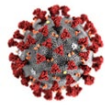
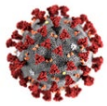


# **PDA Actions in Response to and Recommendations for Novel Coronavirus**

R. M. Johnson  
President & CEO

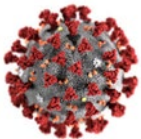


- Like me, you have probably been monitoring the developing novel coronavirus situation. We are all worried about the impact to our families and our communities. We are especially concerned about those whose health has been impacted, and all whose daily routines are being disrupted.
- Every day, we are busy checking the latest updates, so that we can ensure we are taking appropriate steps to safeguard the health and safety of our global members and staff.
- I also encourage our members to follow updates and announcements from their countries' public health agencies. WHO, EMA and the U.S. CDC, among others, are sources of additional information.



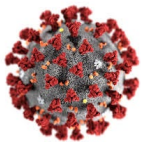
- Our community has a unique challenge; while we are protecting ourselves and our community, many of you have the responsibility to continue to provide critically needed healthcare products.
- In this time of crisis, healthcare products are critical
  - Not just the potential treatments or vaccines for the Novel coronavirus, but also the PPE for healthcare and individuals, and the full spectrum of drugs, biologics and medical devices that are always needed.
  - Suppliers also need to maintain their operations so that the global supply chain is not interrupted
- On behalf of PDA, we want to thank you for your efforts!





# WHAT HAS/IS PDA DOING?

April 2, 2020



**Added special section on PDA website in early February**

June 24-25, 2020 | Washington DC

READ MORE

At PDA, our mission is to advance pharmaceutical/biopharmaceutical manufacturing science and regulation so members can better serve patients.

**! PDA Statement Regarding COVID-19**

New & Noteworthy

- PDA considers safety and health of event attendees as a subject of utmost importance. This is relevant as attendees from various countries, regions, and continents will come to PDA events. The coronavirus outbreak is a global concern. Our sympathies are with those affected around the world.
- PDA is committed to maintaining opportunities for volunteers and individuals from the pharmaceutical industry to meet, wherever we can do so. PDA relies on experts in that field, from global bodies like the World Health Organisation, to national and local health authorities where we are running events, to provide appropriate guidance.
- PDA has implemented a set of measures to protect participants and staff from potential risks related to COVID-19 as best as possible. This includes a close and regular monitoring of the situation, adherence to recommendations of health authorities and official travel warnings, possibilities of remote presentations, and precautions being implemented at our venues.



- For PDA staff, we are suspending all business travel, until further notice. **Our Pandemic Preparedness Plan is in effect and began teleworking for all employees on March 16, 2020.** We will continue to monitor the situation and make other announcements, as necessary.

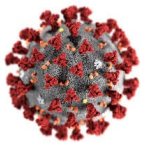
**We have suspended the expiration of existing memberships until the end of June 2020.** As of now, all members will continue to enjoy the benefits of membership even if you are unable to pay due to the impact of the corona virus pandemic.

- Be assured that **we will continue to operate and provide the service** that our members have come to expect from PDA.

## PDA EVENTS

- **2020 PDA Annual Meeting** in Raleigh, NC, was rescheduled to July 20-22, 2020. We are moving to a **Virtual Only** meeting.
- The **Visual Inspection Forum (EU)** planned for April is being moved to October.
- **Interphex** moved from April to July
- We are repositioning the **ATMP Conference** in June (US & EU) to Virtual Only.
- We are repositioning the **Virus Conference** in June (EU) to Virtual Only.
- We are repositioning the **Quality & Regulatory Conference** in June (EU) to Virtual Only.
  - Our staff is urgently evaluating different technical platforms for Virtual events & Exhibitions and we will announce shortly.
- All Training in Europe and US has been cancelled or rescheduled through May.
  - We are rapidly assessing conversion of lecture-based training to Virtual.





- PDA is placing our PDA Letter in the “open’ to allow members and non-members to access it for the time being
- PDA is placing our PDA Journal in the “open’ to allow members and non-members to access it for the time being
- We will be launching a series of webinars to continue providing important information to our community as an alternative to regular meetings.
- We are making our Webinar platform available to Chapters.



