Women In Government welcomes you to #WIGWednesday!

We will get started shortly.

1. All participants are muted through the system.

2. We will have a Q&A period at the end of the presentation, be sure to use the Chat Box feature to ask questions!

3. This virtual round-table event will be recorded and provided on our website once the event is over
Join Mary Kosinski and Sharon Lamberton from PhRMA to Discuss Progress on the Biopharmaceutical Industry Battle Against COVID-19 and How to Remain Hopeful During a Pandemic

Moderated by:

Representative Geran Tarr (AK)
Western Regional Director
Women In Government
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APRIL 15, 2020
Moderated by:

Representative Geran Tarr (AK)
Western Regional Director
Women In Government
Featured Speakers:
Mary Kosinski and Sharon Lamberton

Mary Kosinski
Deputy VP of Science and Regulatory Advocacy
PhRMA

Sharon Lamberton
Deputy Vice President
PhRMA
Biopharmaceutical Industry Battle Against COVID-19: Progress Update and Hope

For Women in Government (WIG)

April 15, 2020

Contact: Julia Worcester

Presenters: Sharon Lamberton & Mary Kosinski
How industry is working to combat COVID-19

R&D Efforts
Screening research portfolio libraries for potential treatments, developing new treatment, vaccines, and diagnostics; deploying existing technologies to scale up production

Partnership
Collaborating with relevant U.S. and global public health authorities

Monetary & In-kind Support
Donating a variety of supplies (e.g., advanced surgical equipment, personal protective equipment, etc.)

Supply Chain Integrity
Continuing to prioritize ensuring the continuity of supply chains
Factors Contributing to Industry’s Quick Response

- Deep scientific knowledge gained from decades of experience with similar viruses

- Decades of investment in technologies that have dramatically shortened the time it takes to decode viruses and develop a potential vaccine.
  - Several member companies are sharing adjuvants — compounds that enhance the effectiveness of vaccines.

- Leveraging partnerships with a broad range of stakeholders:
  - Companies are working together to increase the industry’s manufacturing abilities by sharing available capacity to ramp up production once a successful vaccine or antiviral is identified
  - Companies are collaborating with government agencies, hospitals, doctors and others to donate supplies and medicines to help those affected around the world
  - Companies are working in close collaboration with the NIH and other relevant US and global public health authorities
Overview of the R&D Pipeline

As of April 8, 2020, there are more than 300 global clinical trials for COVID-19 treatments and vaccines and over 150 of these trials are testing PhRMA member company products.
U.S. Clinical Trials

Clinical trials investigating therapeutics are being tested across 37 states and Washington D.C. 11 of the 45 clinical trials are being conducted in more than one state.

Clinical Trials in the United States

[Map of the United States with varying shades indicating the number of clinical trials in each state.]
<table>
<thead>
<tr>
<th>Company</th>
<th>Efforts Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gilead</td>
<td>Gilead has trials underway in the US and China to test the safety and efficacy of</td>
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<tr>
<td></td>
<td>remdesivir in adults diagnosed with COVID-19. Remdesivir is an investigational</td>
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<tr>
<td></td>
<td>medicine with broad-spectrum antiviral activity—it has not been approved anywhere.</td>
</tr>
<tr>
<td>Johnson &amp;</td>
<td>J&amp;J began work on the search for vaccines and therapies in early January 2020</td>
</tr>
<tr>
<td>Johnson</td>
<td>when the viral sequence became publicly available. J&amp;J is leveraging technologies</td>
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<tr>
<td></td>
<td>that provide the ability to rapidly upscale production of the optimal vaccine</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>Sanofi will leverage previous development work for a SARS vaccine which may unlock</td>
</tr>
<tr>
<td></td>
<td>a fast path forward for developing a COVID-19 vaccine. Sanofi will use its</td>
</tr>
<tr>
<td></td>
<td>recombinant DNA platform to produce a novel coronavirus vaccine candidate.</td>
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## Snapshot of PhRMA member R&D efforts

<table>
<thead>
<tr>
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<th>Efforts</th>
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<tbody>
<tr>
<td><strong>Takeda</strong></td>
<td>Takeda is testing existing plasma treatment (which contains antibodies that can work against the virus) for COVID-19, which has previously been shown to be effective in the treatment of several acute viral respiratory infections.</td>
</tr>
<tr>
<td><strong>Pfizer</strong></td>
<td>Working with a 3rd party to screen their antiviral compound library to identify a candidate to work against COVID-19. Pfizer is working with a biotech partner on a mRNA vaccine candidate which is expected to enter clinical testing by the end of April 2020.</td>
</tr>
<tr>
<td><strong>GSK</strong></td>
<td>GSK and the Coalition for Epidemic Preparedness Innovations, formed a new collaboration aimed at helping the global effort to develop a vaccine for COVID-19. GSK is making its established pandemic vaccine adjuvant platform technology available to other companies.</td>
</tr>
</tbody>
</table>
Diagnostic Capabilities to Test Current Population

Industry has been working closely with FDA to develop diagnostic and serological testing

FDA has issued 33 emergency use authorizations for diagnostic tests
89 serological tests to evaluate antibodies to SARS-CoV-2 are being offered in the United States

