Rational Deference:

The FTC’s Well-Founded Cession of Regulatory Authority Over Prescription Drug Advertising to the FDA Has Not Been Supported By States Seeking Penalties for Alleged Violations of “Little FTC Acts”

by Steve Brody

I. Introduction

Two federal agencies—the Food and Drug Administration (“FDA”) and the Federal Trade Commission (“FTC”)—share responsibility for regulating the advertising and promotion of drugs, but with an important division of that responsibility. The FDA has regulatory jurisdiction over drug labeling and advertising of prescription drugs, while the FTC has jurisdiction over advertising of over-the-counter (“OTC”) drugs and defers to the FDA on matters concerning prescription drugs. This split in authority reflects critical distinctions between prescription and OTC medicines.

OTC medicines are those drugs that are “generally recognized as safe and effective” and may be sold without a prescription. They are typically used to treat conditions that do not require the direct supervision of a doctor. OTC drug labels are regulated by the FDA and must contain certain information the FDA has deemed necessary for consumers to select and use the drugs appropriately. In contrast, prescription drugs are typically used to treat more serious and complex health conditions requiring a physician’s intervention. Prescription drug labels contain extensive information mandated by the FDA and are written primarily for doctors, with more limited information provided to consumers.

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3 See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed.Reg. 3922, 3961 (Jan. 24, 2006) (“The purpose of prescription drug labeling is to provide health care practitioners information necessary for safe and effective use.”).
FDA regulations govern prescription drug advertisements and require that certain information be included, while also prohibiting “false or misleading” advertisements, as defined by specific regulatory guidelines. The FDA’s experience evaluating the scientific evidence of the safety and effectiveness of prescription drugs gives it expertise that is not found in the FTC, providing a superior ability to evaluate prescription drug advertising and promotional materials. For this reason, the FTC’s deference to the FDA on prescription drug marketing and promotion makes sense.

Unfortunately, this rational deference has not been shown by state attorneys general bringing claims against prescription drug and medical device manufacturers, even though state consumer fraud and unfair and deceptive trade practice statutes are modeled on the Federal Trade Commission Act (“FTC Act”). State AGs have sought the imposition of monetary penalties for prescription drug advertising and communications that fall under the FDA’s regulatory oversight, targeting advertisements and communications that the FTC would decline to address in deference to the FDA.

II. History of the FDA and FTC

A. The Early FDA and FTC

Throughout the eighteenth and nineteenth centuries, before the FDA was established, patent medicines were widely advertised in U.S. newspapers. By the early twentieth century,however, the publication of Upton Sinclair’s *The Jungle*, a disturbing account of insanitary conditions in meat-packing plants that also contained disclosures about “the use of poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines,” led to heightened public concern about the safety of food and drugs. Congress responded by enacting the Pure Food and Drug Act in 1906 (the “1906 Act”),

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designed to ensure the safety of food and drugs sold in the United States. 6 Although the 1906 Act generally prohibited false or misleading labels on drugs, courts held that the definition of “label” excluded advertising materials.7

The FTC Act was passed in 1914.8 The FTC Act established the FTC as an independent agency charged with enforcing the FTC Act’s ban on unfair methods of competition.9 The FTC’s original mission was to prevent unfair methods of competition as part of the battle to “bust the trusts.”10 Thus, although the prohibition on unfair methods of competition in section 5 of the FTC Act included false advertising,11 the FTC only had authority to regulate deceptive advertisements if it could prove that the advertisements injured another company.12

In 1938, Congress took action to define the power of these two agencies to regulate drugs by enacting the Federal Food, Drug, and Cosmetic Act (“FDCA”), significantly expanding the FDA’s regulatory authority over medications.13 The FDCA gave the FDA authority to regulate the safety, efficacy, and labeling of foods, drugs, cosmetics, and medical devices. The FDA was given jurisdiction over both the “label,” defined as printed and graphic matter appearing on the immediate container accompanying the product, and “labeling,” defined as printed and graphic matter “accompanying such article.”14 The Supreme Court interpreted “labeling” under the FDCA broadly, holding that “accompanying” materials do not physically have to accompany the product but, rather, must have some “textual relationship” to the product that “supplements or explains” it.15 The Court held that its broad interpretation of “labeling” was appropriate to support “[t]he high purpose of the Act to protect consumers.”16

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6 Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (“An Act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors”).
9 Id.
10 See www.ftc.gov/about-ftc.
11 Sears, Roebuck, & Co. v. FTC, 258 F. 307, 310-11 (7th Cir. 1919).
13 21 U.S.C. § 301 et seq.
14 21 U.S.C. § 321(k), (m).
16 Id. at 349.
Also in 1938, Congress expanded the FTC’s role as the nation’s primary consumer protection agency by amending section 5 of the FTC Act to prohibit all “unfair or deceptive acts or practices in or affecting commerce.”\textsuperscript{17} The 1938 Act gave the FTC general authority to regulate food and drug advertising under Section 5, as well as express authority under newly-added Section 12, which prohibits false advertising that is intended to or likely to induce the purchase of food, drugs, devices, services, or cosmetics.\textsuperscript{18}

The early versions of the FDCA and FTC Act did not differentiate between prescription and OTC drugs. No such distinction existed until 1951, when Congress enacted the Durham-Humphrey Amendments to the FDCA.\textsuperscript{19} These amendments created a separate category for drugs that cannot be safely used without medical supervision.\textsuperscript{20}

\textbf{B. The Kefauver-Harris Amendments to the FDCA}

In 1962, Congress passed the Kefauver-Harris amendments to the FDCA. The amendments were spurred by the Thalidomide tragedy in the early 1960s.\textsuperscript{21} Use of the drug led to thousands of birth defects among European children in the 1950s, until it was withdrawn in 1961.\textsuperscript{22} Although the drug was never approved for use in the U.S. by the FDA, the drug had been distributed to some physicians for experimental purposes—a practice which was “lightly regulated.”\textsuperscript{23} Public outcry over this tragic event and concern that manufacturers were exposing people to potentially harmful drugs during clinical testing “served as a catalyst of the enactment of the 1962 drug amendments.”\textsuperscript{24}

\begin{itemize}
  \item \textsuperscript{17} 15 U.S.C. § 45(a)(1).
  \item \textsuperscript{18} 15 U.S.C. § 52(a)(1).
  \item \textsuperscript{19} Schwartz, supra note 4, at 339.
  \item \textsuperscript{20} Id.
  \item \textsuperscript{22} Id.
  \item \textsuperscript{23} Id.
  \item \textsuperscript{24} Id. at 1051.
\end{itemize}
The Kefauver-Harris amendments transferred regulatory authority over prescription drug advertising from the FTC to the FDA. They also required prescription drug manufacturers to provide information about side effects, contraindications, and effectiveness in all advertisements and prohibited marketing for non-FDA approved indications (or “off-label” marketing). William Goodrich, then the Assistant General Counsel for Food and Drugs at the U.S. Department of Health, Education, and Welfare, explained that the 1962 amendments overall sought to improve the quality, reliability, and safety of drugs through a variety of requirements, including more and better data on safety and substantial evidence to support efficacy claims; a system to monitor marketed drugs, including reports of adverse events; and “a better system of control over prescription drug advertising and promotional material,” so that physicians would receive accurate and balanced information about a drug’s effectiveness, side effects and contraindications.

