

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE**

United States of America,

v.

Albert Poet

Hon. Anne E. Thompson, U.S.D.J.

Criminal No. 06-643

**BRIEF OF DEFENDANT ALBERT POET
IN SUPPORT OF MOTION FOR BAIL PENDING APPEAL**

OFFICE OF JEROME A. BALLAROTTO, ESQUIRE
143 White Horse Avenue
Trenton, New Jersey 08610
Phone: 609/581-8555
Fax: 609/581-9509
Attorney for Defendant

On the Brief:

Jerome A. Ballarotto, Esq.

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STATEMENT OF THE CASE

This is a case about alleged fraud, nothing more or less. Elements for proving fraud include whether or not the Defendant intentionally made an untrue statement about an important fact for personal gain. Here, the Government alleged that Dr. Poet knowingly misrepresented to his patients that he was using a Botulin substance he said was “Botox”, but which was not the FDA Allergan approved brand. As a result, the Government alleged, Dr. Poet benefitted financially.

Dr. Poet’s defense to this allegation was, in sum, that the TRI Botulinum Type A was marketed to him as a drug in the FDA approval process, that he found the TRI product to be more efficacious than the Allergan brand, that he referred to all of his wrinkle treatments using the Botulinum using the generic “Botox” and that he did not, as is standard medical practice, routinely tell his patients which drug he was using or that the drug was FDA approved. It was simply not his intent to mislead anyone. In fact, Dr. Poet believed he was acting in the best interests of his patients and according to the highest standards of his profession.

From the beginning, it was the Court’s desire to keep the trial focused on the purported fraud and not wander into other areas, such as whether or not someone was injured. As a result, both prior to and during trial, the Court consistently refused to permit Dr. Poet to enter evidence of his state of mind. That is, Dr. Poet was prohibited from introducing or eliciting evidence:

1. That the term “Botox” has become a generic term for a form of wrinkle treatment;
2. On the quality of the TRI Botulinum Toxin Type A; and
3. Concerning Dr. Poet’s knowledge that the TRI Botulinum Toxin Type A was being marketed as a product in the FDA approval process.

All of these issues were important to Dr. Poet's state of mind as to his intent and formed the heart of his defense. However, the Court was single minded in its determination that only Dr. Poet himself could provide such testimony. Thus, the Court virtually required that Dr. Poet testify and the Court penalized him for his decision not to testify.

The Court's suppression of defense efforts to prove that Dr. Poet's state of mind was inconsistent with the specific intent required by the statute, was based on its reading and interpretation of statements made during a proffer session between Dr. Poet, his original counsel, and the United States Attorney's Office. The Court's interpretation of the statements made by Dr. Poet during the course of that proffer session, reveal that Dr. Poet knew that the Tritox product was not approved for use on human beings and that he used it on patients nevertheless and those statements, as well as other statements by Dr. Poet, establish the specific intent to defraud required by the charges in the indictment. The Court repeatedly stated that Dr. Poet was restricted by what he said in the proffer session, and therefore, that unless he testified, he would not be permitted to put in evidence concerning his state of mind. The Court concluded that there was no other available means to Dr. Poet to submit evidence of his state of mind to the jury notwithstanding attempts by defense counsel on several occasions to utilize various means, including submission of statements made by Dr. Poet that the defense argued was admissible pursuant to Rule 803(3) of the Federal Rules of Evidence, which provides for an exception to the hearsay rule when the statement is offered to establish "the declarant's state of mind. . .". See 13T 16:25-18:4; and T7 9:12-17.¹

1T = Transcript of Hearing, March 12, 2007

2T = Trial Transcript, March 13, 2007

The Court further compromised Dr. Poet's defense by:

1. Prohibiting Dr. Poet from presenting medical expert testimony regarding accepted medical practice using non-FDA approved drugs as well as the duty of physicians to provide the best care and treatment; and
2. Improperly placing a time limit on defense counsel's cross-examination of a key Government witness and by prohibiting counsel from using facts and documents reasonably relied upon by experts in the particular field.

Following trial, Dr. Poet was convicted of mail fraud and misbranding.

The Court's several rulings so hampered Dr. Poet's ability to adequately defend himself against the charges as to deny him due process of the law.

