

MONKEYPOX: THE NEXT HEALTH CARE CHALLENGE?

Understanding it. Reckoning with it.

RICHARD A. MARFUGGI, MD, DMH *and* STEVE BROZAK, DMH

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WHAT YOU NEED TO KNOW ABOUT MONKEYPOX

What is monkeypox? Where did it come from?

Monkeypox is not new. It was first identified in a Copenhagen laboratory monkey in 1958, hence the name. The disease is now endemic to the rainforests of Central and West Africa. The monkeypox virus is a member of the Orthopoxvirus genus, which includes viruses that can infect both animals and humans and that cause diseases such as smallpox, cowpox, and horsepox. The disease not only infects both animals and humans but is also zoonotic—that is, transferrable between animals and humans.

Despite its name, monkeypox is usually carried by rats, squirrels, dormice, and other rodents. (In 2003, 47 people in the United States contracted the disease after coming in contact with [prairie dogs](#) kept as pets.) Until the current outbreak, infections were rare outside Africa. By late summer 2022, medical investigators had not determined the origins or reasons for the current outbreak.

African researchers have reported [changes](#) in monkeypox viral behavior since the 1970s, but their [warnings](#) have gone largely unheeded. They are disheartened that the resources being directed to the United States, Portugal, Spain, and the United Kingdom in response to their monkeypox outbreaks are not being made equally available to African countries where the disease is most prevalent.



Source: Centers for Disease Control and Prevention: cdc.gov

Monkeypox virus particles (above) transfer organic substances from one cell to another.

“Control of this growing international outbreak will require careful coordination among public health officials, clinicians, and the community to disseminate information, obtain appropriate diagnostic testing, implement contact tracing, and ensure that affected individuals and their contacts have access to medical care.” *Journal of the American Medical Association, June 13, 2022*

What are monkeypox symptoms and signs?

The following list includes both symptoms and signs of monkeypox. A symptom is evidence of a disease apparent to the patient; a sign is evidence that a physician perceives. Symptoms are subjective, while signs are objective.

The time from exposure to development of symptoms—the incubation period—ranges from three to seventeen days. Illness typically lasts two to four weeks and may include:

- Flu-like symptoms (fever, chills, exhaustion, muscle aches, nasal congestion)
- Rash, initially appearing as pimples or blisters, that may be painful or itchy
- Swollen lymph nodes
- Backache
- Headache
- Respiratory symptoms (sore throat, cough)

How does monkeypox spread?

Monkeypox can spread to any person through:

- Direct contact with the monkeypox rash, scabs, or body fluids from an infected person or animal
- Contact with respiratory secretions (mucus or saliva) from an infected person or animal
- Direct skin-to-skin contact with an infected person—for example, through hugging, massaging, kissing, prolonged face-to-face contact
- Touching fabrics and objects used by an infected person and not disinfected, such as bedding, towels, armrests, and gym equipment
- Pregnant women can transmit the virus to their fetus
- Direct contact with an infected person in crowded venues, such as day care centers, schools, universities, assisted living residences, and sites of large sporting or social events

Who risks monkeypox infection?

Though the first population segment to contract this disease in significant numbers during the current outbreak has been men who have sex with men (MSM), the disease is spreading to other populations.

Dr. William Sternfeld, president of the American Medical Association Foundation, when asked for a comment on monkeypox, responded:

“The past must be considered while responding to the monkeypox virus outbreak, especially the HIV/AIDS epidemic in the 1980s and 1990s and the disastrous effect the LGBTQ+ community endured from the public response. At the AMA Foundation, we are working with our donors and community partners to combat the stigma surrounding this public health emergency, as well as with our National LGBTQ+ Fellowship consortium designed to further health care equity and education in the LGBTQ+ community.”

The World Health Organization is still identifying monkeypox as a disease predominantly affecting the MSM population, although monkeypox is more than a sexually transmitted disease (STD). The mischaracterization can create a false sense of security: “I’m not like that; it can’t happen to me” is both a false and potentially harmful assumption. It can lead people to drop their guard and abandon common sense behavior. Focusing on a single demographic also places the rest of the population at additional risk by increasing the likelihood that outbreak clusters will remain unidentified during times when early identification could have contained the clusters.