The legislative history indicates that when it transferred authority from the FTC to the FDA, Congress acknowledged that prescription drug advertising is directed primarily at educated physicians, not consumers. For instance, a June 27, 1961 Senate report states that “[i]n the case of ethical drugs—those sold under prescription—the brunt of promotion effort is directed to the prescribing physician.” The report also noted several unique aspects of the prescription drug industry, including the “critical bearing of drugs on public health and welfare,” and the “negation of consumer choice” when consumers must rely entirely on a prescription from their physician. The decision to transfer authority from the FTC to the FDA likely also was influenced by an overall desire for regulatory effectiveness that would come from the FDA’s administrative expertise in evaluating drug safety and effectiveness claims.

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28 Palumbo, supra note 25, at 427.
29 Id. at 427 n.29 (citation omitted).
Since the Kefauver-Harris amendments became effective, the FTC has consistently deferred to the FDA’s jurisdiction over prescription drug advertising. One series of FTC actions spanning the time before and after Congress passed the amendments shows how they changed FTC’s approach. In 1960, the FTC charged Pfizer with violating Section 12 of the FTCA by sending misleading advertising materials to doctors regarding the prescription drug Enarax.32 In its initial opinion issued in August, 1962, the hearing examiner found the challenged statements to be false, but dismissed the FTC complaint on the ground that the statements were not material.33 While the matter was pending before the FTC on appeal, Congress amended the FDCA, giving the FDA primary jurisdiction over prescription drug advertising. The FTC ordered the matter re-argued on the question whether the amendment covered the acts and practices alleged in the complaint and invited the FDA to weigh in.34 After the FDA confirmed that it believed the newly amended FDCA gave it jurisdiction over the advertising at issue,35 the FTC agreed to defer to the FDA, stating:

Congress, in the Drug Amendments of 1962, desired to avoid both regulatory gaps and regulatory conflicts in the policing of prescription-drug advertising by the [FTC] and the [FDA]. Accordingly, since the FDA has asserted jurisdiction under Section 502(n) of the advertisements challenged in the Commission’s complaint, the Commission will not proceed further in this matter, but will set aside the initial decision and dismiss the complaint without an adjudication of the allegations of the complaint. Should the FDA’s assertion of jurisdiction subsequently prove unfounded, in part or in whole, the Commission will take such further action in this area as may be warranted in the public interest.36

The FTC nevertheless noted that the complaint was brought solely under Section 12 of the FTCA, and not Section 5.37 The FTC suggested that this might leave room for additional FTC action because “[t]he Drug Amendments of 1962 were clearly not intended to repeal the Commission’s authority under Section 5 to

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33 Id. at 108-109.
34 Id. at 110-111.
35 Id.
36 Id. at 111.
37 Id.
proceed,” but FTC action would only be anticipated “where appropriate to prevent any regulatory gap against unfair or deceptive representations in the marketing of prescription drugs.”

In 1971, this initial recognition of the appropriate FTC deference to the FDA was formalized in the form of a “Memorandum of Understanding” (“MOU”) to make explicit the FDA’s primary authority over prescription drug advertising. The MOU confirms that the FDA has primary responsibility for the labeling of foods, drugs, devices and cosmetics, while the FTC has primary responsibility for the advertising of foods, over-the-counter drugs, nonrestricted medical devices, and cosmetics. Investigations of the same matter by both agencies are limited to “those highly unusual situations where . . . the public interest requires two separate proceedings.” To avoid duplication and promote consistently, the two agencies are required to communicate in situations where the same or similar claims are made in both labeling and advertising, or when printed materials may be considered both labeling and advertising.

III. FDA and FTC Regulation of Drug Advertising

A. FDA Requirements for Prescription Drug Advertisements

In order to exercise its authority over prescription drug advertising, the FDA promulgated extensive regulations detailing the requirements drug companies must follow for advertising prescription drugs. Although Congress precluded the FDA from requiring pre-approval of all advertisements in response to First Amendment concerns, Congress saw value in strict agency oversight of drug advertisements. Congress therefore required the FDA to adopt regulations establishing a “safe harbor” for pre-submitted advertisements that are approved by the FDA. If the FDA believes a submitted advertisement is

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38 Id..
41 Id.
42 Id.
44 Id.
false and misleading, or otherwise fails to follow FDA’s requirements, the FDA must notify the company and allow “a reasonable time” for it to be corrected.45

FDA regulations require that certain information be included in all prescription drug advertisements. For example, advertisements must include: (1) the generic name and brand name (if applicable) of the drug, (2) the formula showing each ingredient quantitatively, and (3) safety and efficacy information.46 Moreover, prescription drug advertisements: (1) cannot be false or misleading; (2) must present a “fair balance” of information about the risks and benefits of using the drug; (3) must contain “facts” that are “material” to the product’s advertised uses; and (4) in general, the advertisement’s “brief summary” of the drug must include every risk from the product’s approved labeling.47 The regulations include a detailed, but non-exclusive, 20-factor list of reasons why “[a]n advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading.”48 This is followed by a list of 13 additional reasons why an advertisement “may be false, lacking in fair balance, or otherwise misleading.”49 As at least one court has noted, “[t]he degree of discretion inherent in the regulations demonstrates that the FDA envisioned itself occupying an ongoing and extensive role in the supervision of prescription drug advertising.”50

The appropriate presentation of risk information in advertising materials is particularly important to the FDA. In May 2009, the FDA issued a draft “Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion.”51 The draft guidance states that “FDA believes it is critically important to disclose risk information in prescription drug and medical device promotion appropriately and effectively to healthcare professionals and consumers.”52 The draft guidance cautions:

48 Id. § 202.1(e)(6)(i)-(xx).
49 Id. § 202.1(e)(7)(i)-(xiii) (emphasis added).
52 Id. at 2.
Effectively disclosing risk information also requires a consideration of whether an advertisement or promotional material over warns. For example, a drug advertisement that includes a listing of side effects that are not included in the drug’s approved labeling may lead to under-emphasis of the most important and serious risks. FDA takes care to ensure that important risk information is included in the drug’s approved labeling, and sponsors have an obligation to update their labeling with appropriate new safety information. 21 CFR 201.57(c)(6); 201.80(e). Nothing in this guidance should be construed as recommending that the sponsor of a drug include in advertising or promotional materials risk information not in the product’s approved labeling or appropriate for inclusion in the labeling. See 73 Fed. Reg. 2848, 2851 (January 16, 2008).53

Other areas of concern with respect to prescription drug advertising and promotion include overstating the effectiveness of a drug, promoting off-label uses, and making misleading drug comparisons.54

If the FDA believes that a prescription drug advertisement omits required information or is false or misleading, it may take a variety of enforcement actions. It may send an “untitled letter” to the company, warning that the advertisement violates the FDCA or is false or misleading, and asking the company to withdraw the offending ad. The FDA may also send a “warning letter,” for “violations of regulatory significance,” i.e., “those violations that may actually lead to enforcement action if not promptly and adequately corrected.”55 Warning letters are designed to achieve “prompt voluntary compliance with” the law.56 In addition to warning letters, the FDA has a variety of other enforcement actions available to it, including recall, seizure, injunction, administrative detention, civil money penalties and criminal prosecution.57

