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Unveiling the Emergency Use Authorization of COVID-19 Vaccines: Safety, Efficacy and Public Trust

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Abstract

The SARS-CoV-2 virus (COVID-19) has led to an initiative to develop safe and effective vaccines for public health safety. In December 2020, the United States Food and Drug Administration (FDA) administered an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine. Other vaccines from Johnson & Johnson, Moderna, and AstraZeneca shortly followed. This paper aims to examine the EUA process for COVID-19 vaccine approvals, including the requirements for the safety and efficacy of data, along with the role of the FDA and EMA in the approval process. Further, public concerns about vaccine approvals, including issues on the approval process's safety, efficacy, and speed, were also discussed. Using qualitative analysis of the extracted studies, trends and insights into the factors influencing public acceptance of COVID- 19 vaccines, such as vaccine hesitancy and misinformation, were discussed. Overall, a transparent and rigorous regulatory process for vaccine approval is critical for education efforts between policymakers, vaccine developers, and the public to address concerns for increased population vaccine uptake.

Keywords: COVID, United States, Europe, Vaccine Emergency Use Designation, EUA, Vaccine

Introduction

The Wuhan Municipal Health Commission identified the Coronavirus SARS-CoV-2 virus (COVID-19) in December 2019 following an increase in pneumonic cases (1). In response to the pandemic, health systems quickly implemented emergency parameters to try and hinder exposure to the virus, including but not limited to public masking and social distancing mandates (1). The focus of this paper is drawn from a therapeutic perspective. It goes into how the US FDA and EMA (European Medicines Agency) granted Emergency Use Authorization (EUA) approval for BioNTech/Pfizer and Moderna to help combat the severity of symptoms associated with COVID-19, as well as how the FDA allowed fast-track authorizations for clinical trials on COVID-19 vaccines. But first, we must examine the Emergency Use Authorization (EUA), which was created in 2004 to protect against bioterrorist attacks following an attempted threat in 2001 by enhancing national security. Moreover, the EUA then significantly mitigated the detrimental effects of the H1N1 pandemic in April 2009 and, more recently, during the COVID-19 pandemic (2).

The EUA process allows vaccines and other medical products to be used before being approved during urgent public health needs when no other alternative exists without an extensive FDA approval process. The EUA

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process was predicated on the notion that "the known potential benefits must outweigh the risks" and no other alternative exists (3). In the context of the COVID- 19 pandemic, EUA-approved trials focused on exploring numerous vaccination methods to create an effective COVID-19 vaccine to supply the rapidly increasing infected population. The vaccines explored by the FDA included non-replicating viral vectors, inactivated, live attenuated, subunit, DNA, mRNA, and trained immunity (4). Thus far, J&J's AD26.COV2-S, Pfizer's BNT162b2, and Moderna's mRNA-1273 are the only vaccines that provide effective treatment, and they have also been granted EUA authorization. The EUA was established by the Project Bioshield Act of 2004. This program was constructed to allow the FDA to approve the emergency use of unapproved drugs or the off-label use of approved drugs under the notion that no other safe alternatives exist. Multiple amendments were then made to the original program, improving its efficacy and reliability (2). Since introducing the EUA in 2004, it has successfully combated epidemics, including 2009 H1N1, Zika, Ebola, H7N9, and most recently, the COVID-19 Virus (2). The EUA played a crucial role in the COVID-19 epidemic, reducing the average amount of time it took for vaccines to reach the public from 8 years to a little over one year (5). The EUA, therefore, played a pivotal role in flattening the curve of the COVID- 19 pandemic.

Implementing the EUA only mitigated the effects of the COVID-19 pandemic by allowing vaccines to be used before full approval. However, to increase vaccine uptake, it was imperative to obtain Full FDA approval. FDA fast-track, separate from the EUA, allowed the vaccine approval process to be expedited. This allowed Pfizer and Moderna to gain approval for their vaccine in approximately one year instead of the standard 5-10 years (6).

