

Novartis Influenza Vaccines: A Partner in Pandemic Preparedness

Monique K. Mansoura, PhD, MBA

*Head, Medical Countermeasures and Government Affairs, Americas
Novartis Influenza Vaccines*

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Rapid Response for Pandemic Protection

Key features of Pre-pandemic threats

■ Pre-Pandemic Threats

- Persistent, perpetual, and unpredictable in strain, scope, scale, impact

■ Pre-Pandemic Preparedness

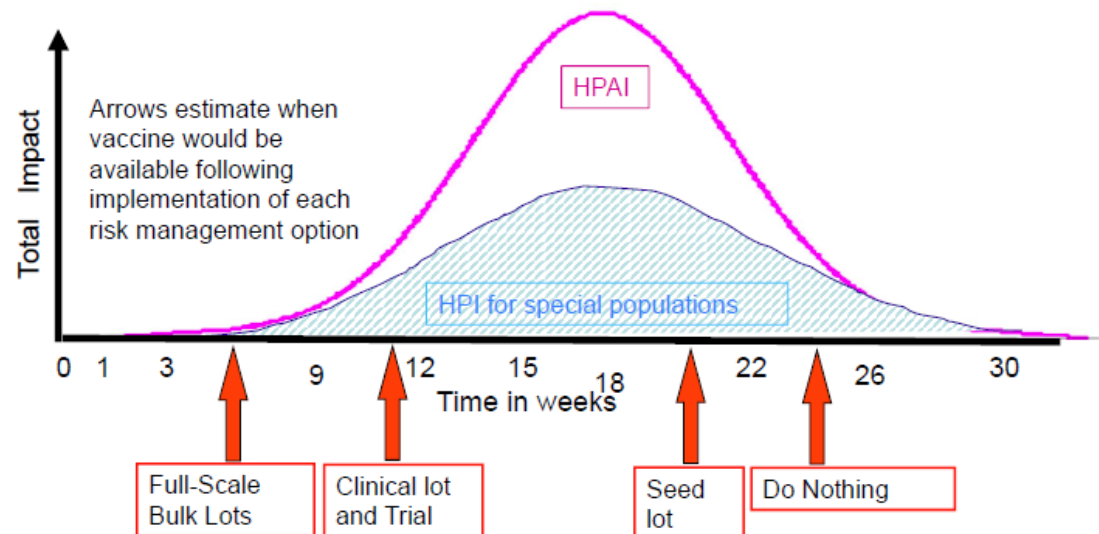
- The Benefits of action
- The Costs of inaction



Pre-Pandemic Influenza Vaccine Availability by Risk Management Option



Two pandemic scenarios represented here: HPAI = high pathogenicity avian influenza
HPI = high pathogenicity influenza



https://www.medicalcountermeasures.gov/media/35698/donabedian_new_approaches_to_stockpiling_risk_assessment_and_management.pdf

Pandemic Influenza Preparedness

Innovating for a more rapid response

REPORT TO THE PRESIDENT ON
REENGINEERING THE INFLUENZA
VACCINE PRODUCTION ENTERPRISE
TO MEET THE CHALLENGES
OF PANDEMIC INFLUENZA