Health care professionals generally appear to agree that the next most vulnerable population to be affected by monkeypox will be [students](#), from

Monkeypox is already being used to stigmatize patients. Stigmatization serves no purpose except to make affected individuals reluctant to seek treatment, while giving the rest of the population a false sense of security.

pre-school and kindergarten to college and [university](#). Several U.S. universities have reported monkeypox cases and are taking precautions to limit spread of the disease as the school year gets underway. These universities include Georgetown University and George Washington University in Washington, D.C., The University of Texas at Austin, and Bucknell and West Chester Universities in Pennsylvania. Public [schools in Georgia](#) were put on alert after three [children](#) contracted monkeypox in their homes, raising the possibility that the disease would spread to their classmates. [Central High School](#) in Keller, Texas reported its first case of monkeypox in late August, stating that a “member of the community” had contracted the disease and that workers were sanitizing the school.

How far has monkeypox spread worldwide?

More than 45,000 cases of monkeypox had been reported worldwide by August 2022. Of the 76 countries with identified cases, only six have had a history of monkeypox infections. According to the World Health Organization, “The unexpected appearance of monkeypox in several regions, in the initial absence of epidemiological links to areas that have historically reported monkeypox, suggests that there may have been undetected transmission for some time.”

In the United States, the current outbreak’s [first case](#) of monkeypox was confirmed in Boston on May 19, 2022. By the end of August, every U.S.

state had reported at least one case. The staggering rise in case numbers includes 15,909 cases in the United States and [3,124 cases](#) in New York State alone. For a number of diverse reasons, not every case is reported or included in national data. The true total, therefore, is likely to be much higher.

How serious is monkeypox?

Early public [discussions](#) of monkeypox suggested that it is a mild disease and not a cause for great concern for those in good health. Based on its history in Africa, however, it is more serious than these discussions imply. By mid-September, two deaths in the United States had been attributed to monkeypox.

The monkeypox virus has evolved into two distinct versions. The most common version, found in the United States and Europe, is the “West African” clade. (A clade is a group of organisms believed to have evolved from a common ancestor.) People infected with the West African clade have a 3.6 percent mortality rate. People infected with the second clade, the “Congo Basin” clade, have a 10.6 percent mortality rate.

These significant mortality rates

are attributed, in part, to suboptimal access to health care and to comorbidities. ([Comorbidity](#) is a term for the simultaneous presence of two or more diseases—such as asthma or cancer—or medical conditions—such as diabetes, heart disease, psychiatric disorders, or substance abuse—in an individual patient.)

Viruses have a predisposition to mutate in order to circumvent vaccine and therapeutic protections. Consider, for example, the number of currently circulating mutations of SARS-CoV-2 (the coronavirus responsible for the COVID-19 pandemic). The monkeypox virus already is circulating in two clades; with wider geographic and larger numeric spread, the likelihood of further mutations increases.

Can smallpox vaccination protect against monkeypox?

Smallpox vaccination offers full [protection](#) against smallpox for three to five years, then the protection gradually wanes. Because the monkeypox virus is a relative of the smallpox virus, smallpox vaccination is believed to give up to 85 percent protection from

In mid-August, the U.S. Centers for Disease Control and Prevention (CDC) reported an apparent decline in the number of new cases. This good news has led to some cautious optimism, which must be tempered. The beginning of the school year and high rate of comorbidities in the U.S. population demand vigilance. As an example of the need for vigilance, there have been two reported deaths due to monkeypox, and in mid-September the CDC reported two cases, one in Colorado and one in Washington, D.C., of encephalomyelitis (swelling of the brain and spinal cord) in patients with monkeypox. Neither patient had any known exposure to monkeypox, and neither had traveled out of the United States. (Any association between monkeypox and encephalomyelitis has not been established or understood.)

The CDC report recommends, “Suspected cases of neurologic complications of monkeypox should be reported” to local and state health departments. Vigilance in the forms of promoting public health awareness about monkeypox, encouraging vaccination against monkeypox for at-risk groups, reporting outbreaks, contact tracing, and developing better treatments for monkeypox may prevent a national threat from becoming a national epidemic.

monkeypox infection. The combination of the smallpox vaccine's less than full efficacy for monkeypox and its waning immune protection means that people vaccinated for smallpox can still contract monkeypox.

The World Health Organization's global smallpox eradication program began in 1959. Routine smallpox vaccination ended in the United States in 1972, when the disease was considered to be eradicated here. Smallpox was not eradicated globally, however, until 1980. Today an estimated 70 percent of the world's population have no protection against smallpox or other closely related Orthopoxviruses such as monkeypox.

