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IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

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Appeal No. 061900

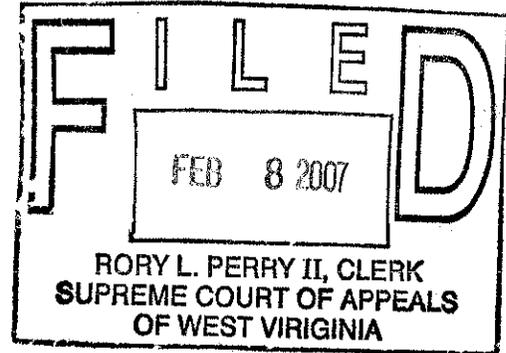
CLINTON SAN FRANCISCO and  
JESSIE SAN FRANCISCO, his wife,

Appellants

v.

WENDY'S INTERNATIONAL, INC.,

Appellee



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**BRIEF OF APPELLANTS**

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**KIND OF PROCEEDING & NATURE OF THE RULING**  
**IN THE LOWER TRIBUNAL**

This appeal stems from an entry of summary judgment against the plaintiffs in a tort action arising from the unwholesome, deleterious food products sold to the appellant, Clinton San Francisco, by the appellee, Wendy's International, Inc. ("Wendy's"). Clinton and Jessie San Francisco, the Appellants herein, appeal from an Order of the Circuit Court of Kanawha County, West Virginia, entered on March 14, 2006 ("the Second Order") (Docket item line 55; FINAL ORDER ENTERED). The Second Order reverses the circuit court's earlier decision of February 10, 2006 (Docket item line 45; O: D MOT FOR SJ DENIED/ZAK) denying summary judgment on the same grounds, holding that the plaintiffs expert witnesses have failed to provide sufficient expert testimony as to the causation of the appellants illness and is required by Daubert v. Merrell Dow, infra.

The Court's reversal of its prior decision and ultimate entry of Summary Judgment imposed a much greater and impermissible burden on the plaintiffs than West Virginia law allows by requiring an expert in the field of gastroenterology or epidemiology to testify to a diagnosis of food poisoning, which was diagnosed in the present case in the emergency room by a qualified and competent board certified physician in the field of internal medicine. This higher standard negated the appropriate differential diagnosis performed by the treating physician, Dr. Peter Gregor, in the emergency room shortly after the onset of Appellant's illness. The Petition for Appeal was granted on January 10, 2007.

**STATEMENT OF THE FACTS OF THE CASE**

On April 30, 2002, plaintiffs Clinton and Jessie San Francisco traveled from their home in

Logan, West Virginia to visit with their daughter in Barboursville, West Virginia. The plaintiffs spent the night with their daughter at her home that night. (C. San Francisco depo at 15, All referenced pages of C. San Francisco's deposition are part of the record as an exhibit to Docket item line 40; P'S RESP IN OPOPS TO D'S MOT FOR SJ W/EXH'S & COS).

The next day on May 1, 2002, the plaintiffs accompanied their granddaughter to a beauty salon in Charleston, West Virginia, where she had a 9:00 a.m. hair appointment. (Id. at 32). After the hair appointment, at approximately noon, the plaintiffs purchased food at the Wendy's on Patrick Street in Charleston, West Virginia. (Id. at 9, 31). While at the drive-thru, Mr. San Francisco ordered a single hamburger with mustard, onions, pickles and tomato and a 7-up soft drink. (Id. at 30). The group then left Wendy's and proceeded towards the interstate and started eating their meals in the car. (Id. at 41-42).

Mr. San Francisco had eaten approximately one-quarter of his hamburger at which point he noticed that the burger was "red inside and wasn't done, it was raw," "tasted funny" and that the texture was "soft." (Id. at 37-39, 40). After this observation, Mr. San Francisco discarded the remainder of the undercooked burger.

Upon approaching Barboursville, Mrs. San Francisco and her granddaughter had decided to stop at the Barboursville Mall to shop for some stockings. (Id. at 46). Mr. San Francisco's stomach began to bother him, and he remained in the car. (Id.) While his wife and granddaughter were in the mall, Mr. San Francisco began to sweat profusely as he grew increasingly ill, and "hot water" came up in his mouth, as he almost vomited. (Id. at 47, 49).

When his wife and granddaughter returned, Mr. San Francisco informed them that he was ill so they drove to their daughter's house. Upon arriving, Mr. San Francisco immediately rushed

to the bathroom where he experienced vomiting and diarrhea. (Id. at 51). The onset of the vomiting and diarrhea was approximately one and a half to two hours after the ingestion of the undercooked hamburger. (Id. at 53).

As a result of his illness, the plaintiff stayed the night with his daughter rather than return home. On May 2, 2002, the plaintiff continued to suffer from nausea, stomach cramps and diarrhea. (Id. at 58). Despite his sickness, the plaintiff traveled home to Logan on May 2, 2002, where his symptoms persisted.

After continued pain and discomfort, on May 3, 2002, Mr. San Francisco was admitted to Logan General Hospital. (Id. at 66). Mr. San Francisco remained in the hospital from May 3, 2002, until May 13, 2002. (Id.) While at Logan General, Mr. San Francisco was treated by Dr. Peter Gregor, who conducted an extensive work up and analysis of the patient and performed a differential diagnosis to determine the cause of the illness. Dr. Gregor is board certified in internal medicine and cardiology and is familiar, based on his extensive clinical experience, with the food poisoning diagnosis. After considering the patient's history and evaluating his condition, and particularly noting the large quantity his patient vomited, Dr. Gregor performed a differential diagnosis to rule out other causes and diagnosed food poisoning from the undercooked Wendy's hamburger. There were no pre-existing gastrointestinal problems, no alcohol use, no peptic ulcer disease and no history of diverticulosis. (P. Gregor depo at 27; all referenced pages of Dr. P. Gregor's deposition are part of the record as an exhibit to Docket item line 40; P'S RESP IN OPOPS TO D'S MOT FOR SJ W/EXH'S & COS). After a thorough examination and investigation, Dr. Gregor formed the diagnosis and opinion as to causation, based on his examination of the patient and his symptoms, the patient's medical history, his recent travel history and his food intake history. In so doing Dr.