3T = Sidebar Transcript, March 13, 2007
4T = Trial Transcript, March 14, 2007
5T = Sidebar Transcript, March 14, 2007
6T = Trial Transcript, March 15, 2007
7T = Sidebar Transcript, March 15, 2007
8T = Trial Transcript, March 16, 2007
9T = Sidebar Transcript, March 16, 2007
10T = Charge Transcript, March 16, 2007
11T = Trial Transcript, March 19, 2007
12T = Trial Transcript, March 20, 2007
13T = Transcript of Hearing, May 14, 2007

PROCEDURAL HISTORY

On August 24, 2006, a fourteen count Indictment was entered against Defendant, charging him with various counts of mail fraud and misbranding.

Beginning on March 13, 2007, a six day trial was held before a jury after which the Defendant was found guilty of the charges.

Thereafter, the Defendant filed a Motion for Acquittal, for Judgment NOV, for new trial, for reconsideration and to set aside the verdict. On May 14, 2007, the motions were denied.

On October 1, 2007, the Defendant was sentenced to a 14 month term of imprisonment, a \$15,000 fine, and \$6,050 in restitution. Defendant's oral application for voluntary surrender was granted.

Dr. Poet's surrender is presently set for November 12, 2007.

STATEMENT OF FACTS

The Generic Nature of the Term “Botox”

The Defendant’s state of mind was directly at issue in this case. Central to Dr. Poet’s defense was his belief that the term “Botox” referred generically to a treatment for wrinkle removal. While the term was patented by Allergan, the defense sought to show the jury that the term has obtained such widespread association with the wrinkle treatment, that few people associated it with Allergan. In fact, each of the testifying witnesses stated under oath that they associated the term “Botox” with a procedure and not Allergan. T6 55:3-56:17; 78:5-14.

Thus the defense merely sought to enter into evidence that the term “Botox” could be used and understood to mean something other than Allergan’s cosmetic product. 3T17-20. However, the Court embraced an incorrect assumption: “This is a medical doctor defendant who had a specific - who would have a specific understanding of the trademark product Botox.” 3T24:9-10. However, this belies the fact that Dr. Poet was responding to the general public understanding of the term.

The Court barred the Defendant from cross-examining the Government’s expert on the use of the term “Botox” in a medical journal article which referred to a substance not made by Allergan. The article had been reviewed by the expert. T4 47:21-48:5.

The Quality of the TRI Botulinum Toxin Type A

The Government charged in the Indictment (at paragraph 6), that Dr. Poet’s purpose was to create an artifice or scheme to obtain money or profit by the use of the TRI product. By refusing to permit the Defendant to introduce an alternate meaning for his actions, the Court denied to the Defendant his fundamental right to defend himself.

First, the Court granted the Government's motion *in limine* to bar the Defendant from introducing any evidence on the quality of the TRI Botulinum Toxin Type A. T1 22-27. The quality of the TRI Botulinum was important in establishing the Defendant's state of mind. That is, the Defendant's use of the TRI Botulinum was because he believed the quality of that product was, in fact, better than the Allergan product. He believed by using the TRI product, he was providing his patients with better care, fulfilling his duty as a physician.

Next, the Court barred the Defendant from eliciting any testimony during cross-examination on the quality of the TRI product, even if it was communicated by the Defendant. T4 131-134. Thus, although the Court permitted the Government to examine a patient of Dr. Poet, Laurie Toth, as to what substance the Defendant administered to her and what he told her about the substance, the Court refused to permit the Defendant from cross-examining her concerning what Dr. Poet told her about the quality of the TRI Botulinum and his purpose for using it. T4 114:21-25.

The Court further barred the defense from cross-examining nurse Kim Caswell on the quality of the TRI substance. T6 58:3-25.

Finally, the Government was permitted to argue on closing that the TRI product's non-FDA approved status denied his patients of a quality substance and that TRI's use was an "unreasonable medical practice." T11 50:20-21; 87:5-88:1.

Thus, the Government was permitted to introduce evidence on issues the defense was specifically barred from introducing. The result was that the Defendant was denied his right to develop his defense and the Government was permitted an unfair advantage before the jury.

The Refusal to Permit Defendant to Proffer Medical Expert Testimony

The Defendant sought to use a medical expert's testimony to assist the jury in understanding Dr. Poet's state of mind. The expert was offered to show, among other things, that:

1. It is a common medical practice not to disclose to patients the FDA approval status of a particular drug;
2. The term "Botox" is so widely used in medical practice and by patients to describe a medical treatment and not a drug that the term has become generic rather than product specific; and,
3. Physicians are under an ethical duty to provide the best care and treatment for their patients, regardless of the FDA status of any particular drug.

