



NEW JERSEY DEFENSE

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PRESIDENT'S LETTER

“THE 3RD LAW”



I have come to learn more than one could imagine about Sir Isaac Newton in the past year. The obsession really started a few years back when I got to see the movie “Gravity” followed by the movie “Interstellar.” Both are great works of art with hidden Easter eggs and layers of depth that can only be discovered through constant re-watching. Ironically, both films explore not only the power of Gravity but the complications that can arise in the absence of it. History credits Newton

with this discovery. Perhaps it is the world’s greatest accidental revelation.

While most know of, or have been told, the story of Newton and the apple, history shows that he was a man of many laws. He worked in many areas of mathematics and physics. He developed his theory of gravitation at the ripe old age of 23. Twenty years later, in 1686, he presented his three laws of motion in the “Principia Mathematica Philosophiae Naturalis.” It is the Third law that I find most intriguing.

“For every action there is an equal and opposite reaction.”

It is helpful to keep this in mind when crafting legal arguments. As lawyers, it is important to understand the “counter argument,” the “opposite viewpoint.” While it may seem that we have the superior position, Newton’s 3rd reminds us of the equal opposite reaction. This certainly helps us better inform our clients.

NJDA is here to help you understand the opposite side. In April, look for our Premises Liability CLE seminar/webinar. It will be our first ever webinar. In June, look for our joint seminar with the Middlesex County Bar Association as we tackle issues relevant to Young Lawyers. We will host our 51st Convention in Hershey, PA, from June 22-25, 2017. It is sure to be fun for all so save the date and bring your family. The convention will feature Hershey Park, WaterPark, Golf, Shopping, Restaurants, 5-6 CLE credits and FUN.

As we head into 2017, we want to encourage you to get involved. Join us, write an article, participate on a committee, follow us on Twitter, like us on Facebook, and find us on LinkedIn.

CHAD M. MOORE, ESQ.



UNCOVERING FRAUD IN THE REFERRAL RELATIONSHIP II

BY MICHAEL A. MALIA, ESQ., LL.M.

Similar to “Uncovering Fraud in the Referral Relationship”, *New Jersey Defense*, Volume 29, Issue 3, April 2014, this article examines a healthcare provider’s fraudulent scheme with a personal injury lawyer. Discovery produced in a civil action brought under the New Jersey Insurance Fraud Prevention Act (IFPA) from a now closed, undercover, criminal investigation by the FBI and the Office of the Insurance Fraud Prosecutor (OIFP), revealed the schemes set forth in both articles. This article outlines a kickback scheme described by a healthcare provider, identified herein as “Dr. A”, with a personal injury lawyer, referred to herein as “Attorney B”; and analyzes valuable corroborative evidence of follow-the-money financial records discovery.

According to Dr. A, Attorney B was the largest source of patient referrals to Dr. A’s offices. In Attorney B’s first meeting with Dr. A, Attorney B told him for every patient referred to Dr. A, Dr. A needed to send five MRI scans to a North Jersey MRI facility. When Dr. A could not send enough MRI scans to the North Jersey MRI facility, Attorney B told Dr. A in the second meeting, “why don’t you just pay me for the patients.” Dr. A agreed to pay an initial price of \$1,200 in cash per patient. In the beginning, Dr. A and Attorney B met once a month, but the monthly cash amount was so large- \$20,000 to \$40,000- that Attorney B wanted to meet twice a month.

Attorney B also suggested alternative kickback methods to reduce the exchange of cash. By way of example, Attorney B told Dr. A to write checks to a company doing marketing for Attorney B under the guise of the marketing company doing advertisements for Dr. A’s offices. Dr. A admitted he did not hire Attorney B’s marketing company for advertising. Rather, the “advertising” payments reduced Dr. A’s “final tally” to Attorney B for purchased

patients. Attorney B also told Dr. A to write a donation check to a certain church. Attorney B also gave Dr. A a “credit” against the per-patient kickback amount he owed to Attorney B for each patient Dr. A referred to a North Jersey hospital for procedures, with the credit amount varying with the procedure.

Financial records discovery in the defense of a personal injury case where Attorney B originally represented the plaintiffs and then referred the plaintiffs to Dr. A corroborated Dr. A’s proffer testimony. Subpoenas of Dr. A’s corporate bank records showed cash generation through check cashing alone in excess of \$850,000. Bank records also disclosed fifteen checks for either \$4,500 or \$5,500 made payable from Dr. A’s entities to Attorney B’s marketing company totaling \$76,500, as well as an \$18,000 “donation” check to a church made payable from Dr. A’s office. Subpoenas of Attorney B’s marketing company’s bank records revealed that Dr. A was not the only healthcare provider writing checks in furtherance of Attorney B’s kickback scheme.

Although less commonly used in defending personal injury cases than in affirmative actions brought under the IFPA, financial records discovery can be just as relevant. Moreover, regardless of the action, it is a basic principle of our jurisprudence that we construe the rules liberally in favor of broad discovery. See *Payton v. N.J. Tpk. Auth.*, 148 N.J. 524, 535 (1997); *Jenkins v. Rainer*, 69 N.J. 50, 56 (1976) (“Our court system has long been committed to the view that essential justice is better achieved when there has been full disclosure so that the parties are conversant with all the available facts.”); *Interchemical Corp. v. Uncas Printing & Finishing Co., Inc.*, 39 N.J. Super. 318 (1956) (“The discovery rules...inaugurated a permanent open season on facts.”); *Catalpa Inv. Grp., Inc.*

v. Zoning Bd. of Adjustment, 254 N.J. Super. 270, 273 (Law Div. 1991) (“...pretrial discovery is afforded the broadest possible latitude and extends not only to relevant information but also to any information that might lead to the discovery of relevant information.”). Under R. 4:10-2(a):

Parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action whether it relates to the claim or defense of any other party... It is not ground for objection that the information sought will be inadmissible at the trial if the information sought appears reasonably calculated to lead to the discovery of admissible evidence; nor is it ground for objection that the examining party has knowledge of the matters as to which discovery is sought.