Gregor stated, “[i]f you ask me, do I think a hamburger at a restaurant with diarrhea, vomiting and fluid loss shortly thereafter was the cause of the hospitalization, I would say yes.” (Id. at 26). “It [the cause of the illness] was the hamburger.” (Id. at 30).

Upon his discharge from Logan General Hospital, the plaintiff was taken home by his brother-in-law. The plaintiff had to be helped inside by his neighbor, Ronald Jones, due to the weakness caused by his illness. (C. San Francisco depo at 72). On the same day he was discharged, his daughter and son-in-law Frances and Gary Edwards picked him up at his home in Logan to take him to Huntington to care for him. (Id. at 73). While in Huntington, Mr. San Francisco’s symptoms of diarrhea and nausea persisted requiring him to be admitted to Cabell-Huntington Hospital. (Id. at 76).

Based upon his first-hand examination of Mr. San Francisco and the information he obtained while treating him, Dr. Gregor is of the opinion to a reasonable degree of medical certainty that Mr. San Francisco suffered from a foodborne illness caused by the Wendy’s hamburger. (P. Gregor depo at 45-46). Dr. Ewen Todd, an expert in food safety and toxicology, and Director of the program at Michigan State University, and well-qualified in the field in which he is offered as an expert, has opined to a reasonable degree of probability that the cause of the plaintiff’s illness was from a verotoxin, or a preformed toxin resulting from *E-coli* in ground beef. (E. Todd depo at 83; All referenced pages of Dr. E. Todd’s deposition are part of the record as an exhibit to Docket item line 40; P’S RESP IN OPOPS TO D’S MOT FOR SJ W/EXH’S & COS). Dr. Todd supported his opinion with an article, Detection and Production of Verotoxin 1 of *Escherichia coli* 0157:H7 in Food, published in a respected journal, Applied and Environmental Microbiology, Volume 57, No. 10.

On February 10, 2006, the Circuit Court of Kanawha County entered an Order denying the defendant's Motion for Summary Judgment, finding that the testimony of plaintiffs' experts was valid and was of such a nature as to defeat summary judgment. (See Docket item line 45; O: DMOT FOR SJ DENIED/ZAK). Shortly thereafter, on March 14, 2006, the circuit court, upon reconsideration of its earlier decision, and without any change in the record before it, entered an Order granting summary judgment to the defendant on the very same issue that the Court had ruled on in favor of the plaintiffs' only one month earlier. (See "Second Order," (Docket item line 55; FINAL ORDER ENTERED) It is from this Order granting summary judgment to the defendant that the plaintiffs now appeal.

#### **ASSIGNMENT OF ERROR**

**The circuit court erred in reversing its prior Order denying the defendant's motion for summary judgement as the Court imposed a higher evidentiary burden upon the plaintiffs for the admission of expert witness evidence than is required under the West Virginia Rules of Evidence.**

#### **STANDARD OF REVIEW**

The Supreme Court of Appeals of West Virginia reviews a circuit court's ruling on the admissibility of testimony for an abuse of discretion, " 'but to the extent the ... [circuit] court's ruling turns on an interpretation of a ... [West Virginia] Rule of Evidence our review is plenary.. See Gentry v. Mangum, 466 S.E.2d 171, 177 (W. Va. 1995). An interpretation of the West Virginia Rules of Evidence presents a question of law subject to *de novo* review. Ordinarily a circuit court's evidentiary rulings are reviewed under an abuse of discretion standard. Id. The trial court's determination regarding whether the scientific evidence is properly the subject of 'scientific, technical, or other specialized knowledge' is a question of law that is reviewed *de novo*. Id.

## ARGUMENT

**The circuit court erred in granting summary judgement by excluding the testimony of Drs. Peter Gregor and Ewen Todd, essentially misinterpreting and misapplying the West Virginia Rules of Evidence.**

### **THE FEDERAL COURT DAUBERT STANDARD**

Daubert v. Merrell Dow Pharmaceutical Inc., 509 US 579 (1993) is the seminal decision transitioning from the common law evidentiary standard for expert witnesses set forth earlier in Frye v. United States, 293 F. 1013, to the modern day Rules of Evidence. The Frye standard dated from 1923. The modern Federal Rules were adopted in 1975, and amended in 2000 to comply with Daubert. As it stands today, Rule 702 of the Federal Rules of Evidence states:

#### Rule 702 Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.”<sup>1</sup>

However, the West Virginia counterpart to Rule 702 is somewhat different, stating:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

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<sup>1</sup>While there is certainly no litmus test for certain components of Daubert, it is interesting to note that both in Daubert and in Bourne ex rel. Bourne v. E.I. DuPont de Nemours & Co., 95 Fed Appx. 964 (S.D. WV 2004) plaintiffs failure to produce epidemiological studies when the subject products have been submitted to exhaustive studies all of which were supportive of the defense proved fatal. Once again, the Daubert standard is flexible because such studies are a factor if available but not a requirement.

Obviously, the court must be cautious in applying the Daubert standard in state court cases when there is a different governing evidentiary rule and when as shown herein even federal courts interpreting this rule differ from the court below in its scope and application by requiring a less strict standard.

Daubert rejected as controlling the general acceptance rule to allow the admission of scientific evidence but did retain it as a factor, 509 U.S. at 594. In the instant case, plaintiffs point to the “scientific” opinions of highly qualified individuals that the plaintiff indeed suffered from food poisoning, the soundness of that diagnosis, and the agreement by Drs. Todd and Gregor as to its cause, consuming an undercooked hamburger. Keep in mind that Dr. Gregor was a treating physician, who coincidentally, is qualified to render a reliable differential diagnosis and testify to it.

The Daubert opinion declined many of the arguments made in defendant’s brief. Defendant over reads Daubert and its progeny to create an insurmountable, almost mythical barrier to exclude all manner of reliable evidence. Specifically, the court said:

“Of course, it would be unreasonable to conclude that the subject of scientific testing must be ‘known’ to a certainty; arguably there are no certainties in science.” 509 U.S. at 590.

Daubert does express that one area for the trial court to address is to determine whether the reasoning or methodology is properly applied to the facts in issue.

This is a particularly apt analysis here in that Dr. Gregor relied on a differential diagnosis which is an acceptable and reliable causation methodology in the Fourth Circuit. Westberry v. Gislaved Gummi AB, 178 F.3d 257 (4th Cir. 1999), a progeny of Daubert.