What vaccines are approved for monkeypox in the U.S.?

Two vaccines are currently approved for monkeypox protection in the United States, although no data are available on the efficacy of either in the context of the current outbreak. This absence of data does not mean that the vaccines do not work; it means that no controlled clinical trials have proved their effectiveness.

ACAM2000 was approved for vaccination against smallpox in 2007. The U.S. Food and Drug Administration (FDA) recently approved ACAM2000 for monkeypox as an Expanded Access Investigational New Drug. The Expanded Access designation is defined by the FDA as "a potential pathway" for patients with serious diseases or conditions to access investigational treatment "outside of clinical trials." (This FDA designation also is known as "compassionate use" authorization, which allows patients to be treated with potentially or probably helpful drugs or therapies that have not been fully evaluated for safety and efficacy.) Four weeks after a single ACAM2000 injection, peak amounts

of smallpox antibody titers (antibodies in the blood), and presumed protection against monkeypox, are reached.

JYNNEOS, marketed under the brand names Imvamune and Imvanex, was approved as a vaccine for monkeypox in 2019. The JYNNEOS vaccine is administered in two doses 28 days apart. Immune response develops fourteen days after the second dose.

Vaccines against numerous human diseases have saved countless lives around the world for generations. The first attempts to vaccinate for smallpox began in the 18th century, but it was not until the middle of the 20th century that an effective vaccine was formulated for global administration. Once global vaccination began, it took over thirty years, until 1980, for the WHO to declare smallpox eradicated. Considering that it took over thirty years to eradicate smallpox through vaccination, it is unrealistic to expect that global protection against monkeypox through vaccination can be achieved quickly.

...it took over thirty years to eradicate smallpox ...

vaccine initiative are low: More than 30 percent of Americans did not receive a COVID-19 vaccination, and only slightly over half of Americans received a flu shot in 2019.

In the United States, prospects for a successful national monkeypox vaccine initiative are low: More than 30 percent of Americans did not receive a COVID-19 vaccination, and only slightly over half of Americans received a flu shot in 2019.

How much monkeypox vaccine is available and accessible in the U.S.?

The U.S. administration announced earlier this year that the United States had an ample supply of monkeypox vaccine in its Strategic National Stockpile. The announcement was based on the ACAM2000 vaccines assembled after September 11, 2001, in preparation for potential bioterrorism attacks.

ACAM2000, which has shown promise in preventing monkeypox in animals but not yet in humans, is not without risks, in part because it is a live virus vaccine. It is contraindicated for immunocompromised patients and has been associated with high rates of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane surrounding the heart).

The supply of JYNNEOS vaccines in the United States is limited. Twenty million doses stored in the Strategic National Stockpile expired without being replaced, leaving only 2,400 usable doses. The 300,000 doses already processed and available from Denmark are not expected to arrive in the United States before October. An additional 5.5 million vaccine vials have been ordered for distribution, but they will need to be filled and labeled before shipment. Recently the U.S. government announced that another 2.5 million vials will become available under a new contract with a U.S. manufacturing company.

As is always the case with drugs, vaccines, and therapies, availability is not the same as accessibility. Having a technology is not the same as having access to the technology.

What is the treatment alternative to vaccination?

Tecovirimat, marketed under the brand name TPOXX, is the first anti-pox viral drug approved by the FDA for treating smallpox. A sizable supply is now stored in the Strategic National Stockpile.

The FDA approved TPOXX for smallpox under its Animal Rule, which provides for approval of drugs and biological products when clinical trials are not feasible and when withholding a potentially beneficial treatment is considered to be unethical. (The FDA invoked the Animal Rule, for example, in the case of the Omicron booster that will be available this fall.) In addition to efficacy for smallpox, TPOXX is expected to be an effective treatment for monkeypox.

Lessons from the COVID-19 response: How they apply to monkeypox

Experience with the coronavirus pandemic can provide public health strategists with guidance in developing an action outline for responding to monkeypox. There have been successes and missteps in addressing the pandemic, and it is important to emulate what works and to avoid repeating what has not worked.

Dealing with an epidemic, pandemic, or national health emergency requires a multipronged approach. Health care challenges require many simultaneous responses, because no one approach or modality, despite its usefulness, can resolve such complex issues by itself. Vaccines, for example, are amazing tools, but they have limitations.

