

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

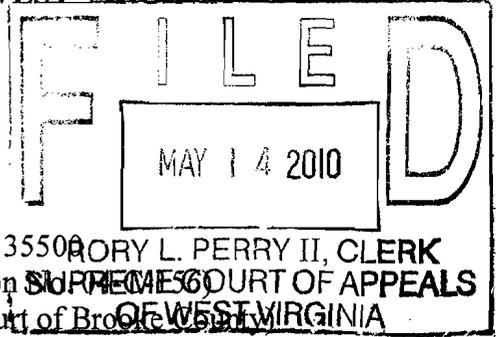
JOHNSON & JOHNSON and JANSSEN
PHARMACEUTICA PRODUCTS, L.P.,

Appellants,

v.

STATE OF WEST VIRGINIA, ex rel. DARRELL
V. MCGRAW, JR., ATTORNEY GENERAL,

Appellee.



) Docket No. 3550
) (Civil Action No. 09-0006)
) (Circuit Court of Brooke County, West Virginia)

**BRIEF OF PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE*
IN SUPPORT OF APPELLANTS**

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TABLE OF CONTENTS

	<u>Page</u>
STATEMENT OF AMICUS CURIAE.....	1
SUMMARY OF ARGUMENT.....	3
BACKGROUND	5
ARGUMENT.....	8
I. THE CIRCUIT COURT MISINTERPRETED FEDERAL LAW REGARDING FDA WARNING LETTERS.....	8
II. THE CIRCUIT COURT’S MISINTERPRETATION OF FEDERAL LAW WOULD OBSTRUCT FDA’S ENFORCEMENT REGIME AND WOULD BE PREEMPTED BY FEDERAL LAW	15
CONCLUSION	20

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Anderson v. Abbott Labs.</i> , 140 F. Supp. 2d 894 (N.D. Ill. 2001).....	11
<i>Biotics Research Corp. v. Heckler</i> , 710 F.2d 1375 (9th Cir. 1983).....	10
<i>Buckman Co. v. Plaintiffs' Legal Comm.</i> , 531 U.S. 341 (2001)	5, 15, 16, 17, 19
<i>Clinical Ref. Lab., Inc. v. Sullivan</i> , 791 F. Supp. 1499 (D. Kan. 1992).....	11
<i>Estee Lauder, Inc. v. FDA</i> , 727 F. Supp. 1 (D.D.C. 1989).....	10
<i>Gallagher v. Abbott Labs.</i> , 269 F.3d 806 (7th Cir. 2001)	11
<i>Genendo Pharm. N.V. v. Thompson</i> , 308 F. Supp. 2d 881 (N.D. Ill. 2003).....	13
<i>McCoy v. VanKirk</i> , 201 W. Va. 718 (1997).....	15
<i>McGraw v. Johnson & Johnson</i> , No. 04-C-156, Order on Mots. for Summ. J.....	3, 12, 16, 17
<i>Profls. & Patients for Customized Care v. Shalala</i> , 847 F. Supp. 1359 (S.D. Tex. 1994).....	11
<i>Schering Corp. v. Heckler</i> , 779 F.2d 683 (D.C. Cir. 1985), <i>rev'd in part sub nom., United States v. Undetermined</i> <i>No. of Cases</i> , 21 F.3d 1026 (10th Cir. 1994).....	11
<i>Schering-Plough Healthcare Prod., Inc. v. Schwarz Pharma, Inc.</i> , 547 F. Supp. 2d 939 (E.D. Wisc. 2008).....	11, 13
<i>Summit Tech., Inc. v. High-Line Med. Instruments Co.</i> , 922 F. Supp. 299 (C.D. Cal. 1996).....	11
<i>Wyeth v. Levine</i> , 555 U.S. ---, 129 S. Ct. 1187 (2009)	5, 19

STATUTES

21 U.S.C. §§ 332-334 9
21 U.S.C. § 352 6
21 U.S.C. § 355 6

REGULATIONS

21 C.F.R. pt. 202..... 5
21 C.F.R. § 10.33..... 12
21 C.F.R. § 10.75..... 13
21 C.F.R. § 10.85(d)..... 9
21 C.F.R. § 10.85(e) 8
21 C.F.R. § 10.85(k)..... 9, 12
21 C.F.R. § 314(b)(3)(i)..... 14
73 Fed. Reg. 2924-01 (Jan. 16, 2008) 18
Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat.
823 § 104, 21 U.S.C. § 379h-1 9, 18

LEGISLATIVE MATERIALS

Direct-to-Consumer Drug Advertising: Hearing Before Sen. Spec. Comm. On Aging,
109th Congress 19 (Sep. 29, 2005) (statement of Rachel Behrman, Deputy Director,
Food and Drug Administration) 18
Prescription Drug User Fees: Hearing on PDUFA IV Proposal before the Health,
Education, Labor and Pensions Comm., 110th Cong. 12 (March 14, 2007) (statement
by FDA Commissioner Andrew von Eschenbach)..... 18
U.S. Gov't Accountability Office, Prescription Drugs: Improvements Needed in FDA's
Oversight of Direct-to-Consumer Advertising 17 (2006), *available at*
<http://www.gao.gov/new.items/d0754.pdf> 14

