

# **Defending an Emerging Threat: Consumer Fraud Class Action Suits in Pharmaceutical and Medical Device Products-Based Litigation**

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## **I. INTRODUCTION**

Consumer fraud class action suits describe a relatively new species of products-based litigation that have found fertile ground in the pharmaceutical and medical device landscape and are grounded primarily, if not exclusively, upon violations of state consumer protection acts (CPAs). All 50 states, the District of Columbia and the territories of Guam and Puerto Rico have enacted one or more statutes to protect consumers. Many of these statutes are patterned after the Federal Trade Commission Act (FTC Act)<sup>1</sup> and generally proscribe “unfair or deceptive acts or practices” in connection with trade or commerce. Unlike the FTC Act, however, at least one CPA in every state and territory, with the exception of Iowa, Guam and Puerto Rico, expressly or implicitly allows private enforcement actions.

In contrast to traditional product liability claims, plaintiffs in consumer fraud actions do not assert claims for personal injuries. In fact, a claim for personal injury frequently is expressly denied. Instead, often citing epidemiological studies in the complaint, plaintiffs typically assert that a drug or device is not as effective as advertised or that a drug or device was improperly promoted for treatment of an “off label” indication for which there is no proven medical benefit. Putative “consumer” classes include not only individual consumers but also healthcare advocacy organizations and third-party payors, such as private health insurers and employee benefit funds.

The incidence of consumer fraud claims has increased significantly within the last two years because they provide the plaintiffs’ bar with an economically and substantively attractive vehicle for litigation. In addition to actual damages, many state CPAs authorize minimum statutory damages as well as multiple damages, punitive damages, and attorneys’ fees. Moreover, CPA claims typically impose less stringent burdens of proof as compared with traditional products liability and common law causes of action. Plaintiffs need not establish specific medical causation, which usually requires expert testimony and which, historically, has been among the most difficult hurdles for plaintiffs to overcome in making their prima facie case in a personal injury action. Similarly, under traditional common law fraud claims, which are increasingly com-

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<sup>1</sup> 15 U.S.C.A. § 45(a)(1).

mon in product liability suits, a plaintiff must establish that he or she reasonably relied upon a material misstatement or omission.<sup>2</sup> Typically, a plaintiff must also prove that the defendant knew (or reasonably should have known) of the falsity of the statement or omission and acted with intent to deceive.<sup>3</sup> Some or all of these elements are diluted or eliminated under most state CPAs.

Because the Class Action Fairness Act of 2005, P.L. 109–2, has significantly relaxed the diversity and amount-in-controversy requirements set forth in 28 U.S.C. § 1332, most consumer fraud class action suits will be litigated in federal court. Nevertheless, defense costs for discovery in consumer fraud actions can be significant. Consequently, an early and aggressive defense to these actions can be critical to the eventual outcome. To that end, this article examines strategies for defending (and defeating) consumer fraud class actions at both the motion to dismiss and class certification stages of litigation.

## II. DEFENDING CPA CLAIMS AT MOTION TO DISMISS STAGE

Consumer fraud class action suits can be assaulted at the motion to dismiss stage—either independently or in concert—on at least four fronts: 1) challenging standing to sue; 2) summoning the protections of CPA “safe harbor” provisions; 3) asserting preemption under the Food, Drug, and Cosmetic Act (FDCA) or the Medical Device Amendments of 1976 (MDA); and 4) invoking the learned intermediary doctrine.

### A. *Challenging Standing To Sue*

Although the plaintiffs’ bar has generally been diligent in collecting, parsing and spinning the epidemiological studies that form the basis for their complaint, they have not been nearly as meticulous with regard to the unique procedural and jurisdictional requirements of each CPA. Therefore, practitioners should be mindful that many CPAs do not provide a legitimate basis for a consumer fraud class action suit, and they should be prepared to attack the putative class representative’s standing to bring suit at the motion to dismiss stage. A non-exhaustive list of potential grounds for asserting that the complaint fails to state a claim includes the following:

- there is no right to assert a private enforcement action under the CPA of Iowa;<sup>4</sup>
- the Nebraska CPA only permits private actions seeking injunctive, not monetary, relief;<sup>5</sup>
- while recognizing private rights of action, Alabama, Alaska, Georgia, Kentucky, Louisiana, Mississippi, Montana, and Virginia do not permit consumers to assert a class action to enforce their CPAs;<sup>6</sup>

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<sup>2</sup> See, e.g., *Marram v. Kobrick Offshore Fund Ltd.*, 442 Mass. 43 (2004); *Water Street Leasehold LLC v. Deloitte & Touche LLP*, 796 N.Y.S.2d 598 (2005); *Ostayan v. Serrano Conveyance Co.*, 77 Cal. App. 4th 1411 (2000); *Cwikla v. Sheir*, 345 Ill. App. 3d 23 (2003); *Simplex Supplies, Inc. v. Abhe & Svoboda, Inc.*, 586 N.W.2d 797 (Minn. App. 1998); see also *Restatement (Second) of Torts* § 537 (1977).

<sup>3</sup> See, e.g., *Mocoviak v. Chase Home Mortgage*, 40 Mass. App. Ct. 755 (1996); *Faribo Oil Co. v. Tatge Oil Co., Inc.*, 501 N.W.2d 699 (Minn. App. 1993); *Abrahami v. UPC Constr. Co., Inc.*, 638 N.Y.S.2d 11 (1996); *Towpath Unity Tenants Ass’n v. Barba*, 182 N.J. Super. 77 (1981); *Thor Bear, Inc. v. Crocker Minzer Park, Inc.*, 648 So. 2d 168 (Fl. App. 1994); see also *Restatement (Second) of Torts* § 526 (1977).

<sup>4</sup> Iowa Code § 714.16.

<sup>5</sup> Neb. Rev. Stat. § 59-1601, et seq.

<sup>6</sup> See Ala. Code § 8-19-10(a)(1); Alaska Stat. § 45.50.531(a); Ga. Code Ann. § 10-1-399(a); Ky. Rev. Stat. Ann. § 367.170; La. Rev. Stat. Ann. § 51:1409(A); Miss. Code Ann. § 75-24-15(4); Mont. Code Ann. § 30-14-133(1); Va. Code Ann. § 59.1-204(A).

- several state CPAs prohibit organizations, such as third party payors, to bring suit;<sup>7</sup>
- more than a dozen state CPAs employ short statute of limitations (three years or less) which are not tolled by the discovery rule;<sup>8</sup>
- roughly another dozen state CPAs have pre-litigation notice requirements that must be satisfied before a court has jurisdiction to hear a claim under the statute;<sup>9</sup>
- nearly half of the state CPAs limit recovery to damages for “personal, household of family use” and, therefore, bar claims brought by third party payors who purchased a drug or device purely for commercial reasons.<sup>10</sup>

While these arguments are not likely to result in a dismissal of claims under all CPAs asserted in a complaint, they can significantly limit the reach of the plaintiffs’ suit, narrow the scope of discovery, and help lay the groundwork for challenging the predominance element at the class certification stage.

### B. *Summoning the Protections of CPA Safe Harbor Provisions*

The CPAs in over a dozen states—including those of Delaware, Illinois and Michigan—contain safe harbor provisions that generally exempt a manufacturer from liability if the marketing of a drug or device is already regulated, or the manufacturer’s conduct is expressly “permitted” or “authorized,” by a state or federal regulatory authority.<sup>11</sup> These provisions present yet another viable ground for a motion to dismiss. Interestingly, although the applicability of safe harbor provisions often turns on an analysis that is similar in focus to that of implied field preemption, both state and federal courts appear more willing to invoke CPA safe harbor provisions than to dismiss claims based upon the federal preemption doctrine.

The District of Delaware discussed the Delaware CPA safe harbor provision in *Pennsylvania Employee Benefit Trust Fund v. Zeneca, Inc.* in which a putative class asserted consumer fraud claims in connection with the sale of the prescription drug Nexium.<sup>12</sup> The Delaware CPA exempts claims based upon “any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of

<sup>7</sup> See *In re Average Wholesale Price Litigation*, 230 F.R.D. at 86, 90 (D. Mass. 2005).

<sup>8</sup> Conn. Gen. Stat. Ann. § 42-110g(f); 10 Del. Code Ann. § 8106; Idaho Code § 48-608; Ind. Code Ann. § 24.5-0.5-5(b); Kan. Stat. Ann. § 60-512(2); Ky. Rev. Stat. Ann. § 367.220(5); La. Rev. Stat. Ann. § 51:1409(E); Mont. Code Ann. § 27-2-211(1); Nev. Rev. Stat. Ann. § 11.190; N.Y. C.P.L.R. 214(2); Ohio Rev. Code. Ann. § 1345.10; Utah Code Ann. § 13-11-19(8); Va. Code Ann. § 59.1-204.1 (A) ; W. Va. Code § 55-2-12.

