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No. 091273

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

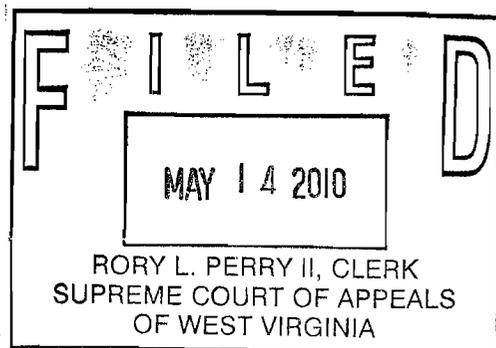
**JOHNSON & JOHNSON,  
JANSSEN PHARMACEUTICA PRODUCTS,  
L.P., and JANSSEN PHARMACEUTICA, INC.,**

*Petitioners,*

v.

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

*Respondent.*



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**BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC.,  
AS AMICUS CURIAE IN SUPPORT OF PETITIONERS AND REVERSAL**

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Stephanie D. Taylor (W. Va. Bar No. 10232)  
JONES DAY  
500 Grant Street, Suite 4500  
Pittsburgh, PA 15219-2514  
412-391-3939

*Attorney for the Product Liability Advisory  
Council, Inc.*

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## I. INTRODUCTION AND SUMMARY OF ARGUMENT

In a feat of legal alchemy, the circuit court transformed an agency staff's letters into official findings of fact and final agency action, a business decision to compromise the staff's letters into a binding admission of wrongdoing, and, consequently, nothing of import into a pot of gold for the State and its contingency fee counsel. The Food and Drug Administration's description of the effect of its staff's warning letters should be dispositive of this appeal: "A Warning Letter is *informal and advisory*. It 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.*" FDA Regulatory Procedures Manual, § 4-1-1 (emphasis added).<sup>1</sup>

Warning letters are issued by the FDA's staff to encourage voluntary compliance without time-consuming litigation. Nevertheless, the circuit court concluded that the FDA staff's warning letters, alleging that Janssen's promotional materials for Risperdal and Duragesic contained false and misleading information, constitute final agency action. It then treated Janssen's acquiescence to sending corrective letters, with which it did not agree in substance, as a conclusive admission of wrongdoing for purposes of a state law claim for civil penalties. (Circuit Court's Opinion and Order on the Parties' Motion for Summary Judgment, Aug. 19, 2008, at 28-29, 31) ("Opinion and Order").

Sound judicial and administrative policy should encourage voluntary compliance with the law and facilitate cooperative compromise of disputes. The ability to compromise claims without further consequences is imperative. Without policies and procedures to permit the

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<sup>1</sup> The FDA Regulatory Procedures Manual can be found online at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm> (last visited May 11, 2010).

voluntary resolution of disputes, our judicial and administrative agencies would face such a crushing log jam that they could no longer carry out their responsibilities. Therefore, rule after rule aims to permit voluntary dispute resolution without any admission of liability or any preclusive effect. *See, e.g.,* W. Va. R. Evid. 407, 408, and 410.

The circuit court's decision stands this essential judicial and administrative policy on its head. Its decision is antithetical not only to the FDA's own policy and regulations, but also to basic principles of civil procedure, evidence, and due process:

*First*, without any adjudication and fact finding, there can be no issue preclusion. Janssen did not even have a prior dialogue with the FDA's staff regarding the allegations within the warning letters.

*Second*, the FDA staff's warning letters are inadmissible hearsay, Janssen's agreement to compromise a dispute is inadmissible, and the corrective letters are inadmissible subsequent remedial measures. W. Va. R. Evid. 801(c), 408 and 407.

*Third*, the circuit court's decision violates due process because there was no fair notice to Janssen of the conclusive effect of its compromise with the FDA staff and no fair opportunity to defend itself against the State's claims. Because Janssen was never given an opportunity to challenge the allegations in the warning letters, it would violate its due process rights for a court to conclude that those allegations are now conclusive, irrebuttable evidence of liability.

*Finally*, the circuit court's decision, if permitted to stand, would thwart the ability of federal as well as state agencies to regulate through voluntary corrective action. The ramifications extend far beyond the FDA to the IRS, MHSA, FTC, CPSC, NHTSA and other federal agencies, as well as their state analogs. Absent the ability to obtain cooperation, agencies would need to bring enforcement after enforcement action. Corporations, small businesses, and

individuals who would prefer to compromise disputes, but are unable because of the dire consequences for later litigation, would suffer, too.

In short, Janssen has been found liable to pay millions of dollars in civil penalties without ever having the opportunity to challenge the truth of Plaintiff's allegations in court. The decision is wrong, unfair, unconstitutional, and harmful to public policy.

## **II. REGULATORY AND FACTUAL BACKGROUND<sup>2</sup>**

The federal Food and Drug Administration regulates the safety, efficacy, and security of human drugs. *See* 21 U.S.C. § 321 *et seq.* An agency within the Department of Health and Human Services, the FDA consists of seven centers and offices. Each office is headed by a deputy commissioner, and each center is headed by a director. These deputy commissioners and directors are assisted by other staff, which helps to investigate and regulate the various products that fall under the FDA's jurisdiction.

