

Rice, Kim

From: Martin-Weis, Kathy
Sent: Tuesday, July 10, 2007 4:00 PM
To: Pawloski, Laura
Subject: FW: Materiality and 1341
Attachments: Lueben - 1001 materiality 838_F_2d_751[1].wpd

More. This might be about it tho.

From: Walsh, Anne [mailto:Anne.Walsh@fda.hhs.gov]
Sent: Wednesday, April 18, 2007 10:00 AM
To: Loveland, Douglas
Cc: Martin-Weis, Kathy
Subject: RE: Materiality and 1341

Doug,

The test for materiality under 18 U.S.C. § 1001 is not whether the false statement actually influenced a government function, but whether it had the capacity to influence. *United States v. Lueben*, 838 F.2d 751, 754 (5th Cir. 1988) (attached); *United States v. Lichenstein*, 610 F.2d 1272, 1278 (5th Cir. 1980). Stated another way, to establish materiality, it is sufficient that the statement have the capacity or a natural tendency to influence the determination required to be made. See *Kungys v. United States*, 485 U.S. 759, 770 (1988); *United States v. Allen*, 892 F.2d 66, 67 (10th Cir. 1989). A commonly cited test for materiality states:

"Material" when used in respect to evidence is often confused with "relevant," but the two terms have wholly different meanings. To be "relevant" means to relate to the issue. To be "material" means to have probative weight, i.e., reasonably likely to influence the tribunal in making a determination required to be made. A statement may be relevant but not material.

United States v. Weinstock, 231 F.2d 699, 701 (D.C. Cir. 1956). The D.C. Circuit held that "the issue to which the false statement is material need not be the main issue; it may be a collateral issue. And it need not bear directly upon the issue but may merely augment or diminish the evidence upon some point. But it must have some weight in the process of reaching a decision." *Id.* at 703.

My quick review (I have a 10 a.m. meeting) didn't reveal any cases in the Third Circuit specifically adopting this rule, but it is pretty universally adopted.

Anne

From: Loveland, Douglas [mailto:Douglas.Loveland@oci.fda.gov]
Sent: Wednesday, April 18, 2007 8:11 AM
To: Walsh, Anne
Subject: RE: Materiality and 1341

Probably New Jersey.

From: Walsh, Anne [mailto:Anne.Walsh@fda.hhs.gov]
Sent: Wednesday, April 18, 2007 7:56 AM
To: Loveland, Douglas
Subject: RE: Materiality and 1341

what district are you planning on pitching this case? D. Md?

8/22/2007

From: Loveland, Douglas [mailto:Douglas.Loveland@oci.fda.gov]
Sent: Wed 4/18/2007 7:39 AM
To: Walsh, Anne
Subject: RE: Materiality and 1341

Anne:

Okay, can you send me some case law where a defendant was convicted on a 1001 charge because the false statement was capable of impacting an agency's decision, but didn't?

Thanks, D.

From: Walsh, Anne [mailto:Anne.Walsh@fda.hhs.gov]
Sent: Tuesday, April 17, 2007 4:58 PM
To: Loveland, Douglas
Cc: Martin-Weis, Kathy
Subject: RE: Materiality and 1341

Doug - The short answer to your question is that yes, there is a materiality element woven into the 1341 mail fraud charge through case law. But that is besides the point because mail fraud is not going to fly here - how is FDA defrauded of money in this instance?

Instead, the Klein conspiracy, as you suggested, would be a viable charge - the fraud on the FDA. I disagree with your assessment of the 1001 charge, however. The question of materiality is not whether the study actually impacted FDA's decision about drug approval, but whether it was capable of doing so - and clearly it was here. Now whether the case loses jury appeal because FDA specifically said it was not relying on the study . . . well, that's another question. I don't think you should dismiss the 1001 charge off-hand.

So I think the best charges are the 1001 and the 371 charges. Avoid mail or wire fraud here unless you can come up with some other victim than FDA.

Hope this is helpful.
Anne

From: Loveland, Douglas [mailto:Douglas.Loveland@oci.fda.gov]
Sent: Tuesday, April 17, 2007 9:58 AM
To: Walsh, Anne
Subject: Materiality and 1341

Hi Anne:

Thanks for double checking Beth's FD&C Act charging in NuMed; it's been a long time since I had to review those things.

On another subject, can you do up a brief on materiality with respect to 18 USC 1341 for me? Here's why:

In the Ketek NDA, the sponsor clearly sent in falsified data in Study # 3014. Aventis knew that such significant issues existed at so many sites that GCP could not be claimed, yet it claimed the study was conducted to GCP. Think "willful blindness" on steroids. But they submitted it anyway.

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Even FDA figured out this trial's data output was nonsense and, after twenty months' worth of DSI inspections, threw the B.S. flag. Then it approved the drug anyway – one month after throwing the flag. In approving the drug, the FDA very carefully identified what data and studies it relied upon, and was very careful to say over and over again that it would not rely upon the data that Aventis submitted from Study #3014. But the appearance was that it's okay to submit falsified data because your study will get approved anyway.

Some members of the public, the FDA and Congress are focusing on the FDA as having screwed this up, as though there is some provision somewhere that says, "If a company submits falsified data, the FDA can't approve its application..." Were t'word it were so. No one is looking at Aventis as the villain – except me.

The problem is, the FDA has gone so far out of its way to document that it did not rely upon the falsified data that it has created insurmountable Brady material with respect to materiality were I to pursue a false statements charge at 18 USC 1001. Indeed, the company itself cited the FDA's own words in a 12/14/06 advisory committee meeting: "These data were not relied on for FDA approval or are referenced in the U.S. prescribing information." Twenty pages later in the transcripts, the Division director not only said the same thing, she listed all the other data the agency did rely on.

This public record was only one of about a dozen where the agency has made such representations. Materiality-wise, I'm screwed at 1001.

However, looking for alternatives, one notes that the literal reading of 18 USC 1341 does not make materiality an element. It simply says the mailing of false representations in the course of a scheme or artifice to defraud, and in the attempts to complete a scheme or artifice to defraud. If we were to mix that with a Kline conspiracy (defrauding the government), would it work?

Can you do the legal research for me to see if there is case law that has adopted materiality as a pre-requisite element in 18 USC 1341?

If 1341 isn't a player, can you offer an idea(s) as to what other criminal cites I might be able to use to get this thing in front of a grand jury? My statute of limitations is starting to get dicey – the false statements were submitted to the government in July 2002.

Thanks, D.
240-276-9402