<sup>9</sup> See Ala. Code § 18-19-10(e); Ga. Code § 10-1-399(b); Ind. Code Ann. § 24-5-0.5-5(a); Kan. Stat. Ann. § 50-634(g); Me. Rev. Stat. Ann. Tit. 5 § 213(1-A); Mass. Gen. Laws c. 93A, § 9(13); Miss. Code Ann. § 75-24-15; *Pointer v. Edward L. Kuhs Co.*, 678 S.W.2d 836 (Mo. Ct. App. 1984); Tex. Bus. & Comm. Code Ann. §§ 17.505, 17.5051; Wyo. Stat. Ann. §§ 40-12-109, 40-12-102(a)(ix).

<sup>10</sup> D.C. Code § 28-3901(a)(2); Haw. Rev. Stat. § 480 -1; 815 Ill. Comp. Stat. 505/1; Ind. Code Ann. § 24-5-0.5-2(a); Kan. Stat. Ann. § 50-624 (b); Ky. Rev. Stat. Ann. § 367.220(1); La. Rev. Stat. § 51:1409(A); Md. Code Ann., Com. Law § 13-101; Mich. Comp. Laws Ann. § 445.911; Mo. Rev. Stat. § 407.025(1); Mont. Code Ann. §§ 30-14-102(1), § 30-14-133(1); NY GEN. BUS. LAW § 349(h); Ohio Rev. Code Ann. § 1345.01(A), (D); Okla. Stat. Ann. Tit. 15, §§ 761.1(A), 752(2), 753; Or. Rev. Stat. § 646.605; 73 Pa. Cons. Stat. Ann. § 201-9.2(a); S.D. Cod. Laws § 37-24-1; Tenn. Code Ann. § 47-18-103; Utah Code Ann. § 13-11-3(2)(a); Vt. Stat. Ann. tit. 9, § 2451a(a); Va. Code Ann. § 59.1-198; W. Va. Code Ann. § 46A-6-102(2).

<sup>11</sup> Alaska Stat. § 45.50.481(a)(1); Ark. Code Ann. § 44-88-101(3); Colo. Rev. Stat. § 6-1-106; Fla. Stat. Ann. § 501.212(1); Ga. Code Ann. § 10-1-374(a)(1); 815 Ill. Comp. Stat. 505/10b(1); Ind. Code Ann. § 24-5-0.5-6; Me. Rev. Stat. Ann. Tit. 5, § 208; Mass. Gen. Laws c. 93A, § 3; Mich. Comp. Laws § 445.904(1)(a); Minn. Stat. § 325D.461; Ohio Rev. Code Ann. § 1345.12(A); Okla. Stat. Ann. Tit. 15, § 754(2); Or. Rev. Stat. § 646.612(1); R.I. Gen. Laws § 6-13.1-4; S.C. Code Ann. § 39-5-40(a); S.D. Codified Laws § 37-24-10; Tenn. Code Ann. § 47-18-111.

<sup>12</sup> Civil Action No. 05-075-SLR, 2005 U.S. Dist. LEXIS 27444, \*1 (D. DE Nov. 8, 2005).

and the statutes administered by the Federal Trade Commission (FTC).<sup>13</sup> Interpreting this provision, the District of Delaware concluded that the plaintiff's claims against AstraZeneca were not actionable.<sup>14</sup> To begin with, the court stated, "The Federal Trade Commission and the Food and Drug Administration (FDA) share exclusive jurisdiction over regulation of drug marketing; the FDA is given primary authority to regulate prescription drugs."<sup>15</sup> Further, the court reasoned that, where a manufacturer receives approval from FDA regarding labeling for a drug, like Nexium, "the FDA has determined that the information complies with its rules and regulations."<sup>16</sup> Accordingly, the court found AstraZeneca exempt from liability under the CPA.<sup>17</sup>

In *Bober v. Glaxo Wellcome PLC*, the Seventh Circuit addressed a similar safe harbor provision in the Illinois CPA.<sup>18</sup> The plaintiff alleged that Glaxo had engaged in false and deceptive advertising in connection with the sale of Zantac 150, a medication for ulcers and esophageal conditions, and Zantac 75, an antacid.<sup>19</sup> The Illinois CPA excludes from liability "actions ... specifically authorized by laws administered by a regulatory body or offices acting under authority of this State or the United States."<sup>20</sup> In interpreting this provision, the Seventh Circuit held that the Illinois CPA "will not impose a higher disclosure requirement on parties than those that are sufficient to satisfy federal regulations."<sup>21</sup> Based upon this reading of the statute, the Seventh Circuit found that Glaxo was exempted from liability.<sup>22</sup> The court further explained:

The pharmaceutical industry is highly regulated, both at the federal level and internationally. Technical requirements abound, and it is not only possible but likely that ordinary consumers will find some of them confusing, or possibly misleading as the term is used in statutes like Illinois' [CPA]. But, recognizing the primacy of federal law in this field, the Illinois statute itself protects companies from liability if their actions are authorized by federal law. (Such protection would amount to nothing if it applied only to statements that were not susceptible to misunderstanding; those statements would escape liability under the [CPA] in any event).<sup>23</sup>

Most recently, in *Duronio v. Merck & Co., Inc.*, the Michigan Court of Appeals held that the safe harbor provision in the Michigan CPA barred consumer fraud claims asserted against Merck in connection with the Vioxx litigation.<sup>24</sup> Like the Illinois CPA, the Michigan CPA exempts "a transaction or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States."<sup>25</sup> The court explained that "the focus of this statutory provision is not the specific misconduct alleged by a plaintiff, but whether the general transaction is authorized by law."<sup>26</sup> It concluded that "[t]he regulations implementing

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<sup>13</sup> 6 Del. C. § 2513(b)(2).

<sup>14</sup> *Id.* at \*14.

<sup>15</sup> *Id.* at \*8.

<sup>16</sup> *Id.* at \*9.

<sup>17</sup> *Id.* at \*17.

<sup>18</sup> 246 F.3d 934 (2001).

<sup>19</sup> *Id.* at 936.

<sup>20</sup> *Id.* at 941.

<sup>21</sup> *Id.* at 942.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 942-943.

<sup>24</sup> Civil Action No. 267003, 2006 Mich. App. LEXIS 1841, \*1 (June 13, 2006).

<sup>25</sup> Mich. Comp. Laws § 445.904(1)(a).

<sup>26</sup> 2006 Mich. App. LEXIS 1841 at \*20.

the [Food, Drug, and Cosmetic Act] are extensive and detailed, and specifically regulate prescription drug advertising,” and, therefore, the safe harbor provision of the Michigan CPA shielded Merck from liability.<sup>27</sup>

It bears noting that not all federal district courts have been as willing to invoke CPA safe harbor provisions at the motion to dismiss stage. In *Scott v. Glaxo Smith Kline Healthcare*,<sup>28</sup> Glaxo Smith Kline (GSK) argued that the safe harbor provisions of the Illinois CPA barred a consumer fraud claim relating to its over-the-counter cold sore treatment, Valtrex. While citing *Bober* with approval and acknowledging that the plaintiff will have “a very difficult burden” demonstrating that GSK’s conduct was not “specifically authorized” by FDA, the Northern District of Illinois denied GSK’s motion to dismiss the consumer fraud claim.<sup>29</sup> The court reasoned that there “was not enough information” to definitively reach a conclusion based upon a 12(b)(6) motion.<sup>30</sup>

Nevertheless, *Scott* appears to be an outlier in the current jurisprudential landscape. And, while courts’ analysis in *Zeneca*, *Bober* and *Duronio* sound in implied conflict preemption, trial court judges appear to find CPA safe harbor provisions to be a more palatable basis for dismissing some, if not all, of a plaintiff’s CPA claims without affirmatively invoking the preemption doctrine that many find unpersuasive.<sup>31</sup>

### C. Asserting Preemption under the FDCA and MDA

Notwithstanding the general resistance of the federal and state court bench, a motion to dismiss grounded upon express or implied preemption remains a viable option in appropriate circumstances and jurisdictions.