Under the Federal Food, Drug, and Cosmetic Act (the "Act"), it is unlawful to introduce or deliver for introduction into interstate commerce any drug that is adulterated or misbranded. 21 U.S.C. § 331(a). A drug is misbranded if the advertisements or promotional materials for it are false or misleading. 21 U.S.C. § 352(n). To enforce the Act in court, the FDA has the power to ask for civil seizures, civil injunctions, and criminal prosecutions. *See* 21 U.S.C. §§ 332-334. The FDA must rely upon the Department of Justice ("DOJ") to initiate an enforcement action after the FDA's chief legal counsel recommends it. *See* FDA Regulatory Procedures Manual, Chapter 6.

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<sup>2</sup> PLAC will rely on and incorporate Janssen's Statement of Facts, Assignments of Error, and Standard of Review in its Petition For Appeal.

The FDA also has formal administrative enforcement powers, such as the power to recall products and to delay, suspend, or withdraw product approvals that must follow administrative procedures. *See generally* FDA Regulatory Procedures Manual, Chapter 5. The FDA can assess civil penalties only after an administrative complaint is issued and the company is given the opportunity for a hearing. *See* 21 C.F.R. Part 17. The FDA's chief legal counsel can also recommend that DOJ initiate an action for civil penalties. *See* 21 U.S.C. § 337(b); FDA Regulatory Procedures Manual, Chapter 5.

Finally, the FDA has several informal tools, such as warning letters, to encourage compliance with the Act and FDA regulations. The FDA uses warning letters "to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action." FDA Regulatory Procedures Manual, § 4-1-1. To encourage compliance and to avoid litigation, the FDA manual provides: "A Warning Letter is *informal and advisory*. It 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.* (emphases added). In brief, the FDA warning letters are unilaterally issued by staff, are preliminary, are not even binding on the FDA, and fall short of any enforcement proceeding, adjudication, or any sort of a hearing.

The State's claim centers around two FDA staff warning letters regarding Janssen's promotional materials for Risperdal and Duragesic sent to health care professionals. On April 19, 2004, the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") sent Janssen a warning letter. It asserted that Janssen's November 10, 2003 letter to health care professionals, after a change to Risperdal's FDA-approved warning label, was false and misleading. Although Janssen disputed the FDA staff's warning letter, Janssen eventually

acceded to the FDA's request and sent a corrective letter, which set forth the FDA staff's points of view and reproduced a copy of the current Risperdal warning label.

On September 2, 2004, DDMAC sent Janssen a different warning letter regarding a Duragesic promotional file card circulated to health care professionals. This warning letter alleged that some information within the file card was false and misleading. Again, though Janssen disagreed with DDMAC's contentions, Janssen acceded to the FDA's request and sent a corrective letter. This corrective letter, too, set forth the FDA staff's allegations and reproduced a copy of the Duragesic warning label.

Neither of DDMAC's warning letters contained an official, final agency determination or finding; both warning letters simply *requested* that Janssen take voluntary action. Each letter then noted that failure to take voluntary action *may* result in FDA regulatory action, such as initiation of judicial or administrative proceedings. Before issuing these warning letters, the FDA staff never gave Janssen an opportunity to be heard on the allegations within the letters. Moreover, Janssen never admitted in either corrective letter that its promotional materials contained false and misleading information, or even that Janssen agreed with the FDA staff's contentions. In fact, the language of the corrective letters, which Janssen drafted and the FDA staff approved, contained only the FDA staff's contentions, not Janssen's views on the issues.<sup>3</sup>

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<sup>3</sup> For example, the corrective letter sent regarding Risperdal states:

- "The Food and Drug Administration's (FDA) Division of Drug, Marketing, Advertising, and Communications (DDMAC) has asked us to contact you because Janssen received a Warning Letter concerning the promotion of Risperdal."
- "Specifically, the Warning Letter stated that the DHCP letter omitted important information regarding . . . ."

Risperdal Warning Letter, dated April 19, 2004.

On August 17, 2004, through contingency fee counsel, the State sued Janssen contending that it had violated West Virginia's Consumer Credit and Protection Act ("CCPA") by making willfully deceptive statements regarding Risperdal and Duragesic. The Amended Complaint merely repeated the allegations made in the FDA staff's warning letters. Granting the State's motion for partial summary judgment, which became the basis for later entry of judgment against Janssen, the circuit court ruled that Janssen's voluntary compliance with the FDA staff's informal, non-binding warning letters established, as a matter of law, that Janssen had disseminated false and misleading promotional materials concerning Risperdal and Duragesic. (Opinion and Order, at 32.)

### **III. ARGUMENT**

Rule after rule permits a person to resolve disputes and to take remedial action voluntarily without a preclusive admission of wrongdoing. The circuit court's decision violates every one.

#### **A. There Can Be No Issue Preclusion Because FDA Warning Letters Are Informal and Advisory, Not Final Agency Determinations.**

Contrary to Plaintiffs' contention in their Response to Defendants' Petition for Appeal, the circuit court gave the FDA staff's warning letters preclusive effects. (Response at 15, 18.) As stated in its Opinion and Order, the circuit court relied on these staff letters as conclusive evidence that Janssen's promotional materials contained false and misleading information. (Opinion and Order, at 32.) Plaintiffs cannot ignore the circuit courts' conclusions.

The circuit court's decision violates the rules of issue preclusion. Although the circuit court did not expressly rely on issue preclusion, it precluded Janssen from contesting the State's claims that the promotional materials were false and misleading by relying on the FDA staff's warning letters. The elements necessary for issue preclusion, however, are not met.