OTHER AUTHORITIES

CDER: Requests for Advisory Comment on Promotional Materials Other than Proposed
DTC TV Ads, *available at* [http://www.fda.gov/AboutFDA/
CentersOffices/CDER/ucm090168.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090168.htm) 14

Compliance Policy Guides, <i>available at</i> http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidance Manual/default.htm	5
Donna Vogt, “Direct-to-Consumer Advertising of Prescription Drugs,” Congressional Research Service Report for Congress (Mar. 25, 2005).....	9
FDA Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, <i>available at</i> http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm	6, 7
FDA Regulatory Procedures Manual (March 2010), <i>available at</i> http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm	3
FDA Seeks User Fees for DTC Television Ad Review, 14 No. 12 FDA Adv. & Promotion Man. Newsl. 10 (Feb. 2007)	15
FDA: The Enforcement Story (March 2009), <i>available at</i> http://www.fda.gov/ICECI/EnforcementActions/EnforcementStory/default.htm#Content	17
Guidance Documents for FDA-Regulated Products, <i>available at</i> http://www.fda.gov/RegulatoryInformation/Guidances/default.htm	5
Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level (Feb. 2000), <i>available at</i> http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126015.pdf	13
Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion (May 2009), <i>available at</i> http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm155480.pdf	6
James O’Reilly, 1 Food & Drug Admin. § 6.2 (2009)	11
Larry Pilot, A Priority for the FDA: Fix the ‘Warning Letter’ Process, 21 Wash. Leg. Found. No. 33 (October 2006), <i>available at</i> http://www.wlf.org/upload/102006pilot.pdf	10
Warning Letters and Untitled Letters to Pharmaceutical Companies 2010, <i>available at</i> http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm197224.htm	7
Wayne L. Pines, FDA Adv. & Prom. ¶ 220	7

STATEMENT OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is a voluntary non-profit association that represents the country’s leading research-based pharmaceutical and biotechnology companies before Congress, the executive branch, state regulatory agencies and legislatures, and courts. PhRMA’s member companies invent and manufacture medicines that allow patients to live longer, healthier, and more productive lives.¹ For decades, they have led the search for new cures, and in 2009, they invested an estimated \$45.8 billion in discovering and developing new medicines.² PhRMA’s mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing new medicines by pharmaceutical and biotechnology research companies.

PhRMA submits this brief in support of the Appellants Johnson & Johnson and Janssen Pharmaceutica Products, L.P. (collectively “Janssen”). PhRMA seeks to participate as an *amicus* because the Circuit Court’s decision could have significant and far-reaching effects on the pharmaceutical industry, particularly with regard to the industry’s relationship with the Food and Drug Administration (“FDA”). The decision below effectively created an irrebuttable presumption that allegations against Janssen advanced in warning letters by an FDA employee were true. The Court accepted those letters as determinative because Janssen had neither burdened FDA with a request for advance approval of the allegedly improper communications to doctors, nor instituted administrative proceedings to challenge those warning letters. Based on

¹ A list of PhRMA’s current membership can be found at http://www.phrma.org/about_phrma/member_company_list/members/. Johnson & Johnson, Janssen’s parent company, is a member of PhRMA, but it has not contributed financially to the preparation of this *amicus* brief.

² Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2010, *available at* http://www.phrma.org/sites/phrma.org/files/attachments/Profile_2010_FINAL.pdf.

those letters, the Court ruled that Janssen's communications with doctors were false and misleading -- taking that issue away from the finder of fact.

PhRMA's member companies address daily the policies, obligations, and burdens imposed by federal regulation of the products they manufacture and market. Thus, PhRMA is very familiar with FDA's practices and procedures, both written and unwritten. PhRMA also has substantial expertise navigating the interrelationship of federal regulation and state law. PhRMA believes that the Circuit Court's opinion misconstrues FDA practices and procedures for reviewing drug advertising and for issuing warning letters. PhRMA submits further that the Circuit Court's misinterpretation of federal law threatens to disrupt the Agency's enforcement regime, discourage cooperative relationships between pharmaceutical companies and FDA, and overload the Agency with advisory requests.

PhRMA's members have a significant interest in preserving and strengthening their collaborative relationship with FDA, which the Circuit Court's decision would undermine, and in ensuring a proper balance between federal and state interests in this area. In fostering this interest, PhRMA can bring a valuable perspective to this Court's consideration of the Appellants' appeal.

