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March 1st, 2020

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

I am sending this newsletter out early because of the COVID-19 epidemic. There is a lot of news on COVID-19 with some confusion as to what is true and what is misinformation. This month we will cover "The Facts About COVID- 19".

Last month I covered "Sick or Injured, Microrobots to the Rescue! If you missed this article, click here to read it.

Please read on for other current news in the Table of Content below. The next newsletter will be published on April 15th, 2020.

We encourage you to share this newsletter with your colleagues by using the social

Please email me, Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, New Product Planning/
Strategic Planning Consultant
BioMarketing Insight

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Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact me for an appointment. For successful commercial adoption of your product or looking to grow your business, contact me for an appointment.

For more information on our services, click on the links below:

Product Development
Market Development
Marketing Strategies

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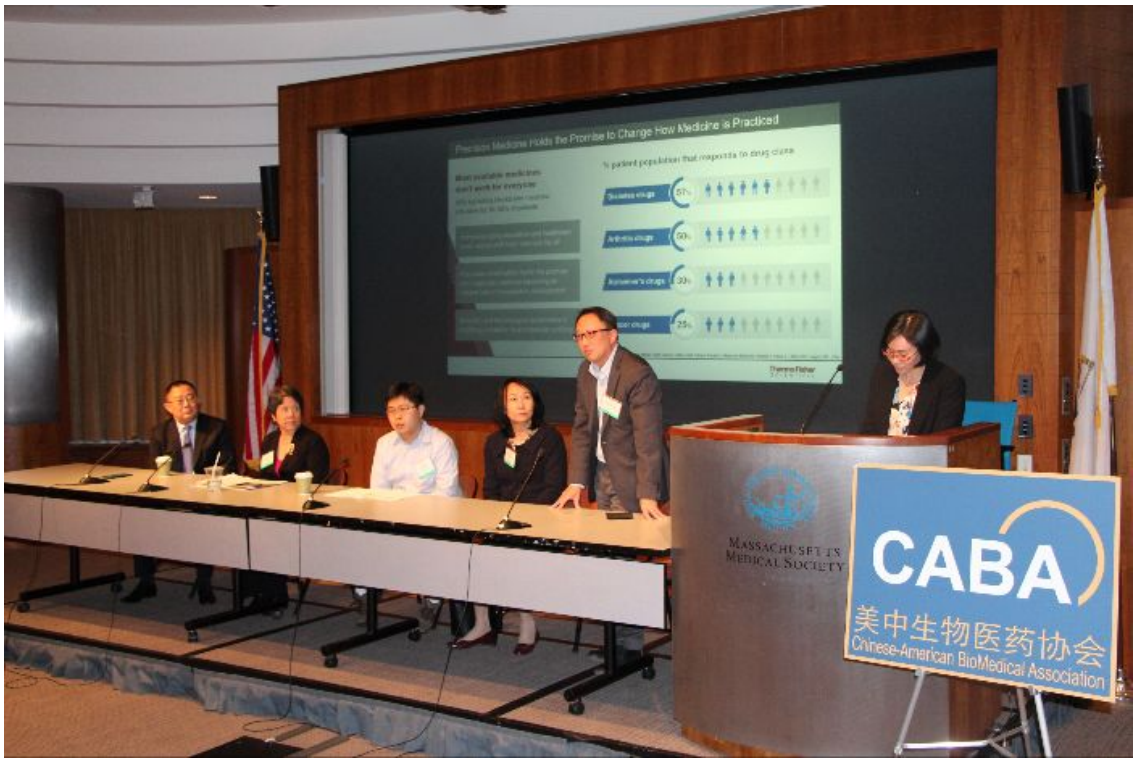
Science from Scientists

I'm pleased to announce that I will be a judge for the Spofford Pond School's 4th Annual Science Fair in Boxford, MA on Friday, March 6, 2020. This fair is hosted by Science from Scientists, their mission is to improve the attitudes & aptitudes of 4-8th graders in STEM. To find out more about this organization, click here.