Because issue preclusion prevents a party from being heard, it must be applied strictly in order to comport with due process. *See Horkulic v. Galloway*, 222 W. Va. 450, 460, 665 S.E. 2d 284, 294 (2008) (concluding that it is improper for a court to apply issue preclusion principles when the prior action did not comport with fundamental due process requirements). Issue preclusion “serves to estop the relitigation by parties and their privies of any right, fact or legal matter which is put in issue and has been once determined by a valid and final judgment of a court.” *State v. Miller*, 194 W. Va. 3, 9, 459 S.E.2d 114, 120 (1995) (internal citations omitted). Issue preclusion will bar a claim only if four elements are met: (1) the issue previously decided is identical to the one presented in the current action, (2) there is a final adjudication on the merits of the prior action, (3) the party against whom the doctrine is invoked was a party in the prior action, and (4) the party against whom the doctrine is raised had a full and fair opportunity to litigate the issue in the prior action. *Id.* Here, there was no prior adjudication of the FDA staff’s allegations, which are not agency findings of fact.<sup>4</sup>

**1. The FDA Warning Letters Are Neither Final Agency Action Nor A Final Adjudication On The Merits.**

The circuit court erred in concluding that the FDA staff’s warning letters constitute final agency decisions. As the FDA procedures manual, FDA regulations, and settled case law demonstrate, these informal, advisory warning letters are sent by FDA staff members to encourage corporations to discuss voluntarily compliance options. The letters are similar to a pre-litigation claim letter. In fact, Plaintiffs in their Response to Defendants’ Petition for Appeal do not acknowledge, or even attempt to address, the FDA polices, regulations, and settled case

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<sup>4</sup> Arguably, the issues are not identical either, as the CCPA has different requirements to prove liability for civil penalties than addressed by the FDA staff. *See Janssen’s Petition for Appeal, Reasons for Granting the Petition*, Section I. B. 3.

law all providing that these staff letters are not final, binding agency action. In short, Plaintiffs do not attempt to counter these binding legal authorities because there is no way for Plaintiffs to explain them away. Ignoring them is Plaintiffs' only option.

First, the FDA Regulatory Procedures Manual instructs that warning letters are not final agency determinations. A warning letter does not even bind the FDA to pursue further action against the corporation, even if it were not to comply with the FDA staff's demand for voluntary corrective action. At most, these letters give prior notice that the FDA may undertake an enforcement action to adjudicate the issue. *See* FDA Regulatory Procedures Manual § 10-2-3; *see also* Risperdal Warning Letter, dated April 19, 2004 (indicating that the FDA *may* take regulatory action if Janssen does not comply with the requested voluntarily action). Therefore, the FDA's own manual contradicts the circuit court's determination that the warning letters are final agency determinations.

Furthermore, the text of the FDA staff's warning letters sent to Janssen follows the FDA's manual. Neither warning letter states that it is a final determination of the FDA. Both warning letters only *request* that Janssen take voluntary action; neither letter *requires* Janssen to send a corrective letter. Moreover, each letter says that the FDA may not necessarily pursue the matter further, but that failure to take voluntary action *may* result in FDA regulatory action. Therefore, these warning letters, by their very terms, belie the circuit court's determination that they are a final adjudication on the merits.

Second, there was no adjudication of the truth of the allegations in the warning letters, because the FDA did not initiate either judicial or administrative enforcement proceedings. The letters represent the opinions of some staff members, not the Commissioner, not an administrative law judge, and certainly not a court. Warning letters are not any type of final

agency determination recognized under the FDA's regulations. *See* 21 C.F.R. § 10.45(d) (limiting final determinations to the Commissioner's final decisions on administrative proceedings or hearings and officially issued advisory opinions).<sup>5</sup> As the regulations provide, a written statement issued by the FDA's staff is not a final agency determination, but "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 the FDA, and does not bind or otherwise obligate or commit the agency to the view expressed." 21 C.F.R. § 10.85(k) (emphasis added). Therefore, the FDA's regulations contradict the circuit court's determination that the warning letters are final agency action.

Third, numerous federal courts have determined that the FDA staff's warning letters are non-final, informal communications that are not final agency action. *See Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983) ("[T]he type of informal letter issued by the FDA . . . does not constitute the kind of formal or final agency action the Supreme Court had in mind . . . ."); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 946 (E.D. Wis. 2008) (rejecting plaintiff's argument that FDA had officially addressed a false and misleading advertising claim by sending the defendant a warning letter); *Prof'ls & 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 between the FDA and the [recipient]

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<sup>5</sup> Pursuant to the regulations, advisory opinions are typically issued in response to an individual's request for the agency to clarify a particular issue. *See* 21 C.F.R. § 10.85(a). Advisory opinions may also be documents interpreting a notice within the Federal Register, trade correspondence, FDA compliance policy guides, and any other documents specifically identified as an advisory opinion. *See id.* § 10.85(d). The warning letters sent to Janssen were not issued in response to an individual's request to clarify a particular issue nor do they involve the FDA explaining an agency policy or a notice within the Federal Register. Moreover, these letters were not labeled as advisory opinions. Therefore, under the regulations, the warning letters are not advisory opinions.

and do not necessarily lead to further sanction.” (internal citations omitted)); *Ester Lauder, Inc. v. U.S. Food & Drug Admin.*, 727 F. Supp. 1, 4-5 (D.D.C. 1989) (concluding that a warning letter could not be challenged in court because “the FDA’s position is not final and is likely to be reconsidered”). The FDA benefits in two ways from using warning letters to resolve disputes: Because these letters are not final agency action, recipients cannot sue the FDA to challenge the allegations made within a warning letter; yet, warning letters carry a strong demand often effective to secure corrective action. *See, e.g., Biotics Research Corp.*, 710 F.2d at 1377.

