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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, . Case No. 06-CR-643 (AET)
. .
v. . 402 East State Street
. Trenton, New Jersey 08608
. .
ALBERT POET, .
Defendant. .
. March 15, 2007
. 11:17 a.m.

TRANSCRIPT OF SIDEBARS ONLY
BEFORE HONORABLE ANNE E. THOMPSON
UNITED STATES DISTRICT COURT JUDGE and JURY

APPEARANCES:

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(At sidebar)

THE COURT: Mr. Hughes.

MR. HUGHES: Yes, Your Honor.

THE COURT: I see you have an open three-ring binder.

MR. HUGHES: I do. The reason that I approach the Court now, Your Honor, is that given Your Honor's previous rulings and limited funds that we have for travel and experts and the like, I would like to seek the Court's counsel on whether or not it intends to allow us to present certain expert testimony and the -- Your Honor's answer will guide us accordingly as to whether or not we should actually spend the money and the time to have this witness travel from a great distance to be here.

We have previously provided notice to the government that we intend to call an expert, a facial plastic expert, a gentleman by the name of Gary S. Brody. Mr. Brody's being offered as an expert in the field of facial plastic surgery and in the use of procedures for patients and the treatment of patients for facial plastic surgery and treatments such as Botox.

Now the -- it is anticipated that he will render the following opinions. That it is not necessary for a doctor to disclose to a patient the FDA status of every substance, drug or device used during the course of a medical procedure, but rather it is within the sound medical judgment of the treating

1 physician to choose the drug, device or substance and also to
2 determine whether or not specific disclosure of these items to
3 the patient is required.

4 Secondly, it is not only legal, but it is accepted --
5 also common and accepted medical practice for a physician to
6 possess non-FDA approved substances and to use these substances
7 in the treatment of patients without disclosing to the patient
8 that either the component substance or the resulting compound
9 are not FDA approved.

10 Thirdly, that the term Botox is so widely used by
11 medical professionals, patients and the general public that it
12 is understood to be a generic term referring to a procedure to
13 reduce facial wrinkles.

14 Fourthly, it is legal and a common practice for
15 physicians to use drugs, devices and substances that are not
16 FDA approved for specific procedures, uses or treatments in an
17 off label manner, meaning that a physician often uses such
18 drugs, devices and substance in a manner not specifically
19 approved or authorized by the FDA if the physician believes it
20 is in the best interest of the patients.

21 Additionally, that drugs are approved by the FDA for
22 human use, and the term for research purposes only not for
23 human use can connote to a physician that the substance has not
24 been approved by the FDA yet for human use. Drugs approved by
25 the FDA for human use are not necessarily safe and drugs not

1 approved for human use are not necessarily unsafe.

2 Additionally, a physician is under a duty to provide
3 the best service and substances to his patients that are in
4 their best interest regardless of the FDA status. That Dr.
5 Poet did not sell Botox or the TRI substance to his patients,
6 rather he sold a medical procedure.

7 He will also testify that patient charts are for use
8 by physicians in course of the treatments of their patients.
9 Dr. Poet's notes indicating that he treated patients with BTX
10 or BTX-A is sufficient medical records keeping. Under the
11 facts then known to Dr. Poet at the time of his purchase of the
12 TRI substance, Dr. Poet violated no standard of care.

13 We would like to know whether or not the Court would
14 allow us to present this type of testimony.

15 THE COURT: All right. I'll hear from the
16 government.

17 MS. COWLES: Your Honor, if I may, I believe there
18 are a few areas for the Court to consider. The first is there
19 was an issue raised in our pretrial motion about the issue of
20 legality or any opinions on the what I believe are state law
21 medical questions as to what it is or isn't legal for a doctor
22 to do.

23 THE COURT: Perhaps I should ask you at this point,
24 putting all that aside as yesterday's doings, kindly address
25 the proffer of Mr. Hughes. What is your position with regard

1 status of the drugs and devices that he's using.

2 But most importantly, Your Honor, the heard of this
3 matter is what the -- is the good faith defense, and the -- it
4 is essential that the a physician testifying as to the
5 reasonableness of an interpretation of a label goes to
6 reasonableness of Dr. Poet's good faith in this case. And we
7 submit that that is highly relevant in this case.

8 THE COURT: Everyone has said everything they'd like
9 to say?

10 MR. HUGHES: Yes, Your Honor.

11 MS. COWLES: Yes, Your Honor.

12 THE COURT: I do not consider Dr. Brody's -- Gary
13 Brody's testimony to be relevant. He's not an appropriate
14 witness to advise what the law is. The law is something that
15 would be given to the jury by the judge. The good faith
16 defense as I see it has to come from the defendant himself. I
17 don't see how somebody else can structure that.

18 I agree with the view that this is not compounding in
19 the preparation of this particular medication would not be an
20 example of compounding it, compounding in the normal sense. I
21 see nothing that this doctor is being offered to present which
22 would be appropriate to come from him. I would find what
23 you're offering to be irrelevant. You asked me for a ruling so
24 as to save you from being him here in Court to be ruled
25 irrelevant so that's my ruling, Mr. Hughes, I'm sorry to say.