Outbreak Breakdown
August 21, 2020

This weekly report is provided as an informal information resource for certain AdvaMed member work groups. Content is provided by staff and is not to be construed as conveying AdvaMed viewpoints or endorsement. AdvaMed's COVID-19 response is led by Chris White, AdvaMed COVID Action Team Leader, COO & General Counsel. Newsletter contacts: Andy Fish, Chief Strategy Officer and Kristina Shultz, Manager, Strategy & Policy.

Please note – there will be no Outbreak Breakdown next week. We'll be back in September.

AdvaMed Notes:

FDA Rescission of LDT Guidances: On Wednesday, the Department of Health and Humans Services (HHS) announced a recission of FDA policies regarding pre-market approval of laboratory developed tests (LDTs), stating that any assertion of the agency's pre-market approval authority over LDTs would have to be made via notice-and-comment rulemaking. While this policy change was announced in the context of COVID-19, it appears to apply broadly to the agency's review of any LDTs, an issue of longstanding interest to AdvaMedDx, AdvaMed's diagnostics division. AdvaMed President and CEO Scott Whitaker released a statement encouraging "the Administration to ensure all diagnostic test developers, of both IVDs and LDTs, are subject to the same standard of test validation during the pandemic and beyond to protect patients and public health". *See related news articles below.*

HHS Uses DPA Authority to Contract for Diagnostic Tests: On August 20th, the Department of Health and Human Services announced that it is using its Defense Production Act (DPA) authority to purchase diagnostic systems and assays from BD and Quidel for rapid, point-of-care antigen testing and expedite shipments to every CLIA-certified nursing home in the United States.

FDA Shortage List: The CARES Act, pandemic relief legislation signed into law in March, contains a requirement that FDA maintain a public list of medical devices that may be in short supply in advance of or during a public health emergency. On August 14, FDA released the first iteration of the device shortage list, covering personal protective equipment, testing supplies and equipment, and ventilation-related products. The CARES Act requires that manufacturers of certain devices notify FDA of a permanent discontinuance or a manufacturing interruption likely to lead to a supply disruption during a declared public health emergency. *See related news article below.*

FEMA Voluntary Agreement: Pursuant to Defense Production Act authorities, the Federal Emergency Management Agency announced on August 17th the formation of a voluntary agreement on "Manufacture and Distribution of Critical Healthcare Resources Necessary To Respond to a Pandemic". The Agreement provides a safe harbor for information sharing, planning, and coordination among participating private sector entities and the federal government including the possible adjustment of commercial operations regarding distribution and allocation to maximize effective pandemic response. What private sector entities will be included is not yet known. AdvaMed submitted comments (here and here) to FEMA during the public meeting and comment process leading to the development of this agreement and earlier sent a letter to the FEMA Administrator urging centralized federal coordination of allocation decisions with input from key stakeholders. *See related news article below.*

AdvaMed Resources:

COVID Testing Supply Registry
PPE Sourcing Program
MedTech Responds

Something Completely Different

A cave in Mexico has revealed that humans were wandering the Americas 15,000 years earlier than previously known. Like the Spinal Tap druids, no one knows who they were or what they were doing, but their legacy remains. That legacy includes a definitive unseating of the early Clovis people as the putative "first Americans", who already had been knocked off their perch. This discovery comes along with recent findings in Asia that push human migration out of Africa back 80,000 years, making it clear there's much left to unearth in the ongoing reassessment of early humans.

Pandemic Snapshot

Global: Current Cases: 22,686,200 Deaths: 793,781

- North and South America remain global hotspots
- New daily cases remain relatively flat at ~250,000 new cases/day
- Cases in Europe are rising steadily and many countries have reimposed restrictions

United States: Current Cases: 5,599,400 Deaths: 174,361

- For the first time in over two months, all the major COVID-19 metrics (cases, hospitalizations, deaths, testing) improved in the same week
- Nationally, cases decreased while the number of tests performed increased, indicating that cases are truly declining across the country. Despite the overall decline, cases in many Midwestern states are still rising (as are hospitalizations).
- A full breakdown of this week's trends is available in this COVID Tracking Project blog post.

Johns Hopkins Daily COVID-19 Situation Reports
AdvaMed COVID-19 Modeling & Data Visualization Resources

News & Insights

Hospital Reporting Developments: After a month of data-reporting turmoil, there was a report this week that HHS would direct hospitals to resume reporting critical COVID-19 information directly to CDC, rather than to HHS. HHS disputed that report, indicating instead that the CDC is building a modernized, automated hospital data reporting system but that hospital data would continue to be reported directly into the HHS Protect program.

