Vaccines and Related Biological Products Advisory Committee Meeting

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

BARDA
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

COVID-19 Vaccine Strain Selection- Points to Consider for Manufacturing Timelines

Robert Johnson, PhD

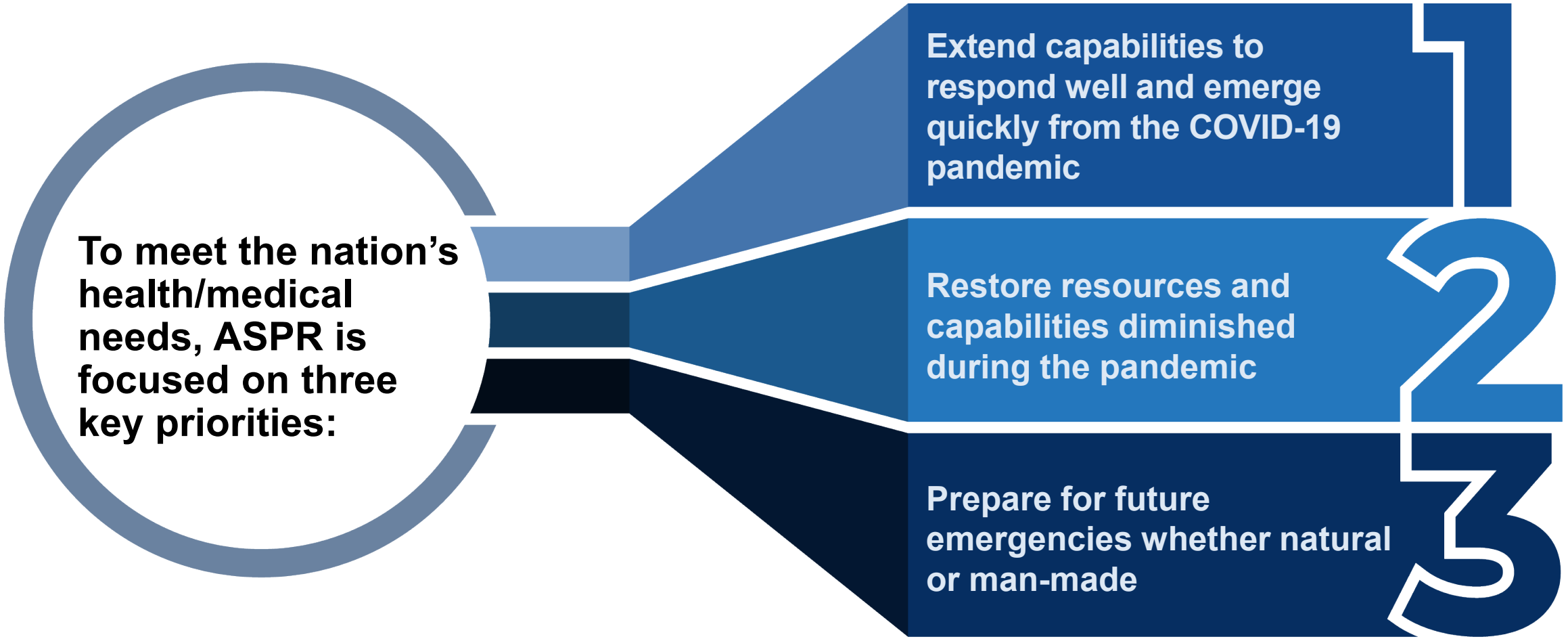
Director, Medical Countermeasure Programs