Among the cases, *Schering-Plough Healthcare Prods.* is particularly instructive. In that case, the FDA had sent a warning letter alleging that the defendant’s advertising statements were false and misleading. 547 F. Supp. 2d at 946. In opposing defendant’s motion to dismiss the Lanham Act claims, the plaintiff offered the warning letter as evidence that the FDA had already determined that the advertisements contained false or misleading statements. *Id.* at 945. The federal district court rejected this contention, concluding that the warning letters only represented the opinions of the FDA staff members who wrote it. *Id.* at 946. Under the FDA’s regulations, the warning letter did not represent official FDA action nor did it have conclusive findings of fact. *Id.* Furthermore, the letter could not constitute a final agency action when the defendant was not given the opportunity for a hearing before the warning letter was issued. *Id.*

Here, as in *Schering-Plough Healthcare Prods.*, the circuit court should not have relied upon the warning letters as conclusive, irrebuttable evidence that Janssen’s promotional materials contained false and misleading statements. These letters were the informal opinions of a few FDA staff members. They are not binding upon the agency and can be revised, or later rejected, by other agency employees. Indeed, the letters are not even sufficient to begin

enforcement proceedings against Janssen. Therefore, established case law contradicts the circuit court's determination that the warning letters are final agency action.

In short, the FDA would have to file an enforcement proceeding and go through a full adjudication before any final determination regarding the truth of the allegations was made. The circuit court's decision turns the entire burden of proof upside down and improperly provides that a pre-complaint letter is conclusive as to the facts alleged in it. Because FDA warning letters do not constitute a final adjudication of a matter, this element of issue preclusion cannot be met.

**2. Janssen Was Not Given A Full And Fair Opportunity To Adjudicate The Allegations Within The FDA Warning Letters.**

Another element of issue preclusion also cannot be satisfied. Janssen did not have a full and fair opportunity to litigate the merits of whether the promotional materials were false and misleading before the warning letters were sent. *See Horkulic*, 222 W. Va. at 460, 665 S.E.2d at 294 (“A fundamental due process point relating to the utilization of collateral estoppel is that any person against whom collateral estoppel is asserted must have had a prior opportunity to have litigated his claim.” (citations omitted)).

Prior to issuing the warning letters, the FDA did not give Janssen the opportunity to present any evidence to any adjudicative authority regarding the truthfulness of the information contained within its promotional materials. Janssen did not even have a prior dialogue with the FDA regarding the allegations within the warning letters. Instead, FDA staff members unilaterally issued these letters. Their unilateral action does not constitute a full and fair opportunity to litigate an issue. *See Wheeling-Pittsburgh Steel Corp. v. Rowing*, 205 W. Va. 286, 517 S.E.2d 763 (1999) (concluding that a determination from an informal grievance process, which is a streamlined process and lacks many of the adversarial accoutrements found in judicial

and formal administrative proceedings, cannot be used to collaterally estop a party from presenting evidence on the merits as that party was not given a full and fair opportunity to adjudicate the issue). Thus, this element is not satisfied.

Because all necessary elements for issue preclusion cannot be established, a court cannot determine that the warning letters are a final adjudication and deprive Janssen of the opportunity to present its defense. Issue preclusion does not apply, and should not apply, to cooperative, pre-litigation compromises with informal agency demands for corrective action.<sup>6</sup>

**B. The FDA Staff's Warning Letters Are Inadmissible Evidence.**

Not only do the FDA's staff warning letters not constitute conclusive evidence, they are not even admissible. First, the warning letters are inadmissible hearsay for which there is no exception. Second, Janssen's decision to accede to the warning letters' request to issue corrective letters should be treated as an inadmissible settlement. Finally, Janssen's decision to send corrective letters is an inadmissible subsequent remedial measure. Thus, the circuit court's decision is contrary to basic evidentiary principles that encourage and protect cooperative action to resolve disputes.

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<sup>6</sup> Because issue preclusion does not apply, the circuit court, at the summary judgment stage, was only left to determine that a genuine issue of material fact existed. The State is only entitled to summary judgment if its evidence is so strong that it would be entitled to a directed verdict at trial. *See Williams v. Precision Coil, Inc.*, 194 W. Va. 52, 62, n. 17, 459 S.E.2d 329, 339, n. 17 (1995). "This burden is very heavy and summary judgment rarely is granted in favor of the party having the burden of proof." *Id.*

The FDA staff's warning letters do not meet the heavy burden necessary to justify a grant of summary judgment to the State. The letters are not final agency determinations or findings, but only allegations made by FDA staff members. In effect, the circuit court adopted the allegations made in the FDA staff's warning letters as true and engaged in impermissible fact-finding at the summary judgment stage. *See Kasserman and Bowman, PLLC v. Cline*, 223 W. Va. 414, 675 S.E.2d 890, 894 (2009) (concluding that the circuit court's function at the summary judgment stage is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial"). The circuit court made inappropriate credibility findings in determining that these informal, non-binding warning letters would permit only one conclusion whatever evidence Janssen might present to prove the truthfulness of its promotional materials. *See Williams*, 194 W. Va. at 59, 459 S.E.2d at 336 (concluding that credibility determination are impermissible at the summary judgment stage).

