

Bull, Jonca

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Sent: Sunday, May 20, 2001 5:52 PM
To: Sandy Kweder
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Subject: Accutane

Sensitivity: Confidential

Sandy, Steven and I met with the team re. next steps. It seems the privacy problems have us boxed in on the assessment side. Triggered by a comment from Steven, we started discussing that maybe the Sloan data collection could be modified into a way to monitor improvement. This might be possible because the volunteers from the Sloan survey reported such terrible compliance of the providers with the terms of the program (ie, pregnancy testing etc). No one knew if some of this was from women who had hyst. or were postmenopausal (why would they be in the program anyway?) and of course there could be a lot of recall bias. But if modified, and if Sloan participation were greatly increased as offered by roche and the ADA, it could certainly be capable of showing progress.

I told the team I'd have to discuss the whole issue with you further, but there seemed to be a general consensus that we should go forward quickly with a voluntary program, while continuing to develop the mandatory program, and have it as the fallback if things don't improve.
jw