Purpose: This paper discusses the FDA's development and approval of COVID-19 vaccines, focusing on Emergency Use Authorization (EUA) and Fast Track designation. It highlights the different types of COVID-19 vaccines available and their unique advantages and disadvantages. The EUA process is explained in detail, including its significance in combating epidemics and reducing the approval timeline for COVID-19 vaccines. It also discusses the challenges associated with communication around EUA and vaccines, including the need to provide accurate information about the safety and effectiveness of the vaccines while addressing concerns and misinformation. We examine various strategies that can be employed to effectively present information about EUA and COVID-19 vaccines, including using clear and coherent language, targeted messaging, and efficient engagement with critical stakeholders. Overall, the paper provides insights into the development and approval of COVID-19 vaccines and their importance in controlling the pandemic while giving insights into the EUA process, the development and approval of COVID- 19 vaccines, and their importance in controlling the pandemic.

Methods

This literature review search was conducted using Pubmed and Google Scholar to critically examine existing research on the FDA's development and approval of COVID-19 vaccines, focusing on Emergency Use Authorization (EUA) and Fast Track designation. The search was performed on March 1, 2023, and included all available articles up to the search date.

Search Terms: The following search terms were used to Identify relevant articles:

1. "Emergency Use Authorization" OR "EUA"
2. "COVID-19" OR "coronavirus" OR "SARS-CoV-2"
3. "vaccine" OR "vaccination"
4. "Fast Track Designation"

Inclusion criteria: Articles were included in the review if they met the following criteria:

- The article was published in a peer-reviewed journal.
- The article discussed EUA for COVID-19 vaccines.
- The article was written in English.

Exclusion criteria: Articles were excluded from the review if they met any of the following criteria:

- The article was not published in a peer-reviewed journal.
- The article did not discuss EUA for COVID-19 vaccines.
- The article was not written in English.

Data analysis

The extracted studies were analyzed qualitatively to identify common themes and trends related to EUA for COVID-19 vaccines. The analysis results were used to develop a comprehensive overview of EUA and its role in developing and deploying COVID-19 vaccines.

Results

Public Perception and Acceptance of EUA-approved COVID Vaccines: The vaccine campaign for the H1N1 virus suffered greatly in its attempt at public vaccination due to a lack of public acceptance and a negative public perception (7). Public perception and acceptance of vaccines for SARS-CoV-2 are dependent on factors that involve both public and governmental factors. On the public side, hesitancy stems from mistrust and misinformation surrounding the COVID vaccine uptake and EUA implications. In 2022, the vaccine acceptance rate in the southern United States in one study was only 44.3% (8); this finding was associated with lower income, low educational skills, and insufficient knowledge

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of the vaccine (8). Another article suggests that economic factors, trustworthiness, and acceptance directly influence vaccine uptake (9). Another study in South Africa found that the acceptance of the COVID vaccine was at a total of 65%, and hesitancy was possibly explained by a lack of education on the safety, efficacy, and fast-tracking process of the vaccines (10). Ethical Factors Influencing Public Trust in EUAs: The introduction of EUA-authorized COVID vaccines has sparked a debate on the potential compromise of patient autonomy and the principle of no harm compared to a regularly approved FDA vaccine (11). The trial designs for EUA-authorized vaccines started arguments on the ethics of the safety of fast-tracked vaccines. Notably, a study published in December 2020 found that 20% of physicians and 33% of nurses and allied health professionals were vaccine-hesitant; there was concern from respondents not only about adverse events and efficacy but that the vaccines were new and 'rushed', and that there was a lack of longitudinal data regarding the vaccine (12). This was caused by little information being shared by the FDA about the new EUA-designated COVID-19 vaccines at the time.

The skepticism about the timeline of the vaccine's roll-out goes back to the ethical dilemma of deploying a vaccine that has the potential to save many lives in a pandemic without the safeguards of a comprehensive FDA approval process. This can lead to misinformation and sensationalization about the EUA among non-experts. In early September 2020, multiple pharmaceutical companies pledged to file for emergency authorization only when they had sufficient evidence illustrating safety and efficacy in clinical trials; this led to the public's perception of the reputation of the pharmaceutical industry as 49% positive, a significant increase compared a pre-pandemic approval score of 32% (13). The FDA Advisory Committee's public meetings with independent experts also helped in enhancing public trust. (15). This shows that sources trusted by the public already can be used to gain public trust and positively influence behavior.