11st CABA Medical Device and Diagnostics Innovation Symposium (MDDI)

I am pleasured to announce that I was a panelist at the MDDI Symposium on Saturday, December 14, 2019 at the Conference Center at Waltham Woods, 860 Winter St, Waltham. The panel discussion was on "Precision Medicine in Medical Device."

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I am pleased to announce that I conducted a workshop titled "Develop Your Leadership Skills While Maintaining Your Authenticity" at the Asian American Women in Leadership Conference on Saturday, November 16th, Simmons University. For more information on the conference, click here.

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BioProcess International

Why Conducting Marketing Due Diligence Early in Product Development Is Important

I am pleased to announce that my article entitled "Why Conducting Marketing Due Diligence Early in Product Development Is Important" was published in the BioProcess International Magazine. To read the article, click here.

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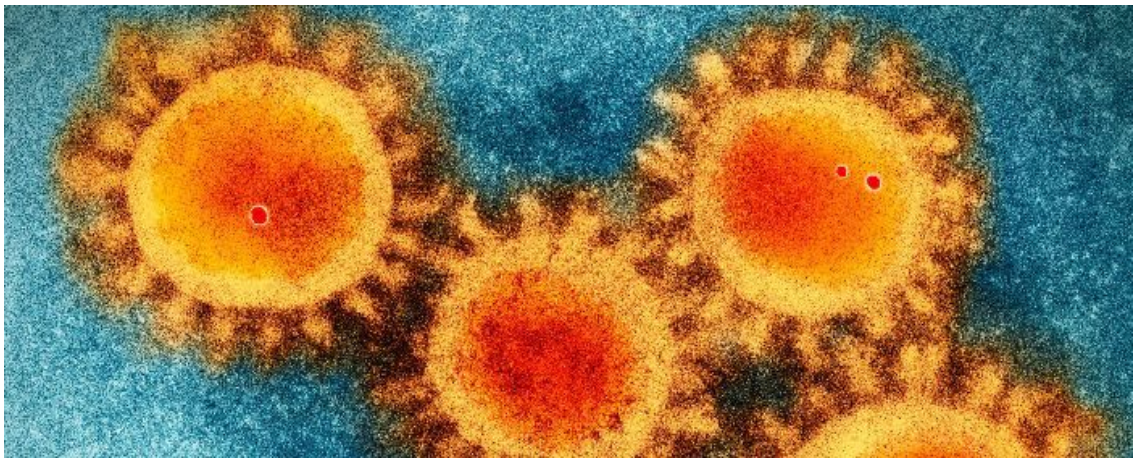

The Facts About COVID- 19

What is COVID-19?

COVID - 19 or Coronavirus Disease 2019 is the name of the respiratory disease. The virus that causes COVID-19 is a Coronavirus (a family of viruses) and more specifically SARS-CoV-2 (Severe Acute Respiratory Syndrome- Coronavirus -2). The virus first appeared in a seafood market in Wuhan, China, in December 2019. With a population of 11 million, Wuhan is the largest city in Hubei Province in Central China. But it's decidedly

SARS-CoV was first identified as an epidemic in 2003 by the World Health Organization (WHO). The virus was thought to be derived from an "animal from an as-yet-uncertain animal reservoir, perhaps bats, that spread to other animals (civet cats) and the first infected human was in Guangdong province of southern China in 2002. In 2003, SARS affected 26 countries, resulted in more than 8000 cases and is transmitted from human to human.

Middle East Respiratory Syndrome (MERS) is another illness caused by a Coronavirus called MERS-CoV and the first known cases of MERS occurred in Jordan in April 2012. Most MERS patients developed severe respiratory illness with symptoms of fever, cough and shortness of breath and is transmitted from human to human. About 3 or 4 out of every 10 patients reported with MERS have died.

SARS-CoV-2, SARS-CoV and MERS-CoV are betacoronavirus because their origin is from bats.