BARDA/ASPR/HHS

Vaccines and Related Biological Products Advisory Committee

6 April 2022

ASPR Key Priorities



The BARDA Model

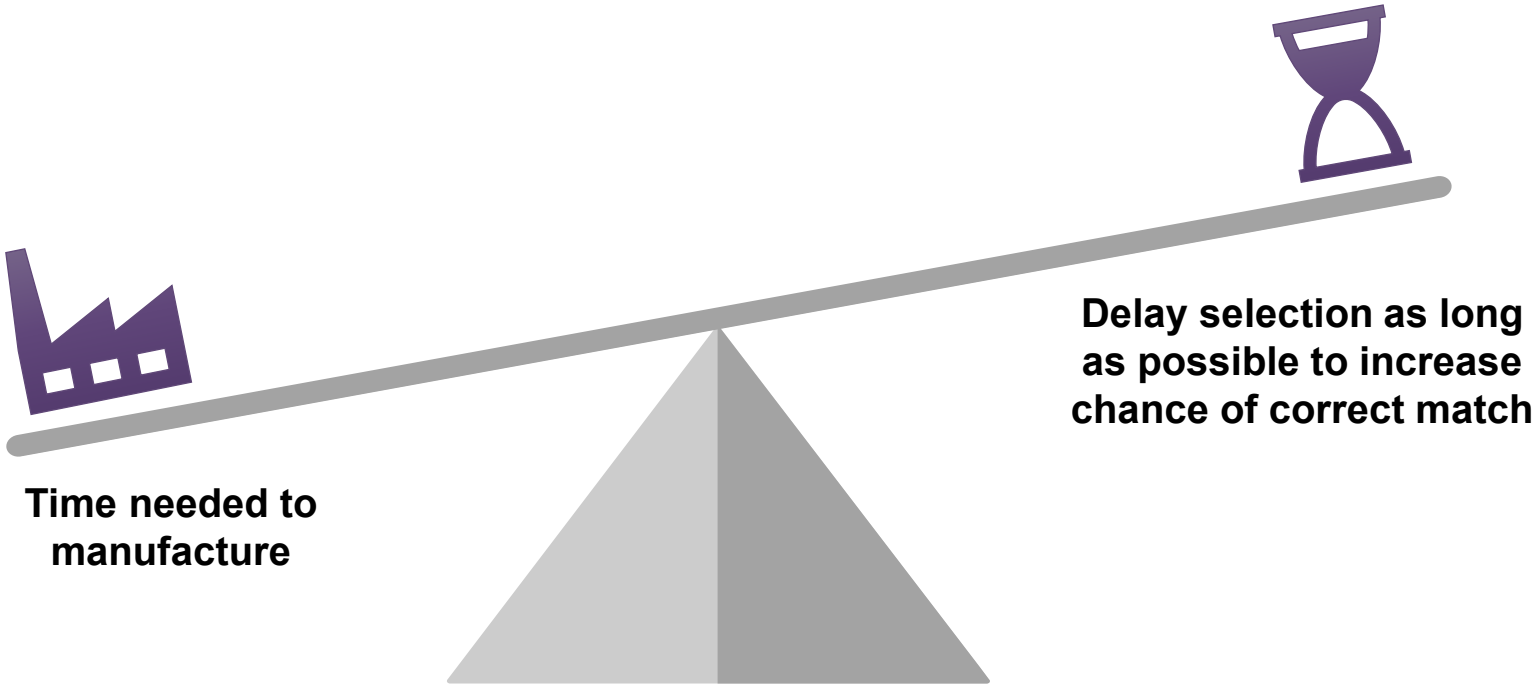
BARDA develops and makes available medical countermeasures **(MCMs)** by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.

- Flexible, nimble authorities
- Multi-year funding
- Cutting edge expertise
- Facilitate partnerships
- Promote innovation

Vaccines: Multi-Valent/Strain Change Life-Cycle Steps

Influenza Vaccine Strain Selection

- **Influenza strain selection**
  - » Occurs annually
  - » Regulatory and manufacturing processes must be in sync to ensure ***enough*** doses are available in time-this requires making decisions well in advance -> sometimes the match between the vaccine strain and circulating strain is not optimal

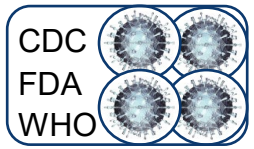


Influenza Vaccine Manufacturing and Regulatory Overview (Northern Hemisphere)