SUMMARY OF ARGUMENT

In this case, the Circuit Court misinterpreted the regulatory practices, procedures, and requirements of FDA. The Court granted the State's motion for partial summary judgment against Janssen on the ground that FDA had found Janssen's communications with doctors to be false and misleading. *See McGraw v. Johnson & Johnson*, No. 04-C-156, Order on Mots. for Summ. J. at 32 (Brooke County Cir. Ct. Aug. 19, 2008). FDA made these findings, the Court concluded, in warning letters sent to Janssen. *See id.* While acknowledging that not every FDA warning letter reflects incontestable findings, the Court posited two reasons why these particular letters did so. First, Janssen did not bring administrative proceedings to challenge the letters, but instead, as the warning letters requested, sent corrective letters to doctors. *See id.* at 29. Second, Janssen had "the unilateral ability to avoid [a warning letter] by waiting for FDA approval of advertising material or a prescriber communication before disseminating it," but had not obtained prior FDA approval. *Id.* at 30.

In so holding, the Circuit Court made several errors of law. To begin with, the Court's basic premise is incorrect. Warning letters do not embody "FDA findings." FDA has specified which statements by its employees reflect a determination by the Agency. Warning letters are not one of them. Rather, they are -- in FDA's words -- "informal and advisory." FDA Regulatory Procedures Manual 4-1-1 (March 2010) ("FDA Manual").³ A Division or Office of FDA sends a warning letter when "the nature of the activity is such that the center would support further regulatory action." *Id.* at 4-1-5. But the Division -- in this case the Division of Drug Marketing, Advertising, and Communication, or "DDMAC" -- must persuade the Agency to commence such regulatory action, and thereafter, FDA must *prove* its charges. To pursue

³ Available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>.

enforcement in court, FDA must persuade the Department of Justice to bring the case. And in such a case, the Department must meet the customary burdens of proof.

The Circuit Court was also incorrect in assuming that a regulated company may bring “administrative proceedings” to challenge a warning letter. To be sure, a company can seek to persuade the author of the letter or higher level employees in the Agency to rescind or modify the allegations, which is an appellate process of sorts. But FDA offers no formal adjudicatory procedure for disputing the allegations unless the Agency and the Department of Justice bring a civil or criminal action against the company.

Third, with exceptions not pertinent here, FDA does not *approve* promotional materials before a company sends them. On a limited basis, DDMAC will provide “advisory comments” on a proposed promotional piece, but the Agency can do so for only a small fraction of communications. Furthermore, FDA’s “advisory comments” are not binding on the Agency. In other words, even though FDA may raise no objections in its review, it still could allege subsequently that the material is false or misleading.

The consequences of the Circuit Court’s misinterpretation of FDA practices and procedures are potentially severe. While FDA sees warning letters as just that, “warnings” -- initial, or, at most, interim steps in a dialogue with regulated companies -- the Circuit Court’s opinion transmutes them into final, definitive agency action that grounds liability under state law when a company accedes to FDA’s regulatory request. While FDA uses warning letters as a tool to achieve “voluntary compliance” with the law, the Circuit Court’s opinion incentivizes conflict by layering those letters with collateral consequences. While FDA offers a limited opportunity for an advisory pre-review of advertising, the Circuit Court’s opinion reshapes this service into a vital and broad-gauged safe harbor against liability under state law, spurring manufacturers to

submit virtually everything to the Agency for review. By thus misreading FDA practice and procedure, the Circuit Court's opinion threatens to skew the regulatory balance the Agency has struck and encourages submissions the Agency does not want and cannot handle. The decision thereby oversteps the bright line the Supreme Court has drawn against intrusion into FDA's regulatory dealings with the pharmaceutical industry. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). To avoid this constitutional collision, this Court should correct the Circuit Court's misinterpretation of federal law.

Wyeth v. Levine, 555 U.S. ---, 129 S. Ct. 1187 (2009), in no way impedes the Court from doing so. That case addressed whether the Federal Food Drug and Cosmetic Act impliedly preempts certain claims under state law. PhRMA is not addressing here the question whether West Virginia's *claim* is preempted. Rather, PhRMA is addressing whether, in resolving that claim, the Circuit Court misconstrued federal law by giving preclusive effect to FDA warning letters, and whether that error, if left uncorrected, will obstruct FDA's ability to carry out its statutory mandate. Because the answer to both questions is yes, the Court should reverse the decision of the Circuit Court.

BACKGROUND

FDA comprehensively regulates pharmaceutical advertising. The Agency has promulgated detailed regulations, issued extensive guidance documents, and developed regulatory practices in decades of interactions with pharmaceutical manufacturers. *See, e.g.*, 21 C.F.R. pt. 202 (regulating prescription drug advertising); Guidance Documents for FDA-Regulated Products⁴; FDA Manual (describing internal procedures used in FDA regulatory and enforcement matters); Compliance Policy Guides (describing FDA standards and procedures

⁴ Available at <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> (last accessed May 1, 2010).

applied when determining industry compliance).⁵ Last year, FDA issued a new draft Guidance for manufacturers entitled, “Presenting Risk Information in Prescription Drug and Medical Device Promotion” (May 2009).⁶ The draft Guidance emphasizes that “FDA relies on a vast scientific body of knowledge regarding human cognition in assessing which factors to consider in evaluating promotional pieces and making regulatory decisions about the presentation of risk information.” *Id.* at 6. FDA stated that the draft Guidance was intended to provide manufacturers “a better understanding of what they should consider as they develop the content and format of their promotional communications.” *Id.* at 21. FDA issued this draft Guidance -- its first broad-gauged, written articulation of many longstanding regulatory practices -- well after the events in question in this lawsuit. That timing highlights the extent to which the Agency’s decision-making and its regulatory dealings with companies reflect tradition and practice, much of which is unwritten and thus not readily accessible to courts attempting to decipher FDA’s actions.

