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FDA Concedes on Ivermectin, Yet Deeper Concerns Exist

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Humans may not fully appreciate the real benefits and values of nature, including its role in preventing epidemics.

Health Viewpoints

After years of controversy over using ivermectin to fight COVID-19, the U.S. Food and Drug Administration (FDA) finally gave in and agreed to remove its social media posts that urge people to stop using the drug.

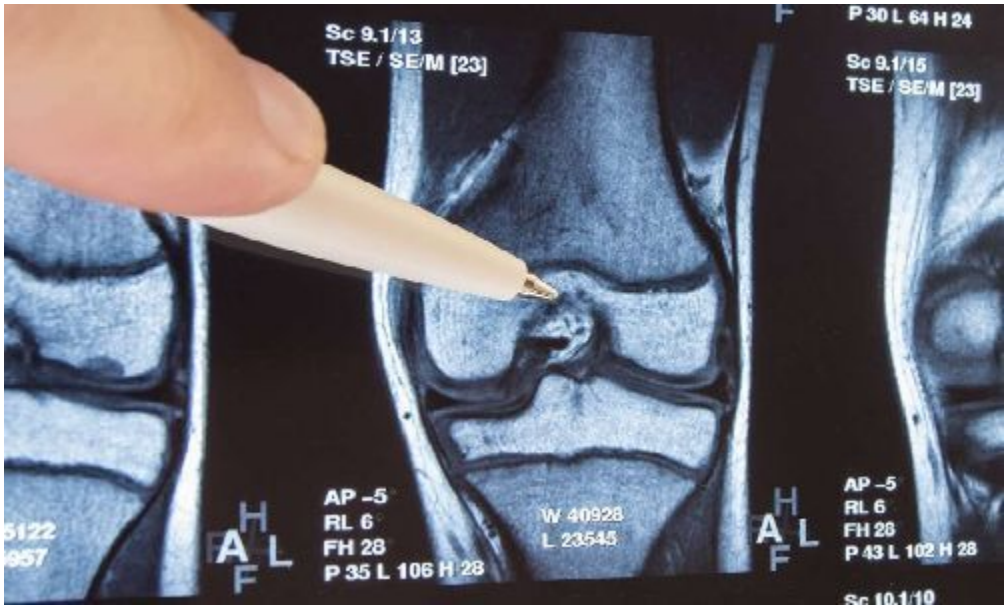
Since 1987, ivermectin has been used to treat human diseases. Doctors are also testing it for cancers outside the COVID-19 spectrum. This contradicts the FDA's claim that ivermectin is an "animal drug."

The ivermectin controversy is just the tip of the iceberg, revealing a much larger problem.

Nature's 'Wonder Drug' and Gift to Humans

Like many low-cost remedies, ivermectin is a gift from nature with a glorious history.

Your Health Matters



Professor Satoshi Omura discovered ivermectin in Japanese soil in 1975. He isolated a bacteria—Streptomyces avermectinius from the soil and found a new compound, avermectin, the precursor to ivermectin. He then modified avermectin into a safer and more effective drug—ivermectin.

This drug has saved hundreds of millions of people around the

world suffering from two parasitic diseases that have plagued tropical regions for centuries—river blindness and lymphatic filariasis. It has also been proven effective in treating many other parasitic infections, including gastrointestinal roundworms, mites, ticks, and scabies.

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Ivermectin has been called a “wonder drug” by many doctors. In 2017, Nature’s Journal of Antibiotics published the article “Ivermectin: enigmatic multifaceted ‘wonder’ drug continues to surprise and exceed expectations.”

When a virus enters a human cell, it is carried by a vehicle-like transporter to replicate inside the cell and spread throughout the body. Ivermectin has the ability to block the function of this transporter, thereby preventing the virus from replicating and spreading.

At the beginning of the COVID-19 outbreak, its safety and multifunctionality attracted global attention.

Impressive Versatility

Modern drug development follows a one-disease, one-target principle, where drugs are designed to target specific pathogens.

As a drug primarily extracted from nature, ivermectin has shown impressive versatility in its uses within the human body. Similar to other natural compounds, ivermectin has the ability to act on multiple targets simultaneously. These types of natural compounds can be thought of as a Swiss army knife, designed not for just one purpose, but with many potential uses waiting to be discovered.

Initially, ivermectin was found to have a specific target, paralyzing certain muscles in worms while having little effect on mammals.

Along with the revelation of multiple effects of ivermectin, scientists started to wonder which precise mechanism of action ivermectin has within the human body. The prevailing hypothesis suggests

that the drug enhances the effectiveness of our immune system, enabling it to better carry out its defensive functions.

Use in Treating COVID-19

When a new viral outbreak occurs, scientists typically test existing drugs for efficacy, as developing new drugs within a short timeframe is often impossible. An example of this is SARS-CoV-2.

Scientists considered using ivermectin as a potential solution, and it proved to be effective, resulting in one success after another.

In mid-2020, Australian scientists found that ivermectin could effectively fight against SARS-CoV-2. Two days after adding ivermectin to a cell model, the virus RNA dropped to 0.001 percent, a 5,000-fold reduction.