### 1. The FDA Staff's Warning Letters Are Inadmissible Hearsay.

The circuit court's reliance on the FDA warnings letters is contrary to West Virginia's hearsay rules. Plaintiffs' current contention – that these letters are not hearsay because they were not offered for the truth of the matter asserted, but instead to show the FDA regulatory process – is a poor excuse offered only after the fact to justify the use of inadmissible hearsay. (Response at 35.)

As the circuit court's Opinion and Order made clear, it used the warning letters, which were out-of-court statements, to prove the "truth" of their allegations — that Janssen's promotional materials contained false and misleading information. This is the definition of hearsay. *See* W. Va. R. Evid. 801(c) (providing that hearsay is an out-of-court statement offered to prove the truth of the matter asserted). These letters are therefore inadmissible, unless some exception to the hearsay rule can be satisfied. *See* W. Va. R. Evid. 802.

No hearsay exception applies. The only exception that could even arguably apply is the public records exception. To be admissible under the public records exception, "evidence must qualify as a 'public report' pursuant to Rule 803(8)." *Gamblin v. Ford Motor Co.*, 204 W. Va. 419, 423, 513 S.E.2d 476, 471 (1998). Rule 803(8) provides an exception for certain hearsay documents created by public officials or agencies that can be deemed reliable because they are official agency determinations or actions.

The FDA staff's warning letters do not satisfy the criteria of Rule 803(8)(A) or (B): they are not records of the agency's activities, nor are they records of matters observed by the agency pursuant to a duty imposed on it by law. *See Smith v. Izuzu Motors Ltd.*, 137 F.3d 859, 862 (5th Cir. 1998) (holding that "preliminary or interim evaluative opinions of agency staff members" do not "'set forth' the 'activities of the agency' within the meaning of Rule 803(8)(A)"); *see also Gamblin*, 204 W. Va. at 423, 513 S.E.2d at 471 (holding that preliminary letter from NHTSA

staff “does not involve matters observed by the agency pursuant to a duty imposed by law as required by Rule 803(8)(B),” such as “accident reports” or “written weather reports”). Warning letters are, by the FDA’s own policies, preliminary allegations made by FDA staff members, not records of activities or observations. *See* FDA Regulatory Procedures Manual, § 4-1-1 (providing that warning letters are “informal and advisory” and do not constitute final agency determinations).

Nor can the preliminary determination qualify as a public report under Rule 803(8)(C) because it is not a “factual finding[] resulting from an investigation made pursuant to authority granted by law.” W. Va. R. Evid. 803(8)(C). This Court has made clear that “interim agency reports and preliminary memoranda do not satisfy Rule 803(8)(C) requirements.” *Gamblin*, 204 W. Va. at 423, 513 S.E.2d at 471.<sup>7</sup>

West Virginia is not alone in this approach. In *Toole v. McClintock*, the Eleventh Circuit ordered a new trial when the district court erroneously admitted into evidence an FDA report containing “‘proposed’ findings” on the dangers associated with silicone breast implants, because “Rule 803 makes no exception for tentative or interim reports subject to revision and review.” 999 F.2d 1430, 1434-35 (11th Cir. 1993). Likewise, the Eight Circuit held that memoranda prepared by NHTSA staff members in favor of establishing stability standards for certain types of passenger vehicles did not qualify as public records within the meaning of Rule 803(8) of the Federal Rules of Evidence (which is virtually identical to W. Va. R. Evid. 803(8)). *Smith*, 137 F.3d at 862 (cited with approval in *Gamblin*, 204 W. Va. at 423, 513 S.E.2d at 471).

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<sup>7</sup> Plaintiffs have purported to distinguish *Gamblin* on the ground that the NHTSA letter at issue in that case was not final, binding agency action. (Response at 38-39 n.56.) Plaintiffs’ observation does *not* distinguish *Gamblin*, but rather demonstrates how it is directly on point. Both the FDA staff’s warning letters and the staff letter at issue in *Gamblin* are preliminary, non-binding, informal agency reports. As such, this category of reports do not satisfy the admissibility requirements of Rule 803(8)(C). *See Gamblin*, 204 W. Va. at 423, 513 S.E.2d at 471 (concluding that “interim agency reports and preliminary memoranda do not satisfy Rule 803(8)(C) requirements”).

The Eighth Circuit explained that “preliminary or interim evaluative opinions of agency staff members” do not “reflect the ‘factual findings’ of the agency”; they only “embody the positions and opinions of individual staff members” that the agency may ultimately reject. *Id.* And in *City of New York v. Pullman, Inc.*, the Second Circuit held that an Urban Mass Transit Administration staff report, concluding that new undercarriages on subway cars were dangerous and that the cars should be retrofitted with another undercarriage design, was not admissible under Rule 803(8). As “an ‘interim’ staff report in the form of a recommendation to the Administrator” and “subject to revision and review, the report did not satisfy the rule’s requirement that the proffered evidence must constitute the ‘findings’ of an agency or official.” 662 F.2d 910, 914 (2d Cir. 1981).<sup>8</sup>

The FDA staff’s warning letters do not come close to meeting the hearsay exception within Rule 803(C) because they are not final or official agency determinations. The FDA procedures manual could not be clearer: the warning letters are “informal and advisory.” *See* FDA Regulatory Procedures Manual, § 4-1-1; *see also Prof’ls & Patients for Customized Care*, 847 F. Supp. at 1365 (“Warning letters issued by the FDA are deemed to be informal communications that do not constitute final agency action.”). Similarly, the warning letters to Janssen, by their own terms, communicate the informal and non-binding opinions of certain FDA staff members, and merely *request* that Janssen take voluntary action.