Other Daubert considerations include peer review or publications. Obviously, that consideration is not one that is always encountered, for as the Court noted, "...in some instances well grounded but innovative theories will not have been published ... some propositions, moreover, are too particular, too new, or of too limited interest to be published." 509 U.S. at 593.

The Court also identified consideration of a known or potential rate of error. 509 U.S. at 564. That consideration is of little application here. Unlike Daubert, where the product was the subject of extensive studies, mostly by a large drug manufacturer which needed to study the product which was designed for human consumption for regulatory and liability reasons, here, there could be no such study when there was a single event.

Ultimately, and perhaps the most significant part of the Daubert was the Court's instruction that "[t]he inquiry envisioned by Rule 702 is we emphasize, a flexible one." 509 U.S. at 594.

In In Re Ephedra Products Liability Litigation, 393 F.Supp.2d 181, 189 (S.D. NY 2005) the Court analyzed Daubert thusly:

"Daubert was designed to exclude 'junk science'. It was never intended to keep from the jury the kind of evidence scientists regularly rely on in forming opinions of causality simply because such evidence is not definite. The legal standard, after all, is preponderance of the evidence, i.e. more-probable-than-not, and that applies to causality as to any other element of a tort cause of action. Rule 702, a rule of threshold admissibility, should not be transformed into a rule for imposing a more exacting standard of causality than more-probable-than-not simply because scientific issues are involved. It is one thing to prohibit an expert witness from testifying that causality has been established 'to a reasonable degree of scientific certainty' when the very exacting standards for determining scientific certainty have not been met. But it by no means follows that a scientific expert may not testify to the scientific plausibility of a particular hypothesis of causality or even to the fact that a confluence of suggestive, though non-definitive, scientific studies made it more-probable-than-not that a particular substance (such as ephedra) contributed to a particular result (such as a seizure).

Drs. Gregor and Todd satisfy this more probable than not standard.

**A. THE LIABILITY AND EVIDENTIARY STANDARD UNDER WEST VIRGINIA LAW FOR ADMISSION OF EXPERT WITNESS TESTIMONY.**

This products liability action arises from the sale of an unwholesome, unsafe, deleterious food product. The West Virginia Supreme Court in Morningstar v. Black & Decker, 253 S.E.2d 666 (W.Va. 1979) acknowledged the long standing policy of strict liability in tort for defective products citing as far back as Peters v. Johnson, Jackson & Co., 41 S.E. 190 (W. Va.1902), where a plaintiff who used a drug but had not purchased it was permitted to recover damages in a tort action against the druggist. In explaining such a concept of liability, the Morningstar Court stated the following:

*A manufacturer is strictly liable* in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being. *Recognized first in the case of unwholesome food products*, such liability has now been extended to a variety of other products that create as great or greater hazards if defective. . .

Morningstar at 677 [emphasis added].

The defendant now seeks to avoid liability by challenging qualified expert witness testimony of plaintiff's board certified treating physician who made the food poisoning diagnosis. Importantly, in Gentry the West Virginia Supreme Court mandated that "[b]ecause of the 'liberal thrust' of the rules pertaining to experts, circuit courts should err on the side of admissibility." Gentry, 466 S.E.2d at 184. Here, the court did the exact opposite. In furtherance of this philosophy, the Gentry Court pointed out the following:

Our message is consistent with that of the United States Supreme Court: "Conventional devices," like vigorous cross-examination, careful instructions on the burden of proof, and rebuttal evidence,

may be more appropriate instead of the “wholesale exclusion” of expert testimony under Rule 702.

Gentry, at 184-85 (citing Daubert, 509 U.S. at 598). See Wilt v. Brubaker, 443 S.E. 2d 196 (W. Va. 1994) and W.Va. R. Evid 702.

In determining who is an expert, “a circuit judge must determine whether the proposed expert (a) meets the minimal educational or experiential qualifications (b) in a field that is relevant to the subject under investigation (c) which will assist the trier of fact.” Gentry, at 184. Second, “the circuit court must determine that the expert’s area of expertise covers the particular opinion as to which the expert seeks to testify.” Gentry, at 184.

Once the issues relating to qualifications are dealt with, “[t]he first and universal requirement for the admissibility of scientific evidence is that the evidence must be both ‘reliable’ and ‘relevant.’” Gentry, at 174. Significantly, “the reliability requirement is met only by a finding by the trial court under Rule 104(a) of the West Virginia Rules of Evidence that the scientific or technical theory which is the basis for the test results is indeed ‘scientific, technical, or specialized knowledge.’” Gentry, at 174. Furthermore, the “relevancy requirement compels the trial judge to determine, under Rule 104(a), that the scientific evidence ‘will assist the trier of fact to understand the evidence or to determine a fact in issue.’” Gentry, at 174 (citing W. Va. R. Evid. 702).

In order to further assess the reliability of the proposed scientific expert testimony, the trial judge must act as a “gatekeeper” pursuant to Daubert.<sup>2</sup> In so doing, the Court must look at the

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<sup>2</sup> Importantly, the Gentry Court was careful to point out that concerns over the reliability of evidence go to the weight, not the admissibility of the evidence:

The axiom is well recognized: the reliability of evidence goes ‘more to its weight than to the admissibility of the evidence.’

proffered testimony in order to ensure that the “expert testimony reflects scientific knowledge, whether the findings are derived by scientific method, and whether the work product amounts to good science.” Gentry, at 174. Additionally, the Court must ensure that the scientific testimony is “relevant to the task at hand.” Gentry, at 182. The trial court’s goal in acting as a “gatekeeper” is simply to determine at the outset whether “the reasoning or methodology underlying the testimony is scientifically valid.” Gentry, at 177 (citing Daubert, 509 U.S. 592-93). In order to assess the reasoning and methodology underlying the expert’s testimony, the circuit court analyzes such factors as “the ability to be tested, peer review and publication, and potential rate of error.” Gentry, at 180. Here, of course, the situation calls for the reliable methodology of a differential diagnosis. In short, the circuit court’s task is the following:

Under Daubert/Wilt, the circuit court conducts an inquiry into the validity of the underlying science, looking at the soundness of the principles or theories and the reliability of the process or method as applied in the case. *The problem is not to decide whether the proffered evidence is right, but whether the science is valid enough to be reliable.*

Gentry, 466 S.E.2d at 182 (emphasis in original). It is hard to imagine how Dr. Gregor’s differential diagnosis is not reliable or good science particularly where it is uncontested he followed appropriate medical diagnostic standards and when by every standard as board certified in internal medicine he is qualified to make this diagnosis.