- We are focusing articles in the PDA Letter on how people are dealing with the Novel Coronavirus
- We are launching a survey to gather data about pharma issues arising out of the situation
- Our Board of Directors is meeting monthly to stay updated on our Coronavirus efforts

- We have initiated a Task Force to develop guidance on the Coronavirus effects on manufacturing
  - Task Force Members to be Selected from Industry
  - Task Force Meetings will be held online
  - Task Force Output will be Webinars and Point to Consider Documents
  - Task Force expected to be in place for no more than 6 months unless formal extension granted by the board.

## Track 1

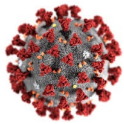
- This track will be focused on GMP process and controls that proactively take into account the potential for viral outbreaks involving manufacturing personnel to reduce or eliminate the impact infected employees and resulting absenteeism have on product and supply. The goal will involve the sharing and publishing of best practice that have been developed within the industry.

## Track 2

- This track will focus on actions that are recommended for consideration to ensure the continued manufacturing and supply of product during an active outbreak.
- New emergency regulations to ensure urgent supply to meet enormous surge in demand are anticipated. The track force will provide input, comments, and suggestions to mitigate shortages.
- Examples would be the temporary suspension of country importation retesting requirements, postponement of equipment preventative maintenance (due to employee shortages (employee out sick) or need to keep equipment in operation) meet to higher demand, shifting of products to different filling lines with limited qualification data sets to add capacity, etc.)

# PUBLIC INFORMATION THAT MAY BE USEFUL





- During previous outbreaks due to other coronavirus (Middle-East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS), human-to-human transmission occurred through droplets, contact and fomites, suggesting that the transmission mode of the COVID-19 can be similar. The basic principles to reduce the general risk of transmission of acute respiratory infections include the following:
  - *Avoiding close contact with people suffering from acute respiratory infections.*
  - *Frequent hand-washing, especially after direct contact with ill people or their environment.*
  - *Avoiding unprotected contact with farm or wild animals.*
  - *People with symptoms of acute respiratory infection should practice cough etiquette (maintain distance, cover coughs and sneezes with disposable tissues or clothing, and wash hands).*

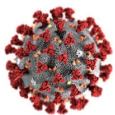
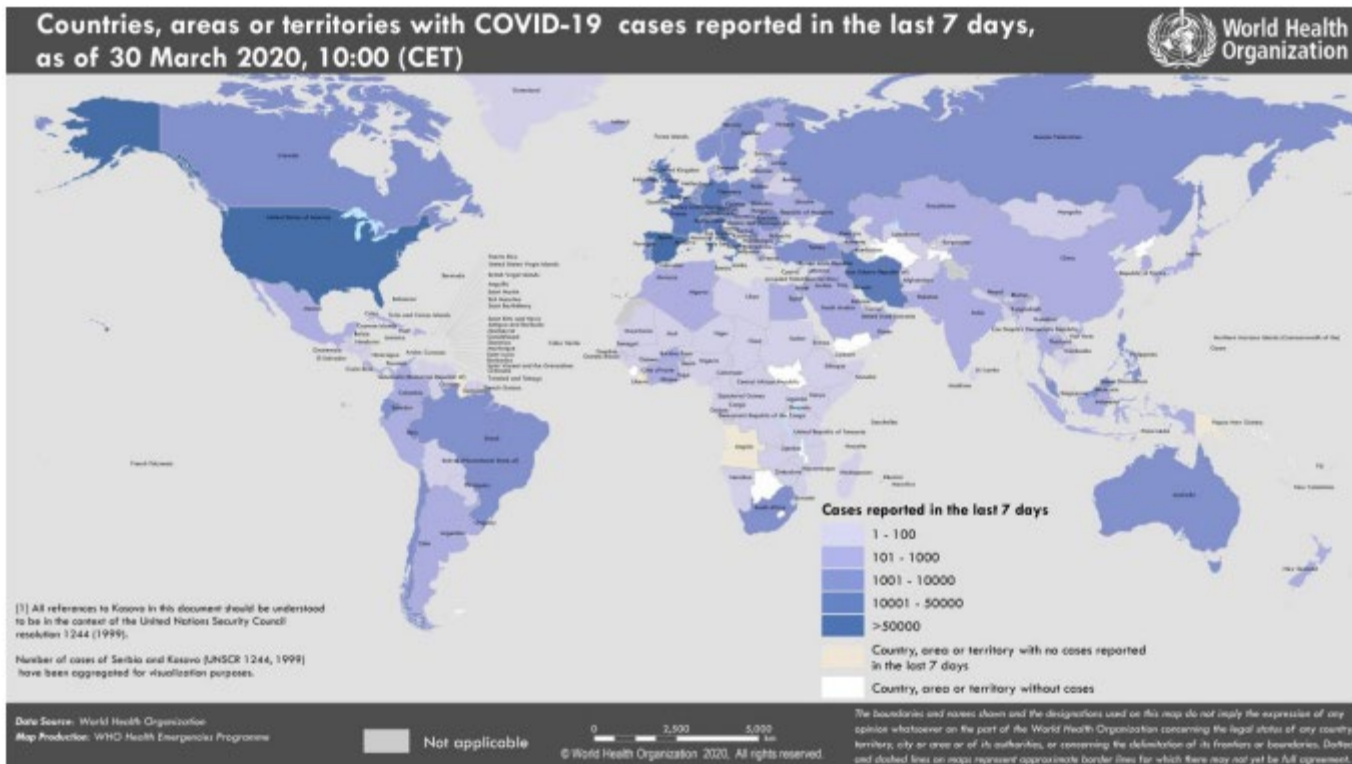
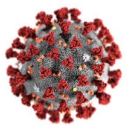