It is relevance that creates a presumption in favor of discovery. *Seacoast Builders Corp. v. Rutgers, the State Univ.*, 358 N.J. Super. 524, 541 (App. Div. 2003). In deciding whether evidence is relevant, the focus is on the logical connection between the proffered evidence and a fact in issue. *Horizon Blue Cross v. State*, 425 N.J. Super. 1 (App. Div. 2012). The relevance standard implicates not only facts that would be admissible into evidence, but information that could lead to admissible evidence. *In re the Liquidation of Integrity Ins. Co.*, 165 N.J. 75, 82 (2000). As a general rule, substantial liberality in the granting of discovery is the standard. See *McKenney v. Jersey City Med. Ctr.*, 167 N.J. 359, 372 (2001); see also *Pfenninger v. Hunterdon Central*, 167 N.J. 230, 237 (2001).

In *State v. McAllister*, 184 N.J. 17, 19 (2005), the Supreme Court recognized the legitimate need to obtain financial records discovery in fraud cases:

Crimes involving corruption and fraud depend on secrecy and misinformation. Those who commit them, when confronted, hide behind walls of silence, making detection difficult. See *Addonizio*, supra, 53 N.J. at 135, 248 A.2d 531 (recognizing that “a direct inquiry” of offender “is not likely to be productive”); *United States v. Alexandro*, 675 F.2d 34, 43 (2d Cir.) (acknowledging need for “special investigative techniques to uncover insidious corruption”), cert. denied, 459 U.S. 835, 103 S.Ct. 78, 74 L.Ed.2d 75 (1982). The State’s inability to investigate and prosecute such offenses corrodes the public’s faith in its government. Furthermore, the same technology that raises Orwellian concerns of governmental heavy-handedness also enables criminals to conduct clandestine financial transactions quickly and easily.

Cf. Alexandro, supra, 675 F.2d at 43 (“Modern crime fighting methods . . . often are the only means of discovering breaches of the fundamental mandate of one’s office.”).

McAllister, 184 N.J. at 39.

Financial records discovery is necessary to unearth cash generation and expose hidden kickback methods, such as sham payments for “advertising” and “donations.” This type of discovery of kickback arrangements is relevant to establishing both the treating doctor’s positional bias in defending a personal injury lawsuit and the broader scheme in an affirmative IFPA suit. Sophisticated fraud schemes require financial records discovery to break through the secrecy, misinformation and walls of silence occurring before law

enforcement action and to corroborate evidence obtained thereafter.

Michael A. Malia, Esq., LL.M., a member of Pringle Quinn Anzano’s Insurance, Healthcare and Financial Fraud Litigation Practice Group, investigates, litigates and tries to verdict lawsuits involving sophisticated fraud schemes. Mr. Malia is the Chair of the Fraud and ADR Committees for the New Jersey Defense Association and also serves on the Board of Directors. He can be reached at (732) 280-2400 or mmalia@pringle-quinn.com.



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PHILADELPHIA TO PROHIBIT ASKING JOB APPLICANTS ABOUT THEIR PRIOR WAGE HISTORY

BY MARK SALOMAN, ESQ.

The City of Philadelphia amended its Fair Practices Ordinance (Ordinance) on January 23, 2017, to prohibit employers from inquiring about an applicant's wage history during the hiring process. The law is the first of its kind adopted by a city in the United States and takes effect on May 23, 2017. The Ordinance is based upon the Philadelphia City Council's belief that "[i]n Pennsylvania, women are paid 79 cents for every dollar a man makes." Based upon these and other "findings" by the Council, the Ordinance is designed to narrow the gender wage gap.

UNLAWFUL EMPLOYMENT PRACTICES

To that end, the Ordinance creates several new unlawful employment practices, including:

- inquiring about or requiring disclosure of a prospective employee's wage history;
- conditioning employment or consideration for an interview on disclosure of wage history;

- relying on wage history—at any stage in the employment process—to determine wages for the new hire; and
- retaliating against a prospective employee for failing to comply with a wage history inquiry or otherwise opposing an act outlawed by the Ordinance.

The Ordinance also requires employers to post notices referencing the new requirements. These notices will be available from the Philadelphia Commission on Human Relations.

EXCEPTIONS

The Ordinance excludes actions by employers or employment agencies authorized by a federal, state, or local law allowing disclosure or verification of wage history for employment purposes. The Ordinance also allows employers to rely on wage information knowingly and willingly disclosed by the prospective employee.

THE BOTTOM LINE:

New Jersey employers with Philadelphia employees must review hiring procedures and protocols, including their job applications, to remove any reference to a candidate's prior salary or wages. In addition to obtaining the new posting (when it becomes available), employers should train human resources personnel, internal recruiters, and hiring managers about these new unlawful practices. That a private right of action is now available to candidates/employees under the Ordinance increases the risk of litigation if Philadelphia employers fail to proactively review and revise existing hiring policies and procedures.

Mark Saloman is a partner in FordHarrison LLP's Berkeley Heights, New Jersey office and Co-Chair of the Firm's Non-Compete & Trade Secrets practice group. If you have any questions regarding the Fair Practices Ordinance or other labor or employment issues, please contact Mark at (973) 646-7305 or msaloman@fordharrison.com.

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A RETROSPECTIVE ON BRENMAN AND THE ACT OF REMINDING THE JURY

BY MICHAEL J. MCCAFFREY, ESQ.

Many of us who have tried cases of alleged injury resulting from accidents with automobiles have offered to the jury photographs of showing only slight damage to the vehicles involved. For several years the court has charged the jury as suggested in *Brenman v. Demello*, 191 N.J. 18 (2007). This article suggests retrospectively that the charge to the jury, the “Brenman charge,” is flawed, with the effect of providing a boon to plaintiffs.

In *Brenman*, the attorney for the defense suggested at the start of the trial and in closing argument that plaintiff likely had not been injured because there had been minimal damage to her car. Not surprisingly, the jury agreed. On appeal the issue was the evidentiary admissibility of the photographs when there had been no expert opinion to support the inference urged by the defense. ATLA-NJ filed a brief as *amicus curiae* in a vigorous effort to preclude the use of

photographs without expert testimony and thus to preclude the jury from employing the obvious premise that a slight impact usually means no more than a slight physical insult.