Congress has charged FDA with evaluating whether pharmaceutical promotion is false or misleading and preventing dissemination of false or misleading materials. *See, e.g.*, 21 U.S.C. §§ 352(a) & (n); *id.* §§ 355(d) & (e). The Agency has effective tools to enforce its determinations. *See, e.g.*, FDA Manual at 4-2 (“[E]nforcement strategies ... are based on the particular set of circumstances at hand and may include sequential or concurrent FDA enforcement actions such as recall, seizure, injunction, administrative detention, civil money penalties and/or prosecution to achieve correction.”); FDA Center for Drug Evaluation and

⁵ Available at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm> (last accessed May 1, 2010).

⁶ Available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pcf>.

Research, Division of Drug Marketing, Advertising, and Communications (describing the means by which DDMAC reviewers ensure that information in promotional materials is not false or misleading).⁷ DDMAC -- an office of about 40 employees within one of the six FDA Centers responsible for different areas of regulation -- is at the front line of this effort. *See, e.g.*, Wayne L. Pines, *FDA Adv. & Prom.* ¶ 220. One way that DDMAC exercises regulatory oversight of pharmaceutical promotion and conveys its views regarding promotional materials is through warning letters. *See, e.g.*, *Warning Letters and Untitled Letters to Pharmaceutical Companies 2010*.⁸ For DDMAC and for FDA generally, such warning letters are an *informal* instrument in the Agency's store of enforcement tools, representing only a first stage of what is usually an extended dialogue between FDA and pharmaceutical manufacturers to resolve disagreements regarding communications with doctors and patients. Although FDA has more potent weapons in its enforcement arsenal, both FDA and industry regard accommodation as more desirable than escalation, and FDA strongly prefers to achieve compliance without the disruption, cost, and delay entailed in more draconian steps. FDA thus carefully calibrates how it deploys these enforcement tools, marshaling its limited resources to best advantage in advancing the public health.

⁷ Available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm> (last accessed May 1, 2010).

⁸ Available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm197224.htm> (last accessed May 1, 2010).

ARGUMENT

I. THE CIRCUIT COURT MISINTERPRETED FEDERAL LAW REGARDING FDA WARNING LETTERS

DDMAC sent two warning letters to Janssen: one regarding the drug Risperdal, and one regarding the drug Duragesic. Janssen responded that it disagreed with the positions DDMAC took in the warning letters. But rather than engage in an extended dispute, Janssen issued corrective letters, as FDA had requested. Based on these events, the Circuit Court accorded the FDA warning letters preclusive force, denying Janssen even an opportunity to dispute that its statements were false or misleading. In so ruling, the Circuit Court accorded warning letters a function and status that FDA does not intend.

A warning letter is just what its name suggests. It is a warning that the recipient should modify its conduct, or DDMAC will consider enforcement action -- or, more accurately, will consider attempting to persuade FDA and ultimately the Department of Justice to initiate an enforcement action charging that the company violated the law. Contrary to the Circuit Court's conclusion, a warning letter does not reflect "findings" by FDA. Employees of FDA communicate constantly with Congress, regulated companies, the public, other government agencies, and many others, through testimony, letters, telephone conversations, speeches, memos, press releases, and many other media. With more than 10,000 employees, FDA has recognized that not every pronouncement emanating from the Agency can qualify as one that reflects its findings. Therefore, in various regulations, FDA has specified when such statements rise to the level of a formal FDA finding. For example, FDA has created a procedure for issuing an advisory opinion, which "represents the formal position of FDA on a matter . . . [and] obligates the agency to follow it until it is amended or revoked." 21 C.F.R. § 10.85(e). Advisory

opinions include preambles to regulations published in the Federal Register and compliance policy guides, but not warning letters. *See id.* § 10.85(d). And FDA makes clear that statements, like warning letters, falling outside this category are *not* findings or decisions of FDA:

A statement or advice given by an FDA employee orally, or given in writing but not under this section or 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Id. § 10.85(k).⁹

There are other mechanisms through which FDA can make a formal finding regarding a violation of law. But with regard to advertising, FDA's only practical options at the time of the events at issue in this case were the enforcement actions threatened in the warning letters. And such enforcement actions required filing lawsuits seeking an injunction, seizure of the products, or criminal penalties. *See, e.g.*, 21 U.S.C. §§ 332-334.¹⁰ Those proceedings carry all the safeguards of judicial procedures, and in them, FDA bears the burden of proof.