T7 2:5-4:14.

However, the Court ruled that the Defendant was barred from presenting any medical expert testimony. T7 9:12-25. In sum, the Court believed that "a good faith defense must come from the Defendant himself" and not from other witnesses. Id.

On the other hand, the Government was permitted to offer its own expert who opined that an experienced physician could not reasonably use a non-FDA approved substance. T2 158. This expert was also permitted to explain to the jury the law concerning the approval of drugs. Id., at 130:14-132:10. The Government was also permitted in closing argument to argue that the use of a non-FDA approved substance was, in itself, an unreasonable, uncommon and illegal act. T11 50:20-21; 87:5-88:1.

Thus, the Government was given an unfair advantage over the Defendant, whose ability to mount an adequate defense was compromised by the decisions of the Court.

Limiting the Defendant's Cross Examination of the Government's Expert

During direct examination, the Government elicited testimony from its expert concerning the complex FDA approval process, what FDA approval means, the nature of botulinum type A toxin and the history of Allergan's Botox approval process. The Government managed to condense its direct questioning to about an hour in length. This testimony was based on over a thousand pages of regulations and statutes, numerous learned treatises and articles on botulinum toxin type A and several hundred pages of FDA documents on the Allergan Botox approval process.

During defense counsel's cross examination of the Government's expert witness, the Court inexplicably limited counsel's time within which to complete the examination. Moreover, this limiting instruction was given before the jury:

The Court: How much longer do you think you'll be, Mr. Hughes?

Mr. Hughes: I'm going to be a while, Your Honor.

The Court: I think I'm going to -- I think we've -- I'm timing both sides, and there's a certain amount of time I'm allotting for both sides. So I'm going to ask you to see if you can't wrap it up now within the last -- next -- certainly fifteen minutes.

T4 30:25-31:7. The Court thereafter interrupted counsel's cross-examination several times to indicate that it was limiting counsel's time to fully question the Government's expert. Id., at 36:5; 40:9-18; 48:2 and 56:8.

During a break, defense counsel objected to the time limitation. T3:2-3. During that conference, the Court re-emphasized that it intended to limit the time that defense counsel could question the Government's witness. Id.

The Government was further permitted to argue during closing the testimony it elicited from its expert, which the Government was able to fully develop.

Simply, the Court did not like the pace, or the manner, of the defense cross-examination and arbitrarily limited the defense examination. This limitation was harmful to Defendant's ability to properly defend himself and was prejudicial.

LEGAL ARGUMENT

The standard for bail pending appeal is set forth in 18 U.S.C. § 3143(b), which provides, in pertinent part:

(b) Release or detention pending appeal by defendant

(1) Except as provided in paragraph (2), that a judicial officer shall order that a person who has been found guilty of an offense and sentenced to a term of imprisonment, and who has filed an appeal . . . be detained unless the judicial officer finds -

(A) By clear and convincing evidence that the person is not likely to flee or pose a danger to the safety of any other person or the community if release . . .

(B) That the appeal is not for the purpose of delay and raises a substantial question of law or fact likely to result in -

(I) Reversal

(ii) An order for a new trial;

(iii) A sentence that does not include a term of imprisonment, or

(iv) a reduced sentence to a term of imprisonment less than the total of the time already served plus the expected duration of the appeal process.

If the judicial officer makes such findings, such judicial officer shall order the release of the person in accordance with section 3142(b) or ©) of this title . . .

(2) Judicial officer shall order that a person has been found guilty of any offense in a case described in sub-paragraph (A), (B), or ©) of sub-section (f)(1) of section 3142 and sentenced to term of imprisonment, and who has filed an appeal . . . be detained.