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<sup>8</sup> *See also Koonce v. Quaker Safety Prods. & Mfg. Co.*, 798 F.2d 700, 720 (5th Cir. 1986) (holding memo outlining future inquiries into safety measures and offering opinions on expected results inadmissible under Rule 803(8)(C)); *Ake v. General Motors Corp.*, 942 F. Supp. 869, 879-80 (W.D.N.Y. 1996) (holding that NHTSA’s preliminary finding that was “tentative and might have been revised or withdrawn after a hearing” was not “a true ‘finding’” for the purposes of Rule 803(8)); *Cramer v. Kuhns*, 630 N.Y.S.2d 128, 131-32 (N.Y. App. Div. 1995) (finding NHTSA study inadmissible because it was “preliminary in nature,” “there was very little detail provided as to the actual tests conducted upon the various motorcycle models,” and it presented in a “conclusory fashion” observations based “upon the owner surveys and accident reports, neither of which were admissible”).

The allegations within the warning letters — which the FDA could reject — do not satisfy the requirements of Rule 803(8)(C). Thus, the circuit court's decision conflicts with settled hearsay rules.

**2. Janssen's Compromise Of Its Dispute With The FDA Staff Is Not An Admission Of Liability And Is Inadmissible Under Rule 408.**

The circuit court was heavily influenced by the fact that Janssen compromised its dispute with the FDA staff and agreed to send corrective letters regarding the Risperdal and Duragesic promotional materials. The circuit court seemed to believe that, because Janssen made a "business decision" not to fight the FDA staff's request, Janssen admitted the allegations within the warning letters for all times. (Opinion and Order, at 29-30.) The circuit court's reasoning is factually incorrect and directly contrary to West Virginia Rule of Evidence 408.

First, Janssen never admitted that its promotional materials were false and misleading. In fact, it expressed its strong disagreement to the FDA staff. The language of the corrective letters was carefully drafted by Janssen, with the FDA's approval, to state the FDA staff's concerns, not Janssen's views on the issues. There was no admission.

Second, Rule 408 provides that evidence of "(1) furnishing or offering or promising to furnish, or (2) accepting or offering or promising to accept, a valuable consideration in compromising or attempting to compromise a claim which was disputed as to either validity or amount, is not admissible to prove liability." Under Rule 408, not only is evidence of a compromise inadmissible, but evidence of conduct or statements made in the compromise negotiations are also inadmissible. The Advisory Committee Note to Federal Rule of Evidence 408 explains the basis for the rule: not only is the evidence of a compromise irrelevant, "since the offer may be motivated by a desire for peace rather than any concession of weakness of

position,” but “[a] more consistently impressive ground is promotion of the public policy favoring the compromise and settlement of disputes.”

Rule 408 applies not only to evidence of a compromise between the parties, but also to evidence of a compromise between a party and a nonparty. In discussing Federal Rule of Evidence 408, on which West Virginia’s rule is based, federal courts have consistently held that Rule 408’s exclusion is not limited to compromises between private parties, but also applies to compromises between private parties and government agencies. *See Bowers v. Nat’l Collegiate Athletic Ass’n*, 563 F. Supp. 2d 508, 536 (D.N.J. 2008); *see also Wilson v. Parisi*, 78 Fed. Evid. Serv. 547 (M.D. Pa. 2009) (“Courts generally agree that Rule 408 applies to consent decrees.”); *N.J. Turnpike Auth. v. PPG Indus., Inc.*, 16 F. Supp. 2d 460, 473 (D.N.J. 1998) (same). And “Rule 408 prevents a party from introducing settlement — and compromise — related evidence against the compromising party whether or not the party seeking to introduce the evidence was party to the compromise agreement.” *Bowers*, 563 F. Supp. 2d at 536.

Janssen’s decision to compromise with respect to the FDA’s request to send corrective letters falls squarely within Rule 408’s prohibition. This compromise resolved the FDA staff’s concerns that Janssen’s promotional materials contained false and misleading information. Janssen’s agreement to send the corrective letters in no way creates a conclusive, irrebuttable admission of liability — it is not even valid, admissible evidence.<sup>9</sup> *See United States v. Contra Costa County Water Dist.*, 678 F.2d 90, 92 (9th Cir. 1982) (concluding that settlement evidence is of only limited relevance as settlements are often “motivated by a desire for peace rather than from a concession of the merits of the claim” (quoting Fed. R. Evid. 408 Advisory Comm.

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<sup>9</sup> In fact, if Janssen had entered into a similar compromise with the West Virginia Attorney General regarding Janssen’s promotional materials, that agreement would not be admissible against Janssen in later civil actions. *See W. Va. Code § 46A-7-107* (providing that an assurance of voluntary compliance entered between an individual and the attorney general is not “an admission of violation for any purpose”).

Note)). This rule, too, applies to foster pre-litigation dispute resolution with federal and state agencies.<sup>10</sup>

**3. Janssen's Decision To Send Corrective Letters Is Inadmissible Under Rule 407.**

Under West Virginia Rule of Evidence 407, subsequent remedial measures are not admissible to show culpability. *See* W. Va. R. Evid. 407 (providing that “[w]hen, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of subsequent measures is not admissible to prove . . . culpable conduct”). This rule has a strong policy in favor of encouraging manufacturers to make improvements to the safety of their product without fear that those improvements will be used as evidence against them. *See Diehl v. Blaw-Knox*, 360 F.3d 426, 429-30 (3d Cir. 2004); *Raymond v. Raymond Corp.*, 938 F.2d 1518, 1523 (1st Cir. 1991); *Werner v. Upjohn Co.*, 628 F.2d 848, 857 (4th Cir. 1980).

