The 1968 Hazleton study of intramuscular injection into rabbits demonstrated inflammation, muscle degeneration and necrosis.

This was reported by their pathologist, Busey.

In May 1968 a meeting took place between representatives from the FDA, Lafayette, Dpi, and Hazleton.

It was noted that all tested animals showed CNS toxicity but Hazelton's representative, Jessup, suggested that this was due to mechanical effects of the injectate rather than chemical (toxic) effects.

In November 1968, Jessup wrote to Embree at Dpi about the Hazleton teratology study, suggesting that there were problems due to the administration of the dye and systemic problems.

He again emphasised the mechanical nature of the effects of the dye.

Fassett, of the Laboratory of Industrial Medicine, wrote to Embree and put forward the idea that the tested animals (rabbits) had problematic anatomy and that this might result in exacerbating the mechanical adverse effects.

He also remarked:

"removing a more diluted material might be more difficult..." might expect more side effects due to"..."cellular irritant effects of residual radiopaque."

This clearly demonstrates that Fassett was fully aware of the adverse effects and that he informed Kodak's subsidiary, Dpi, via Embree.

To make matters worse, Hazleton submitted the data from their 15-week intrathecal study in dogs to Dpi rather than Lafayette.

It seems never to have reached as far as the FDA.

Busey, the pathologist involved, wrote extensively about the severe reactions seen in the study and Jessup outlined effects in various organs (surprisingly omitting mention of effects on the liver).

The dogs studied suffered from effects such as: granulomatous meningitis in the brain and spinal cord, fibrosis, thickening of the meninges, meninges adherent to the floor of the vertebral column.

The majority of reactions were of a subacute or chronic nature.

More systemic effects included pituitary cysts, lung nodules, spleen nodes, reddened renal medulla.

The spinal effects were of differing location and severity according to which concentration of dye was used; both Pantopaque I and II were studied. 0.014 ml/kg produced predominantly lumbar lesions, whereas 0.14 ml/kg induced severe cervical and thoracic cord reaction, slightly less in the lumbar region.

Jessup's report also mentions clotted blood at the base of the brain and anterior spinal cord in one dog after Pantopaque and four after Pantopaque II.

He also noted

"oil material, possibly compound, in areas of the meninges."

(What the material could be other than the dye is hard to imagine!).

Needless to say, this type of data was pretty damning not only of the newly proposed product (Pantopaque II) but also its predecessor, the original Pantopaque, which was by now in widespread clinical use and had been for some 20 years or so.

One might expect that this type of result would raise alarm bells not only within the pharmaceutical company, but also their associates (Kodak) and not least, the licensing authorities.

However, one can only assume that they never saw the light of day, because no further action was forthcoming.

The only plausible explanation for this was that these results were SUPPRESSED by the company and/or their associates, who stood to lose a great deal financially if the study results became widely known.