

TURNER, Eric (CIT)

De: STENNELER, Claude (CIT)
Envoyé: lundi 29 octobre 2001 09:56
À: TURNER, Eric (CIT); Zazenski, Rich (LNA); Harris, Dan (LNA); Godla, Jon (LNA)
Cc: ROESER, Joachim (CIT)
Objet: RE: Confidential - NTP Update and Issues

Critère de diffusion: Confidentiel

Dear all,
I fully support Eric conclusion about keeping CRE involved and putting pressure to NTP.
Web site is an issue which means an individual capable to be proactive and to answer all the hits. It is certainly expensive versus an uncertain impact. My feeling is consequently mitigated about this aspect of the proposal.
Regards
Claude

-----Message d'origine-----

De: TURNER, Eric (CIT)
Date: 26 October 2001 09:43
À: Zazenski, Rich (LNA); Harris, Dan (LNA); Godla, Jon (LNA)
Cc: STENNELER, Claude (CIT); ROESER, Joachim (CIT)
Objet: RE: Confidential - NTP Update and Issues
Critère de diffusion: Confidentiel

Rich,

I am as convinced as you that keeping CRE "on the case" is essential. My questions were directed specifically at the notion of an "IPD". So your 1-7 items are a useful summary of benefits, but you are preaching to the converted there. It is your last para in sec 2 which speaks to my concerns.

As you say you need to talk with CRE and see how they respond to my points and then we can weigh the costs and benefits.

I fully support the approach of keeping up the pressure.

I judge that our success so far has been the result of a "pincer movement", with CRE/legal on one flank and the technical analysis on the other. It's a powerful combination and one I want us to continue with.

Eric

-----Message d'origine-----

De: Zazenski, Rich (LNA)
Date: jeudi 25 octobre 2001 22:51
À: TURNER, Eric (CIT); Harris, Dan (LNA); Godla, Jon (LNA)
Objet: RE: Confidential - NTP Update and Issues
Critère de diffusion: Confidentiel

Eric - Here are my initial responses to your questions. Knowing that the format of these e-mails sometimes gets garbled as they pass through different servers, I've included a copy of this e-mail as a Word document.

1. Does the word "determination" in line 2 mean that CRE has found out for sure that this is the case? Does NTP have the capacity to do this at the same time as the 11th Edition ?

With the events of September 11th, there is very little certainly in Washington on any of these lesser issues. Jim simply told me that his contacts over at NIEHS did not expect any movement on the talc issue until mid-year 2002 at the earliest. No firm dates were mentioned. I will rely more on Bill Kelly's specific inquiries as we move into next year and we see what unfolds with the terrorism issue.

2. On the idea of an "IPD": how would interested parties know that was a place to go ? If only those that

we tip off to go there post anything to it, how valid would it be ? Will NTP and others not assume that we "filter" the items prior to release? If you recall there was not a single "anti" talc submission in the official public comment process. Wont NTP and Dept of H&HS just take this as another form of industry special pleading? What would it cost us to allow (fund) CRE to do it ?

Let me first state that I have no doubt that agencies like NIEHS and NTP recognize CRE for what it really is - an industry sponsored "advocate" group whose purpose is to pursue the interests of its clients. CRE is not unlike CTFA in this manner. However, I believe CRE does offer some important capabilities that CTFA is not equipped to provide. As such, special pleading by CRE may actually be more effective than if it came directly from industry:

1. **Client Confidentiality.** While CRE is actively promoting the interests of talc and challenging the NTP review process, NTP does not know for sure who is sponsoring the effort.

Redacted

3. **Threat of Court Action.** CRE has already taken NTP to court over dioxin. In doing so, CRE has established some important precedents for future actions. NTP was fully aware that CRE and/or Luzenac was going to pursue court action if they proceeded with a listing recommendation on talc. I have no doubt that this "very real threat" factored into NTP's decision to defer a vote on talc.
4. **Rulemaking Knowledge in Washington.** The CRE team demonstrated their thorough knowledge of the NTP evaluation process and the criteria necessary to sustain a listing recommendation - certainly more than CTFA. Knowing such, Bill Kelly (CRE attorney) helped us construct sound arguments that addressed some of the finer points that he knew NTP had to consider.
5. **Aggressiveness.** CRE can afford to be aggressive and visible in their efforts without risking credibility. CRE can often side-step the "rules for the general public" (i.e., public comment periods) and use whatever means necessary to drive home their points. Tolerance of such tactics is usually only extended to "insiders" or "powerful lobby groups". It is how business is conducted in Washington.
6. **Perceived Power.** Jim Tozzi, founder of CRE, is a former Deputy Administrator, Office of Information and Regulatory Affairs, The White House, Office of Management and Budget. CRE has been successful because Tozzi and his network of advisors are fairly well "connected". This networking capability does not go un-noticed by political appointees' and ambitious staffers.
7. **Narrower Focus.** Unlike CTFA, CRE can afford to expend considerable political capital on a just few issues. They can be aggressive. CTFA on the other hand, seemed to take a low-key approach to the talc defense. It appeared that they did not want to risk losing credibility or objectivity in defending talc - lest they need it to defend some other cosmetic substance next month.