The appellate court agreed that the photographs were good and relevant evidence, even without their being evaluated by an expert. Adopting language of the trial court, the Court wrote: “Juries are entitled to infer [without expert testimony] that which resides squarely in the center of everyday knowledge: the certainty of proportion and the resulting recognition that slight force most often results in slight injury and great force most often is accompanied by great injury.” 191 N.J. at 32. The opinion to that point was a victory for common sense.

Wait! The Court then wrote that the judge at trial should “remind” the jury that “some bad accidents result in slight injury and that some

minor accidents result in serious injury.” 191 N.J. at 36. Huh? The suggestion in *Brenman* later was incorporated into the *Model Jury Charges, Civil*, § 5.34. Although our jurisprudence approves a court’s giving a “limiting instruction” or a “cautionary instruction” where appropriate, it struck many of us odd that the trial court should be instructed to “remind” the jury that there are exceptions to that which resides “at the center” of the jury’s common knowledge.

Consequently, your author has searched cases in New Jersey looking for another case in which the trial court “reminded” the jury that things are not always what they seem or reminded the jury of anything. We found only twenty published cases that included the phrase “remind the jury.” In only five of those cases did the court at trial “remind” the jury in the act of charging it with the law. In those five cases the reminders were respectively:



(1) that defendant is representing himself; (2) of previously-given instruction concerning the process of deliberation; (3) of the right of the accused not to take the stand; (4) that its verdict should be based only on testimony; and (5) that plaintiffs had been invitees.¹

In no case was the trial court required to remind the jury, or did remind the jury, that there are events “outside the heartland of common knowledge.” In no other case was the trial court directed by an appellate court to remind the jury of anything, much less to tell the jury to assume a fact; such as the “fact” that *sometimes* small damage can coincide with big injury. Your author has reviewed the entire corpus of the *Model Jury Charges, Civil*. In no other proposed charge is the jury instructed to assume a specific fact, much less to assume a premise or conclusion regarding the anatomical effect of forces. The admonition in *Brenman* is unique.

The “reminder” imposed by *Brenman* requires the trial court to give an opinion otherwise correctly reserved for a biomechanical expert. The opinion in *Brenman* makes reference to no data or study suggesting that a “minor” accident may result in “serious” injury. What force, applied along what axis,

what vector, under what ameliorative circumstances, constitutes a “minor” accident, is not delineated in the opinion. Should the proposition urged by the court be that an accident generating only slight acceleration or deceleration of a victim’s body in some rare circumstance has produced serious injury, then one may reasonably question the grounds upon which the court reaches that proposition or why that rarity, among all other peripherally relevant events a jury could contemplate, should be mentioned by the judge. Is the court espousing anecdote? Is such event so unusual as to be not worthy of mention to the jury?

We all may easily imagine uncommon circumstances in which an accident with minimal damage to the vehicles could produce serious injury, such as where an unrestrained occupant strikes the windshield. Conversely, we all have read of accidents where the car has been demolished and the occupant has emerged unharmed. Why then should it be necessary for the court to remind a jury, in broad and vague language, of such a relatively rare event?

Some would conclude that in effect the “reminder” acts as a thumb on the scale of justice. In compensation, in opening statement or in closing argument, in a case where photographs show slight damage to motor vehicles, a defendant’s attorney may wish to recite for the jury the very eloquent language of *Brenman*, reprinted above, language that invokes knowledge repositied in the heartland of common sense, the heartland occupied by us all.

¹(1) *State v. Reddish*, 181 N.J. 553 (2004); (2) *State v. Figueroa*, 190 N.J. 219; (3) *State v. Corby*, 47 N.J. Super. 493; (4) *State v. DiFrisco*, 137 N.J. 434; and (5) *Ambrose v. Cyphers*, 29 N.J. 138.

Michael J. McCaffrey has been certified by the Supreme Court of New Jersey as a Civil Trial Attorney since 1992. He received a B.A. (philosophy) from Rutgers University in 1978 and was graduated from the Indiana University School of Law, Bloomington, where he was selected through a writing competition to serve on the Indiana Law Journal.



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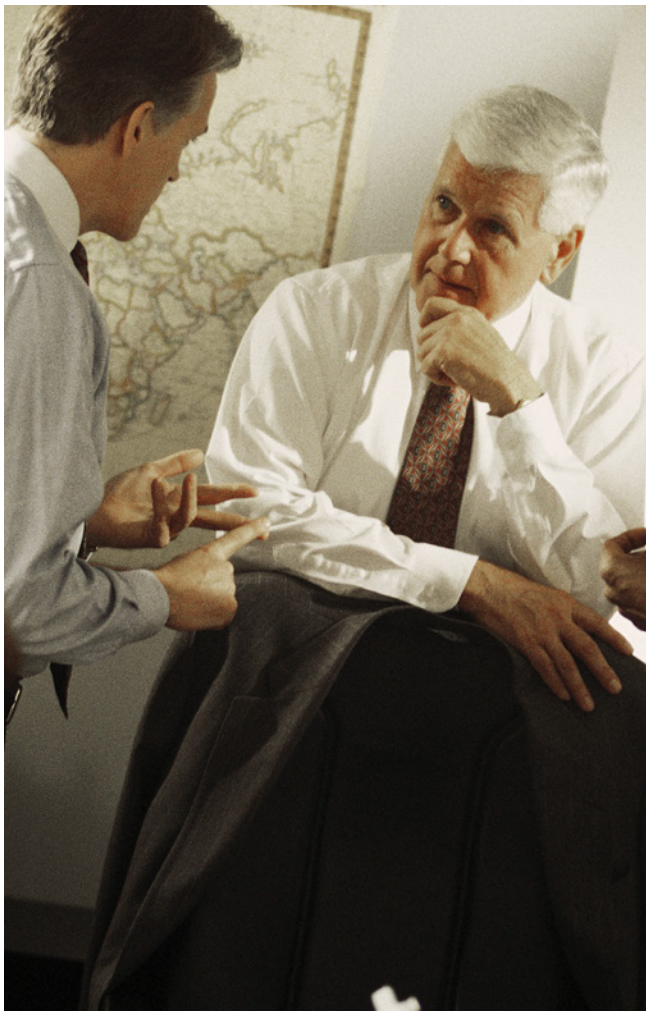
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OFF-LABEL PROMOTION OF DRUGS AND MEDICAL DEVICES: IS THE FDA LISTENING?