Figure 1. Countries, territories or areas with reported confirmed cases of COVID-19, 30 March 2020

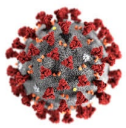






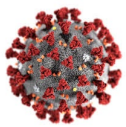
(as of March 31, 2020)

- If you are not in an area where COVID-19 is spreading or have not travelled from an area where COVID-19 is spreading or have not been in contact with an infected patient, your risk of infection is low.
- It is understandable that you may feel anxious about the outbreak. Get the facts from reliable sources to help you accurately determine your risks so that you can take reasonable precautions (see Frequently Asked Questions). Seek guidance from WHO, your healthcare provider, your national public health authority or your employer for accurate information on COVID-19 and whether COVID-19 is circulating where you live.
- It is important to be informed of the situation and take appropriate measures to protect yourself and your family (see Protection measures for everyone).

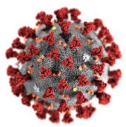


(as of March 31, 2020)

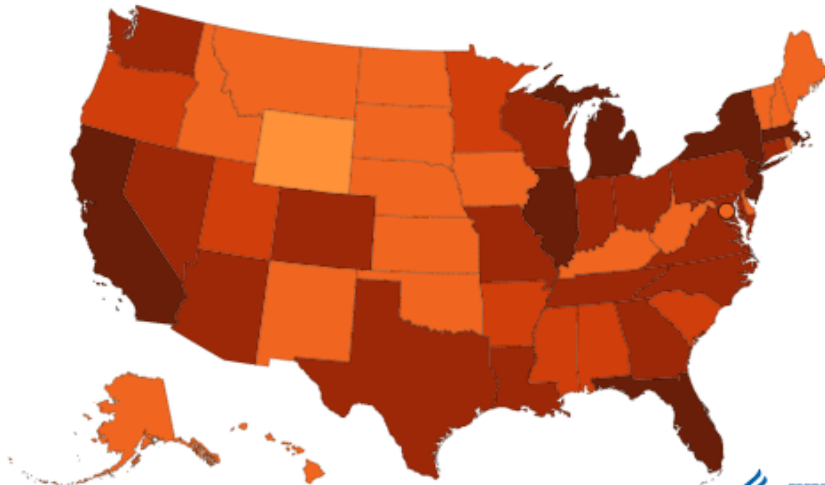
- If you are in an area where there are cases of COVID-19 you need to take the risk of infection seriously. Follow the advice of WHO and guidance issued by national and local health authorities. For most people, COVID-19 infection will cause mild illness however, it can make some people very ill and, in some people, it can be fatal.
- Older people, and those with pre-existing medical conditions (such as cardiovascular disease, chronic respiratory disease or diabetes) are at risk for severe disease (See Protection measures for persons who are in or have recently visited (past 14 days) areas where COVID-19 is spreading).



