Duke | MARGOLIS CENTER *for* Health Policy

Innovations and Policy Solutions

Gillian Sanders Schmidler PhD
Deputy Director
Duke Margolis Center for Health Policy
Professor of Medicine
Duke University

Stephen Colvill
Research Associate
Duke Margolis Center for Health Policy
Duke University

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Mission

Improve health, health equity, and the value of health care through practical, innovative, and evidence-based policy solutions.

Vision

To catalyze Duke's leading capabilities, including interdisciplinary academic research and capacity for education and engagement, to inform policy making and implementation for better health and health care.

DUKE-MARGOLIS FOCUS AREAS

Health Care Transformation

- Value-based care and payment reform evidence and policy development
- Evidence and support for practice innovation and transformation
- Improving equity & addressing social drivers of health
- Identifying strategies for improving care during COVID19 & public health emergencies

Medical Product Payment & Biomedical Innovation

- Better evidence and methods for regulatory decisions
- Value-based payment reforms for medical products
- Advancing regulatory and development science for drugs, devices, diagnostics, digital health

Global Health

- Value-based care and payment reforms in high-income countries
- Value-based care and payment reforms in low/middle income countries
- Role of private sector in financing and developing/ scaling innovation

Education

- Undergraduate Education
- Graduate and Professional Education
- Experiential learning through real-world projects and internships
- Margolis Scholars
- Continuing and Executive Education

Reducing Health Inequities

How Can We Improve Biomedical Innovation?

Medical product regulation and payment must address many considerations— assuring safety and effectiveness, addressing important patient needs, and doing so as efficiently and affordably as possible. Health policy reforms can have a critical impact:

- **Enhancing the pipeline:** Improving how drugs, devices, and medical products are developed, tested, regulated, distributed, and monitored in the marketplace to ensure that life-saving, treatments and therapies are available to and affordable for the patients who need them.
- **Lowering development costs:** finding ways to modernize clinical trials to be more efficient, equitable, and representative of the patient populations in need.
- **Advancing FDA regulatory science:** Improving data, endpoints, methods, and regulatory processes to advance efficiency, equity, and patient-focused product development.
- **Ensuring value:** Reforming payments to support the development and effective use of new therapies to promote high-value care and societal benefit
- **Improving market incentives**: developing models that leverage public and private funding for critical areas in need of therapeutic research and medical product development.
- **Real-world data:** determining best ways to use information about how medical products perform in the "real world" to feed back into product development and regulation, and decisions about care.

July 2021 Whitepaper: Identified factors contributing to shortages…

Market Forces

- Manufacturers operate on small margins, and are unable to invest in resilient manufacturing

Geographic Concentration

- Supply is concentrated in a few countries – mainly China and India - and vulnerable to international trade disputes, natural disasters, etc.

Quality Oversight Challenges

- Quality issues arise frequently, and oversight has been challenging

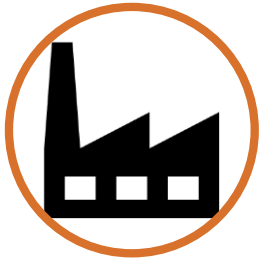
Lack of transparency

- It is difficult for regulators to track vulnerabilities, and for buyers and manufacturers to observe and invest in resiliency

…and recommended policy responses

Financial Incentives

- Targeted subsidies and tax Incentives
- Contracts contingent on promotion



Implement New Technologies

- Fund and support technology to improve supply chain resilience
- Pilot and address regulatory and practical barriers to adoption

Promote Transparency

- Government collect more comprehensive data and conduct supply chain assessments
- Private sector needs information to inform drug purchasers

Implementing Manufacturing Technologies Using Regulatory and Policy Levers

Financial Incentives:

- Grants to develop Centers of Excellence
  - HR 4369 National Centers of Excellence in Advanced and Continuous Pharma Manufacturing

- Accelerated reviews and filing fee waivers for products with innovative technology

Implementing Manufacturing Technologies Using Regulatory and Policy Levers

Regulatory Approaches:

1) Set future date when older tech will no longer be approved
   - i.e. Track and Trace
2) Set "grandfathered" approval status for older tech
   - Manufacturers must implement a plan to move to the new tech
   - Approval can be revoked if a competitor comes to market with the new tech
3) Collaborate with international regulators to promote standardization
4) Include technology types in FDA Quality Management Maturity Model

Duke-Margolis Next Steps

- Further research on the regulatory and policy levers
- Engage with manufacturers to identify more specific regulatory barriers
- Identify technologies other than continuous manufacturing most deserving of pilot programs