BY JODI SYDELL ROSENZWEIG, ESQ.

TRUTHFUL AND NON-MISLEADING SPEECH AND THE FIRST AMENDMENT

In November 2016, the Food and Drug Administration (“FDA”) held hearings on its regulations governing manufacturer communications about unapproved uses of FDA-approved medical products. See *Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products*, Docket No. FDA-2016-N-1149, 81 FED. REG. 60299 (Sept. 1, 2016) (“Notice”). Unapproved, or off-label, uses of drugs and medical devices include treatment of indications (*i.e.*, symptoms or conditions), uses in patient populations (*e.g.*, pediatric or geriatric patients) and use at doses that are different than those approved and identified in FDA-approved labeling. Physicians can legally prescribe drugs and medical devices for off-label use; however, relying on the misbranding provisions of the Federal Food, Drug and Cosmetic Act (“FDCA”), the FDA often refers manufacturers for criminal prosecution for off-label promotion.

FDA restrictions on truthful and non-misleading speech promoting lawful off-label use have

been the subject of recent successful First Amendment challenges. In the Notice, the FDA did not reference the case law, but requested feedback on the impact of off-label communications on public health and various policy issues. See 81 FED. REG. 60302-303. Due to concerns about its failure to address the First Amendment issue, the FDA added a memorandum to the docket. *Memorandum, Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products* (Jan. 2017), available at <https://www.regulations.gov> (Docket No. FDA-2016-N-1149) (“FDA Memorandum”).

This article includes a review of off-label use and promotion and a summary of First Amendment case law with commentary on the analysis in the FDA Memorandum.

OFF-LABEL USE AND PROMOTION

Under the FDCA, pharmaceutical companies may not introduce misbranded drugs or medical devices into interstate commerce. 21 U.S.C. § 331(a). A drug or device is mis-

branded if its labeling fails to include “adequate directions for use,”¹ 21 U.S.C. § 352(f), defined as “directions under which the lay[person] can use a drug [or device] safely and for the purposes for which it is intended,” 21 C.F.R. §§ 201.5, 801.5. Objective intent may be “shown by labeling claims, advertising matter, or oral or written statements.” 21 C.F.R. §§ 201.128, 801.5. When it decides a manufacturer’s off-label promotion constitutes evidence that a drug or device is intended for an unapproved use, the FDA may refer the matter for criminal prosecution – a misdemeanor or for misbranding or felony for fraudulent misbranding. See 21 U.S.C. § 333(a).²

Clinical studies frequently support off-label use of medical products. According to the American Medical Association (“AMA”), “[u]p to date, clinically appropriate medical practice at times requires the use of pharmaceuticals for ‘off-label’ indications.” Memorandum of the AMA House of Delegates, Resolution 820, *Off-Label Use of Pharmaceuticals* (Sept. 21, 2005). “Off-label use is widespread ... and often is essential to giving patients optimal medical care[.]” *Buckman Co. v. Plaintiffs’*

Legal Comm., 531 U.S. 341, 351 n.5 (2001) (quoting Beck, J.M., et al., *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 72 (1998)). The FDA acknowledges that off-label use may “constitute a medically recognized standard of care.” *Guidance for Industry: Good Reprint Practices for Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* at 3 (Jan. 2009), available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm> (“*Reprint Practices, 2009 Guidance*”).

Up-to-date clinical practice requires that physicians keep apprised of medically-recognized off-label uses. Appreciating the public health benefits of providing truthful and non-misleading information about unapproved uses, the FDA has identified certain “safe harbors” for manufacturers. See, e.g., *Reprint Practices, 2009 Guidance at 3; Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices, Revised Draft Guidance at 6* (Mar. 2014), available at <http://www.fda.gov/downloads/drugs/guidanceregulatoryinformation/guidances/ucm387652.pdf> (“*Distributing Publications, 2014 Revised Draft Guidance*”). These include manufacturer responses to unsolicited requests for off-label information, distribution of reprints of scientific and medical publications about unapproved uses, and dissemination of clinical practice guidelines (“CPGs”).³ *Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, Draft Guidance* (Dec. 2011), available at <http://www.fda.gov/downloads/drugs/guidances/ucm285145.pdf> (“*Unsolicited Requests, 2011 Draft Guidance*”); *Distributing Publications, 2014 Revised Draft Guidance*. The safe harbors have restrictions. For example, manufacturers may not distribute journal articles about their research, or research they sponsor, about off-label use of their own products. *Distributing Publications, 2014 Revised Draft Guidance* at 9. Because manufacturers often study their own products, these restrictions have a negative impact on the scientific exchange of truthful and non-misleading information.

FIRST AMENDMENT PROTECTION OF TRUTHFUL AND NON-MISLEADING SPEECH

The FDA Memorandum is intended to address free speech issues raised by stakeholders, see FDA Memorandum at 1, in accordance with recent cases challenging off-label promotion and misbranding actions based on First Amendment grounds, see *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Amarin Pharma, Inc. v. United States Food & Drug Admin.*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).⁴ The FDA argues that the First Amendment does not preclude restrictions on truthful and non-misleading speech as evidence of intended uses. See FDA Memorandum at 21-25. The FDA’s analysis of off-label promotional speech, however, is based on its misstatement of the applicable standard and misinterpretation of the constitutional protection.