- World Health Organization (WHO) – [Novel coronavirus \(2019-nCoV\) outbreak](#)
- Center for Disease Control and Prevention (CDC) – [2019 Novel Coronavirus](#)
- European Medicines Agency (EMA) – [Novel coronavirus](#)
- [Government of Canada COVID 19 Update](#)
- [European Center for Disease Prevention and Control](#)



## States Reporting Cases of COVID-19 to CDC\*



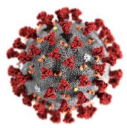
### Reported Cases

(last updated March 30, 2020)

- None
- 1 to 5
- 6 to 50
- 51 to 100
- 101 to 500
- 501 to 1000
- 1001 to 5000
- 5001 or more

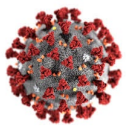
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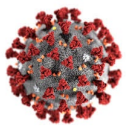


## Surfaces

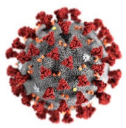
- If surfaces are dirty, they should be cleaned using a detergent or soap and water prior to disinfection.
- For disinfection, diluted household bleach solutions, alcohol solutions with at least 70% alcohol, and most common EPA-registered household disinfectants should be effective.



- Diluted household bleach solutions can be used if appropriate for the surface. Follow manufacturer's instructions for application and proper ventilation. Check to ensure the product is not past its expiration date. Never mix household bleach with ammonia or any other cleanser. Unexpired household bleach will be effective against coronaviruses when properly diluted.
- Prepare a bleach solution by mixing:
  - 5 tablespoons (1/3<sup>rd</sup> cup) bleach per gallon of water or
  - 4 teaspoons bleach per quart of water



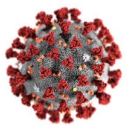
- Products with EPA-approved emerging viral pathogens claims are expected to be effective against COVID-19 based on data for harder to kill viruses. Follow the manufacturer's instructions for all cleaning and disinfection products (e.g., concentration, application method and contact time, etc.).
- For soft (porous) surfaces such as carpeted floor, rugs, and drapes, remove visible contamination if present and clean with appropriate cleaners indicated for use on these surfaces. After cleaning:
  - If the items can be laundered, launder items in accordance with the manufacturer's instructions using the warmest appropriate water setting for the items and then dry items completely.
  - Otherwise, use products with the EPA-approved emerging viral pathogens claims that are suitable for porous surfaces



## Linens, Clothing, and Other Items That Go in the Laundry

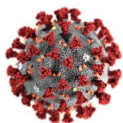
- Do not shake dirty laundry; this minimizes the possibility of dispersing virus through the air.
- Wash items as appropriate in accordance with the manufacturer's instructions. If possible, launder items using the warmest appropriate water setting for the items and dry items completely. Dirty laundry that has been in contact with an ill person can be washed with other people's items.
- Clean and disinfect hampers or other carts for transporting laundry according to guidance above for hard or soft surfaces.





## Personal Protective Equipment (PPE) and Hand Hygiene:

- **Cleaning staff should wear disposable gloves and gowns for all tasks in the cleaning process, including handling trash.**
  - Gloves and gowns should be compatible with the disinfectant products being used.
  - Additional PPE might be required based on the cleaning/disinfectant products being used and whether there is a risk of splash.
  - Gloves and gowns should be removed carefully to avoid contamination of the wearer and the surrounding area. Be sure to **clean hands** after removing gloves.
- Gloves should be removed after cleaning a room or area occupied by ill persons. Clean hands immediately after gloves are removed.
- Cleaning staff should immediately report breaches in PPE (e.g., tear in gloves) or any potential exposures to their supervisor.
- **Cleaning staff and others should clean hands often**, including immediately after removing gloves and after contact with an ill person, by washing hands with soap and water for 20 seconds. If soap and water are not available and hands are not visibly dirty, an alcohol-based hand sanitizer that contains 60%-95% alcohol may be used. However, if hands are visibly dirty, always wash hands with soap and water.