The central question raised by the statute is the existence of a ‘substantial question.’ A ‘substantial question is one that can be considered “fairly debatable.” See United States v. Smith,

793 F.2d 85, 89 (3d. Cir. 1986); United States v. Messerlian, 793 F.2d 94 (3d. Cir. 1986). In Smith, supra, the Court stated:

Instead, the Handy court emphasized its support of the historically-based “fairly debatable” interpretation of the term “substantial.” We find this approach consistent with that traditionally taken by the courts. For example, the Supreme Court of the United States, in a different context, recently affirmed that”

“In requiring a ‘question of some substance’, or a ‘substantial showing of the denial of [a] federal right,’ obviously the petitioner need not show that he should prevail on the merits. He has already failed in that endeavor. Rather, he must demonstrate that the issues are debatable among jurists of reason; that a court *could* resolve the issues [in a different manner]; or that the questions are ‘adequate to deserve encouragement to proceed further. (Citations omitted)

In U.S. v. Miller, 753 F.2d 19 (3d. 1985), the Court held that

Language “likely to result in reversal or an order for a new trial,” as used in the Bail Reform Act as a criterion for determining whether to grant bail pending appeal, refers to the likelihood that reversal or a new trial would result if the Court of Appeals were to rule contrary to the lower court on a substantial question of law or fact, but it does not refer to the likelihood that the court will, in fact, make such a ruling; thus, once it has been determined that there is no likelihood of flight and that the appeal is not for the purpose of delay, court must determine that question raised on appeal is one which is either novel, which has not been decided by a controlling precedent, or which is fairly doubtful and then must determine whether the issue is sufficiently important to the merits that a contrary appellate ruling is likely to require reversal or a new trial.

Id., at 22-24.

As the Southern District Court of Florida aptly stated, based on United States v. Miller, supra:

In determining whether there is a “substantial question” within the meaning of the Bail Reform Act governing release on bond pending appeal, court must keep in mind that it is not being asked to reverse its position on issues decided at trial, nor is it being asked to grant a new trial; it must decide only that a significant issue existed that merits appellate review and that the issue is critical enough to the defendant’s conviction that a contrary appellate ruling would warrant a reversal.

U.S. v. Hicks, 611 F.Supp 497, 499 (S.D.Fla. 1985).

Dr. Poet is entitled to bail pending appeal. First, Dr. Poet is not likely to flee or pose a danger to the safety of any other person or the community if released pending appeal. Dr. Poet has been on bail now for many months and continues to remain free on bail without incident, pending surrender to the Bureau of Prisons, which is presently scheduled for November 12, 2007. He has met every obligation imposed on him and attended every proceeding that he has been required to attend. He has been diligent in meeting his bail obligations to this point and there is no reason to believe that he would be anything but diligent in continuing with bail.

Dr. Poet is not taking an appeal and seeking bail pending appeal merely for the purposes of delay. Dr. Poet has a significant interest in preserving his professional license, a fact he would not be able to do if he failed to cooperate in all aspects of his bail. Thus, the appeal will go forward irrespective of the Court's determination concerning bail. The nature of the appeal is closely tied to the Court's determination as to the purpose of the appeal. For example, were the Court to believe that the issues raised on appeal were completely frivolous, no substantial question would be raised and it would therefore appear that the nature of the appeal was for the purposes of delay. The opposite to that suggestion is that if the court finds a substantial question, then the nature of the appeal cannot be for purpose of delay. Thus, Dr. Poet suggests for the reasons that follow, bail should be granted pending appeal.

POINT I

THE GENERIC NATURE OF THE TERM “BOTOX”

The status of commercial symbols can change over time to reflect shifts in consumer perception of their significance. It has happened that even some of the most descriptive product trademarks have become generic when they were adopted by the public as the name of the product rather than the mark of the producer. Examples include Aspirin, Cellophane and Thermos, all of which were once trademarks of a manufacturer, but are no longer because of the public perception. See Bayer Co. v. United Drug Co., 272 F. 505 (S.D.N.Y. 1921); DuPont Cellophane Co. v. Wax Products Co., 85 F.2d 75 (2d. Cir. 1936), cert. den. 299 U.S. 601 (1936); King-Seeley Thermos Co. v. Aladdin Industries, Inc., 321 F.2d 577 (2d. Cir. 1963).

Thus, when

the public no longer perceive(s) the trademark significance of the symbol at issue . . . consumers adopt(s) the mark as the name of the product behind the symbol. Symbols that fall most readily into public usage as generic names are often associated with products that are themselves novel items which the consumer has never before encountered. In such circumstances, the mark placed on the product cannot function to distinguish one manufacturer from another because there is little or no brand competition. Thus, the public recognizes the new symbol not as a brand name but as the name of a new product.

