Biopharmaceutical Industry Efforts to Fight COVID-19, Lessons Learned and Preparing for Future Pandemics

February 2023
COVID: Biopharmaceutical Industry Response

Preparing for the Next Pandemic

Efforts to Address Antimicrobial Resistance

Assistance Programs for Patients
PhRMA Members’ Efforts to *Fight* Coronavirus

- **We rapidly screened our vast global libraries of medicines** to identify potential treatments and have thousands of clinical trials underway to test new and existing therapies.

- **We expanded our unique manufacturing capabilities and shared capacity** to manufacture over 16 billion doses of vaccines.

- **We dedicated our top scientists, invested in new technologies and worked closely with regulators** to speed the development of safe and effective vaccines.

- **We shared the learnings from clinical trials in real time** to advance the development of additional therapies.

- **We collaborated with government agencies, hospitals, doctors and others** to donate supplies and medicines to help those affected around the world.

- **We worked with governments and insurers** to ensure that treatments and vaccines were available and affordable for patients.
PhRMA Members Conducted Hundreds of COVID-19 Clinical Trials
Biopharmaceutical Industry Clinical Trials Resulted in Treatments and Vaccines for Patients

America’s biopharmaceutical companies came together to achieve one shared goal of fighting COVID-19. The decades-long investments we have made in new technology, research and treatments prepared us to act swiftly.

4
U.S. Approved & Emergency Use Authorized Vaccines

7
U.S. Approved and Emergency Use Authorized Therapeutics

As of Feb. 13, 2023, Source: U.S. Food and Drug Administration
COVID-19 Vaccinations to Date: A Global Success

COVID-19 Vaccinations

16.1B
DOSES DELIVERED
Globally

13.2B
DOSES ADMINISTERED
Globally

632.9M
DOSES ADMINISTERED
United States

Data as of 2/14/2023
Ongoing Research on Long-COVID-19

- Estimated 1 in 5 American Adults who had COVID, have long COVID*
- **Symptoms** (typically lasting >6 months after infection) include fatigue, cough/SOB, muscle pain, GI issues, neurological impairment, pain, diabetes
- Biopharmaceutical companies are researching treatment options

- Biopharmaceutical research companies are seeking to identify biomarkers and endpoints to better address symptoms of “long-COVID-19”
  - A biomarker (short for biological marker) is a measure or physical sign used to evaluate how the body is functioning.
- 46 active global clinical trials, including from industry-sponsored, are underway**
- Vaccines continue to demonstrate strong efficacy. People who had been vaccinated against COVID-19 were roughly half as likely to develop “long COVID-19” symptoms***

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**Source: ClinicalTrials.gov
*** Source: https://www.gov.uk/government/news/ukhsa-review-shows-vaccinated-less-likely-to-have-long-covid-than-unvaccinated
Industry Licensing Agreements Made Possible by Intellectual Property Are Meeting Demand for COVID-19 Treatments

143 COVID-19 Treatment Licensing Agreements Span 31 Nations

Source: Airfinity. As of October 2022
Clinical Trials for COVID-19 Have Helped Boost Local Economies*

- Over **$24 billion** has been spent on clinical trials for COVID-19 vaccines and treatments in the United States – supporting about **100,000 U.S. jobs**
- Another **$80 billion** will be spent in the United States over the next several years if vaccines and treatments in the pipeline continue through clinical trials to approval – supporting approximately **110,000 U.S. jobs** annually

**U.S. COVID-19 Clinical Trial Costs:**

- **$24 Billion** to Date
  - Therapeutics 87%
  - Vaccines 13%

Sources: Informa data used to identify clinical trials for COVID-19 vaccines and treatments in the United States. Evaluate data used to estimate clinical trial costs. PhRMA analysis of U.S. Department of Commerce (BEA) RIMS II (Type II) multipliers used to estimate the total (direct and indirect) impact of clinical trial spending in the United States. *Data includes biopharmaceutical industry, government and academia."
Thousands of U.S. Jobs Are Supported by the Development and Manufacturing of COVID-19 Vaccines and Treatments

Total Jobs Directly and Indirectly Supported by Development and Manufacturing Inside and Out of Biopharmaceutical Industry