SEP OCT NOV DEC JAN FEB MAR APR MAY JUN JUL AUG SEP OCT NOV

Influenza Surveillance

Vaccine Strain Selection



Annual sBLA Approval

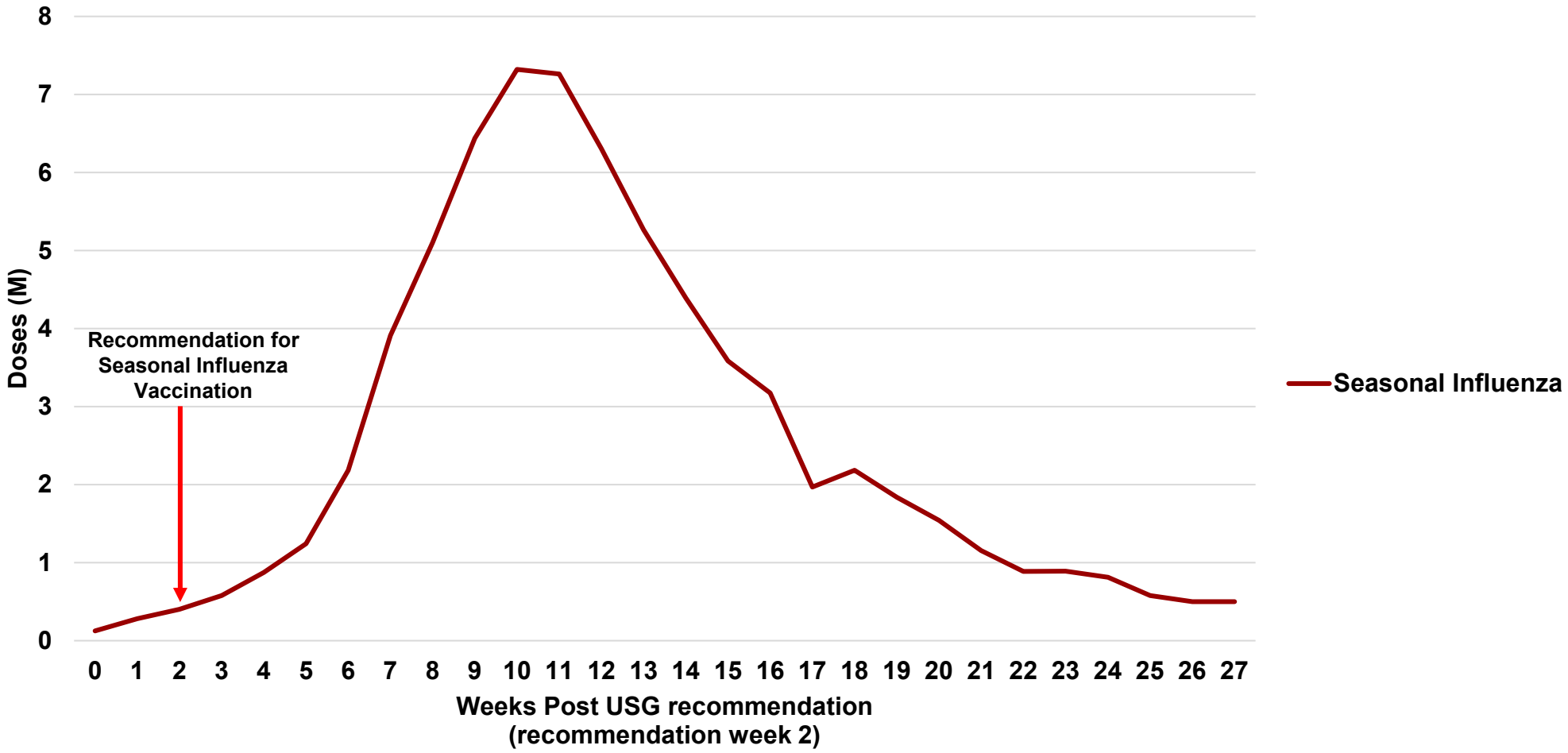
Vaccine Bulk Production

At risk

Vaccine fill final container

Distribution/Administration (~175M doses in 7 months)

Vaccine Demand Relative to Recommendation Drives Timing of Dose Requirement



Seasonal Influenza Vaccines – What Makes it Work

PRODUCTION PLATFORMS

Characteristics, production process and yield of current vaccines across strains well understood

Currently licensed vaccines are all capable of containing antigens from multiple influenza strains

Each manufacturer customizes initiation of production based on their capabilities, capacity, and estimated demand

ABILITY TO MATCH SUPPLY WITH DEMAND

Predictable vaccine demand-allows manufacturers to right-size production capacity

Comprehensive surveillance strategy and reporting allows production to begin at risk for some strains prior to formal regulatory decision

Multiple manufacturers allows flexibility unexpected demand and/or production problems at one manufacturer

REGULATORY PATHWAY

Well defined process and timelines for strain selection allows advanced planning/scheduling by manufacturers

Known requirements for clinical, non-clinical, and any in vitro testing, as well as vaccine lot release testing

FDA determines strain selection, but manufacturers decide number of strains (three or four) in the vaccine

