

ANNEX 1 to witness statement 467B of Dr Anne Maddocks

Annex 1

Re Unlicensed Preparations and Devices or Hormones

See Marilyn Duncan's statement **WS 536**.

Ms Duncan, a pharmacist, worked in Supplies Technology Division (STD) on Medical Devices.

1. At para 22. p.9

Ms Duncan describes STD 'Standard Practice' in relation to Medical Devices Ms Duncan contrasts high volume multi-user products – syringes, needles, and surgical dressings with implants etc. She states “These rarely presented the risks that could arise from devices which were innovative, at that time, such as implants or life support machines”.

2. At para 31 p. 12

Dura mater problems with CJD are discussed together with various licensing situations.

Ms Duncan states “In 1987 I received a minute about a dura mater graft which alerted me to the problems of the possibility of CJD contaminating lyophilised human dura mater (**YB87/02.10/2.1**). However this was a licensed product and therefore dealt with by the Medicines Division. It was of interest because of the non-standard (chemical) procedures used in its manufacture. Non-licensed medical devices made of animal tissues were also sterilised by non-standard (chemical) methods but not as I recall by the same methods as human dura mater any non-licensed human tissue devices were not commercially available.”

The underlined category clearly covers the very alarming case, many years ago for which I acted as an expert witness. There a “home made” dura graft was used from a “cottage industry” (ie. made in nearby mortuary, placed in weak disinfectant in unsealed honey pot). As the case of life threatening infection with permanent damage was settled out of court, I do not wish to enlarge further, but it is because I was acquainted with this human case and activities in the 1970s that I was quite prepared to believe in unofficial pituitary hormones, also in the 1970s, whether as described by Dr Little, or in other circumstances, for animal use.

This was a 'grey area', which will now be more supervised than in the 1970s.

ANNEX 2 to witness statement 467B of Dr Anne Maddocks

Annex 2

Use of various species' hormones and surprising durability of potency – 23 years

Quotes from Research papers show hormones have been used regardless of species in varying combinations. See “Fractionation of Protein Hormones from Horse Pituitary Glands” Stockell Hartree et al. *Reprod. Fert* (1968) 17, 291-303 (J/RF/17/291); “Follicular Development in Heifers infused with Follicle-stimulating hormone”, D B Laser *Reprod. Fert* (1972) 28, 285-289 (J/RF/28/285); “Pituitary preparations and ovulation in hens” Kyoshi Imai, *Reprod Fert* (1973) 33, at p.93 (YB73/03.06/1.1-1.2).

The fact that there were jars of pituitaries (or extract) around on shelves is attested by the still potent 1943 pituitaries, described in Stockell Hartree et al. (J/RF/17/291) which had come from the lab. at Mill Hill. Having taken the trouble to collect them, they were not lightly thrown out.