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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 13, 2007  
. . . . . 10:07 a.m.

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

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1 comes to attention for many people, over medical -- human  
2 medical products which include the medical devices and the  
3 medical biological drugs and the more conventional type of  
4 human drugs.

5 Q Now, what is the FDA looking for in the drugs it  
6 regulates? What is the FDA's purpose in regulating those  
7 drugs, if you will?

8 A In broad terms, it's to ensure that they are safe and  
9 effective and it is adequately understood and described how to  
10 use them in a safe and effective manner.

11 Q Now, just for clarification, does the FDA regulate the  
12 practice of medicine?

13 A No, the FDA does not regulate the practice of medicine.

14 Q You mentioned regulation of drugs in our discussion.  
15 Could you explain what a drug is?

16 A Under the Food and Drug Act, a drug is a substance which  
17 could be listed in something like the United States Pharmacopea  
18 or the United States Pharmacopeia or the National Formulary.  
19 But, more clearly, it's a product which is for the diagnosis,  
20 treatment, mitigation, cure or prevention of a disease in man  
21 or a product which affects the structure or function of the  
22 human body.

23 Q Now, we've used another term that maybe confusing. What  
24 is a biologic?

25 A A biological product is a product which is in the terms of

1 the law is a product which is a serum, a toxin, an antitoxin, a  
2 blood component or a vaccine which is for the treatment  
3 mitigation or cure of -- or prevention -- sorry -- of a disease  
4 or condition in man.

5 Q Now, can a biological product also be a drug?

6 A Yes, biological products are actually all either  
7 classified as also being a device or also being a drug.

8 Q In the simplest of terms, what is a new drug?

9 A In the simplest of terms, a new drug is a drug that was  
10 not already marketed for a specific use at the time that the  
11 Food and Drug Act was amended back in 1938.

12 Q So, in a way of thinking about it simply, it would be a --  
13 something that came on the market now as new, would that be  
14 considered a new drug?

15 A Yes, anything that is coming on the market now that is  
16 entirely new or is sought to be marketed for a new type of use  
17 will be classified as a -- what's called a new drug.

18 Q If a drug or a biological product that's also a drug is  
19 new, what needs to be done before that product can be  
20 introduced into interstate commerce in this country?

21 A A drug or a biological drug must have an approved  
22 marketing application in order for it to be moved in interstate  
23 commerce.

24 Q And when you say an approved marketing application, what  
25 does that mean?

1 A I use that term because there are two different kinds of  
2 marketing applications that a product can have. The  
3 conventional sorts of drugs have what is called a new drug  
4 application is the official term. And that's the type of  
5 application that a company makes for those drugs. Those have  
6 to be approved for the drug to be sold. For biological  
7 products, however, they have a different type of a marketing  
8 application which is called a biological license application.  
9 And those biological products have to have that type of  
10 application submitted and approved.

11 Q What kind of information is submitted in these new drug or  
12 biological license applications coming into the FDA?

13 A In broad terms, both have similar kinds of information.  
14 They have to have very detailed information about what the  
15 product actually contains in terms of the chemical components  
16 about the purity of the product, about the stability of the  
17 product when it is stored, about any sorts of minor components  
18 which might be very minor contaminants within the products and  
19 the limits on them, information about how it is manufactured.  
20 It has to have information about the toxicity testing that was  
21 done in animals and it has to have very detailed information as  
22 well about all the testing that was done in people with regards  
23 to the safety and effectiveness of the product in people.

24 Q Why does the FDA look at so many different areas of  
25 information when it's asking for a biological license or new

1 contaminants within the product, what the stability of the  
2 product is. There are all these reasons that might be  
3 different from Allergan's product.

4 Q Now, even though TRI's botulinum toxin Type A was not  
5 approved, as you have testified, by the FDA, couldn't an  
6 experienced doctor simply mix it up like Botox and use it in  
7 the same manner?

8 A No one, neither an experienced doctor or anyone else,  
9 would have adequate information to know how to mix it up in a  
10 way that could -- where they could have confidence to know what  
11 the safety or efficacy was going to be.

12 Q And why do you say that?

13 A Because there was no reliable way of knowing what was  
14 actually in those vials or what the consistency of the product  
15 was from time to time.

16 Q Could a doctor safely assume if that doctor knew that  
17 TRI's substance was a botulinum toxin Type A that TRI's -- the  
18 units of TRI's botulinum toxin Type A would be equivalent to  
19 Allergan's Botox units?

20 A No, it would not be safe to assume that.

21 Q And why not?

22 A Because the assay under which these toxins are assessed  
23 for their potency, that test is very dependent upon the exact  
24 circumstances, the exact manner of performance, including what  
25 type of mice are used, what size of mice, how the product is