Historically, vaccine development has required years of research and testing in areas of safety and efficacy before the developer seeks FDA approval of the vaccine. Once the vaccine receives approval, it enters the

stages of manufacturing, packaging, and distribution that precede administering the vaccine to people.

COVID-19 vaccines are an exception. Through FDA [Emergency Use Authorization](#), the entire process was shortened to less than a year. Increased speed in making a vaccine available is welcome, but such speed comes with a cost of lower safety and efficacy testing. When assessing risks versus benefits, discounting the risks and overemphasizing the benefits must be avoided.

[Vaccine development is expensive](#), with U.S. Department of Health and Human Services estimates ranging from \$700 million to over \$1 billion for the development and manufacture of a new vaccine. And availability of a vaccine does not translate into acceptance: Vaccine hesitancy is a major obstacle. As the United States prepares to distribute and administer a third booster to the two-shot Moderna and Pfizer vaccines for protection against new strains of the SARS-CoV-2 coronavirus, the U.S. administration and public health officials face a population increasingly wary of seemingly unending vaccination recommendations. Even a small, but significant, number of [health care workers](#) remain vaccine hesitant.

Combining costs, logistical hurdles, and persistent vaccine hesitancy, it becomes apparent that vaccination cannot be the sole method of dealing with an infectious pathogen (any organism that causes a disease). Medical experts and other health professionals should not turn away from vaccines, but rather advocate for adding therapeutics, such as drugs, antibody transfusions, and other therapies, to augment the vaccination regimen. Pathogens adapt in order to survive; a multipronged response utilizing vaccines and therapeutics makes that adaptation less effective.

RESPONSE RECOMMENDATIONS

Strengthening the CDC's role in monkeypox response

CDC Director Rochelle Walensky announced in mid-August significant changes to her organization intended to improve responses to public health threats. The national monkeypox threat provides an opportunity for the CDC to fulfill that promise.

To succeed, the CDC would do well to heed lessons from its COVID-19 response. The CDC's [mission](#) is to protect the nation's health. In working toward that goal, the organization must stop allowing [political pressure](#) to overshadow scientific reality. Viruses do not discriminate, but they do target the most vulnerable. The CDC must do its best to ensure that the least advantaged people are afforded protection and care, along with those who have easier access to health care.

Dealing with the monkeypox vaccine shortage

The U.S. monkeypox vaccine supply is inadequate to meet demands of all Americans who are eligible to receive it (people with known or suspected exposure to the disease) and who want to receive it. The shortage is the result of many factors. The two primary causes are: first, existing stores of vaccine were allowed to [expire](#) without being replaced (*see page 4*), and second, the U.S. vaccine supply currently held in Denmark has not yet been placed in vials and distributed.

The U.S. government asked Bavarian Nordic, manufacturer of the expired vaccine doses still kept in the Strategic National Stockpile, to

reexamine the doses. The company found the expired vaccine to be viable. The FDA is expected to replicate testing of the expired doses to determine whether or not they are safe and effective.

To stretch the limited supply of the JYNNEOS vaccine, the FDA recommended that a single dose be divided and used to treat five people, a departure from the vaccine's standard administration protocol. The agency based its recommendation on a 2015 [study](#) of the vaccine's efficacy for smallpox that involved 524 people. Half of the study participants received the standard vaccine dose; the other half received 20 percent of the standard dose.

The [European Medicines Agency](#), which evaluates and monitors medicines within the European Union, has joined the FDA in endorsing the lower dose regimen. The recommendation constitutes a big gamble, especially for patients. If the gamble succeeds, the payout is large, but if it fails, the consequences could worsen the impact of monkeypox on public health.

In the study cited above, 20 percent of participants failed to return for their second dose of the two-dose JYNNEOS vaccine. In a larger population, such a high percentage of people choosing not to receive the full dosage would result in significant numbers of partially vaccinated people. These people would be left with limited protection, while they could provide an ideal environment for viral mutation.

Administering 20 percent of the standard dosage contained in one vial requires extracting five doses from each vial. Clinicians are finding this procedure to be difficult. Routinely available syringes leave a small amount of vaccine in the syringe after a vaccination. The residue must

be discarded along with the syringe. Because of the vaccine that must be "wasted," each vial yields only three or four, rather than five, doses. Clinicians have limited access to the more expensive, specialized "No Waste" syringes that extract and administer exactly the required dosage from a vial.