#### 1. Express Pre-emption Post-Lohr

In the 10 years following the U.S. Supreme Court’s plurality opinion in *Medtronic, Inc. v. Lohr*,<sup>32</sup> the majority of federal circuit and district courts have held that the Medical Device Amendments of 1979 (MDA) expressly preempt state product liability claims if a medical device was subject to the premarket approval process.<sup>33</sup> Since the enactment of the Food and Drug Administration Modernization Act (FDAMA), which contains an express preemption provision relating to “nonprescription drugs,”<sup>34</sup> the express preemption argument has also been successful in cases implicating over-the-counter (OTC) medications.<sup>35</sup> Accordingly, practitioners representing a manufacturer

<sup>27</sup> *Id.* at \*21.

<sup>28</sup> No. 05 C 3004, 2006 U.S. Dist. LEXIS 18630 \*1 (N.D. Ill. April 12, 2006).

<sup>29</sup> *Id.* at \*6-\*9 (emphasis in original).

<sup>30</sup> *Id.* at \*9-\*10.

<sup>31</sup> See also *Price v. Philip Morris, Inc.*, Docket No. 96236, 2005 Ill. LEXIS 2071 (Ill. S. Ct. Dec. 15, 2005) (construing the “safe harbor” provision of the Illinois Consumer Fraud Act to bar class action claims against Philip Morris in connection with the sale of Marlboro Light cigarettes on the grounds that the FTC, through a course of regulatory action over many years, “specifically authorized” the language contained on Philip Morris’ packaging).

<sup>32</sup> 518 U.S. 470 (1996).

<sup>33</sup> See, e.g., *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419 (E.D. Pa. 2004); *Chambers v. Osteonics Corp.*, 109 F.3d 1243 (7th Cir. 1997); *Fowler v. Smith & Nephew Richards, Inc.*, No. 97-1380, 1999 WL 1132967 (M.D. Fla. Sept. 27, 1999); *Lewis v. Intermedics Intraocular*, 19 F. Supp. 2d 625 (E.D. La 1998); *Chmielewski v. Stryker Sales Corp.*, 966 F. Supp. 839 (D. Minn. 1997); *Berish v. Richards Med. Co.*, 937 F. Supp. 181 (N.D.N.Y. 1996).

<sup>34</sup> 21 U.S.C. § 379r.

<sup>35</sup> *Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780 (2002); *Warner-Lambert v. Mills*, No. 09-02-173, 2003 WL 2210389 (Sept. 11, 2003). The plaintiff appealed this decision to the Texas Supreme Court. *Mills v. Warner Lambert Co.*, 157 S.W. 3d 424 (Tex. Sup. Ct. 2005). The Texas Supreme Court reversed and

of a medical device that has been subject to PMA under the MDA or a manufacturer of an OTC therapy should strongly consider raising an express preemption argument in consumer fraud class action suits (and, indeed, in traditional product liability actions) at an early stage of litigation.

## 2. Implied Preemption Under *Buckman*

Outside the express preemption context, the success of preemption-based arguments has been, at best, uneven. In *Buckman Co. v. Plaintiffs' Legal Committee*, the U.S. Supreme Court recognized the possibility of implied preemption under FDA's regulatory scheme.<sup>36</sup> The late Justice Rehnquist, who authored the majority opinion, stated:

As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of the 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by enacting the FDCA and the MDA .... In effect, ... fraud-on-the-FDA claims could cause the agency's reporting requirements to deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine. Conversely, fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the agency, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the agency neither wants or needs, resulting in additional burdens on the FDA's evaluation of an application.<sup>37</sup>

A number of manufacturers have argued that Rehnquist's holding and reasoning should apply with equal force to both common law fraud claims and consumer fraud claims brought under state CPAs. Generally speaking, most courts have interpreted *Buckman* narrowly and have held that its reach does not extend that far.<sup>38</sup>

In *Zeneca*, after concluding that the plaintiff's claims were barred by the Delaware CPA safe harbor provision, the District of Delaware also found that its claims were barred by the implied preemption doctrine.<sup>39</sup> The Court stated, "The issue of whether one more drug is more effective than another drug is clearly within the expertise of FDA and should not be resolved in a court of law through the adversarial system."<sup>40</sup> The Court, therefore, held that the plaintiff's claims under the CPAs of the 50 states were preempted by FDA regulation.<sup>41</sup> Similarly, in *Dusek v. Pfizer, Inc.*, the Southern District of Texas held the plaintiffs' failure to warn claims in connection with the sale of the anti-depressant medication Zoloft were preempted because the application of plaintiffs' proposed warnings "would result in Texas common law requiring a warning that FDA has explicitly rejected after significant study."<sup>42</sup> The court also noted, however, that it did

remanded the Texas Court of Appeals' decision, holding that it had improperly found that the FDCA deprived the trial court of subject matter jurisdiction. *Id.* at 425. The court did not address the question of whether the FDCA would provide a full defense to the plaintiff's claims based upon preemption. *Id.*

<sup>36</sup> 531 U.S. 341 (2001).

<sup>37</sup> *Id.* at 350-351.

<sup>38</sup> Compare *Zeneca, Inc.*, 2005 U.S. Dist. LEXIS 274444; and *Dusek v. Pfizer Inc.*, Civil Action No. H-02-3559, 2004 U.S. Dist. LEXIS 28056, \*1 (S.D. Tx. Feb. 20, 2004); with *Brasher v. Sandoz Pharms. Corp.*, Civil Action No. CV-98-TMP-2648-S, 2001 U.S. Dist. LEXIS 18364, \*1 (N.D. Ala. Sept. 21, 2001).

<sup>39</sup> 2005 U.S. Dist. LEXIS 274444 at \*14.

<sup>40</sup> *Id.* at \*17.

<sup>41</sup> *Id.* at \*15.

<sup>42</sup> 2004 U.S. Dist. LEXIS 28056 at \*41.

not consider FDA drug approvals to generally preempt failure to warn claims and “that FDA approval generally does not shield a drug manufacturer from tort liability.”<sup>43</sup>

Conversely, in *Brasher v. Sandoz Pharms. Corp.*, the Northern District of Alabama rejected an implied preemption argument as a bar to a plaintiff’s claims for fraud, negligent misrepresentation and failure to warn under Alabama law in connection with the drug Parlodel.<sup>44</sup> The Court reasoned that “the *only* claim set forth in *Buckman*, and therefore the only claim considered by the Supreme Court, was that certain information had been misrepresented to FDA, thereby causing FDA to find that the medical device at issue was a ‘substantial equivalent’ of a predicate device.”<sup>45</sup> As a result, the district court concluded that state law claims beyond simply a “fraud-on-the-agency” theory are not preempted if they do not rest on the theory that the federal agency was itself the victim of the fraud.<sup>46</sup> Citing the “strong presumption” against preemption, a number of other district courts have also interpreted *Buckman* narrowly.<sup>47</sup>

### 3. *The Impact of the FDA’s 2006 Prescription Drug Labeling Requirements*

On January 18, 2006, FDA promulgated new labeling requirements for prescription drugs, which may breath new life into the implied preemption argument.<sup>48</sup> These requirements were, in part, a response to requests by industry members and courts alike for a more definitive statement about preemption by FDA. In the Preamble, FDA unequivocally states that “under existing preemption principles, FDA approval of labeling under the act ... preempts conflicting or contrary state law.” The Preamble further explains that state law decisions rejecting the preemptive authority of the labeling requirements “rely on and propagate interpretations of the Act and FDA regulations that conflict with the agency’s own interpretations and frustrate the agency’s implementation of its statutory mandate.” More specifically, FDA announced its view that “*at least* the following claims would be preempted by its regulation of prescription drug labeling”:

- 1) Claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling;
- 2) claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug’s sponsor has used Highlights consistently with the FDA draft guidance regarding the “brief summary” in direct-to-consumer advertising ...;
- 3) claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in the rule, ...;

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<sup>43</sup> *Id.* at \*38. Other federal district courts subsequently have rejected a conflict preemption argument in cases involving Zolof based upon substantially the same facts and arguments. *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726 (D. Minn. 2005); *McNellis v. Pfizer, Inc.*, Civil Action No. 05-1286, 2005 U.S. Dist LEXIS 37505, \*1 (D. N.J. Dec. 29, 2005).

<sup>44</sup> 2001 U.S. Dist. LEXIS 18364 at \*25.

<sup>45</sup> *Id.* (emphasis in original).

<sup>46</sup> *Id.* at \*26.