FDA employees bear no such burden in sending a warning letter. A warning letter does not reflect adjudicated facts. Signed by an FDA official several levels below the Commissioner,

⁹ Section 10.90 is not pertinent. It relates to regulations promulgated in the Federal Register and codified in the Code of Federal Regulations, FDA recommendations regarding matters authorized by laws administered by FDA, and formal agreements with FDA that are maintained in the Agency's public file.

¹⁰ Donna Vogt, "Direct-to-Consumer Advertising of Prescription Drugs," Congressional Research Service Report for Congress (Mar. 25, 2005), at 22 ("If Warning Letters fail to rectify the situation, FDA can work with the Department of Justice to seek injunctions against companies, or criminally prosecute firms, or FDA can seize products deemed to be misbranded by intentional and/or serious misstatements, or can withdraw the drug's approval."). Since the events at issue in this lawsuit, Congress has authorized the Secretary of Health and Human Services to assess civil money penalties for direct-to-consumer advertisements that are false or misleading. *See* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 § 901(d)(4), 21 U.S.C. § 333(g). The statute guarantees certain procedural safeguards, including a hearing for the person against whom a penalty is assessed. *Id.* § 333(g)(2).

the warning letters here reflected *allegations* advanced by a Division of FDA, not formal findings.¹¹ If, hypothetically, FDA had filed a complaint in the Circuit Court making those claims, the Court would not have given the allegations preclusive effect. FDA would have had to prove them. Yet, when a subdivision of FDA made the allegations in letters, and Janssen, while disputing the claims, acquiesced in the relief requested by FDA rather than challenging FDA on its threat to bring an enforcement action, the Circuit Court conclusively assumed the truth of FDA's charges. That result is neither fair nor consistent with FDA practice.

FDA's Regulatory Procedures Manual likewise confirms the provisional nature of a warning letter, describing it as "informal and advisory." FDA Manual at 4-1-1. A warning letter "communicates the Agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA *does not* consider Warning Letters to be final agency action on which it can be sued." *Id.* at 4-1 (emphasis supplied); *see also Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (holding that regulatory letters from FDA do not "constitute a final decision by the FDA"); *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 6-7 (D.D.C. 1989) (concluding that an FDA regulatory letter was not the agency's "final position"). The regulatory predecessor to the warning letter was a "Notice of Adverse Findings." By replacing the Notice of Adverse *Findings* with the warning letter, FDA made clear that this

¹¹ *See* Larry Pilot, A Priority for the FDA: Fix the 'Warning Letter' Process, 21 Wash. Leg. Found. No. 33 (October 2006) (warning letters contain "'allegations' of violations for which the federal court system ultimately provides the opportunity to determine whether any violation exists. Where appropriate, its issuance should be useful. If the recipient is not responsive to the realistic and lawful expectations of the FDA, the burden to prove that a violation exists is the responsibility of the FDA through such statutory enforcement actions as product seizure, preliminary and/or permanent injunctive relief, and criminal prosecution."), *available at* <http://www.wlf.org/upload/102006pilot.pdf>. The Office of the Chief Counsel at FDA now reviews warning letters before they are sent. That a lawyer reviews the letters does not in any way change the communication from an allegation into a final determination.

regulatory step did not reflect an Agency “finding,” but a *position* -- such as one takes in litigation -- which must be established. *See* James O’Reilly, 1 Food & Drug Admin. § 6.2 (2009). Moreover, FDA has emphasized that the purpose of a warning letter is to prompt voluntary action to avoid -- not precipitate -- administrative proceedings, formal findings, or serious penalties. *See* FDA Manual at 4-2 (“Warning Letters are issued to achieve voluntary compliance and to establish prior notice.”). *Cf. Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894, 902 (N.D. Ill. 2001) (“There is nothing magical about [an FDA] warning letter. Although the language sounds ominous, it really is rather boilerplate.”), *aff’d sub nom., Gallagher v. Abbott Labs.*, 269 F.3d 806 (7th Cir. 2001).

Courts evaluating the legal significance of FDA’s regulatory letters have reached similar conclusions.¹² For example, in *Schering-Plough Healthcare Prod., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939 (E.D. Wisc. 2008), the Court assessed false advertising claims much like those advanced here, except that they arose under the Lanham Act rather than West Virginia law. The defendants moved to dismiss the claims on the ground that they required the Court to interpret and apply the Food Drug and Cosmetic Act before FDA had a chance to do so. The plaintiff responded that FDA had spoken on the question when it issued warning letters finding the advertisements at issue false or misleading, and the defendants had essentially acquiesced in