Another limiting factor is the significant number of health care providers who are not experienced in using the new vaccine administration protocol. When using one fifth of the standard dosage, the vaccine must be administered within the skin (intradermally, as in a TB test) rather than under the skin (subcutaneously, as in a flu shot).

According to Jeanne [Marrazzo](#), an infectious disease physician at the University of Alabama at Birmingham, delivering vaccines into skin leaves little room for error. Improper administration leads to injection site bleeding or bruising. In the JYNNEOS study, many of the 20 percent who failed to return for their second dose cited the local skin reaction they experienced to the first injection as the reason for skipping the next dose.

When injected too deeply, a vaccine has decreased effectiveness, because the vaccine is absorbed and eliminated too quickly to generate the desired immune response. When the injection is too shallow, the vaccine oozes from the injection site. If either error occurs, the patient is effectively under-vaccinated or totally unvaccinated. Because intradermal injections are more difficult to administer, clinicians require additional training to achieve proficiency.



Source: [Monkeypox in the United States: What Clinicians Need to Know: cdc.gov](#)

Addressing the training gap during an August 9, 2022 [briefing](#), the White House Monkeypox Response Team announced that videos and other training materials on proper intradermal administration technique would be sent to health care providers. The difference between intradermal and subcutaneous injections is anything but insignificant. Any new skill requires a learning curve, and it is reasonable to expect a significant number of errors occurring during the early administration process.

Accessing TPOXX therapy

Availability of a therapeutic, a treatment such as a drug or a vaccine, does not always translate into accessibility. TPOXX is no exception to this tenet. Part of the TPOXX accessibility problem stems from a Byzantine process for obtaining the drug. The United States has no national protocol for obtaining TPOXX: Each state and jurisdiction has its own rules and regulations, although [clinicians may apply directly to the CDC for the drug](#). Assuming a patient finds a provider willing to complete the application, receiving the drug from the Strategic National Stockpile can take several days.

A national monkeypox response is needed

Testing: Point of care, pre-symptomatic, and rapid COVID-19 experiences teach the importance of rapid testing and of ongoing systematic collection, analysis, and interpretation of health data. Point of care diagnostic tests are carried out at the time a clinician sees a patient. Point of care tests do not require that the test sample be sent to a laboratory for analysis, and they can detect the presence or absence of a disease when the patient is first evaluated.

In the case of monkeypox, a pre-symptomatic test would diagnose the disease before scabs or lesions or other symptoms appear. The current diagnostic monkeypox test is severely limited because it requires analyzing a swab of material from a suspected lesion. By the time monkeypox lesions develop, 21 to 25 days after exposure, the disease is well advanced. The current test, at best, confirms rather than diagnoses monkeypox.

The most logical sources for point of care testing are saliva, blood, or other body fluids. The test must have both high sensitivity (high likelihood that the test will detect the disease if it is present) and specificity (high accuracy, with low levels of “false positive” or “false negative” results). Higher levels of sensitivity and specificity in a test indicate higher levels of accuracy.

If the time between collection of a test sample and report of a positive result is three or four days, an infected person may be spreading the disease unknowingly. For a test to be considered rapid, it should have a turnaround time for results of no more than three hours.

Clear messaging

Another lesson from COVID-19 is the damaging effects of poor [messaging](#). A successful response to monkeypox requires coherent, comprehensible, and coordinated messaging. Information from the highest levels of the U.S. administration to local health care providers and community centers must be consistent to provide better public understanding and, therefore, to encourage compliance with health care recommendations. Media also have a role in disseminating accurate, timely information.

The U.S. public needs accurate information about:

- the nature of the disease
- signs and symptoms
- modes of transmission
- available testing
- available treatments
- protective actions
- the importance of contact tracing

Monkeypox has a long incubation period: signs and symptoms appear three to seventeen days after exposure. If either a person or his or her clinician suspects a monkeypox infection—that is, if either has what is called a “high index of suspicion”—prompt vaccination of an unvaccinated patient and close monitoring of the patient may prevent disease spread and unnecessary suffering. Exercising a “high index of suspicion” is preferable to waiting for a definitive diagnosis.

Clear messaging on monkeypox would emphasize that if people even think they may have been exposed to the disease, they should be monitored closely and modify their behavior—for example, by avoiding close and crowded settings and by sanitizing personal effects such as bedding and sports equipment.

