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clear dist betw tox & exp studies — "product in use" studies

- init dos / tox effect defns
- Visits in or out?
- Any Health Study in or out?

neither is 3-P

Jim A says wkr exp is interventional testing

- Follow FDA model - defn of clinical study
- P.I.U studies require monitoring for effects to be blind
- Educ T & U studies should not be covered
- HSRB should follow FDA model - strictly confidential - highly sensitive info

- The fact that a test is planned is competitive info. FDA is not a FACA cmte. (10)

Explain SID to KB & analogy to FDA.

Ray McA: Re kids — never say never. — Consistent w/ NAS.
— Allergenicity of biotech products — diff for kids? Can't know without testing.

Jim A: Intent makes it a pesticide. If other uses, could children be tested? Could an old FDA kid study be considered in suppt of a pesticide.

Some workers may legally be children, albeit old enough for DOL.

(2) Jean Reviews

Pat Donnelly: re head lice (FDA) vs pesticide (EPA)
EPA should not be forbidden to consider drug studies

Bruce - we should prevent Bayer from misunderstanding or misstating the meaning of the rule

Jim: Distinguish testing kids from using data on kids who were tested.

Ray: How to determine intent of investigators/sponsors — e.g. study read by another govt?

Ray: Pesticides have benefits. Rule should say so. Testing, too, has benefits.

Ray: Contain inflammatory rhetoric. Don't repeat or acknowledge it in preamble. Be careful how, if at all, you mention it.
Q. (Ray) Steve J told NAS scope would reach all of EPA.
We want a rule quickly – ∴ narrow better
Don't like being singled out, but speed is most imp.
Jim: Won't be able to meet FQPA deadline. Would do it anyway. Just do the rule first. Then proceed ASAP.
Jim: Don't release IZA's before 9/30.
" Not a lot of tolerances involved ~~**~~ (2a)
Ray: Q timetable?