¹² *See, e.g., Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996) (“[R]egardless of any warning letters that FDA may have sent to Defendants, it is clear that the FDA has not completed its investigation.”); *Profls. & Patients for Customized Care v. Shalala*, 847 F. Supp. 1359, 1365 (S.D. Tex. 1994) (“Warning letters issued by the FDA are deemed to be informal communications that do not constitute final agency action.... Warning letters merely establish a dialogue ... and do not necessarily lead to further sanctions.”) (citation omitted), *aff’d* 56 F.3d 592 (5th Cir. 1995); *Clinical Ref. Lab., Inc. v. Sullivan*, 791 F. Supp. 1499, 1503-04 (D. Kan. 1992) (“Regulatory letters such as the one sent [by FDA], however, do not amount to final agency action.”), *rev’d in part on other grounds sub nom., United States v. Undetermined No. of Cases*, 21 F.3d 1026 (10th Cir. 1994); *Schering Corp. v. Heckler*, 779 F.2d 683, 686 n.18 (D.C. Cir. 1985) (concluding that “statements by FDA officials do not constitute ‘final agency action.’”).

the relief sought. The Court rejected the argument. The warning letters, the Court found, “indicate that, *in the opinions of the FDA officials who wrote the letters*, the defendants’ products are misbranded. However, pursuant to FDA’s own regulations, the FDA has not yet taken any official position concerning the labeling of the defendants’ products to which the court can defer.” *Id.* at 946 (emphasis supplied). The Court noted that the warning letters had not accorded the defendants a hearing on the allegations advanced, and it emphasized that under FDA regulations, 21 C.F.R. § 10.85(k), the letters reflected the views of the authors, not of the Agency. *Id.* at 947. The Court therefore refused “to step into the shoes of the FDA” and make the determination the Agency had not made -- that the advertisements were false and misleading. *Id.* at 946-47.

The ruling here stands in stark contrast. The Circuit Court made the opinions of FDA employees determinative and deemed an *unofficial* position, *official*, thereby stripping away Janssen’s ability to defend against state law penalties and converting a warning letter from a shot across the bow under federal law to one that sinks the target under state law.

One factor that led the Circuit Court to overstate the impact of the warning letters to Janssen was that Janssen had acquiesced in FDA’s request and sent corrective letters to doctors. *See* Order on Mots. for Summ. J. at 28-29 (“[C]orrective letters constitute mandatory FDA action and the FDA’s official judgment as to the matters addressed in the letters.”); *id.* at 32 (holding that evidence of FDA’s communications with Janssen was sufficient to establish that Janssen’s materials violated federal and state law). In the Court’s view, Janssen could have “institute[d] administrative proceedings to challenge the Warning Letter on scientific, First Amendment, or other grounds.” *Id.* at 25. For this proposition, the Circuit Court cited 21 C.F.R. § 10.33. *Id.* at 15 n.16. That section, however, relates to the *Commissioner’s* decision resulting from a *formal*

administrative proceeding. The warning letters were not actions of the Commissioner, and they did not result from any *formal* administrative proceeding. In fact, contrary to the Circuit Court's apparent understanding, there is no *formal* adjudicative procedure for challenging a warning letter within the Agency, with such protections as evidentiary standards, the opportunity to examine witnesses, and the right to an impartial decision-maker. Rather, FDA offers only channels for protest that are the equivalent of complaining to the boss of the official who wrote the letter. See Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level, at 1 (Feb. 2000).¹³ Nor could Janssen have readily secured direct judicial review of the letters. FDA has taken the position, and courts have held, that a warning letter is not a final agency action susceptible to judicial review. See, e.g., *Genendo Pharm. N.V. v. Thompson*, 308 F. Supp. 2d 881, 885 (N.D. Ill. 2003) (statements of agency officials below the Commissioner "do not rise to the level of final agency action -- even when they are contained in warning letters or other official regulatory correspondence") (citations omitted). As in the *Schering* case, where the defendants also did what FDA asked, that fact did not amplify the warning letters into FDA findings or final agency action. *Schering*, 547 F. Supp. 2d at 946.

As is commonly the case with warning letters, Janssen's options were to accede to FDA's request or risk an enforcement proceeding. By deciding to avoid that risk, Janssen was not conceding -- indeed, it specifically disputed -- the legal soundness or factual accuracy of the FDA's charges. There are many reasons a company, though disagreeing with FDA, may do what

¹³ Available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126015.pdf>. Though the Guidance bills this process as "formal," it does not have the key procedural protections that typically attend formal proceedings. Thus, the Guidance explains that under 21 C.F.R. § 10.75, a party can obtain review "by raising the matter with the supervisor of the employee who made the decision. If the issue is not resolved at the primary supervisory level, the interested person may request that the matter be reviewed at the next higher supervisory level. This process may continue through the Agency's chain of command, through the Centers to the Commissioner of Food and Drugs." *Id.* at 1.

the Agency requests. It may decide that FDA's suggestion, even if not correct, is not harmful. Given FDA's role as *the* regulatory gate-keeper, it may not want to undermine its relationship with the Agency. It may determine that while the prospect of an enforcement action is remote, the adverse consequences if one occurred are disproportionate to the burden of complying. Because there are many reasons for cooperating with FDA that are far more likely than an intent to admit the Agency's allegations, it is inappropriate to treat such cooperation as conclusively establishing the truth of those allegations.

