Lack of New Tests as a Threat to Blood Safety

Paul A. Mied, Ph.D.

IVD Roundtable
August 12, 2010

Problems that Threaten Blood Safety

- Disappearance of donor screening tests
- Lack of new donor screening tests
- Lack of tests for emerging agents
- Lack of supplemental tests

CBER

Some Factors Contributing to the Problem

Economics:

- Donor testing market is small
  - Small profit margin, low growth potential, high risk
- Test kit manufacturers need marketing commitments
- Manufacturers perceive barriers to test development (e.g., clinical trials are costly)

Some Factors Contributing to the Problem (cont.)

- Manufacturers cannot recover capital costs or development costs under IND
- User community concerned with costs of adding new tests
- User community/hospitals cutting costs: dropping tests that are not recommended

CBER

A Shared Responsibility

Protecting blood safety is a responsibility shared by test manufacturers, blood organizations, and FDA.

Each party needs flexibility to ask:
"What can <u>we</u> do to solve this problem?"

C B
E R

Potential Strategies to Encourage Development of New Tests

1. **Improved communication and cooperation:**

- **A Joint Forum among blood organizations, trade organizations, CMS and FDA to clarify issues and develop possible solutions**
- **Liaison meetings and periodic workshops organized by industry on scientific issues of new test development**

CBER

Potential Strategies to Encourage Development of New Tests (cont.)

2. Alleviate the costs associated with test development and licensure:

- Public funding (e.g., governmental grants, SBRAs)
- Legislative solutions: Orphan drug model
- Encourage user community to partially subsidize assay development and clinical trials: a blood surcharge ?
- Partnerships between blood establishments and small manufacturers to develop small market tests

CBER

Potential Strategies to Encourage Development of New Tests (cont.)

3. **Actions FDA could take:**

- Timely issuance of guidance documents recommending new tests for emerging agents
- Timely discussion of criteria for approval of new tests for emerging agents
- Encourage manufacturers to meet with FDA about product development pathways
- Transparency: Non-binding discussions with industry and blood organizations

CBER