It is important to remember that “Daubert/Wilt granted circuit judges the discretion and authority to determine whether scientific evidence is trustworthy, even if the technique involved has

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Gentry, 466 S.E.2d at 187 (citations omitted).

not yet won general scientific acclaim.” Gentry, at 180. Moreover, the Gentry Court provided that “Daubert firmly rejected the notion that scientific evidence may be excluded simply because it represents a new approach that has not yet been subject to the discipline of professional scrutiny through publication and peer review.” Gentry, at 186. Notably, Gentry also mandated that “[d]isputes as to the strength of an expert’s credential’s, mere differences in the methodology, or lack of textual authority for the opinion go to weight and not the admissibility of their testimony.” Gentry, at 186. Here, Dr. Gregor’s methodology cannot be challenged and Dr. Todd’s methodology is supported in the literature and by his well known and extensive work in the field of food safety.

Ironically, defendant somehow convinced or at least confused the circuit court into believing that a common food poisoning diagnosis requires a Nobel prize level of scientific scrutiny which exceeds any bound of reason or common sense. The Circuit Court’s decision to exclude the plaintiffs’ experts is contrary to the thrust of Rule 702 of the West Virginia Rules of Civil Procedure and the seminal cases in this jurisdiction which have interpreted it. While the Circuit Court focuses on the fact that Dr. Gregor’s specialty in internal medicine is cardiology, the Circuit Court has ignored the fact that “there is no ‘best expert’ rule.” Jones v. Patterson Contracting, Inc., 524 S.E.2d 915, 920 (W. Va. 1999) (citing Gentry at 184). In Jones, this Court reiterated the precedent set forth in Gentry as to what is required of an expert to be qualified to testify. Citing to Gentry, the Jones Court stated, “[i]t cannot be interpreted to require … that the experience, education, or training of the individual be in complete congruence with the nature of the issue sought to be proven.” Id.

The defendants emphasis, embraced by the Circuit Court, of the fact that Dr. Gregor stated, in regard to certain issues, that he would defer to a gastroenterologist or an epidemiologist is of no

relevance to his qualification to testify as an expert witness. Again, in Jones, discarding of such a notion, this Court stated the following:

The failure of an expert to be able to explain all aspects of a case or a controlling principle in a satisfactory manner is relevant only to the witness's credibility. "Should ... [a] witness later fail to adequately [explain], define, or describe the relevant standard of care, opposing counsel is free to explore that weakness in the testimony."

Jones at 921.

Even at a higher level of science than this case requires, the court said: "[t]he inquiry envisioned by Rule 702 is . . . a flexible one. Its overarching subject is the scientific validity -- and thus the evidentiary relevance and reliability -- of the principles that underlie a proposed submission.

*The focus, of course, must be solely on principles and methodology, not on the conclusions that*

*they generate."* Daubert, 509 U.S. at 594-95 [emphasis added]. The United States Supreme Court

took pains to underscore the flexibility of the federal evidentiary rules throughout the opinion.

Perhaps most importantly, the court noted that inasmuch as there are no certainties in science, "it

would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a

certainty." Daubert, 509 U.S. at 590.

**B. PLAINTIFFS' EXPERT PETER GREGOR, M.D., IS QUALIFIED TO RENDER AN OPINION REGARDING DIAGNOSIS AND CAUSATION OF FOOD POISONING IN A HOSPITAL EMERGENCY ROOM AND IN A COURTROOM**

The arguments proffered by the defendant in its Motion for Summary Judgment ultimately boil down to a disagreement with the opinions offered by opposing experts. For reasons never explained, the circuit court created a higher level of proof than set forth in Daubert and Gentry and their progeny by the wholesale exclusion the testimony of the plaintiffs' well qualified experts. Simply stated, the defendant disagrees with the ultimate conclusions of the plaintiffs' experts because they offer adverse causation and liability opinions. The defendant guises its argument by

attacking the qualifications and the reliability of the opinions rendered. In accepting the defendant's argument, the circuit court imposed an unattainable and impermissible standard for the introduction of plaintiffs' experts testimony. The effect of the circuit court's "Second Order" (Docket item line 55; FINAL ORDER ENTERED) says that for a patient to be properly diagnosed with food poisoning, he would have to be admitted only to a tertiary care medical facility where world class specialists practice and where a battery of extensive tests produce scientifically certain results. That does not even happen on "CSI". This is quite simply not the burden that any plaintiff must meet to satisfy the good science requirement in any personal injury case. The circuit court misapplied and misunderstood the threshold outlined in the Daubert/Wilt/Gentry line of cases, erroneously increasing plaintiff's burden to a virtually insurmountable and impermissible level. Such a burden is not required by relevant authorities nor by Rule 702 of the W. Va. R. Evid. The testimony of plaintiffs' experts is reliable and scientifically sound when a differential diagnosis is used, even in the absence of publication or routine peer review and despite the absence of a specific identification of the foodborne organism causing Mr. San Francisco's illness. See Bussey v. E.S.C. Restaurants, Inc., 620 S.E.2d 764 (Va. 2005). In granting summary judgment for the defendant, the circuit court has ignored all relevant case law regarding the admissibility of expert testimony.

- 1. Plaintiffs' medical expert, Peter Gregor, M.D., is sufficiently qualified as Mr. San Francisco's treating physician to render expert testimony regarding diagnosis and causation.**

The plaintiffs have disclosed Peter Gregor, M.D. as their medical expert in this case, to offer opinions regarding the diagnosis of Mr. San Francisco's illness and the proximate cause thereof. Dr. Gregor is board-certified in internal medicine with a sub-specialty in cardiovascular disease. Dr.