Comparison of EUA to standard vaccine approval process: The standard vaccine approval process involves several phases of clinical trials, beginning with small-scale testing for safety and efficacy, then more extensive trials involving thousands of participants, and finally, submission of data to regulatory agencies for review and approval. This process can take several years and involves extensive testing and evaluation: the median clinical approval was found to be 8 years (14). On the other hand, emergency use authorization (EUA) is a streamlined process used during public health emergencies to make vaccines available more quickly. This means that the vaccine can be authorized before the completion of the standard clinical trials. Though the process is quicker, the data requirements for EUA are still rigorous and involve significant review and evaluation by regulatory agencies. Comparison to Regulatory Processes Before Introduction of EUA: The parallel track and Accelerated Approval (AA) programs are regulatory processes in the United States that allow for expedited approval of drugs for life-threatening diseases. The parallel track program, introduced in 1989, was the first attempt by the US Public Health Service to provide expanded access to experimental drugs to patients with AIDS. The program allowed for the approval of dideoxyinosine (ddI) for AIDS patients while clinical trials were still underway (2). This program served as the foundation for the Accelerated Approval program of 1992, which allowed the FDA to grant expedited approval of novel drugs based on surrogate endpoints. The parallel track and Accelerated Approval programs were designed to speed up the drug approval process for serious and life-threatening diseases The AA program was designed to allow the FDA to approve drugs that showed promise in treating severe diseases based on surrogate endpoints, such as tumor size reduction or improvement in laboratory tests, rather than on traditional clinical endpoints like overall survival and morbidity (6). In general, it is required for drugs approved through the Accelerated Approval pathway to promptly undergo a post-marketing confirmatory trial; the FDA retains the power to pull a drug from the market if the manufacturer does not comply with the confirmatory trial; for example, the leading immune checkpoint inhibitor, pembrolizumab, was withdrawn as in indication for small cell lung cancer in March of 2021 (15). Similarly, the FDA introduced the Emergency Use Authorization (EUA) in 2004 to allow for using unapproved medical products or unapproved use of approved medical products during public health emergencies such as pandemics or natural disasters. The EUA process is intended to provide timely access to medical products that may help to save lives during an emergency. The evidence required for approval under the EUA program is lower than that required under the AA program/Parallel Track. The EUA program allows for the use of medical products based on less rigorous data, including animal data, observational studies, and uncontrolled clinical trials. The EUA program is intended to be temporary and is in effect only during a public health emergency. In contrast, the AA program/Parallel Track is a permanent regulatory pathway that allows for expedited approval of medical products for serious and life-threatening diseases (6).

Strengths and Weaknesses

The arrival of COVID-19 led to an urgent need for vaccines to be developed rapidly. Adjustments were made in regulatory and developmental processes to accelerate vaccine production. Many lessons can be learned from the COVID-19 pandemic, especially regarding the EUA process. While the EUA allows the timely approval of vaccines in the face of pandemics such as COVID- 19, this expedited process

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can prove detrimental to efficacy and public confidence in approved medical interventions. The EUA is predicated upon the fact that the known and potential benefits should outweigh the known and potential risk (16). the unavailability of any other effective interventions, and an efficacy standard of 50% (16). These principles have resulted in the revocation of COVID-19 drugs such as hydroxychloroquine and chloroquine (17). Another concern regarding the EUA is that it uses the MedWatch Adverse Event Report program, which has been criticized for under-reporting and incomplete reports (18). A lack of proper communication between vaccine developers and the public can decrease public trust in vaccines. Public confidence in EUA can be increased by the development of a patient registry overseen by the FDA, including patient demographics, clinical outcomes, and medical interventions administered, which are made accessible to the public (19).

Adjustments in Regulatory Authorization

One lesson learned from the COVID-19 pandemic was that adjustment of regulatory processes through the Emergency Use pathway was necessary to approve the COVID-19 vaccine in many countries. The FDA and the EMA allowed trial development where different steps were carried out in parallel instead of one after the other. This allowed sponsors to obtain and assess data more quickly. Rolling reviews by the EMA allowed for data from clinical trials to be assessed as soon as they were generated (22). National authorities such as the Paul-Ehrlich Institute also initiated rolling reviews and allowed vaccine candidates to be investigated simultaneously within the same trial (22).