53 Id. at 2 n.5.
56 Id.
57 Id.; 21 U.S.C. § 333(g).
B. FTC’s Determination of Deception and Substantiation

As would be expected given its consumer protection mission, when analyzing potentially deceptive advertisements, the FTC is primarily concerned with protecting consumers. The FTC’s Policy Statement on Deception, issued in 1983, clarified the agency’s approach to determinations of allegedly deceptive trade practices. Through this Policy Statement, the FTC established three important principles it will consider when determining whether an advertisement is deceptive. First, there must be a representation or omission that is likely to mislead the consumer. Second, the advertisement must be judged from the perspective of a reasonable consumer, and the knowledge and sophistication of the relevant audience must be considered when determining whether an advertisement is deceptive or misleading. Third, the misrepresentation or omission must be “material” in that it is likely to affect the consumer’s conduct or decision with regard to a product or service.58

Advertisements that are inadequately substantiated may also be deceptive.59 The FTC Policy Statement Regarding Advertising Substantiation provides that advertisements making specific claims must be supported by a “reasonable basis” before they are disseminated to the public.60 “Reasonable basis” means objective evidence that supports the claims. Express claims of substantiation require the advertiser to have “at least the advertised level of substantiation,” while implied claims require the advertiser have “the amount and type of substantiation the ad actually communicates to consumers.”61

Advertisements that make health or safety claims must be supported by “competent and reliable scientific evidence,” meaning tests, studies, or other scientific evidence that has been evaluated by people qualified to review it. Any tests or studies “must be conducted using methods that experts in the field

59 Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 227 (3rd Cir. 1990) (“The FTC has the authority under Sections 5 and 12 of the [FTCA] to find that an inadequately substantiated advertising claim regarding a non-prescription drug is deceptive or misleading, and thus illegal”).
61 Id.
accept as accurate.”62 Consistent with these policy statements, a recent FTC warning letter challenging the marketing of supplements for the treatment of various diseases includes the following statement regarding what constitutes adequate substantiation: “[I]t is unlawful under the FTC Act. . . to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made.”63 And in Thompson Medical Company, Inc., discussed infra, the ALJ stated that “the obvious need for regulatory harmony and uniform standards governing the issue of OTC drug efficacy dictates that the same level of scientific evidence required by the FDA for OTC drug labeling/marketing be demanded by the FTC for OTC drug advertising with respect to the issue of efficacy.”64

In Bristol-Myers Co. v. FTC,65 however, the court differentiated between the FDA’s review of clinical efficacy and safety data and the FTC’s advertising substantiation requirements. The FTC had upheld an ALJ finding that Bristol made numerous misrepresentations about the efficacy and lack of side effects of its OTC analgesics Bufferin and Excedrin.66 The court denied Bristol’s petition for review of the FTC’s order prohibiting the company from making various representations, including “comparative establishment claims asserting the superior effectiveness or freedom-from-side-effects of its OTC internal analgesics without proof consisting of ‘two or more adequate and well-controlled clinical investigations’” or “any therapeutic performance or freedom-from-side-effects claim” without a “reasonable basis” consisting of “competent and reliable

64 104 F.T.C. 648 at *54 (1984). See also James M. Serafino, Developing Standards for Health Claims-The FDA and the FTC, 47 Food & Drug L.J. 335, 337, 341-43 (1992) (discussing cases) (“Despite the primary responsibility of the FTC to regulate advertising of products regulated by the FDA, the FTC has traditionally used the expertise of the FDA in evaluating advertising claims for OTC drugs, cosmetics, foods, and devices.”); see also David C. Vladeck, Director FTC Bureau of Consumer Protection, Priorities for Dietary Supplement Advertising Enforcement (Oct. 22, 2009) at 11, available at http://www.ftc.gov/speeches/vladeck/091022vladeckcrnspeech.pdf (“we will also seek orders [regarding the amount and type of scientific evidence required to substantiate health claims] that harmonize with laws and regulations administered by the FDA.”).
65 738 F.2d 554 (2nd Cir. 1984).
66 Id. at 557 (citation omitted).
scientific evidence” supporting the claim.67 Rejecting Bristol’s reliance on FDA regulations approving similar claims for OTC internal analgesics, the court stated:

the FDA’s regulations are concerned almost exclusively with absolute claims. Part I of the Commission’s Order here deals solely with comparative establishment claims. Therefore almost nothing would be gained by allowing the FDA’s regulations to be used as requested by Bristol. Moreover FDA determinations are usually complex and subject to varying interpretations. To allow Bristol to rely on its evaluation of these determinations could conceivably lead to more deceptive advertisements and to more disputes with the FTC.”68

It would not be correct to say that the decision stands for a categorical rule regarding comparative claims, but it is important precedent in for OTC advertising claims.

C. The FDA’s Specialized Expertise

Although the FTC has suggested that it interprets the FDCA and FTCA as giving it some legal authority over prescription drug advertising, in reality the FTC has not attempted to exercise jurisdiction over any prescription drug advertising since the MOU has been in place.69

The transfer of primary jurisdiction over prescription drug advertising from the FTC to the FDA indicates Congress’s recognition of the FDA’s unique and specialized expertise in this area.70 For example, a recent law giving the FDA regulatory authority over tobacco products states that “[n]either the [FTC] nor any other Federal agency except the [FDA] possesses the scientific expertise needed to implement effectively all provisions of the Family Smoking Prevention

67 Id.
68 Id. at 559-60 (emphasis added).
69 See In the Matter of Chas. Pfizer & Co., Inc., 66 F.T.C. 1000 (1964); see also FTC Policy Statement on Deception, supra note 58 (stating that, while Section 502(n) of the FDCA gave the FDA primary jurisdiction over prescription drug advertising, the section revoked FTC’s authority only with regard to three areas: the drug name, its formula, and the summary information regarding the drug’s effectiveness and side effects).
and Tobacco Control Act.” And the FTC itself recognizes that it does not have the same “level of scientific and technical knowledge” as the FDA.\footnote{71 Pub. L. No. 111-31 § 45, 123 Stat. 1776 (2009).}

The FTC has also acknowledged differences between the FTC and the FDA that justify entrusting the FDA with authority over prescription drug advertising. As one FTC Commissioner cogently explained:

Although the FTC’s mission is to protect consumer sovereignty, this sovereignty can be limited by various legal prohibitions. Leaving aside special rules for the protection of children, even consenting adults cannot buy and sell whatever they want. Specifically, adults do not have unfettered freedom to buy certain drugs that are either illegal or obtainable only with a doctor’s prescription. These substantive limitations are not the Commission’s business, and should not be; the FTC has expertise about consumer perception, not consumer health.\footnote{72 Deborah Platt Majoras, Chairman, FTC, Food for Thought: The FTC and Market Influences on Consumer Health (Apr. 12, 2007) at 2, available at http://www.ftc.gov/speeches/majoras/070412FDL_DK.pdf.}

Both Congress and the FTC have thus explicitly recognized the FDA’s superior expertise for the evaluation of prescription drug labeling and advertising.

