

Appendix A. Cascade of Competing Characterizations and Potential Consequences

<u>CHARACTERIZATION</u>	<u>CONSEQUENCES</u>				
		<u>Regulatory</u>	<u>Tort</u>	<u>Payment</u>	<u>Patent</u>
Medical procedure (vs. product)?	YES →	State (vs. fed.) control	Negligence (med. mal.)	experimental exclusion?	unenforceable?
	↘ NO				
Human organ (vs. tissue)?	YES →	HRSA (vs. FDA)	Negligence (tissue ≠ product)	sales prohibition	unpatentable?
	↘ NO				
Minimally manipulated?	YES →	HCT/Ps regs. only	"	unrestricted	patentable
	↘ NO				
Biologic (vs. Device)?	YES →	BLA reqt.	Strict prod. liability	"	"
	↘ NO				
Substantially equivalent?	YES →	PMN reqt.	"	"	" (novel?)
	↘ NO				
Custom device?	YES →	exempt from PMA reqt.	[same consequences as in first row?]		
	↘ NO				
Humanitarian use exemption?	YES →	mini PMA	Preemption defense?	sales prohibition	patentable
	↘ NO				
		full PMA	Preemption defense	unrestricted	"