- Follow normal preventive actions while at work and home, including cleaning hands and avoiding touching eyes, nose, or mouth with unwashed hands.
  - Additional key times to clean hands include:
    - After blowing one’s nose, coughing, or sneezing
    - After using the restroom
    - Before eating or preparing food
    - After contact with animals or pets
    - Before and after providing routine care for another person who needs assistance (e.g., a child)

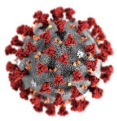
**COVID 19**  
CORONAVIRUS DISEASE

## STOP THE SPREAD OF GERMS

Help prevent the spread of respiratory diseases like COVID-19.

- Avoid close contact with people who are sick.
- Cover your cough or sneeze with a tissue, then throw the tissue in the trash.
- Clean and disinfect frequently touched objects and surfaces.
- Wash your hands often with soap and water for at least 20 seconds.
- Stay home when you are sick, except to get medical care.
- Avoid touching your eyes, nose, and mouth.

For more information: [www.cdc.gov/COVID19](http://www.cdc.gov/COVID19)



**COVID 19**  
CORONAVIRUS DISEASE

## SYMPTOMS OF CORONAVIRUS DISEASE 2019

Patients with COVID-19 have experienced mild to severe respiratory illness.

Symptoms can include

**FEVER**



**COUGH**



\*Symptoms may appear 2-14 days after exposure.

**SHORTNESS OF BREATH**



If you have been in China or in close contact with someone with confirmed COVID-19 in the past 2 weeks and develop symptoms, call your doctor.



For more information: [www.cdc.gov/COVID19](http://www.cdc.gov/COVID19)

CS15022.A

The most common symptoms of COVID-19 are dry cough, tiredness and fever. Some people may develop more severe forms of the disease, such as pneumonia. The best way to confirm if you have the virus producing COVID-19 disease is with a laboratory test. You cannot confirm it with this breathing exercise, which can even be dangerous.

**FACT:**

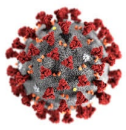
Being able to hold your breath for 10 seconds or more without coughing or feeling discomfort DOES NOT mean you are free from the coronavirus disease (COVID-19) or any other lung disease.



World Health Organization

#Coronavirus

#COVID19



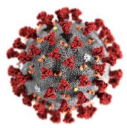
You can catch COVID-19, no matter how sunny or hot the weather is. Countries with hot weather have reported cases of COVID-19. To protect yourself, make sure you clean your hands frequently and thoroughly and avoid touching your eyes, mouth, and nose.

## FACT:

Exposing yourself to the sun or to temperatures higher than 25C degrees DOES NOT prevent the coronavirus disease (COVID-19)



#Coronavirus #COVID19



From the evidence so far, the new coronavirus can be transmitted in ALL AREAS, including areas with hot and humid weather.

Regardless of climate, adopt protective measures if you live in, or travel to an area reporting COVID-19.

The best way to protect yourself against COVID-19 is by frequently cleaning your hands. Eliminate viruses that may be on your hands and avoid infection that could occur by then touching your eyes, mouth, and nose.



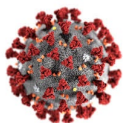
World Health Organization

#Coronavirus #COVID19

**FACT:**  
The new coronavirus can be transmitted in areas with hot and humid climates



9 March 2020



There is no reason to believe that cold weather can kill the new coronavirus or other diseases.

The normal human body temperature remains around 36.5°C and 37°C, regardless of the external temperature or weather.

The most effective way to protect yourself against the new coronavirus is by frequently cleaning your hands with alcohol-based hand rub or washing them with soap and water.