In contrast, in cases involving allegedly false or deceptive advertising of over-the-counter drugs and dietary supplements, the FTC and FDA have often instituted parallel proceedings and courts have regularly held that such concurrent proceedings are proper. In the early 1970s, for example, the FDA began a significant undertaking to evaluate the safety and efficacy of 26 broad categories of OTC drugs, such as cold remedies, and to prepare monographs for each drug category establishing “the conditions under which the drugs involved are generally recognized as safe and effective and not misbranded.”\footnote{73 Thomas B. Leary, The Ongoing Dialogue Between the Food and Drug Administration and the Federal Trade Commission, 59 Food & Drug L.J. 209, 212 (2004) (emphasis added).} At the same time, the FTC filed a complaint against Warner-Lambert, alleging that its advertising for Listerine contained false and misleading statements about

Listerine’s effectiveness in treating colds and sore throats. Warner-Lambert sought to restrain both the FTC from taking further proceedings with regard to Listerine and the FDA from further proceedings with its review of all OTC cold remedies, unless the agencies took steps to avoid simultaneous, duplicative proceedings. Warner-Lambert argued, among other things, that such duplicative proceedings would violate the 1971 MOU. The court held that the proceedings were not duplicative, as the FTC proceeding was an adversarial proceeding involving only Warner-Lambert, while the FDA proceeding was a rule-making proceeding involving “thousands of manufacturers” of OTC drugs. The court noted that in signing the MOU, the FDA and FTC intended to limit “proceedings where the FTC would file a complaint seeking a cease-and-desist order on the basis of false and misleading claims, and the FDA would institute a seizure proceeding seeking to condemn the product on the same grounds.” The court further held that Supreme Court precedent was clear that “the same issues and parties may be proceeded against simultaneously by more than one agency,” and thus that concurrent FDA-FTC proceedings were proper in any event.

Notably, courts have held that the FDA does not have jurisdiction over advertising of OTC drugs. In Thompson Medical Co. v. FTC, the FTC charged the manufacturer of the OTC topical pain reliever Aspercreme with violations of sections 5 and 12 of the FTC Act. The Commission found that Thompson’s advertising for Aspercreme was false and misleading, ordered Thompson to cease making unsubstantiated claims about Aspercreme’s effectiveness, and required the company to disclose that Aspercreme does not contain aspirin in the product’s labeling and advertising. Thompson argued that the FTC’s action was “not in the public interest” because the FDA, which is charged with evaluating and regulating drugs, was concurrently engaged in a review of OTC drugs. Thus, Thompson argued, the FDA “should be allowed exclusive regulatory authority over the marketing and labelling [sic] of OTC drugs while its

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75 Id. at 950.
76 Id.
77 Id. at 951.
78 Id. at 952.
79 Id.
80 Id. at 952-53.
81 791 F.2d 189 (D.C. Cir. 1986).
82 Id. at 190.
83 Id. at 192.
review is pending." The court rejected this argument, noting that “ours is an age of overlapping and concurring regulatory jurisdiction.” The court stated that “[t]he FTC has substantial expertise in evaluating claims of drugs’ absolute and comparative efficacy, and in assessing whether advertisements are misleading and deceptive.” Moreover, the court held that the FDA would not have occasion to consider the comparative efficacy claims which the FTC considered misleading. “Rather, the FDA’s evaluation of OTC drugs only involves a determination of the safety and efficacy of individual drugs . . . . Hence no conceivable doctrine of deference or expertise would justify awaiting the results of the FDA’s over-the-counter drug evaluation program.”

While the FDA and the FTC’s jurisdiction over drug labeling and advertising clearly overlaps in some areas, and action by one agency does not necessarily preclude action by the other, the principle of res judicata bars one agency from reaching a different result from the other under the same facts. Thus, an order of the FTC prohibiting a distributor of “Gizzard Capsules,” a remedy for worms in poultry, from making certain representations regarding the therapeutic value, efficacy, and effect of the product in advertising, was vacated in George H. Lee Co. v. FTC, where it appeared that in a prior government proceeding alleging the product was misbranded in violation of the FDCA, an adjudication had been made in favor of the distributor. The court in the prior proceeding rejected the government’s claim that the distributor’s representations were false because the product did not have the claimed therapeutic qualities. In the subsequent FTC proceeding, the court held that the FTC was bound by the result of the first determination, because the underlying issue in both proceedings was the same.

IV. State “Regulation” of Drug Advertising Through Litigation

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84 Id.  
85 Id.  
86 Id. at 193.  
87 791 F.2d at 193 (citation omitted)  
88 113 F2d 583 (8th Cir. 1940).  
89 Id. at 585.  
90 Id. See also, United States v. Willard Tablet Co., 141 F2d 141 (7th Cir. 1944) (dismissing a condemnation action by the government alleging that the labeling of defendant’s tablets was false in violation of the FDCA where the statements relied upon by the government in support of its misbranding claim were identical to statements that had been approved by the FTC in an earlier proceeding).
Today, every state in the country has some form of state consumer protection statute.\textsuperscript{91} Often referred to as “little FTC Acts,” all of these statutes are related to the FTC Act, and many are directly modeled after the FTC Act.\textsuperscript{92} Those that are modeled after the FTC Act broadly prohibit unfair or deceptive acts or practices in trade or commerce and typically encourage litigants to act as “private attorneys general.”\textsuperscript{93} Twenty-nine states explicitly provide that their consumer protection statutes should be construed consistently with the FTC Act either by statute or case law.\textsuperscript{94}

\textsuperscript{91} Alan Brown and Larry Hepler, Comparison of Consumer Fraud Statutes Across the Fifty States, 55 FDCC Quarterly, Spring 2005 at 263.

\textsuperscript{92} Id. at 263, 269. See, e.g., CAL. BUS. & PROF. CODE § 17200; CONN. GEN. STAT. ANN. § 42-110(b); FLA. STAT. ANN. § 501.204; GA. CODE ANN. § 10-1-391; HAW. REV. STAT. ANN. § 480-2; LA. REV. STAT. ANN. § 51:1405; ME. REV. STAT. ANN. tit. 5, § 207; MASS. GEN. LAWS ANN. ch. 93A, § 1; MONT. CODE ANN. § 30-14-103; NEB. REV. STAT. §§ 59-1601 to 59-1623; N.Y. GEN. BUS. LAW § 349; N.J. GEN. STAT. § 75-1.1; OHIO REV. CODE ANN. § 1345.02; R.I. GEN. LAWS § 6-13.1-2, 1-3; S.C. CODE ANN. § 39-5-20; VT. STAT. ANN. tit. 9, §§ 2451, 2453; WASH. REV. CODE § 19.86.920.

\textsuperscript{93} Id. at 269.

\textsuperscript{94} See, e.g., ALA. CODE §8-19-6 (“[I]n construing Section 8-19-5, due consideration and great weight shall be given where applicable to interpretations of the [FTC] and the federal courts relating to [§5], as from time to time amended.”); ALASKA STAT. § 45.50.545 (“[D]ue consideration and great weight should be given the interpretations of [§5] . . . .”); ARIZ. REV. STAT. ANN. § 44-1522(c) (“[T]he courts may use as a guide interpretations given by the [FTC] and the federal courts to 15 United States Code §§ 45, 52 and 55(a)(1).”); CONN. GEN. STAT. ANN. § 42-110b (“[T]he commissioner and the courts of this state shall be guided by interpretations given by the [FTC] and the federal courts to [§5], as from time to time amended.”); FLA. STAT. ANN. § 501.204(2) (“[D]ue consideration and great weight shall be given to the interpretations of the [FTC] and the federal courts relating to [§5] as of July 1, 2013.”); GA. CODE ANN. § 10-1-391(b) (“It is the intent of the General Assembly that this part be interpreted and construed consistently with the interpretations given by the [FTC] in the federal courts pursuant to [§5] . . . .”); HAW. REV. STAT. § 480-2(b) (“[T]he courts and the office of consumer protection shall give due consideration to the rules, regulations, and decisions of the [FTC] and the federal courts interpreting[§5], as from time to time amended.”); IDAHO CODE ANN. § 48-604 (“[D]ue consideration and great weight shall be given to the interpretation of the [FTC] and the federal courts relating to [§5], as from time to time amended . . . .”); 815 ILL. COMP. STAT. ANN. 505/2 (“In construing this section consideration shall be given to the interpretations of the [FTC] and the federal courts relating to [§5].”); Gour v. Daray Motor Co., 373 So. 2d 571 (La. Ct. App. 1979) (holding federal decisions & FTC interpretations are appropriate sources of precedent); ME. REV. STAT. ANN. tit. 5 § 207(1) (“[T]he courts will be guided by the interpretations given by the Federal Trade Commission and the Federal Courts to [§5].”); MD. CODE ANN., COM. LAW § 13-105 (“[I]n construing the term ‘unfair or deceptive trade practices’, due consideration and weight shall be given to the interpretations of [§5] by the [FTC] and the federal courts.”); MASS. GEN. LAWS ANN. ch. 93A § 2(b) (“[T]he courts will be guided by the interpretations given by the [FTC] and the Federal Courts to [§5].”); MISS. CODE ANN.
State consumer protection laws are intended to protect individual consumers and businesses from unfair methods of competition and deceptive practices in trade or commerce. They serve an important purpose in protecting consumers from things like pyramid schemes, fraudulent telemarketing, and false or misleading advertising. State consumer protection statutes may have relaxed causation or reliance requirements, often provide for recovery of attorneys’ fees, may permit treble damages for willful, knowing or bad faith violations, and may allow state authorities to obtain injunctive and, sometimes, monetary relief. As a result, actions based on these statutes have become increasingly attractive to plaintiffs.

