

What would happen if you needed 10,000 subjects to demonstrate efficacy and there were only 4000 cases per year in the U.S.? Something has to give.

## **ANOTHER ROUTE ALLOWING A DEVICE TO BE MARKETED**

**REGULATION:** 21 CFR 814.100 to .126

Devices have multiple routes to market. One is the Humanitarian Use Device. Obtaining marketing approval for a HUD involves two steps:

- (1) HUD designation from FDA Orphan Products  
HUD (humanitarian use device) means a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year
- (2) HDE designation from FDA Office of Device Evaluation.  
HDE means a premarket approval application submitted pursuant to this subpart seeking a humanitarian device exemption from the effectiveness requirements of sections 514 and 515 of the act as authorized by section 520(m)(2) of the act.

## **IRB REQUIREMENT 21 CFR 814.124 FDA Guidance, 7/21/01, Q 17.**

The HDE holder must ensure that the HUD is used under IRB approval. Full board review is required for initial review; expedited review may be used for continuing review and minor modifications. (Addition of a new site is considered a minor modification.)

The problem is that proposals made to use an HUD have no research component. The HDE is granted market clearance for treatment. The criteria an IRB is required to apply (56.111) are not relevant. FDA has clarified that IRB approval is a means to allow notification of the performance site and to see if there are any local issues involved with its use.

Continuing review is required for HUD activities.

## **CAUTIONS AND NOTES**

1. Studies of effectiveness are recommended but are not required. *Use of the humanitarian device and study of the humanitarian device should be distinguishable.*
2. Consent is consent for treatment rather than consent to be in a study. An information sheet or Patient Insert may be a useful substitute.