Roche’s diagnostic test has received an Emergency Use Authorization from the FDA
AstraZeneca and GlaxoSmithKline have announced a commitment for accelerated diagnostic testing
Vaccines to Prevent COVID-19

6 vaccines in preclinical testing are supported by PhRMA member companies
PhRMA Member Vaccines

6 vaccines in preclinical testing are supported by PhRMA member companies

- **Johnson & Johnson** is leveraging technology from the Ebola vaccine to begin testing COVID-19 vaccine candidates

- **GlaxoSmithKline** is making their adjuvant technology available to 2 vaccine researchers
- **Sanofi** is building on previous efforts with SARS to develop an advanced vaccine to target COVID-19’s surface proteins

- **Pfizer** is partnering with BioNTech to develop a novel mRNA-based vaccine
- **Sanofi** is partnering with TranslateBio to develop a novel mRNA-based vaccine
Vaccines to Prevent COVID-19

Several previously utilized and unique approaches are being pursued to develop a COVID-19 vaccine:

- Live Attenuated (Measles)
- Inactivated (Influenza, Polio)
- Protein Subunit (Hepatitis B)
- Non-replicating Viral Vector (MERS, HIV, Influenza)
- Replicating Viral Vector (Measles, Horsepox, Influenza)
- DNA (Novel approach)
- RNA (Novel approach)
Vaccines to Prevent COVID-19

COVID-19 vaccines currently under investigation include over 70 unique “shots on goal”

- 68 vaccines in preclinical testing
  - Supported by PhRMA member companies
- 5 vaccines in Phase 1 and Phase 2 testing
- BCG vaccine for TB in Phase 3 testing

CONFIDENTIAL - For Discussion Purposes Only
PhRMA Member Investigational Therapies

158 clinical trials are testing 41 unique investigational therapies from PhRMA member companies
PhRMA Member Investigational Therapies

158 clinical trials are testing 41 unique therapies from PhRMA member companies

Selected company highlights:

29 clinical trials are testing Abbvie's lopinavir/ritonavir (Kaletra), which is approved for the treatment of HIV

10 clinical trials are testing Gilead's remdesivir

24 clinical trials are testing Genentech's tocilizumab (Actemra), which is approved for certain forms of arthritis
Investigational Therapies to Treat COVID-19

326 clinical trials across the globe are testing 146 unique therapies

Number of Unique Therapies

- 18 clinical trials are testing convalescent plasma therapies
- 158 clinical trials are testing PhRMA member company products
- 41 unique therapies from PhRMA member companies are being tested
Investigational Therapies to Treat COVID-19

The 326 clinical trials across the globe are testing:
- Approved therapies being repurposed
- Repurposed therapies in development for other conditions
- New therapies developed for COVID-19

Clinical trials are targeting one or more aspects of COVID-19:
- SARS-CoV-2 Infection: 184 trials
- Overactive immune response (Cytokine Storm): 79 trials
- Downstream effects (Acute Respiratory Distress Syndrome): 78 trials
Selected PhRMA Resources

- Full list of member company efforts to combat Coronavirus outbreak – continuously updated
  [https://phrma.org/Coronavirus/PhRMA-Member-Efforts](https://phrma.org/Coronavirus/PhRMA-Member-Efforts)
- Factsheet on the pipeline for new vaccines and treatments - [https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/IndustryResponseCOVID19.pdf](https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/IndustryResponseCOVID19.pdf)
- Industry Principles on Coronavirus - [https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Industry-Principles-on-Coronavirus.pdf](https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Industry-Principles-on-Coronavirus.pdf)
- PhRMA blog on industry efforts - [https://catalyst.phrma.org/america-biopharmaceutical-companies-are-working-around-the-clock-to-beat-coronavirus](https://catalyst.phrma.org/america-biopharmaceutical-companies-are-working-around-the-clock-to-beat-coronavirus)
- One pager on how industry is helping those affected by COVID-19 - [https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/nji-pmt-pharma-coronavirus-onepg.pdf](https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/nji-pmt-pharma-coronavirus-onepg.pdf)
Questions & Answers

Featured Speaker
Mary Kosinski
Deputy VP of Science and Regulatory Advocacy
PhRMA

Moderator
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Western Regional Director
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Sharon Lamberton
Deputy Vice President
PhRMA
Let’s be social!

#ConnectingLegislativeLeaders

#WIGWednesdays

@WomenInGovernment

@WomenInGovernmentFoundation

@WomenInGovt

Women In Government

Women In Government
We hope you enjoyed our #WIGWednesday session

Please join us for these upcoming #WIGWednesdays programs:

**April 22, 2020**: Developing a Vaccine for COVID-19, Moderated by WIG Board Member Assemblywoman Lisa Krasner with featured speaker Clement Lewin, PhD, MBA, Associate Vice President Head BARDA Office & NV Stakeholder Engagement, Sanofi Pasteur

**April 29, 2020**: What the CARES Act Means for Small Businesses, Individuals and Non-profits with featured speaker Katie Vlietstra Wonnenberg, Principal, Public Private Strategies.
The Women In Government team thanks you for participating today!

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