

NLWJC - Kagan

DPC - Box 028 - Folder 004

Health - Biomaterials

3/10

Biotech mtg

14 suppliers - question of business - or extracting incorrect terms from manuals.

Bill same as last yr, but w/ breast implant carveout

Q of supplier fraud - really couldn't address - couldn't come up w/ something that didn't initiate bill
 Probs - still have discovery!

Title II of S.S (P.L.) - not new w/out carveout - will be amended.

Also - stand alone bills in H. + Senate - w/ carveout

Hearings this wk on S.S

Answer - Mar 20 (don't know if will address Lio)

Q - Any other way to ensure pub re suppliers, even if no provision in hand.

Answer: FDA has ^{full} approval auth over

~~Class 2~~ - has to show any changes in mat'l justifies
 Has to check → product applicator
 material substitution
 design criteria.

Q - If CI 3 exempti - would that solve most of probs?

- No.

2) Make more all applicants - whether 2 or 3 -
 have requisite levels of material scrutiny

Existing tier system to ID risky products??

Tier 3??

Q - How has gov found money unless a firm disclosed

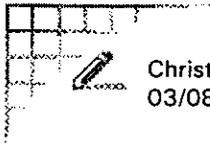
any claim of safety.

Parma - uneasy. Unwrap. supplier would stamp disclaimer on.

Update of Avonov report(?)

Key - all disclaimer.

Health - biomaterials



Christopher C. Jennings
03/08/97 06:10:46 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:

Subject: Re: Biomaterials

Yes. Some. The industry was quite frustrated with our position last year; they felt that there was a legitimate compromise that could have moved separate and apart from the product liability bill. They thought we were the one, real big hang up. However, I never pushed very hard or got too much involved because I didn't see any hope in legislation moving. I am sure there were numerous reasons why Bruce (and perhaps you?) did not want this to move.

I do think there is a chance this year for something constructive to emerge this year, which might be good a reasonable compromise and also good for the President. The industry really wants something and may be willing to give more in this round. Specifics are always the problem and, if you want, I can update my memory banks. I can tell you now, however, that I would have to do that in order to be of any real assistance to you.

cj

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