Since November 2000, we have paid CRE \$144,000 for their services (\$12,000/month retainer). They were instrumental in helping us achieve a dramatic reversal of opinion in the talc review (remember, RG1 and RG2 voted 13-2 to list talc as a carcinogen - no other substance receiving RG1 and RG2 listing nominations have avoided RoC listing). I would strongly recommend that we continue our association with CRE in some capacity in the event NTP finds cause to list talc as a carcinogen. If it comes down to a court challenge to avoid listing, the legal arm of CRE would be our only viable counsel.

I need to get more details from Kelly on the proposed IPD and its perceived benefits. Short of anything else, it would demonstrate to NTP that CRE (and its sponsors) are not going to relax on this issue because of the deferral decision. I believe we want NTP to be "looking over their shoulder" and seeing CRE is right there watching their every move until this issue is properly resolved.

3. OMB's Data Quality Guidelines would help us if talc had been listed on the basis of NTP's current evidence. However I imagine they will make a much better job the next time around (not least because they will be aware that they must meet these new criteria).

The Data Quality issue is far-reaching, extremely complex and goes well beyond just doing better research. With NTP, the Data Quality issue may challenge the very existence of NTP and their issuance of their Report on Carcinogens. Many have criticized the relevance of listing a substance as a possible human carcinogen if risk factors are not considered (i.e., you may get cancer from saccharin if you consume the equivalent of 600 cans per day - over a lifetime - of artificially sweetened soda). This type of "data" issued by the government serves no benefit or value to the public and actually is a disservice. This is precisely why

Tozzi and Kelly are excited about this new legislation. It may actually signal the beginning of the end for unscientific, irrelevant rules and regulations.

4. What has been NTP's reaction to the various offers of assistance that talcers have made ?
I don't have any feedback for you yet on this question.

<< Fichier: Response to Eric.doc>>

-----Original Message-----

From: TURNER, Eric (CIT)
Sent: Thursday, October 25, 2001 8:27 AM
To: Zazenski, Rich (LNA); Harris, Dan (LNA); Godla, Jon (LNA)
Subject: RE: Confidential - NTP Update and Issues
Sensitivity: Confidential

Dear All,

Some points and questions:

1. Does the word "determination" in line 2 mean that CRE has found out for sure that this is the case? Does NTP have the capacity to do this at the same time as the 11th Edition ?
2. On the idea of an "IPD": how would interested parties know that was a place to go ? If only those that we tip off to go there post anything to it, how valid would it be ? Will NTP and others not assume that we "filter" the items prior to release? If you recall there was not a single "anti" talc submission in the official public comment process. Wont NTP and Dept of H&HS just take this as another form of industry special pleading? What would it cost us to allow (fund) CRE to do it ?
3. OMB's Data Quality Guidelines would help us if talc had been listed on the basis of NTP's current evidence. However I imagine they will make a much better job the next time around (not least because they will be aware that they must meet these new criteria)

What has been NTP's reaction to the various offers of assistance that talcers have made ?

Eric

-----Message d'origine-----

De: Zazenski, Rich (LNA)
Date: mercredi 24 octobre 2001 18:22
À: TURNER, Eric (CIT); Harris, Dan (LNA); Godla, Jon (LNA)
Objet: Confidential - NTP Update and Issues
Critère de diffusion: Confidentiel

Jim Tozzi from The Center for Regulatory Effectiveness called me today to discuss several issues and proposals. Of primary interest was their determination that the talc issue will be re-visited by NTP sometime midyear or early fall of 2002. NTP will then determine if the "historical" studies are valid for use in the NTP evaluation process. If there are sufficient studies to re-review talc, the review process would start from the beginning again (RG1/RG2).

One of the suggestions for a "offensive" strategy for us to consider is to allow (fund) CRE to set up a Interactive Public Docket (IPD) for talc on the CRE website. We (CRE) would post pertinent essays, articles and comments about the NTP review of talc and invite "public comment". CRE would then package and funnel "feedback" to NTP and NIEHS. In other words, this would be a "Washington" communication channel that would operate outside the normal "public comment" periods for NTP reviewed substances. We of course, would then encourage other "talc interested parties" to participate in the feedback process.

A second topic for consideration is new legislation that involves the Office of Management and Budget (OMB) and "Data Quality Guidelines". Essentially, new legislation was passed this year that requires each government department (HHS, EPA, DOL. etc.) to develop standards for information and data used in new legislation and rule-making. The bottom line for us on this issue is that it will "raise-the-bar" for agencies like NTP for reviewing and ruling on substances like talc. According to Bill Kelly (CRE attorney), if talc were to be listed by NTP based on the current studies, the new OMB data quality guidelines would improve our chances with the courts if we decided to seek an injunction on the listing. Supposedly, we would have better standing to challenge the "data quality" used by NTP in their listing recommendation. While this issue may seem arcane to most of us, Washington insiders like Bill and Jim are quite excited about this new requirement. They say it will stymie

capricious and arbitrary rulemaking.

I will have more details (and recommendations) on these issues in the near future.