Gregor spent a great deal of his time in practice from 1979 until 2002 in internal medicine, where he would treat numerous conditions including gastroenteritis. (P. Gregor depo at 14). In dealing with patients with gastroenteritis over the years, Dr. Gregor previously diagnosed multiple patients suffering from foodborne illnesses. (Id. at 15).<sup>3</sup>

The defendant attacks the qualification of Dr. Gregor to testify as plaintiffs' medical expert in this case. Despite being a licensed physician and board certified in internal medicine, the circuit court focused on the fact that Dr. Gregor's sub-specialty is in cardiology, rather than gastroenterology or epidemiology. However, the Gentry Court made clear that "[o]nce an expert passes the minimal threshold, further credentials *affect the weight* of the testimony *not its admissibility*." Gentry at 182 [emphasis added]. The court seemed to mistake the weight of evidence for its admissibility, a reversible error.

To clarify, the Gentry Court found the lower court to have erred in excluding the plaintiff's expert testimony on the basis that the witness had no special expertise in the subject matter of his testimony, as it ignored the witness's extensive practical experience. Gentry at 183. Further elaborating on this point, and in direct opposition to the basis of the defendant's argument which is an argument and hardly a fact, that Dr. Gregor does not have specialization in gastroenterology or epidemiology. The Gentry Court disposed of this argument, stating "[n]either a degree nor a title is essential, and a person with knowledge or skill borne of practical experience may qualify as an

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<sup>3</sup>Food poisoning from undercooked hamburger meat is well known, well identified, and well accepted. Wendy's own standards are violated by serving an undercooked hamburger. The danger from undercooked hamburgers is created because entire parts of the cattle are used in the slaughtering process and this includes portions of the cow contaminated with fecal matter. The only way to completely eliminate the bacteria is by achieving the proper cooking temperature which did not happen here.

expert.” Gentry at 184. In fact, Dr. Gregor has testified to an even higher level of qualification in that in addition to his board certification in internal medicine, he has diagnosed and treated foodborne illnesses as part of his hospital practice on numerous occasions over the past twenty years. (Id. at 15).<sup>4</sup> Additionally, evidencing the liberal thrust of the W. Va. R. Evid. 702 favoring admissibility, the Gentry Court stated that “[i]t cannot be interpreted to require ... that the experience, education or training of the individual be in complete congruence with the nature of the issue sought to be proven.” Gentry at 184 (citation omitted). As such, Dr. Gregor’s education, experience, skill and training in internal medicine clearly qualify him as a medical expert to render a diagnosis and opinion concerning this food poisoning.

The defendant contends that Dr. Gregor’s examination and consultation of the plaintiff was solely to evaluate for a heart condition, not gastrointestinal problems. That is at best a jury issue. Significantly, the testimony of Dr. Gregor directly refutes this made for litigation fabrication, as he explained that part of his process in consulting Mr. San Francisco was to determine why he developed gastroenteritis. Id.

Furthermore, this court in State ex rel Wiseman v. Henning, 569 S.E.2d 204 (W.Va. 2002), suggested that “the testimony of a treating physician is qualitatively different from that of a physician hired solely to testify.” Henning at 210, footnote 2 (citing Logerquist v. McVey, 1 P. 3d 113, 123 (Ariz. 2000) (refusing to apply a “gatekeeper analysis to a treating doctor’s testimony).

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<sup>4</sup>Dr. Gregor’s impressive medical credentials including teaching and publishing are detailed in his CV attached as part of the record as exhibits to Docket item line 40; P’S RESP IN OPOPS TO D’S MOT FOR SJ W/EXH’S & COS.

Again, the appropriate means to challenge an expert is by vigorous cross-examination, careful instructions on the burden of proof and rebuttal evidence rather than wholesale exclusion of expert testimony under Rule 702. Gentry at 185, citing Daubert. However, the principles adopted by the circuit court is the Gentry Court's reference to McCormick on Evidence: "While the court may rule that a certain subject of inquiry requires that a member of a given profession, such as a doctor, an engineer, or a chemist, be called, *usually a specialist in a particular branch within the profession will not be required.*" [emphasis added] Gentry at 185. Clearly, this means it is not required that Dr. Gregor be a gastroenterologist to render an expert opinion about food poisoning. Even more simply, defendant's argument would require every trial court to micromanage the qualifications and standards for expert witnesses in a way not envisioned under Rule 702 or adopted by any federal court.

Also, "[d]isputes as to the strength of an expert's credentials, mere differences in the methodology, or lack of textual authority for the opinion *go to the weight and not the admissibility* of their testimony." Gentry at 186 [emphasis added]. Accordingly, the circuit court's ruling that Dr. Gregor is not qualified to testify as an expert witness regarding the diagnosis and causation of Mr. San Francisco's illness misapplies the law.

2. **Dr. Gregor's testimony as to the diagnosis and causation of Mr. San Francisco's illness has a sufficient factual background based on his observation and treatment of the patient and will assist the trier of fact.**

Dr. Gregor was on staff at Logan General Hospital in Logan, West Virginia, and treated Mr. San Francisco in the emergency room there on May 3, 2002. He now is on the medical faculty at

Santa Clara Valley Medical Center in San Jose, California, Gregor depo. at p. 4. Dr. Gregor noted that Mr. San Francisco vomited 1.8 liters while in the emergency room, which he considered very substantial. After considering the patient's history, Dr. Gregor was able to rule out other causes for the illness by performing a differential diagnosis which included his findings of no pre-existing gastrointestinal problems, no alcohol use, no peptic ulcer disease and no history of diverticulosis. (P. Gregor depo at 27). After a thorough clinical examination, Dr. Gregor was able to reach a diagnosis and opinion as to causation, based on his examination of the patient and his symptoms, the patient's medical history, his recent travel history and his food intake history. Each item was specifically considered. In so doing Dr. Gregor stated, "[i]f you ask me, do I think a hamburger at a restaurant with diarrhea, vomiting and fluid loss shortly thereafter was the cause of the hospitalization, I would say yes." (Id. at 26). "It was the hamburger." (Id. at 30).

A differential diagnosis has long been recognized as a reliable method supporting expert testimony. Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) ("Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated"). Furthermore, it is widely accepted as reliable:

[T]he overwhelming majority of the courts of appeals that have addressed the issue have held that a medical opinion on causation based upon a reliable differential diagnosis is sufficiently valid to satisfy the first prong of Rule 702 inquiry.