Management and development of therapeutics

Antiviral therapies used to treat diseases other than monkeypox may be found effective for monkeypox treatment at a later date, but none to date has been deemed as effective as TPOXX. A streamlined path is essential for getting TPOXX from the Strategic National Stockpile to health providers and their patients.

Equally important as responding with vaccines to infectious disease-causing pathogens, is development of therapies that target the damage done by such organisms. While infections are not totally preventable, the damage they cause may be mitigated or prevented through targeted therapies.

Developing new therapeutics is expensive. Costs for research and development, clinical trials, manufacturing, the process of filling vials and packaging them for distribution, distribution, and administration to patients are staggering. This work cannot be done by the private sector alone; it requires significant public support. The U.S. government must join the private sector in this effort, because failure to invest now will result in a never-ending cycle of chasing the next virus, bacterium, fungus, epidemic, or pandemic.

Targeted use of resources

In the early days of HIV, countless numbers of people suffered because they lacked access to care and treatment. To prevent such lack of access today, monkeypox must be contained and treated by targeted use of available resources. For example, rather than stigmatizing MSM, that demographic should be encouraged to seek testing and treatment. As the school year progresses, the focus of concern will likely change to the student population.

Though pathogens vary, the damage they cause follows an all too familiar pattern. The most serious infections lead to disruption and dysregulation of the immune system. When the immune system works properly, foreign invaders (substances causing allergic reactions, bacteria, viruses, fungi, etc.) are neutralized. However, when the immune system is hijacked by a pathogen, it may become hyperactivated and turn the body's own defenses against the body it was designed to protect. This dysfunction results in the often-fatal condition known as [sepsis](#). Therapeutics that prevent immune system dysregulation would be invaluable in treating monkeypox, as well as a broad spectrum of infectious diseases.

Rachel [Cox](#), an assistant professor at the Massachusetts General Hospital Institute of Health Professions, studies infectious disease epidemiology and explains that traditional college parties, dancing, and sharing of towels and bedding in dorms can increase students' risk of transmission.

Educating parents and students about monkeypox will create channels of information necessary to help identify disease hot spots and enable

rapid response at each new monkeypox outbreak site. As monkeypox spreads to the general population, the importance of unified public demand for data collection, access to rapid testing and treatment, and health care equity cannot be overemphasized.

Strong leadership from the U.S. Surgeon General

U.S. Surgeon General Vivek Murthy issued a [statement](#) on May 20, 2022

reassuring the U.S. public about the monkeypox situation. He said that Americans need to be aware of the new monkeypox outbreak but not necessarily to worry about it. A few days later, Dr. Rachel Levine, the assistant U.S. secretary of health, joined Dr. Murthy at a private listening session on health care worker burnout at the Phoenix Indian Medical Center. She reiterated that the [risk](#) to the American public from monkeypox is low.

Three months later, the monkeypox landscape has changed. Americans need strong leadership from the surgeon general, who is the medical officer known as "the Nation's Doctor" and [charged](#) with "providing Americans with the best scientific information available on how to improve their health and reduce the risk of illness and injury." The U.S. Surgeon General needs to address the current lack of strong leadership.

It's not too late to act . . .

and to address the litany of challenges presented by the monkeypox health care threat. Strong leadership, coordinated messaging, pre-symptomatic testing, contact tracing, and increased accessibility to both vaccines and existing therapeutics, as well as a national public-private partnership to develop new therapies: all are needed. The United States spends more per capita on health care than any other country. Now is the time for ensuring the best use of health care spending to prevent a monkeypox threat from turning into a national epidemic. It can be done. It is not too late to act.

Dr. Richard Marfuggi, the first medical doctor to hold a doctorate in medical humanities, is a board-certified surgeon, educator, philanthropist, and medical ethicist. He is an American Medical Association Foundation Commissioner for LGBTQ+ Health, a presenter and advisor to the American Medical Association Leadership Development Initiative, and Medical Director of the WBB Research Institute.

Dr. Steve Brozak is CEO of WBB Securities, a dedicated life science investment bank and equity research firm. He founded the WBB Research Institute, a healthcare and technology think tank, and he is a prolific health research writer. An award-winning analyst, he has been recognized year after year for accuracy and performance by the financial industry.



551 Fifth Avenue
30th Floor
New York, New York 10176