§ 75-24-3(c) (“[T]he courts will be guided by the interpretations given by the Federal Trade Commission and the federal courts to [§5.]”); MONT. CODE ANN. § 30-14-104(1) (“[D]ue consideration and weight shall be given to the interpretations of the [FTC] and the federal courts relating to section [§5], as amended.”); N.H. REV. STAT. ANN. § 358-A:13 (“[C]ourts may be guided by the interpretation and construction given [§5], by the [FTC] and the federal courts.”); N.M. STAT. ANN. § 57-12-4 (“[T]he courts to the extent possible will be guided by the interpretations given by [the FTC] and the federal courts.”); Lefkowitz v. Colo. St. Christian Coll. of Church of Inner Power, Inc., 346 N.Y.S.2d 482 (N.Y. Sup. Ct. 1973); Marshall v. Miller, 276 S.E.2d 397 (N.C. 1981) (holding that federal precedent interpreting §5 may be used to interpret the North Carolina Little FTC Act); OHIO REV. CODE ANN. § 1345.02(c) (“[T]he court shall give due consideration and great weight to [FTC] orders, trade regulation rules and guides, and the federal courts’ interpretations of[§5], as amended.”); Commonwealth v. Hush-Tone Indus., Inc., 4 Pa. Commun. 1, 21 (1972) (holding federal decisions & FTC interpretations are appropriate sources of precedent); R.I. GEN. LAWS § 6-13.1-3 (“[D]ue consideration and great weight shall be given to the interpretations of the [FTC] and the federal courts relating to [§5], as from time to time amended.”); S.C. CODE ANN. § 39-5-20(b) (“[I]n construing paragraph (a) of this section the courts will be guided by the interpretations given by the [FTC] and the Federal Courts to [§5], as from time to time amended.”); TENN. CODE ANN. § 47-18-115 (“[T]his part shall be interpreted and construed consistently with the interpretations given by the [FTC] and the federal courts pursuant to [§5].”); TEX. BUS. & COM. CODE ANN. § 17.46(c)(1) (“[C]ourts to the extent possible will be guided by Subsection (b) of this section and the interpretations given by the [FTC] and federal courts to [§5].”); UTAH CODE ANN. § 13-11-2(4) (“To make state regulation of consumer sales practices not inconsistent with the policies of [§5] relating to consumer protection.”); VT. STAT. ANN. tit. 9 § 2453(b) (“[I]n construing subsection (a) of this section, the courts of this state will be guided by the construction of similar terms contained in [§5.]”); WASH. REV. CODE ANN. § 19.86.920 (“[T]he courts be guided by final decisions of the federal courts and final orders of the [FTC] interpreting the various federal statutes dealing with the same or similar matters . . . .”); W. VA. CODE ANN. § 46A-6-101(1) (“It is the intent of the legislature that, in construing this article, the courts be guided by the interpretation given by the federal courts to the various federal statutes dealing with the same or similar matters.”).

In particular, in recent years private plaintiffs and state AGs have been bringing cases against pharmaceutical companies alleging that prescription drug advertising and promotional materials violate state consumer protection acts. Relying on broad state statutes that mirror the FTC Act, plaintiffs, with court approval, have increasingly been seeking to impose liability on pharmaceutical companies for conduct that is regulated by the FDA.


As one particularly notable example, West Virginia Attorney General Darrell McGraw filed a lawsuit against Janssen Pharmaceuticals seeking to recover penalties for, first, Janssen’s use of a file card to promote the prescription pain patch Duragesic to doctors, and second, a letter sent to health care providers containing its scientific opinion of the epidemiological evidence regarding the comparative risk of diabetes in Risperdal and other antipsychotics. McGraw alleged that the communications violated the West Virginia Consumer Credit and Protection Act (“CCPA”) and asked for a $5,000 civil penalty per “violation,” contending that each copy of the file card and letter sent to West Virginia health care providers was a separate violation. McGraw did not allege that anyone was actual misled or any damage caused, and he stipulated that he would not offer evidence of harm at trial.

Janssen argued that the CCPA should not apply to the challenged communications, noting that the West Virginia Legislature has directed that courts construing the CCPA “be guided by the interpretation given by the federal courts to” the Federal Trade Commission Act (the “FTCA”), 15 U.S.C. § 45. Janssen therefore urged the court to read the CCPA in a manner consistent with the federal courts’ approach to the FTCA and find that, like the FTCA, it does not regulate communications between drug companies and doctors. Instead,

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96 West Virginia, ex. rel. McGraw v. Johnson & Johnson, Civil Action No. 04-C-156 (Brooke Cnty., W. Va.).
97 See W. VA. CODE § 46A-6-101(1); see also § 46A-6-103 (rules and regulations promulgated by Attorney General under CCPA “shall conform as nearly as practicable with the rules, regulations and decisions of the federal trade commission and the federal courts in interpreting the provisions of the ‘Federal Trade Commission Act,’ as from time to time amended”).
Janssen further argued, the trial court should hold that such communications are regulated exclusively by the FDA, without interference from the FTC.  

One of the issues that arose and was argued at the same time was the concern that even if the CCPA were otherwise unclear, the regulatory context at issue in the case—FDA oversight of prescription drug marketing—would caution against an expansive interpretation of the CCPA that would apply it to communications to doctors and other health care providers. The FDA’s authority over prescription drugs is both comprehensive and pervasive. As summarized above, Congress has charged the agency with reviewing all available scientific evidence and determining precisely how the risks and benefits of a prescription drug must be conveyed on its label. The agency’s authority extends to the marketing of prescription drugs, an area covered by myriad regulations and requirements depending on the claims made and the product advertised. It is therefore hard to imagine justification for interpreting a state consumer protection statute expansively to require either additional or varying state-law-based requirements on top of the specific and comprehensive requirements imposed under federal law and enforced through the FDA’s comprehensive authority and specialized expertise.