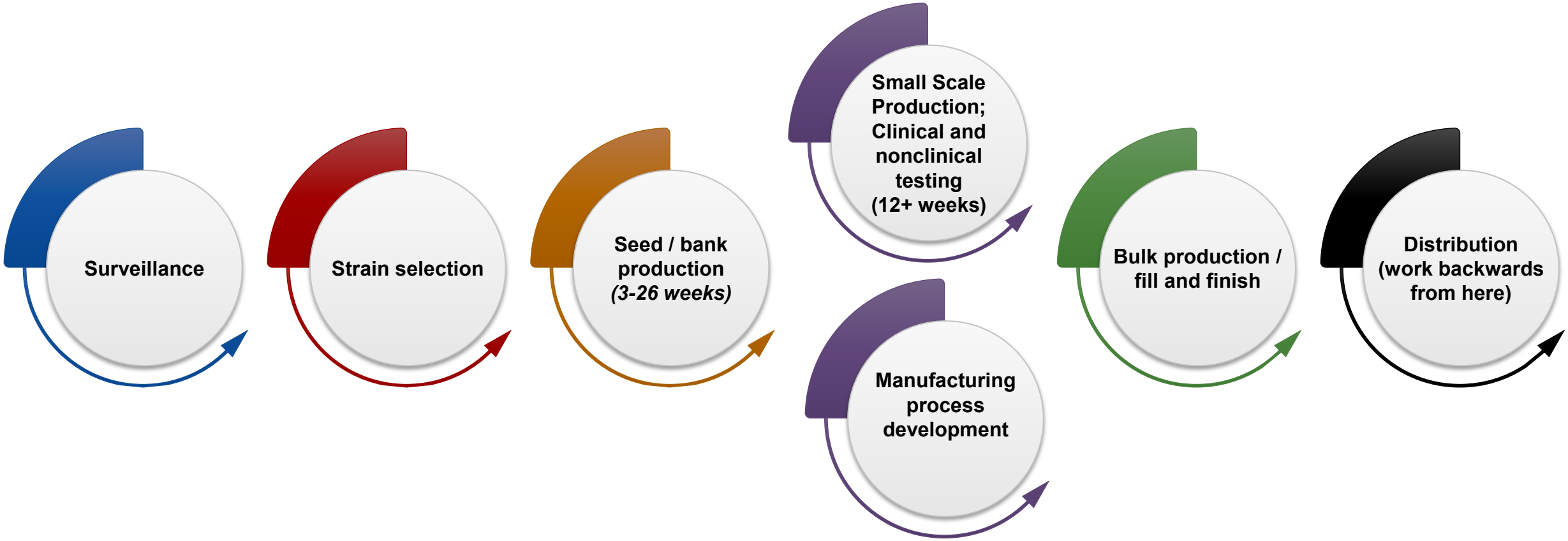
Vaccine label/recommendation is to prevent influenza disease- irrespective of manufacturer or timing of previous vaccination

How is the COVID-19 Vaccine Process Different – and What Drives the Timeline for Making a Decision

DIFFERENCES ACROSS DIFFERENT PLATFORMS	DIFFERENCES WITHIN SAME PLATFORM	OTHER FACTORS THAT WILL DRIVE PRODUCTION TIMELINES
Time to create construct	Each manufacturer has a different production capacity	Level of testing to support new strains- for example, purification process development, or clinical trials
Time to make and release master and work banks	Vaccine yield varies greatly between vaccine manufacturers	Does the manufacturer have seed banks available for selected strains
Feasibility of multivalent vaccine	Different manufacturers are using a different dose	Ongoing need to produce prototype vaccine to vaccinate naïve individuals
	Global commitments-dictates how much production can be targeted for the US	How much 'at risk' production will manufacturers do prior to regulatory decisions and known demand

- For all vaccines, ability to produce sufficient doses by a set time will depend in part on whether the vaccine is monovalent or mulit-valent, and if monovalent, if it is the current 'prototype' strain or a different strain
- Every manufacturer will have a different 'cut-off' date for producing a certain number of doses by a certain date