Moreover, where a manufacturer, in cooperation with a government agency, voluntarily takes remedial measures, evidence of those measures should be excluded under Rule 407. *See O'Dell v. Hercules, Inc.*, 904 F.2d 1194, 1203-1205 (8th Cir. 1990) (finding inadmissible evidence of voluntary remedial action taken after initiation of Center for Disease Control investigation); *Cameron v. Otto Bock Orthopedic Indus., Inc.*, 43 F.3d 14, 17-18 (1st Cir. 1994) (concluding that a “Dear Customer” letter sent after plaintiff’s injury was inadmissible under Federal Rule of Evidence 407); *Wolf ex rel. Wolf v. Proctor & Gamble Co.*, 555 F. Supp. 613

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<sup>10</sup> The Note to Federal Rule of Evidence 408 distinguishes an express admission of fault during compromise negotiations with a government regulatory agency as opposed to a compromise, “which is not very probative of the defendant’s guilt.” As the Note observes, “admitting such an offer or acceptance could deter a defendant from settling a civil regulatory action, for fear of evidentiary use in a subsequent criminal action.” That fear would gain considerable force if the circuit court’s decision were permitted to stand.

(D.N.J. 1982) (voluntary notification and withdrawal of tampon from market in settling FDA inquiry constituted subsequent remedial measure and was not admissible under Rule 407).

In acceding to the FDA staff's request to send the corrective letters, Janssen agreed to undertake a voluntary, subsequent remedial action. Using these corrective letters as evidence to show Janssen's culpability violates not only the text of Rule 407, but also the important policy of stimulating voluntary cooperation between manufacturers and federal agencies, such as the FDA, to promptly and efficiently mitigate potential dangers to the public. That policy would be undermined if evidence of manufacturers' remedial efforts in cooperating with the FDA could be used against them in subsequent civil actions. Thus, the circuit court's decision flies in the face of Rule 407.

**C. A Determination That Informal Agency Action Constitutes Conclusive Evidence Would Violate Due Process.**

The circuit court's decision deprives Janssen — and other persons who wish to engage in cooperative, informal resolution with a federal or state agency — of basic due process rights. Every person has a fundamental due process right to have a fair opportunity to be heard regarding the allegations against him or her. *See Goldberg v. Kelly*, 397 U.S. 254, 267 (1970) (“The fundamental requisite of due process of law is the opportunity to be heard.” (internal quotation marks omitted)); *see also In re Charleston Gazette FOIA Request*, 222 W. Va. 771, 777, 671 S.E.2d 776, 778 (2008) (“The fundamental requirement of due process is an opportunity to be heard upon such notice and proceedings as are adequate . . .”). Before issuing the warning letters, Janssen had no opportunity to present evidence contrary to the allegations made by FDA staff members. By giving conclusive, irrebuttable weight to the mere FDA staff allegations, the circuit court violated due process. *See Vlandis v. Kline*, 412 U.S. 441, 445 (1973) (concluding that it was a violation of due process for a state to determine that certain evidence,

which was not necessarily or universally true, to be considered conclusively and irrebuttably evidence). Indeed, it is equivalent to giving full conclusive effect to a complaint.

Moreover, to satisfy due process, a person must be given prior notice that a preliminary agency staff letter, if not formally challenged through an administrative agency proceeding, would constitute conclusive, irrebuttable evidence as a matter of law. *See, e.g., Hathcock v. Navistar Intern. Transp. Corp.*, 53 F.3d 36, 41 (4th Cir. 1995) (concluding that it is a violation of due process to impose penalties or sanctions without prior notice to a party). Janssen had no prior notice of the severe consequences of informally cooperating with the FDA, especially in light of the legal principles prohibiting the admissibility of voluntary compromises with informal requests for corrective action to prove liability. The FDA's own policies and settled case law provide that the warning letters are not final agency determinations or binding upon either party. *See* FDA, Regulatory Procedures Manual, § 4-1-1. A party must have prior notice of such consequences; if not, as here, due process is violated. *See Hathcock*, 53 F.3d at 41.

**D. The Circuit Court's Improvident Decision Would Have Far-Reaching, Adverse Ramifications.**

Allowing the circuit court's judgment to stand would have far-reaching effects beyond Janssen or the FDA. It would dramatically affect how a multitude of corporations and individuals interact with federal and state agencies. Other than the FDA, many federal agencies have consistently used non-binding, preliminary determinations, preliminary reports, or informal requests to encourage voluntary compliance with federal regulations, and none treats preliminary determinations or informal requests to be final agency action:

- Internal Revenue Service, *see* 26 C.F.R. § 301.6110-7(b) (prohibiting written determinations such as private letter rulings from being used or cited as precedent);