<sup>47</sup> See, e.g., *Kittleson v. Sandoz Pharms. Corp.*, Civil Action No. 98-2277, 2001 U.S. Dist LEXIS 25990, \*1, \*12 (D. Minn. Sept. 19, 2001); *Colacicco v. Apotex, Inc.*, Civil Action No. 05-5500, 206 WL 1443357, \*1, \*18 (E.D. Pa. May 25, 2006).

<sup>48</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (to be codified at 21 CFR Parts 201, 314, and 601).

- 4) claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time a plaintiff claims the sponsor had an obligation to warn ...;
- 5) claims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising; and
- 6) claims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's label.

A battle in the courts over the scope and propriety of FDA's preemptive authority has already ensued.

In *Colacicco v. Apotex, Inc.*, the plaintiff asserted claims against GSK and Apotex, Inc. in connection with GSK's antidepressant medication Paxil as well as a generic version of Paxil that Apotex manufactured.<sup>49</sup> The plaintiff alleged that his wife committed suicide after 22 days of taking Paxil and the Apotex generic, and he asserted consumer fraud and traditional product liability causes of action (including failure to warn) against both companies.<sup>50</sup> GSK and Apotex argued that a warning regarding the risk of suicide would conflict with FDA labeling requirements and would "thwart" the FDCA.<sup>51</sup> The plaintiff responded that FDA's regulatory authority under the FDCA creates a floor and not a ceiling<sup>52</sup> and, therefore, a warning above and beyond what FDA had approved was permissible and would *not* conflict with the FDCA.<sup>53</sup> As it has in other cases involving antidepressants and warnings regarding the risk of suicide,<sup>54</sup> FDA submitted an amicus brief at the court's request that argued in favor of a finding of preemption.<sup>55</sup> FDA contended, in particular, that: 1) "public policy requires that warnings be scientific and substantiated;" 2) "[d]issemination of unsupported warnings ... would deprive patients of an efficacious treatment; and 3) drug makers could not unilaterally "strengthen" warnings without express FDA approval."<sup>56</sup>

The court acknowledged that a number of other federal district courts<sup>57</sup> had declined to find preemption when confronted with similar factual issues and that it found the reasoning of these decisions "forceful," "analytical," and persuasive.<sup>58</sup> However, based upon FDA's amicus brief and the Preamble, the Eastern District of Pennsylvania held that all of the plaintiff's claims were barred by preemption.<sup>59</sup> Central to the court's holding was level of deference to be afforded the FDA.<sup>60</sup> At the outset, citing *Hillsborough*

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<sup>49</sup> Civil Action No. 05-5500, 2006 U.S. Dist. LEXIS 34217, \*1 (E.D. Pa May 25, 2006).

<sup>50</sup> *Id.* at \*4.

<sup>51</sup> *Id.* at \*12.

<sup>52</sup> FDA's labeling guidelines reject this view: "FDA interprets the act to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading." 71 Fed. Reg. 3922.

<sup>53</sup> *Id.* at \*34-\*35.

<sup>54</sup> *Dusek v. Pfizer Inc.*, Civil Action No. H-02-3559, 2004 U.S. Dist. LEXIS 28056, \*1 (S.D. Tx. Feb. 20, 2004); *Kallas v. Pfizer, Inc.*, Civil Action no. 04-cv-0998 (D. Utah Sept. 15, 2005); *Motus v. Pfizer Inc.*, 358 F.3d 659 (9th Cir. 2004).

<sup>55</sup> *Colacicco*, 2006 U.S. Dist. LEXIS 34127 at \*6.

<sup>56</sup> *Id.* at \*31.

<sup>57</sup> *McNellis v. Pfizer, Inc.*, 2005 U.S. Dist. LEXIS 37505, \*17, Civ. No. 05-1286 (D.N.J. Dec. 29, 2005); *Witczak v. Pfizer*, 377 F. Supp. 2d 726, 729 (D. Minn. 2005); *Zikis v. Pfizer, Inc.*, 2005 U.S. Dist. LEXIS 9591, \*10, Civ. No. 04-8104 (N.D. Ill. May 9, 2005); *Cartwright v. Pfizer*, 369 F. Supp. 2d 876, 882 (E.D. Tex. 2005); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018 (S.D. Ill. 2001).

<sup>58</sup> *Colacicco*, 2006 U.S. Dist. LEXIS 34127 at \*58-\*59.

<sup>59</sup> *Id.* at \*24-\*26.

<sup>60</sup> *Id.* at \*24-\*55.

*County v. Automated Med. Labs. Inc.*, 471 U.S. 707 (1985), the court concluded that “in the absence of clearly expressed Congressional intent or subsequent developments that reveal a change in that position, the FDA’s position on the preemptive scope of its regulatory authority is dispositive” and, citing *Geier v. Am. Honda Motor Co., Inc.*,<sup>61</sup> that “such preemptive intent may be properly communicated in *amicus* briefs.”<sup>62</sup> Therefore, the court concluded that the *amicus* brief was entitled to “significant deference.”<sup>63</sup>

Urging the court to attach no weight to the Preamble, the plaintiff argued that the Preamble merely constituted a “legal argument” which does not have the affect of law.<sup>64</sup> The court disagreed, concluding, based upon *Chevron*, *Geier*, and *Hillsborough County*, that the Preamble was also entitled to “significant deference”:

[T]he subject matter of the FDCA is technical; and the relevant history and background are complex and extensive, and we find that the FDA is uniquely qualified to comprehend the likely impact of state requirements. Given the overwhelming case law on the issue of deference, and specifically the Supreme Court’s holdings in *Geier* and *Hillsborough County* that preemptive intent may properly be communicated in ... preambles and interpretive statements, we find Plaintiff’s argument lacks merit. Further it is not the function of this Court, or for a jury empanelled to decide this case, to substitute its judgment for the FDA’s about these medical issues. Congress has given the FDA, broad power, the President has appointed its executives, some subject to the advice and consent of the Senate, and it has rendered its judgment on these issues. The FDA has acted within its authority, and this Court must respect its expert judgment ...<sup>65</sup>

The court also rejected the argument that FDA’s position regarding preemption has been inconsistent and that the Preamble did not have a retroactive application.<sup>66</sup>

Five days after the Eastern District of Pennsylvania’s decision in *Colacicco*, District of Nebraska reached the opposite conclusion in a matter involving antidepressant medications sold by Pfizer and Wyeth<sup>67</sup>. As in *Colacicco*, in *Jackson v. Pfizer, Inc.*, the plaintiffs asserted common law product liability claims based upon the allegation that the antidepressant medications (Pfizer’s Zoloft and Wyeth’s Effexor) failed to include warnings regarding the risk of suicide<sup>68</sup>. Like Apotex and GSK, Pfizer and Wyeth argued, *inter alia*, that the plaintiffs’ claims were preempted by FDA’s Preamble.<sup>69</sup> However, the District of Nebraska rejected this assertion out of hand, concluding, “The recent notice issued by the FDA claiming preemption is not persuasive.”<sup>70</sup>

Explaining its conclusion in a footnote, the District of Nebraska stated, “The FDA failed to comply with its requirements to states and to allow the states an opportunity to participate in the proceedings prior to a preemption decision.”<sup>71</sup> In support of this holding, the court cited to Executive Order 13132, which, in Section 4(c), requires agencies

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<sup>61</sup> 529 U.S. 861 (2000).

<sup>62</sup> *Id.* at \*25-\*26.

<sup>63</sup> *Id.* at \*37.

<sup>64</sup> *Id.* at \*39.

<sup>65</sup> *Id.* at \*40-\*41 (internal punctuation and citations omitted).

<sup>66</sup> *Id.* at \*41-\*55.

<sup>67</sup> *Jackson v. Pfizer*, 432 F. Supp. 2d 964 (D. Neb. 2006)

<sup>68</sup> *Id.* at 965.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 968.

<sup>71</sup> *Id.* at 968 note 3.

proposing to preempt state law to “provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.” FDA squarely addresses this issue in the labeling guidelines and asserts that, indeed, it did comply with the Executive Order:

Officials at FDA consulted with a number of organizations representing the interests of state and local governments and officials about the interaction between FDA regulation of prescription drug labeling (including this rule) and state law.... [T]he agency believes that it has complied with all of the applicable requirements under Executive Order 13132 and has determined that this final rule is consistent with the Executive Order.

The District of Nebraska did not articulate why it disagreed with FDA’s position.

