Infected Blood Inquiry

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The manufacture of Blood Products

Armour Pharmaceutical was an American company founded in 1951 and went through many changes of ownership and corporate structure. In 1975 they acquired a plasma collection company, Plasma Alliance, which operated 22 plasma centres in the US collecting blood from paid donors.

They obtained their first UK product license for Factorate in 1975 subject to a number of conditions relating to the right of the Inspectorate to inspect their manufacturing and collection premises and information about pool size.

This was the time of the World in Action programme which had raised concerns about imported blood supplies. The programme forced a response by the FDA who wrote to the CMO [Yellowlees] challenging the allegation that an American company was selling products that would not be licenced in the US.

The programme also stimulated the UK Medicines Division to remind other government departments and agencies that the Lister Institute who supplied the NHS from its centre in Elstree also needed a product license.

There was some doubt that it could meet the standards set for commercial companies. It is at this point that Dr David Owen instructs officials to refer any future license applications that involved imported products to him. The system was beginning to tighten up the licensing process.

Even at this early date Armour were advising clinicians that the hazards [small] from administering Factorate concentrate should be measured against the medical consequences of withholding it.

By 1980 the company was supplying the NHS with 16m units a year and became far and away the largest supplier of blood products to the NHS.

They were the cheapest in the market.

Two years earlier they had reduced their prices by 50% as part of a major marketing campaign.

By 1983 they were seeking permission to extend their heat treatment trials of Facturate but by now serious concerns were beginning to emerge about blood contamination.

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Armour stopped their trial when two suspicious adverse events occurred. The licensing authorities wanted stronger assurances about the quality of the heat treatment processes. Was dry heat at 60* adequate?

Amid growing public and patient concern Armour commissioned Dr Peter Jones from Newcastle to undertake an independent inspection of its Plasma Alliance centres. He judged the centres he visited to be a “first class organisation with a sound commitment to quality control”.

Is it possible that some companies were much better than others but were all tarnished by the same brush?

Armour wrote to all Haemophilia Centre Directors in 1983 about the high rate of Aids transmission in the US and set out what they had done to restrict collection from high-risk donors and described the screening they undertook to ensure their guidelines were followed.

A witness from Armour will appear sometime next month.

Next is Bayer, Cutter, Miles and Speywood all related companies involved in the manufacture and distribution of a F8 concentrate called Koate.

It was first distributed in 1974 [presumably on a named patient basis] but a product license was applied for in 1975.The application included the fact that the blood collection was carried out at a number of State penitentiaries. Pool sizes were between 3-5000 donors.

The license was approved with conditions although evidence emerges that some may not have been complied with.

Cutter also advised clinicians to weigh risk against benefits for patients.

Then in 1982 an internal Cutter paper reports.

"AIDS has finally come to the United Kingdom with a force that has caused a virtual panic in the Department of Health.

For one year this department has blocked every application for registration of heat-treated factor VIII products and now in the space of one week they are in a panic responding to the newspaper demands for action concerning the AIDS risk to haemophiliacs. The action by the Department of Health comes after the announcement in the Sunday Mail that “…two haemophiliacs have died from AIDS."

For more than three decades the Arkansas prison has profited from selling blood plasma

Cutter switched almost immediately to a heat-treated product and called in stocks of the non-heat-treated product.

This fast-moving scene produced a flurry in the market as NHS clinicians made decisions about when to change to heat treated products [now 68^0 for 72 hours]. Cutter promised next day delivery for phoned orders and free home treatment packs.

Dr. Wensley in Manchester was promised a £10,000

sponsorship programme for research when he promised Cutter all his business in the next contract.

Cutter's marketing at this time included leaflets, booklets, posters, magazines, home care packs as well as supported meetings and conferences and support for the Haemophilia Nurses Association.

Koata was eventually withdrawn from the market in 1990 when safer products became available, had not provided sufficient data on safety and efficacy.

Next on the agenda is an examination of Cutter's successful applications to the FDA to import blood from Mexico, Haiti and Nicaragua.

Cutter owned over 20 collection sites but utilised output from over a hundred centres including those managed by the American Red Cross and the American Association of Blood Banks.

In 1985 there were discussions between a number of companies about abandoning their "gentlemen's agreement" not to use blood collected at prison centres.

Price was clearly part of some clinicians' choice of product.

Why these decisions were left to individual Haemophilia Centre directors remains an important issue for the Inquiry.

Should they have acted together or should the CMO, ministers or senior NHS managers have intervened?

In 1984 Cutter launched another product Konyne [F9] in the US.

It's application for a UK license was blocked on the grounds that the company

They decided to hold off and Cutter introduced an education programme for high-risk donors. As one internal report put it "the real risk of prison collection was less than the perceived risk".

A Cutter employee gives evidence in a deposition in a legal case to the effect that people in Cutter knew in 1970-72 that patients who had received Konye were developing hepatitis and dying, although the incidents were very rare. Finally, Counsel reviews the evidence presented by Kelly Dudd a journalist in the US.

For more than three decades the Arkansas prison has profited from selling blood plasma from inmates infected with viral hepatitis and Aids. Thousands of unwitting victims around the world who were transfused from this blood died as a result. Haemophiliacs were regarded as "canaries in the mine "for blood borne diseases.

As well as Arkansas, Cutter had collection centres in Oklahoma and Alabama prisons, and he claimed British officials knew this"

All Bayer products now included the advice to clinicians to weigh the risks and benefits.

Speywood a British company part owned by the National Enterprise Board marketed Koate in the UK for a couple of years until Cutter stopped the supply. Cutter were not

best pleased when Speywood asked them for compensation as they had to refund some NHS centres who had been supplied with Koate that had lower than advertised potency.

Speywood then launched an identical product under the name Humanate. It was sourced through an intermediary, but it looks as if Cutter knew what was going on and chose not to intervene.

The licensing authorities were unhappy with the arrangement as it proved difficult to trace batches back to the manufacturer and donor pool.

Speywood became quite competitive offering clinicians' different deals. Prof Bloom in Cardiff switched away for Immuno when it became too expensive.

Price was clearly part of some clinician's choice of product. Bloom asked for help from Speywood with his research programme. Humanate was withdrawn from the market in 1981

The Head of Science at Speywood later gives personal evidence and described her work on a porcine product. The porcine product sourced from pigs raised in herds in rural England had shown some success with inhibitor patients and some speculated that it might eventually replace human blood despite its shocking reputation with earlier versions.

It was however four times the cost of products from human blood and needed storing in a deep freezer. It was licensed in the UK in 1984 but used mainly just for major emergencies.

A new fractionization process had also been researched in some depth by the company which would, it was thought, produce a purer product, but its potential was never realised.

Next Abbott and related companies who do not appear to have yet submitted evidence to the Inquiry. Counsel will explain why.