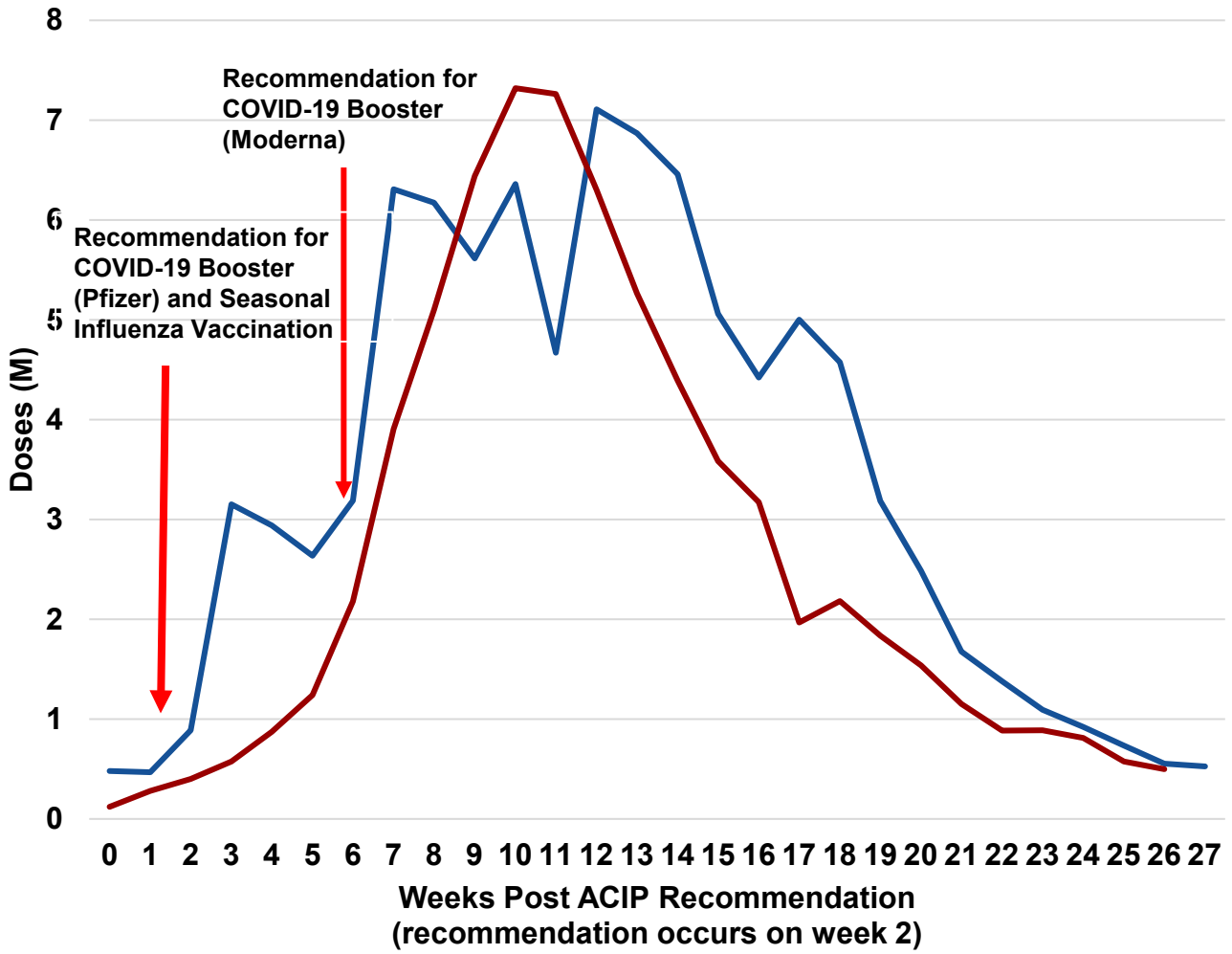
Multi-strain/Strain Change Life-Cycle Steps



Regulatory Factors Beyond Strain Selection that Will Determine Vaccine Availability by a Given Date

Decision Points/Timelines	
Identify strains under consideration to provide opportunity for seed stock/bank generation	Clarifying if there will be any requirements differences between platforms
Clear expectations for clinical and non clinical testing requirements	Will primary series and/or “first boost” still be prototype strain?
Decision process/who makes decision regarding strains and number of strains/vaccine	Will timing of boost be in the context of previous dose, or in the context of just getting a ‘routine annual vaccination’ similar to seasonal influenza?

Vaccine Demand Relative to Recommendation Drives Timing of Dose Requirement



COVID 19 administration:
Week 11- Thanksgiving