<table>
<thead>
<tr>
<th>Total Jobs Impact from Clinical Trials for COVID-19 Vaccines and Treatments</th>
<th>Total Jobs Impact from Manufacturing of COVID-19 Vaccines and Treatments</th>
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</thead>
<tbody>
<tr>
<td>Scientific Research Jobs</td>
<td>Biopharmaceutical Manufacturing</td>
</tr>
<tr>
<td>55%</td>
<td>62%</td>
</tr>
<tr>
<td>4%</td>
<td>31%</td>
</tr>
<tr>
<td>41%</td>
<td>7%</td>
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310,900

Sources: Informa data used to identify clinical trials for COVID-19 vaccines and treatments in the United States. Evaluate data used to estimate clinical trial costs. PhRMA analysis of U.S. Department of Commerce (BEA) data on U.S. exports, gross output of biopharmaceutical goods and RIMS II (Type II) multipliers used to estimate the total (direct and indirect) impact of clinical trial spending and biopharmaceutical manufacturing in the United States.
Exports Drive Over 55% of COVID-19 Product Manufacturing in the United States

U.S. Exports of Biopharmaceutical Products Have Surged to Highest Levels on Record

- Over 300,000 U.S. jobs are supported by the surge in U.S. biopharmaceutical manufacturing for COVID-19 vaccines and treatments
- 55% of these jobs are supported by U.S. exports of biopharmaceutical products
- U.S. exports of biopharmaceutical products increased over 60% after the U.S. amended COVID-19 vaccine contracts in mid-2021

U.S. Biopharmaceutical Exports from 2012 to Q2 2022

Sources: PhRMA analysis of U.S. Department of Commerce (BEA) data on U.S. exports, gross output of biopharmaceutical goods and RIMS II (Type II) multipliers used to estimate the total (direct and indirect impact) of biopharmaceutical manufacturing in the United States.
Current Status of Fighting COVID-19 in the U.S.

81% of Americans have at least one COVID-19 vaccine dose with bivalent vaccines authorized by FDA to address two strains of COVID

Multiple options are available for the prevention and treatment of COVID-19

Public-private collaborations across key health stakeholders at the state, national and international levels are continuing to help communities fight the pandemic

Ongoing research by biopharmaceutical companies to be prepared for what comes next
COVID-19 Vaccines and Treatments have Saved Millions of Lives and Billions of Dollars

699,110 life years in the U.S. alone were saved thanks to COVID-19 vaccines and treatments in first year of their widespread use

Resulting in $371.6 billion in direct economic benefit

$933.1 billion economic activity produced in part from medical interventions

## Key Lessons Learned from COVID Response

<table>
<thead>
<tr>
<th>Public and private collaboration</th>
<th>Strong IP protections</th>
<th>Broader acceptance of telemedicine and digital health tools</th>
<th>Demonstrated potential of increased use of real-world data and evidence in drug development</th>
</tr>
</thead>
<tbody>
<tr>
<td>helped facilitate large scale manufacturing prior to approval and highlighted value of remote assessments by FDA</td>
<td>enabled global partnerships and encouraged investment in research and development</td>
<td>made clinical research during COVID possible</td>
<td></td>
</tr>
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</table>
Next Steps for Industry, U.S. Policymakers and Stakeholders

• **Modernize data & reporting infrastructure** to detect, identify & mitigate emerging infectious diseases

• **Continue adoption of regulatory flexibilities** implemented to bolster supply chains and streamline product development

• **Increase and strengthen public-private collaboration** with U.S. and its trading partners to maintain robust pandemic response capability and supply chain security

• **Foster increased R&D and advanced manufacturing** through public policies incentivizing investment

• **Strengthen cybersecurity of medical supply chain** through improved monitoring, information sharing and response

• **Provide enhanced guidance** on criteria and process for declaring and ending public health emergencies
Efforts to Address Antimicrobial Resistance (AMR)
**What is antimicrobial resistance?**

Antimicrobial resistance occurs when microorganisms such as bacteria, viruses, fungi and parasites develop the ability to survive against the drugs designed to kill them. *Inappropriate use of antimicrobial medicines may lead to resistance.*

AMR infections are directly attributable to at least **1.27 million deaths per year globally**, higher than HIV/AIDS and malaria combined.