The circuit court rejected Janssen’s arguments, holding the CCPA applicable to communications with doctors regarding prescription drugs and rejecting any level of deference, notwithstanding the fact that the FTC would not have stepped into the FDA’s regulatory zone. In doing so, the circuit court similarly rejected the argument that its ruling would undermine the FDA’s ability to regulate through cooperative and informal means, as it had done with respect to the communications at issue, negotiating resolution and correction of what it saw as potential regulatory violations without adjudication.

**B. Preemption and State Consumer Fraud Claims**

The court’s ruling arguably ran directly afool of the United States Supreme Court preemption decision in *Buckman v. Plaintiffs’ Legal*

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99 See, e.g., 21 C.F.R. § 202.1; id. at 314.81(b)(3)(i).
Committee. The plaintiffs in *Buckman* sued a consulting company, alleging that the company had defrauded the FDA into approving the device that injured them. All nine Justices agreed that the claims were preempted. The Court observed that “the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.” As the Court explained, the FDCA “amply empowers the FDA to punish and deter fraud against the Administration,” and the FDA uses that power to “achieve a somewhat delicate balance of statutory objectives”: helping beneficial drugs and devices to come on the market quickly while ensuring that consumers are protected from dangerous products. But that balance “can be skewed by allowing fraud-on-the-FDA claims under state tort law.” Such claims not only create “an incentive to submit a deluge of information that the Administration neither wants nor needs,” but also discourage companies from seeking approval of beneficial drugs and devices in the first place. Thus, state fraud-on-the-FDA claims alter how FDA-regulated companies interact with the FDA in ways the agency itself is powerless to counteract. And because such claims interject the states into the FDA regulatory process, they are preempted.

*Wyeth v. Levine*, 555 U.S. 555 (2009), is no cure-all for the serious preemption issues presented in *McGraw* and other cases where AGs have brought similar claims against pharmaceutical manufacturers. The states have often cited *Wyeth* in opposition to preemption arguments, but the decision does not withstand the weight placed upon it because it did not change the analysis under § 337(a) or *Buckman*. Notably, *Wyeth* concerned only whether the FDA’s approval of a prescription drug label preempted a traditional state-law claim seeking compensation for injuries that resulted from a prescription drug manufacturer’s breach of the state-law duty to adequately warn of the risks associated with its products. The Court rejected the manufacturer’s claim of

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101 See id. at 343.
102 Id. at 347.
103 Id. at 348.
104 Id.
105 Id. at 350-51.
106 555 U.S. at 557-58.
impossibility preemption because the manufacturer failed to offer “clear
evidence that the FDA would not have approved a change to [the] label” to add
the information that the jury necessarily found was not disclosed.\textsuperscript{107} And in
ruling that the state-law claim did not create an obstacle to the enforcement of
federal law, the Court emphasized “[s]tate tort suits uncover unknown drug
hazards and provide incentives for drug manufacturers to disclose safety risks
promptly” and “also serve a distinct compensatory function that may motivate
injured persons to come forward with information.”\textsuperscript{108}

State efforts to directly or indirectly enforce FDA regulations stand in
stark contrast to \textit{Wyeth} and the traditional tort-law compensation claim
addressed there. \textit{Wyeth} did nothing to change the prohibition on state
enforcement of FDA regulations. \textit{Wyeth} in no way undermined either § 337(a)’s
express preemption provision or \textit{Buckman}’s declaration that a state law cause of
action is preempted if it creates an “extraneous pull on the scheme established
by Congress.”\textsuperscript{109} It cannot be read to silently overturn an express preemption
statute, and in any event cites \textit{Buckman} as good law, distinguishing \textit{Wyeth} only
as a case that does not involve “state regulation of health and safety.”\textsuperscript{110} In that
respect, \textit{Wyeth}’s conclusion of no preemption rests in part on the conclusion
that the products liability suit before it fell within “a field which the States have
traditionally occupied,” and that state tort suits “serve a distinct compensatory
function that may motivate injured persons to come forward with
information.”\textsuperscript{111} But neither of those is true in state efforts like the one at issue
in \textit{McGraw} and subsequent cases. Most significantly, those suits serve \textit{no}
compensatory objective. Instead, the states are using FDA regulations to
attempt to prove alleged state law violations. But that usurps the FDA’s ability
to enact policy through the calibrated exercise of its enforcement authority.

In this respect, the Supreme Court’s recent decision in \textit{Arizona v. United
States}\textsuperscript{112} is instructive. In \textit{Arizona}, the Court invalidated as preempted most of a
state law that sought to enforce federal immigration law. The Court first
invalidated a provision that made it a state misdemeanor for aliens to fail to

\begin{itemize}
\item \textsuperscript{107} \textit{Id.} at 571-72.
\item \textsuperscript{108} \textit{Id.} at 579.
\item \textsuperscript{109} 531 U.S. at 353.
\item \textsuperscript{110} 555 U.S. at 565 n.3.
\item \textsuperscript{111} 555 U.S. at 565, 578.
\item \textsuperscript{112} 567 U.S. \textit{____}, No. 11-182 (June 25, 2012)
\end{itemize}
carry immigration documents required by federal law.\footnote{113} In so doing, the Court rejected the state’s argument that its law was not preempted because it had “the same aim as federal law and adopt[ed] its substantive standards.”\footnote{114} The Court noted that “[p]ermitting the State to impose its own penalties for the federal offenses here would conflict with the careful framework Congress adopted,” citing \textit{Buckman} approvingly.\footnote{115} According to the Court, the state could not “bring criminal charges against individuals for violating a federal law” because such charges might conflict with policy decisions by “federal officials in charge of the comprehensive scheme” that certain “prosecution[s] would frustrate federal policies.”\footnote{116}

The Court in \textit{Arizona} also invalidated a state law making it a misdemeanor for an alien to work without proper federal authorization. Noting that the comprehensive federal regime governing the ability of aliens to work did “not impose federal criminal sanctions on the employee side,” the Court found the state’s attempt to create such criminal penalties preempted.\footnote{117} As the Court observed, “conflict in [enforcement] technique can be fully as disruptive to the system Congress enacted as conflict in overt policy.”\footnote{118} Because “Congress decided it would be inappropriate to impose criminal penalties on aliens who seek or engage in unauthorized employment” a state law creating such criminal penalties stands as “an obstacle to the regulatory system Congress chose.”\footnote{119}

The Court then ruled that a provision permitting a warrantless arrest of any person believed on probable cause to have committed an offense rendering him removable was preempted.\footnote{120} According to the Court, this was inconsistent with Congress’s scheme because it allowed state officials to arrest aliens for immigration violations “without any input from the Federal Government about whether an arrest is warranted in a particular case.”\footnote{121} And that in turn could permit a state “to achieve its own immigration policy,” perhaps resulting in

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  \item \footnote{113} Slip op. at 9.
  \item \footnote{114} \textit{id.} at 10-11.
  \item \footnote{115} \textit{id.} at 11.
  \item \footnote{116} \textit{id.; see also id.} (“Conflict is imminent whenever two separate remedies are brought to bear on the same activity” (internal quotation marks and alteration omitted)).
  \item \footnote{117} \textit{See id.} at 13-15.
  \item \footnote{118} \textit{id.} at 15 (internal quotation marks and alteration omitted).
  \item \footnote{119} \textit{576 U.S.} \textit{____, No. 11-182} at 15
  \item \footnote{120} \textit{id.} at 15-19.
  \item \footnote{121} \textit{id.} at 17.
\end{itemize}
}
“unnecessary harassment of some aliens . . . whom federal officials have determine should not be removed.”122

In the end, the West Virginia Supreme Court of Appeals overturned the McGraw ruling on other grounds. It was then voluntarily dismissed after remand to the trial court and there was never a final decision on the arguments raised by Janssen in the trial court and later reiterated on the appellate level. As a result, the West Virginia experience does not offer guidance for, or any precedent counseling against, the numerous other “little FTC Act” claims that have been filed by State AGs, including claims related to antipsychotics such as Zyprexa and Seroquel, cox-2 inhibitors such as Celebrex and Vioxx, and countless other medications. In these recurring cases, the same issues that were litigated in McGraw are being litigated again all across the country, and more often than not, courts are allowing claims based on the application of state consumer fraud statutes to prescription drug advertising to survive dismissal and proceed to discovery.

