

WRITTEN QUESTION E-1749/02

by Ian Paisley (NI)
to the Commission

Subject: Criteria for evaluating medical devices

1. What are the criteria used in evaluating artificial medical devices (i.e. heart valves) manufactured in the USA or outside the EU for use within the EU?
2. Why should these devices be used in the EU prior to approval in the USA, or country of origin/manufacture?
3. What analysis/testing was done in the case of the 'St. Jude, "Masters" Series, silzone-coated artificial mechanical valve prosthesis' prior to approval for use in the EU?
4. Why was this device accepted and approved in Europe for over a year before approval by the Food and Drug Administration (FDA) in the USA?
5. Considering that EU citizens are not in a position to file for punitive damages, what steps can be taken to ensure that these citizens are not being used as human 'guinea pigs' in an effort to provide a cheap testing ground for these 'prototypes'?