How is COVID-19 Spread?
COVID-19 is spread primarily via respiratory droplets similar to the flu. When someone coughs, sneezes or speaks, little blobs of liquid are released and the viruses contained in these droplets can infect other people via the eyes, nose, or mouth when they land directly on somebody's face or when they're transferred there by people touching their face with contaminated hands.

Because respiratory droplets are too heavy to remain suspended in the air, the virus can only spread normally when people are in close contact or within about six feet of each other, according to the Centers for Disease Control and Prevention (CDC). Or in a medical setting, when someone has to handle respiratory secretions such as saliva or mucus from an infected person. COVID-19 is not fully understood and reported illnesses have ranged from mild to severe, including illness resulting in death.

The Facts on Face Masks to Prevent COVID-19 Transmission
The demand for face mask or surgical mask has soared to to the point where people are breaking into hospitals to steal supplies. It has also created a fear that there will be a shortage of surgical masks for healthcare professionals.

The CDC only recommends masks for people who are already infected with SARS-CoV-2, so as "to prevent contamination of the surrounding area when a person coughs or sneezes," or if you are a healthcare worker working with infected patients. A 2019 study of health-care workers suggested that surgical masks may also provide the wearer some protection from respiratory illness because it reduces the number of times a person touches their face, according to researchers. However, the CDC notes that frequent

The best way to avoid the spreading of this virus, is to stay home.

Status Updates
On January 30, 2020, the International Health Regulations Emergency Committee of the WHO declared the outbreak a “public health emergency of international concern external icon” (PHEIC).

On February 24, 2020, the WHO reported the following:

1. As of 6am Geneva time, China has reported a total of 77,362 cases of COVID-19 to WHO, including 2618 deaths.
2. In the past 24 hours, China has reported 416 new confirmed cases, and 150 deaths
3. They found that the epidemic peaked and plateau between the 23rd of January and the 2nd of February, and has been declining steadily since then.
4. They have found that there has been no significant change in the DNA of the virus.
5. They found that the fatality rate is between 2% and 4% in Wuhan, and 0.7% outside Wuhan.
6. Outside China, there are now 2074 cases in 28 countries, and 23 deaths.
7. The sudden increases of cases in Italy, the Islamic Republic of Iran and the Republic of Korea are deeply concerning.
8. There’s a lot of speculation about whether these increases mean that this epidemic has now become a pandemic.
9. But there are at least three priorities.
    - First, all countries must prioritize protecting health workers.
    - Second, we must engage communities to protect people who are most at risk of severe disease, particularly the elderly and people with underlying health conditions.
    - And third, we must protect countries that are the most vulnerable, by doing our utmost to contain epidemics in countries with the capacity to do it.

Many Countries Have Implemented a Lock-down.
According to a personal source, the people in **China** have been in a lock-down since Chinese New Year, January 25, 2020. There is no public transportation, no schools, non-essential services are closed, and people can only leave their homes for 3 hours at a time and monitored where ever they go.

South Korea, the country second hardest hit by the disease, reported 602 cases with six deaths as of February 23th, has raised its national threat level to “red alert” and is prepared to implement lock-downs of affected cities and travel restrictions.

Majority of the outbreak is in the area surrounding Daegu, South Korea's fourth-largest city where hundreds of those infected are members of a Christian sect known as the

Italy reports 152 cases, 3 deaths forcing 11 cities, ten towns in the Lombardy region and one in Veneto to be placed on lock-down, with schools, businesses and train stations closed and scheduled public events canceled.

People in affected towns are being asked not to leave unless they are granted special permission, as health officials scramble to contain the sudden jump in cases.

Before Feb. 21, 2020, officials reported just three cases in Italy, but in three days, the number had climbed to 152, making it the worst outbreak in Europe.

Iran reported 43 cases and 12 deaths as of Feb. 23, with majority of the cases occurring in Qom, a city south of Tehran, the country's capital.