The other reason the Circuit Court cited for its conclusion that these warning letters are outcome determinative under state law was that Janssen purportedly could have asked for FDA's approval of its material *before* sending the material out in the first place. This suggestion, too, misapprehends FDA's practice. Although FDA receives promotional communications at the time companies first use them, 21 C.F.R. § 314(b)(3)(i), it does not pre-approve those materials. Rather, upon request by a company, FDA has provided occasional advice before particular promotional pieces are published. *See, e.g.,* CDER: Requests for Advisory Comment on Promotional Materials Other than Proposed DTC TV Ads;¹⁴ U.S. Gov't Accountability Office, Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising 17 (2006) ("2006 GAO Report").¹⁵ Indeed, FDA does not even regard its own advice to be binding. The Agency repeatedly has said that even where it has provided favorable

¹⁴ Available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090168.htm> (last accessed May 1, 2010).

¹⁵ Available at <http://www.gao.gov/new.items/d0754.pdf>.

advisory comments regarding an advertisement, “it reserves the right to take enforcement action if it finds violations after an ad launch.”¹⁶

II. THE CIRCUIT COURT’S MISINTERPRETATION OF FEDERAL LAW WOULD OBSTRUCT FDA’S ENFORCEMENT REGIME AND WOULD BE PREEMPTED BY FEDERAL LAW

It is settled law that courts should avoid interpreting statutes and regulations in a manner that raises constitutional questions. *Cf. McCoy v. VanKirk*, 201 W. Va. 718, 728 (1997) (“courts must exercise due restraint, in recognition of the principle of the separation of powers in government among the judicial, legislative and executive branches.”). The Circuit Court’s misinterpretation of federal law, effectively deeming FDA warning letters to be conclusive evidence that promotional labeling is false or misleading, unwittingly creates a significant constitutional issue. If the decision were to stand, it would interfere with FDA’s enforcement efforts. Such state law interference with federal prerogatives would be preempted. The imperative to avoid such unnecessary constitutional issues further counsels rejection of the Circuit Court’s misreading of federal law.

In *Buckman*, the Supreme Court held that federal law preempted a state cause of action for fraud on the FDA. At the outset, the Court determined that the interactions between a regulated company and its federal regulator, FDA, are “inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.” 531 U.S. 347. The Court therefore refused to apply any presumption against preemption or to let state law intrude into this federal domain. Here, too, the Circuit Court’s opinion deals with the meaning and intended effect of FDA communications and enforcement measures, issues that are inherently federal in character.

¹⁶ FDA Seeks User Fees for DTC Television Ad Review, 14 No. 12 FDA Adv. & Promotion Man. Newsl. 10 (Feb. 2007).

After resolving this issue, the Court in *Buckman* turned to an examination of FDA's enforcement system. The Court found that FDA had promulgated detailed regulatory requirements governing its dealings with industry. *Id.* at 349. To enforce these requirements, the Court noted, FDA can invoke provisions "aimed at detecting, deterring, and punishing false statements" *Id.* FDA had at its "disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Agency." *Id.* In other words, FDA can calibrate its enforcement efforts, determining how much firepower it should employ to accomplish its objectives without causing undue disruption, consuming resources needed elsewhere, or extending deterrence beyond the targeted conduct. Thus, in the Court's view, FDA was able to use its "authority . . . to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. And, significantly, that balance "sought by the [agency] can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.*

The Circuit Court's opinion similarly would skew the balance FDA seeks in its enforcement efforts. By conferring upon FDA warning letters legal consequences that FDA does not intend, the Circuit Court's opinion would undermine the utility of those warning letters for the purpose FDA *did* intend -- prompting a dialogue that resolves the problem expeditiously and without a legal confrontation. With the collateral consequences of a warning letter magnified so dramatically, FDA could no longer calibrate the impact of its enforcement tools. Moreover, those consequences would create greater incentives for manufacturers not to cooperate with FDA, and instead to make FDA try -- and potentially fail -- to prove its allegations.

If, as the Court's opinion seems to suggest, pharmaceutical companies that do not challenge the merits of a warning letter thereby endorse its allegations, *see* Order on Mots. for Summ. J. at 25, 27, companies would be more likely to mount such challenges. Driving

regulated companies toward more adversarial dealings with FDA would not merely skew the balance of FDA's enforcement regime, it would submerge FDA's priorities. In 2008 alone, FDA sent 455 warning letters. FDA: The Enforcement Story (March 2009) 10-2.¹⁷ The number of enforcement actions FDA initiated is a small fraction of this number. *Id.* Particularly in the area of advertising and promotion, companies almost invariably complied with FDA's requests. *See* 2006 GAO Report at 27. Court rulings under state law that discourage companies from acquiescing in FDA's requests -- that impel them to fight rather than negotiate -- will strain FDA's resources and, if anything, delay changes in marketing materials that FDA employees believe are warranted.