Saliva-Based Diagnostic Test: The FDA granted an emergency use authorization (EUA) for a saliva-based diagnostic test developed by researchers at Yale and piloted by the NBA. SalivaDirect does not require specialized containers to hold specimens, does not require proprietary supplies or reagents to process, and costs less than $5 per test for materials. Yale has made the test "open source" so that any laboratory can order supplies and run the test. This test could greatly expand testing capacity, allowing for widespread, rapid testing to detect both symptomatic and asymptomatic infections while relieving some of the stress on current testing infrastructure.

Convalescent Plasma: The New York Times reported this week that FDA will, for now, hold off on granting an emergency use authorization (EUA) for the use of convalescent plasma as a treatment for COVID-19. Data from a large study run by the Mayo Clinic was recently released as a pre-print (pre-peer review). Although the study included 35,000 participants, it was observational – not a randomized controlled trial – which limits the conclusions that can be drawn from the results. Several federal health officials, including Dr. Francis Collins and Dr. Anthony Fauci, warned that the data was not adequate to support an EUA at this time.

Antibodies and Reinfection: An outbreak of COVID-19 on a fishing vessel provided the first evidence that antibodies to SARS-CoV-2 can protect against reinfection in humans. Over the course of 18 days at sea, 104 crew members (out of 122) on the fishing boat became infected with SARS-CoV-2. Three crew members, who were the only crew members who tested positive for SARS-CoV-2 antibodies prior to departure, did not develop an infection. Follow-up testing showed no evidence of viral infection, indicating that the presence of neutralizing antibodies from prior infection was protective against reinfection. These findings aren't surprising – most experts expected prior infection with SARS-CoV-2 to provide some immunity against reinfection for some period of time. However, it's still unknown how protective that immunity may be and how long it may last.

Avoiding a 'Twindemic': HHS and CDC announced steps they are taking this week to increase influenza vaccinations in order to, hopefully, avoid what has been coined a 'twindemic,' where seasonal flu and SARS-CoV-2 are circulating widely at the same time. HHS announced that pharmacists will be allowed to administer all scheduled immunizations – including the flu vaccine – to children as young as three years old. CDC announced that a high-dose quadrivalent (protecting against four strains, rather than the usual three) flu vaccine will be available for people 65 and older.

K-12 School Closures and Quarantines Tracker: Earlier this year, a teacher in Kansas started an informal, state-wide tracker to track positive cases of COVID-19 linked to local schools and associated school quarantines and closures. That effort has now grown into a nationwide tracker of K-12 school closures, quarantines, and deaths (including this map of cases in schools).

Trump Administration Bars FDA From Regulating Some Laboratory Tests, Including for Coronavirus | The Washington Post, August 20
Trump Administration Limits FDA Review of Some Coronavirus Tests | Politico, August 19
Evidence Grows That Children May Play a Larger Role in Transmission Than Previously Believed |Washington Post, August 20
Schools Have No Good Options for Reopening during COVID-19 | Scientific American, August 20
An 'Unprecedented' Effort to Stop the Coronavirus in Nursing Homes | New York Times, August 20
Long-Haulers Are Redefining COVID-19 | The Atlantic, August 19
Trail of Bubbles Leads Scientists to New Coronavirus Clue | KSAT, August 19
COVID-19 Mystery: How Did the Coronavirus Return to New Zealand? | Wall Street Journal, August 19
WHO Warns Young People Are Emerging as Main Spreaders of the Coronavirus | Washington Post, August 18
Coronavirus Quarantine Rules Complicate College Move-In | The Wall Street Journal, August 18
FEMA Pitches Voluntary DPA Pact to Bolster Medical Supply Chain During Pandemic | MedTech Dive, August 18
The U.S. Forced Major Manufacturers to Build Ventilators. Now They're Piling up Unused in a Strategic Reserve. | Washington Post, August 18

Cellphone Data Shows How Las Vegas Is "Gambling With Lives" Across the Country | ProPublica, August 18
Seven Months Later, What We Know About COVID-19 — and the Pressing Questions That Remain | STAT News, August 17
Don't Just Look at COVID-19 Fatality Rates. Look at People Who Survive — but Don't Entirely Recover. | Washington Post, August 16
FDA Creates First Ever Medical Supply Shortage List Including Masks Swabs | The Hill, August 14
A Deadly Coronavirus Was Inevitable. Why Was No One Ready? | Wall Street Journal, August 13

More News

MIT Technology Review Coronavirus Coverage
Tulane Outbreak Daily
Prevent Epidemics Weekly Science Review
Helio COVID-19 Resource Center
Johns Hopkins Novel Coronavirus Research Compendium