Incentivizing the Development of New Diagnostics

Sam Bozzette, MD, PhD

VP, Medical Affairs-Americas, bioMerieux

Adjunct Professor, UC San Diego and U North Carolina

PIONEERING DIAGNOSTICS

BIOMÉRIEUX

Mission: Contribute to the improvement of public health worldwide through *in vitro* diagnostics

- **Marcel Mérieux worked with Louis Pasteur in 1894**

- **Founder of Institut Mérieux in 1897,**
  which led to the development of companies **in human and veterinary medicine,** that are **major players** in Public Health today

Our activity

The clinical field (~ 82% of sales):

Improving population and patient health

- A complete range of diagnostic solutions for the diagnosis of:
  - infectious diseases
  - cardiovascular diseases
  - targeted cancers

The industrial field (~ 18% of sales):

Ensuring consumer safety, product quality and animal health

- Solutions for detecting microorganisms in order to prevent and track product contamination in:
  - food
  - biopharmaceuticals and cosmetics
- A complete range of veterinary diagnostic solutions for:
  - infectious diseases
  - fertility monitoring

In vitro diagnostics: playing an important role at a minimal cost

- **60 to 70% of medical decisions are based on *in vitro* diagnostic tests, which make up only 2 to 3% of healthcare spending[1]**
  - Pharmaceutical industry[1] €977 billion
  - *In vitro* diagnostics[3] €51 billion

- **Improved diagnostics and use of tests should result in better:**
  - Patient care
  - Optimization of medical expenditures
  - Population health
  - Alignment with societal goals (e.g. re: AMR)

[1] The Lewin Group, Inc. *The Value of Diagnostics Innovation, Adoption and Diffusion into Healthcare (July 2005)*

Pharmaceuticals and Diagnostics are Different

Pharmaceuticals	Diagnostics
Much larger market	Much smaller market
Much more research support	Less research funding/activity
Reimbursements much larger (value-based pricing)	Reimbursement smaller (commodity)
Direct relationships with payers	Payer relationships via provider
Regulatory requirements greater	Regulatory requirements growing
HTAs needed	HTAs becoming more common

In vitro Diagnostics: Issues

- **Underutilization of existing tests is a clinical and public health issue**
  - Insufficient ordering
    - Lack of awareness
    - Slow incorporation into clinical guidelines
    - Provider / patient attitudes
  - Narrow claims
- **Underdevelopment of new tests is also a clinical and public health issue**
- **Development limited by poor return on investment (ROI)**

Drivers of Return on Investment

Development is costly

- New platforms: 20 – 100M USD
- New tests on existing platforms: 10-20M
- Cost rising quickly in part because of need for
  - More challenging technologies and new platforms (e.g., POC)
  - Increasing need for complex clinical outcome studies for registration
  - HEOR and Health Technology Assessments

Returns are limited

- Underutilization
  - Market access activities new to diagnostics
  - Limited indications (e.g., to place)
  - Slow uptake of medical innovation into practice
  - Sense that testing is often only an additive expense (ie, compare to simply prescribing).
- Commodity as opposed to value-based pricing
  - Clinical value rarely considered in pricing
  - Sharp contrast to pharmaceuticals
  - Social value not considered

Example of Incentives that are Working

- **Tax credits (e.g., Research and Experimentation Tax Credit)**
- **Contracts and grants for development (e.g., NIH SBIRs, BMGF, IMI)**
- **Enhancing market reliability and size**
  - Advance purchases (e.g. BARDA contracts)
  - Direct subsidies (e.g., GenXpert TB)
- **Enhanced IP protection (e.g., as in GAIN Act for drugs)**
- **[Prizes (e.g. Longitude, NIH/BARDA Challenge)]**

Recommended Non-Financial Measures

- **Lower development costs**
  - Increased funding for relevant (“high-risk”) basic science
  - Improve public infrastructure for clinical research in diagnostics
    - Enhance clinical trials networks
    - Increase availability of reagents
    - Bio-repositories
- **Optimize utilization**
  - Education
  - Regulation
    - Require appropriate testing for reimbursement / quality measures
    - Proposed CMS rule on infection control and inappropriate antibiotic use is a good step

Recommended Non-Financial Measures (2)

- **Expanded IP protection**
- **Regulatory considerations**
  - Lower barriers to approval
  - Broader use of existing data
    (with or without post-market studies)
  - Fast track approvals
  - Provisional approvals
  - More guidances on specific topics

Recommended Financial Incentives

Increased funding for R&D

- Sources: individual governments, Global Innovation Fund, foundations, hybrids (e.g., Innovative Medicines Initiative)
- Strong alignment of funding streams with national/international goals re AMR
- Including Health Economics and Outcomes Research needed for both marketplace and Health Technology Assessments

Guaranteed revenue

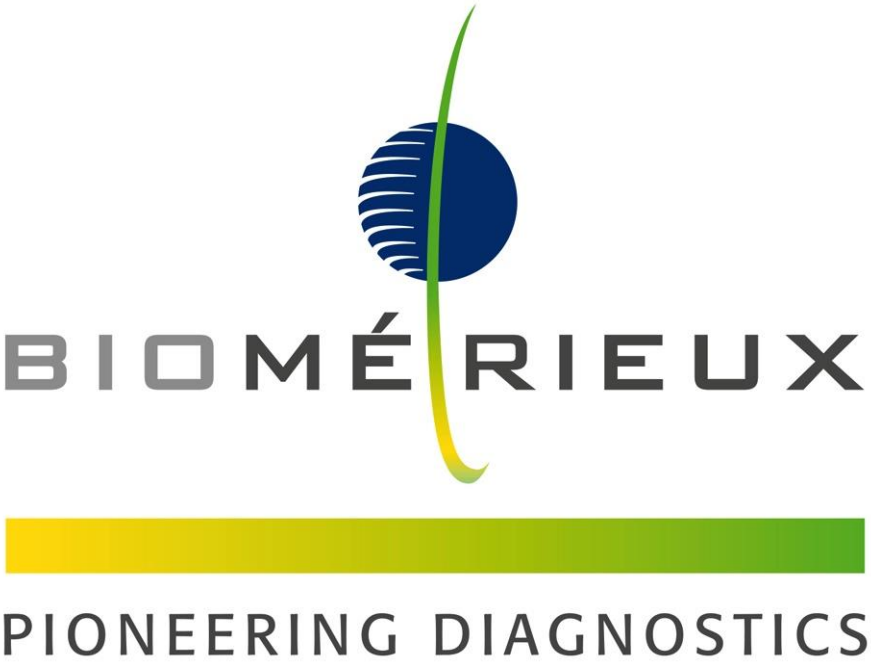
- Advance purchase agreements
- Market entry payments
- Top-off payments for sales in developing countries

Promote value-based pricing for relevant tests

- Incorporate clinical and societal value
- Base reimbursements on value/outcomes rather than cross-walk to existing tests
- Lack of direct connection with payers is a problem

Recommended Financial Incentives (2)

- **Prizes: not so much**
  - Amounts generally too small for industry
  - Bigger prices introduce too much uncertainty into ROI
  - Winners might not be strong commericializers (e.g., academics, start-ups)
- **Enhanced tax credits**
  - Increase Research and Experimentation Tax Credit
  - Clinical trials tax credit for innovative / rapid diagnostics (Reinvigorating Antibiotic and Diagnostics Innovation [READI] Act)
- **Permanent repeal of the device tax (or exemption for high value diagnostics)**
- **Omit key tests from PAMA-associated reimbursement cuts**


BIOMÉRIEUX
PIONEERING DIAGNOSTICS