Although content-based restrictions on speech are subject to heightened judicial scrutiny, *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 565-66 (2011), the FDA contends that because manufacturers have economic motivations to distribute medical products, a lesser intermediate standard applies. See FDA Memorandum at 23-25 (citing *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557 (1980)). In *Central Hudson*, the Court held if commercial speech involves lawful activity and is not misleading, the government may impose restrictions so long as the regulation serves a substantial governmental interest, “directly advances” the interest, and is “not more extensive than necessary to serve that interest.” 447 U.S. at 566. In contrast, under *Sorrell’s* heightened scrutiny, “[c]ontent-based regulations are presumptively invalid.” *Sorrell*, 564 U.S. at 571 (quoting *R.A. V. v. St. Paul*, 505 U.S. 377, 382 (1992)).

In *Sorrell*, the Court invalidated a Vermont statute restricting the disclosure and use of pharmacy records that revealed physicians’ prescribing practices and precluded pharmaceutical detailers from using the information to market their drugs. The Supreme Court stated, “Speech in aid of pharmaceutical marketing, . . . , is a form of expression protected by . . . the First Amendment.” 564 U.S. at 557. Although heightened scrutiny governs content- and speaker-based restrictions, the Court noted the outcome would be the same under

Central Hudson’s commercial speech inquiry. *Id.* at 571-72. The Court did not define heightened scrutiny.

The FDA maintains restrictions should only apply to manufacturers due to their “economic motivation related to product distribution.” FDA Memorandum at 25. Noting that manufacturers “are best positioned to conduct the research and gather information necessary for premarket review[,]” the FDA suggests that pending evaluation, they may rely on insufficient or incomplete data to support unapproved uses, exposing patients to risks. *Id.* The FDA’s reasoning is circular. Because manufacturers are best positioned to provide thorough truthful and non-misleading information, restrictions fail to advance the government’s substantial interest in preventing harm to public health.

Moreover, the FDA fails to cite the Supreme Court’s subsequent opinion in *Reed v. Town of Gilbert*, 135 S. Ct. 2218 (2015). There, the Court held laws, like the statute in *Sorrell*, that are content-based on their face are subject to strict scrutiny, which requires that the Government prove “the restriction furthers a compelling interest and is narrowly tailored to achieve that interest.” *Id.* at 2228, 2231. *Caronia* and *Amarin* were decided before *Reed*.

In *Caronia*, the Second Circuit vacated the conviction of a pharmaceutical sales representative, holding “[t]he government’s construction of the FDCA’s misbranding provisions to prohibit and criminalize the promotion of off-label drug use by pharmaceutical manufacturers is content- and speaker-based⁵ and, therefore, subject to heightened scrutiny.” 703 F.3d at 164-65. The court also applied the lesser standard, noting “the government cannot justify a criminal prohibition even under *Central Hudson’s* less rigorous intermediate test.” *Id.* at 164, 165-68.

The *Caronia* court observed that off-label promotion in general involves lawful activity (off-label use) and is not false and misleading, and the promotion in the case was not false or misleading. 703 F.3d at 165, 167. Further, because off-label use is lawful, precluding truthful off-label promotion did not directly advance the proffered governmental interests – promoting “drug safety and public health,” “preserving the effectiveness and integrity of the FDCA’s drug approval process” and “reducing patient exposure to unsafe and ineffective drugs.” *Id.* at 166-67. The court

explained, “The government’s construction of the FDCA essentially legalizes the outcome—off-label use—but prohibits the free flow of information that would inform that outcome.” *Id.* at 167. Finally, the court found the regulation more extensive than necessary to serve the government’s interests. *Id.* The court concluded:

[E]ven if speech can be used as evidence of a drug’s intended use, we decline to adopt the government’s construction of the FDCA’s misbranding provisions... as it would unconstitutionally restrict free speech. We construe the misbranding provisions... as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs. ... We conclude simply that the government cannot prosecute pharmaceutical manufacturers and their representatives ... for speech promoting the lawful, off-label use of an FDA-approved drug.

Id. at 168-69. The FDA complains, without discussion, that the court limited its review to the constitutionality of the FDCA and did not address the FDA’s “implementation approach.” FDA Memorandum at 23. It also faults the court for failing to consider “multiple components of public health interests.” *Id.*

In *Amarin*, the court, following *Caronia*’s rationale, granted the manufacturer’s motion for a preliminary injunction after the FDA threatened a misbranding action based on off-label promotion. 119 F. Supp. 3d 196. The FDA argued that *Caronia* is fact-based and does not preclude misbranding actions where promotional speech constitutes evidence that drugs are intended for unapproved uses.⁶ *Id.* at 223-24. The court disagreed, holding that “[w] here the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under *Caronia*, cannot be the act upon which an action for misbranding is based.” *Id.* at 226.

The FDA contends, “[T]he Second Circuit later confirmed that ‘*Caronia* left open the government’s ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included on the drug’s FDA-approved label.’” FDA Memorandum at 22 (quoting *United States, ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 615 n.2 (2d Cir. 2016)). There is

ample support for the holding that truthful and non-misleading speech promoting off-label use is protected by the First Amendment:

- The *Amarin* Court distinguished misbranding prosecutions based on promotional activity – e.g., rewarding doctors with vacations for off-label prescribing practices – where off-label promotional statements may be admissible on the issue of intent. 119 F. Supp. 3d at 228.
- In the cited *dicta* in *Polansky*, the court did not address whether the First Amendment precludes misbranding actions based solely on truthful and non-misleading speech. 822 F.3d at 615 n.2.
- The FDA subsequently settled *Amarin* and agreed “to be bound by the Court’s conclusion that *Amarin* may engage in truthful and non-misleading speech promoting the off-label use ... , and under *Caronia*, such speech may not form the basis of a prosecution for misbranding.” *Amarin*, No. 1:15-cv-3588-PAE, Stipulation and Order of Settlement, ECF No. 84 (S.D.N.Y. Mar. 8, 2016).
- In *United States v. Vascular Solutions, Inc.* – where a medical device manufacturer was acquitted of misbranding charges – the court instructed the jury: “It is also not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device. If you find that [Defendant’s] promotional speech to doctors was solely truthful and not misleading, then you must find the Defendants not guilty of the misbranding offense.” No. 5:14-CR-00926, 2016 WL 1742175, at p. 6 (W.D. Tex. Feb. 25, 2016).