Officials closed schools and cultural and religious centers across 14 provinces beginning on Sunday, Feb. 23rd. Many public events in affected areas were also cancelled in response to the outbreak. Soccer games will be held in empty stadiums because authorities have barred fans from attending matches.

Turkey and Pakistan also announced they were temporarily closing their borders with Iran as a response to the Coronavirus.

What is Being Done?

On January 31, 2020, Health and Human Services Secretary Alex M. Azar II declared a public health emergency (PHE) for the United States to aid the nation's healthcare

The CDC has responded with the following highlights:

1. Established a COVID-19 Incident Management System on January 7, 2020. On January 21, CDC activated its Emergency Operations Center to better provide ongoing support to the COVID-19 response.
2. Suspended entry of foreign nationals who have been in China within the past 14 days.
3. U.S. citizens, residents, and their immediate family members who have been in Hubei province and other parts of mainland China are allowed to enter the United States, but they are subject to health monitoring and possible quarantine for up to 14 days.
4. Recommended to avoid nonessential travel to China, South Korea, Italy and Iran, with Practice Enhances Precautions for Japan and Hong Kong and reconsider cruise ship voyages into or within Asia.
5. CDC has developed a real time Reverse Transcription-Polymerase Chain Reaction (rRT-PCR) test that can diagnose COVID-19 in respiratory samples from clinical specimens. On January 24, CDC publicly posted the assay protocol for this test.

Life Science Industry

Johnson & Johnson, the first big pharmaceutical company, at least eight biotech companies, and three academic groups have announced vaccine and therapeutic programs (see charts below)

Company/group	Technology	Organization type
Johnson & Johnson	Viral vector	Pharma/big biotech
Inovio Pharmaceuticals; Beijing Advaccine Biotechnology	DNA vaccine	Biotech
Codagenix	Live attenuated vaccine	Biotech
Novavax	Protein-based	Biotech
Sichuan Clover Biopharmaceuticals	Protein-based	Biotech
CureVac	RNA vaccine	Biotech
Moderna	RNA vaccine	Biotech
Stermirna Therapeutics; Tongji University	RNA vaccine	Biotech
GeoVax Labs; BravoVax	Viral vector	Biotech
Baylor College of Medicine; University of Texas Medical Branch; New York Blood Center; Fudan University	Protein-based	Academic
University of Queensland	Protein-based	Academic
University of Saskatchewan	Protein-based	Academic

2019-nCoV therapeutics development programs

Company/group	Technology	Organization type
AbCellera Biologics	Antibody	Biotech
Regeneron Pharmaceuticals	Antibody	Biotech
Vir Biotechnology	Antibody	Biotech
WuXi Biologics	Antibody	Biotech
Sorrento Therapeutics; Celularity	Cell therapy	Biotech
Sirnaomics	siRNA	Biotech
National Institutes of Health	Antibody	Academic

Source: Biocentury.com

Recently **Sanofi** Pasteur announced that they are teaming up with BARDA to use recombinant DNA technology to make a vaccine against COVID-19. Sanofi plans to further investigate an advanced pre-clinical SARS vaccine candidate that could protect against COVID-19 according to David Loew, Global Head of Vaccines at Sanofi.

“While we are lending our expertise where possible, we believe the collaboration with BARDA may provide the most meaningful results in protecting the public from this latest outbreak.”

GlaxoSmithKline (GSK) has an agreement with Clover Biopharmaceuticals of Chengdu, China in providing their pandemic adjuvant for use in Clover's COVID-19 vaccine candidate. Clover had originally developed recombinant subunit-trimer vaccines for HIV and other enveloped RNA viruses and now with GSK's AS03 adjuvant technology, they plan to incorporate the mix of squalene, DL-α-tocopherol and polysorbate into its preclinical tests.

Moderna in partnership with the Coalition for Epidemic Preparedness and Innovations (CEPI) and NIH's National Institute of Allergy and Infectious Diseases (NIAID) shipped their first batch of its rapidly developed Coronavirus vaccine on Monday, Feb. 24th to the

volunteers at the end of April.