Westberry, 178 F.3d at 263. See also Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1383-85 (4<sup>th</sup> Cir. 1995) (holding that expert testimony by treating physician concerning cause of plaintiff's liver failure -- acetaminophen combined with alcohol -- was admissible despite the lack of epidemiological data);

Heller v. Shaw Indus., Inc., 167 F.3d 146, 154-55 (3d Cir. 1999) (noting “that differential diagnosis consists of a testable hypothesis, has been peer reviewed, contains standards for controlling its operation, is generally accepted, and is used outside of the judicial context” (internal quotation marks omitted)). Needless to say, when the federal courts of appeal accept a differential diagnosis as a reliable methodology, there is good reason to recognize its validity and no reason for the circuit court to reject it here.

When questioned regarding his opinion as to causation, and why he chose the undercooked hamburger as the cause of the plaintiff’s illness as opposed to other possibilities, Dr. Gregor accurately explained, “[i]t’s the highest *probability* of a series of possibilities.” (P. Gregor depo at 34) [emphasis added]. In a recent decision, the Supreme Court of Virginia in Bussey v. E.S.C. Restaurants, Inc., *infra*, a case which dealt with allowing expert testimony in a case pertaining to food poisoning, the court stated, “[w]ith regard to proximate causation where there is no direct proof, the circumstantial evidence must be sufficient to show that the causation alleged is ‘a *probability* rather than a mere possibility.’” Bussey at 766 [emphasis added]. Under the rationale of the Bussey Court’s interpretation of the admissibility and sufficiency of evidence, Dr. Gregor’s testimony is sufficient to raise a genuine issue of material fact, as it was based on facts obtained through examination and treatment of the plaintiff in the clinical setting of the hospital.

The defendant attempts to discredit the resources utilized by Dr. Gregor in arriving at his opinion, referencing that he “had performed internet research on foodborne illnesses to educate himself...” (Docket item line 36; D’S MOT FOR SJ; MEMO OF LAW IN SUPP OF MOT W/EXHS & COS). However, this is merely an argument not an accurate reflection of the record. Dr. Gregor reviewed a wealth of information and literature pertaining to foodborne illnesses, as well as the

plaintiff's medical records from his hospital stay arising from the illness in question. (P. Gregor depo at 16-20). Dr. Gregor relied not only upon his years of experience, but also upon a significant amount of science pertaining to foodborne illnesses in arriving at his expert opinion as documented in his testimony. Such diligence is all that is required under the rules of evidence and corresponding case law. Had he not reviewed the literature, which he testified was corroborative of his well founded diagnosis, it is a sure bet the defense would have scolded him for not exercising care to support his findings.

The diagnosis and causation of a foodborne illness requires expert medical knowledge and experience. Dr. Gregor qualified under both standards. Such factors are simply beyond the knowledge and understanding of the typical lay person. The determinative factor in whether testimony will assist the trier of fact depends on "whether the untrained layman would be qualified to determine intelligently and to the best possible degree the particular issue without enlightenment from those having specialized understanding of the subject involved in dispute." Gentry at 187 quoting Mason Ladd, *Expert Testimony*, 5 Vand.L.Rev. 414, 418 (1952).

The requirement that testimony aid the trier of fact relates primarily to relevance. Daubert at 591. Here, the testimony of Dr. Gregor is directly relevant to the cause of action pursued by the plaintiffs, as Dr. Gregor's testimony explains the complex and detailed diagnosis of the plaintiff's illness as well as the causative factor of the illness. As such, his testimony will aid the trier of fact in explaining testing, terminology and expertise beyond the knowledge of the mere layman.

**C. PLAINTIFFS' EVIDENCE REGARDING A FOODBORNE ORGANISM SATISFIES THE DAUBERT STANDARD.**

The circuit court erroneously held that the plaintiffs' expert evidence fails to meet the standard for admissibility under Daubert/Wilt. The defendant's argument adopted by the circuit court questions the time of onset of the plaintiff's symptoms and challenged the reliability of the theory proposed by plaintiffs' food safety expert, Ewen Cameron David Todd, Ph. D., Director of the Center for Food Safety at Michigan State University. (A copy of Dr. Todd's CV evidencing his impressive credentials in this field is part of the record as an exhibit to Docket line 40; P'S RESP IN OPOPS TO D'S MOT FOR SJ W/EXHS & COS) The defendant has no argument to challenge the qualifications of Dr. Todd. He is the Director of the Michigan State University Center for Food Safety. The defendant's misguided interpretation of Daubert, as applied by the circuit court, has led to this misconception as to the effect of reliability on the admissibility of evidence. The gist of this contention is that the methodology or scientific approval of Dr. Todd's theory deems it immaterial. However, such contention overlooks one of the basic tenets of Gentry, which mandates that "[d]isputes as to ... mere differences in the methodology, or lack of textual authority for the opinion go to weight and not the admissibility of their testimony." Gentry, at 186.

**1. Dr. Todd's "verotoxin theory" meets the requirements set forth under Daubert.**

The circuit court disallowed Dr. Todd's testimony regarding the verotoxin or pre-formed toxin deriving from *E. coli* O157:H7. In so doing, the circuit court relied on the defendant's argument that there has to date been limited publication or peer review on this subject. However, this argument ignores there is support in the literature, and that Dr. Todd has a wealth of knowledge,

experience, education and expertise in his field on which he may rely. Dr. Todd is unquestionably well qualified as an expert in his field. That surely is not the issue.

The Gentry Court made clear that a novel issue is not a bar:

Even the modern validity standard envisioned by Daubert/Wilt does not let courts exclude scientific evidence on the basis of a simple test: Daubert firmly rejected the notion that scientific evidence may be excluded simply because it represents a new approach that has not yet been subject to the discipline of professional scrutiny through publication and peer review ... Thus, this case *could present a novel, yet well grounded, conclusion that should be resolved by the trier of fact.*

Gentry at 186 [emphasis added].

The Gentry Court re-emphasized the point that “reliability of evidence goes more to its weight than to the admissibility of the evidence.” Gentry at 187. It is important to remember that “Daubert/Wilt granted circuit judges the discretion and authority to determine whether scientific evidence is trustworthy, even if the technique involved has not yet won general scientific acclaim.” Gentry, at 180.