C. The Illusory Promise of Safe Harbor

Certain state consumer protection acts contain “safe harbor” provisions which implicitly recognize this issue. For example, the Arkansas Deceptive Trade Practices Act (“ADTPA”) provides that it does not apply to “(1) [a]dvertising or practices which are subject to and which comply with any rule, order, or statute administered by the Federal Trade Commission; . . . [or] (3) [a]ctions or transactions permitted under laws administered by ... [a] regulatory body or officer acting under statutory authority of this state or the United States.”123 The Arkansas Supreme Court recently held that this safe harbor provision barred an ADTPA action alleging that a pharmaceutical company’s advertising for the prescription drug Nexium was false and misleading where the advertising was supported by Nexium’s FDA-approved label.124 The court highlighted the FDA’s unique and expansive role in evaluating prescription drug labeling and advertising.125 In discussing this role, the court quoted directly from an FDA notice:

122 Id.
125 Id. at *10-11.
The major purpose of prescription drug product labeling is to help ensure that prescribing health care professionals have the information necessary to prescribe products in a safe and effective manner. When the agency determines that a sponsor has provided the requisite scientific data to allow marketing of a product in the United States, the approved labeling communicates the conclusions of FDA review of the data in the product's new drug application (NDA). Because the NDA review process provides access to the raw data from clinical trials, the product labeling may provide the only comprehensive, independently reviewed source of medical/scientific information about newly approved products and new indications for older products.\textsuperscript{126}

The court held that “by approving information to be included in the drug labeling, the FDA has determined that the information complies with its rules and regulations” and is not “false or misleading.” Therefore, any advertising statements for an FDA-approved drug that are supported by the label “are not actionable under the ADTPA.”\textsuperscript{127}

But while the Arkansas decision gave appropriate deference to the FDA, this type of reasoning has not been widely adopted, even in the many of the States where legislatures have directed that courts construing their state consumer protection statutes “be guided by the interpretation given by the federal courts to” the FTC Act, as well as “the rules, regulations and decisions of” the FTC.\textsuperscript{128}

\textbf{D. The (very small) Elephant in the Room: Caronia and First Amendment Protection}

Less obvious than the preemption concerns that cast a shadow on AG enforcement efforts, the First Amendment may provide a backstop to runaway assertions of AG power. On this front, the Second Circuit’s long-waited decision
in United States v. Caronia\textsuperscript{129} did not disappoint, but the impact the decision will have in AG cases is uncertain.

On December 3, 2012, the court vacated the criminal conviction of a pharmaceutical representative for alleged violations of the FDCA, holding that the First Amendment did not permit criminalization of the simple act of promoting an off-label use of a prescription drug. The ruling is a setback for the FDA’s efforts to enforce restrictions on off-label promotion, though what impact the case may have on future federal and state actions, including state consumer fraud claims, is an open question.

The facts were straightforward. In 2005, Alfred Caronia was hired as a sales consultant for a pharmaceutical company then known as Orphan Medical, Inc. (“Orphan”) to promote Xyrem, a central nervous system depressant.\textsuperscript{130} Xyrem has potentially serious side effects and was approved by the FDA to treat only two medical conditions—narcolepsy patients who suffered from cataplexy and narcolepsy patients with excessive daytime sleepiness.\textsuperscript{131} The agency required that Xyrem be accompanied by a “black box warning”—the most serious type of warning used for prescription drugs—and permitted only one pharmacy in the country to distribute the drug nationally.\textsuperscript{132}

In connection with his promotional efforts for Xyrem, Caronia began “speaker programs” in which he recruited doctors to discuss the benefits of Xyrem with other doctors.\textsuperscript{133} Subsequently, a government cooperator taped conversations in which Caronia and another doctor promoted off-label uses of Xyrem to potential customers, including for unapproved indications and an unapproved subpopulation.\textsuperscript{134} In those conversations, Caronia noted that Xyrem was only approved for the two types of narcolepsy and that it had not been approved for individuals under the age of sixteen, but also discussed other conditions for which it could be used and said that he knew of instances in which it had been prescribed to people younger than sixteen.\textsuperscript{135}

\textsuperscript{129} 703 F.3d 149 (2d Cir. 2012).
\textsuperscript{130} 703 F.3d at 155.
\textsuperscript{131} Id.
\textsuperscript{132} Id.
\textsuperscript{133} Id. at 156.
\textsuperscript{134} Id.
\textsuperscript{135} Id. at 156-57.
The government charged Caronia with two counts of violating the FDCA: (1) conspiracy to introduce a misbranded drug into interstate commerce (consisting of two prongs: (a) knowingly conspiring to introduce a misbranded drug, and (b) as part of the conspiracy, marketing a drug for unapproved uses knowing that the drug lacked adequate directions and warnings for those uses and where those uses could be dangerous), and (2) introducing a misbranded drug into interstate commerce. Following a jury trial, Caronia was convicted of the first prong of Count 1, but acquitted of Count 2 and of the second prong of Count 1. He then appealed his conviction on the ground that it violated his First Amendment speech rights.

The Second Circuit agreed and vacated the conviction in a 2-1 decision. The majority first dispensed with the government’s argument that Caronia’s speech had only been used as evidence of the intended off-label uses of Xyrem, and not as the conduct prohibited itself. The court found that the government had throughout the trial focused on Caronia’s marketing and promotion activities, that the government had not argued that Caronia had conspired to take any other actions to misbrand Xyrem, and that the jury instructions had indicated that the speech itself could be determinative of guilt.

Having found that Caronia was convicted for his speech, the majority then considered the conviction’s constitutionality. Noting that “the FDCA itself does not expressly prohibit or criminalize off-label promotion,” it held that the court would “decline the government’s invitation to construe the FDCA’s misbranding provisions to criminalize the simple promotion of a drug’s off-label use by pharmaceutical manufacturers and their representatives because such a construction—and a conviction obtained under the government’s application of the FDCA—would run afoul of the First Amendment.” This was so, the majority held, because the government’s interpretation of the misbranding provisions imposed restrictions on speech that were both content-based (because it would only prohibit speech about drug uses that had not been approved by the government) and speaker-based (because it applied only to pharmaceutical manufacturers); as a result, the government’s interpretation of the FDCA was “subject to heightened scrutiny and was ‘presumptively

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136 703 F.3d at 157. The government also charged Gleason and Orphan under the FDCA’s misbranding provisions, and both pled guilty. Id. at 158.
137 Id. at 158-59.
138 Id. at 160-61.
139 Id. at 162.
invalid.” And even under the less stringent standard set out in *Central Hudson Gas & Electric Corp. v. Public Service Commission of N.Y.*, 447 U.S. 557 (1980), which applied intermediate scrutiny to commercial speech restrictions, the majority found that the government’s interpretation of the FDCA could not be justified. Accordingly, it concluded that while the FDA could regulate prescription drug marketing, “the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.”