Global Collaboration

The COVID-19 vaccine would not have been approved within ten months had it not been for effective global harmonization between regulatory authorities, the government, and the private sector. The European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) needed to collaborate in March 2020 due to the pandemic, which led them to discuss sharing pre-clinical data requirements (22). The collaboration between the EMA and FDA allowed for emergency use authorizations to be sped up and allowed regulatory authorities to share important clinical information. The FDA's global harmonization movement allowed for quicker research and more concise data to be collected promptly. The COVID-19 Evidence Accelerator was made to establish a platform on which government, research institutes, and global and health institutes could share information between over 200 groups (20). Furthermore, the collaboration between the Oxford vaccine group and AstraZeneca allowed both organizations to combine their strengths. The Oxford vaccine group worked on the initial vaccine development, while AstraZeneca shared its expertise in large-scale drug development and manufacturing (21).

Pre-existing data

Previous data on past coronavirus outbreaks proved extremely beneficial in the early stages of vaccine development (22). The spike glycoprotein of SARS-Cov-2 was chosen as the vaccine antigen mainly because of past experience with SARS-COV and MERS (22). Besides the COVID vaccines, viral vectors have been researched in the last 30 years, resulting in effective immune responses in other diseases and cancer. An example of a viral vector being used for COVID-19 is the Johnson & Johnson vaccine. First authorized by the EUA to open the vaccine market to more people in need, the J&J vaccine provides a different type of vaccine in that it is a single dose treatment that works by using a modified version of a relative virus in order to prevent severe symptoms in COVID-19 (22). The J&J vaccine provides treatment without the risk of allergic reactions to polyethylene glycol, while also being easier to store and only needing a single dose instead of multiple injections (23). However, some may prefer the Pfizer and Moderna vaccines because unlike the J&J vaccine, they were not directly produced through abortion cell lines. The J&J vaccine is directly grown from abortion cell lines (26). mRNA technologies have also undergone research in the last twenty years, and the proficiency of mRNA technology was studied before the COVID-19 pandemic. This prior information allowed for early discussions on the vaccine's development and the mRNA principles involved in it.

Funding

Without funding, companies would not have been able to engage in the financial risks that sped up vaccine development. Operation Warp Speed (OWS), a US private-public initiative, made many investments possible for several vaccine candidates, including $456 million for Moderna's vaccine and $1.2 billion for the Oxford/AstraZeneca vaccine (24). OWS has made many other investments estimated to be worth $18 billion into late-stage covid-19 vaccine developments (27). On the other hand, the Coalition for Epidemic Preparedness Innovation (CEPI) is another big contributor to the funding and development of COVID-19 vaccines. CEPI has been estimated to invest around $1-4 billion into covid-19 vaccine development around the world (25). As the vaccine was not available to countries with less infrastructure, the COVID-19 Vaccine Global Access Facility (COVAX) was founded to supply over 90 low-income and middle-income countries (LMICs) with over 1 billion vaccines; this is planned to be a 4 billion USD investment. Many countries, including China and the United States, have already planned to commit to the COVAX plan (14). Long-Term Impacts of EUAs on Vaccine Development and Public Health: Before COVID- 19, the average time for vaccine development was a decade or longer. This was because of the multiple steps in the regulatory processes required by the FDA and EMA. These steps

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include the preclinical stages, clinical development (Phase I, Phase II, Phase III), review and approval, manufacturing, quality control, and then post-authorization studies (14). The COVID-19 pandemic exposed the deficiencies found in the vaccine developmental systems, such as a lack of compliance between regulatory authorities and real-time guidance. Due to these deficiencies being resolved, the development of vaccines may take a shorter time in the future. Another long-term impact of EUAs may be unforeseen medical issues, and this has been an ethical challenge since the incipient approval of the EUA process. These fast-tracked vaccines have a possibility of causing serious medical issues long term, even if serious adverse effects on a massive scale are unlikely (26).

Discussion

Comparison of the EUA and Standard Approval Process: To truly understand the Emergency Use Authorization (EUA) process, it is important to compare and contrast it with the standard FDA Approval process. The FDA approval involves a lengthy and rigorous process of submitting a Biologics License Application (BLA), which includes data from various stages of vaccine development, such as research and discovery, pre-clinical, clinical development (phase I, II, III, and optional stage IV). After compiling data from the various stages, vaccine developers submit a Biologics License Application (BLA), which is reviewed by the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) before FDA approval. Manufacturers must also demonstrate the ability to consistently and reliably manufacture vaccines.

