

Rewarding Antibiotic Development And Responsible Stewardship (RADARS)

January 2013

Executive Summary

➤ **Objective of RADARS program:**

- Create an economic platform to incentivize innovators to develop new antibiotics to combat resistant organisms
- Preserve the usefulness of these antibiotics for as long as possible
- Do so without creating an additional financial burden on hospitals

➤ **Program Structure:**

- Designed to work hand-in-hand with LPAD & QIDP/GAIN
- Guarantees innovators a minimum revenue level for 5 years at attractive pricing
- Allows hospitals to be reimbursed (above DRG) for on-label use guided by stewardship programs
- Government only pays for successes and does not have to pick winners prior to approval

RADARS: Basic Concepts

- HHS will set up an incentive program that will reimburse hospitals directly for the use of a new LPAD antibiotic (akin to current NTAP payments for Difucid for *C. difficile*)
- Payment will only be made upon submission by the hospital of documentation showing that the patient had limited treatment options due to the presence of known or suspected resistant organisms consistent with the drug's LPAD designation
- Hospitals would be required to have an approved LPAD stewardship program in place to be eligible for reimbursement
- HHS/CMS Payments would be over and above normal DRGs for the patient and would be designed to bring the net cost to the hospital to parity with standard existing treatment options

RADARS: Basic Concepts (Cont.)

- HHS would guarantee the innovator a certain minimum revenue stream per year at fixed prices for a period of 5 years (akin to Project BioShield)
- Per patient pricing would be high in the first year (~\$1,300/day) to compensate for low initial volumes and correspondingly high production costs, but would decline over the 5 years to ~\$700/day
- The guaranteed minimum revenue would be \$100 million in the first year and rise to \$350 million in the 5th year (if total hospital purchases are less than this amount, HHS will pay innovator the difference)

Basic Concepts (cont.)

- NTAP-type payments would continue for 10 years, but the guaranteed revenue minimum to the innovator would only apply to the first five years
- Price per patient per day for years 6-10 would fall to \$400 to \$500
- In exchange for these benefits, innovator agrees it will not promote the product through its sales force in any way; MSL's may be utilized for information exchange only
- No sales volume based incentive compensation permitted
- HHS/FDA would use either the QIDP or LPAD designation to define eligibility; no other application required

Economic Example for a New LPAD Antibiotic

Year	Purchase Commitment (\$ thousands)	Price per Day of Treatment	Average Days of Treatment	Total Cost per Patient	Number of Patients Covered
1	\$ 100,000	\$ 1,300	10	\$13,000	7,692
2	\$ 200,000	\$ 1,100	10	\$ 11,000	18,182
3	\$ 250,000	\$ 1,000	10	\$ 10,000	25,000
4	\$ 300,000	\$ 850	10	\$ 8,500	35,294
5	\$ 350,000	\$ 700	10	\$ 7,000	50,000

Feasibility/Societal Benefit

- Between the NTAP mechanism and BARDA/Project BioShield, all of the key components to implement this program are already in place-- they would just need to be adapted and the funds appropriated
- Out of pocket costs are likely to be lower than if these new antibiotics were developed and marketed in a traditional way and used widely
- In reality, given the cost of treating resistant infections the net cost to the health care system is likely to be negligible
- The program should significantly enhance the useful life of important new antibiotics
- Since many of these antibiotics are likely to also be active against bioterror organisms, this program should help to address this need as well