“Going into a Phase One trial within three months of getting the sequence is unquestionably the world indoor record. Nothing has ever gone that fast,” said NIAID Director Dr. Anthony Fauci.

Co-Diagnostics' Logix Smart Coronavirus COVID-19 test for detecting SARS-CoV-2 was granted CE-IVD by European regulators. The reverse-transcriptase quantitative PCR assay uses proprietary Co-Primer technology that the company claims could improve specificity of the test, reducing the likelihood of a false positive diagnosis. Co-Diagnostics originally disclosed it was developing its assay in mid-January.

"We look forward to scaling up production to meet global demand with this regulatory clearance in place, and to obtaining approvals from other bodies that will allow us to further increase the reach of this invaluable diagnostic tool," Co-Diagnostics CEO Dwight Egan said in a statement. There are also a number of other companies working on a diagnostic tests for SARS-CoV-2.

Harvard University scientists are collaborating with the Guangzhou Institute of Respiratory Disease with a $115 million boost from the China Evergrande Group.

The five-year research collaboration goal is to find new therapies against the novel Coronavirus. Harvard Medical School and the Harvard T.H. Chan School of Public Health will lead the efforts in the US where the medical school will act as a centralized hub bringing together biotech and life science researchers to focus on the problem.

Guangzhou Institute and Zhong Nanshan, a pulmonologist and epidemiologist who heads up the Chinese 2019-nCoV Expert Taskforce and is director-general of the China State Key Laboratory of Respiratory Diseases will lead the efforts in China.

In Nebraska, a placebo-controlled study run by a division of the NIH has begun recruiting patients at the University of Nebraska Medical Center, where 14 Americans are being monitored and treated for Coronavirus infections. The clinical trial will test remdesivir, an antiviral originally developed by Gilead for use against the Ebola virus.

There's no human data that demonstrates that the drug remdesivir has any activity against this new Coronavirus, but previous animal testing by Gilead found the drug to be active against both the SARS and MERS viruses, which are genetically similar to SARS-CoV-2.

"There's only one drug right now that we think may have real efficacy. And that's remdesivir." said Bruce Aylward, a senior advisor and international leader of the World Health Organization's joint mission to China for COVID-19, at a press conference.

recruiting patients has proved difficult, due in part to the surge in studies of other potential treatments.

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Closing Thoughts

Scientists are still trying to understand the mechanism of action of the new SARS-CoV-2 virus. It is different from the original SARS-CoV-2 which makes it difficult to develop a treatment and a vaccine to protect others from getting the disease.

According to Charles Chiu, MD/PHD Professor, Laboratory Medicine and Medicine / Infectious Diseases; Director, UCSF-Abbott Viral Diagnostics and Discovery Center who spoke on a panel at the WuXi special online forum on COVID-19, said that the viral load peaks early as the disease progresses. Then there are people who may be asymptomatic while they are contagious and those who maybe carriers who never get sick but are infecting people. This could explain why there are so many people who are contracting COVID-19 so quickly.

Scientist don't know why some people contract the disease while others don't. But the elderly and the sick or immuno-compromised are more susceptible to contacting the disease. From past studies of the original SARS and MERS, more men than women were susceptible to this virus.

The upside is that even though more people are contracting COVID-19, the mortality rate is about 2% which is lower than the original SARS and MERS which had the highest mortality rate according to Dr. David Ho, Founding Scientific Director of the Aaron Diamond

Dr. Ho also advised as a precautionary tale that when the outbreak of SARS in 2003 occurred, a lot of resources was given to treat the disease. But when the outbreak subsided, people lost interest in continuing research on the coronaviruses. Ho said, this is one of the reasons why we are not prepared for the COVID-19 epidemic today. We need to continue to do more research because another coronavirus will emerge in the future and we need to have a plan in place for the next epidemic.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition, target product profile and economic value of your product for reimbursement, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.

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