

## Artificial Retina Highlighted in State of the Union: Three Keys to Getting It to Patients Quickly

The artificial retina described by President Clinton in his State of the Union address is just one of the many medical miracles that we can expect to achieve in the coming years. It also underscores the major regulatory hurdles facing innovative medical technologies.

Researchers at Johns Hopkins University have been working on the implantable retinal prosthesis for about 10 years. Investigators predict that it will not enter human clinical trials for another two to five years, and that FDA market approval is another ten years off. After receiving FDA approval, the technology must obtain separate coverage and payment approvals at Medicare before it will be available to America's seniors. The multiple stages of FDA and Medicare review could six years to complete (see chart on p. 2 for FDA/HCFA review timeline and recommended reforms).

Three key steps can be taken to make sure breakthroughs like the artificial retina get to patients as quickly as possible:

### **Medicare needs reasonable coverage standards to foster timely patient access.**

- HCFA should not use cost-effectiveness and other economic considerations as criteria for Medicare coverage. Coverage is fundamentally a patient care decision, not a financial one. Cost factors are appropriately considered in the context of payment policy.
- Medicare should establish reasonable, objective coverage standards that recognize the rapid, incremental nature of technology innovation and result in timely beneficiary access to appropriate care.
- Medicare coverage policies, especially those that set restrictions on patient access, should be updated frequently. Furthermore, policies should be consistent with the advice of medical specialty groups.

### **Medicare should adopt timely, open technology payment procedures.**

- Even after HCFA decides to cover a new technology, it can take many more months for it to assign a procedure code and payment amount. Until this happens, the product will not be generally available to Medicare beneficiaries.
- Further, if HCFA sets the payment level too low it likely will discourage access to the technology and discourage further innovation in this area. For coronary stents, for example, Medicare beneficiary access went from only 5- 25% of eligible patients to 70-80% after HCFA corrected a payment error.
- Needed improvements include: creation of open, objective payment procedures that result in fair reimbursement amounts; more rapid issuance of new payment codes; and establishment of a new Medicare advisory committee to make sure innovative technologies are quickly made available to beneficiaries.
- The Medicare Patient Access to Technology Act (S. 1626/H.R. 2030) introduced by Sen. Orrin Hatch (R-

UT) and Rep. Jim Ramstad (R-MN) would take important steps to ensure that HCFA makes timely, appropriate payment decisions for products like the artificial retina.

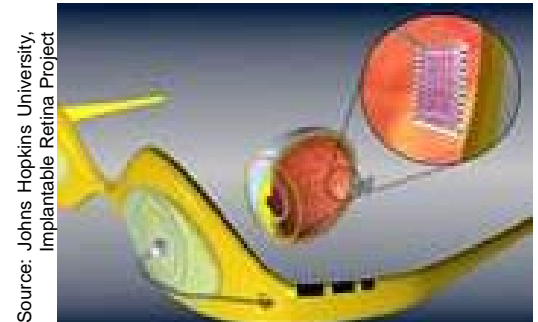
**FDA should complete implementation of modernization legislation to speed up device approvals.**

- Although FDA has made significant strides in implementing the FDA Modernization Act and reducing premarket review times, a few key provisions are not yet in place. Two of these – holding early meetings with product sponsors on data requirements and creating a “least burdensome” premarket review policy – can help move innovative products through FDA more quickly.
- For the artificial retina, an early meeting with FDA would give product sponsors a good idea of the types of data needed to receive approval. This helps ensure that time is not spent collecting unnecessary data and that the implant will be approved quickly once it is submitted for FDA review. FDA should encourage early meetings with product sponsors.
- Implementation of the “least burdensome” approach to product reviews would ensure that artificial retina researchers and other product sponsors will not have to collect data beyond that needed for approval.

**QUOTE OF THE WEEK**







“I’ve never looked at the face of my grandson...but I do believe I will before I die.”  
**-Harold Churchey, 72-year-old participant in trials of prototype artificial retina at Johns Hopkins University**

ILLUSTRATION OF ARTIFICIAL RETINA



Source: Johns Hopkins University, Implantable Retina Project

**GETTING THE ARTIFICIAL RETINA TO PATIENTS**  
**Current FDA/HCFA Approval Process Can Take 5 1/2 Years**

FDA REVIEW		MEDICARE COVERAGE AND PAYMENT REVIEWS		
 FDA Premarket Approval  <i>Time: 12.5 mos.</i>	 Coverage Determination  <i>Time: ?</i>	 Market Experience Requirement  <i>Time: 6 mos.</i>	 Assigning a New “Code”  <i>Time: 15 mos.-2 yrs.</i>	 Determining Appropriate Payment  <i>Time: 2 yrs. +</i>
FDAMA		Hatch/Ramstad Technology Access Bill		
Implement FDAMA provisions on written agreements and “least burdensome” review.	Advisory Committee to Streamline: ♦ Coverage ♦ Coding ♦ Payment	 Eliminated	Cuts Coding Delays in Half	♦ More Frequent Updates ♦ Expanded Use of External Data