What effect the *Caronia* decision will have on future enforcement efforts related to off-label promotion—a frequent target of state attorney general consumer fraud claims—is not yet clear. The *Caronia* court was careful to cabin its decision in a number of ways, emphasizing that it applied only to truthful speech and only to drugs for which off-label use was permitted. Most importantly, the court’s ruling applied only to situations in which the speech itself was prohibited; the court did not reach the question whether the government could use off-label promotional speech to prove the intended uses of a drug for the purpose of a misbranding allegation. Because that is the FDA’s usual approach to misbranding claims, it is possible that *Caronia* will have little effect on the agency’s enforcement activities and, in turn, those of the states.

Indeed, it appears the FDA has already embraced that position. It announced in January 2013 that it would not be seeking review of the Second Circuit’s decision at the Supreme Court, indicating that it construed the opinion narrowly and that it “does not believe that the Caronia decision will significantly affect the agency’s enforcement of the drug misbranding provisions of the Food, 27

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140 Id. at 163-65 (quoting Sorrell v. IMS Health, Inc., 131 S. Ct. 2653, 2662-64 (2011)).
141 Id. at 168. Pursuant to *Central Hudson*, the majority found as a threshold matter that the regulated speech concerned lawful activity and was not false or misleading. While it acknowledged that there was a substantial governmental interest in drug safety, it held that the restriction of off-label promotional speech did not directly advance that interest and that less speech-restrictive alternatives (including the restriction or even prohibition of off-label prescriptions themselves) were available, and thus that the government’s interpretation of the FDCA did not satisfy the *Central Hudson* test. *Id.* at 165-68.
142 703 F.3d at 169.
143 *Id.* at 168-69.
144 *Id.* at 161-62, 168.
Drug, and Cosmetic Act.” But while the FDA might indeed feel confident about the limited effect the case will have on future enforcement efforts, risk aversion could also have played a part in the decision to let Caronia stand. Currently, Caronia is controlling law only in the Second Circuit’s courts. While defendants in other jurisdictions will no doubt argue that the same reasoning should be applied to their cases, it has yet to gain wider traction.

In fact, a Maryland court specifically rejected Caronia’s reasoning in McDonald-Lerner v. Neurocare Associates, P.A., finding it “unfathomable that Congress authorized the FDA to approve and limit the sale and distribution of drugs and medical devices for specific purposes, under specific conditions, and impose stringent premarket approval and subsequent labeling requirements, setting out those purposes and other conditions of approved use, but yet allow manufacturers and their representatives to ignore those same requirements with impunity by touting off-label uses to physicians.” The court sidestepped the First Amendment question by concluding that “even if the two-judge majority [in Caronia] is correct, its holding is limited to criminal prosecutions. Similar first amendment concerns do not apply to civil cases.” Other courts have commented on Caronia most frequently in the context of preemption, or because Medtronic relied on Caronia for its often-advanced position that federal law does not bar off-label promotion, rendering any claims based on off-label use preempted.

147 Id. at *22-23.
148 Id. at *24.
149 See McCormick v. Medtronic, Inc., 2014 Md. App. LEXIS 117, at *31-33 (Md. Ct. Spec. App. Oct. 6, 2014) (“MDA does not expressly preempt state-law claims that are based on a violation of the federal prohibition of false or misleading off-label promotion”); Lawrence v. Medtronic, Inc., 2013 Minn. Dist. LEXIS 3, at *21-22 (Minn. Dist. Ct. Aug. 7, 2013) (“This Court does not necessarily agree that federal law prohibits all promotion of off-label uses of medical devices (citing Caronia). However, whether or not off-label promotion in the abstract may be permissible, the Court finds that neither federal nor state law permits such promotion to be based on falsehoods or misrepresentations.”).
Thus far, there has been no move by courts to expand Caronia’s holding. But while Caronia has been narrowly construed to date, it presents the opportunity to raise other challenges to mislabeling prosecutions. Although the Second Circuit held only that truthful off-label promotion could not in itself be criminalized, other courts may employ similar reasoning to find that some arguably misleading types of promotion are protected speech or even that off-label promotion cannot be used to prove misbranding. Indeed, the Second Circuit raised the latter issue when dismissing the government’s claim that Caronia’s speech rights were not implicated because his speech had only been used as evidence of Xyrem’s intended uses. The court said in response that “[e]ven assuming the government can offer evidence of a defendant’s off-label promotion to prove a drug’s intended use and, thus, mislabeling for that intended use, that is not what happened in this case.”151 It then raised the issue a second time later in its opinion, saying more pointedly that although it need not reach the question, it is “unclear how the government would identify criminal misbranding from communications between drug manufacturers and physicians authorized to prescribe drugs for off-label use.”152 With that invitation on the table, it seems inevitable that the federal courts will at some point see a challenge to the FDA’s use of off-label promotion to prove mislabeling. But unless and until such a challenge succeeds, Caronia is unlikely to significantly alter the FDA’s enforcement powers.

Caronia is less likely still to greatly affect suits related to prescription drug advertising and promotion that are brought under state consumer protection laws. Those statutes create liability only for promotion that is false or misleading, and thus—in theory—any activity found to have violated state consumer protection law will necessarily be outside the First Amendment protection Caronia announced for truthful promotional statements. It is possible, however, that state courts finding Caronia persuasive will engage in more searching review of consumer fraud actions where the conduct alleged is arguably non-deceptive, especially at the appellate level where constitutional challenges receive de novo review.153 And state courts that embrace Caronia may also confront questions at the margins regarding when a promotional statement is sufficiently false or misleading as to strip it of its First Amendment

an appeal of a criminal conviction [of] a pharmaceutical sales representative . . . . In contrast, the plaintiff here is bringing a civil action against the manufacturer itself”)(emphasis omitted).
151 703 F.3d at 161 (emphasis added).
152 Id. at 162 n.9.
153 Id. at 160.
protection. For example, it is not clear whether Caronia would permit suit for an otherwise truthful statement that omits allegedly material facts, or whether Caronia’s conviction would have stood if his otherwise protected statements about off-label uses for Xyrem had failed to note that the drug was not approved for those indications.

Beyond such narrow questions, Caronia appears unlikely to significantly change the landscape for state-law claims, making it even more important that courts and state AGs recognize the boundaries between matters of FDA regulatory concern and the types of conduct state consumer fraud laws were designed to address.

V. Conclusion

Courts should read state consumer fraud statutes in a manner consistent with the federal courts’ approach to the FTCA. Prescription drug advertisements are regulated exclusively by the FDA, without interference from the FTC. 154 This division of responsibility has been respected by the FDA and FTC for decades. State consumer fraud statutes, which are modeled after the FTC Act, should not be interpreted to reach such communications. Moreover, the comprehensive nature of FDA oversight of prescription drug marketing cautions against an expansive interpretation of state consumer protection statutes.

Yet in the absence of a reasonable check from the courts, the States continue to pursue unfair and deceptive trade practice claims against pharmaceutical companies aggressively, whether individually or in multi-state groups acting through executive committees representing consumer fraud sections. While some of these inquiries are resolved in the investigation stage, others continue to reach the courts, where claims target things like off-label marketing or disclosure of risk information. All of these claims, whether confined to the investigatory stage or not, place significant costs and burdens on pharmaceutical manufacturers and interfere with manufacturers’ ability to rely on certainties that should be provided by compliance with a comprehensive federal regulatory scheme.

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