Van Well Nursery, Inc. v. MONY Life Insurance Co., 421 F.Supp.2d. 1321, 1328 (E.D.Wash. 2006).

In determining whether or not a term has become generic, courts look to whether consumers understand the word to refer only to a particular producer’s goods or whether the consumer understands the word to refer to the goods themselves. If buyers understand the terms as being identified with “a particular producer’s goods or services, it is not generic” Surgicenters

of Am., Inc. v. Medical Dental Surgeries Co., 601 F.2d 1011, 1016 (9th Cir. 1979). “But if the word is identified with all such goods or services, regardless of their suppliers, it is generic.” Id., citing King-Seeley Thermos Co. v. Aladdin Industries, Inc., supra.

The term “Botox” has accrued such a generic meaning. The general public does not refer to the drug as “Allergan” Botox. The general public appears to understand the term as a treatment, not necessarily any longer as the drug itself. Given this perception, it seems likely the mark has passed from one that identifies the producer to a generic term that identifies a procedure and specific drug.

In this case, one key prong of the Government’s claim was that Dr. Poet “misbranded” the TRI Botulinum Toxin Type A, referring to it as the Allergan Botox. However, Dr. Poet’s position was, and continues to be, that when he used the term “Botox” he was referring to the treatment for wrinkles that the general public has come to refer to as “Botox” treatments. This was confirmed during the trial by the testimony of Government witnesses. See T6 55:3-56:17 (Nurse Kim Caswell testifying that she considered the term Botox to refer to a treatment and not Allergan’s product); T6 78:5-14 (Nurse Susan Wernick answering the Court’s question that she believed Botox to be a wrinkle treatment). How the term is used by the public is precisely one of the factors which indicate its generic use. See, Beyer Co. v. United Drug Co., 272 F. 505, 513 (S.D.N.Y. 1921). See also, Am. Thermos Products Co. v. Aladdin Industries, Inc., 207 F.Supp. 9 (D.Conn. 1962).

It is respectfully submitted that the Court’s refusal to allow the defense to show the jury how a trademarked term, specifically “Botox,” could come to mean something other than the trademarked product, was an error, which prejudiced the defense. Without such evidence, the

jury was left with the impression, as argued by the Government during closing, that the term Botox could refer only to one thing - Allergan's Botox. T11 85:17-86:10.

Finally, barring the Defendant from presenting any evidence of the generic nature of the Botox term severely undermined Dr. Poet's ability to advance his state of mind defense. As the Supreme Court has held, "jurors [are] entitled to have the benefit of the defense before them so that they [can] make an informed judgment" David v. Alaska, 415 U.S. 308, 317 (1974).

POINT II

The Refusal to Permit Defendant to Offer Medical Expert Testimony or Other Evidence of Dr. Poet's State of Mind

This is a specific intent case. Central in determining specific intent is understanding the Defendant's state of mind at the time of the alleged crime. The Third Circuit has repeatedly held that expert testimony relating to the custom and practice in a particular industry is both proper and helpful to a jury, particularly in a crime requiring specific intent like this one. United States v. Leo, 941 F.2d 181, 196-197 (3d. Cir. 1991). In that case, much like this one, the Defendant was charged with a specific intent crime. Similarly, there was an issue as to whether the expert could testify in Leo as to the custom and practice of the industry as well as the law. Id. Rather than bar the entire testimony, the District Court allowed the testimony only as to custom and practice. The Circuit Court held that this testimony was "helpful to the jury in understanding what someone with [the defendant's] experience in that industry was likely to have known." Id. See also, United States v. Mathis, 264 F.3d 321, 340 (3d. Cir. 2001) (expert witness to testify to matters relevant to the jury "should generally, absent explicable reasons to the contrary, be welcomed by federal courts, not turned away.")