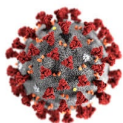
World Health  
Organization

#Coronavirus

#COVID19

**FACT:**  
Cold weather and snow  
**CANNOT** kill the new  
coronavirus





Most of the people who catch COVID-19 can recover and eliminate the virus from their bodies. If you catch the disease, make sure you treat your symptoms. If you have cough, fever, and difficulty breathing, seek medical care early – but call your health facility by telephone first if possible. Most patients recover thanks to supportive care.

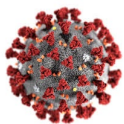
## FACT:

You can recover from the coronavirus disease (COVID-19). Catching the new coronavirus DOES NOT mean you will have it for life.



World Health Organization

#Coronavirus #COVID19



Taking a hot bath will not prevent you from catching COVID-19. Your normal body temperature remains around 36.5°C to 37°C, regardless of the temperature of your bath or shower. Actually, taking a hot bath with extremely hot water can be harmful, as it can burn you.

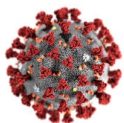
The best way to protect yourself against COVID-19 is by frequently cleaning your hands. By doing this you eliminate viruses that may be on your hands and avoid infection that could occur by then touching your eyes, mouth, and nose.

**FACT:**  
Taking a hot bath does not prevent the new coronavirus disease



#Coronavirus #COVID19





To date there has been no information nor evidence to suggest that the new coronavirus could be transmitted by mosquitoes.

The new coronavirus is a respiratory virus which spreads primarily through droplets generated when an infected person coughs or sneezes, or through droplets of saliva or discharge from the nose.

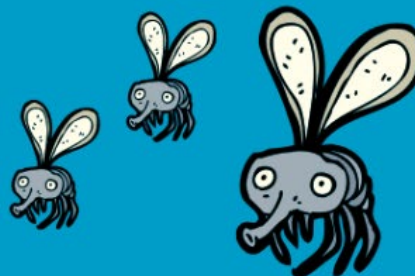
To protect yourself, clean your hands frequently with an alcohol-based hand rub or wash them with soap and water. Also, avoid close contact with anyone who is coughing and sneezing.

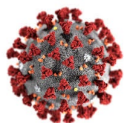


#Coronavirus

#COVID19

**FACT:**  
The new coronavirus  
**CANNOT**  
be transmitted through  
mosquito bites





**No. Hand dryers are not effective in killing the 2019-nCoV.**

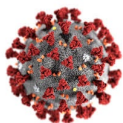
To protect yourself against the new coronavirus, you should frequently clean your hands with an alcohol-based hand rub or wash them with soap and water. Once your hands are cleaned, you should dry them thoroughly by using paper towels or a warm air dryer.



#2019nCoV

Are hand dryers effective in killing the new coronavirus?





Thermal scanners are effective in detecting people who have developed a fever (i.e. have a higher than normal body temperature) because of infection with the new coronavirus.

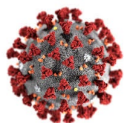
However, they cannot detect people who are infected but are not yet sick with fever. This is because it takes between 2 and 10 days before people who are infected become sick and develop a fever.



#2019nCoV

## How effective are thermal scanners in detecting people infected with the new coronavirus?





People of all ages can be infected by the new coronavirus (nCoV-2019).

Older people, and people with pre-existing medical conditions (such as asthma, diabetes, heart disease) appear to be more vulnerable to becoming severely ill with the virus.

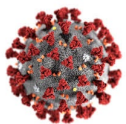
WHO advise people of all age to take steps to protect themselves from the virus, for example by following good hand hygiene and good respiratory hygiene.



#Coronavirus

## Does the new coronavirus affect older people, or are younger people also susceptible?

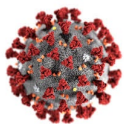




UV lamps should not be used to sterilize hands or other areas of skin as UV radiation can cause skin irritation.

Can an ultraviolet disinfection lamp kill the new coronavirus?





