Sent: Friday, January 29, 2010 11:41 AM
To: Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Subject: RE: Draft Surrogate Data Justifications

Stu,

I can but you said John already has this one. Do you want a "what's at stake" write up for Amchitka.

Dave

(b)(5)

Kraus, Kim M. (CDC/NIOSH/DCAS)

From: Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Sent: Thursday, February 04, 2010 3:17 PM
To: Calhoun, Grady (CDC/NIOSH/OD); Neton, Jim (CDC/NIOSH/OD); Allen, David (CDC/NIOSH/OD); Rutherford, LaVon B. (CDC/NIOSH/OD)
Subject: RE: Draft Surrogate Data Justifications

OK, we won't debate this in email any more. I was absolutely serious in my third paragraph, though. Dr. Melius wrote the Surrogate Data WG's latest product on surrogate data. Congressional staffers (one staffer mainly) are the ones pushing on John and Lew.

So far I haven't been asked about numbers of claims affected either way. By my way of thinking, a particular surrogate use is either scientifically defensible or not (feasible or not feasible). The number of claims affected either way is irrelevant to that decision.

I'll try to capture some of the flavor of your comments in the Impacts section. Will likely word them a little differently though.

Stu

From: Calhoun, Grady (CDC/NIOSH/OD)
Sent: Thursday, February 04, 2010 3:03 PM
To: Hinnefeld, Stuart L. (CDC/NIOSH/OD); Neton, Jim (CDC/NIOSH/OD); Allen, David (CDC/NIOSH/OD); Rutherford, LaVon B. (CDC/NIOSH/OD)
Subject: RE: Draft Surrogate Data Justifications

Comment on first paragraph below:
We (the HPs, you, and Jim) believe in the use of surrogate data. Those above you do not. Remember that success was recently described as adding more SECs.

Comment on second paragraph below:
Because, by definition, an SEC prohibits us from assigning some portion of dose, non-presumptive cancers and non-qualifying presumptive cancers are not assigned the dose that most accurately represents the actual dose received. We believe that assigning surrogate data overestimates or bounds the dose actually received or we wouldn't be using it. I agree that not using surrogate data doesn't introduce an inequity other than the one introduced by the SEC process but using surrogate data eliminates the inequity introduced by the SEC process. Assigning an SEC because we cannot bound dose is never negative. It is positive. Assigning an SEC because of political pressure (as described below as the population of congressionals, advocates and claimants) is negative. The rules haven't changed and the science hasn't changed so our applications shouldn't change.

Comment on third paragraph below:
Seriously?

Comment on fourth paragraph below:
I left out the fact that not using surrogate data will result in recommending an SEC because we are not using surrogate data to prevent adding a class. We are using it because it is the best scientific approach.

General question
Do we want something as generic as what I wrote or do we want something that outlines how many cases will be doable and not doable; comped and non-comped; and SEC and not SEC?

From: Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Sent: Thursday, February 04, 2010 1:49 PM
To: Neton, Jim (CDC/NIOSH/OD); Allen, David (CDC/NIOSH/OD); Calhoun, Grady (CDC/NIOSH/OD); Rutherford, LaVon B. (CDC/NIOSH/OD)
Subject: FW: Draft Surrogate Data Justifications

With respect to the first bullet, the rest of the surrogate data justification should not only explain that we believe in the use of surrogate data, but also explain why surrogate data is appropriate in this circumstance. We've made it pretty clear in conversation that we believe surrogate data is a valid approach in the right circumstances.

With respect to the second bullet below (bullet 1 on the attachment), help me understand the "equitable dose reconstruction to all employees of the facility" argument (on the attachment we use the words "fair and equitable", so I conclude the reasoning is the same for both). I don't see how not using surrogate data introduces an inequity other than the one introduced by the SEC process. There's kind of an expectation that SEC classes will be added, arguably in the statute and certainly in the population of congressionals, advocates and claimants, so I don't see how that will be seen as a negative impact of not using surrogate data.

(b)(5)

Bullets 2 and 3 on the attachment are right on the money. There is the obvious one that you didn't include, which is that it won't be feasible to fully reconstruct internal and external doses, so not using surrogate data will prompt a recommendation to add a class to the SEC.

Stu

PS, Do I have this section for Hooker yet?

From: Calhoun, Grady (CDC/NIOSH/OD)
Sent: Friday, January 29, 2010 12:30 PM
To: Allen, David (CDC/NIOSH/OD)
Cc: Rutherford, LaVon B. (CDC/NIOSH/OD); Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Subject: RE: Draft Surrogate Data Justifications

OK. This is a new rock hunt. I've attached a small paragraph for Clarksville. I think we really need to focus on the facts that

- We believe in the use of surrogate data and
- Not using surrogate data prevents us from providing equitable dose reconstructions to all employees of the facility

I'd like to include the fact that not using surrogate date because it makes the board happy is arbitrary and capricious but I wont.

Let me know if this is close to the right size, shape, color, and weight.

<< File: Whats at Stake-Clarksville.doc >>

From: Allen, David (CDC/NIOSH/OD)
Sent: Friday, January 29, 2010 12:00 PM
To: Calhoun, Grady (CDC/NIOSH/OD)
Cc: Rutherford, LaVon B. (CDC/NIOSH/OD); Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Subject: RE: Draft Surrogate Data Justifications

No more cynical than me. That is why I wanted to start with Amchitka.

