To: Shapiro, Deborah R.; Reicin, Alise S.; Nies, Alan S.
From: Scolnick, Edward M.
Cc Scolnick, Edward M.
Bcc:
Date: 2000-03-09 23:18:40
Subject: vigor

To all: I just received and went through the data. Thank you for sending it to me. There is no doubt about the pub data. very very strong. as expected. general safety is better than could hope for in this patient population. incidences of hypertension, renal anything ,edema, liver, all great-very safe.very very safe. The CV events are clearly there. Since no obvious correlate right now ie not steroids , maybe smoking and prior a bit this is real. It is important to find out about the cases that oates told us about. When we present in May we should present those also if he will let us so it is clear to the world that this is class effect. all the ideas you talked about are important: plipid antibodies-but I doubt it will correlate.Many vein tbosis in what is probably a somewhat restricted patient group. I think we should run an asa low dose endoscopy study. placebo low dose asa vioxx and both to show people that you can sefly use asa low dose with vioxx ie that it is no different from asa alone and then some version of the tylenol study we discussed to further assess safety. also wpse should give us a full postmarketing analysis with incidneces of whatever as background. It is a shame but it is a low incidence and it is mechanism based as we worried it was.Oates and Alan and barry were right about the metabolite meanings ie urine Pg data.It is important that they not appear to be different. This will limit the class somewhat but the GI safety is superb. I really would like to know the histroy of what patients were on and what ulcer history in the data as you dig in.

In May we need to be able to present in total pciture that is OA safety data base from all studies -ours and ushh. and postmarketing so we can frame 25mg in OA vs 50mg in RA.And that is why we need a 25mg in OA study for more safety.End point studies tell the truth. We have a great drug and like angioedema with vasotec and seizures with primaxin and myopathy with mevacor there is always a hazard. The class will do well and so will we / see you at coming meetings / Ed

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