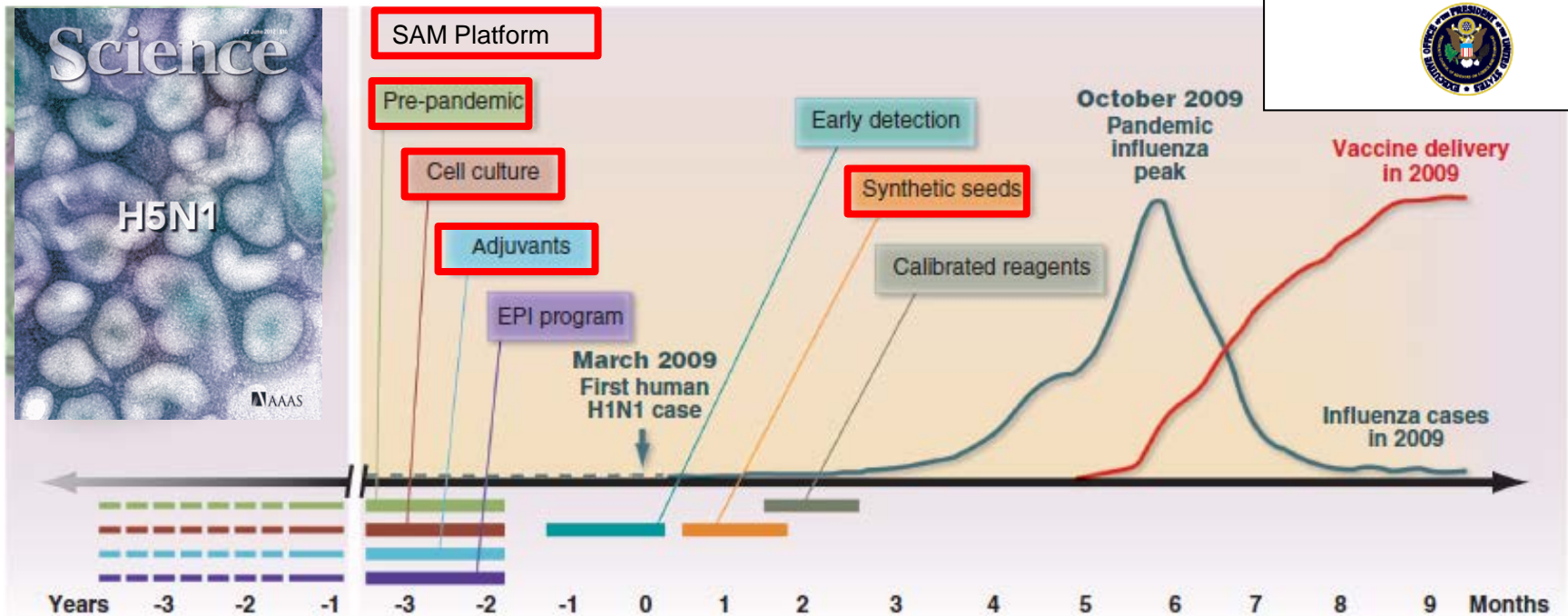
Executive Office of the President

President's Council of Advisors on
Science and Technology

AUGUST 2010



= Novartis activity

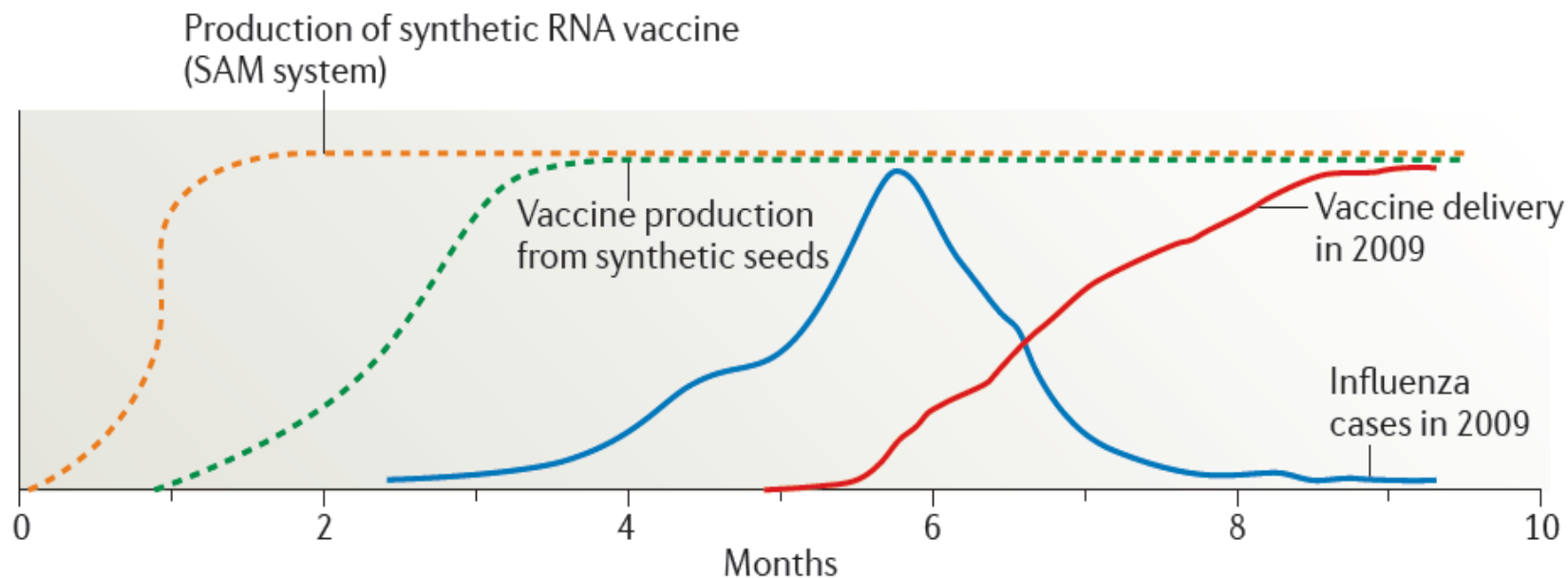


Summary of Options to Improve Pandemic Influenza Preparedness and Response

(adapted from R Rappuoli and P R Dormitzer, *Science* 2012;336:1531-1533, published by AAAS)

Vaccines 'on demand': Science fiction or a future reality?

Ulmer, Mansoura, Geall (*Expert Opinion Drug Discovery*, 2015)



From De Gregorio and Rappuoli, *Nat. Rev. Immunol.* 14, 505-14, 2014

Rapid Response for Pandemic Protection

A Value Proposition Beyond Stockpiles (> insurance policy)

- Vaccine Developers are “1st Responders” to pandemic influenza threats
- Pandemic Plans ≠ Effective Pandemic Performance
 - Making vaccines is challenging: Training is an imperative.
 - Seasonal influenza manufacturing is necessary, but not sufficient
 - Effective pandemic performance requires practice under similar condition
 - Test the ecosystem – S&T, policy/decision-making, permitting, contracting, etc.
- **Drive, test and evaluate innovative technologies, strategies, policies (biosafety assessment, permitting, etc.) to keep improving**
- Build an expanding strain-specific knowledge-base
 - Manufacturing, clinical, end-to-end performance metrics
 - Novartis’ portfolio includes multiple pandemic/pre-pandemic strains
 - Identify weak links that may be strain-specific
 - Use real experiences to improve models and tracking tools
- Develop regulatory science; integrate new technologies