Is blood a good? Shifting from public health directives to ECJ cases based on consumer law

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- Short comments today are based on several decades of research in EU health law. This shows that it is a mistake to adopt a superficial approach to the meaning and significance of EU health law: we need to be careful and look deeply at it.
- Generalise out a bit more – look at broader contexts, not just specifics of one or two cases of ECJ involving blood and plasma.
- Think about this in terms of 'constitutional genetics' of EU – roles of national courts (particularly under preliminary reference procedure) and EU courts; and of national and EU legislatures – which are balanced in ways that cannot be understood as if the EU were a state – it is not a state.

- Substances of human origin are not 'products'
- Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, Articles 5 & 6: the human body cannot constitute a patentable invention; inventions are not patentable where their commercial exploitation is contrary to ordre public or morality
- Directive 2002/98/EC on Blood Safety, rec 1, legal basis Article 168 TFEU: not based on Article 114 TFEU, not part of internal market law, but part of EU's public health law and policy
- EU Charter of Fundamental Rights, Article 3 (2): prohibits the human body and its parts being a source of financial gain

- Medicinal products derived from blood or plasma are 'products'
- Directive 2001/83/EC, Article 1: scope of the Blood Safety Directive is whole human blood, blood cells and plasma, but EU pharmaceutical law has priority where plasma products fall within definition of medicinal products. Thus EU law inverts the normal *lex specialis* rule here.
- C-512/12 *Octapharma* : confirms that industrially produced plasma is covered by Directive 2001/83 on medicinal products, where plasma meets definition by 'presentation' (substance presented for treating or preventing human disease) or 'function' (substance modifying physiological functions by exerting a pharmacological, immunological or metabolic action').
- C-421/09 *Humanplasma;* C-296/15 *Medisanus:* confirm that medicinal products derived from human blood or plasma are products for the purposes of Article 34 TFEU on the free movement of goods in the internal market

- EU 'constitutional genetics' appears to be about markets, and risk regulation within markets

- Even the Blood Safety Directive is about regulating risk. Context of the legislation is prevention of future HIV-infected transfusions, following deaths of thousands of

haemophiliacs in the 1980s and 1990s. Securing blood safety in EU about precautionary approach to risk. Argument goes that this is a narrow approach to risk, based on consumer/patient safety. It doesn't consider broader risks to European society of commodification/market-based narratives.

- But there is more to EU law than that.

1. EU legislation articulates an ethic of care

- Blood Directive Article 20: voluntary blood donation
- EU self-sufficiency in blood & blood products (eg Directive 2001/83, rec 19; Directive 2002/98, rec 4)
- EU Clinical Trials Directive and Regulation prohibit financial incentives

2. EU law articulates ethic of dignity & human rights

- Implementing Directive 2005/62/EC: includes informed consent provisions, which make sure that donors are fully informed – links to human rights of dignity and autonomy/integrity of the body
- EU CFR Article 3 integrity of the person, non-commodification; Article 1 human dignity: these are important touchstones when the ECJ interprets EU legislation and national legislation implementing EU law
- See also *Neth v Parl & Council (Biotech) Brustle; International Stem Cell :* not blood cases per se, but involve substances of human origin. In these cases, the CJEU is careful to articulate the non-commodification principle

3. CJEU respects national preferences (eg *Humanplasma, Leger*), except where disproportionate protectionism (eg *Humanplasma, Medisanus*) or breach of general principles of EU law (eg *Leger*)

However, all of that said, there is scope for greater specificity in EU legislation, leaving less room for courts to act. The kinds of balancing decisions that are involved in blood safety and self-sufficiency are questions that are better for elected legislatures, than for the specificity of litigation before courts.

Return to 'constitutional genetics' point. EU's internal market law – as with its law on substances of human origin – is 'coded' to respect a 'European way' of thinking about health, healthcare systems, and human bodies.