In contrast, a EUA is issued by the FDA commissioner when there is a state of a public health emergency and when the “potential benefits of the vaccine outweigh the known and potential risks” (27). The EUA process overlaps with vaccine developers' processes and facilities, including establishing Data Safety Monitoring Boards (DSMB). These boards possess access to unblinded data, which allows them to provide feedback to vaccine manufacturers during phase II trials and determine if clinical endpoint criteria are met. If the vaccine developer decides to submit a EUA, the FDA's Center for Biologics Evaluation and Research (CBER) reviews the application and convenes with the VRBPAC. This step is present in both BLA and EUA pathways. If the vaccine is deemed effective and the endpoint criteria are met, the FDA grants EUA authorization. A EUA lasts as long as the public health emergency persists, and all adverse effects are monitored by the Centers for Disease Control's Vaccine Adverse Event Reporting System (VAERS) and studied by the Vaccine Safety Datalink (VSD).

In summary, while the standard FDA Approval process is a comprehensive and lengthy process involving various stages of vaccine development, a EUA is issued under emergency circumstances when the benefits of a vaccine outweigh its risks. The EUA process includes DSMBs, which facilitate an expedited process and remain subject to review by the FDA's VRBPAC, providing thorough safety and efficacy checks in the short term.

EUA Issuance Criteria

Criteria for the issuance of a EUA include: (a) the agent must help treat a serious or life-threatening disease; (b) there must be sufficient evidence that the product may be effective in diagnosing, treating, or preventing the disease; (c) the benefits must outweigh the risks; and (d) there must be no adequate, approved, and available alternative to the product. The FDA has permissive authority to revoke a EUA if the circumstances described in the declaration no longer exist, the criteria for issuance are no longer met, or circumstances make a revision or revocation appropriate to protect public health or safety (28). Noting this, the EUA can also be petitioned. Petitions for the EUA process must underline and prove that one of the four criteria for issuance is not met. Recently, there was a petition for the Pfizer and Moderna vaccines to be used on individuals aged 5-17, but in the end, the FDA stated that the petition did not have a proper basis (31).

Advantages of Using EUA for COVID-19

The EUA played a crucial role in developing COVID- 19 vaccines, as it effectively reduced the authorization timeline, enabling the creation of an effective vaccine in a time-sensitive manner. The Standard Approval process saw the development of 21 vaccines between January 2010 and June 2020 (5).In comparison, the EUA-approved Pfizer COVID-19 vaccine was under clinical development for just six months and received EUA within a month, ultimately achieving full FDA approval within eight months (8). This is a dramatic departure from the standard FDA process, which has a median development and approval period of 8 years (14). Additionally, the FDA's EUA provision allowed vaccines to enter the market without full approval, but only during times of emergency. Given the significant infection and mortality rates during the pandemic, Pfizer and Moderna quickly distributed their vaccines to populations deemed "at risk” for severe symptoms due to underlying health conditions. While there have been criticisms of the EUA process, particularly concerning safety and efficacy, the urgency of the COVID-19 pandemic underscored the need for a rapid and effective response. The EUA played an indispensable role in facilitating the speedy development, authorization, and distribution of COVID-19 vaccines, potentially saving countless lives and marking a significant achievement in the history of public health.

Disadvantages of EUA for COVID-19

Although the EUA process can be advantageous during

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emergencies, it has some drawbacks compared to the standard FDA process. There is less extensive tracking of adverse events of patients and no stage IV for long-term safety and efficacy monitoring (17). Without phase IV, patients using EUA-approved vaccines could face serious health risks in the future, although this is typically unlikely. The FDA also issued guidance for developers on June 30, 2021, which included efficacy measures, statistical considerations, and safety thresholds. However, the minimum primary efficacy standard of 50% proved controversial. This is another disadvantage of the EUA process due to this standard being inferior to the HPV and Polio minimum standard of 90% efficacy (29). The lower efficacy standard proved disadvantageous for COVID-19 vaccines and drugs, leading to EUAs being issued for later rescinded drugs such as hydroxychloroquine and chloroquine. These drugs were granted a EUA based on insubstantial in vitro and limited clinical data.