In *Coutu v. Tracy*,<sup>72</sup> the Rhode Island Superior Court was also unmoved by the FDA Preamble, although for reasons different than those articulated in *Jackson*. In *Coutu*, the plaintiffs asserted failure to warn claims against AstraZeneca in connection with Propofol, a sedative agent.<sup>73</sup> More specifically, the plaintiffs claimed that AstraZeneca failed to provide warnings—through a “Dear Doctor Letter” or other means—of the potential adverse effects of Propofol on children.<sup>74</sup> AstraZeneca moved for summary judgment on the grounds that the plaintiffs’ claims were preempted based upon the FDA Preamble.<sup>75</sup> The Rhode Island Superior Court held that they were not, reasoning, *inter alia*, the Preamble was inconsistent with positions that FDA had previously expressed on the issue of preemption—an argument that the *Colacicco* court rejected.<sup>76</sup>

*Colacicco*, *Jackson* and *Coutu* illustrate that the amount of deference, if any, afforded to the Preamble will likely hinge upon the dispositive force of *Chevron*, *Geier* and *Hillsborough County* and Executive Order 13132 as well as the weight afforded to the consistency of FDA’s position on preemption. Absent intervention by the Supreme Court, much will still depend upon whether a particular trial court judge holds strong convictions for or against implied preemption in the pharmaceutical context.

#### D. The Learned Intermediary Doctrine

The learned intermediary doctrine has been effectively employed to defeat personal injury products-based claims for over two decades. Perhaps due to the recent incidence of consumer fraud claims and the novelty of asserting a traditional personal injury product liability defense in the context of a non-personal injury consumer fraud action, few courts have weighed in on the learned intermediary defense in the consumer fraud context. Those courts that have, however, are increasingly recognizing it as a bar to consumer fraud claims.

The decision of the U.S. District Court for the District of New Jersey in *Heindel v. Pfizer Inc.* is particularly instructive.<sup>77</sup> *Heindel* involved claims under the Pennsylvania CPA<sup>78</sup> by a putative class of purchasers and users of Cox-2 prescription medications

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<sup>72</sup> Civil Action No. PC/00-3720, 2006 WL1314261, \*1 (R.I. Super May 11, 2006).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at \*2.

<sup>75</sup> *Id.*

<sup>76</sup> *Id.* at \* 4.

<sup>77</sup> 381 F. Supp. 2d 364 (D.N.J. 2004).

<sup>78</sup> In the Complaint, the plaintiffs asserted claims under the New Jersey CPA as well as “other states’ consumer protection statutes.” *Id.* at \*23. After a detailed choice of law analysis, the District of New Jersey held that the Pennsylvania law applied. *Id.* at \*23-\*40.

Vioxx and Celebrex. The defendants, Pfizer and Merck, moved for summary judgment on the grounds that the plaintiffs' CPA claims were barred by the learned intermediary doctrine.<sup>79</sup> The court agreed, positing several reasons for its conclusion. First, citing two Pennsylvania state trial court decisions,<sup>80</sup> the Court found that manufacturers of prescription drugs only owed a duty to disclose warnings and information to physicians, not directly to patients and purchasers of the medication.<sup>81</sup> Second, "to permit a cause of action under the [Pennsylvania CPA] ... would effectively make a drug manufacturer the absolute guarantor of the anticipated results and effects of a prescription drug," which, the court held, was inconsistent with Pennsylvania law.<sup>82</sup> Third, the plaintiffs did not produce evidence that they read the warning labels or otherwise relied upon misrepresentations made by Pfizer or Merck.<sup>83</sup> Instead, they merely relied upon the information and advice provided by their physicians. The court added, "Even if [the plaintiffs] had offered evidence that they had relied in some way on Defendants' misrepresentations, it would ultimately be of no consequence. The learned intermediary breaks the chain in terms of reliance, since the patient cannot obtain prescription drugs without the physician no matter what they believe about them."<sup>84</sup>

Similarly, in *New Jersey Citizen Action v. Schering-Plough*, the Superior Court of New Jersey found that the learned intermediary doctrine barred claims under the New Jersey CPA in connection with statements made through direct-to-consumer advertising regarding the prescription allergy therapy Claritin.<sup>85</sup> The court reasoned, "The intervention by a physician in the decision-making process necessitated by his or her exercise of judgment whether or not to prescribe a particular medication protects consumers in ways respecting efficacy that are lacking in advertising campaigns for other products."<sup>86</sup> Emphasizing that the pharmaceutical industry is "highly regulated," the court further explained, "The ultimate consumer is not in fact free to act on claims made in advertising."<sup>87</sup>

The Eastern District of Pennsylvania also found that the learned intermediary defense was a bar to consumer fraud claims in the *Colacicco* decision discussed previously.<sup>88</sup> The court explained, "The consumer protection statute forbids deceptive acts or practices likely to mislead a reasonable consumer, ... while the [learned intermediary doctrine] dictates that all pharmaceutical information is directed at physicians, not consumer-patients."<sup>89</sup>

In short, while perhaps over-looked in the short history of consumer fraud products-based litigation, the learned intermediary defense may prove as, or more, effective than any other defense available at the motion to dismiss stage.

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<sup>79</sup> *Id.* at 384.

<sup>80</sup> *Albertson v. Wyeth*, 2003 WL 21544488, \* 1 (Pa. Comm. Pl. July 8, 2003) (holding that the learned intermediary doctrine barred consumer fraud claims under the Pennsylvania CPA relating to prescription hormone replacement therapy medications); *Luke v. American Home Products Corp.*, 1998 WL 1781624, \* 1 (Pa. Comm. Pl. 1998) (holding that the learned intermediary doctrine barred consumer fraud claims under the Pennsylvania CPA relating to a prescription weight loss treatment).

<sup>81</sup> 381 F. Supp. 2d at 384.

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> 842 A.2d 174, 176 (2003).

<sup>86</sup> *Id.* at 177-178.

<sup>87</sup> *Id.* at 178. *See also* *Warfarin v. Sodium Antitrust Litigation*, 212 F.R.D. 231, 256 (D. De 2002) (in approving a proposed class action settlement in a matter brought under the Delaware CPA as well as CPAs "of the fifty states" for misrepresentations in connection with the sale of anticoagulant medication, the court found that the learned intermediary doctrine would "present[] a barrier to proving that any deceptive representations made by defendant were the proximate cause of the plaintiff's injuries.").

<sup>88</sup> 2006 U.S. Dist. LEXIS 34127 at \*108.

<sup>89</sup> *Id.*

## V. DEFEATING CLASS CERTIFICATION OF CONSUMER FRAUD CLASS ACTIONS

If a 12(b)(6) challenge to a consumer fraud class action proves unsuccessful, (or only successful in part), defeating CPA claims at the class certification stage remains a viable, if not more potent, option. In most instances, a consumer fraud action brought by one or more individual plaintiffs will not present an economically attractive proposition to the plaintiffs' bar. Consequently, defeating class certification will often result in a voluntary dismissal of a plaintiff's claims.

Due to the enactment of the Class Action Fairness Act of 2005, which significantly relaxes the diversity of citizenship and amount-in-controversy requirements under 28 U.S.C. § 1332, the majority of consumer fraud class actions will be filed in, or removable to, federal court where Fed R. Civ. P. 23 will apply.<sup>90</sup> Decisions on class certification under Rule 23 in consumer fraud claims typically hinge on the requirement that plaintiffs establish "questions of fact or law common to the members of the class predominate over any questions affecting only individual class members."<sup>91</sup> An examination of state choice of law provisions under *Phillips Petroleum Co. v. Shutts*,<sup>92</sup> often plays a central role in the analysis.

### A. Challenging Class Certification Based Upon CPA Variability

Where plaintiffs have attempted to certify nationwide classes under one or more state CPA, defense counsel have argued that the variability among the state CPAs regarding burdens of proof and availability of damages precludes a finding of predominance. On the whole, the federal courts seem increasingly resistant to nationwide classes and, therefore, this argument has been well-received. The federal courts are more receptive, however, to the certification of statewide class actions under the CPA of the forum state. Where plaintiffs have attempted to certify nationwide classes under one or more state CPAs, defense counsel have argued that the variability among the state CPAs regarding burdens of proof and availability of damages precludes a finding of predominance. Decisions from three multidistrict litigations—*In re Bridgestone/Firestone Tires Product Liability Litigation*, *In re Silzone Heart Valve Products Liability Litigation*, and *In re Average Wholesale Price Litigation*—are illustrative of the federal courts' different approaches to both nationwide and statewide class actions.