In the instant matter, the Court's failure to permit medical expert testimony prejudiced the Defendant as it hampered his ability to mount a meaningful defense. The Court's refusal to recognize other legally sufficient means to establish Dr. Poet's state of mind denied him due process and the right to a fair trial. The Court repeatedly ruled that testimony concerning statements made by Dr. Poet that were clearly admissible pursuant to Rule 803(3) was not admissible because Dr. Poet could not commit that he would in fact testify at trial. The Court

utilized the fact that he gave a proffer statement that may be interpreted as being inconsistent with the offered testimony as a basis to deny the testimony. By doing this, the Court not only wrongfully excluded the evidence based on a mistaken interpretation of Rule 803(3), but also permitted the proffer statements to be used against Dr. Poet, which is in complete contravention of the proffer agreement made with the United States Attorney's Office that was the basis for the statements in the first place. If indeed, the Court found that evidence submitted in the case was inconsistent with statements made by Dr. Poet in the proffer agreement, the remedy is not the exclusion of the evidence, but rather, the admission of the statements contained in the proffer agreement. Under those circumstance, the credibility of the evidence contained both in the statements at trial as well as the statements made in the proffer agreement, would be correctly evaluated by the jury. Instead, the Court usurped that authority from the jury and used the existence of the proffer statement to wrongfully deny the admission of the evidence.

In cases involving a specific intent crime, such a failure is significant, requiring a new trial. See United State v. McBride, 786 F.2d 45 (2d. Cir. 1986) (refusal to allow psychiatric expert to testify on the defendant's ability to formulate requisite state of mind was an abuse of discretion). See also United States v. Sebresos, 972 F.2d 1347 (9h Cir. 1992).

POINT III

Limiting the Defendant's Cross Examination of the Government's Expert

In this case, the Government elicited testimony from its expert concerning the complex process of obtaining FDA approval, what FDA approval means, the nature of botulinum toxin type A; and the history of the Botox approval process. While the Government was permitted to present to the jury, without judicial interruption, its entire case on these issues, the Defendant was limited by time restraints imposed by the Court and suffered repeated interruptions from the bench to either move the questioning along or cease a line of questioning. All of this was done in the presence of the jury.

Both the Supreme Court and the Third Circuit law are clear: the “Sixth Amendment guarantees the opportunity for effective cross-examination.” United States v. Riggi, 951 F.2d 1368, 1376 (3d. Cir. 1991) (citing Delaware v. Fensterer, 474 U.S. 15, 20 (1985)); Lee v. Illinois, 476 U.S. 530, 539 (1986) (“The right to confront and cross-examine witnesses is primarily a functional right that promotes reliability in criminal trials.” A defendant “states a violation of the Confrontation Clause by showing that he was prohibited from engaging in otherwise appropriate cross-examination designed to show a prototypical form of bias on the part of the witness, and thereby, ‘to expose the jury to facts from which jurors . . . could appropriately draw inferences relating to the reliability of the witness.’” United States v. Chandler, 326 F.3d 210, 222 (3d. Cir. 2003) (citing Delaware v. Van Arsdale, 475 U.S. 673, 680 (1986)).

In Chandler, *supra*, the Third Circuit reversed the conviction of a defendant based upon the trial court's refusal to allow defense counsel to fully question two Government witnesses

concerning bias. Similarly, in Riggs, the Third Circuit reversed a conviction for the trial court's failure to allow a full and effective re-cross of the witness that went beyond re-direct. Id., at 951 F.2d at 1375-1376 ("so essential is cross-examination to this purpose that the absence of proper confrontation 'calls into question the ultimate integrity of the fact-finding process.'").

The Third Circuit has been clear that a local court's discretion to manage a trial must give way to a Defendant's Sixth Amendment right to a full and fair trial. Government of the Virgin Islands v. Charleswell, 115 F.3d 171 (3d. Cir. 1997) ("a rigid insistence on expedition despite a legitimate reason for delay may deprive an accused due process of law.") See also Chandler, supra, and Riggs, supra.

In this case, the Court's insistence on limiting defense counsel's time within which he could cross-examine the Government's expert, combined with the Court's repeated interruptions, conspired to deprive the Defendant of his Sixth Amendment right to confrontation.

CONCLUSION

For the foregoing reasons, Defendant Dr. Poet submits he raises substantial questions that are debatable concerning the conduct of the trial. While this Court is not being asked to reverse its position on issues decided at trial, nor is it being asked to grant a new trial, Dr. Poet has established that significant issues exist that merit appellate review, that the issues strike to the heart of Defendant's conviction and are critical enough that a contrary appellate ruling would warrant a reversal.

Thus, Dr. Poet is entitled to bail pending appeal.

Respectfully submitted,

/s/ JEROME A. BALLAROTTO

Jerome A. Ballarotto, Esq.

Dated: October 22, 2007