From: Calhoun, Grady (CDC/NIOSH/OD)
Sent: Friday, January 29, 2010 11:50 AM
To: Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Cc: Rutherford, LaVon B. (CDC/NIOSH/OD); Allen, David (CDC/NIOSH/OD)
Subject: RE: Draft Surrogate Data Justifications

I assume that if making the site an SEC is one of the items at stake we will almost certainly be told not to use surrogate data.

Is that being too cynical?

(b)(5)

Kraus, Kim M. (CDC/NIOSH/DCAS)

From: Allen, David (CDC/NIOSH/OD)
Sent: Tuesday, February 09, 2010 9:32 AM
To: Dickey, Joseph (CDC/NIOSH/OD) (CTR)
Cc: Corwin, Christine (CDC/NIOSH/OD) (CTR)
Subject: (b)(6)

Joe,

This one is a Hooker, Electro Met, and LOOW claims. It is an easy pay (63.34%). The problem is I still haven't gotten approval to use the Hooker doses because they are based on surrogate data. They are a very small part of this claim and I'm sure it will be a pay without it. Can you eliminate that little bit of dose please. Don't forget to put something in the language indicating it wasn't necessary to reconstruct that dose (don't say anything about surrogate data).

Dave

Kraus, Kim M. (CDC/NIOSH/DCAS)

From: Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Sent: Tuesday, April 20, 2010 1:08 PM
To: Rutherford, LaVon B. (CDC/NIOSH/OD)
Cc: Sundin, David S. (CDC/NIOSH/OD)
Subject: RE: Hooker Electro Chemical

I doubt we'll be able to present Hooker, because I don't have confidence we'll get quick approval to use surrogate data, even TBD-6001, in SEC even after I get my "endorsement" of the justification to OGC and OD. Given my schedule this week, I don't see how I'll get it out this week, although it's partially written and largely formed in my mind.

I'll take Weldon Spring with me today to see if I can sign it.

Stu

From: Rutherford, LaVon B. (CDC/NIOSH/OD)
Sent: Tuesday, April 20, 2010 12:36 PM
To: Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Subject: Hooker Electro Chemical

Stu,

We are about to reach our drop dead date on Hooker. If the report does not go out this week or early next week, I don't see how we can present the report. It has to go to DOE for final ADC review. We also have Weldon Springs, Mound, LANL (83.14), and BWXT. Weldon Springs is with you for signature and Mound is being routed for signature now. We are still waiting on our petitioner for LANL to send us the form A. BWXT is due back to us Thursday for final review and Approval.

Bomber

Kraus, Kim M. (CDC/NIOSH/DCAS)

From: Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Sent: Tuesday, April 27, 2010 12:56 PM
To: (b)(6); Katz, Ted (CDC/NIOSH/OD); Rutherford, LaVon B. (CDC/NIOSH/OD)
Cc: Neton, Jim (CDC/NIOSH/OD)
Subject: Re: Hooker Electro Chemical

It uses TBD-6001

Stu

Sent from my BlackBerry Wireless Device

From: James Melius <(b)(6)>
To: Katz, Ted (CDC/NIOSH/OD); Rutherford, LaVon B. (CDC/NIOSH/OD)
Cc: Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Sent: Tue Apr 27 10:21:37 2010
Subject: RE: Hooker Electro Chemical

What is the surrogate data issue with Hooker?

From: Katz, Ted (CDC/NIOSH/OD) [mailto:tmk1@cdc.gov]
Sent: Tuesday, April 27, 2010 10:08 AM
To: Rutherford, LaVon B. (CDC/NIOSH/OD)
Cc: James Melius; Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Subject: Re: Hooker Electro Chemical

Okay, thanks Bomber. --Ted

Sent using BlackBerry

From: Rutherford, LaVon B. (CDC/NIOSH/OD)
To: Katz, Ted (CDC/NIOSH/OD)
Cc: Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Sent: Mon Apr 26 08:04:37 2010
Subject: Hooker Electro Chemical

Ted,

The Hooker evaluation is still held up internally because of the surrogate data issue and it does not look like it will be resolved in time to get the report to the petitioner and the Advisory Board in time for the May meeting. Therefore, we need to remove it from the May meeting agenda. We will contact the petitioner and explain this to them. Let me know if you have any questions. Thanks,

Bomber

Kraus, Kim M. (CDC/NIOSH/DCAS)

From: Hinnefeld, Stuart L. (CDC/NIOSH/OD)
Sent: Tuesday, April 27, 2010 6:30 PM
To: Rutherford, LaVon B. (CDC/NIOSH/OD)
Cc: Katz, Ted (CDC/NIOSH/OD); Allen, David (CDC/NIOSH/OD); Calhoun, Grady (CDC/NIOSH/OD); Neton, Jim (CDC/NIOSH/OD); Sundin, David S. (CDC/NIOSH/OD)
Subject: Hooker

Bomber,

Is the ER for Hooker drafted? If I can get John an Lew to say OK on Friday, could we get it to thje advisory Board next week?

Stu

Sent from my BlackBerry Wireless Device