#### 1. *Bridgestone/Firestone I and II*

##### a. *Bridgestone/Firestone I*

The Seventh Circuit's companion opinions in *In re Bridgestone/Firestone Tires Product Liability Litigation* are representative of those federal courts that are disinclined to certify consumer fraud class actions, particularly putative nationwide classes.<sup>93</sup> The *In re Bridgestone/Firestone* litigation related to the abnormally high failure rate that Firestone tires on Ford Explorer SUVs experienced in the late 1990s, which ultimately resulted in the recall of several brands of Firestone tires.<sup>94</sup> The plaintiffs in these cases can be categorized into two species: 1) those seeking recovery for personal injuries; and

<sup>90</sup> It does bear noting, however, that some CPAs have independent (and often less onerous) class certification provisions, which may raise issues under *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938).

<sup>91</sup> See Fed. R. Civ. P. 23(b)(A)(3).

<sup>92</sup> 472 U.S. 797 (1985).

<sup>93</sup> 288 F.3d 1012 (7th Cir. 2002) (*Bridgestone/Firestone I*); 333 F.3d 763 (7th Cir. 2003) (*Bridgestone/Firestone II*).

<sup>94</sup> *Bridgestone/Firestone I*, 288 F.3d at 1014.

2) those seeking recovery under state CPAs for economic loss sustained as a result of decreased resale value caused by the "risk of failure" of their tires or SUV.<sup>95</sup> The U.S. District Court for the District of Indiana certified a nationwide class of individuals who had owned or leased a Ford Explorer between 1991 and the date of the recall (Explorer Class) as well as a nationwide class of owners and lessees of Firestone tires (Firestone Class).<sup>96</sup> The case was first heard by the Seventh Circuit on appeal by the defendant manufacturers from the certification of both classes.<sup>97</sup>

Although the Explorer Class and the Firestone Class each included class members who had suffered personal injuries, in the Seventh Circuit's view, most of these individuals "were sure to opt out and litigate independently."<sup>98</sup> Consequently, the court treated both classes as though only CPA claims were asserted.<sup>99</sup> Viewing the claims through this lens, the court rejected certification of a nationwide class of both classes.<sup>100</sup> At the outset, the Seventh Circuit faulted the district court for improperly applying Indiana choice of law principles to find that the claims of each of the class members of the Explorer class and the Firestone class could be resolved under the CPA of a single state (Michigan in the case of the Explorer class and Tennessee in the case of the Firestone class).<sup>101</sup> Applying Indiana's *lex loci delicti* standard, the Seventh Circuit held that claims of the class members were more properly governed by the laws of the state in which they suffered harm, which, in all likelihood, would require the independent application of the laws of all 50 states.<sup>102</sup> Examining the state CPAs as a whole, the Seventh Circuit concluded that "[s]tate consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state's law to sales in other states with different rules."<sup>103</sup> Therefore, "[b]ecause these claims must be adjudicated under the law of so many jurisdictions, a single nationwide class is not manageable."<sup>104</sup> In addition the Seventh Circuit stated, "[l]est we soon see a Rule 23(f) petition to review certification of 50 state classes, we add that this litigation is not manageable as a class action even on a statewide basis."<sup>105</sup>

### b. Bridgestone/Firestone II

Following remand, the plaintiffs filed suits in other jurisdictions seeking the certification of the same nationwide class rejected by the Seventh Circuit.<sup>106</sup> In response, the defendants filed a motion with the District of Indiana under the Anti-Injunction Act, 28 U.S.C. § 2283, asking the court to enjoin any class action based upon similar claims, regardless of whether the putative class was nationwide or statewide.<sup>107</sup> The district court denied the motion, and the defendants again appealed to the Seventh Circuit.<sup>108</sup> The Seventh Circuit reversed the district court's decision as it applied to nationwide classes.<sup>109</sup> Recognizing the realities of forum shopping in any case where certification is denied, the court explained:

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<sup>95</sup> *Id.* at 1016.

<sup>96</sup> *Id.* at 1015.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 1016.

<sup>99</sup> *Id.*

<sup>100</sup> *Id.* at 1021.

<sup>101</sup> *Id.* at 1015-1018.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.* at 1018.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Bridgestone/Firestone II*, 333 F.2d at 765.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* at 769.

That these [consumer fraud class action] suits are multiplying suggests that some lawyers have adopted a strategy of filing in as many courts as necessary until a nationwide class comes into being and persists.... Suppose that every state in the nation would as a matter of first principles deem inappropriate a nationwide class covering these claims and products. What this might mean in practice is something alike "9 out of 10 judges in every state would rule against certifying a nationwide class." ... Although the 10% that see things otherwise are a distinct minority, one is bound to turn up if plaintiffs file enough suits—and, if one nationwide class is certified, all the no-certification decisions fade into insignificance. A single positive trumps all negatives.<sup>110</sup>

The Seventh Circuit ordered the entry of an injunction enjoining all members of the putative class and their attorneys from attempting to have nationwide classes certified based upon the same claims.<sup>111</sup> It did not, however, order the entry of an injunction enjoining statewide claims.<sup>112</sup> Back-peddling a bit from its earlier decision, the Seventh Circuit stated, "The district court had not certified, and thus our decision did not address, any statewide classes."<sup>113</sup> Accordingly, the Seventh Circuit ruled that it had not made a "judgment" on the propriety of statewide classes for purposes of the Anti-Injunction Act and, therefore, it had no grounds to bar plaintiffs from seeking certification of statewide classes in other jurisdictions.<sup>114</sup>

## 2. *Silzone Heart Valve Litigation*

After receiving approval from FDA for its Silzone prosthetic heart valve, St. Jude Medical sponsored a clinical trial comparing patient experiences with Silzone and non-Silzone implants.<sup>115</sup> Data from the study showed a statistically significant two percent increase in paravalvular leaks among patients receiving the Silzone heart valves.<sup>116</sup> In response, St. Jude Medical recalled all unimplanted Silzone devices.<sup>117</sup> After a number of cases were filed and consolidated in an MDL in the U.S. District Court for the District of Minnesota, five plaintiffs filed an amended complaint on behalf of themselves and over 11,000 other Silzone heart valve recipients.<sup>118</sup> Concluding that common issues of law and fact predominated over the plaintiffs' claims, the District of Minnesota certified a nationwide class under Minnesota's several CPAs.<sup>119</sup>

On appeal to the Eighth Circuit, St. Jude Medical argued that certification was improper for two separate and independent reasons: 1) certification of a nationwide class under the CPA of a single state violated the Due Process and Full Faith and Credit clauses of the U.S. Constitution; and 2) the plaintiffs had not satisfied the predominance requirements of Fed. R. Civ. P. Rule 23.<sup>120</sup> The Eighth Circuit ultimately reversed and remanded the finding of certification based upon St. Jude Medical's constitutional arguments.<sup>121</sup>

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<sup>110</sup> *Id.* at 766-767 (emphasis in original).

<sup>111</sup> *Id.* at 769.

<sup>112</sup> *Id.* at 766.

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *In re St. Jude Medical, Inc. Silzone Heart Valve Products Liability Litigation*, 425 F.3d 1116 (8th Cir. 2005).

<sup>116</sup> *Id.* at 1118.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.* The District of Minnesota also certified a nationwide "medical monitoring class" and conditionally certified a nationwide personal injury class that it later decertified.

<sup>120</sup> *Id.* at 1119-1120.

<sup>121</sup> *Id.* at 1120-1121.