Critiques of the EUA Process

The safety and efficacy of EUA-approved COVID-19 vaccines have become a topic of concern in recent times, partly due to the spread of misinformation and a lack of information from reliable sources. This has resulted in low uptake rates of the COVID-19 vaccines, as evidenced by a study conducted in Alabama. The study found that only 44.3% of the 3,781 respondents reported their intention to receive the vaccine, while 28.1% were unsure. In comparison, the early stages of the influenza vaccine had a 56% uptake rate (8). The low uptake rate may be due to several factors, including inadequate public health education on COVID-19 and the EUA process to combat the disease. Furthermore, respondents lacking insurance and access to proper healthcare could also contribute to the low uptake rate. Without proper education on the EUA process and knowledge of COVID-19, misinformation spreads, creating doubts about the safety and efficacy of the vaccine when it could be entirely safe to use.

Concerns About the EUA Process

One of the key reasons critics are concerned about the EUA process is related to the safety and efficacy data of the vaccines. Some experts have raised concerns that the EUA process is not rigorous enough to evaluate the long-term effects of the vaccines. For instance, some critics have cited the example of hydroxychloroquine, a drug that was initially approved for emergency use but was later found to be associate with blood clots (6). In a comprehensive study conducted in China involving 181 individuals, 84 participants were administered hydroxychloroquine. However, the trial yielded disheartening results, as it revealed that the group receiving the drug did not experience a faster recovery from COVID-19 compared to those who did not receive the drug. Furthermore, the study highlighted a concerning finding that hydroxychloroquine was associated with potential heart complications (30). Adverse effects have been found in patients receiving high doses of hydroxychloroquine. In a randomized clinical trial from Brazil, people who received the high dose of 600 mg twice daily for ten days were found to have arrhythmia within 2 to 3 days. On the sixth day of the trial, 11 patients died and immediately the second phase was stopped. Therefore, chloroquine (and as result hydroxychloroquine) can cause serious heart issues at high doses. Other side effects associated with hydroxychloroquine are gastrointestinal symptoms, retinal damage and possibly blindness (31). However, it is worth noting that the FDA requires extensive data on safety and efficacy before granting EUA authorization. Moreover, the FDA continues monitoring safety and efficacy data even after granting EUA authorization, ensuring that potential adverse effects are identified and addressed promptly. Therefore, while there may be concerns about the EUA process, it is still a rigorous process in theory that ensures the safety and efficacy of vaccines.

Ethical Implications of EUA

The Emergency Use Authorization (EUA) is a process used by the Food and Drug Administration (FDA) that allows for the expedition of the vaccine approvals and other medical products during public health emergencies. For example, in response to the COVID- 19 pandemic, the FDA used the EUA process authorize several vaccines before approval, which has raised ethical concerns about informed consent and equitable vaccine access. The informed consent process is one of the most scrutinized implications of the EUA. Informed consent requires that individuals are fully informed about the risks and benefits of a medical product before they consent to receive it. Some critics argue that with the EUA process, informed consents lack the proper data to be given to participants because data is only taken for 2 months instead of the typical 6-month data collection (17). This means that individuals receiving the vaccine may not have had access to complete information about its potential risks and benefits (29). This is particularly problematic for those more vulnerable to adverse effects, such as pregnant women, children, and those with preexisting conditions. To combat this, systems such as the U.S Vaccine Adverse Event Reporting System (VAERS) are being used to help track adverse events associated with COVID-19 vaccines. A total of 44,451 adverse events associated with the Moderna and Pfizer vaccines were reported (32).

Implications for future vaccine development and regulatory processes

The COVID-19 pandemic has highlighted the crucial role of the Emergency Use Authorization (EUA) process in vaccine development and regulatory processes. The EUA process has allowed the FDA to expedite the authorization

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of vaccines to prevent COVID-19 under emergency circumstances, which has been crucial in limiting the spread of the disease. However, as with any new process, advantages and disadvantages must be carefully evaluated for future EUA authorizations. One of the most significant lessons learned from the COVID-19 pandemic is the need for more awareness and knowledge about the EUA process (8). The public should be better informed about the implications of EUA authorization, including the potential long-term impacts on vaccine development and public health policy. Additionally, it is essential to have more clinical trials conducted for long-term adverse effects after EUA authorization. The speed of the EUA process during the pandemic has also highlighted the necessity to save lives quickly. However, the potential long-term effects of EUA-authorized vaccines remain unknown. It may be necessary to provide healthcare benefits to individuals experiencing long-term health effects due to EUA-authorized medicines in the future.

