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April 28, 2009

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PUTTING IT ALL TOGETHER: PRIORITIES & OBJECTIVES FOR AN ATRIAL FIBRILLATION SAFETY REGISTRY

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Background

The AdvaMed AF industry working group believes that initiation of a National Atrial Fibrillation Registry is premature in the absence of any precipitating events

- Ablation therapy development remains in a high evolutionary state
- The primary research focus today is to further develop the therapy to improve safety and/or efficacy
- We need to secure FDA approval on multiple ablation systems designed to specifically treat AF
- Initiation and support of important landmark, post-market outcomes trials is important to industry, i.e. CABANA, RAAFT

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Topics for Further Discussion/Consideration

- What is the goal for such a registry?
  - What are the right research questions to be asked?
  - Do we understand the problem before a solution is prescribed?
  - Not a surrogate for prospective comparative studies of therapy evaluation, product performance, or physician techniques

- What is the right timing for such a registry?
  - Registries cannot take the place of controlled clinical trials
  - Competition for patients
  - Competition for research resources ($$ and time)

Topics for Further Discussion/Consideration, cont'd

- Who will fund such a registry?
  - Set-up
  - Maintenance
  - Data monitoring; cost vs value if not monitored
  - Access, reporting
- Impact to FDA imposed post-market study as condition of PMA approval?
  - Each PMA has unique needs for further study
  - Would it really serve to reduce requirements?

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In summary:

The AdvaMed AF industry working group believes that initiation of a National Atrial Fibrillation Registry is premature in the absence of any precipitating events

Should the time become appropriate for such registry, we believe that it should be Complementary, not Redundant:

- ***Drive utilization of the Guidelines and Consensus***
- ***Support the evolutions of AF Ablation Therapy***
- ***Allow for a variety of catheter technologies***
- ***Improve clinical workflow***

In Closing:

Any future registry should be a partnership to support a clear and unique contribution to the mutual goals of:

- ***Patient access to safe and effective therapy***
- ***Advancing the science***

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Date