In its choice-of-law analysis, the District of Minnesota had concluded that Minnesota law could and should apply to all class members because the Minnesota CPAs permit “any person” to bring suit there-under and that, because St. Jude Medical was headquartered in Minnesota, it had “significant contacts” with the state.<sup>122</sup> The Eighth Circuit rejected this analysis as inadequate.<sup>123</sup> Based upon *Shutts* and *Allstate Ins. Co. v. Hague*,<sup>124</sup> the court held that District Court had failed to engage in an inquiry as to the nature of the out-of-state class members’ contact with Minnesota, if any.<sup>125</sup> While these constitutional principles served as the ultimate basis for its decision, the Eighth Circuit nevertheless seemed to share the Seventh Circuit’s disapproval of nationwide consumer fraud classes.<sup>126</sup> Quoting *Bridgestone/Firestone I*, the Eighth Circuit commented that “state consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state’s law to sales in other states with different rules.”<sup>127</sup> It further stated, “Application of Minnesota law to all plaintiffs’ claims ultimately may be appropriate, although we suspect Minnesota lacks sufficient contacts with all the parties’ claims, and the different states have material variances between their consumer protection laws and Minnesota’s. There is no indication out-of-state parties had any idea that Minnesota law could control when they received their Silzone-coated valves.”<sup>128</sup>

### 3. Average Wholesale Price Litigation

While the Seventh and Eighth Circuits are representative of jurisdictions that are resistant to nationwide (and to some extent, statewide) classes, the U.S. District Court for the District of Massachusetts’ decision in *In re: Pharmaceutical Industry Wholesale Price Litigation*,<sup>129</sup> reflects a more accepting view. In *In re: Pharmaceutical Industry Wholesale Price Litigation*, the plaintiffs asserted claims against several pharmaceutical companies and their affiliates in connection with the sale of various brand name and prescription drugs.<sup>130</sup> The plaintiffs alleged that the pharmaceutical companies, acting in concert, fraudulently inflated the price of medications by making misstatements regarding the “average wholesale price” of their various drugs.<sup>131</sup> As a consequence of these misrepresentations, the plaintiffs contended that “millions” of individual consumers and some 11,000 third party payors overpaid for medications.<sup>132</sup>

Among the several putative classes, the plaintiffs sought to certify a nationwide class asserting claims under the CPAs of various states.<sup>133</sup> This proposed class was comprised of all persons or entities who paid for drugs administered by physicians and further divided into three subclasses: 1) persons who made co-payments for physician-administered drugs under Medicare; 2) third party payors that paid MediGap supplemental insurance for co-payments made by Medicare beneficiaries; and 3) third party payors that made payment for physician-administered drugs outside the context of Medicare.<sup>134</sup> Like

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<sup>122</sup> *Id.* at 1120.

<sup>123</sup> *Id.*

<sup>124</sup> 449 U.S. 302 (1981).

<sup>125</sup> *Id.*

<sup>126</sup> *Id.* at 1120-1121.

<sup>127</sup> *Id.* at 1120.

<sup>128</sup> *Id.* (internal quotations and punctuation omitted).

<sup>129</sup> 230 F.R.D. 61 (D. Mass. 2005).

<sup>130</sup> *Id.* at 65.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at 66-67, 77-91. In addition to the physician-administered class, the plaintiffs sought to certify two classes of third party payors that had made payment for patient-administered drugs. One putative class

the defendants in *Bridgestone/Firestone* and *In re Silzone Heart Valve*, the pharmaceutical companies argued in opposition to the certification of each of these subclasses that common issues of fact and law did not predominate because of the many substantive differences among the state CPAs.<sup>135</sup> This argument was less persuasive to the District of Massachusetts, however, than it was to the Seventh and Eighth Circuits.

The District of Massachusetts first addressed the proposed subclass of individuals who made co-payments under Medicare.<sup>136</sup> Regarding the question of predominance, the court held, at the outset, that the Massachusetts choice of law rules required the application of Massachusetts law.<sup>137</sup> The court did recognize that "variations in state law may swamp common issues and defeat predominance."<sup>138</sup> It, therefore, excluded claims under the Iowa CPA, which does not recognize a private right of action, as well as the CPAs of the eight states that do not recognize a right to bring a class action to enforce the statute.<sup>139</sup> In addition, claims brought under the CPAs of 11 additional states were conditionally excluded because the plaintiffs had not demonstrated that they had complied with the pre-litigation notice requirements set forth in these statutes.<sup>140</sup> Nevertheless, the court certified a nationwide class under the CPAs of the remaining 30 states.<sup>141</sup> The court explained that, because the plaintiffs in this putative class alleged that the defendants had intentionally made fraudulent misstatements, variations among the various state CPAs regarding the element of scienter did not present individual issues.<sup>142</sup> Additionally, with respect to the elements of reliance and causation, the court stated, "there is no indication that different definitions of reliance and causation will matter or cannot be resolved as a matter of law prior to trial."<sup>143</sup>

The court declined, however, to certify nationwide classes for third-party payors who made both Medicare and non-Medicare payments for physician administered drugs.<sup>144</sup> In arguing against certification, the pharmaceutical companies again asserted that the plaintiffs could not establish predominance because of disparities among state CPAs, particularly the fact that organizations did not have standing to assert claims under many of these statutes.<sup>145</sup> The court found this argument compelling for both of these subclasses, stating, "[p]laintiffs have not proposed feasible groupings of these statutes, as would be necessary to proceed."<sup>146</sup> As a result, the court denied certification of a nationwide class, but it did so without prejudice, theoretically leaving the door open for nationwide classes upon a sufficient showing of "feasible groupings" by the plaintiffs.<sup>147</sup> In the interim, however, the court certified statewide classes under the Massachusetts CPA for both of these subgroups, reasoning that the Massachusetts CPA did not bar claims by organizational defendants.<sup>148</sup>

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sought relief based upon CPA violations; the other under RICO. The court denied certification of both of these classes, finding that they were simply too large to permit effective management as a class action. This article focuses only on the physician-administered class because the court's treatment of that putative class is the most germane to our discussion.

<sup>135</sup> *Id.* at 77-91.

<sup>136</sup> *Id.* at 77.

<sup>137</sup> *Id.* at 83.

<sup>138</sup> *Id.* at 82.

<sup>139</sup> *Id.* at 84.

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* at 66, 85.

<sup>142</sup> *Id.* at 85.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.* at 86, 90.

<sup>145</sup> *Id.* at 86, 87.

<sup>146</sup> *Id.* at 86.

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

### B. Challenging Class Certification Based Upon Causation

In addition to raising the variability of each CPA as a means of defeating class certification (which may still result in the certification of a statewide class), practitioners should consider challenging class certification of CPA claims based upon causation. Individual factual and legal issues with respect to causation have traditionally stood as a roadblock to the certification of nationwide and statewide product liability personal injury claims.<sup>149</sup> An analogous argument may gain traction in the consumer fraud context.

Despite the elimination or relaxation of other elements of a typical common law fraud claim, nearly all of the states still require plaintiffs to demonstrate a “causal nexus” between unfair or deceptive conduct and the plaintiff’s injury. On its face, this principle seems counter-intuitive—particularly in jurisdictions where plaintiffs need not demonstrate reliance as part of their *prima facie* case—because reliance and causation are typically intertwined. Courts have struggled to craft standards that address this apparent paradox. Some have imposed liability under state CPAs simply upon a showing of “an unfair or deceptive” act without regard as to whether there was proof that an individual plaintiff suffered actual, “direct” harm.<sup>150</sup> Two recent decisions by the Supreme Judicial Court (SJC) of Massachusetts, which boasts one of the more “consumer-friendly” CPAs, suggest that courts may be retreating from this illogical position.

In *Aspinall v. Philip Morris Companies, Inc.*, the plaintiffs initiated a statewide class of Massachusetts consumers who purchased Marlboro Light cigarettes, which were marketed as providing “lowered tar and nicotine” to smokers.<sup>151</sup> The plaintiffs alleged that Philip Morris had “[misled] the public into believing that ... Marlboro Lights would deliver lower levels of tar and nicotine, when [Philip Morris] knew the truth to be otherwise and, in fact, intentionally designed the product so that most smokers of Marlboro Lights would receive as much, or more, tar and nicotine than if they had smoked regular cigarettes.”<sup>152</sup> The trial court granted class certification under the certification provisions set forth in the Massachusetts CPA.<sup>153</sup> The finding of certification was affirmed by the Massachusetts SJC on appeal.<sup>154</sup>

Philip Morris argued before the SJC that class certification was inappropriate because the plaintiffs were unable to establish that its allegedly deceptive advertising caused actual harm to each class member.<sup>155</sup> Further, Philip Morris contended that some smokers of Marlboro Lights did in fact receive lowered “tar and nicotine” (which the plaintiffs conceded) and that, consequently, there could be no finding of deceptive advertising with respect to those members because “they got what the advertising was promising.”<sup>156</sup>

Rejecting each of the Philip Morris’ arguments, the SJC stated:

A successful [Massachusetts CPA] action based on deceptive acts or practices does not require proof that a plaintiff relied upon the representation or that the defendant intended to deceive the plaintiff, or even knowledge on the part of

<sup>149</sup> See, e.g., *Costano v. American Tobacco Co.*, 84 F.3d 734, 746-747 (5th Cir. 1996); *Ball v. Union Carbide Corp.*, 212 F.R.D. 380, 389 (E.D. Tenn. 2002); *Perez v. Metabolife Int’l, Inc.*, 218 F.R.D. 262, 270 (S.D. Fla. 2003).

<sup>150</sup> *Aspinall v. Philip Morris Companies, Inc.*, 442 Mass. 381, 382-385 (2004); *Gilbert v. Philip Morris, Inc.*, 621 N.W.2d 2 (Minn. 2001).