**Frequent or excessive alcohol consumption can increase your risk of health problems.**

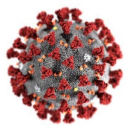
**FACT:**

**Drinking alcohol DOES NOT protect you against COVID-19 and can be dangerous**



World Health Organization

#Coronavirus #COVID19



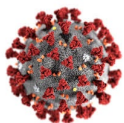
No. Spraying alcohol or chlorine all over your body will not kill viruses that have already entered your body. Spraying such substances can be harmful to clothes or mucous membranes (i.e., eyes, mouth). Be aware that both alcohol and chlorine can be useful to disinfect surfaces, but they need to be used under appropriate recommendations.



#2019nCoV

## Can spraying alcohol or chlorine all over your body kill the new coronavirus?





No. Vaccines against pneumonia, such as pneumococcal vaccine and Haemophilus influenza type B (Hib) vaccine, do not provide protection against the new coronavirus.

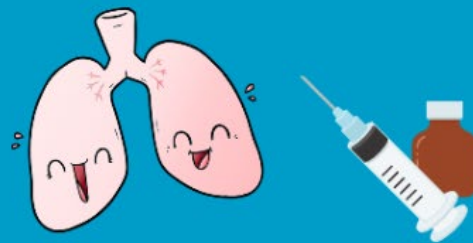
The virus is so new and different that it needs its own vaccine. Researchers are trying to develop a vaccine against 2019-nCoV, and WHO is supporting their efforts.

Although these vaccines are not effective against 2019-nCoV, vaccination against respiratory illnesses is highly recommended to protect your health.



#2019nCoV

## Do vaccines against pneumonia protect you against the new coronavirus?





Question	Response
<p>I hear a lot about shortages of masks and other supplies. What can we, as an industry, be doing to make sure that people on the front lines have the supplies that they need? any particular device shortages, etc?</p>	<p>If you have the capability to manufacture, do so. I suggest risk analysis to determine how to minimize usage. There are reports of shortages of PPE.</p>
<p>How PDA is making useful resources available to everyone in industry</p>	<p>We are making PDA Letter and Journal open for the time being. We are planning webinars to keep information flowing.</p>
<p>How many US pharmaceutical contract manufacturing organizations still operational?</p>	<p>Our survey will gather this information, but I am not aware of any shutdowns.</p>
<p>Future schedules are tenuous, at best. Will registration fees for PDA events be fully refundable?</p>	<p>Yes</p>
<p>PDA's decision on the best way to go forward with the annual meeting, conferences, etc. at national and chapter levels.</p>	<p>PDA has converted all events to virtual through July of this year. We expect to offer virtual as an option even when we are able to resume F2F events. Chapters are also suspending F2F meetings, and are exploring virtual events.</p>
<p>Aside from some of the more obvious prophylactic measures for preventing the outbreak of COVID-19 (especially in the production &amp; shipping area), what are other prudent actions that a firm could take?</p>	<p>This is one of the areas the Task Force will be addressing.</p>
<p>What is your opinion for the expected end of social distancing?</p>	<p>I wish I knew. I expect this to continue through May at least.</p>

Question	Response
<p>As a microbiologist, I have always told people about "Time, Distance and Shielding" (similar to radiation exposure) as a simple way to remember how to limit exposure to droplet infections (i.e. colds, flus, COVID-19). Distance is a probability function.</p>	<p>Good advice.</p>
<p>The say COVID-19 can travel up to 27 feet in the air based on an MIT study. Is that really possible?</p>	<p>I am not familiar with this study, but most guidance suggests minimum of 2 meters.</p>
<p>I am interested how this will impact the Drug Supply Chain as well as events.</p>	<p>This is one of the aspects of the survey</p>
<p>looking for best practice on manufacturing contingency plan during the restricted condition of covid 19 pandemic. Medicine is importantly needed but manufacturing staff should also be protected.</p>	<p>The task force is addressing this.</p>
<p>Thank you for organizing this. Has there been any suggestions or reports of slowing the import or export of raw materials or finished drug products to different regions of the world?</p>	<p>There are reports of export restrictions from some countries, and shortages are beginning to be reported. This is in the survey.</p>
<p>Discussion on Anti Virus Drug.</p>	<p>There are a number of candidates that are being evaluated.</p>



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