According to the CDC, at least **3 million antibiotic-resistant infections occur in the U.S. each year**, resulting in nearly **50,000 deaths in the U.S. each year**.

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AMR is “one of the biggest threats to global health, food security, and development today.”—WHO

The pandemic has increased the spread of drug-resistance infection. “We have every reason to believe the problem has gotten worse.”—Dr. Susan S. Huang, UC Irvine Medical School

### COVID-19 and Impact on AMR

**AMR became a more prominent threat during the pandemic¹**

<table>
<thead>
<tr>
<th>Drug Resistance</th>
<th>Percentage Increase</th>
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<tbody>
<tr>
<td>Carbapenem-resistant <em>Acinetobacter</em></td>
<td>↑78%</td>
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<tr>
<td>Antifungal-resistant <em>Candida auris</em></td>
<td>↑60%</td>
</tr>
<tr>
<td>Multidrug-resistant <em>P. aeruginosa</em></td>
<td>↑32%</td>
</tr>
</tbody>
</table>

After years of decline, drug-resistant “superbug” infections caused a 15% increase in hospitalizations and deaths in 2020 alone.

Hospital-acquired infections became alarmingly more resistant from 2019 to 2020:

6 of the 18 most alarming **antimicrobial resistance** threats cost the U.S. more than $4.6 billion annually.

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Antibiotic Company Bankruptcies Underscore the Challenging Environment for Developing Medicines to Combat AMR

**Misaligned incentives plague the development of new medicines**

- Developing a new antimicrobial medicine can take **10 – 20.5 years** and **$568 - $700 million**

- Just **1 in 15** products will ultimately be approved and reach patients

- **Stewardship programs designed to slow resistance** ensure that newer medicines are used as sparingly as possible, making it challenging for companies to recoup R&D investment

- Several high-profile recent **bankruptcies** highlight the funding challenges and lack of commercial sustainability – today only a handful of major biopharmaceutical companies and a few dozen small biotechs remain involved

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**PARMA**
## The Unique Innovation Ecosystem for AMR

Public-private partnerships and initiatives have emerged to address the market failure

<table>
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<tr>
<th>CARB-X</th>
<th>AMR Action Fund</th>
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<tr>
<td>• Global non-profit partnership dedicated to advancing AMR research by accelerating preclinical candidates toward clinical development for priority pathogens</td>
<td>• Partnership that seeks to strengthen R&amp;D through provision of industry resources and expertise</td>
</tr>
<tr>
<td>• Between 2016 and 2022, will fund $480M to achieve this goal</td>
<td>• Aims to bring 2-4 new antibiotics to patients by 2030</td>
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<tr>
<td></td>
<td>• Will invest more than $1B in smaller companies to help products get to market</td>
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The Innovation Ecosystem Cannot Solve the Problem Alone

Comprehensive policy reforms are also needed

**PASTEUR Act**

- Would offer “subscription” contracts to manufacturers to provide full access to antimicrobial products for patients covered under federal programs
- De-links payment from volume for government payers, with contracts offered ranging from $750M - $3B based on certain characteristics of the medicine
- Intent is to incentivize companies to develop highly novel antimicrobial medicines
- Includes provisions for appropriate stewardship and to ensure a reliable supply chain
Assistance Programs for Patients
Many of America’s Biopharmaceutical Companies Are Expanding Their Assistance Programs To Help More People

The Medicine Assistance Tool (MAT) is a web platform designed to help patients, caregivers and health care providers learn more about some of the resources available to assist in affording their medicines.

www.MAT.org
Where to Go for More Information
For More Resources and Information Visit: PhRMA.org/Coronavirus or PhRMA.org/AMR

- Member company efforts to combat COVID-19
- Factsheets on the pipeline for new vaccine and treatments and medicines to address AMR
- Updated clinical trial data and approved and authorized treatment and vaccine figures
- PhRMA blog posts on COVID-19 and AMR
- Infographics on how the industry is fighting COVID-19 and AMR