<sup>151</sup> 442 Mass. at 382-385.

<sup>152</sup> *Id.* at 382.

<sup>153</sup> *Id.* at 384-385.

<sup>154</sup> *Id.* at 385.

<sup>155</sup> *Id.* at 393.

<sup>156</sup> *Id.*

the defendant that the representation was false . . . . Our cases . . . also establish that advertising need not be totally false in order to be deemed deceptive in the context of [the Massachusetts CPA]. The criticized advertisements may be true as a literal matter, but still create an over-all misleading impression through failure to disclose material information.<sup>157</sup>

In dicta, the SJC also took the opportunity to “comment” on the question of causation and the issue of damages.<sup>158</sup> The court stated, “in the event that the plaintiffs are unsuccessful in their attempt to prove actual damages, . . . they will be entitled to recover statutory damages under [the Massachusetts CPA].”<sup>159</sup> Thus, while acknowledging that “causation is a required element of a successful [Massachusetts CPA] claim,” the SJC indicated that a finding of “deceptive advertising” established “a per se injury on consumers who purchased the cigarettes represented to be lower in tar and nicotine.”<sup>160</sup> Moreover, the SJC suggested that, in the absence of actual damages, they would be implied as a matter of law. The court explained:

It follows that, if the violations of the [Massachusetts CPA] alleged by the plaintiffs are proved, all members of the class of purchasers of Marlboro Lights in Massachusetts will have been injured (regardless of whether some smokers actually received lowered tar or nicotine). This is so because all purchased (and, presumably, smoked) a product that was deceptively advertised, as a matter of law, because it was falsely labeled, or at least created the overall misleading impression that all smokers would receive “lowered tar and nicotine.” Thus, all will be entitled to statutory damages, without regard to whether the plaintiffs are successful in establishing that consumers were overcharged for the deceptively advertised cigarettes.<sup>161</sup>

In short, it appeared under *Aspinall* that all that was required to establish causation was proof that a class member purchased and consumed a “deceptively advertised” product.<sup>162</sup>

On January 17, 2006, in *Hershenow v. Enterprise Rent-A-Car Co. of Boston, Inc.*, the SJC issued its first decision on the Massachusetts CPA in the consumer fraud context since *Aspinall*.<sup>163</sup> At bottom, *Hershenow* appears to effect a significant retreat from, if not abolition of, the “per se injury” rule. In *Hershenow*, the plaintiffs purchased collision insurance in connection with the rental of an automobile from Enterprise Rent-A-Car.<sup>164</sup> It was undisputed that the certain terms in the Enterprise policy were void as a matter of Massachusetts statutory law.<sup>165</sup> As a result, although neither plaintiff suffered an accident nor filed a claim, the plaintiffs alleged that the sale of a facially invalid policy constituted an “unfair and deceptive” act in violation of the Massachusetts CPA. Citing *Aspinall*, the plaintiffs contended that this violation inflicted a “per se injury,” which entitled them to recovery. The SJC disagreed, holding that the alleged “per se” deception did not cause the plaintiffs to suffer a loss, and, thus, plaintiffs could not support a valid

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<sup>157</sup> *Id.* at 395-396.

<sup>158</sup> *Id.* at 398-399.

<sup>159</sup> *Id.* at 400.

<sup>160</sup> *Id.* at 402.

<sup>161</sup> *Id.*

<sup>162</sup> *See id.*

<sup>163</sup> 2006 WL 73594.

<sup>164</sup> *Id.* at \*1-\*2.

<sup>165</sup> *Id.* at \*2.

93A claim.<sup>166</sup> In reaching this conclusion, the SJC reasoned that no event triggered the violative provision in the agreement, and therefore, the plaintiffs could not establish that Enterprise caused them to suffer injury or harm:

Nothing in the statutory language or legislative history suggests that the [Legislature] eliminated or altered the requirement of a causal connection to a loss ... A misrepresentation of legal rights in a consumer contract may indeed be per se “unfair” or “deceptive” under [the Massachusetts CPA]. But a plaintiff seeking a remedy under [the statute] must demonstrate that even a per se deception caused a loss.<sup>167</sup>

Fairly read, Justice Marshall’s majority opinion instructs that, if a plaintiff suffered some damage or injury and can show this actual harm as a result of some unfair or deceptive act, then he or she is entitled to an award greater than zero dollars, and possibly the statutory minimum. On the other hand, if the unfair or deceptive conduct does not result in any loss, whether personal or economic, then a plaintiff is not entitled to any damages, not even the statutory minimum. More succinctly, “A consumer is not ... entitled to redress under [the Massachusetts CPA], where no loss has occurred.”<sup>168</sup> While Justice Marshall refused to expressly overrule *Aspinall* or *Leardi v. Brown*—a prior SJC decision on which *Aspinall* relies<sup>169</sup> (electing instead to distinguish the cases on their facts)—the holding in *Hershenow* is so fundamentally inconsistent with these decisions that it appears to nevertheless signal the death knell for the “per se injury” rule under the Massachusetts CPA.

Interestingly, support for this interpretation of *Hershenow* is most readily found in the dissent authored by Justice Greaney, who asserts (with conviction) that the majority’s decision effectively sets the principles stated in *Aspinall* and prior decisions aside.<sup>170</sup> Similarly, Justice Cowin, in his concurrence, criticized the majority’s refusal to overrule *Aspinall* and characterized Justice Marshall’s attempt to distinguish *Hershenow* from prior decisions as artificial.<sup>171</sup> Justice Cowin states, in particular, “The court’s effort to distinguish the cases seems to me to arise not so much from analytical conviction but a desire to avoid acknowledging that *Leardi* was wrongly decided.”<sup>172</sup> Justice Cowin further added:

[*Leardi*’s] holding diverged markedly from the language of [the Massachusetts CPA] which plainly requires a showing of injury as we have traditionally understood as the concept: proof that the plaintiff has, in fact, been harmed. The Legislature never intended [the statute] to allow a plaintiff who has not been adversely affected to recover nominal damages leading to attorneys’ fees. The *Leardi* decision itself acknowledged that [statute] did not authorize “vicarious suits by self-constituted private attorneys-general.”<sup>173</sup>

In a similar vein, in *Payton v. Abbot Labs*, the U.S. District Court for the District of Massachusetts rejected the notion that there could be common injury suffered by all

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<sup>166</sup> *Id.* at \*6.

<sup>167</sup> *Id.* at \*4.\*5.

<sup>168</sup> *Id.* at \*7.

<sup>169</sup> *Leardi v. Brown*, 394 Mass. 151, 159 (1985) (holding that “injury” under the Massachusetts CPA encompassed “the invasion of any legally protected [tangible or intangible] interest of another”).

<sup>170</sup> *Id.* at \*11.

<sup>171</sup> *Id.* at \*8.

<sup>172</sup> *Id.*

<sup>173</sup> *Id.* at \* 10.

members of a putative class and, therefore, held that causation must be proven on a case-by-case basis.<sup>174</sup> Thus, *Hershenow*, in concert with *Payton*, now arms defense counsel in Massachusetts with ample language to defeat or decertify a class where plaintiffs allege effects or non-effects of prescription drugs or other "consumer frauds" and fail to satisfy causation requirements. Further, *Hershenow* should provide persuasive authority in those jurisdictions that have either relied upon *Aspinall* or tracked its logic.

## VI. CONCLUSION

There is no question that consumer fraud actions are being filed by the plaintiffs' bar with increasing frequency. Due to the relaxed burdens of proof and the availability of multiple forms of damages, their numbers are likely to multiply. An early and aggressive defense is critical. At the motion to dismiss stage, practitioners should pay particular attention to the nature of the putative class, which CPAs are asserted, and whether they are vulnerable to a targeted attack on standing grounds or are barred by safe harbor provisions in the CPA. Preemption-based defenses remain viable, particularly in light of FDA's Preamble, as does the learned intermediary doctrine. If the complaint survives an initial dispositive motion, maximum effort should be devoted to defeating class certification. Finally, counsel should be creative. At its core, this new breed of products-based litigation implicates unresolved questions of federalism as well as issues of regulatory and public policy. While the number of consumer fraud class action suits is on the rise, courts may ultimately view these cases very differently than traditional claims involving personal injury, may reject what is, essentially, lawyer-driven strike litigation and, ultimately, may stem the tide of consumer fraud suits as a whole.

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<sup>174</sup> 100 F.R.D. 336, 338-39 (D. Mass. 1983).