- Securities and Exchange Commission, *see* 17 C.F.R. § 202.1 (providing procedures for Commission staff to express opinions regarding compliance with the statutes the Commission administers and emphasizing that these staff opinions should not be relied upon as an official expression of the Commission's views); *see also New York City Emples. Ret. Sys. v. SEC*, 45 F.3d 7, 14 (2d Cir. 1995) (holding that SEC no-action letters "do not oblige or prevent action by the SEC, the parties, or the courts" and that "rules announced in no-action letters also have no binding authority"); SEC Staff Interpretations, *available at* [www.sec.gov/interps.shtml](http://www.sec.gov/interps.shtml) (stating that SEC no-action letters and staff interpretations only represent the views of staff and are not legally binding);
- Consumer Product Safety Commission, *see* 16 C.F.R. § 1115.20(a) (authorizing the CPSC to enter into corrective action plans with firms to correct a substantial product hazards, but noting the plans have no legally binding effect);
- Mine Safety and Health Administration, *see* 30 C.F.R. § 104.4 (requiring MSHA to notify mine operators in writing when a potential pattern of violations is identified and providing the mine operators procedures to contest the finding prior to issuance of a decision from the Administrator);
- Federal Trade Commission, *see* 16 C.F.R. § 1.1 *et seq.* (providing procedures for FTC staff to issue advisory opinions and emphasizing those opinions are issued by staff and may be freely revoked by the Commission);
- Customs Service, *see* 19 C.F.R. § 177.9 (stating that ruling letters may be subject to modification or revocation without notice and warning against relying on the letters as precedent);
- National Highway Traffic Safety Administration, *see* 49 C.F.R. § 554.10 (outlining procedures for sending staff letters informing manufacturers of an initial determination that a product is defective and providing a process for subsequently making that determination final);
- Housing and Urban Development, *see* 24 C.F.R. § 3282.407 (permitting the Secretary to make a preliminary determination of an imminent safety hazard based on "information indicating the possible existence" of a hazard and providing procedures for making such a determination final); and
- Legal Services Corporation, *see* 45 C.F.R. § 1606.6 (requiring the Corporation to issue letters informing grant recipients that the Corporation has made a preliminary determination to terminate a grant and providing for interim funding before the determination is made final).

Through these cooperative initiatives, which are essentially pre-litigation negotiations to compromise disputes, federal agencies are able to more quickly and efficiently resolve alleged violations without initiating formal, costly judicial or administrative proceedings.

If the circuit court's decision were affirmed, corporations whose products or activities are regulated would lose incentive to compromise with a federal or state agency. Under the circuit court's decision, corporations would automatically become liable and risk millions of dollars in damages or civil penalties in potentially every state simply because they agreed to resolve allegations preliminarily made by an agency's employee. Facing a cascade of harsh consequences, the corporation would have little choice but to litigate to the hilt. The circuit court's decision would effectively force any corporation that receives a preliminary determination or informal request for a corrective measure to fight the request and provoke formal administrative or judicial action. As a result, federal and state agencies would be stripped of much of their ability to regulate through informal, cooperative means. More litigation, more cost, more delay, and fewer corrective actions would occur. Public policy, in contrast, prudently seeks to reduce litigation and encourage cooperative measures.

In sum, the circuit court's decision would have far-reaching and unconstitutional effects, not only on Janssen and the FDA, but on a host of corporations, individuals, and federal and state agencies. This decision forecloses corporations and other persons from engaging in pre-enforcement compromise negotiations or voluntary corrective actions for fear of nationwide, massive liability or civil penalties. Persons would be deprived of their opportunity to be heard, even though they never admitted the agency staff's allegations. One agency employee, with no hearing and no impartial adjudicator, could control the fate of a company or individual and could set national policy on critical issues such as health, transportation, or competition. Such a

perverse rule would affect not only large pharmaceutical corporations stalked by the contingency fee bar, but also small business owners, impecunious individuals and sole practitioners who become ensnared in, but cannot afford to contest, agency investigations and demands.

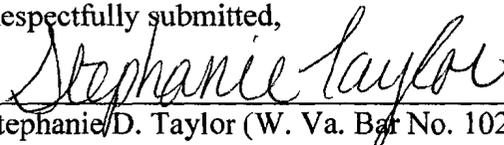
In this case, the FDA staff accomplished its mission and moved on. As the well-settled rules of civil procedure and evidence confirm, penalizing decisions to cooperate voluntarily with public agencies is bad judicial policy.

**IV. CONCLUSION**

For the foregoing reasons, the circuit court's judgment, finding as a matter of law that the FDA staff's warning letters are conclusive, irrebuttable evidence that Janssen's promotional materials contain false and misleading information, should be reversed.

Dated: May 13, 2010

Respectfully submitted,

  
Stephanie D. Taylor (W. Va. Bar No. 10232)  
JONES DAY  
500 Grant Street, Suite 4500  
Pittsburgh, PA 15219  
Telephone: 412-391-3939

*Attorney for the Product Liability Advisory  
Council, Inc.*

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

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

*Petitioners,*

v.

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

*Respondent.*

**CERTIFICATE OF SERVICE**

I, Stephanie D. Taylor, do hereby certify that I have served the foregoing Brief of the Product Liability Advisory Council, Inc., as Amicus Curiae in Support of Petitioners and Reversal, by Federal Express, this 13th day of May, 2009:

Barry M. Hill, Esq.  
Hill Williams PLLC  
89 12<sup>th</sup> Street  
Wheeling, WV 26003

Rebecca A. Betts, Esq.  
Allen Guthrie McHugh & Thomas, PLLC  
500 Lee Street, East, Suite 800  
P.O. Box 3394  
Charleston, WV 25333-3394

Frances A. Hughes  
Chief Deputy Attorney General  
State Capitol Building – Room 26E  
1900 Kanawha Blvd., East.  
Charleston, WV 25305

  
Stephanie D. Taylor (W. Va. Bar No. 10232)