CONCLUSION

Despite its rejection of the First Amendment protection, the FDA concedes that “relevant, truthful, and non-misleading scientific or medical information regarding unapproved uses ... may help health care professionals make better individual patient decisions.” 81 FED. REG. at 60301. The FDA has held hearings, is accepting comments (through April 19, 2017), and continues to provide guidance on its policies. Time will tell whether the FDA is listening.

¹A drug is also misbranded if its labeling is false or misleading or fails to include and prominently display required information; its container is misleading; or it is dangerous to health when used as prescribed, recommended, or suggested on the label. 21 U.S.C. §§ 352(a)-(n).

²Additionally, the FDA may pursue civil actions under the False Claims Act based upon alleged false claims submitted to government healthcare programs for non-covered and non-FDA-approved uses. See *Amarin Pharma, Inc. v. United States Food & Drug Admin.*, 119 F. Supp. 3d 196, 205 (S.D.N.Y. 2015) (citing 31 U.S.C. § 3729). It may also send “Warning Letters” for alleged “illegal promotional activities.” FDA, *Regulatory Procedures Manual* (July 2012), Ch. 4: Advisory Actions, §§ 4-1-1, 4-1-5, available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf>. Warning Letters are “informal and advisory” and the FDA’s “principal means of achieving prompt voluntary compliance with the [FDCA].” *Id.* at § 4-1-1.

³“CPGs” include recommendations that help clinicians make patient care decisions where there are no, or limited, approved treatment options, either because approved drugs or devices are not indicated for a condition or approved therapies have not been successful. *Distributing Publications, 2014 Revised Draft Guidance* at 14.

⁴FDA restrictions on off-label promotion have long been the subject of successful First Amendment challenges. See, e.g., *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) (holding off-label promotion via distribution of reprints of publications and continuing medical education was protected by the First Amendment), *appeal dismissed*, *Washington Legal Found. v. Henney*, 202 F.3d 331, 336, 337 n.7 (D.C. Cir. 2000) (noting, where plaintiff no longer had a constitutional objection, “[i]n disposing of the case in this manner, we certainly do not criticize the reasoning or conclusions of the district court”); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002) (holding provisions that precluded pharmacies from advertising and promoting compounded drugs violated First Amendment).

⁵It is content-based because it differentiates “favored speech” (speech about approved uses) from “disfavored speech” (speech about off-label uses), and it is speaker-based because it is targeted solely at manufacturers. *Caronia*, 703 F.3d at 164.

⁶In *Caronia*, although the government argued the defendant’s off-label promotion was evidence that the drug was intended for unapproved uses, the government did not raise that argument at trial and prosecuted the defendant for his speech. 703 F.3d at 160-61.

Jodi Sydell Rosenzweig, Esq. is counsel at Drinker Biddle & Reath LLP in the Florham Park office. She devotes her practice to drug and medical device defense litigation and represents pharmaceutical companies in multicounty and multidistrict litigation before both the trial and appellate courts. Jodi can be reached at jodi.rosenzweig@dbr.com.



O'TOOLE'S COUCH

AULD LANG SYNE

If you have read "O'Toole's Couch" before, you may remember that I grew up in a three-family house that my grandfather and his brothers built. This home, on Chapman Place in Irvington, NJ, was occupied by my grandparents on the third floor, my aunt's family on the second, and my parents, brother and I on the first. We also had several aunts and uncles who lived right across the street from us. "In the old days," prior to the invention of television, families went to great lengths to establish their own rituals. We were no different. On New Year's Eve, each family would bring two or three dishes to share, which always included my grandmother's sauerbraten and my mom's roast beef. My favorite of the plethora of desserts were my aunt's wonderful rice pudding and my mom's applesauce cake.

As midnight approached, my uncle would get out his mandolin, Mom would tune-up her violin, cousin Mary would play the piano, brother Joe would play the harmonica, and the rest of us had pots and spoons at the ready. When you added it all up, there was certainly a cacophony of sounds to ring in the New Year, concluded with everyone marching around the dining-room table.

(At which time I made sure to get the last piece of applesauce cake!)

As we "kids" got older, routines changed, and we started to go out to restaurants on New Year's Eve for dinner and dancing. Cousins and friends would gather at Mayfair Farms, or at the Coronet in Irvington, which had a great rock band. The Friar Tuck Inn in Cedar Grove, the Wayne Manor and Pal's Cabin in West Orange were more of our favorites. These parties were a great bang for your buck, with relatively good food, four-hour open bar, live entertainment and a breakfast buffet. After over ten years of this ritual we started going to each other's houses, alternating at different homes each year.

Advance forward to more recent times, when Sunny and I started a Progressive Dinner Party on New Year's Eve. Five couples participate, visiting four different homes. The first stop is for appetizers and cocktails. The second home serves soup and salad. The third couple provides the entrée and the fourth house is for champagne to toast in the New Year, and desserts. It is a great way to celebrate because you get to see each other's

homes decorated for the holidays. The evening flies by as we walk from home to home, and there seems to be less time for drinking. Also, each couple is pleased to only be responsible for one course.

When Sunny and I return home, usually around 2 a.m., we always have a drink together and talk about some milestones of the past year. We also try to make one New Year's Resolution that we might be able to keep, and doesn't include weight loss, which is always a constant concern in January. (Years ago I decided it might be easier to get taller rather than lose weight. Unfortunately, that never worked out.)

With respect to future alternatives, we have heard excellent reviews of the Morristown "First Night" event. It sports a full complement of shows, choirs, bands and specialty acts. Several of our friends have raved about it, and it is especially well-suited to families with young children.

Albeit a bit late, Sunny and I would like to take this opportunity to extend our wishes to you for a happy, healthy and prosperous New Year!