The circuit court, in adopting the defendant’s arguments, failed to recognize another vitally important line of cases. There is clearly established law that expert opinion testimony is reliable and valid even if there are no peer reviewed studies supporting the expert’s position. In Donaldson v. Central Illinois Public Service Co., 730 N.E.2d 68 (Ill. App. 2000), four children from the same community were diagnosed with neuroblastoma over a period of approximately two years. This number was alarming in light of the fact that statistically, 9 out of every 1,000,000 children born develop this disease. All of the plaintiffs resided next to an area where a gas manufacturing plant

was located. An analysis of the soil showed several chemicals associated with coal tar, including polynuclear organic aromatic hydrocarbons (PAHs) and volatile organic compounds (VOCs). Some of the PAHs and VOCs found in the soil and groundwater are associated with cancers, but not specifically with neuroblastoma. The plaintiffs alleged that the statistical excess of neuroblastoma cases can only be connected to the contaminants found at the contaminated site.

In upholding the admissibility of plaintiffs' experts under the standard set forth in Frye v. United States, 193 F. 1013 (D.C. Cir. 1923)<sup>5</sup>, the Donaldson court noted the following:

Plaintiffs' toxicology and epidemiology experts cannot specifically link neuroblastoma to the carcinogens involved. However, they are able to point to numerous studies directly linking those same carcinogens to other forms of cancer. Extrapolating from these studies, the experts conclude that, logically, the carcinogens could have caused the neuroblastomas at issue in this case. While obviously these are not terribly strong opinions, they are causation opinions utilizing the accepted extrapolation method and are therefore admissible under Frye. . . . Contrary to CIPS's argument, an expert's causation testimony is not inadmissible simply because it is 'couched in terms of probabilities or possibilities based upon certain assumed facts.' . . . *[W]e do not believe that plaintiffs were required to prove with 100% certainty that neuroblastoma was caused by the carcinogens to which plaintiffs were exposed. What is clear is that many components of coal tar are toxic and carcinogenic in nature. Coal tar has not been specifically linked to neuroblastoma. . . . Just because presently there is no study connecting coal tar to neuroblastoma does not exclude coal tar as the cause. Coal tar is known to cause cancer. Coal tar could have very easily caused the neuroblastomas at issue in this case. . . . The weight of the testimony simply does not affect its admissibility. To hold otherwise unfairly penalizes injured parties. . . .* Plaintiffs concede that they cannot quantify individual exposures. At trial, there was testimony that the affected radius was four miles from the Site. All plaintiffs lived within four miles of the Site. . . . To summarize, and simplify, all

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<sup>5</sup> This is important because, as noted above, the Frye standard is much more rigid and strict than the Daubert standard.

plaintiffs fall in the realm of possible exposures. We therefore conclude that there was adequate evidence of causation with respect to plaintiffs' exposures to the carcinogens involved.

Donaldson, 730 N.E.2d at 78-81 [emphasis added].

Several other cases have held similarly. In Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1535-36 (D.C. Cir. 1985), the court admitted expert testimony despite the fact there were no epidemiological studies supporting the expert's opinions. See McCulloch v. H.B. Fuller Co., 61 F.3d 1038, 1043 (2d Cir. 1995)(affirming admission of treating doctor's testimony despite fact that he "could not point to a single piece of medical literature that says glue fumes cause throat polyps"); Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802 (3d Cir. 1997) (allowing expert testimony and noting that peer review and publication is not necessary in every case when dealing with reliability issues); Becker v. National Health Prods., Inc., 896 F.Supp. 100, 103 (N.D.N.Y. 1995)(admitting expert testimony despite no peer-reviewed documentation that any of the ingredients at issue caused the disease contracted by plaintiff and noting that "the fact that the expert's theories were not subject to peer review and publication or general acceptance goes to the weight of the testimony rather than its admissibility").

Accordingly, the criticism and ultimate exclusion of Dr. Todd's theory is entirely misapplied. The relevant case law has shown that publication, peer review and epidemiological studies are not prerequisites for admissibility, but merely affect what weight the jury may give such testimony. Ultimately, no reviewing court could say a reasonable jury was wrong to conclude plaintiff sustained food poisoning from an undercooked hamburger, indeed, that seems to comport with, not conflict with common sense.

**2. Dr. Todd's testimony is admissible and is within the bounds required for scientific testimony.**

The crux of the defendant's second argument presumes that Dr. Todd's testimony regarding verotoxin is inadmissible. However, as detailed herein this testimony is proper for introduction into evidence so that the jury may determine the weight his testimony. Dr. Todd has provided testimony indicating that a foodborne organism was involved and that will aid the trier of fact.

The defendant relies exclusively on the argument that no foodborne organism was identified in Mr. San Francisco's laboratory results. Of course, that argument completely overlooks that laboratory facilities were not adequate but that Dr. Gregor did perform an adequate differential diagnosis. Moreover, the Bussey Court, 620 S.E.2d 764 (Va. 2005), in its decision regarding the trial court's reliance on the lack of laboratory tests showing the existence of staphylococcal bacteria stated, "[w]e have never required proof positive by scientific testing to establish a factual basis for medical diagnosis and opinion." Bussey, *supra* at 767. This theory would also apply in the present case, where no testing was able to identify a specific foodborne organism. Again, as Dr. Gregor pointed out, the hospital has limited testing capability, nor is it a standard medical practice to retain these bodily fluids for later testing.

Just as in the present case, in Bussey, there was a time discrepancy between the onset of symptoms and time typical for an onset. The plaintiff [Bussey] had testified that the onset of her symptoms occurred four hours after eating at the Golden Corral restaurant, whereas the plaintiff's expert, Dr. Gaylord, testified that most cases of bacterial food poisoning with manifestations such as Bussey's arise within 6 to 24 hours. Despite the difference in the time frames testified to by the plaintiff and her expert, the Bussey Court stated, "the suggested conflict merely reflects the

difference between symptoms experienced in the general population and those experienced by Bussey in particular, and *created a jury issue regarding the weight to be given to the testimony.*” Bussey, supra at 767 [emphasis added]. This analysis disposes of the defendant’s identical argument in the present case.

In light of the evidence and the testimony offered by the plaintiffs, there exists issues to be determined and weighed by the trier of fact. In entering Summary Judgment, the circuit court relied on a narrow misinterpretation of the law, in an effort to nullify testimony that is damning to its position. However, careful review of the rules of evidence and the case law interpreting these rules plainly reveals that the defendant lacks a viable argument for summary adjudication.