Moving forward, there may be changes to the regulatory landscape in response to the pandemic, including increased scrutiny of vaccine development and regulatory processes. To ensure safety and efficacy, the FDA may require more data and evidence before authorizing vaccines for use under EUA. The EUA process currently lacks a standardized equivalent to the phase IV trial to test long-term safety and efficacy (14). To improve the EUA process, it is crucial to ensure that patients who meet the criteria for Expanded Access (EA) can access investigational drugs and that there is enough supply to meet demand. The reimbursement for EA drugs is also a complex issue that needs to be addressed. Therefore, incentives like Operation Warpspeed (OWS) and the COVID-19 Vaccine Global Access Facility (COVAX) have been implemented to help those in need (25). Finally, the government must invest more funding into educational programs about EUA drugs and vaccines to decrease misinformation and scrutiny surrounding EUA authorization. In conclusion, the EUA process has been critical in limiting the COVID-19 pandemic's spread, and it is necessary to evaluate its advantages and disadvantages for future EUA authorizations carefully.

Recommendations for improving the EUA process

COVID-19 vaccine development and distribution through EUA was motivated by calculated risk. The EUA of the vaccine was necessary to ameliorate the disastrous effects of the virus. However, the need for a vaccine did not halt public hesitancy surrounding the efficacy and ethicality of the EUA. Reviewing literature from the chaos that was COVID-19, it is evident that communication between the policymakers, vaccine developers, and the general mass was a key factor in vaccine administration and public trust. Public trust in the vaccine revolved around efficacy and ethical parameters, which the policymakers and vaccine developers determined. Standards for COVID-19 efficacy are at 50% compared to previous standards of over 90 percent (HPV and Polio) (29). In addition, revoking hydroxychloroquine and chloroquine only increased the skepticism surrounding drugs and vaccines approved by the EUA. Ethically, improving public trust in the vaccine also proved difficult due to the nature of the EUA. Authorization based on availability did not help create public trust, either. This study is not a comprehensive review of vaccines and COVID therapies approved through the EUA. Our review did not extensively delve into the legal, regulatory, or financial aspects of EUA. In summary, the benefits of the EUA outweigh its risks, but refinements can be made to promote its future use and patient safety.

Conclusion

The EUA (Emergency Use Authorization) process enabled the COVID-19 vaccines to be released earlier to the public when compared to the regular FDA approval process. The EUA designation served to flatten the curve of the pandemic and prevented unnecessary deaths through the use of unapproved vaccines. At the same time, this may have also sacrificed some of the rigorous tests for safety and efficacy that are usually required for full FDA approval, particularly the phase IV trial. The language surrounding the EUA depicting it as the approved use of an unapproved vaccine reduced public confidence, which negatively impacted vaccine uptake. This setback in mass vaccination can be rectified through education on the different regulatory processes invented by the FDA and transparency between the FDA, vaccine manufacturers, and vaccine recipients. Another potential downside of the current EUA designation is the potential for misinformation, causing a drop in public confidence in the vaccines that are created. Currently and in the past, this is due to the little or no clear communication between the FDA and the public, which can lead to misconceptions and mistrust. To promote high vaccine uptake rates and trust in the vaccines and limit misinformation, the FDA must implement education about EUA-facilitated vaccines, their development process, and the potential risks involved. This education will be vital in providing promising and clear evidence that future vaccines can provide efficacy while having proper safety measures. This will overall limit the impact of misinformation on the public, allowing for higher vaccine uptake. Therefore, the EUA process and fast-track designation must have more transparency in the future, with clear communication about the development and safety of the vaccines. This can be achieved by informing the public about the benefits and potential risks associated with these regulatory mechanisms. Ultimately, transparency and communication will be critical in promoting public trust and high vaccine uptake rates, particularly in the context of future epidemics or outbreaks.

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