OFFICERS & COMMITTEES

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Gregory F. McGroarty, Esq.
Cooper Maren Nitsberg Voss & DeCoursey
485 Route 1 South, Bldg. A, Ste 200
Iselin, NJ 08830
732-362-3289
Gregory_F_Mcgroarty@progressive.com

PRESIDENT

Chad M. Moore, Esq.
Hoagland Longo Moran Dunst & Doukas, LLP
40 Paterson Street
New Brunswick, NJ 08902
732-545-4717
cmoore@hoaglandlongo.com

PRESIDENT-ELECT

Natalie H. Mantell, Esq.
Gibbons, P.C.
One Gateway Center
Newark, NJ 07102
973-596-4533
nmantell@gibbonslaw.com

SECRETARY-TREASURER

Aldo J. Russo, Esq.
Lamb Kretzer LLC
110B Meadowlands Parkway
Secaucus, NJ 07094
201-798-0400
ajr@lambkretzer.com

VICE PRESIDENTS

NORTHERN REGION

Michelle M. O'Brien, Esq.
Purcell Mulcahy Hawkins & Flanagan LLC
One Pluckemin Way
Bedminster, NJ 07921
908-306-6707
Mbrien@pmhfl.com

CENTRAL REGION

Melissa Steedle Bogad, Esq.
Winston & Strawn, LLP
One Riverfront Plaza
Newark, NJ 07102
973-848-7643
mbogad@winston.com

SOUTHERN REGION

C. Robert Luthman, Esq.
Weir & Associates, LLP
108 Straube Center Blvd.
Pennington, NJ 08534
609-737-9511
rluthman@weirattorneys.com

DIRECTORS

2014 – 2017

Stephen R. Banks, Esq.
Haddix & Associates
161 Gaither Drive
Mt. Laurel, NJ 08054
856-439-5422
Stephen.Banks@aig.com

Brian J. Chabarek, Esq.
Davison Eastman Munoz Lederman & Paone, P.A.
100 Willow Brook Road, Suite 100
Freehold, NJ 07728
732-410-2350
bchabarek@demplaw.com

2015 – 2018

Ryan Richman, Esq.
McCarter & English, LLP
100 Mulberry Street
Newark, NJ 07102
973-622-4444
rrichman@mccarter.com

Michael Malia, Esq.
Pringle Quinn Anzano, P.C.
701 7th Avenue
Belmar, NJ 07719
732-280-2400
mmalia@pringle-quinn.com

2016 – 2019

John V. Mallon, Esq.
Chasan Lamparello Mallon & Cappuzzo
300 Lighting Way
Secaucus, NJ 07094
201-348-6000
jvmallon@chasanlaw.com

Natalie S. Watson, Esq.
McCarter & English, LLP
100 Mulberry Street
Newark, NJ 07102
973-622-4444
nwatson@mccarter.com

DRI STATE REPRESENTATIVE

Mario J. Delano, Esq.
Campbell Foley Delano & Adams, LLC
601 Bangs Avenue
Asbury Park, NJ 07712
732-775-6520
mdelano@campbellfoley.com

COMMITTEES

AMICUS CURIAE

Stephen J. Foley, Jr., Esq.
Campbell Foley Delano & Adams
601 Bangs Avenue
Asbury Park, NJ 07712
732-775-6520
sfoleyjr@campbellfoley.com

BY-LAWS

J.R. Peter Wilson, Esq.

CONVENTION

Chad M. Moore, Esq.
Hoagland Longo Moran Dunst & Doukas, LLP
40 Paterson Street
New Brunswick, NJ 08902
732-545-4717
cmoore@hoaglandlongo.com

DIVERSITY

Natalie Watson, Esq.
McCarter & English, LLP
100 Mulberry Street
Newark, NJ 07102
973-622-4444
nwatson@mccarter.com

FINANCE

Aldo J. Russo, Esq.
Lamb Kretzer LLC
110B Meadowlands Parkway
Secaucus, NJ 07094
(201)798-0400
ajr@lambkretzer.com

LEGISLATIVE

Jeffrey Bartolino, Esq.
NJM, 301 Sullivan Way
West Trenton, NJ 08628-3496
609-883-1300
jbartolino@njm.com

LONG TERM PLANNING

Kevin J. DeCoursey, Esq.
Cooper Maren Nitsberg Voss & DeCoursey
485 Route 1 South, Bldg. A,
Suite 200, Iselin, NJ 08830
732-726-7180
kDecour1@progressive.com

MEDICAL DIRECTORY

Michael J. Leegan, Esq.
Goldberg Segalla
902 Carnegie Center
Princeton, NJ 08540
609-986-1320
mleegan@goldbergsegalla.com

MEMBERSHIP

Michael J. Leegan, Esq.
Goldberg Segalla
902 Carnegie Center
Princeton, NJ 08540
609-986-1320
mleegan@goldbergsegalla.com

Kevin J. DeCoursey, Esq.
Cooper Maren Nitsberg Voss & DeCoursey
485 Route 1 South, Bldg. A,
Suite 200, Iselin, NJ 08830
732-726-7180
kDecour1@progressive.com

NEW JERSEY DEFENSE

Natalie H. Mantell, Esq.
Gibbons, P.C.
One Gateway Center
Newark, NJ 07102
973-596-4533
nmantell@gibbonslaw.com

PUBLIC RELATIONS

Ryan Richman, Esq.
McCarter & English, LLP
100 Mulberry Street
Newark, NJ 07102
973-622-4444
rrichman@mccarter.com

Michelle O'Brien, Esq.
Purcell Mulcahy Hawkins & Flanagan
One Pluckemin Way
Bedminster, NJ 07921
908-306-6707
mbrien@pmhfl.com

TECHNOLOGY

Charles P. Hopkins, II, Esq.
908-601-3100
Charles.hopkins.esq.bc.edu

TRIAL COLLEGE

C. Robert Luthman, Esq.
Weir & Associates
108 Straube Center Blvd.
Pennington, NJ 08534
609-737-9511
rluthman@weirattorneys.com

TRIAL COLLEGE & WOMEN AND THE LAW

Marie A. Carey, Esq.
Law Offices of Marie A. Carey, Esq.
325 Columbia Turnpike
Florham Park, NJ 07932
973-443-9100
marie.carey@usaa.com