**D. THE PLAINTIFFS HAVE OFFERED QUALIFIED, CREDIBLE SCIENTIFIC AND MEDICAL OPINIONS AS TO THE CAUSATION OF THE PLAINTIFF’S ILLNESS**

The defendant seeks to classify the plaintiffs’ expert testimony, and it appears the circuit court agreed, as nothing more than a guess off the top of the head. As set forth above, however, the testimony of Drs. Gregor and Todd is sufficient to pass muster under W. Va. R. Evid. 702 and the Daubert/Wilt/Gentry line of cases. In essence, the defendant’s third argument is no more than a hopeful fall back position.

- 1. Plaintiffs’ have provided sufficient evidence and testimony of proximate cause despite the absence of lab results specifically identifying the foodborne organism.**

The defendant posed the proposition and the circuit court adopted it, that only those victims who are fortunate (or unfortunate) enough to become afflicted with food poisoning in a tertiary care facility can present qualified expert opinion evidence. Logan General Hospital was simply not

equipped with the facilities to perform the battery of laboratory tests to specifically identify the specific foodborne organism causing Mr. San Francisco's illness. Parenthetically, food poisoning and its diagnosis long predated modern medicine and all the tools of modern medicine are not required for its diagnosis. Dr. Gregor, did however, reach a differential diagnosis of the patient, and concluded that the undercooked hamburger was the cause of his illness. "Cases involving food poisoning present unique circumstances because the primary source of evidence is usually consumed and transmuted in the ordinary course of its use. As a result, most cases will necessarily rely upon circumstantial evidence." Bussey supra at 767.

Also, recall that in Bussey, the court held that proof positive by scientific testing was not required. Bussey at 767. Furthermore, the defendant relied on Castleberry's Food Co. v. Smith, 424 S.E.2d 33 (Ga. 1992), wherein the plaintiff claimed to have sustained food poisoning from canned lasagna. However, in Castleberry the court stated "[i]n the absence of direct evidence of the defectiveness of the food, recovery could be supported by circumstantial evidence if every other reasonable hypothesis as to the cause of the plaintiff's illness could be excluded." Castleberry at 35. In Castleberry, the court relied heavily on the fact that a microbiologist testified that spoilage of the lasagna would have been evident to the plaintiff in the form of abnormal smell or taste, and that the plaintiff testified that the lasagna looked smelled and tasted good. However, in the case at hand, Mr. San Francisco testified that the hamburger was "red inside and wasn't done, it was raw," and that it tasted soft and funny. (C. San Francisco depo at 37, 38). There is a clear difference between the evidence in Castleberry and the present case.

Another food poisoning case relied upon by the defendant was Burnett v. Essex Insurance Company, 773 So.2d 786 (La. 2000). In Burnett, the plaintiffs, husband and wife, both had suffered from pre-existing conditions including gastritis, intractable abdominal pain, an acidic pre-ulcer condition, chronic abdominal pain, and prior incidents of gastroenteritis including one only two days prior to the event in question. Burnett at 788. The Burnett Court focused a great deal of attention on the health conditions of the plaintiffs and chronic bouts of abdominal distress in finding that the plaintiffs did not meet their burden.

Conversely, in the present case, it is undisputed that Mr. San Francisco suffered no prior gastrointestinal or stomach diseases, conditions or ailments prior to his illness following his consumption of the “red, raw” hamburger. The plaintiffs’ testimony pertaining to the raw, undercooked burger distinguishes this case from the line of cases cited by the defendant. Here there is evidence of the deleterious condition of the burger purchased from Wendy’s. Clearly, the plaintiffs’ evidence and testimony are sufficient to establish a question of fact to be determined by a jury.

**2. Plaintiffs’ Expert Has Performed a Differential Examination and Diagnosed the Most Probable Cause of Mr. San Francisco’s Illness.**

The defendant’s arguments accepted by the circuit court are no more than abstraction to void the expert testimony of two expert witnesses highly qualified and respected in their fields. The circuit court’s Second Order wrongly suggests that the plaintiffs’ experts must rule out all potential causes of Mr. San Francisco’s illness to render a valid opinion. Such a stringent threshold for admissibility would render it impossible for any patient to ever prove food poisoning. The only

burden that the expert must satisfy is that the causation is a probability, not merely a possibility. Such a factor is for a jury to determine the weight given this testimony, not its admissibility. Here, the record is replete with evidence and testimony that such burden has been met.

Dr. Gregor performed a clinically sound differential examination of Mr. San Francisco, taking into account the patient's medical history, contact with other persons or animals, and the food intake history of the patient, and was able to rule out other causes, having found no pre-existing gastrointestinal problems, no alcohol use, no peptic ulcer disease and no history of diverticulosis. (P. Gregor depo at 27). Clearly, Dr. Gregor, as the treating emergency room physician, has the greatest frame of reference for diagnosing the plaintiff's illness.

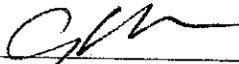
The Burnett Court reiterated the proposition that the plaintiff "need not negate every conceivable cause nor produce a scientific analysis of the alleged contaminated food." Burnett supra at 790 (citation omitted).

#### **PRAYER FOR RELIEF**

Pursuant to the foregoing, Clinton and Jessie San Francisco respectfully request that this Honorable Court set aside the Order granting defendant Wendy's Motion for Summary Judgment, entered by the Circuit Court of Kanawha County on March 14, 2006 and remand this case for trial.

Respectfully Submitted,

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JESSIE SAN FRANCISCO, his wife  
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IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

Appeal No. 061900

CLINTON SAN FRANCISCO, and  
JESSIE SAN FRANCISCO, his wife

Appellants,

vs.

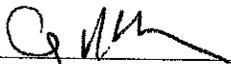
WENDY'S INTERNATIONAL, INC.

Appellee

CERTIFICATE OF SERVICE

The undersigned does hereby certify that the foregoing original of the BRIEF OF APPELLANTS, has been served upon counsel of record by depositing a true and exact copy thereof, via United States mail, postage prepaid and properly addressed on this **8th** day of **February, 2007**, as follows:

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