In September 2020, a U.S. lab published a modeling study showing that ivermectin docks to the SARS-CoV-2 spike receptor-binding domain, prohibiting the virus from attaching to human cells, thus stopping its infection. A lab in Bangladesh found a similar effect.

In June 2021, an Indian review used artificial intelligence-based and molecular dynamics simulation-based studies and reached a conclusion that ivermectin is a potential treatment for COVID-19.

It has also demonstrated efficacy in specific human studies.

A large-scale prospective clinical observational study in Brazil that included 159,561 residents found that administering ivermectin at a dose of 0.2 mg/kg for two consecutive days every 15 days significantly reduced infection, mortality, and hospitalization during the Omicron epidemic period. The study showed that treatment

with ivermectin was associated with a decrease of 44 percent, 68 percent, and 56 percent in infection, mortality, and hospitalization rates, respectively, as compared to the non-treatment control group.

Another analysis of the same study setting, based on 88,012 subjects, showed that regular use of ivermectin for 150 days was linked with an even greater effect on COVID-19, reducing the infection, mortality, and hospitalization rates by 49 percent, 92 percent, and 100 percent, compared to non-users.

These observational studies have a strict level of control and exclude the bias from confounding factors in treated and non-treated groups, presenting an advantage over randomized controlled trials (RCT).

Furthermore, a real-time meta-analysis of 101 studies indicated significant improvement using ivermectin treatment, with a 62 percent improvement for early treatment.

If a drug has treatment potential and is relatively safe, doctors should be allowed to use it off-label as long as they follow the correct human dosage.

Even though the FDA typically approves a drug based only on RCTs, RCTs have limitations. They normally recruit hundreds of participants, seldom reaching thousands, as in this study. Also, the design of an RCT study could easily be flawed or wrongly interpreted if the study designer lacks knowledge of the drug's properties.

A recent pre-proof study of ivermectin published in the Journal of Infection had at least two critical problems with the study design: Firstly, the recruited patients were at a relatively later stage—two

weeks from the onset of symptoms. Secondly, ivermectin was used only once per day for three days, which is much lower than recommended by the Front Line COVID-19 Critical Care Alliance (FLCCC). The FLCCC guidelines are based on the experience of many critical care doctors using ivermectin off-label to treat COVID-19 patients.

Limitations and Cautions

While every drug has its benefits, they should always be taken responsibly due to potential side effects.

Ivermectin is contraindicated in patients taking the immunosuppressive agent tacrolimus and may increase the effects of one or both medications.

In general, ivermectin has a very favorable preclinical safety profile compared to most other antiviral drugs. It is not carcinogenic or genotoxic and does not impact fertility. However, it appeared to be teratogenic when given at 10 to 100 times higher human doses, and like most antiviral drugs, it should be avoided in pregnancy.

Ivermectin has different formulations for humans and animals, and the dosage for animals is significantly higher. People should be cautious and avoid mistakenly taking large doses of ivermectin, as it may cause unnecessary harm.

More to Be Corrected

The labeled indications of an approved drug are often limited due to sluggish industry procedures or knowledge gaps. As a result, doctors in the United States are allowed to prescribe drugs off-label for a purpose other than the one for which the drug was

approved.

Despite strong clinical evidence for the use of ivermectin in COVID-19 treatment, the drug has been largely underutilized and has even been banned by authorities for non-scientific reasons.

As noted at the beginning of the article, the recent settlement of the ivermectin case is a significant step in reducing the FDA's excessive involvement in the relationship between doctors and patients. Many lives could have been saved if ivermectin and other early treatments had been made available instead of being ignored, vilified, and underutilized.

A low-cost, naturally derived drug was found to be effective against COVID-19, yet newly developed, less effective drugs and vaccines costing billions were promoted and resulted in many more serious adverse events than expected.

What constitutes genuine science? And what is the appropriate path to advance science and medicine?

When Mr. Omura received the Nobel Prize for ivermectin, he referred to his "profound belief that microorganisms never engage in futility; it is just our lack of knowledge and vision that prevents us from understanding what they produce, how and for what purpose."

Humans may not fully appreciate the real benefits and values of nature, including its role in preventing epidemics.

Since the outbreak of COVID-19, a silent war started between those pursuing cutting-edge technology and those favoring more traditional approaches.

One side pursuing advanced technology has chosen to develop

vaccines, even utilizing mRNA technology despite its immaturity. This has led to an unprecedented, bold and massive experimentation in hundreds of millions of humans.

The other approach involves looking inward, improving our diet and lifestyle, balancing our immunity, and utilizing natural remedies.

This is not to say we shouldn't develop new drugs or vaccines; it's undoubtedly positive if they are effective. However, we should not let human arrogance, money, or politics blind us and tarnish real science.

The ultimate goal of scientific research is to benefit people—not solely to pursue advanced medical treatments.

Advanced pharmaceuticals do not always equate to superior medications, just as everyone is aware that high-tech, synthetic foods are not optimal for our health.

When Hippocrates, the father of Western medicine, pioneered the systematic study of clinical medicine, he could not have envisioned this present-day scenario.

How far have we strayed? When will we abandon these harmful ideas and return to the right path?

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