YOUNG LAWYERS

Christopher A. Rojao, Esq.
McCarter & English, LLP
100 Mulberry Street
Newark, NJ 07102
973-622-4444
crojao@mccarter.com

Katelyn E. Cutinello, Esq.
Bubb Grogan & Cocca, LLP
25 Prospect Street
Morristown, NJ 07960
973-539-6500
kcutinello@bgc-law.com

SUBSTANTIVE COMMITTEE

CHAIRS AND VICE CHAIRS 2016 - 2017

ADR

Michael Malia, Esq.
Pringle Quinn Anzano, P.C.
701 7th Avenue
Belmar, NJ 07719
732-280-2400
mmalia@pringle-quinn.com

APPELLATE PRACTICE

Natalie H. Mantell, Esq.
Gibbons, P.C.
One Gateway Center
Newark, NJ 07102
973-596-4533
nmantell@gibbonslaw.com

AUTOMOBILE LIABILITY

Juliann Alicino, Esq.
Hoagland Longo Moran Dunst & Doukas
40 Paterson Street
New Brunswick, NJ 08902
732-545-4717
jalicino@hoaglandlongo.com

CONSTRUCTION LAW

Michael J. Leegan, Esq.
Goldberg Segalla
902 Carnegie Center
Princeton, NJ 08540
609-986-1320
mleegan@goldbergsegalla.com

EMPLOYMENT LAW

Brian Chabarek, Esq.
Davison Eastman Munoz Lederman & Paone
100 Willow Brook Road, Suite 100
Freehold, NJ 07728
732-462-7198
bchabarek@demplaw.com

ENVIRONMENTAL LAW

Joanne Vos, Esq.
Maraziti Falcon, LLP
150 JFK Parkway
Short Hills, NJ 07078
973-912-9008
jvos@mfhenvlaw.com

Jacob Grouser, Esq.
Hoagland Longo Moran Dunst & Doukas, LLP
40 Paterson Street
New Brunswick, NJ 08903
732-545-4717
jgrouser@hoaglandlongo.com

FRAUD

Michael Malia, Esq.
Pringle Quinn Anzano, P.C.
701 7th Avenue
Belmar, NJ 07719
732-280-2400
mmalia@pringle-quinn.com

INSURANCE LAW

Nathan Buurma, Esq.
NJM
301 Sullivan Way
West Trenton, NJ 08628-3496
609-883-1300
nbuurma@njm.com

PHILANTHROPY

Denise M. Luckenbach, Esq.
Sellar Richardson, P.C.
293 Eisenhower Parkway, Suite 170
Livingston, NJ 07039
973-992-6677
dluckenbach@sellarichardson.com

PREMISES LIABILITY

Jeffrey Maziarz, Esq.
Hoagland Longo Moran Dunst & Doukas, LLP
40 Paterson Street
New Brunswick, NJ 08903
732-545-4717
jmaziarz@hoaglandlongo.com

PRODUCTS LIABILITY

Robert M. Cook, Esq.
Goldberg Segalla
902 Carnegie Center
Princeton, NJ 08540
609-986-1380
rcook@goldbergsegalla.com

PROFESSIONAL LIABILITY

Herbert Kruttschnitt, Esq.
Law Offices of Gerard Green
200 Schultz Drive
Red Bank, NJ 07701
732-933-7900
Herbert.kruttschnitt@cna.com

PUBLIC ENTITY LAW

Natalie Watson, Esq.
McCarter & English, LLP
100 Mulberry Street
Newark, NJ 07102
973-622-4444
nwatson@mccarter.com

Aldo J. Russo, Esq.
Lamb Kretzer, LLC
110B Meadowlands Parkway
Secaucus, NJ 07094
201-798-0400
ajr@lambkretzer.com

PIP

Nicole R. Cassata, Esq.
Chasan Leyner & Lamparello, P.C.
300 Harmon Meadow Blvd.
Secaucus, NJ 07094
201-348-6000
ncassata@chasanlaw.com

TRUCKING LAW

Robert M. Cook, Esq.
Goldberg Segalla
902 Carnegie Center
Princeton, NJ 08540
609-986-1320
rcook@goldbergsegalla.com

WORKERS' COMPENSATION

Stephen Banks, Esq.
Dempster & Haddix
161 Gaither Drive, Suite 201
Mt. Laurel, NJ 08054
856-778-7841
stephen.banks@aig.com

Michele G. Haas, Esq.
Hoagland Longo Moran Dunst & Doukas
40 Paterson Street
New Brunswick, NJ 08902
732-545-4717
mhaas@hoaglandlongo.com

George C. Roselle, III, Esq.
Lamb Kretzer, LLC
110B Meadowlands Parkway
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ger@lambkretzer.com

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CONTACT

MARYANNE R. STEEDLE
Executive Director
New Jersey Defense Association
P.O. Box 463
Linwood, NJ 08221
(609) 927-1180
njda@comcast.net

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New Brunswick, NJ

MAY 19-20

**DRI ATLANTIC/
NORTHEAST
REGIONAL MEETING**

Ocean Place Resort & Spa
Long Branch, NJ

JUNE 1

**YOUNG LAWYERS
COMMITTEE JOINT
SEMINAR WITH
MIDDLESEX COUNTY
BAR ASSOCIATION
YOUNG LAWYERS
DIVISION**

5 p.m. – 7 p.m.
Hoagland Longo Moran Dunst
& Doukas
Followed by Networking
Event at Mike's Courtside

JUNE 22-25

**51ST ANNUAL
CONVENTION**

The Hotel Hershey
Hershey, PA

NOVEMBER 10

**WOMEN AND THE
LAW**

8:30 a.m. – 12:30 p.m.
APA Hotel Woodbridge
Woodbridge, NJ

NOVEMBER 21

**AUTO LIABILITY
SEMINAR**

8:30 a.m. – 1:00 p.m.
APA Hotel Woodbridge
Woodbridge, NJ

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