never attempted to include all her claimed side effects in the Chantix labeling. However, Pfizer did add a boxed warning to the Chantix label about the risk of changes in mood and behavior before plaintiff used the drug. After reviewing a large clinical trial, FDA determined the risks of serious neuropsychiatric events were lower than previously suspected and concluded the benefits of stopping smoking outweigh the risks.

Pfizer moved to dismiss the amended complaint based on failure to state a cause of action and based on documentary evidence to refute plaintiff's factual allegations. New York's Supreme Court, New York County found that Plaintiff sufficiently buttressed the failure to warn claim with articles and information pertaining to newly acquired information that could have permitted a change of the Chantix label under the CBE (changes being effected) regulation. Therefore, the failure to warn claims were not preempted.

Additionally, the informed intermediary doctrine was not sufficient to require the wholesale dismissal of the failure to warn claims, as the complaint alleged the physician did not receive adequate warnings. However, the failure to warn claim was dismissed to the extent it was premised on a failure to warn plaintiff and the public, as opposed to the prescribing physician. The Court declined to dismiss the warranty and unjust enrichment claims at this pleading stage but dismissed the plaintiff's request for punitive damages, as nothing in the complaint alleged that Pfizer engaged in any morally culpable conduct.

Reynolds-Sitzer v. Eisai, 586 F. Supp.3d 123 (N.D.N.Y. 2022)

Plaintiff alleged the first-in-class oral selective serotonin 5HT2c receptor agonist weight loss drug Belviq caused her to develop thyroid cancer. Upon a motion to dismiss pursuant to FRCP 12(b) (6), the Court evaluated plaintiff's claims under the products liability theories of negligence, strict liability, express warranty, and implied warranty. Plaintiff also asserted fraudulent misrepresentation and concealment. For the defective design claim, defendants' motion argued plaintiff's complaint did not identify a particular problem in the design of the drug or plead facts alleging the existence of a feasible alternative design. Plaintiff claimed that since Belviq was designed as a serotonin receptor agonist for weight loss, this posed a substantial likelihood of harm and a safer alternative was a drug that did not affect the serotonin pathway.

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Although plaintiff did not posit an alternate design, the Court ruled that requiring plaintiff to do so at the pleading stage would require technical or scientific knowledge that goes beyond Rule 8's notice pleading requirement. As such, the design defect claim was plausibly pled to withstand a motion to dismiss. As for the failure to warn claim, defendants sought dismissal only to the extent the allegations were premised upon on duty to warn plaintiff directly or, for that matter, anyone other than the prescribing physician. The Court found that defendants were getting ahead of themselves, and a motion premised upon the learned intermediary doctrine would be more appropriate after discovery. The breach of warranty claims was not time barred due to the New York Executive Order 202.8 "COVID-19 toll." Further, under New York law, where a product is for retail sale or intended for human consumption, there is no requirement for pre-suit notice under the New York Uniform Commercial Code. Lastly, the Court found the allegations of fraud did not meet the particularity requirements of Rule 9 and therefore were dismissed.

Pharmaceuticals | Potential Implications for Future Cases

The learned intermediary doctrine, known as the informed intermediary doctrine in New York, is an important tool to defend against warning claims for FDA regulated products. However, New York state and federal courts are unlikely to dismiss failure to warn claims at the pleading stage, where the extent of knowledge of the prescribing physician is not yet known. The better course is to take discovery, including testimony from the prescriber, to show the physician assessed the risks and benefits of the drug, advised the patient of its possible risks and side effects, and exercised appropriate independent medical judgment in prescribing the product.

Moreover, an early pre-answer dismissal motion of the design defect claims based upon the absence of a safer alternative feasible design may not result in outright dismissal, but rather provide plaintiff with the opportunity to replead; and in some cases, claim the technical or scientific knowledge to plead the precise type of alternative safer feasible design requires discovery from the manufacturer.

Medical Devices

Redd v. Medtronic Inc., 21-CV-06448, 2022 U.S. Dist. LEXIS 223697, 2022 WL 17584377 (S.D.N.Y Dec. 12, 2022)

Plaintiff alleged medical screws inserted into his back during spinal surgery broke one year after surgery, necessitating a second surgery. Defendant Medtronic moved to dismiss the complaint and plaintiff, proceeding *pro se*, did not submit an opposition. The Court, while finding *pro se* complaints are held to less stringent standards than those drafted by lawyers, dismissed the constitutionally-based claims against Medtronic.

Considering plaintiff's complaint with the liberality required of *pro se* pleadings, the Court construed the complaint as asserting a product liability claim under New York law. However other than alleging the screws were broken, the complaint failed to speak to their design, manufacture or warnings, and the products liability claim was therefore dismissed.

Poulin v. Boston Sci. Corp., 22-CV-553, 2022 U.S. Dist. LEXIS 222564 (W.D.N.Y. Dec. 9, 2022)

Plaintiff alleged decedent's death by cardiac arrest was due to a vena cava filter, a medical device implanted into a blood vessel to prevent blood clots from traveling into the lungs and maintain blood flow; this product liability action alleged failure to warn, design defect, breach of express and implied warranty, and consumer fraud.

Following removal to federal court based upon diversity jurisdiction, defendant moved to dismiss the amended complaint for failure to state a claim. Upon autopsy, the filter was found to be partially embedded into the vessel and focally perforating with a blood clot found to be near totally occluding the filter. To support the dismissal motion, defendant submitted the device's instructions for use (IFU) containing warnings of both perforation of the vena cava and migration of the filter.

Because the plaintiff disputed the authenticity of the IFU, particularly that the version supplied to the Court was not in effect at the time of the implant, the Court did not consider the IFU and its warnings on the motion. Because plaintiff alleged an absence of any warning, as opposed to an inadequacy of a specific warning, plaintiff was not required to identify how the missing warning was inadequate and the Court permitted the failure to warn claim. Plaintiff's design defect claim was dismissed, as the pleading did not adequately allege a safer alternative feasible design, or one that would have prevented the injuries. The breach of express warranty claim was dismissed because it was premised only upon marketing materials and the implied warranty claim was concededly time barred. Plaintiff's allegations of consumer fraud and deceptive trade practices premised upon New York General Business Law §349 were dismissed, as there were no allegations the alleged misrepresentations were directed to consumers, including physicians and their patients, and plaintiff did not allege reliance on the alleged materially misleading conduct. Finally, the motion seeking dismissal of the punitive damages allegations was denied as premature, pending discovery.

Medical Devices | Potential Implications for Future Cases

The Court may dismiss a design defect claim upon a pre-answer motion to dismiss if the pleading does not even allege a safer alternative feasible design would have prevented the injuries. Claims of consumer fraud and deceptive trade practices premised upon New York General Business Law are not typically claimed in personal injury product liability medical device cases and are subject to dismissal where there are no allegations, or reliance on, claims that the alleged misrepresentations were directed to consumers.

The developments of 2022 indicate that it is critical to remain informed about changes in the law in order to develop the strongest product liability defense of pharmaceuticals and medical devices. We know it takes an enormous investment to develop innovative pharmaceuticals and medical devices to improve life experiences. That's why our attorneys, with a national reputation for aggressively defending some of the largest entities in the regulated pharmaceutical, medical device, cosmetics, and nutritional supplement industries, leverage their combination of medical and legal credentials to protect your critical life sciences products.