

FTC's Roundtable
Panel: Policy and New Drug Development

Developing Innovative Vaccines for Global Health Needs



AVANT
IMMUNOTHERAPEUTICS, INC.

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Vaccines are at a Crossroads

- New understanding of molecular immunology
- Genetic engineering, rather than selection
- Adult and adolescent markets, as well as pediatric
- Therapeutic as well as preventative

But Issues Remain:

- Irrational public fear
- Enormous Phase 3's for safety
- Plaintiff's bar
- Reactogenicity to adjuvants
- Manufacturing capacity
- Uncertain regulatory pathways
- Cumbersome reimbursement

The Big Issues

- Return on Investment
- Indemnification for Manufacturers
- Regulatory Predictability

State of Play

Vaccines for Children

- Largely preventative, highly successful
- Government monopsony (low margins)
- VFC, VAERS, VICP
- Complex relationship between federal government, states and insurers

State of Play

Vaccines for Children

Newer Vaccines

- For adolescents and adults
- Therapeutic as well as prophylactic
- Inadequate infrastructure
- Social issues

State of Play

Vaccines for Children

Newer Vaccines

Pandemic and Biodefense Countermeasures

- Manufacturing: surge capacity/warm base
- Government monopsony, purchase commitments for dose and price
- Indemnification – shaky legislation in place
- “Valley of death” funding – BARDA a good start
- Regulatory predictability
- Dual use: tiered pricing – patents are critical

Regulatory Issues

Large Phase 3 Safety Trials

versus

Post-Marketing Surveillance

(we don't need add-on regulatory burdens)

Regulatory Issues

PDUFA reauthorization

- Increased costs
- Not shortened timelines
- May fuel fears of industry control

Need more congressional support for FDA

Some Solutions (risk reduction)

- Calculable safety and manufacturing regulation
- Freedom from liability except for willful misconduct
- Committed purchase (number of doses and price)
- All insurers cover immunization
- Infrastructure for adult and adolescent vaccines

Questions

Will there be

- new vaccines?
- access for all?
- acceptance by all?
- a U.S. vaccine manufacturing industry?

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