In *Buckman*, the Supreme Court worried that if state courts could decide claims of fraud on the Agency, pharmaceutical manufacturers applying for FDA approval of a drug or medical device "might fear 'that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court,' and consequently 'submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on [FDA].'" 531 U.S. at 351. The Circuit Court's opinion here raises precisely analogous concerns. The risk in this case is that companies would be more contentious in dealing with FDA, thereby increasing litigation, disrupting FDA's enforcement regime, and overtaxing FDA's limited resources.

The Circuit Court also justified giving preclusive effect to the FDA warning letters on the ground that Janssen did not seek pre-approval of the promotional materials at issue. *See* Order on Mots. for Summ. J. at 30 ("[D]efendants have the unilateral ability to avoid [liability under state law] by waiting for FDA approval of advertising material or a prescriber communication

¹⁷ Available at <http://www.fda.gov/ICECI/EnforcementActions/EnforcementStory/default.htm#Content>.

before disseminating it”); *id.* at 24 (noting that Janssen did not offer “evidence of a reason why they could not have” sought pre-approval of a communication to health care providers); *id.* at 27 (“defendants did not ask the FDA to review the contents of the file card before they began to distribute it, and there is nothing in the record indicating a reason why the defendants could not have done so”). In addition to misconstruing what FDA *does* -- mistaking the Agency’s informal advice for approval of advertisements -- the Court also misunderstood what FDA *can do*. In 2004, pharmaceutical companies distributed more than 52,000 promotional pieces. *See Direct-to-Consumer Drug Advertising: Hearing Before Sen. Spec. Comm. On Aging, 109th Congress* 19 (Sep. 29, 2005) (statement of Rachel Behrman, Deputy Director, Food and Drug Administration). DDMAC has the capacity to review only a tiny portion of this material before it is disseminated. *See, e.g., Prescription Drug User Fees: Hearing on PDUFA IV Proposal before the Health, Education, Labor and Pensions Comm., 110th Cong. 12* (March 14, 2007) (statement by FDA Commissioner Andrew von Eschenbach) (“[I]t is impossible for FDA to review all of the DTC television advertisement advisory submissions it receives in a timely manner.”). Indeed, in 2007, in determining that FDA should review more direct-to-consumer advertising before it is published, Congress adopted a user-fee system to pay for additional FDA employees because the Agency otherwise could not have adequately handled the additional load. *See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 § 104, 21 U.S.C. § 379h-1.*¹⁸ And direct-to-consumer advertisements constitute a small fraction of the promotional communications potentially affected by the opinion below. Thus, by inducing manufacturers to seek the cover of prior FDA review of promotional pieces or else risk the draconian result that occurred here, the Circuit Court threatens to deluge FDA in unwanted

¹⁸ Because of inadequate appropriations, FDA did not initiate the Direct-to-Consumer television advertisement user fee program in 2008. *See* 73 Fed. Reg. 2924-01 (Jan. 16, 2008).

submissions, increase delay, and decrease the effectiveness of FDA's review in protecting public health. Under the Supremacy Clause of the United States Constitution, as elucidated in *Buckman*, it is FDA's prerogative to control the flow of information and the regulatory inquiries it receives. Actions under state law that usurp or erode that control are preempted.¹⁹

This Court thus should reverse the Circuit Court's interpretation of FDA practices and procedures to avoid the clash between federal and state law that the Circuit Court's opinion provokes. Should this Court conclude, however, that federal law and West Virginia law compel the conclusion the Circuit Court reached, then the Court should address the issue of preemption. If this Court does so, the logic is inescapable that the approach of the Court below stands in the way of FDA enforcement, obstructs the accomplishment of FDA's goals, and encumbers FDA's regulatory processes with collateral consequences FDA never intended.

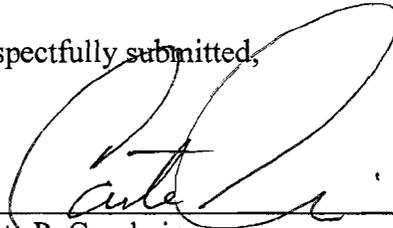
¹⁹ Nothing in *Levine*, 555 U.S. ---, 129 S. Ct. 1187, affects this analysis of preemption. The Court did not address the issue presented here -- whether communications by FDA employees that are not final agency action have preclusive effect. In any event, *Levine* expressly preserved its reasoning in *Buckman*. *See id.* at --- n.3, 129 S. Ct. at 1195 n.3.

CONCLUSION

The Circuit Court's opinion converts an FDA warning that a manufacturer should resolve issues to *avoid* liability into an FDA resolution of those issues that *results in* liability under state law. By thus distorting FDA's enforcement tools, the lower court's opinion threatens the regulatory balance the Agency has chosen to strike and oversteps the bright line the Supreme Court has drawn regarding permissible state regulation.

This Court should correct the errors of the Circuit Court.

Respectfully submitted,



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